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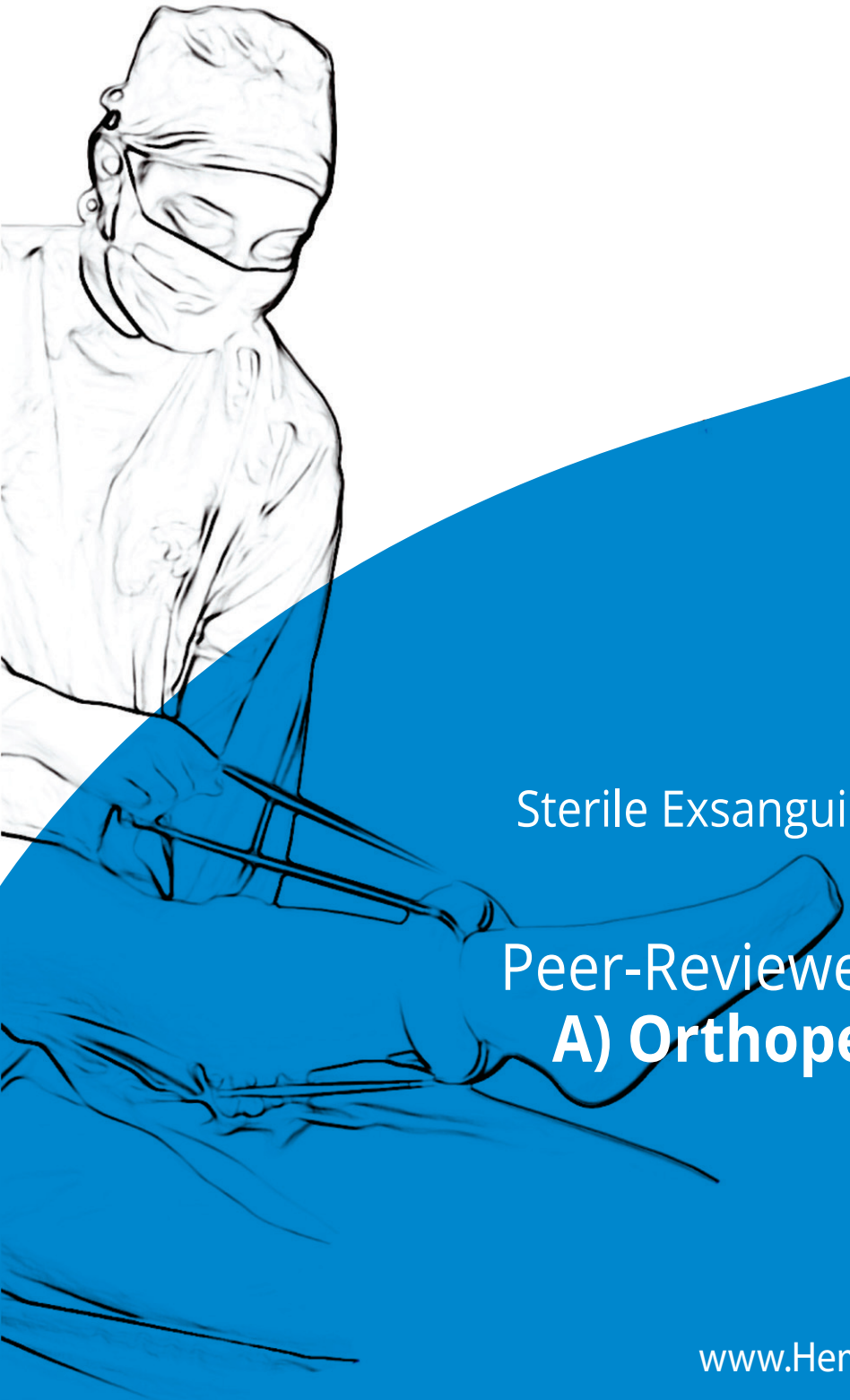

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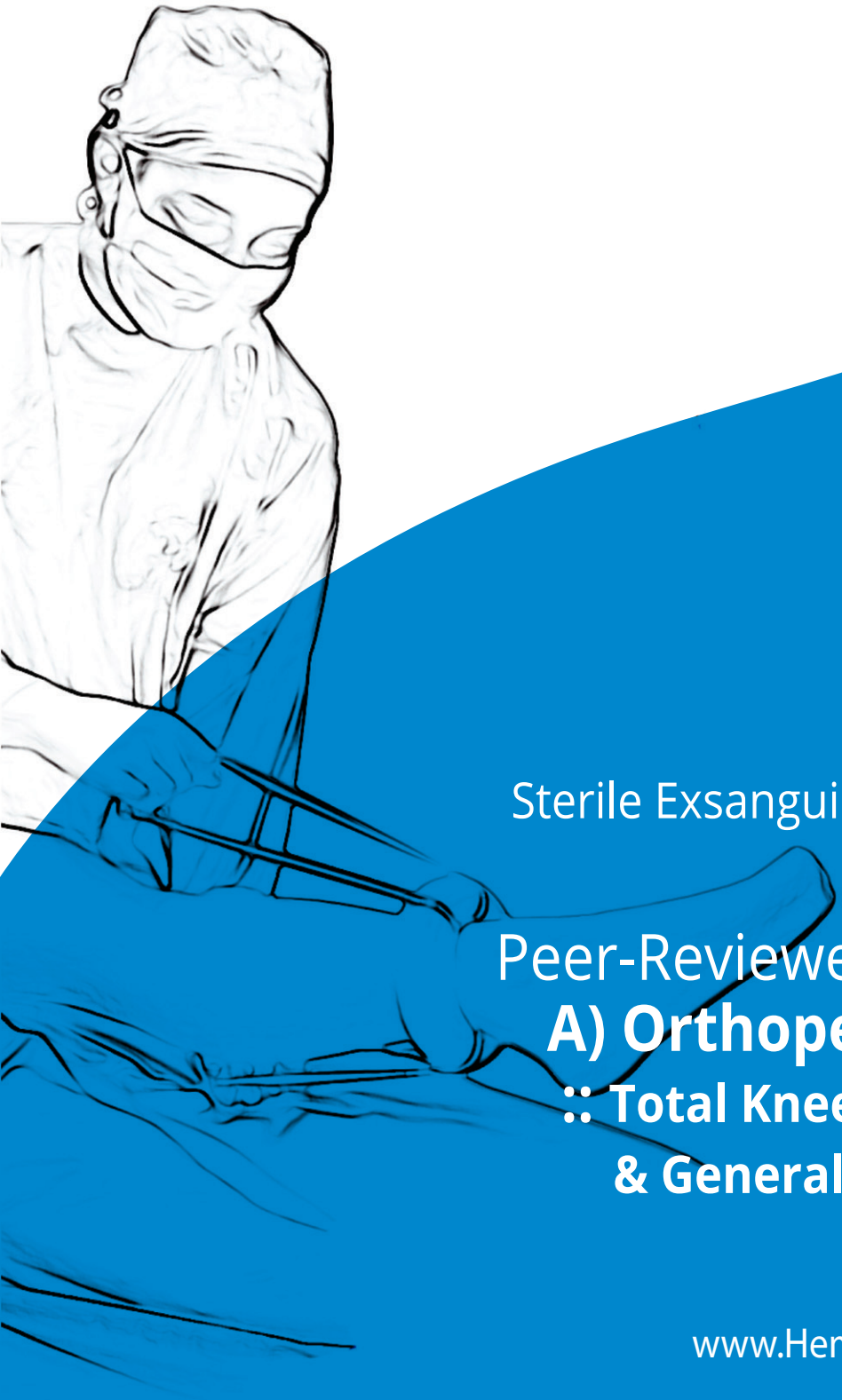

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Nondrainage Decreases Blood Transfusion Need and Infection Rate in Bilateral Total Knee Arthroplasty

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ABSTRACT

This retrospective study enrolled 526 patients undergoing bilateral total knee arthroplasties at our institution. In nondrainage group (Group 1) of 255 patients (510 knees), a disposable elastic sterile exsanguination tourniquet (HemaClear), wound closure in layers and Jones Bandage, without pre-tourniquet removal hemostasis or Hemovac drain were used. In drainage group (Group 2) of 227 patients (454 knees), pneumatic tourniquet, post-deflation hemostasis, a Hemovac drain and Jones bandage were used. The maximal drop in hemoglobin was significantly greater in Group 2 than Group 1 ($P < 0.001$). Also infection rate was significantly lower in Group 1 ($P = 0.017$). The use of sterile tourniquet removed after wound closure without Hemovac drain decreases blood transfusion need, infection rate, tourniquet related pain and postoperative complications.

TKA, as a major orthopaedic procedure, is usually accompanied by significant blood loss and postoperative allogenic blood transfusion (ABT), which is considered as tissue–cell transplantation. The average blood loss after bilateral standard TKA can be high; Lin reported 1222 ml of blood loss and similar values have been reported in literature [1–5]. ABT is associated with potential risks of increased infection rate [6], transmission of infectious diseases [7], down-modulation of the immune system [8] and matching errors which can lead to significant medical problems, and even death. The infection rate after TKA also varies, with most studies reporting infection as the most challenging complication after TKA, at an incidence of 1%–4% [9–11].

Use of drains and tourniquet deflation prior to full wound closure have previously been shown to increase blood loss during and following TKA. To decrease postoperative bleeding, platelet-rich plasma gel application, tranexamic acid injection, fibrin tissue adhesive use, minimally invasive surgery, drain clamping and tourniquet use have all been attempted [12–15]. In addition, prevention of the infection is a substantial part of management after TKA. Therefore, identifying and treating possible sources of infection before surgery, lowering theatre traffic, using laminar flow, preoperative antibiotics, meticulous exposure and treating preoperative anemia have been used [16–18]. Because of lack of established evidence, it has not been determined whether the above mentioned modalities are more beneficial than other conventional methods in controlling postoperative bleeding and infection.

The research question of this study was whether nondrainage with a disposable sterile elastic exsanguination tourniquet application will decrease blood transfusion need, infection rate and postoperative complications in TKA when compared to application of pneumatic tourniquet, post-deflation hemostasis, a Hemovac drain and Jones bandage. For this purpose, a retrospective controlled study was designed to evaluate the results in two groups of patients.

Materials and Methods

Between May 2005 and July 2007, 526 patients (total of 1052 knees) were enrolled in the study, all with grade III or IV osteoarthrosis. Institutional review board approval was obtained. Of these patients, comorbidities which can alter the rates of postoperative bleeding or infection rate such as inflammatory arthrosis (n = 31), preoperative anemia (n = 5) and preoperative history of deep vein thrombosis (DVT) (n = 2), malignancy (n = 1), or uncontrolled hypertension (n = 2), diabetes mellitus (n = 1), bleeding disorder (n = 1) or coronary artery disease (n = 1) were excluded. Other patients who had any of the above co-morbidities but were considered medically controlled or who had undergone previously an arthroscopic debridement or a high tibial osteotomy

The work was performed at Kecioren and Ataturk Education and Research Hospitals, Ankara, Turkey.

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were not excluded from the study. As such, 44 patients (8%; 88 knees) were excluded from the study, leaving a total of 964 knees of 482 patients for evaluation.

There were two intervention groups: non-drainage group (Group 1), using disposable sterile elastic exsanguination tourniquet that was released after closure (Fig. 1, HemaClear, OHK Medical) and drainage group (Group 2), using pneumatic tourniquet that was deflated prior to haemostasis and closure with Hemovac drain. Group 1 consisted of 255 patients (39 male, 216 female) with an average age of 64.4 years (range, 47–84 years). Group 2 comprised 227 patients (26 male, 201 female) with an average age of 63.9 years (range, 43–88 years) (Table 1). There were no demographic differences between the two groups (Table 2). There were no statistical differences between the groups in terms of co-morbidities such as hypertension, diabetes mellitus or coronary artery disease and both groups had the same levels of preoperative hemoglobin (13.1 ± 2.5 and 12.8 ± 1.8 g/dl; respectively, Tables 1, 2).

All operations were performed under spinal anaesthesia by 2 staff surgeons (KK and AO) who regularly perform at least 150 knee arthroplasty operations per annum using a midline approach. Implants were supplied by Corin Ltd, Cirencester, UK PCL retaining cemented prosthesis with Rotaglide mobile polyethylene inserts and were used for all patients. In the first group, potential bleeding sources were coagulated intraoperatively, wound closure was done in layers and a sterile Jones bandage was applied prior to the release (by cutting) of the sterile exsanguination tourniquet (Group 1, n = 255, 510 knees). In the second group, exsanguination of the leg was performed by Esmarch bandage, and a pneumatic tourniquet was inflated to a mean pressure that was 100 mm/Hg above the systolic blood pressure. At the end of the operation the tourniquet was deflated, careful haemostasis was performed, a Hemovac drain was inserted, the surgical wound was closed in layers and a Jones bandage was applied (Group 2, n = 227, 454 knees).

The two groups of patients were compared in terms of postoperative blood transfusion need as a primary outcome. In addition to comparison of the lowest levels of postoperative hemoglobin and infection rates, DVT, pulmonary emboli (PE) rates, postoperative tourniquet related pain defined as pain in the quadriceps muscle underneath the tourniquet cuff [19], duration of operation, haemarthrosis, and requirement for post operative analgesia (IM 100 mg Tramadol per ampule) were also determined. Blood transfusion need was evaluated for the entire duration of hospitalization. All of the patients included in the study received antibiotic prophylaxis of 1 g Cephazolin Sodium one hour before induction of anesthesia. During their stay in the hospital, patients were administered 1 g cephazolin sodium three times a day for the first day postoperatively.

Infection was followed up by observing local and systemic signs such as erythema, swelling, elevated ESR, CRP and white blood cell count. In case of any suspicion for deep infection, fluid and tissue cultures were taken and aspirate was sent for cell count and differential. For management of postoperative pain, iv tramadol was given through PCA on postoperative day 1 and diclofenac sodium was used on the following days. At the preoperative stage, all the patients were administered 40 mg Enoxaparin prophylaxis beginning at the postoperative 12th hour and the INR was measured preoperatively and 12 h postoperatively. The patients were administered 40 mg prophylaxis of enoxaparin once a day, for 3 weeks.

Preoperative standard haemoglobin level had to be 10 g/dl or higher to be operated on and thereby included in the study. Blood transfusion (Erythrocyte suspension) was given to patients with haemoglobin levels of 7.9 g/dl or less in the postoperative 3rd day follow-up in both groups. In addition, blood transfusion was given to symptomatic patients in the postoperative 3rd day follow-up with haemoglobin levels of 8–10 g/dl in the postoperative period if their heart rate was over 120 or systolic blood pressure was less than 90 mm Hg. Intraoperative blood loss was not usually used as an indicator of transfusion unless there was an excessive blood loss exceeding 10% of the patient's estimated total blood volume. Colloid solutions were infused for less significant blood loss (<10%).

All of the data for this study were obtained from the hospital's computerized medical records. For analysis of differences within and between groups, Excel and the statistical software package SPSS (v.15, Chicago, Illinois) were used. To analyze differences between the groups, a 2-way, repeated-measure analysis of variance was used. An unpaired 2-sided t-test was used to analyze differences between means and 2-sided z-test was used to analyze the significance of differences between proportions. All P values < 0.05 were considered significant.

Table 1
Demographics and Preoperative Haemoglobin Levels of the two Patient Groups.

Demographic/hb	Group 1 (n = 255)	Group 2 (n = 227)	P
Average age (years)	64.4 (47–84)	63.9 (43–88)	0.41
Male:female	39:216	26:201	0.32
Prhb	12.8 ± 1.8	13.1 ± 2.5	0.62

Hb = Haemoglobin; Prhb = Preoperative haemoglobin.

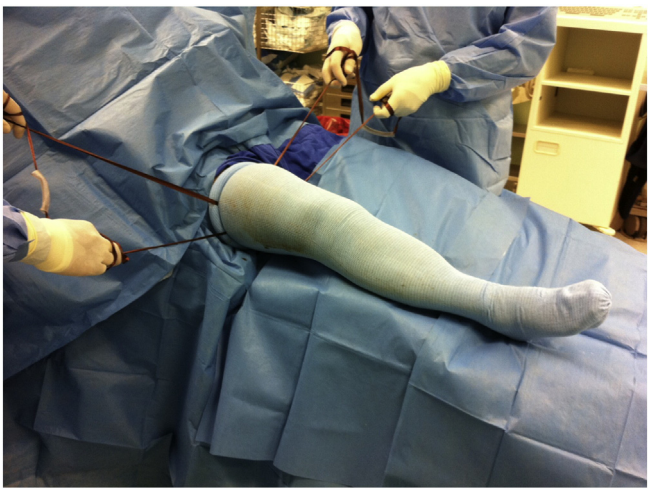

Fig. 1. Application of sterile elastic exsanguination tourniquet. The torus, consisting of a silicon ring wrapped by a stockinette is rolled up the disinfected and draped leg by pulling the straps (top) all the way to the upper thigh (middle). The pressure applied by the rolling ring along the way effectively exsanguinates the limb and arterial flow into the leg is blocked (bottom). The elastic ring is cut with a scalpel at the end of surgery (not shown) to resume blood flow.

Table 2
Comparison of Comorbidities Among Patient Groups.

	Group 2	Group 1	P
Overall comorbidity rate	132 (51.8%)	128 (56.4%)	0.309
Ht	88 (34.5%)	81 (29.2%)	0.192
DM	51 (20%)	48 (17.3%)	0.429
CAD	31 (12.2%)	28 (10.1%)	0.452
Ht + DM + CAD	6 (2.4%)	4 (1.4%)	0.531
Ht + DM	18 (7.1%)	13 (4.7%)	0.245
Ht + CAD	14 (5.5%)	11 (4%)	0.408
Weight (kg)	83 ± 6.5	79 ± 4.2	0.376
Height(m)	1.643 ± 1.7	1.661 ± 2.1	0.445
BMI (kg/m^2)	30.9 ± 3.87	30.1 ± 2.2	0.657
Surgical time (min)	156 ± 12.39	162 ± 11	0.721
Previous surgery	11 (4.8%)	14 (5.5%)	0.237

Ht = Hypertension; DM = Diabetes Mellitus; CAD = Coronary artery disease.

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Table 3
Comparison of Blood Transfusion Rates and Postoperative Haemoglobin Levels.

Blood units	Group 1	Group 2	*P*
0	61 (23.9%)	0 (0%)	s.
1	121 (47.5%)	1 (0.4%)	s.
2	63 (24.7%)	28 (12.3%)	s.
3	9 (3.5%)	113 (49.8%)	s.
4	1 (0.4%)	81 (35.7%)	s.
5	0 (0%)	4 (1.8%)	s.
Total units	278	740	
AV	1.09 ± 0.81	3.26 ± 0.71	<0.001
Pohb	7.2 ± 1.1 g/dl	6.5 ± 1.8 g/dl	<0.001

s = significant ($P < 0.05$); AV = average number of blood units per patient; Pohb = Postoperative haemoglobin.

Results

Blood transfusion rate was three fold higher in Group 2 (Table 3). A total of 740 U were transfused in Group 2 (3.26 ± 0.71 U/patient, mean ± SD) and only 278 U in Group 1 (1.09 ± 0.81 U/patient) ($P < 0.001$). There were no reported significant complications or side effects due to blood transfusion in either group aside from the higher cost of treatment. The mean lowest post-operative haemoglobin was 6.5 ± 1.8 g/dl in Group 2 and 7.2 ± 1.1 g/dl in Group 1 ($P < 0.001$).

The infection rates which were seen unilaterally among the two groups are shown in Table 4. Superficial wound infection was diagnosed in 11 patients in Group 2 (4.85%) and in 5 patients (1.96%) in Group 1 ($P = 0.078$). Deep prosthesis infection was found in 6 patients (2.64%) in Group 2 and in 2 patients (0.78%) in Group 1 ($P = 0.1$). Surgical treatment was needed for 6 of the 8 patients diagnosed with deep prosthesis infection (5 in Group 2 and 1 in Group 1). In 1 of the infected patients in Group 2, with two failed revision attempts, the revision type prosthesis was removed and arthrodesis was performed. Other cases were treated with two step revision surgery which included prosthesis removal, antibiotic impregnated spacer application, at least 6 weeks of medium specific IV antibiotic therapy and revision total knee arthroplasty. All of these patients were eventually healed. Note that the percentages reported above were calculated based on the number of patients and should be divided by 2 if the rates per operated knee are sought. The overall (superficial wound and deep prosthesis) infection rates were 7 (2.7%) in Group 1 and 17 (7.5%) in Group 2 ($P = 0.017$).

Additional complications and side-effects were noted for both groups and these are shown in Table 5. The rate of tourniquet related pain was more commonly seen in Group 2 (18 vs. 5 patients, $P = 0.002$). Deep vein thrombosis (DVT), which was diagnosed by sonography after clinical suspicion was observed in 12 patients (5.29%) in Group 2 and in 4 patients (1.57%) in Group 1 ($P = 0.023$). There was no haemarthrosis in Group 2 (Table 5, $P = 0.1$). Among the patients in Group 1, haemarthrosis developed in 3 knees (0.6%) and was treated by aspiration, cold-pack and application of compressive dressing. No further complications were observed during the follow-up of these patients.

Pulmonary embolism was diagnosed in 7 patients (3.1%) in Group 2 and in 2 in Group 1 (0.78%) ($P = 0.06$). All of them survived with supportive therapy. No other major complications were noted. Statistical analysis showed a minor yet significant difference between the two groups with respect to their analgesic need (Table 5). The mean duration of the operations (each knee) was 22.4 min (24.2%) longer for Group 2 (115.1 ± 14.4 min) than for Group 1 (92.7 ± 6.7) ($P < 0.001$). The length of stay in the hospital was essentially the same for both groups.

Table 4
Comparison of Infection Rates.

Infection Rate	Group 1 (n = 255)	Group 2 (n = 227)	*P*
Total	7 (2.7%)	17 (7.5%)	0.0168
Deep	2 (0.78%)	6 (2.6%)	0.111
Superficial	5 (1.96%)	11 (4.85%)	0.0776

Table 5
Postoperative Complications.

	Group 2	Group 1	*P*
Urinary tract infection	10 (4.4%)	11 (4.3%)	0.961
Deep venous thrombosis	12 (5.3%)	4 (1.6%)	0.023
Pulmonary embolism	7 (3.08%)	2 (0.78%)	0.063
Hemarthrosis	0 (0%)	3 (1.2%)	0.101
Tourniquet related pain	18 (7.9%)	5 (2%)	0.0022
Post op analgesics need[a]	3.1 ± 0.5	2.9 ± 0.4	<0.001

[a] Tramadol 100 mg/ampule.

Discussion

This study showed a dramatic reduction in blood transfusion needs, which can be explained by the non-linear nature of applying a rigid policy for blood transfusion that was applied. Quantitatively, a difference of 0.2 g/dl or 2 g/l means a total difference of 10 g of hemoglobin loss which is only about 125 ml of blood in a patient who has a blood volume of 5 l and hemoglobin level of 8 g/dl. Although it is quite inaccurate to try to infer the reduction of blood loss between Group 1 and Group 2 from their lowest post operative hemoglobin, we can attempt to estimate it as $(7.2-6.5)/6.5 \times 5000$ ml = ~ 540 ml. While this calculation is rough at best, it provides an order of magnitude estimation of the difference in blood loss between the methods.

The overall infection rate was determined to be lower in Group 1 ($P = 0.016$). The rates of deep prosthesis and superficial wound infections individually were non-significant when the two-sided statistical analysis was used (i.e. generic null hypothesis of difference, rather than of Group 2 infection rate being greater than in Group 1). This difference in infection rate can be attributed to: (a) no drain in Group 1; (b) sterile tourniquet in Group 1 versus non-sterile one in Group 2; (c) shorter procedure duration in Group 1; and (d) less blood transfusion in Group 1. It is not possible to discern which of these factors actually played a dominant role in the reduced infection rate. If, however, the trend for reduced deep infection is an indication, the drop from 2.6% (based on patient number) or 1.3% (based on knees number) to 0.8% (0.4%) could translate into a substantial improvement in outcome and a very significant financial saving (e.g. over $140,000 per 1000 TKAs in our institution).

In the present study an alternative set of procedures was evaluated with the primary aim of reducing blood loss and thereby minimizing the need for blood transfusion. Firstly, the Esmarch and pneumatic tourniquet were replaced with the sterile exsanguination tourniquet (HemaClear) in the first group due to its ease of use, drier surgical field and sterile application. The second change was in the sequence of activities towards the end of the operation. In particular, the incision was first sutured in layers, the Jones dressing was applied and only then was the exsanguination tourniquet removed by cutting it. No Hemovac drain was used in this set. By so doing, a substantial reduction in blood loss was anticipated during the period from (pneumatic) tourniquet deflation to application of the compressive dressing. The physiological reactive hyperemia that occurs at this time due to the extreme vasodilatation, promotes bleeding beyond the amount usually observed from a surgical incision. It was felt that perhaps much of the blood accumulation inside the closed surgical wound (which is subsequently drained by the Hemovac in the traditional approach) could be avoided by properly packing the knee with the Jones dressing prior to removal of the arterial occlusion. The results of this study confirm our hypothesis as outlined below.

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Other researchers have investigated blood loss in and around TKA. The methods commonly used to estimate intra-operational blood loss have been the measurement of volume and the haematocrit of the liquid accumulating in the suction container and weighing the sponges [20]. The extent of post-operative blood loss has usually been determined from measuring the volume of blood accumulating in the drainage container(s) in the first 24, 48 or 72 h postoperatively. The sum of the two volumes was used as a measure of the tangible total blood loss. Most of these studies also reported pre and post operative hemoglobin levels, calculated the "hidden loss" and specified the need for blood transfusion. We believe our study, which uses the need for blood transfusion as the primary endpoint for the investigation while applying a rigorous protocol for the determination of transfusion requirement, provides a simple, quantitative and objective way of comparing surgical strategies with blood loss as a primary objective.

Three patients in Group 1 (1.2%) developed haemarthrosis, while none was seen in Group 2. This is believed to be a direct result of not releasing the arterial blood flow blocking in Group 1 prior to the closure of the incision. The haemarthrosis that developed despite the Jones bandage could have been from arterial vessels. However, none of the 3 patients required open haemostasis in the OR. They were successfully managed with needle aspiration, cold packs and compressive dressing with no consequences.

A number of unexpected results were observed in this study; the statistically significant reduction in DVT rate and the trend for a lower rate of Pulmonary Emboli (PE) were not foreseen. In fact, we do not fully understand the mechanism of these findings. It could be speculated that the smaller area under compression by the narrow ring of the elastic exsanguination tourniquet as compared to the larger volume of tissue (and length of the underlying veins) that is under compression by the wide pneumatic tourniquet may have contributed. Competing theories may include the shorter operations in Group 1 and the improved exsanguination, not leaving clotted blood behind in the veins for the duration of the operation. We are not aware that transfusion of RBC suspension promotes DVT, but this could theoretically be yet another factor.

Significantly fewer patients reported pain in the thigh at the site of the placement of a sterile elastic exsanguination tourniquet than at the site of the pneumatic tourniquet. This finding, again, was not expected, but correlates with the results of several studies that have compared the way volunteers tolerated an elastic exsanguination tourniquet to a pneumatic tourniquet [21,22]. The need for post operative analgesia was 6.6% less in Group 1 than in Group 2, but this small difference was nevertheless statistically significant. While tourniquet pain may have been a factor in this finding, other elements such as no drain and limited use of diathermy intra-operatively may have played a role.

The concern about blood loss in TKA and its prevention has been the subject of many studies carried out in order to understand its extent and causes and to find strategies to minimize it [23–27]. In 1991 Lotke et al [32] documented a significant blood loss in unilateral TKA with the mean value being 1519 ml and called attention to the need for preoperative preparation of sufficient blood products for the patient. Bottner, Pavone et al [4,28] studied the need for blood transfusion in patients undergoing one-stage bilateral TKA. In a group of 461 patients described in 2003 [28] and in an expanded group of 501 patients described in 2004 the mean blood transfusion need was 2.8 U, which is not very different from the 3.26 ± 0.71 U reported for Group 2 in the current study (Table 3). Passad et al [29] studied the risk factors associated with greater blood loss and need for transfusion. They found that men lost significantly more blood than women ($P = 0.001$) which may be relevant to our own study where there were substantially more women than men. They also found a significant correlation between tourniquet time and operation duration. This observation may contribute, in part, to the reduced blood loss in our Group 1 patients.

Among the strategies for reduction in blood loss during TKA there have been multiple reports on the effects of the timing of tourniquet release, on the placement of drains and combinations thereof, and on the use of Tranexamic acid. Steffin and Green-Riviere [30] studied the effect of a blood-salvage drain on the haematocrit drop in 37 patients randomized into either an early or late tourniquet release groups. No differences were observed between the groups in maximal haematocrit drop, drainage amounts or total surgical time. The authors concluded that the use of a blood salvage drain should not influence the preference of timing of tourniquet release in TKA. A recent study by Li et al [31] also evaluated blood loss in 100 patients undergoing TKA randomized into two groups: with and without a drain. They found that blood loss was more than 300 ml higher in the with-drain group with a higher need for blood transfusion, with no detrimental consequences in the no-drain group. They concluded that placement of a drain does not present a significant advantage in TKA. The beneficial effect of Tranexamic acid was recently described [32] with blood loss reduction of nearly 500 ml, a lower drop in hemoglobin and a lesser need for transfusion. Other studies on this topic have shown similar results.

There are several significant limitations of this study that should be outlined. Although the same surgeons performed the operations on both groups and the temporal proximity was close, one may argue that the technical and clinical skills of the entire team may have improved from the first to the second year. Additionally, the interpretation of the study results are complicated by the fact that more than one parameter was changed between the groups. In fact, five parameters were varied from Group 1 to Group 2: (a) drain/no drain; (b) tourniquet type; (c) exsanguination method; (d) hemostasis technique; and (e) timing of tourniquet release. As such, the full impact of these changes will probably be transferable only if all five changes are implemented together.

The exclusive inclusion of one-stage bilateral knee arthroplasty population in the current study raises the question of if and to what extent the findings are transferable to unilateral TKA cases. The need and use of blood transfusion post TKA performed in the traditional way vary considerably from no transfusion at all to 2 U as a standard in nearly all patients. While it is plausible that the blood loss and need for transfusion will be reduced using our new method, it is necessary in our opinion to repeat the study in a unilateral TKA population. Other findings, such as reduced infection, reduced DVT and PE, reduced operative time and less tourniquet pain are probably still relevant to unilateral TKA cases as for these parameters, each knee that was operated on in the current study can be viewed as an independent observation.

In conclusion, the results of this study confirmed our hypothesis that better exsanguination and tourniquet removal only after suturing and packing with a Jones dressing without a drain will reduce blood loss and infection rate and the need for blood transfusion. The study was sufficiently powered to provide conclusive statistical significance. The additional observations indicate that this approach is safer and more effective than the traditional method. The occurrence of haemarthrosis in 3 of 510 knees that were operated on is a non-negligible complication that should be watched for and treated promptly by aspiration, cold pack and compressive Jones dressing. We do not consider it a reason for not using the non-drainage method described here in view of the range of its benefits.

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The Sterile Elastic Exsanguination Tourniquet vs. the Pneumatic Tourniquet for Total Knee Arthroplasty

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ABSTRACT

We compared the sterile elastic exsanguination tourniquet and the pneumatic tourniquet for total knee arthroplasty. 145 patients were operated on using a pneumatic tourniquet and 166 with the sterile elastic exsanguination tourniquet. Patients with the sterile elastic exsanguination tourniquet had a smaller decrease in hemoglobin on post-operative days one ($P < 0.028$) and three ($P < 0.045$). The amount of blood collected from drains at 24 h was significantly lower in the sterile elastic exsanguination group. A trend towards a higher rate of wound complications within 3 months following the operation was found in the pneumatic tourniquet group. The sterile elastic exsanguination tourniquet works at least as good as the pneumatic one.

Bloodless limb surgery was first introduced by Friedrich von Esmarch in 1873 using an elastic ("Esmarch") bandage that was further improved in 1908 by Dr. Cushing with the introduction of the pneumatic tourniquet. This century-old technique is broadly used in upper and lower extremity surgery. The existing tourniquet system consists of many elements (i.e., pump, gas tubes, cuff, padding, cover) that make it cumbersome. The tourniquet cuff is often non-sterile and, therefore, must be placed at the proximal portion of the limb, away from the surgical field. In addition, the methods of exsanguination (limb elevation and/or Esmarch) may leave a substantial amount of blood in the vessels [1–3].

Recently, we started using the new sterile elastic exsanguination tourniquet by HemaClear (OHK Medical Devices, Haifa, Israel) [4–6] for bloodless limb surgeries, including trauma and total knee arthroplasty (TKA) operations. This device can replace the traditional pneumatic tourniquet. It has 3 main functions: 1) Blood removal from the operated extremity (exsanguination); 2) Arterial flow occlusion; and 3) It serves as a sterile stockinet [7].

TKA is a limb surgery that is usually performed with the assistance of a tourniquet to create a bloodless field [8]. Recently, we started to use the sterile elastic exsanguination device instead of a pneumatic tourniquet. In the following article, we report the results of 166 TKA procedures using the sterile elastic exsanguination tourniquet, compared to 145 that were operated on with the assistance of a pneumatic tourniquet. Our hypothesis is that the sterile elastic exsanguination tourniquet works at least as good as the pneumatic one. We assume that the blood amount that will be collected from the drainage will be with no significant difference between the two groups and so will be the post-operative hemoglobin reduction. We also assume that the rate of wound complications will be lower in the sterile elastic exsanguination tourniquet.

Methods

Patients

We reviewed files of patients who underwent TKA in our department. We included only patients who went through elective unilateral primary TKA. We excluded revision TKAs, cases with a history of infected knee, and patients who had a history of a tibial plateau or a femoral condyle fracture. We divided the patients into two groups according to the type of tourniquet that was used in their operation. The pneumatic tourniquet group consisted of 145 patients that were operated on during 2006–2007 using a pneumatic tourniquet. In 2008 and 2009 we used both tourniquets for TKAs in our institute. Since 2010, we have exclusively used the sterile elastic exsanguination tourniquet for TKA; hence, the second group included 166 patients who were operated on during 2010–2011 using the sterile tourniquet.

Outcome Measures

The following measures were collected and compared: 1) Mean decrease in hemoglobin on the first and third post-operative days relative to pre-operative high levels; 2) Post-operative blood transfusion within the first week after surgery; 3) The amount of blood that was drained from the intra-articular space within the first 24 h after the operation; 4) Wound and soft tissue complications within 3 months of the operation.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2014.11.022.

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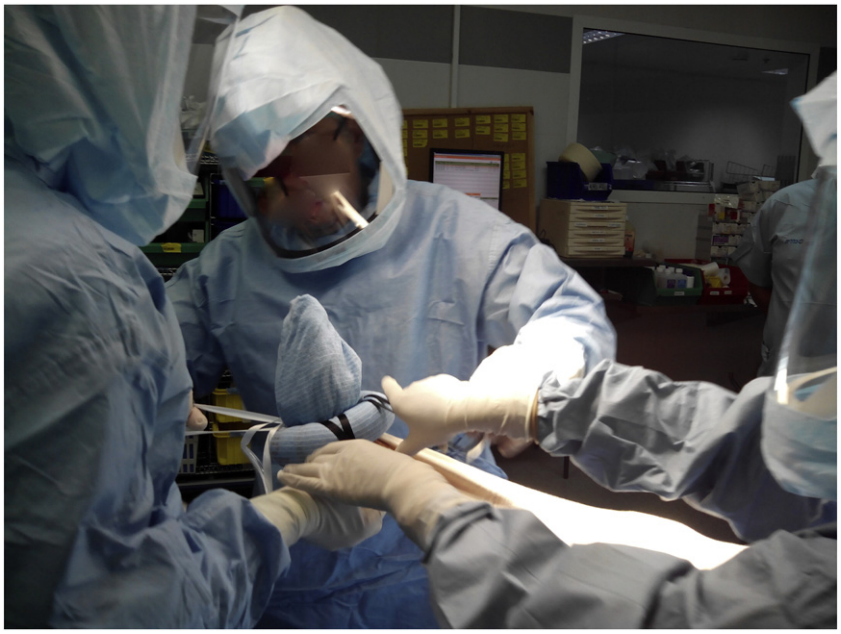

Fig. 1. The physician places the ring on the toes.

Knee Systems

All patients randomly received either the NexGen LPS-Flex Mobile Bearing Knee (Zimmer, Inc., Warsaw, IN, USA) or the PFC Sigma rotating platform knee system (DePuy Orthopaedics, Inc., Warsaw, IN, USA). Both systems are cemented total knees for all components and are posterior cruciate ligament substitutes. In all cases, we resurfaced the patella.

The Sterile Elastic Exsanguination Tourniquet:

The sterile elastic exsanguination tourniquet consists of a silicon ring wrapped in a stockinet sleeve and pull straps. The physician places the ring on the fingers or toes and then pulls the straps proximally. The silicon ring rolls up the limb and the stockinet sleeve unrolls onto the limb (Figs. 1–3). During proximal rolling, the device displaces the blood out of the limb and then blocks the arterial blood flow distally. When the elastic ring reaches the preferred occlusion location, the pulling motion is stopped (Fig. 3). The ring exerts supra systolic pressure on the limb thereby blocking arterial blood flow into the limb and thus acts as a tourniquet [7]. In all patients, the sterile elastic tourniquet provided continuous arterial occlusion for the entire duration of the procedure. We use two sizes for our patients: large and extra-large. The pressure range as reported by the manufacturer is 286 $\pm$ 54 mmHg for the large size, and 326 $\pm$ 21 mmHg for the extra-large size. These pressures are similar to the levels we usually use with the pneumatic tourniquet. The stockinet sleeve unrolls onto the limb, covering it entirely up to the occlusion level and thus drapes a sterile cover over the surgical field [7] (Figs. 3, 4). At the end of the procedure, the ring is cut with a blade. The

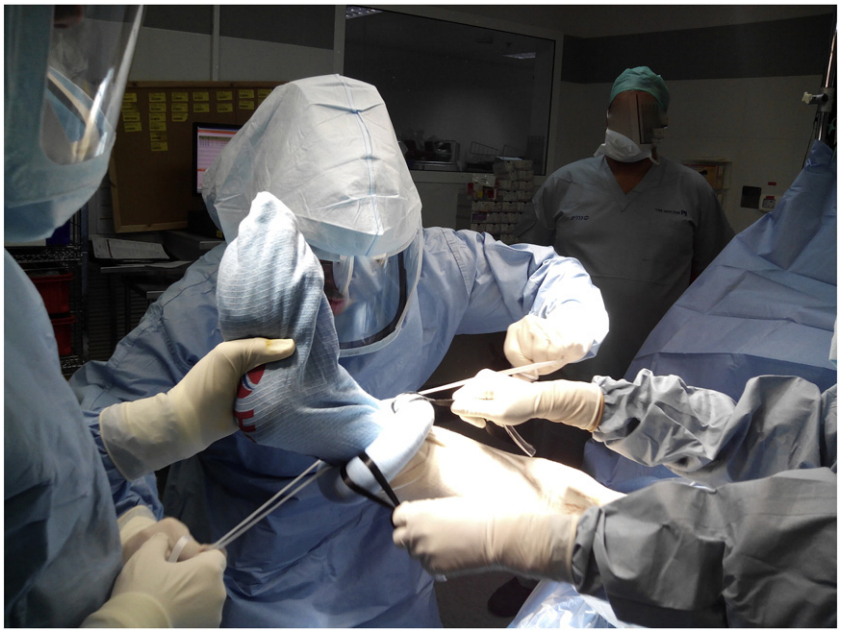

Fig. 2. The physician pulls the silicon ring proximally.

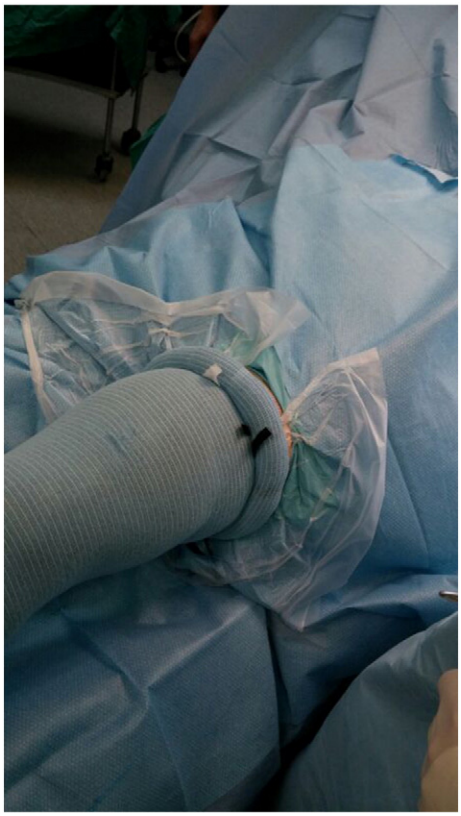

Fig. 3. The stockinet sleeve unrolls onto the limb, covering it entirely up to the occlusion level and thus drapes a sterile cover over the surgical field.

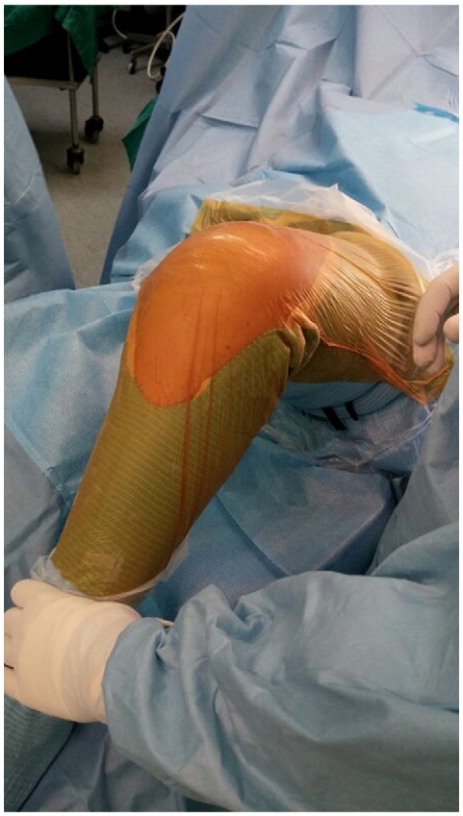

Fig. 4. The stockinet sleeve is cut and provides a sterile surgical field.

sterile stockinet is cut away with scissors, and the blood supply to the limb is resumed.

Surgical Technique

All patients were operated on by the same senior arthroplasty staff in our department, under spinal or general anesthesia. In 86% of the patients a spinal anesthesia was used. The others were operated under general anesthesia. A dose of 2 g cefazolin was given intravenously shortly prior to the skin incision. Clindamycin was used for patients with an allergy to penicillin. Surgery was performed with an above-the-knee tourniquet. The pneumatic tourniquet was placed on the thigh and inflated to 100–150 mmHg above the patient's systolic blood pressure after limb elevation. The sterile tourniquet was placed on the disinfected and prepped leg prior to the skin incision. All patients received a posterior stabilized cemented prosthesis with patellar resurfacing as described above. The skin was incised from the upper border of the patella to the tibial tubercle. In all cases a mid-vastus capsulotomy was done. The femur distal cut was completed with the assistance of an intramedullary guide. The proximal tibial cut was done with the assistance of an extramedullary guide. The pneumatic or sterile tourniquet was released or removed, respectively, before wound closure. After achieving good hemostasis of the operative field, a Biovac™ closed wound system drain, including a 450 ml bulb and a 14Fr PVC drain (Biometrix, Gronsveld, The Netherlands), was inserted in all knees prior to fascia closure. Fascial layers were closed in the usual fashion and staples were used superficially. A compression bandage was applied to the limb following closure. In all the knees, hemovac drains were used for 24 h and the amount of blood drainage from the knee was recorded in the patients' files. All patients were treated with subcutaneous enoxaparin 40 mg per day for 35 days following the operation. The treatment started in the hospital, and continued in the patients' home by the patients or by a nurse in cases when the patients had difficulties in injecting the drug. Physiotherapy with full weight bearing ambulation with the assistance of a walker began in the department on the 1st post-operative day, and continued at the patients' home.

Statistical Analysis

Nominal data were described as numbers and percentages and continuous data as mean and standard deviation. Differences between pneumatic and sterile elastic exsanguination tourniquets were calculated using Chi-Square test for nominal variables and t-test for continuous. Comparisons along time were compared with paired t-tests. A P value of $< .05$ was considered statistically significant. The post-hoc power was 78%.

We assumed that a decrease of more than 0.5 mg in hemoglobin after 3 days will be considered clinically significant. In addition, a decrease of 4% or more in wound complications within 3 months will also be considered clinically significant. We estimated that a sample size of 150 patients per group will suffice to achieve a power of 80% for a significance level of 5%.

All analyses were performed using SPSS-21 software.

Results

A total of 311 cases of primary TKA were included in the study. Of these, 73% of the patients were female and 27% were male with no significant difference between the two groups. The mean age was 71 ± 8.6 years. All the patients completed the prophylaxis protocol with no adverse effects. Patients' demographics are described in Table 1.

The patients were divided into two groups: The 145 cases operated on from 2006 to 2007 using the pneumatic tourniquet and the 166 patients who were operated on using the sterile elastic exsanguination tourniquet during 2010–2011.

Pre-operative hemoglobin levels were similar in both groups with 13.2 ± 1.2 2 g/dl in the pneumatic tourniquet group and 13 ± 1.2 g/dl

Table 1
Demographics.

Variable	Sterile Elastic Tourniquet N = 166	Pneumatic Tourniquet N = 145	*P* Value
Males	28.3%	26.2%	ns
Age	71.85 ± 8.6	70 ± 8.6	ns
BMI	29 ± 5.2	29.5 ± 4.9	ns
Spinal Anesthesia	142	124	ns

in the sterile elastic exsanguination tourniquet group. Both groups experienced a significant decrease in hemoglobin between pre-operative and post-operative hemoglobin levels on the first post-operative day, as well as in the second blood exam that was done on the third day following the operation (13 ± 1.2 vs. 10 ± 1.2). At the first post-operative day, hemoglobin dropped by 2.78 ± 0.98 g/dl in the pneumatic tourniquet group and 2.53 ± 0.95 g/dl in the sterile elastic exsanguination tourniquet group ($P < 0.0001$). The decrease in hemoglobin on the third post-operative day was also greater in the pneumatic tourniquet group (3.28 ± 1.18 g/dl) compared to the sterile elastic exsanguination tourniquet (3.0 ± 1.14 g/dl) ($P < 0.0001$). There was no significant difference in the number of patients who received a blood transfusion between the groups.

There was a significant difference in the amount of blood drained from the knee at 24-h post-surgery. In the pneumatic tourniquet group, the mean amount of blood that was drained from the knee was 346.1 ± 186.3 cc, and in the sterile elastic exsanguination tourniquet group it was 252.8 ± 142.4 cc ($P < 0.001$).

Under the definition of wound complications we included the following: superficial wound infections, cellulitis around the surgical wound/scar, and wound dehiscence. We found a higher percentage of wound complications within 3 months of the operation in the pneumatic tourniquet group (7.7% vs. 4.2%). 10 cases of superficial wound infections and one wound dehiscence were observed in the pneumatic tourniquet group. Among the infections, 2 were treated by debridement and I.V. antibiotics; the others were treated only by I.V. antibiotics. In the Sterile tourniquet group there were 6 cases of superficial wound infections and one case of wound dehiscence in the same time. One of the infected cases was treated by wound debridement and I.V. antibiotics, and the others were treated only by I.V. antibiotics. There were no cases of deep infections in both groups. The difference between the two groups was not statistically significant, but there was a tendency to more wound complications in the pneumatic tourniquet group. The results are summarized in Table 2.

There was one case of DVT in the pneumatic tourniquet group and two cases in the sterile tourniquet group.

Discussion

This is the first study that compares the non-sterile pneumatic tourniquet with the elastic exsanguination sterile tourniquet for the control of bleeding in unilateral TKA. Our results might indicate the benefits of using the sterile elastic exsanguination tourniquet.

Decreased hemoglobin after TKA is well known and described in many papers. Most authors described decreases in hemoglobin of 2–3 g/dl following TKA [9–14]. We also showed a decrease in hemoglobin levels in the first 24 h following the operation, but we found a significantly lower post-operative hemoglobin reduction in the elastic exsanguination sterile tourniquet group. We showed the same difference on the third post-operative day. Although the difference between the two groups was small, it could change the patient's overall clinical condition; even a small difference in hemoglobin level can play a role in the decision for blood transfusion, especially when the hemoglobin level is close to a specific transfusion threshold.

The use of a surgical drain was believed to be effective in decreasing hematoma formation [15–17], which has been theoretically thought to decrease post-operative pain, swelling, and the incidence of infection [18]. Several authors reported drainage volume within the first 24 h following surgery. According to those reports, the volume at the first 24 h is in the range of 330–796 ml [19–23]. We showed that when we used the sterile elastic exsanguination tourniquet, we measured a significant mean reduction in blood drainage volume in the range of 100 cc. This reduction reflects a decrease in intra-articular bleeding.

The two factors mentioned above, decrease in post-operative hemoglobin reduction and post-operative intra-articular bleeding are important in the recovery period. Both factors reflect total blood loss, which might lead to significant anemia and predispose the patient to increased risk for cardiopulmonary events, transfusion reactions, delayed ambulation and increased health care costs [24]. One of the main advantages of the sterile tourniquet is that it squeezes the blood out of the extremity during proximal rolling, and then blocks the arterial flow into the extremity when it reaches its occlusion position [7]. We assume that the proximal rolling and squeezing make the difference in the decreased blood loss because the surgical field during the operation is empty of blood. It is important to understand that while the extremity is exsanguinated only by elevation prior to the inflation of the pneumatic tourniquet, the sterile elastic tourniquet serves also as an esmarch, and causes a complete exsanguination of the limb. This is one of the advantages of the sterile elastic exsanguination tourniquet.

In the present study, we found no difference in the rate of blood transfusion between the two groups. This finding was surprising as we described lower volumes of intra-articular blood drainage and lower rates of hemoglobin reduction with the sterile tourniquet. The best way to explain this contradiction is related to the non-standardized clinical criteria for transfusions in our department.

The last item that was compared in this study was the rate of wound complications in both groups of tourniquets within 3 months of the operation. It has been discussed recently that pneumatic tourniquets could be contaminated. Two studies have demonstrated 100% contamination among the tourniquets they had sampled. The bacteria collected included: *S.* coagulase negative, *P. aeruginosa*, MRSA and *S. aureus* [25,26]. The main problem is that most institutes do not have a standard protocol for cleaning tourniquets [27]. Thompson compared the bacterial load of non-sterile pneumatic vs. sterile elastic tourniquets [28]. His results showed that the sterile tourniquet was free of bacterial growth, not only as it comes out of the package but also at the end of the procedure, whereas the non-sterile pneumatic tourniquet was contaminated in 23 of 34 of cases (68%). According to these studies, we believed that we would find a significant difference in the rate of wound infections and complications at 3 months following the operation. Our results showed

Table 2
Main Results.

Variable	Sterile Elastic Tourniquet N = 166	Pneumatic Tourniquet N = 145	*P* Value
Hb pre-op	13 ± 1.2 g/dl	13.2 ± 1.2 g/dl	$P = 0.143$
Hb reduction first post-operative day	2.53 ± 0.95 g/dl	2.78 ± 0.98 g/dl	$P < 0.028$
Hb reduction third post-operative day	3 ± 1.14 g/dl	3.28 ± 1.18 g/dl	$P < 0.045$
Blood drained from the knee at first 24 h	252.8 ± 142.4 ml	346.1 ± 186.3 ml	$P < 0.001$
Wound complications within 3 months	7/167 (4.2%)	11/143 (7.7%)	$P = 0.189$

Hb = hemoglobin.

a higher percentage of wound complications in the pneumatic tourniquet group within 3 months of the operation, which was not statistically significant. These results might have been significant if our groups were larger.

This study found some important advantages in using a sterile elastic exsanguination tourniquet instead of a pneumatic tourniquet. We should keep in mind that one main disadvantage to the sterile tourniquet is the cost, which could get up to 70 EUR according to the manufacturer. Nevertheless, although its cost is higher, we believe that this will be offset by cost savings due to fewer complications and improved patient well-being. Thus, we support using the sterile elastic exsanguination tourniquet during TKA.

This study had a few limitations. The study was a retrospective one and we used a historical control group. The authors were not blinded when collecting the data from the patient's files, since we knew when the sterile elastic exsanguination tourniquet began to be used. Collecting data on larger cohorts might have changed the results and found even greater differences between the two groups. In order to find a difference in blood transfusion between the two groups, we should specify a hemoglobin level for transfusion. We believe that there is a place for future prospective blinded studies with larger groups of patients, to better define the differences between the two tourniquets.

Summary

Our findings demonstrate that the sterile elastic exsanguination tourniquet works at least as good as the pneumatic one, and has several advantages over it: first, it reduces the decrease in post-operative hemoglobin and intra-articular blood drainage, most probably due to its proximal rolling and blocking character. Second, it is a sterile tourniquet and might have the potential to keep the wound field cleaner.

We recommend the usage of the sterile elastic exsanguination tourniquet for TKA.

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The Silicone Ring Tourniquet in Orthopaedic Operations of the Extremities

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ABSTRACT

Tourniquets provide a bloodless field in limb operations and their introduction in orthopaedic operative technique has been considered as a landmark. A new tourniquet device, a silicone ring tourniquet (SRT) (HemaClear or S-MART, OHK Medical Devices, Haifa, Israel), was introduced into clinical practice a few years ago. A few clinical studies as well as comparative studies in volunteers have reported its use in a relatively small number of cases.

The aim of this prospective study is to report the clinical use of this device in a large number of patients, including all possible applications of a tourniquet. The SRT was used in 536 cases including 337 male and 119 female patients with a mean age of 43.7 years (range 6 to 87 years). The average tourniquet time was 58.5

minutes (range 6 to 180 minutes). It was applied in 362 (67.5%) elective and in 174 (32.5%) trauma cases including fractures (n:109, 62.6%) and soft-tissue injuries (n:65, 37.4%). The most frequent application site was the femur (n:255, 47.6%), followed by the forearm (n:154, 28.7%), humerus (n:65, 12.1%), and calf (n:62, 11.6%).

Because the device is sterile it was possible to use it in operations in which the pneumatic tourniquet cannot be used, such as open reduction and internal fixation of humeral shaft and femoral supracondylar fractures. In 14 patients (2.6%), the tourniquet failed intraoperatively, and the cause was an unexpected raised blood pressure. The SRT - with a pre-set pressure according to the size and the tension model - is easy to apply. It is sterile, and occupies a narrow area of the limb. Its application combines three functions at the same time: exsanguination, tourniquet, and stockinet application. Although it cannot entirely replace the classic pneumatic tourniquet, it is a safe and useful device in orthopaedic operations because of its advantages.

INTRODUCTION

A tourniquet is a constricting or compressing device used to control venous and arterial circulation to an extremity for a period of time. This device provides a bloodless field in limb operations and its introduction in orthopaedic operative technique has been considered a landmark.[1] The bloodless field provided by a tourniquet: (a) enables easier surgical interventions on the extremities, (b) in delicate operations of the hand is essential for accurate dissection and to avoid damaging small vital structures, and (c) theoretically, provides a better cement-bone interface in a cemented arthroplasty.[2–4]

Pneumatic tourniquet (PT) is the most commonly used tourniquet since its introduction by Harvey Cushing in 1904[1]; its use has become almost routine as it is considered the safest device.[5] The Esmarch tourniquet is considered less safe than a pneumatic tourniquet, but is still in use by some surgeons mainly in podiatric surgery.[6,7]

Nevertheless, pneumatic tourniquet use is associated with potential risks of complications as well as clinically relevant sequels,[5] and although serious

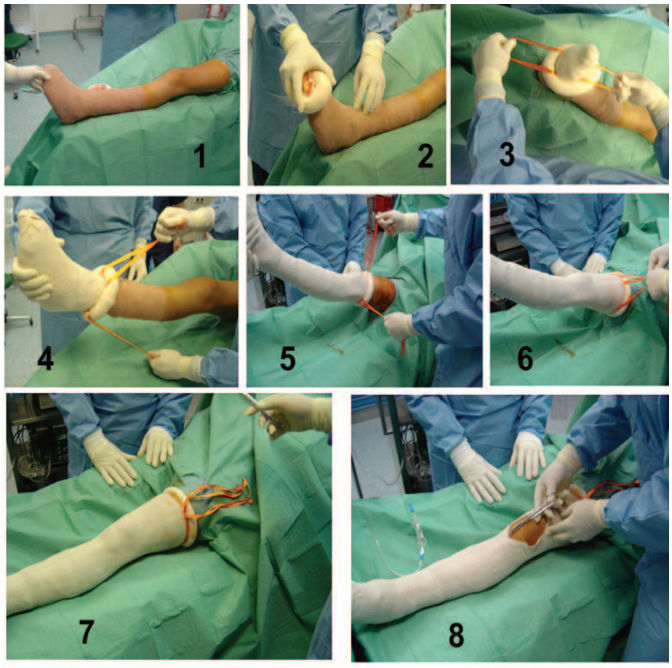


Figure 1. Above knee application of a silicone ring tourniquet.

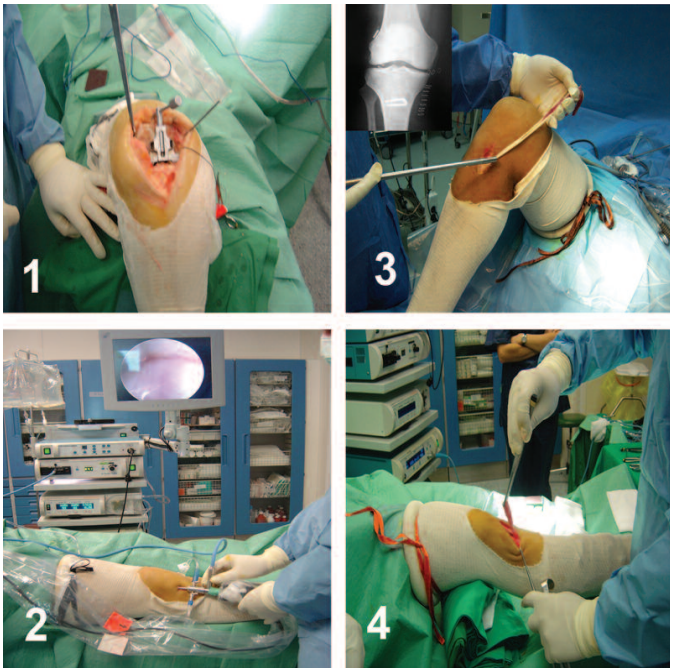


Figure 2. Above knee application of a silicone ring tourniquet in elective cases. (1) Total knee replacement, (2) knee arthroscopy, (3) ACL reconstruction with hamstrings graft, (4) ACL reconstruction with patellar tendon graft.

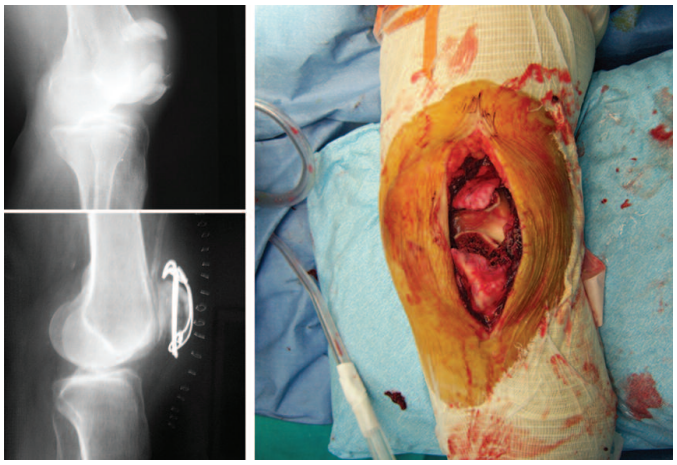


Figure 3. Open reduction and internal fixation of a patellar fracture using a femoral silicone ring tourniquet.

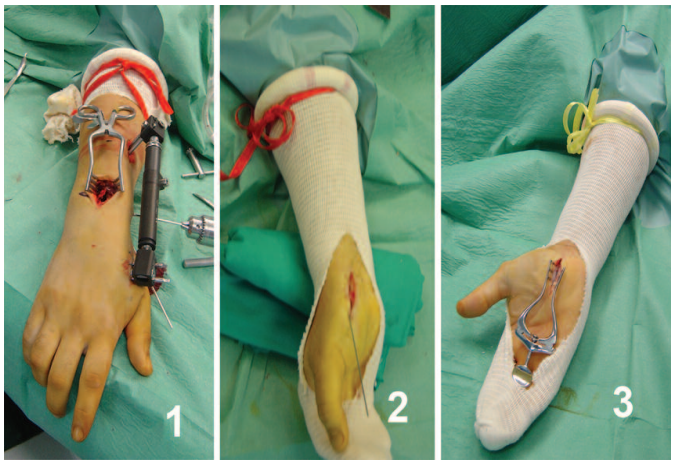


Figure 4. Forearm application of a silicone ring tourniquet. (1) Fixation of a distal radial fracture, (2) scaphoid fracture fixation, (3) carpal tunnel release.

complications of the use of a tourniquet are rare, there is a definite morbidity.[8] Because of the known risks, much effort has been directed at assessing the safe time and pressure for their use.[9]

Apart from the well-known contraindications and measures to avoid, regular checks and tests are required even for modern pneumatic tourniquet device complications.[5] One important issue is whether the selected tourniquet pressure actually is applied by the device at the tourniquet application site during the whole procedure.

A new tourniquet device (HemaClear or S-MART, OHK Medical Devices, Haifa, Israel) was introduced into clinical practice a few years ago.[10–14] This device consists of a silicone ring wrapped within an elastic sleeve (stockinet) and two straps attached to pull handles, and is designed for exsanguination and occlusion of the blood flow to the limb. The entire device is sterile and comes in different sizes and different tension models, and the pressure that is applied to the limb is preset. There are four different sizes: (a) a small size for pediatric use; (b) a medium size for the upper limb (circumference of the limb at the occlusion site 24–40 cm); (c) a large size for the leg (circumference of the limb at the occlusion site 30–55 cm); and (d) an extra-large size for the leg (circumference of the limb at the occlusion site 50–90 cm and systolic blood pressure ≤160 mmHg). There are also three tension models (systolic blood pressure ≤130 mmHg, <160 mmHg, <190 mmHg) for the medium and large sizes, and the appropriate model is selected for each patient according to the systolic blood pressure measured in the operating room before the placement of the device.[14] The device is removed by cutting the ring, which cannot be re-attached.

This device has been compared with the pneumatic tourniquet in healthy volunteers,[15–17] and in two clinical studies of patients who underwent upper-extremity operations.[11,14]

A relatively small number of cases have been included in both the clinical as well as the volunteers' studies. Nevertheless, no complications have been reported in any of these studies, but a failure of the device was reported in some cases in one study.[11] Furthermore, apart from the study in children, the other clinical studies are referred to the upper limb applications.

The aim of this prospective study is to report the clinical use of this device in a large number of patients, including all possible applications of a tourniquet.

PATIENTS AND METHODS

The SRT was used routinely in all upper and lower limb operations including elective and trauma cases in the department of orthopaedic surgery in two hospitals: the Athens Naval Hospital and the University General Hospital of Alexandroupolis. Our contraindications were the same as for every tourniquet device and included patients with (a) peripheral vascular disease or having an underlying prosthetic vascular graft, (b) sickle cell disease, (c) open fractures, and (d) intramedullary nailing.

The appropriated SRT model was used, according to the systolic blood pressure measured in the operating room directly before the placement of the device. Any failure of the tourniquet intraoperatively was recorded.

Patients' demographics, diagnosis and type of operation, site of tourniquet

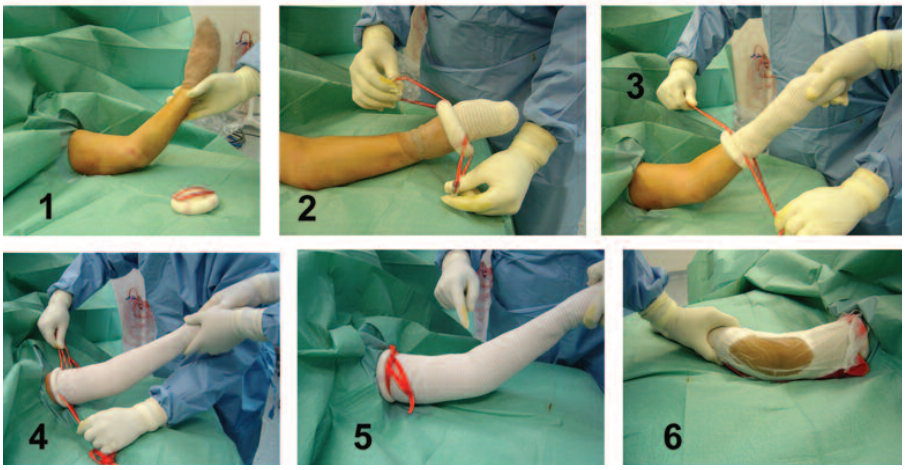


Figure 5. Humeral application of a silicone ring tourniquet.

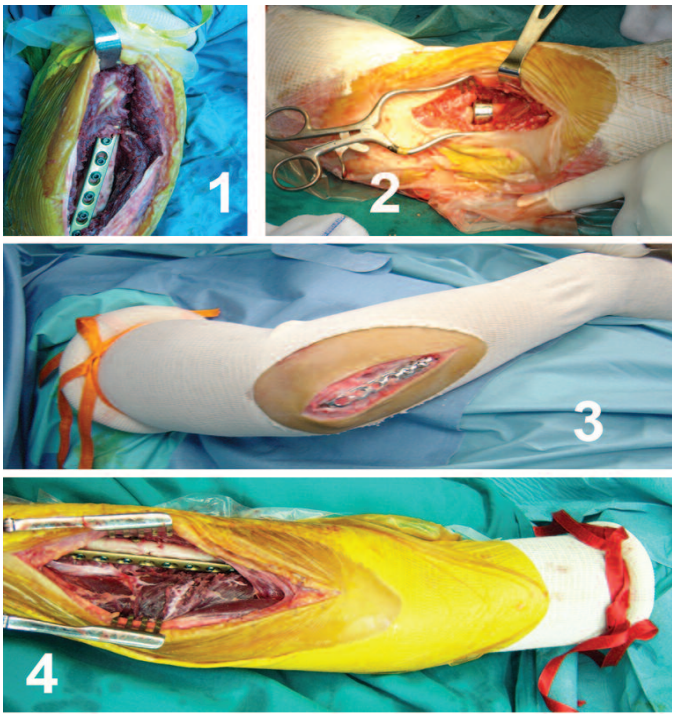


Figure 6. Humeral application of a silicone ring tourniquet. (1) Internal fixation of a humeral shaft fracture, (2) radial head replacement, (3) removal of ulnar plate, (4) internal fixation of a radial fracture.

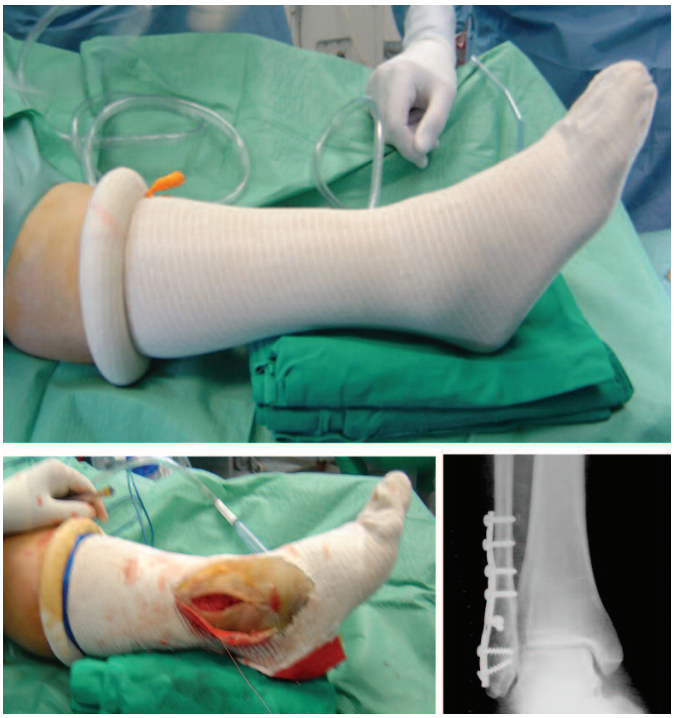
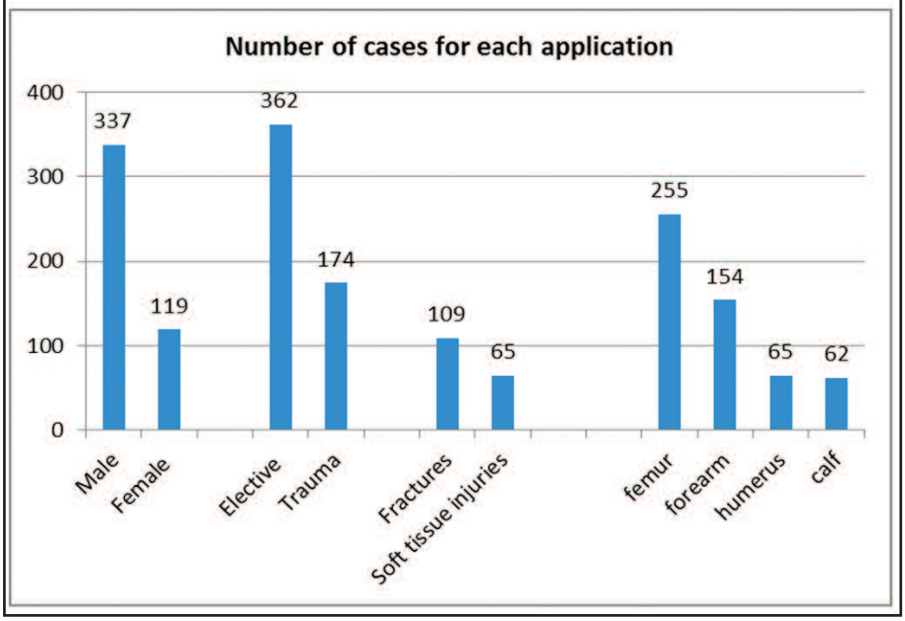


Figure 7. Open reduction and internal fixation of a lateral malleolar fracture using a calf silicone ring tourniquet.

application, and tourniquet time were recorded. All patients were routinely monitored postoperatively and were reviewed the first postoperative day and every day while staying in the hospital and subsequently at two weeks postoperatively. Complications that may be related to the tourniquet were recorded, and these included: (a) skin injuries underneath the tourniquet, (b) post-tourniquet syndrome, (c) nerve paralysis that was followed by either complete recovery (neurapraxia) or permanent nerve damage (paralysis), and (d) any other immediate intraoperative or post-operative complication that may be related to the tourniquet use.

Surgeons were asked to make comments regarding the ease of the application of the device and the quality of the exsanguination, particularly in hand operations.

Table I
Results of the Data Collection



RESULTS

The SRT was used in 536 cases including 337 male and 119 female patients with a mean age of 43.7 years (range 6 to 87 years). The average tourniquet time was 58.5 minutes (range 6 to 180 minutes) (Table I).

The SRT was applied in 362 (67.5%) elective operations and in 174 (32.5%) trauma cases including fractures (n:109, 62.6%) and soft-tissue injuries (n:65, 37.4%). The most frequent application site was the femur (n:255, 47.6%) (Figs. 1–3), followed by the forearm (n:154, 28.7%) (Fig. 4), humerus (n:65, 12.1%) (Figs. 5 & 6), and calf (n:62, 11.6%) (Fig. 7).

In the forearm applications in particular, a general anaesthesia was applied in 50 patients (32.5%), a local anaesthesia in 43 patients (27.9%), and a Bier's block in 61 patients (39.6%).

In cases with Bier's block (either humeral or forearm) (Figs. 8 & 9), if the

patient experiences discomfort at the occlusion site, the silicone ring can be rolled distally a few centimeters (over the anaesthetized area) and the procedure can be extended.

Because the device is sterile it was possible to use it in operations where the pneumatic tourniquet cannot be used such as open reduction and internal fixation of humeral shaft and femoral supracondylar fractures (Fig. 6).

In 14 patients (2.6%) the tourniquet failed intraoperatively, and the cause was an unexpected raised blood pressure.

Surgeons described the following advantages of the devices: (a) the device is applied easily by the surgeon and one assistant; (b) three steps are done together, exsanguination, tourniquet, and stockinet application; (c) the exsanguination was excellent in all cases (Fig. 10); (d) the device is sterile and can be applied after skin preparation and draping and also can be used in certain applications where the pneumatic tourniquet cannot be used; and (e) there is no need for regular check and maintenance.

On the other hand, they noticed two disadvantages: (a) there is a limitation concerning the limb circumference of the limb at occlusion site, and (b) the applied pressure is pre-set and cannot change unless the tourniquet is cut and another model re-applied.

DISCUSSION

The traditional teaching and belief among orthopaedic surgeons is that a wide pneumatic cuff is safer compared with a narrow cuff (and much safer compared with a narrow elastic ring) as far as the soft tissue damage and nerve injury in particular are concerned. Our initial concern was what would happen if we kept a narrow elastic ring around the limb for 1 or 2 hours. Eventually, the results of this study showed that the SRT is safe and practical and is in agreement with previous clinical studies concerning this device.[10–14]

It seems to be the first report of its clinical use in all possible applications in a significantly large number of cases compared with the previous reports.[10–14]

We found no complications related to its use, while surgeons noticed several advantages. Actually, SRT can replace

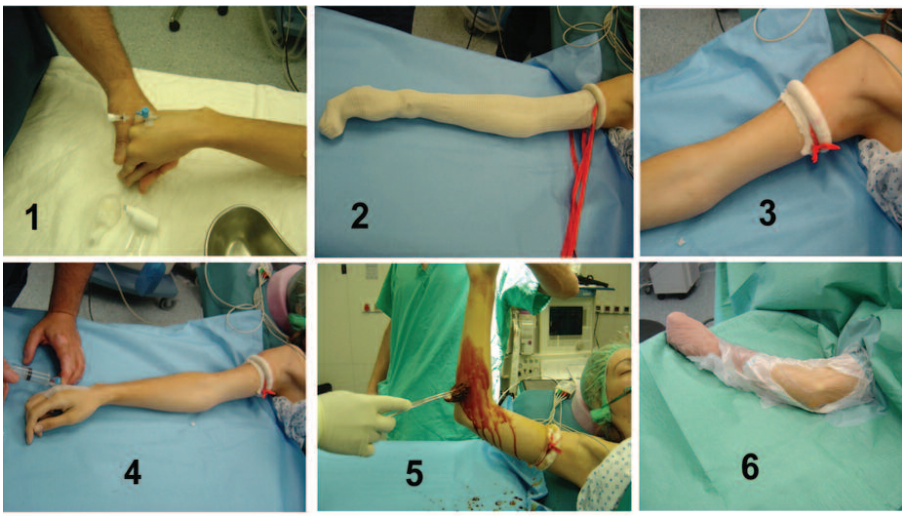


Figure 8. Bier's block using a humeral silicone ring tourniquet.

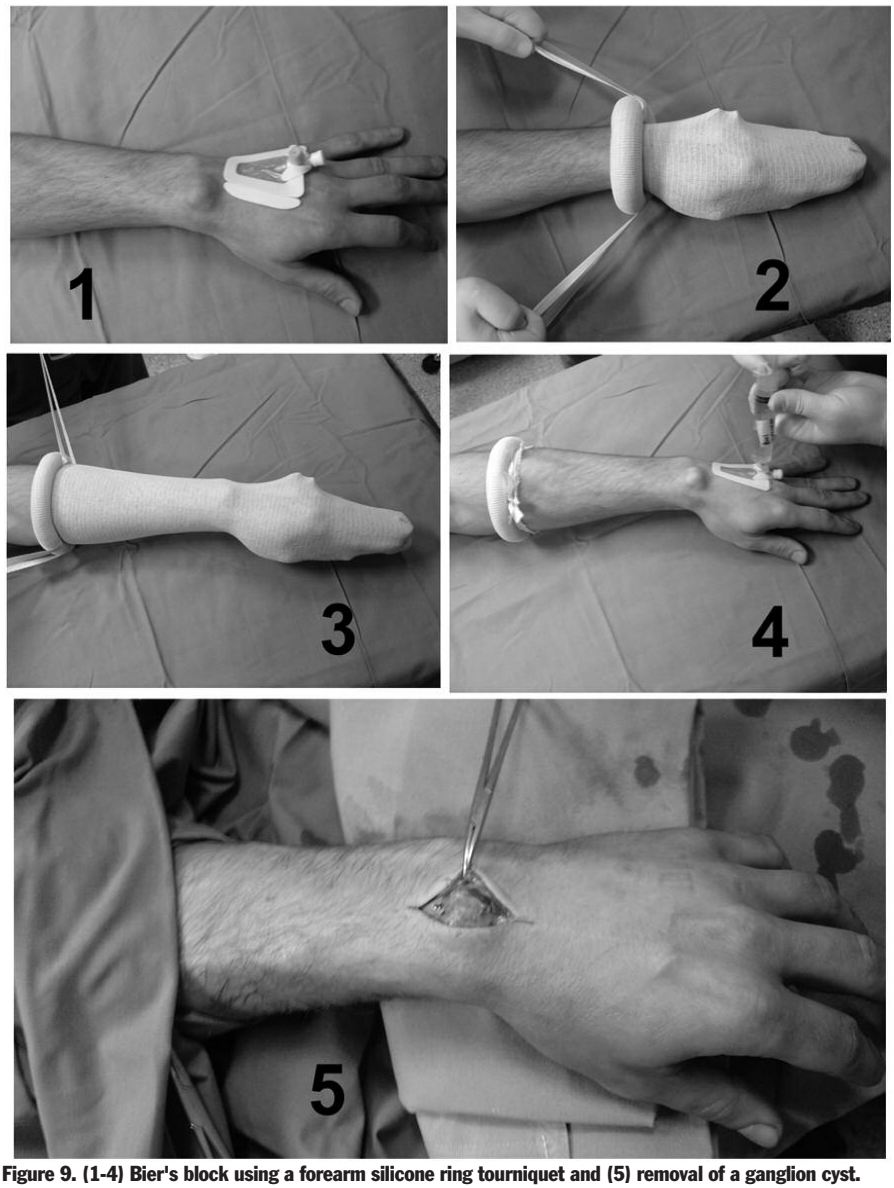


Figure 9. (1-4) Bier's block using a forearm silicone ring tourniquet and (5) removal of a ganglion cyst.

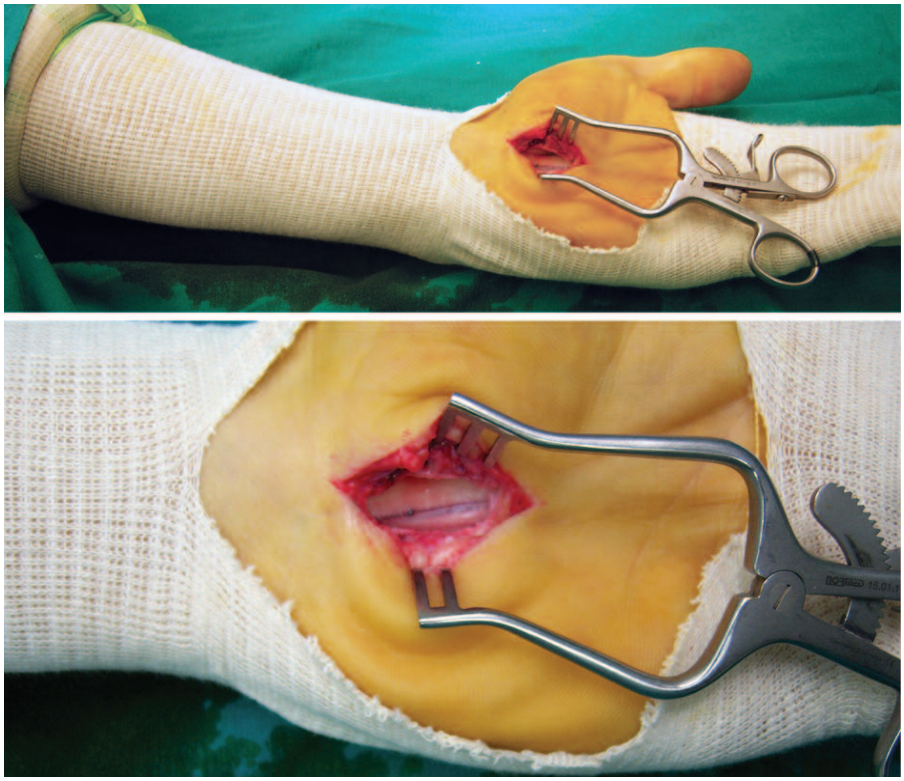


Figure 10. Carpal tunnel release. Excellent exsanguination of the hand using a forearm silicone ring tourniquet.

the pneumatic tourniquet in most — but not all — orthopaedic operations where a bloodless field is required. A pneumatic tourniquet is still required in our theaters because there is a limitation concerning the upper limb circumference at the occlusion site when the HemaClear tourniquet is used.

Pneumatic Tourniquets

Pneumatic tourniquets are essential devices in orthopaedic theaters. Although prospective randomized clinical trials have shown no significant long-term deleterious effects of using pneumatic tourniquets in extremity surgery,[18,19] their use is still associated with potentially serious morbidity[20–22] and even mortality.[23]

Modern pneumatic tourniquets are designed to minimize the incidence of complications,[5] but complications do still occur, and a recent study showed that the incidence of tourniquet complications is still at least as high as that estimated in the 1970s.[24]

Pneumatic tourniquets should be kept in good condition by routinely checking all valves and gauges by performing (a) daily calibration checks, (b) intraoperative monitoring of tourniquet function at frequently intervals, and (c) rigorous monthly performance-assurance tests.[25]

The tourniquet should be tested by inflation and then completely deflated before application, and before its application the limb should be padded with a soft dressing to prevent the wrinkles and blisters that may occur when the skin is pinched.[5]

Application should be performed only by experienced personnel who are knowledgeable about its use and potential complications.[5]

When exsanguination of the limb is needed, this is applied by (a) tightly wrapping an Esmarch bandage (soft rubber compression bandage or a cotton elastic bandage) around the limb starting from its distal end, after which a pneumatic cuff is inflated around the proximal limb,[3,5,26,27] or (b) elevating the limb for 3 to 5 minutes,[5] for 2 minutes,[3] or for 30 seconds.[9]

SRT

With SRT there is no need for maintenance; exsanguination and tourniquet application are done together.

The device is also sterile. It can be used in certain applications where the pneumatic tourniquet cannot be used — such as in certain humeral and femoral fractures — and in every case a device so close to the surgical site is not contaminated. A significant contamination with bacteria commonly implicated in surgical site infections has been found in most tourniquets and exsanguinators presently used in the orthopedic theaters.[28–30] The use of sterile single-use disposable tourniquets where possible has been recommended.[30] The same authors believe that the availability of an alternative should now set the new standard of care, and they also recommend adopting this as a current guideline for control of surgical site infection.[30]

In 43 cases, the SRT was used in hand operations under local anaesthesia and no additional medication was used. In all but one previously reported study, the SRT is at least as comfortable if not more comfortable than the pneumatic tourniquet in hand operations under local anaesthesia.[10,14–17]

The experience gained with previous studies[14,15] and this study as well, has shown that the application of SRT produces an immediate discomfort or pain at the site of the tourniquet application. This gradually subsides to a tolerable level within a few minutes. We believe that it is important to inform the patients about this initial feeling.

Finally, the SRT is disposable, so there is a direct cost. On the other hand, there is an indirect cost for pneumatic tourniquets as they require regular maintenance, repairs, and replacements, as well as routine checking and daily calibration.

CONCLUSION

This new tourniquet device — a silicone ring tourniquet with a pre-set pressure according to the size and the tension model — is easy to apply, is sterile, and occupies a narrow area of the limb. Its application combines three functions at the same time: exsanguination, tourniquet, and stockinet application. Although it cannot entirely replace the classic pneumatic tourniquet, it is a safe and useful device in orthopaedic operations because of its advantages. The device is available in the United States and in many European countries. STI

AUTHORS' DISCLOSURES

The authors have no financial interest in or benefit from this device.

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Exsanguinating tourniquet assessed

Consultant orthopaedic surgeon MATTHEW S HENDERSON FRCS (Trauma and Orthopaedics), MBChB, describes how the The S-MART™ sterile exsanguinating tourniquet from Summit Medical shows significant potential for improving efficiency in ankle surgery at Gloucester Royal Hospital.

The use of tourniquets for both upper and lower limb surgery has been common practice in amputations for many centuries.

However, although methods of exsanguination used today (such as limb elevation and the Esmarch bandage) appear to date back to the early 19th Century, it was not until around 1860 that the use of bloodless surgery was first applied, by Joseph Lister, in procedures other than amputations.

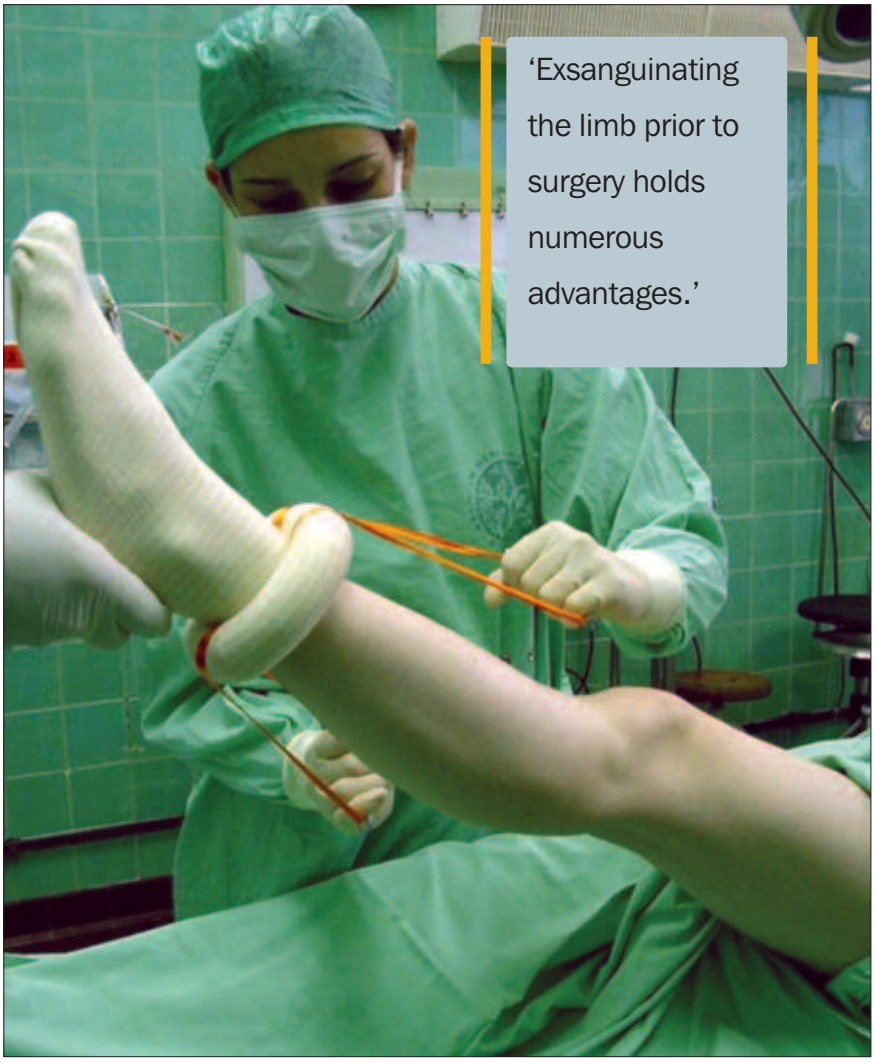
Exsanguinating the limb prior to surgery holds numerous advantages including establishing a clear operating field, reducing overall blood loss and reducing the risk of micro-emboli on tourniquet release.

The limb is usually exsanguinated through elevation, Esmarch bandage or Rhys-Davis techniques. The tourniquet is then applied to the limb to prevent the blood from returning to the exsanguinated limb during surgery. The tourniquet is usually a pneumatic cuff, which is placed on the upper arm or thigh and is inflated by a machine to a pre-determined pressure.

This pressure is typically 200-250 mmHg for upper limbs and 300-350 mmHg for lower limbs, although this may vary with limb size and the systolic pressure of the patient. The idea is to provide a clear bloodless field throughout the duration of surgery.

TOURNIQUET TECHNIQUES

Using the current methods employed at Gloucester Royal Hospital, the patients undergoing foot and ankle surgery receive a regional block at the knee with a pressure tourniquet placed on the upper thigh, at 350 mmHg, after exsanguination by elevation.



'Exsanguinating the limb prior to surgery holds numerous advantages.'

Applying S-MART.

The thigh is chosen as a placement site in order to keep the non-sterile pressure tourniquet well away from the surgical site, therefore reducing the risk of cross-infection. So while the patient feels no pain at the surgical site, he or she routinely requires further anaesthesia due to the discomfort experienced from the pressure tourniquet.

NEW APPROACH

We have recently employed the use of a new type of tourniquet called the S-MART™. This is a single use and sterile tourniquet that exsanguinates on application and occludes arterial flow at its placement site.

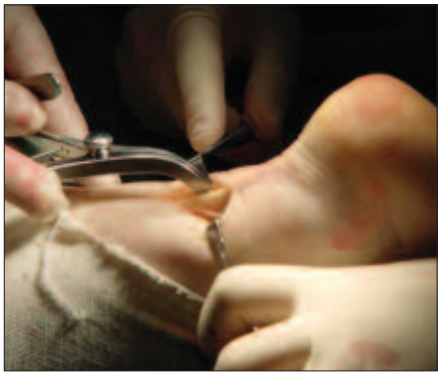
By using the sterile S-MART, a more distal placement site is possible (15 cm proximally to the lateral malleolus) without increasing the risk of infection. Not only does this reduce the volume of ischemic tissue but the tourniquet pressure is applied within the anaesthetised area. The theory is that the use of this method reduces the need for the subsequent general anaesthetic often required to alleviate pain created by the pressure tourniquet on the thigh.

The evaluation of S-MART was performed in order to assess the feasibility of a more detailed and statistically significant study aimed at assessing its use as an alternative method to the current utilisation of pressure tourniquets. The key variables identified for assessment from further evaluation are: patient wellbeing and recovery, use of appropriate anaesthesia and occurrences of complications. The information in this text summarises the evaluations that have taken place so far at Gloucester Royal Hospital and the conclusion as to the feasibility of a further and more detailed study.

EVALUATIONS

The initial evaluation of S-MART was carried out in March 2006 during a carpel tunnel release performed on a 43 year old woman under local anaesthetic. The new tourniquet was placed mid-forearm following the preparation of the limb, and knife to skin was within 20 seconds of it being applied. The ability to site the device after preparation is due to the device sterility. The resulting shorter than normal duration between placement and incision means we were able to achieve a reduction in the overall tourniquet time. In this case, the tourniquet time was only seven minutes.

There were two further cases on the day. Case 1 (34 year old man) was a ganglion removal from the wrist and case 2 (32 year old man) a knee arthroscopy and debridement. Both procedures were performed under general anaesthetic. As with the carpel tunnel release, an excellent bloodless field was established using the new tourniquet and, in all cases, a satisfactory clinical outcome was achieved.



S-MART effectiveness demonstrated in ankle ligament surgery.

Due to the initial successes, we considered further procedures where the device could demonstrate clinical benefits. It was at this stage that the methods we currently employ for ankle surgery were highlighted and the potential use of the new tourniquet was centred around the possibility of reducing the need for additional anaesthetic by applying the device over the area covered by our regional anaesthesia.

So far to date we have completed two foot and ankle cases using the new tourniquet. Both local anaesthetic and regional block were employed and this allowed us to asses tolerance of the tourniquet and the ability of the device to reduce the need for GA.

The first case was the removal of a cyst from the toe of a 44 year old man under local anaesthetic. The S-MART was sited approximately 40 cm from the toes and by using the correct system delivered a pressure of 228 mmHg. This is considerably lower than the 350 mmHg routinely applied using a pneumatic tourniquet on the thigh.

The patient was prepped and draped and the new tourniquet was applied in the final moments before knife to skin, again allowing us to reduce tourniquet time. On this occasion the patient tolerated the tourniquet over a non-anaesthetised area for over 13 minutes and until the procedure was completed.

Family of S-MART devices.

The second case was an ankle arthroscopy and debridement on a 42 year old man. A clear bloodless field was achieved and, importantly, there was no requirement for additional anaesthetic during the surgery. The tourniquet time in this instance was 49 minutes, which was well tolerated as the device could be placed close to the surgical site over an anaesthetised area. This result would not have been achievable with a pressure cuff as the infection risk would have meant placing the pressure cuff on the thigh. The 49 minute duration with the cuff at 350 mmHg would certainly have resulted in severe patient discomfort and the subsequent need for general anaesthetic.

HOW THE DEVICE WORKS

The new tourniquet uses a simple yet innovative approach to limb exsanguination and arterial occlusion. The basis of the idea stems from the original Esmarch device invented by Johann T. Friederich von Esmarch in the 19th Century. The name Esmarch is today widely associated with the elasticated bandages used for limb exsanguination but the original Esmarch device was an altogether more innovative approach.

The Esmarch device was a rubber tube that was wound tightly around the limb and then moved proximally using a wooden roller. This process provided consistent pressure leading to good exsanguination but the device then also served as a tourniquet at the appropriate placement site. The new tourniquet uses a similar idea in order to encapsulate the exsanguination and tourniquet properties in a single device.

In the case of S-MART, the rubber tube is replaced by a silicone ring, the tensile properties of which vary by device type, depending on the force required to generate the appropriate internal pressures. The type of device chosen will therefore be dictated partly by the patient's systolic pressure. The device's pull straps facilitate placement and a stockinette unravels during application in order to provide a sterile barrier.

The dimensions of patients' limbs vary as does their systolic pressure. An understanding of both is required to ensure that the correct S-MART is chosen for surgery. So, the device is available in different sizes for upper and lower limbs. There are also two other sizes that may be appropriate for extreme limb dimensions – one is for small or paediatric limbs and the other is for oversized limbs.

So, before selecting the device, the limb circumference at the desired placement site must be measured along with the patient's systolic pressure. Using charts supplied by the manufacturer, the most appropriate device can be identified (Fig. 1). The device should be offered into the sterile field using a normal aseptic technique. There is a plastic card inside the device. This card is

also sterile and must be retained as it is used to protect the patient's skin on removal of the device post-operatively.

The sterile device is opened using normal aseptic technique. The patient's fingers or toes are placed into the device aperture and the straps pulled proximally along the limb. Exsanguination takes place during proximal movement of the device as does the application of the stockinette. The device must be stopped at the pre-identified placement site to ensure that the selected system is still operating within its dimensional capabilities. From here, the stockinette can be cut away, or a window opened through it at the surgical site. Pressure charts provided by the manufacturer allow the skin pressure to be recorded.

Device selection in our practice was largely dictated by the limb size and was usually independent of the patient's systolic pressure. The reason for this was because the tibialis posterior artery "hides" between the medial malleolus and the Achilles tendon. In order to ensure the most effective exsanguination and occlusion, the manufacturer recommends that the highest pressure system is always used under these circumstances (for us, this was usually the yellow system) and that it should be placed 15 cm above the lateral malleolus.

In order to remove S-MART, the retained card should be placed proximally, the device rolled over the corner of the card, and the ring cut gently with a scalpel.

Limb circumference	Patient blood pressure		
	<130 mmHg	<160 mmHg	<190 mmHg
S-MART SM pediatric arm and leg 14-28 cm	●		
S-MART 40 arm and ankle 24-40 cm	●	●	●
S-MART 60 leg 30-60 cm	●	●	●
S-MART XL leg 50-90 cm		◐	

Figure 1: Device selection chart.

CONCLUSIONS

In conclusion, my team at Gloucestershire Royal Hospital are currently investigating use of the S-MART in patients having foot and ankle surgery. We found the device to be better tolerated by patients undergoing shorter duration surgeries under local anaesthetic, and that the routine use of general anaesthetic, due to pressure cuff discomfort during ankle surgery, was avoidable.

The evaluations that have taken place so far lead us to believe that the device can provide clinical benefits to our patients, improve our processes in preparing the patients for surgery and reduce the cost of surgery by removing the routine use of general anaesthetic.

Further evaluations will take place in an attempt to quantify results and to demonstrate compliance to these hypotheses.

As such, the aims of further evaluations, in foot and ankle surgery, are likely to be as follows:

- To assess improvement to patient wellbeing.
- To reduce intra-operative tourniquet pain and reduce the need for additional general anaesthesia.
- To reduce average recovery time by reducing use of general anaesthesia.

We are confident that such aims are achievable by continuing to apply our new methods.

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ORIGINAL PAPER

Silicone ring tourniquet or pneumatic cuff tourniquet for total knee arthroplasty

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Abstract
Purpose The goal of the present study was to evaluate the potential advantages of a silicon ring tourniquet in comparison to the conventional pneumatic cuff tourniquet. The tested hypothesis was that the calculated blood loss will be decreased after use of the silicone ring tourniquet.
Methods The study was monocentric and mixed retrospective and prospective evaluation of prospectively collected data. Inclusion criterion was implantation of a total knee arthroplasty. The retrospective control group involved 39 patients operated on with a pneumatic cuff tourniquet. The prospective study group involved 33 patients operated on with a silicone ring tourniquet. All patients were followed for three months. Primary criterion was the calculated blood loss (OSTHEO formula). Secondary criteria were pain on third post-op day, need for allogenic transfusion, haemoglobin drop, delay of discharge, and occurrence of complications.
Results The mean calculated blood loss was 901 ml in the study group and 989 ml in the control group (NS). There was no significant difference in pain evaluation and haemoglobin drop between the two groups. There was a non significant decrease of allogeneic transfusion and length of stay in the study group. There was a significant decrease of complication rate in the study group, and especially for skin complications.
Conclusions The tested hypothesis was not confirmed: there was no significant change in the calculated blood loss. No bias was identified in complication analysis. The decreased rate of skin complication might be a positive influence of the silicone ring tourniquet.

Keywords Calculated blood loss · Silicone ring tourniquet · Tourniquet · Total knee arthroplasty

Introduction

Use of a tourniquet remains controversial during total knee arthroplasty (TKA) [1–3]. Satisfactory outcomes have been observed after TKA implanted without tourniquet [4]. Documented advantages are a bloodless operative field [5], less intra-operative blood loss [6], and a better cement penetration [7]. However, disadvantages may be more post-operative blood loss [2], a greater occurrence of venous thrombosis [3], neuromuscular [8] or cutaneous [9] damage, and delayed rehabilitation [10]. Especially, tourniquet time over 100 minutes increases the risk of complications after TKA, and special attention should be given to reduce the tourniquet time [11]. Consequently, alternate procedures have been suggested. The half-course tourniquet strategy [12] could decrease the total peri-operative blood loss in primary TKA, and may be beneficial in helping patients to achieve earlier functional recovery by improving the pain experience and limb swelling early in the post-operative period.

Use of a silicone ring tourniquet (SRT) (Hemaclear ®, Provin Medical, Lyon, France) has been suggested [13]. It is postulated that this tourniquet will decrease blood loss through a better exsanguination, and will decrease soft tissue damage through a smaller compression area [14]. The goal of the present study was to evaluate advantages and disadvantages of this new tourniquet for TKA. The tested hypothesis was that the calculated total blood loss after TKA will be decreased with

Level of evidence: Level III – retrospective comparative study

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use of the SRT in comparison to a conventional pneumatic cuff tourniquet (PCT).

Material and methods

The study followed the ethical standards of the Helsinki declaration of 1975 as revised in 2000, and was accepted by the institutional ethical committee. It was a monocentric evaluation which mixed retrospective and prospective analysis of prospectively collected data. Inclusion criterion was implantation of a TKA for end-stage knee osteoarthritis. Exclusion criteria were a contra-indication to the intra-operative use of a tourniquet and bilateral procedures.

Seventy two patients were selected after having given their informed consent. The retrospective control group involved 39 patients operated on with a PCT between May 2014 and December 2014. The prospective study group involved 33 patients operated on with a SRT between January 2015 and June 2015. There were 24 men and 48 women, with a mean age of 67 years (±10) and a mean body mass index (BMI) of 32.9 kg/m^2 (±8.9). All patients received a cemented TKA (e.motion ® TKA, Aesculap, Tuttlingen, FRG) implanted by one single surgeon (JYJ) under control of a navigation system (OrthoPilot ®, Aesculap, Tuttlingen, FRG). Hemostasis was performed during the whole procedure with electrocautery according to the surgeon's judgment. No drainage was left, either in the joint or in the soft tissue.

In the control group, the PCT was applied by the operating nurse around the upper thigh before draping. Exsanguination was performed by gravity by lifting the foot for five minutes, and the tourniquet was inflated just prior to skin incision. The tourniquet was deflated after dressing application.

In the study group, the SRT was applied by the operating surgeon after draping just prior to skin incision. The ring was sectioned after dressing application.

All patients followed the same regimen of pre-operative, intra-operative and post-operative drugs, including the intra-operative use of 1 g of tranexamic acid (Exacyl ®, Sanofi-Aventis, Paris, France), and a six week post-operative deep venous thrombosis (DVT) prophylaxis by enoxaparin (Lovenox ® 4000 UI/d, Sanofi-Aventis, Paris, France). All patients followed the same accelerated rehabilitation process, with immediate full weight bearing and unrestricted knee range of motion [15].

All patients were evaluated after three months. Primary criterion was the calculated blood loss (CBL) according to the OSTHEO formula [16]. Secondary criteria were duration of tourniquet inflation, pain on third post-operative day measured by a visual analogic scale (VAS), need for allogeneic transfusion, hemoglobin drop, delay of discharge, and occurrence of complications. All criteria were compared between both groups with the appropriate statistical tests at a 0.05 level of significance. The sample size was calculated to detect a difference of 200 ml in the CBL with a power of 0.80.

Results

There was no significant difference between both groups for pre-operative items. Especially, the mean pre-operative hemoglobin level was 13.5 g/dL (±1.5) in the control group and 13.7 g/dL (±1.2) in the study group (NS).

The mean CBL was 989 mL (±505) in the control group and 901 mL (±488) in the study group (NS). The mean duration of tourniquet inflation was 95 minutes (±18) in the control group and 86 minutes (±18) in the study group ($p = 0.04$). The mean pain evaluation on third post-operative day was 2.9 (±1.7) in the control group and 3.2 (±1.3) in the study group (NS). The mean haemoglobin drop was 2.2 g/dL (±1.0) in the control group and 1.8 g/dL (±0.8) in the study group (NS). There was a non significant, but clinical relevant decrease of allogeneic transfusion in the study group (one case, 4 units) in comparison to the control group (five cases, 10 units). There was a significant decrease in the delay for discharge in the study group (3.8 ± 1.9 d) in comparison to the control group (5.4 ± 2.8 d) ($p = 0.05$). There was a significant decrease of complication rate in the study group (one case of skin dehiscence) in comparison to the control group (four cases of skin dehiscence, three cases of delayed rehabilitation with prolonged stay, one case of symptomatic DVT, and one case of fracture after a fall) ($p = 0.02$).

Discussion

Few papers have been published about SRT. The results are controversial for carpal tunnel syndrome. Pereira et al. [17] reported no clinically significant advantage in a retrospective comparative study. However, Drosos et al. [13], in a prospective randomized study, observed a significant decrease in pain evaluation, suggesting less soft tissue damage. Only one evaluation during TKA has been reported [14]. Patients with SRT had a smaller decrease in haemoglobin on post-operative days one and three, and the amount of blood collected from drains at 24 h was significantly lower.

The primary hypothesis of the present study was not confirmed: the decrease in CBL observed in the study group was not statistically significant. This statement was confirmed by the absence of significant difference in the haemoglobin drop and the need for allogeneic transfusion between both groups. The theoretical positive impact on blood loss due to the SRT was not confirmed. The difference with a previous study [14] is probably due to a lack of power of the present study with fewer patients included (72 versus 311), as the absolute figures were similar for blood loss and haemoglobin drop. The

decreased need for allogeneic transfusion was felt to be clinically relevant. Furthermore, the operating surgeon had the subjective feeling that the operative field, and especially the osteotomized bone areas were drier in the study group than in the control group; but this statement could not be documented. The SRT cannot currently be considered as a blood preserving technique, and alternate techniques should be used, such as pre-operative haemoglobin optimization, femoral canal obturation, limited incision and release, peri- and intra-articular use of saline with adrenalin, tourniquet release after skin closure, and tranexamic acid [18].

Some significant differences were still observed.

The decrease in operating time was nine minutes in the study group. This might be due:

- To a less frequent need for haemostasis during surgery, in correlation with the subjective feeling of drier operative field;
- To a faster drying of the bone areas before cementing: pulsed lavage was frequently considered unnecessary by the operating surgeon.

The rate of complication was significantly decreased in the study group. Especially, the occurrence of skin necrosis was dramatically lower. This might be due to a decreased pressure trauma by the SRT. The smaller area of compression decreases the amount of soft tissue deformation under the ring in comparison to the cuff. It has been demonstrated that the seric enzymes elevation was lower in an experimental setting on rabbits [19]. The significant decrease in tourniquet time may be theoretically favorable to decrease the risk of tourniquet induced complications [11]. Furthermore, an electromyographic study showed that wider cuffs resulted in more severe changes in the nerve [20]: the SRT with its narrower compression may be beneficial.

An earlier discharge was also observed in the study group, but the detailed analysis showed that this change was clearly correlated to the treatment of complications.

No cost analysis was performed during this study. However, one can postulate that the extra-cost of the SRT (50€ in France), might be compensated:

- by a decreased operating time. It has been estimated recently that one minute operating time in France has a cost of 10.8 € [21];
- by a decreased need for allogeneic transfusion: one blood unit cost in France was about 180 € in 2015;
- by an earlier discharge: hospital charge for a TKA in France was about 5000 € in 2015 whatever the length of stay.

However, this medico-economic evaluation should be performed in a separate study to provide reliable results.

The present study has several limitations. Its retrospective design and the absence of randomization may induce uncontrolled biases. However, the comparability of both groups was controlled retrospectively, and no change in the operating technique or post-operative care occurred during the whole study. The study was powered to analyze the impact of the SRT on calculated blood loss; the significant differences observed in the secondary criteria must be considered with caution, and a further study is mandatory to confirm these differences. The potential benefit of using a sterile tourniquet instead of an off the shelf one for bacterial contamination [22] was not addressed. Finally, no actual cost analysis was performed, and the cost-effectiveness ratio could not be retrieved from the collected data.

However, the present study has some strength. This is the first evaluation of the SRT in TKA. Patient inclusion was consecutive, and no patient was lost of follow-up. No data in the retrospective control group was missing, and data collection in the study group was prospective. Sample size was calculated to be able to detect a clinically significant difference in CBL.

The CBL and the need for allogeneic transfusion were not significantly decreased by the use of SRT and cannot be considered as an advantage of this device. However, the significant decrease in operating time and the significant decrease in complication rate warrants further investigation. If these results are confirmed, the cost-effectiveness of the SRT might be positive.

Compliance with ethical standards

Conflict of Interest JYJ receives royalties from B-Braun Aesculap and is a paid consultant for B-Braun Aesculap, FH Orthopedics, Exactech. DB has nothing to disclose. No conflict interferes with the present paper.

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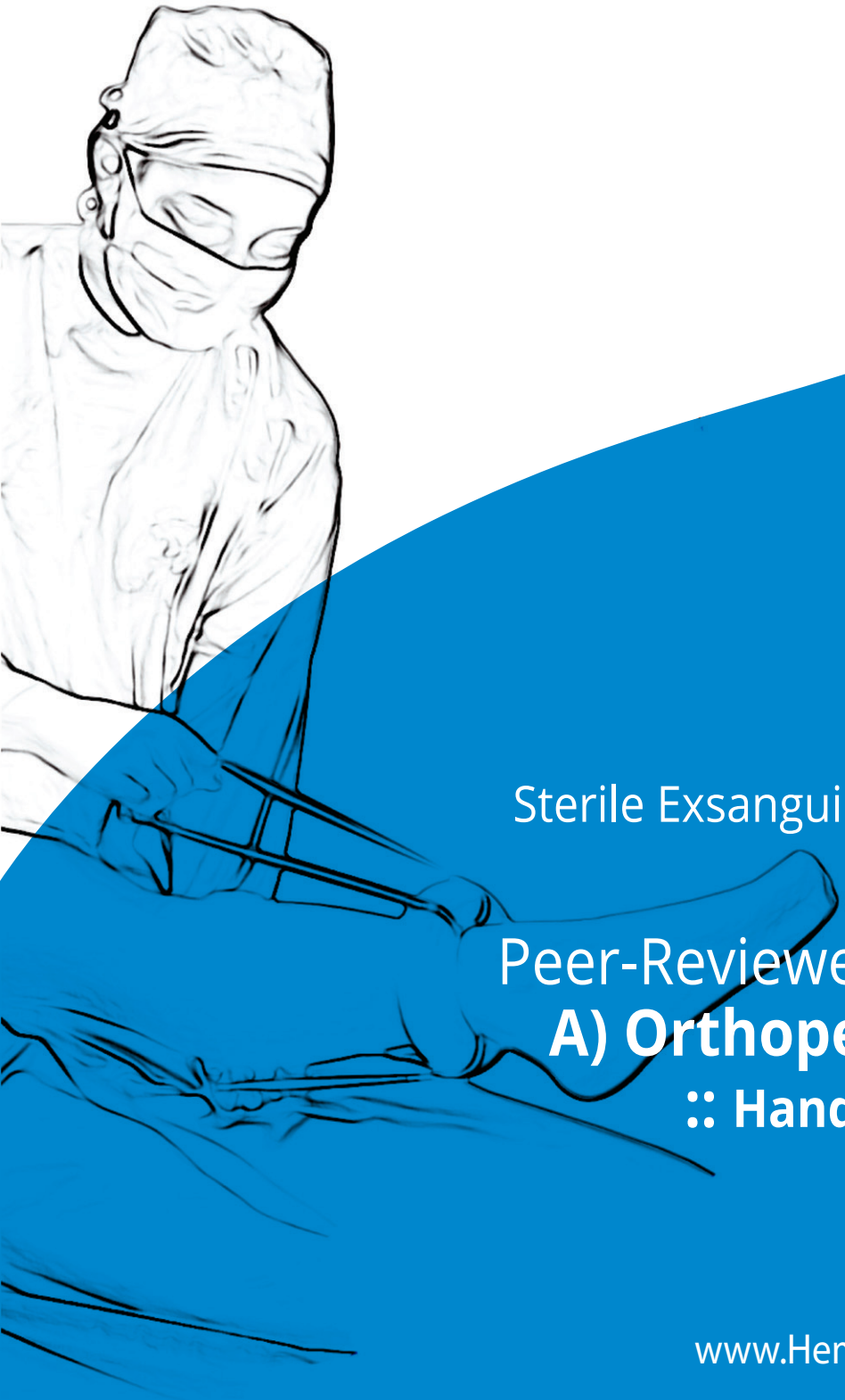

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EVALUATION OF A NOVEL TOURNIQUET DEVICE FOR BLOODLESS SURGERY OF THE HAND

M. BOIKO and M. ROFFMAN

From the Department of Orthopedics, Carmel Medical Center and the Rappaport Faculty of Medicine, Technion, Haifa, Israel

This study evaluates a new device (S-MART™) for exsanguination and occlusion of the blood flow to the arm for hand surgery. The device consists of a silicone ring wrapped within a sterile stockinette and pull straps. It is applied by placing it on the patient's fingers and rolling it up the limb to the desired occlusion site by pulling on the straps. The time for placement and removal of the device was measured during trigger release and carpal tunnel surgery and the quality of exsanguination was evaluated. The device could be placed and removed quickly and provided an excellent bloodless field. At follow-up examination no signs or symptoms were seen at the site of the S-MART™ occlusion and no complications were observed in any patient.

Journal of Hand Surgery (British and European Volume, 2004) 29B: 2: 185–187

Keywords: bloodless surgery, tourniquet, carpal tunnel release, trigger finger release, esmarch

INTRODUCTION

Surgical procedures on the upper and lower extremities are most often performed using a tourniquet (Wright Philips, 1981). Exsanguination is usually done by tightly wrapping an Esmarch bandage around the limb starting from its distal end, after which a pneumatic cuff is inflated around the proximal limb (Pedowitz, 1991; Reid et al., 1983; Wakai et al., 2001). The aim of the present study is to evaluate a new device, S-MART™ (OHK Medical Devices, Haifa, Israel) for exsanguination and occlusion of the blood flow to the arm.

The evaluation of the device in this study consisted of measurement of the time taken to apply and remove the device, the effort required for placement of the device, rating of exsanguination during the procedure, and a postoperative follow-up.

METHODS AND MATERIALS

The local ethics committee of Carmel Medical Center approved the study protocol. Following informed consent, patients undergoing hand surgery were recruited into the study. Exclusion criteria were a limb circumference at the occlusion site of greater than 40 cm or smaller than 20 cm, a systolic blood pressure in excess of 190 mmHg, open skin lesions and an unstable (e.g. fractured) limb.

The patients were recruited consecutively from operation lists conducted in the hospital's out-patient facility. All the procedures were performed by a single surgeon (MB).

The S-MART™ (OHK Medical Devices, Haifa, Israel) consists of a silicone ring (internal diameter 52 mm, external diameter 76 mm) wrapped within an elastic sleeve (stockinette) and two straps attached to pull handles (Fig 1). The device is inserted over the patient's fingers (Fig 2) and is then rolled proximally up the limb (Fig 3) by pulling the handles towards the desired occlusion site (Fig 4). As the device rolls proximally, it compresses the limb and expels blood from the extremity into the central circulation. When the device is positioned at the proximal occlusion location (mid-forearm for hand and wrist surgery; upper arm for tendon and elbow surgery), it continues to exert supra-systolic pressure on the limb which prevents arterial flow. During the rolling of the ring onto the limb, the sterile stockinette unfolds to provide a sterile draping (Fig 4).

The S-MART™ comes in two sizes: a small size for the arm and a large size for the leg and for large arms (circumference at occlusion site greater than 40 cm). Each size has three colour-coded tension models, each providing occlusion for different ranges of blood pressure: Green (G): up to 130 mmHg; Red (R): 130 to 160 mmHg; Yellow (Y): 160 to 190 mmHg.

The device is sterile and double packaged. When used on an arm, the device applies a skin pressure of 250 to 350 mmHg, depending on the model chosen (see below) and the actual limb circumference. In larger diameter limbs that require somewhat higher pressure to occlude the arterial circulation, the applied pressure is self-adjusted and is higher than in thin limbs. The applied pressure is factory pre-set and cannot be changed once the device is on the patient.

Each patient received the appropriate model according to the systolic blood pressure measured in the operating room directly before the placement of the device.

A case report form was completed by the surgeon and assessed the ease of device placement on a 1 to 10 scale (1 = very easy, 10 = very difficult) and the visual quality of surgical site (1 = unacceptable, 2 = poor, 3 = fair, 4 = good, 5 = excellent).

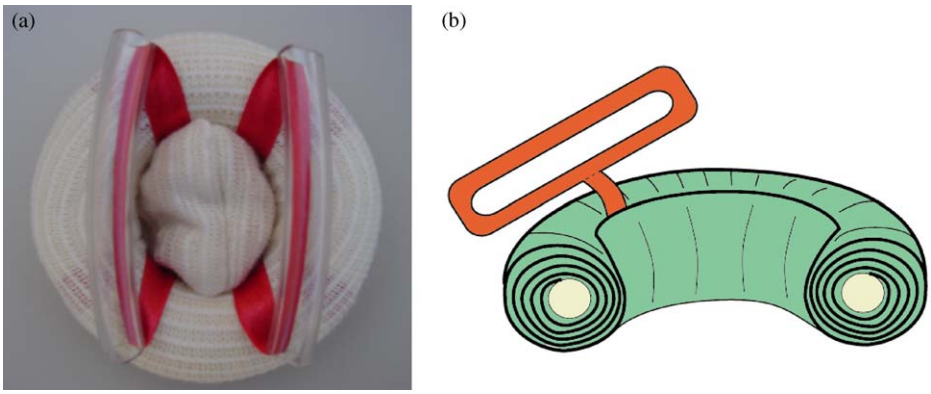

Fig 1 S-MART:arm.

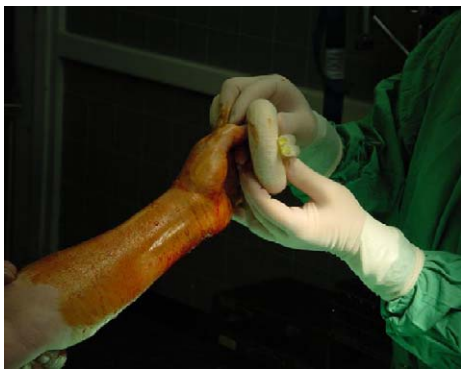

Fig 2 Placed on the fingers.

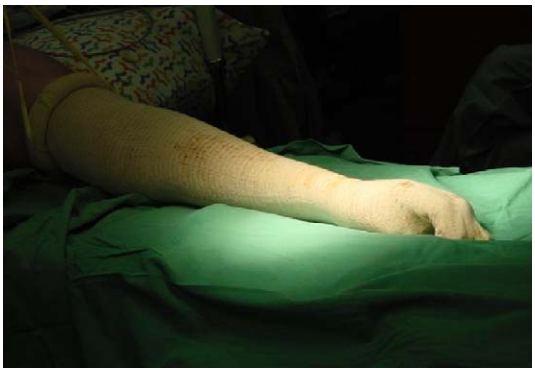

Fig 4 Final occlusion position.

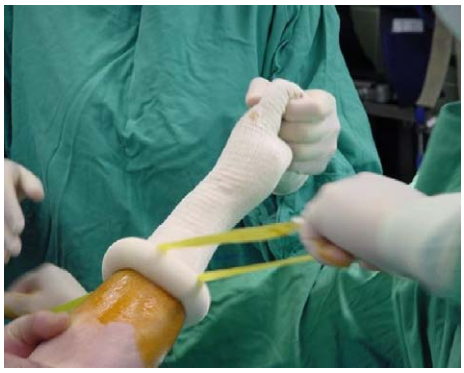

Fig 3 Pulled up the arm.

The surgical procedures were all performed under local anaesthesia by local infiltration of the tissues; a brachial block was never used. The hand and arm were prepared with a Betadine solution to about 5 to 10 cm beyond the anticipated site of the occluding ring. The S-MART™ was then applied by pulling on its handles until the ring reached the occlusion location. The stockinette over the hand was then cut and pulled up the arm and the surgical procedure was performed. The tourniquet was released according to the manufacturer's instructions, by cutting the silicone ring and the elastic sleeve of the device.

RESULTS

There were nine men and nine women with an average age of 63 (range, 45–82) years who underwent either trigger digit or carpal tunnel release. All their arms had a limb circumference of between 20 and 40 cm, the allowable range for the S-MART™.

The placement score was 1 or 2 (out of 10) in all but one patient whose score was rated at 3 by the surgeon. The longest placement time was 15 seconds, with 10 seconds being the typical time.

The original plan was to measure the blood loss at the surgical site during the surgery by weighing the gauze swabs. However, in all but one patient, the blood loss was minimal and could not be measured. In the other patient the blood loss was 5 ml.

The device was applied for a mean of 14 (range, 6–27) minutes. No deterioration in the visual quality in the surgical site was noted during any of the operations and

the device was tolerated well by all the patients. No analgesia was needed to counteract the compression discomfort. Follow-up examination was performed 8 days following the operation according to a standard postoperative protocol for hand surgery procedures. No symptoms or signs at the site of the S-MART occlusion and no complications were observed in any of the patients.

DISCUSSION

The S-MART™ performed very well in carpal tunnel and trigger digit release procedures. Its major advantages over conventional methods are the visual quality of the surgical field, the ease and speed of application and the fact that the device is sterile and applied after skin preparation and draping, thus shortening the tourniquet time. Also the placement and removal of the device are quickly done by the surgeon alone, eliminating the need for assistance from the operating room staff.

The preferred site for the S-MART™ for most surgery on the hand is the forearm. Tendon surgery or complex soft tissue reconstruction procedures (as well as elbow surgery) need placement of the device on the upper arm. Placement of the device near the surgical field is possible because the S-MART™ is sterile and effectively occludes the blood flow at the forearm location.

The device is well-tolerated by patients but a quantitative, comparative evaluation of the pain caused by the S-MART™ device and a standard pneumatic cuff is required. The concentric force of the elastic silicone ring is evenly distributed around the limb circumference, thus reducing the skin wrinkling which often occurs with pneumatic tourniquets. Furthermore, some of the stockinette stays wrapped around the ring and provides a built-in cushion that further reduces the impact of the device on the skin. No skin lesions were observed after the operation or at follow-up.

The tension of the device is factory pre-set to 250 to 350 mmHg at the skin surface, depending on the model (colour coded) and the patient's limb circumference. Unlike a standard pneumatic cuff, it is not possible to adjust the pressure during the operation, and thus an increase in the blood pressure during the operation could cause leakage of blood under the ring and bleeding at the surgical site. If this is a concern, it is possible to select a model that is suitable for a higher blood pressure than that measured at the beginning of the procedure. No leaks were seen in any of our patients whose blood pressure fluctuations during the procedure were within the blood pressure range for each model.

Another difference between the S-MART™ and standard tourniquets is that the pressure cannot be released temporarily during the procedure. The device is removed by cutting the ring which cannot be re-attached. While the cases in the present group were short, we recommend that the S-MART™ should not be applied for more than 2 hours, as for a pneumatic tourniquet (Pedowitz, 1991). As the current device cannot be used for limbs that have a circumference less than 20 cm, it is not suitable for children or small people. Other limitations are that it should not be used on unstable (fractured or dislocated) limbs or on patients with venous thrombosis (to avoid the risk of embolization).

Acknowledgements

OHK Medical Devices, (www.ohkmed.com) Haifa Israel supplied the S-MART™ free of charge. The authors have received no other financial benefit and have no financial interest in the device.

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Research Article

The Use of the S-MART Tourniquet in Hand Surgery: A Safe and Effective Way to Provide a Bloodless Field

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We have retrospectively reviewed our use of the S-MART sterile silicon ring self-exsanguinating tourniquet in 300 consecutive minor hand surgical procedures. A total of 3 postoperative complications were identified, only 1 of which was directly related to the tourniquet's use. We outline the reasons of why we feel that this device provides a safe and effective bloodless field and the benefits of its use.

1. Introduction

The S-MART tourniquet (OHK Medical Devices, Newark, NJ) is a novel single-use tourniquet, which provides exsanguination of the limb, arterial occlusion, and application of sterile stockinet in one device. Its use in extremity surgery has been documented, but the largest series to date has been 51 patients [1, 2].

The S-MART tourniquet works by virtue of a core silicon ring which provides the pressure required to expel luminal blood during application and maintain arterial occlusion throughout the procedure once in situ. This ring is wrapped in sterile stockinet with pull handles attached to facilitate application. Figure 1 shows a cross section of the S-MART and Figure 2 shows its application.

In a recent article, Noordin et al. [3] criticized the use of nonpneumatic ring type tourniquets such as the S-MART in nonbattlefield settings claiming that their use may increase the occurrence of tourniquet-related adverse events. The article discussed two particular adverse events: tourniquet-related nerve injury and skin blistering.

We have been using the S-MART tourniquet for all appropriate hand and wrist procedures in our day surgery department for a number of years; anecdotally we have not noticed any increase in the complications suggested by Noordin et al. and thus felt it would be worthwhile to review a cohort of patients to ensure this was the case; we report our experience.

2. Methods

Our cohort included the last 300 patients undergoing one of the 4 most common procedures in our department: carpal tunnel decompression, De Quervain's decompression, trigger finger release, and ganglion excision with a minimum of 6-month follow-up (prior to January 2010). Exclusion criteria were incomplete notes, no documented postoperative follow-up, inability to use S-MART tourniquet (limb circumference too great), and preexisting soft tissue damage or neurological lesion (other than carpal tunnel syndrome) affecting the limb concerned. All procedures were carried out under the supervision of the senior author (P. Davey); 50 patients were excluded (47 missing or incomplete notes, 1 no follow-up, 0 pneumatic tourniquet used, and 1 preexisting soft tissue or nerve injury). We retrospectively reviewed all medical notes relating to our cohort and documented the procedure type, tourniquet time, adequacy of the bloodless operative field, and any intraoperative or postoperative complications, with particular reference to neuropraxia or skin damage at the tourniquet site.

3. Results

250 patients fulfilled the inclusion criteria and were reviewed for the purpose of this study, 141 females and 109 males, average age 59 (32–96); the procedure breakdown is shown

Table 1: Table of results.

Procedure	Number	Tourniquet time	Inadequacy	Complication
Carpal tunnel decompression	159 unilateral, 37 bilateral	6 mins	1 venous tourniquet	1 wound infection
Trigger finger release	27	7 mins		1 wound infection
Ganglion excision	8	9 mins		
De Quervain's decompression	5	11 mins		

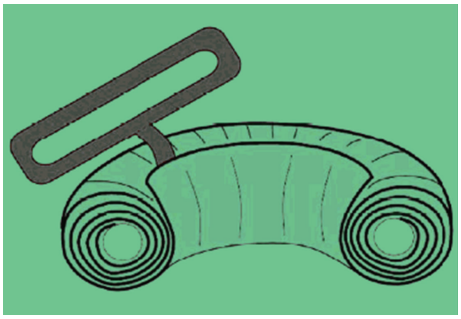

Figure 1: Cross section of the S-MART tourniquet.

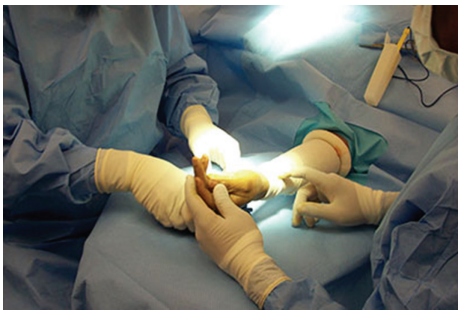

Figure 2: S-MART after application.

in Table 1 along with the average tourniquet time for the procedure and any complications. A total of 3 postoperative complications were identified, only 1 of which was directly related to the tourniquet's use (1 neuropraxia which resolved by 6 months, 2 superficial wound infections), and the use of the tourniquet was discontinued intra-operatively in 1 case as a result of a venous tourniquet effect and inadequate bloodless field.

4. Discussion

In our experience, the S-MART tourniquet provides effective exsanguination and bleeding control when used in minor upper limb surgery. We experienced very few complications as a result of its use as suggested in Noordin's article, and we feel that its benefits certainly outweigh any risks in its use.

In particular, we feel that this type of tourniquet provides the following advantages.

Decreased Tourniquet Times. Whilst we have no data to confirm our thoughts, anecdotally we certainly feel that application of the tourniquet after formal draping of the patient reduces wasted time with the pneumatic tourniquet inflated after nonsterile exsanguination, and the application technique is faster than that using an esmarch bandage for sterile exsanguination.

Less Interference with the Operative Field. Whilst not a particular problem with hand and wrist surgery, for procedures involving more proximal extension of the operative field the ring type sterile tourniquet provides benefit in terms of its nonmigratory character. Large pneumatic tourniquets have a tendency to slip distally on the limb and encroach on the surgical field; we found this not to be a problem with the S-MART.

Reliable Tourniquet Effect. Effective use of a pneumatic tourniquet relies upon adequate exsanguination, proper tourniquet placement, and a good pressure seal between the tourniquet and pressurisation machine. In our experience, failure in one of these three aspects often leads to an inadequate bloodless field. The constricting elastic ring in the S-MART is factory made, and the occlusion pressure is preset. There is a choice of tourniquet depending on the desired limb occlusion pressure and the size of the limb to which it will be applied. This gives a more reliable occlusive effect on the arterial supply to the limb whilst not exerting a pressure that is so high as to cause local soft tissue problems.

Downsides to the use of this type of tourniquet are that the pressure cannot be released temporarily during the procedure as this requires division of the silicone ring with a scalpel; also it cannot be used in cases where there is an unstable fracture in the affected limb due to the risk of embolisation.

5. Conclusion

In our experience, the use of the S-MART exsanguination tourniquet is an effective and safe way to provide a bloodless field in hand and wrist surgery. Its use in our department in 250 cases did not indicate a higher tourniquet-related complication rate when compared to the use of a pneumatic tourniquet as suggested by Noordin et al. The use of S-MART is being driven by the infection control benefits of single-patient use coupled with the creation of a superior bloodless field, improved access to operative sites, versatility of site placement, and time saving capabilities.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Use of a New Exsanguination Tourniquet in Internal Fixation of Distal Radius Fractures

Doron Norman, MD, Inbal Greenfield, MD, Nabil Ghrayeb, MD, Eli Peled, MD, and Lior Dayan, MD

Abstract: We describe our experience using a new device that results in a bloodless field in open repair of distal radius fractures. The device, an exsanguinating tourniquet (HemaClear model/40, OHK Medical Devices, Haifa, Israel), replaces the traditional methods of limb elevation, Esmarch bandaging, pneumatic tourniquet pressurizing and the associated components. HemaClear/40 is an elastic silicon ring with a tubular elastic sleeve rolled onto it. The device has attached straps that, when pulled, unroll the sleeve, rolling the ring mesially on the limb. The pressure exerted by rolling HemaClear/40 is supra-systolic thereby exsanguinating the limb and occluding the arterial inflow. Our experience in 49 patients demonstrated quick application, superior exsanguination and that the device could be placed on the forearm instead of the upper arm. No side effects or complications were noted. In our opinion, the fact that HemaClear/40 is a sterile, single-patient device makes it superior over the traditional technology.

Key Words: bloodless surgical field, ORIF, fracture wrist

(*Tech Hand Surg* 2009;13: 173–175)

HISTORICAL PERSPECTIVE

Bloodless limb surgery was first introduced by Friedrich von Esmarch in 1873 using an elastic ("Esmarch") bandage that was further improved in 1908 by Dr Cushing with the introduction of the pneumatic tourniquet. This century-old technique is broadly used in upper and lower extremity surgery despite significant drawbacks such as time consumption and postoperative clean-up. The existing tourniquet system consists of many elements (ie, pump, gas tubes) that make it cumbersome. The tourniquet cuff is often nonsterile and, therefore, must be placed at the proximal part of the limb, away from the surgical field. In addition, the methods of exsanguination (limb elevation and/or Esmarch) may leave a substantial amount of blood in the vessels.[1–3]

Recently, we started using a novel exsanguination tourniquet[4–6] in upper extremity operations. We report here the use of the device in 49 consecutive distal radius internal fixation patients.

INDICATIONS AND CONTRAINDICATIONS

HemaClear is used in procedures that require a bloodless surgical field and can replace the traditional method (Esmarch+Tourniquet).

From the Department of Orthopedic and Traumatology B', Rambam Medical Center, Haifa, Israel.
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The authors of this manuscript do not own any stocks in OHK Medical Devices and neither they nor their family have any benefits from the sale of this product.
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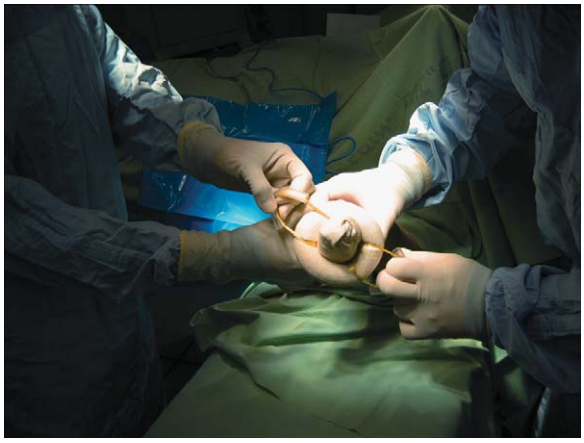

FIGURE 1. HemaClear is placed on the fingers.

Contraindications include:

- Not leaving HemaClear on the patient's limb for more than 120 minutes.
- Not placing HemaClear directly over the ulnar nerve (at the elbow) or peroneal nerve (at proximal tibia).
- Not using HemaClear on patients with poor peripheral blood flow, edema, or deep vein thrombosis.
- Not using HemaClear if the limb has significant skin lesions (skin disease, burns).
- Not using HemaClear if the limb is infected or has a malignancy.
- Immediate removal of HemaClear if the device does not stop the blood flow to the limb.

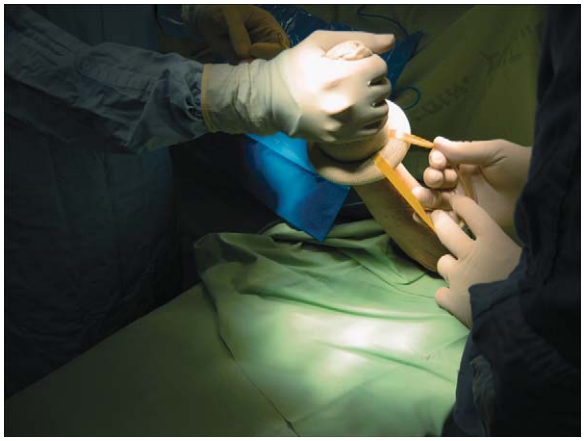

FIGURE 2. Fingers are held together and the straps are pulled proximally.

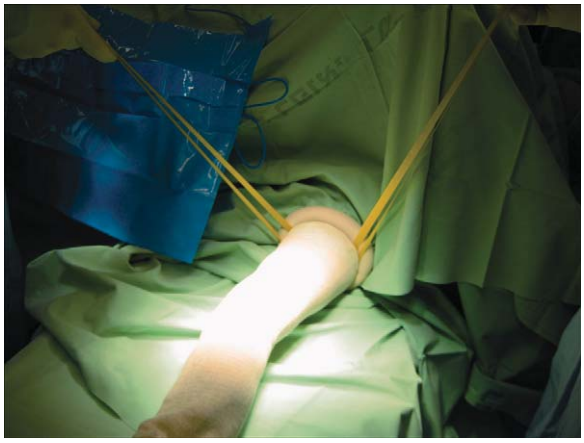

FIGURE 3. Straps are pulled proximally and the sterile stockinet unrolls onto the limb.

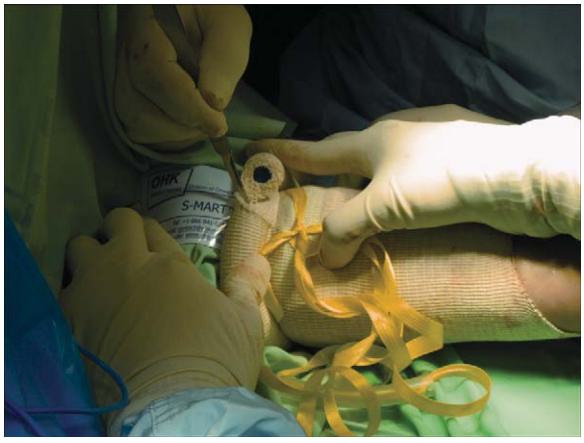

FIGURE 4. Protective card inserted beneath the ring and the HemaClear is cut using a scalpel.

Warning:

If the limb is unstable (fracture, dislocation), use axial traction to stabilize limb during HemaClear application.

TECHNIQUE

HemaClear performs 3 functions:

1. Blood removal (exsanguination)
2. Arterial flow occlusion
3. Placement of sterile stockinette

HemaClear may be used on the upper or lower extremities and is available in 4 circumference ranges: 14 to 28 cm, 24 to 40 cm, 30 to 60 cm, and 50 to 90 cm. In this study, we used the HemaClear/40 (24 to 40 cm) only.

HemaClear consists of a silicon ring wrapped in a stockinette sleeve and pull straps.

The physician places the ring on the fingers (or toes) and then pulls the straps proximally. The silicon ring rolls mesially and the stockinette sleeve unrolls onto the limb (Figs. 1–3). If the limb is unstable due to fracture or dislocation, axial traction by 2 operators should be used.[7]

During the proximal rolling, the ring exerts pressure and squeezes the blood away from the limb, thus performing the exsanguination function quickly and effectively.

When the elastic ring reaches the occlusion location, the pulling motion is stopped. The ring exerts pressure on the limb at this position, blocking arterial blood flow into the limb and thus acts as a tourniquet.

PRESSURE BY HemaClear® 40 / Medium / Yellow

Patient Systolic Blood Pressure <190 mmHg	DISTANCE FROM FINGERS / TOES (cm) TO OCCLUSION LOCATION					
LIMB CIRCUMFERENCE (cm) AT OCCLUSION LOCATION	20-30	30-40	40-50	50-60	60-70	70-80
24-26	231	224	216	208	199	190
26-28	233	228	222	215	206	196
28-30	251	242	232	222	214	202
30-32	270	260	248	236	229	214
32-34	283	274	265	249	244	226
34-36	325	304	288	263	259	238
36-38	NPD	333	314	288	274	249
38-40	NPD	368	344	339	311	261

How to use the HemaClear® Pressure Table:

Measure the Limb Circumference at the Occlusion Location and select the correct HemaClear model (S,M,L,XL). Measure the Distance from the tips of the fingers/toes to the Occlusion Location. Refer to the appropriate color coded Pressure Table. Find the column in the Table that corresponds to the distance and the row in the Table that corresponds to the Limb Circumference at the Occlusion Location. The number in the column-row intersect is the pressure in mmHg that the HemaClear ring applies at the skin surface.
NPD – Non Physiological Dimension.

FIGURE 5. HemaClear pressure table.

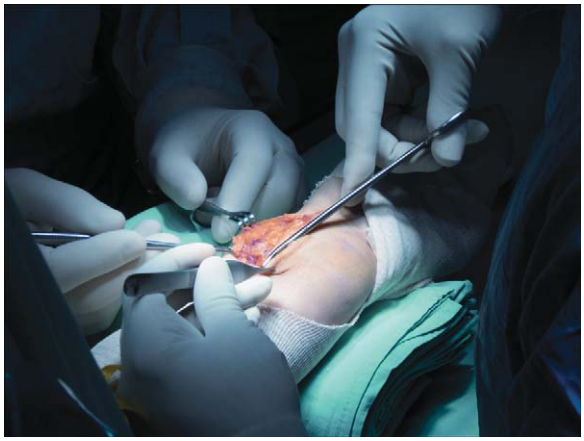

FIGURE 6. Bloodless surgical field using HemaClear.

During the proximal movement of the device over the limb, the stockinette sleeve unrolls onto the limb, covering it entirely up to the occlusion level and thus drapes a sterile stockinette over the surgical field.

When the surgical procedure is over, the protective card is inserted beneath the ring and the HemaClear ring is cut using a scalpel (Fig. 4). The stockinet is then cut away using scissors so that the blood flow into the limb is resumed.

RESULTS AND CONCLUSIONS

We performed ORIF (open reduction internal fixation) in 49 distal radius fracture patients [17 men and 32 women of 49.14 ± 18.05 y (range, 17-83 y)]. No complications or adverse effects of using HemaClear were noted. No tourniquet failure was observed, there were no signs of tourniquet paralysis/paresis/lost of sensory innervations and no signs of tourniquet burns. The patients had a systolic blood pressure within the range of 90 to 160 mm Hg (123.82 ± 15.6 mm Hg) and the circumference of the limb was 22 to 33 cm (26.25 ± 2.23 cm). The pressure under the HemaClear ring was 216 to 274 mm Hg. The pressure was determined according to patient measurements taken at the occlusion site as defined by the pressure table (Fig. 5). The tourniquet time with HemaClear was of 20 to 100 minutes (48.04 ± 20.21 min). In all the patients, HemaClear was placed on the forearm approximately 12 cm above the wrist. The clarity of the surgical field was invariably excellent (Fig. 6). The application time on an average took less than 15 seconds and the preparation of HemaClear was more simple in comparison to the multiple components of the traditional tourniquet method. The cost of the HemaClear device was equivalent to the alternative combined cost of a sterile cuff, an Esmarch bandage, a stockinette, and other materials. In addition the workflow was better and the tourniquet machine was available for use in other operating rooms.

Three major advantages of the HemaClear:

(a) The device is sterile, simple, and easy to use.
(b) The device can be placed on the forearm close to the surgical incision. This reduces the volume of tissue under ischemic conditions and allows better control over operative site exposure.
(c) The device provides consistent occlusion compared with the pneumatic tourniquet that may leak.

It is reasonable to conclude that HemaClear is a useful addition to the available perioperative techniques in upper extremity surgical procedures.

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Use of the S-MART Tourniquet in Total Elbow Arthroplasty

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This study evaluates the use of a sterile, single use silicone ring exsanguination tourniquet. Used as an alternative to elevation/wrapping and a pneumatic tourniquet, the S-MART device (OHK Medical Devices, Haifa, Israel) is designed to provide exsanguination, arterial flow occlusion and sterile stockinette application in one movement.

A total of 20 total elbow replacements were done using the S-MART tourniquet over a three-year period by the senior author (MF). Total tourniquet time ranged from 1 hour 20 minutes to 2 hours. No intra-operative or early postoperative problems were encountered. Follow up at 2 and 6 weeks revealed no wound complications or neurological complications. Patients were followed up for one year after the surgery.

It is paramount in elbow replacement to have a good bloodless operative field without the tourniquet encroaching upon the surgical field and increasing the risk of infection in elbow arthroplasty. We conclude that use of the S-MART tourniquet in total elbow arthroplasty is convenient and safe, with no complications recorded in our study group. The narrow width of the tourniquet allows better draping of the limb without compromising the surgical field. As S-MART is a sterile tourniquet it reduces the risk of infection. Combined exsanguination provides a better haemostasis as compared to the pneumatic tourniquet. This is the first study in literature looking at the use of this novel tourniquet in total elbow arthroplasty.

J Orthopaed Traumatol
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ORIGINAL ARTICLE

Silicone ring tourniquet versus pneumatic cuff tourniquet in carpal tunnel release: a randomized comparative study

G. I. Drosos · A. Ververidis · N. I. Stavropoulos · R. Mavropoulos · G. Tripsianis · K. Kazakos

Received: 14 March 2012 / Accepted: 20 December 2012

Abstract
Background The aim of the present study was to compare the pain levels resulting from the use of a silicone ring tourniquet (SRT) to those resulting from the use of a classic pneumatic cuff tourniquet (PT) in patients undergoing carpal tunnel release under local anesthesia.
Materials and methods Fifty patients that underwent carpal tunnel release under local anesthesia were randomized using the technique of stratified randomization by minimization. A forearm tourniquet was applied: a standard PT was used in 25 patients, and an SRT was used in the other 25 patients (the model of SRT used was selected according to the standard systolic blood pressure). Patient demographics and complications were recorded. Pain levels were assessed with the visual analogue scale and were recorded (a) just after tourniquet application, (b) 5 min after tourniquet application, and (c) just before tourniquet removal.
Results There was no statistical significant difference in patient demographics between the two groups. The mean tourniquet time was similar for both groups ($p = 1.000$). The difference between the mean final pain level and the mean initial pain level was statistically significant for the SRT group ($p = 0.010$) and highly statistically significant for the PT group ($p < 0.001$). The mean final pain level for the PT group was higher than that for the SRT group ($p = 0.043$).
Conclusions According to the findings of this study, in patients who underwent carpal tunnel release under local anesthesia, the pain levels at the end of the operation and those just before the removal of the tourniquet were higher in the PT group than in the SRT group of patients.

Keywords Tourniquet · Pneumatic tourniquet · Silicon ring tourniquet · Tourniquet pain

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Introduction

Tourniquet devices are commonly used in orthopedic procedures in order to provide a bloodless operating field during surgical procedures involving the extremities. Pneumatic tourniquets (PTs) are preferred by most surgeons, and modern pneumatic tourniquets are designed to minimize the incidence of complications [1]. Nevertheless, complications do still occur, and a recent study showed that the incidence of tourniquet complications is still at least as high as that estimated in the 1970s [2].

However, a new device known as a silicon ring tourniquet (SRT) was introduced into clinical practice relatively recently [3–6]. This a novel device (marketed as the S-MART or HemaClear, OHK Medical Devices, Haifa, Israel) consists of a silicone ring wrapped within an elastic sleeve (stockinet) and two straps attached to pull handles, and is designed for exsanguination and occlusion of the blood flow to the limb.

The entire device is sterile and comes in different sizes: (a) a small size for pediatric use; (b) a medium size for an

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upper limb (circumference of the limb at the occlusion site 24–40 cm); (c) a large size for the leg (circumference of the limb at the occlusion site 30–55 cm); and (d) an extra-large size for the leg (circumference of the limb at the occlusion site 50–90 cm and systolic blood pressure ≤160 mmHg). There are three tension models (systolic blood pressure ≤130 mmHg, <160 mmHg, <190 mmHg) for the medium and large sizes, and the appropriate model is selected for each patient according to the systolic blood pressure measured in the operating room before the placement of the device.

This device has been compared to the pneumatic tourniquet in healthy volunteers [7, 8], and in a clinical study of patients that underwent upper extremity operations [4].

The aim of this randomized prospective study was to compare the pain levels resulting from the use of the classic pneumatic tourniquet to the pain levels resulting from the use of this new device in patients undergoing carpal tunnel release.

Materials and methods

Study design

Patients who were scheduled for carpal tunnel release under local anesthesia and had no previous fracture or operation in the affected limb as well as no history of anemia, malignancy, or neurological disorder were included in this study. All of the patients gave their informed consent prior to being included into the study. The study was authorized by the local ethical committee (hospital ethics committee approval: UGHA 157/2-7-2010), and was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki, as revised in 2000.

Fifty patients were randomized using the technique of stratified randomization by minimization [9, 10]. The patients were assigned to a treatment group (SRT or PT) according to a stratified and blocked randomization method. The randomization was based on four parameters: age (30–39, 40–49, 50–59 years), gender (male, female), body mass index (BMI) (less than 25, 25–29.9, more than 30), and whether the patient was a smoker (yes or no). Each patient's age, gender, body mass index (BMI), smoking status, occupation, other illnesses, medications, and dominant hand were recorded. Patients were followed up for any complications related to tourniquet use or to the operation up to 30 days postoperatively.

Tourniquet types

A standard pneumatic tourniquet (PT) with an 8 cm wide cuff and the appropriate SRT model (selected according to the standard systolic pressure) were used.

Procedure

The procedure was explained to all participants. They were also instructed how to use the visual analogue scale for discomfort/pain (0 = no discomfort/pain; 10 = the worst pain) [11]. The patients were placed in a comfortable, supine position out of sight of clocks or monitoring equipment. The systolic and diastolic blood pressures and the pulse rate were monitored using a noninvasive monitor, and the cuff/cables were applied to the unaffected upper limb. After a 10 min period to allow the values of the recorded variables to stabilize, the systolic pressure was measured and used as the standard.

A forearm tourniquet was used in all patients. A PT with an 8 cm wide cuff was applied over two layers of smoothly applied cast padding. The limb was elevated for 3 min before tourniquet inflation. The PT inflation pressure was 100 mm Hg above the standard systolic blood pressure. The appropriate SRT model was selected according to the standard systolic blood pressure and applied as recommended by the manufacturer.

The VAS levels for pain were recorded (a) just after tourniquet application (initial pain, T_0), (b) 5 min after the tourniquet application (T_5), and (c) just before the tourniquet removal (final pain, T_{final}).

The surgical technique employed was the same in all patients. Open carpal tunnel release was performed under local anesthesia with ropivacaine. A curved skin incision was made ulnar to and parallel to the thenar crease, followed by an inline incision of the subcutaneous tissue and the palmar aponeurosis. The distal end of the transverse carpal ligament was identified and the ligament was incised. The flexor tenosynovium was inspected before the skin closure with 3-0 nylon suture. A compressive dressing was applied and the hand was kept elevated for two days, during which time the patients were instructed to perform active finger movements. Subsequently, a smaller dressing was applied and the patient was encouraged to gradually resume normal use of the hand. The sutures were removed after 12–14 days.

Statistical analysis

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS), version 19.0 (SPSS, Inc., Chicago, IL, USA). All quantitative variables were expressed as the mean ± SD, while qualitative variables were expressed as frequencies (and percentages). The normality of the quantitative variables was tested with the Kolmogorov–Smirnov test. The χ^2 test and Student's t test were used to assess differences in demographic characteristics between the two groups of patients. Between-group differences in VAS score were assessed by

Student's t test, while within-group differences were examined by one-way repeated-measures ANOVA (rmANOVA); post hoc analysis was performed using Bonferroni's correction. The interaction between the type of the tourniquet and the change in VAS score over time was established by performing two-way analysis of variance. All tests were two-tailed and statistical significance was considered for p values of less than 0.05.

Results

Patients

There were no complications related to the tourniquet in either group, or wound infections. There were no statistically significant differences in gender ($p = 0.713$), age ($p = 0.658$), BMI ($p = 0.712$), smoking status ($p = 1.000$), occupation ($p = 0.758$), other illness ($p = 0.569$), medication ($p = 0.569$), or the dominant hand ($p = 0.208$) between the two groups of patients (Table 1).

Table 1 Patient demographics and pain scores (VAS)

	SRT	PT	p value
N	25	25	
Gender male [no (%)]	5 (20.0)	4 (16.0)	0.713
Age (years; mean ± SD)	54.28 ± 11.17	55.56 ± 9.06	0.658
BMI (mean ± SD)	29.08 ± 5.35	29.57 ± 3.89	0.712
Smoking status [no (%)]	7 (28.0)	7 (28.0)	1.000
Manual work (no %)	18 (72.0)	17 (68.0)	0.758
Other illness [no (%)]	13 (52.0)	15 (60.0)	0.569
Medication [no (%)]	13 (52.0)	15 (60.0)	0.569
Dominant hand right [no (%)]	20 (80.0)	16 (64.0)	0.208
Tourniquet time (min; mean ± SD)	10.20 ± 2.78	10.20 ± 3.58	1.000
VAS score (mean ± SE)			
T_0	3.92 ± 2.12	3.12 ± 2.05	0.181
T_5	4.44 ± 1.80	3.88 ± 1.92	0.294
T_{final}	4.96 ± 1.65	5.88 ± 1.48	0.043
Change in VAS score			
From T_0 to T_5	0.52 ± 1.56 [13.3 %]	0.76 ± 1.96 [24.4 %]	0.634
From T_5 to T_{final}	0.52 ± 1.33 [11.7 %]	2.00 ± 1.83 [51.5 %]	0.002
From T_0 to T_{final}	1.04 ± 1.59 [26.5 %]	2.76 ± 2.05 [88.5 %]	0.002

SRT silicone ring tourniquet, *PT* pneumatic tourniquet, *BMI* bone mass index, *VAS* visual analogue scale

T_0 pain level after tourniquet application, T_5 pain level 5 min after tourniquet application, T_{final} pain level just before tourniquet removal

Tourniquet time

The mean tourniquet time was identical in the two groups ($p = 1.000$): 10.20 ± 2.78 min (median time, 10 min) for SRT and 10.20 ± 3.58 min (median time, 10 min) for PT.

Pain levels

The VAS score for pain at the site of tourniquet application is shown for each device in Table 1 and Fig. 1. Since the Kolmogorov–Smirnov test did not show any significant deviation from the normal distribution, the VAS score was expressed as the mean ± SD.

One-way repeated-measures ANOVA showed statistically significant changes in the VAS score over time (SRT: $F_{2,48} = 6.030$, $p = 0.005$; PT: $F_{2,48} = 26.791$, $p < 0.001$).

Post hoc analysis, using Bonferroni's adjustment for the number of comparisons, was then performed: SRT application produced a gradual elevation of the VAS score from one measurement to the next by 13.3 and 11.7 %, respectively, but none of these changes reached statistical significance ($p = 0.324$ and $p = 0.185$, respectively). Overall, SRT application resulted in a statistically significant elevation of the pain score by 26.5 % ($p = 0.010$) compared to the initial pain score (from T_0 to T_{final}). In the PT group, an initial nonsignificant ($p = 0.195$) elevation of the VAS score by 24.4 % (from T_0 to T_5) was followed by a statistically significant elevation of the VAS score by 51.5 % ($p < 0.001$) (from T_5 to T_{final}). Overall, PT application produced a highly significant elevation of the pain score by 88.5 % ($p < 0.001$) compared to the initial pain score (from T_0 to T_{final}).

The time courses for the pain experienced by the two groups were compared via two-way mixed ANOVA. This analysis revealed a statistically significant interaction between the type of the tourniquet and the change in VAS score over time ($F_{2,48} = 7.189$, $p = 0.001$). In this regard,

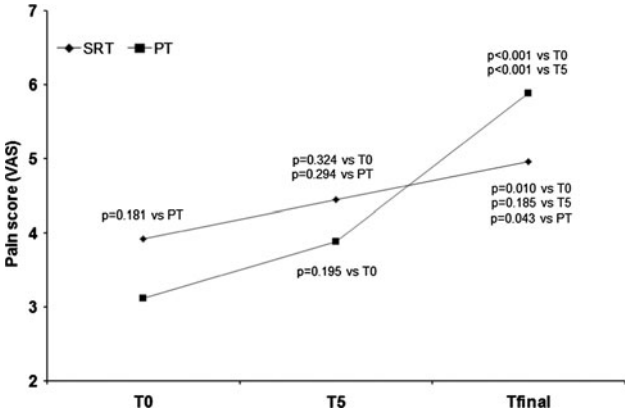

Fig. 1 Mean pain scores over time. *SRT* silicone ring tourniquet, *PT* pneumatic tourniquet

although the initial elevation of the VAS score was similar for the two groups (13.3 % in SRT vs. 24.4 % in PT, $p = 0.634$), the pain increased more dramatically in the PT than in the SRT group from the second measurement until tourniquet removal (11.7 % in SRT vs. 51.5 % in PT, $p = 0.002$). In addition, the increase in the pain score from tourniquet application until removal was greater in the PT than in the SRT group (26.5 % in SRT vs. 88.5 % in PT, $p = 0.002$).

A comparison of the post-application VAS scores of the two groups of patients at each measurement showed that there was: (1) no statistically significant difference between the PT and SRT groups just after tourniquet application ($p = 0.181$) and 5 min after this application ($p = 0.294$); (2) a significantly higher VAS score for the PT than for the SRT group just before tourniquet removal ($p = 0.043$).

Discussion

According to the findings of this study, patients that underwent carpal tunnel release under local anesthesia and with the use of a forearm pneumatic tourniquet experienced more pain at the end of the procedure compared to patients for whom the silicone ring tourniquet was used. The pain levels just after the application of the tourniquet were higher in the SRT group and remained higher 5 min later when compared to the PT group. After that, the pain levels in the SRT group continued to gradually increase in the same manner as they did during the first 5 min. However, for the PT group, a more rapid increase in pain levels was observed, and the mean pain levels in the PT group had become higher than those in the SRT group by about 6–7 min after the application of the tourniquet . These fluctuations in pain levels are similar to those seen in a recently reported study of healthy volunteers [7].

A forearm tourniquet was used in our study because, according to previous studies, a forearm tourniquet is tolerated for longer than an upper arm tourniquet [8, 12].

According to previously published studies [3–6], the SRT has several advantages: it is easily applied (thus decreasing the time and effort required for tourniquet application); it is sterile and can be applied intraoperatively (saving tourniquet time); no additional step for limb exsanguination is required; and it covers a narrow area of the limb. On the other hand, the pressure applied by the SRT is fixed (cannot be adjusted), and the SRT cannot entirely replace the PT since it cannot be used in very obese patients due to limitations on the limb circumference. Furthermore, the SRT is disposable, so there is a direct cost. On the other hand, there is an indirect cost for PTs. The device requires regular maintenance, repairs, and replacements, as well as routine checking, daily calibration checks of all valves and gauges, intraoperative monitoring of tourniquet function at frequent intervals, and rigorous monthly performance-assurance tests [1].

Two recently reported studies of healthy volunteers showed that the SRT performs similarly to the classic PT in terms of tolerance time [7], and may be more comfortable than the PT when used on the upper arm [8].

The etiology and the neural pathways of tourniquet pain seem to be multifactorial [13]. The pressure applied by the tourniquet is certainly one of the responsible factors. Narrow cuffs require a higher arterial flow occlusion pressure [14, 15], and this theoretically increases the chance of pressure-related complications. Furthermore, using a non-pneumatic tourniquet for extended periods may increase the incidence of tourniquet-related adverse events. Nevertheless, such complications have not been reported in published clinical series, where the SRT was used for up to 1.5–2 h [3–6].

On the other hand, a study of human volunteers showed that narrow cuffs resulted in less pain and were tolerated for a longer time than wider cuffs [16] and, more recently, nerve conduction studies showed that wider cuffs result in more severe nerve changes than narrow cuffs inflated to the same pressure and used for the same period of time [17]. These findings may explain the results of our study.

In conclusion, according to the findings of this study, in patients who underwent carpal tunnel release under local anesthesia, the pain levels at the end of the operation and those just before the removal of the tourniquet were higher in the PT group than in the SRT group of patients. Therefore, it seems that SRT may be advantageous compared to the classic pneumatic tourniquet from a tourniquet pain perspective in hand operations performed under local anesthesia, such as carpal tunnel release.

Conflict of interest None.

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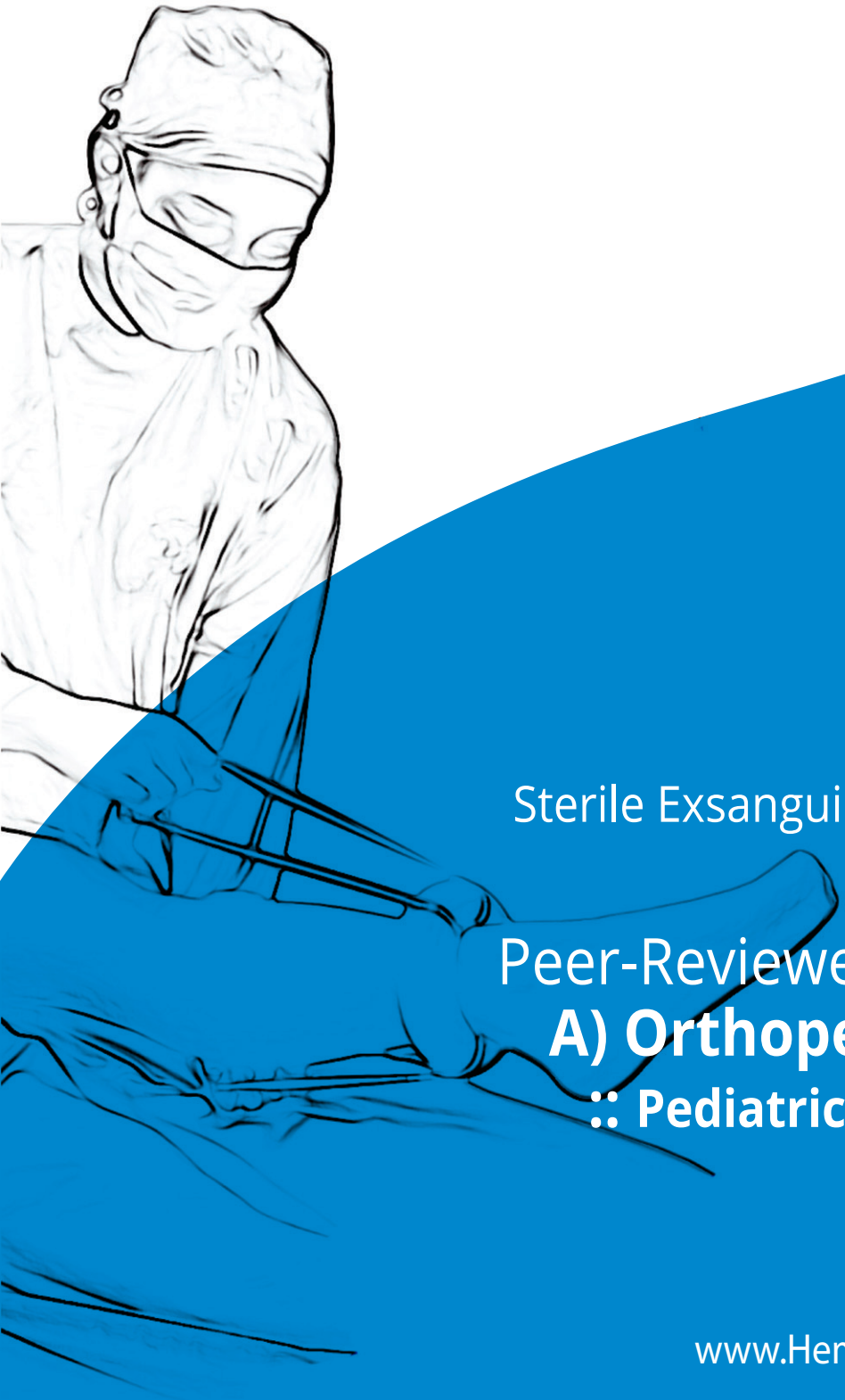

Sterile Exsanguination Tourniquet

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A novel elastic exsanguination tourniquet as an alternative to the pneumatic cuff in pediatric orthopedic limb surgery

Mark Eidelman, Alexander Katzman and Viktor Bialik

We describe our experience with a novel surgical exsanguination tourniquet (S-MART; OHK Medical Devices, Haifa, Israel) in clinical pediatric orthopedics. We evaluated the surgical exsanguination tourniquet's properties and clinical use in 51 patients and compared our observations with our long-standing experience with the Esmarch bandage, pneumatic tourniquet and sterile stockinet. Using the surgical exsanguination tourniquet, we found superior exsanguination quality, quick application and the ability to place the occlusion ring closer to the surgical field. No side effects or ischemic complications were observed. After removal, the skin under the ring was intact in all cases. We conclude that the surgical exsanguination tourniquet is safe and valuable in our practice. ***J Pediatr Orthop B*** **15:379–384 © 2006 Lippincott Williams & Wilkins.**

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Keywords: biomechanics, bloodless surgery, limb exsanguination, tourniquet

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Sponsorship: OHK Medical Devices supplied some of the S-MART units used in this study free of charge. No other financial support was provided by the manufacturer. The investigators did not receive any financial remuneration from the manufacturer, nor do they have any financial stake in the company.

Introduction

A bloodless technique is used in most limb surgical procedures, including pediatric orthopedics. The surgical care of the child's limb, however, often presents special circumstances that render the use of the traditional methods difficult or impossible. The two most unique problems are (i) the size of the limb, in which there is little or no space left for the tourniquet on the patient's thigh or upper arm, and (ii) the acute taper of the young child's thigh, which often results in inadvertent distal sliding of the tourniquet. The latter may result in loss of tourniquet compression and cause blood leakage into the surgical field. In addition, many tourniquets slide too close to the surgical incision, causing a breach of sterility and interference in the surgical field. Additional problems that are known to be associated with use of pneumatic tourniquets and are not necessarily unique to the pediatric population are tourniquet chemical burns and abrasions and mechanical failure of the tourniquet and its compressed air and pressure regulation support system [1,2]. In cases in which non-sterile pneumatic tourniquets are used, the risk of cross contamination is not negligible [3]. We hereby report our initial experience with an alternative novel elastic surgical exsanguination tourniquet (SET) (S-MART; OHK Medical Devices, Haifa, Israel).

Methods and patients

The SET was approved for clinical use by the Israel Ministry of Health, Department of Medical Devices. We performed 51 surgical procedures on 43 patients aged 4–17 years (mean ± SD, 9.9 ± 3.9 years; median, 10 years) during 2004. outlines the patients' demographics, diagnoses and procedures performed.

Patient selection

Only patients with limb dimensions within the range specified by the manufacturer (circumference > 24 cm) were included. Exclusion criteria included patients with grossly misaligned and unstable limb fracture or dislocation, deep vein thrombosis, severe skin disorders and procedures with tourniquet time expected to last longer than 2 h.

Evaluation criteria

The following criteria were considered to evaluate the benefits and usefulness of the new device.

1. Ease of application
2. Time of application
3. Tourniquet position on the limb
4. Quality of exsanguination – bleeding upon first incision
5. Prevention of subsequent bleeding – throughout the entire procedure
6. Interference with surgical site/procedure
7. Limb/joint mobility distal and proximal to the tourniquet ring
8. Quality of stockinet cover
9. Ease of removal
10. Postoperative complications

a. Surgical outcome
b. Infection

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Demographics, diagnoses and procedures of the patients

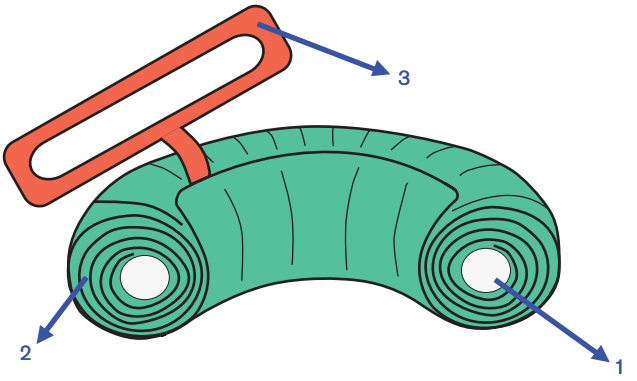
No.	Model	Tourniquet time (min)	Area of application	Procedure	Sex	Diagnosis	Side	Age (years)
1	Yellow	50	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Left	4
2	Blue	30	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	14
3	Blue	30	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	14
4	Blue	35	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	13
5	Blue	70	Distal leg	Tendon lengthening + subtalar fusion	M	Cerebral palsy	Right	17
6	Yellow	65	Mid leg	Calcaneal lengthening	M	Cerebral palsy	Bilateral	11
7	Yellow	65	Mid leg	Calcaneal lengthening	M	Cerebral palsy	Bilateral	11
8	Yellow	35	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Right	6
9	Yellow	35	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	7
10	Yellow	40	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	7
11	Yellow	30	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Right	5
12	Blue	30	Mid thigh	Hamstrings release	F	Cerebral palsy	Right	10
13	Blue	40	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	13
14	Yellow	30	Mid thigh	Closed reduction + internal fixation by Nancy nails	F	Fracture of femur	Left	9
15	Blue	20	Mid Thigh	Insertion of Nancy nails	M	Fracture of femur	Right	9
16	Yellow	15	Mid Thigh	Insertion of nails	F	Fracture of femur	Left	6
17	Yellow	50	Mid arm	Open reduction + Kirschner wires	M	Fracture of lateral condyle	Left	8
18	Yellow	50	Mid arm	ORIF by three Kirschner wires	F	Lateral condyle fracture of the humerus	Right	6
19	Yellow	60	Mid thigh	Knee flexion, contracture release	F	Arthrogryposis	Left	7
20	Yellow	70	Mid thigh	Knee flexion, contracture release	F	Arthrogryposis	Left	7
21	Blue	40	Mid thigh	ORIF	M	Avulsion of tibial eminence	Right	14
22	Blue	20	Distal thigh	High tibial osteotomy, applied for osteotomy only	M	Blount disease	Right	14
23	Blue	70	Mid leg	Feet reconstruction (circumference was enhanced with elastic bandage)	F	Cleft feet	Bilateral	14
24	Blue	75	Mid leg	Feet reconstruction (circumference was enhanced with elastic bandage)	F	Cleft feet	Bilateral	14
25	Yellow	65	Mid leg	Tibialis anterior transfer	M	Clubfoot	Right	5
26	Yellow	70	Mid leg	Tibialis anterior transfer	M	Clubfoot	Left	7
28	Yellow	50	Above knee	Through knee amputation	F	Congenital short femur and tibial aplasia	Right	6
29	Yellow	35	Mid arm	Valgus osteotomy of the humerus	M	Cubitus varus	Left	9
30	Yellow	30	Mid leg	Bilateral tendon Achilles lengthening	M	Duchenne muscular atrophy	Bilateral	7
31	Yellow	30	Mid leg	Bilateral tendon Achilles lengthening	M	Duchenne muscular atrophy	Bilateral	7
32	Yellow	70	Mid leg	Tendon transfer	M	Equinovarus	Right	6
33	Blue	45	Mid thigh	Excision of exostosis	M	Exostosis of proximal tibia leg	Right	16
34	Yellow	65	Mid thigh	Tibial osteotomy	M	Fibrous dysplasia	Right	6
35	Yellow	70	Distal tibia	Calcaneal osteotomy	M	Flat feet	Bilateral	12
36	Yellow	65	Distal Tibia	Calcaneal osteotomy	M	Flat feet	Bilateral	12
37	Yellow	20	Proximal leg	Adductor halucis release	M	Metatarsus Varus	Right	3
38	Yellow	65	Mid leg	Excisional biopsy	F	Osteoid osteoma distal tibia	Left	11
39	Blue	40	Mid thigh	Excisional biopsy	M	Popliteal cyst	Right	11
40	Yellow	40	Mid leg	Excisional biopsy	F	Soft-tissue tumor of the leg	Left	4
41	Blue	25	Mid thigh	Removal of Nancy nails from the femur	M	Status after femoral fracture	Right	7
42	Blue	35	Mid thigh	Removal of nails and revision of the scar	M	Status after nailing of the femur	Left	11
43	Yellow	30	Distal leg	Excision of exostosis	F	Subinguinal exostosis	Right	11
44	Yellow	40	Mid arm	Open reduction and internal fixation by three Kirschner wires	M	Supracondylar fracture of the humerus	Left	9
45	Blue	30	Mid leg	Tendon Achilles lengthening	M	Thigh Achilles	Bilateral	12
46	Blue	30	Mid leg	Tendon Achilles lengthening	M	Thigh Achilles	Bilateral	12
47	Yellow	25	Mid thigh	High tibial osteotomy (osteotomy only)	M	Tibia valga	Right	16

(*Continued*)

No.	Model	Tourniquet time (min)	Area of application	Procedure	Sex	Diagnosis	Side	Age (years)
48	Blue	35	Mid thigh	Bilateral stapling of the tibia	M	Tibia vara bilateral	Left	17
49	Blue	40	Mid thigh	Bilateral stapling of the tibia	M	Tibia vara bilateral	Left	17
50	Blue	40	Mid thigh	High tibia osteotomy	M	Tibial torsion	Right	16
51	Yellow	60	Distal leg	Naviculectomy	M	Vertical talus	Left	4
52	Yellow	30	Mid forearm	Excisional biopsy	F	Wrist ganglion	Left	12

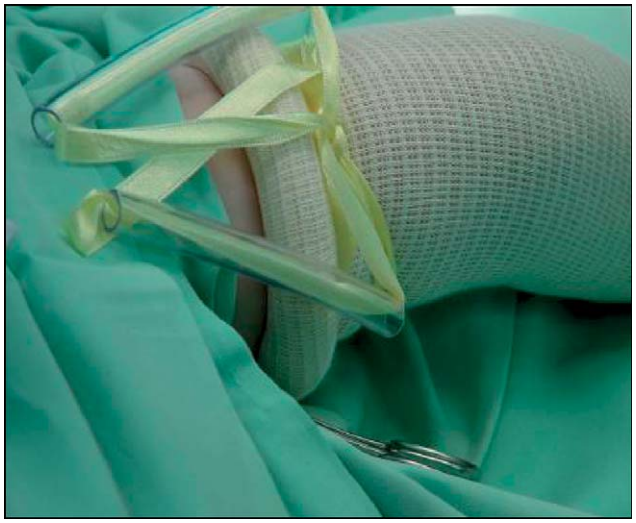
DVT, deep vein thrombosis.

Fig. 1



Schematics of the surgical exsanguination tourniquet showing the inner elastic ring (1), the stockinet wrapped around it (2), and the straps with pull handles (3).

Fig. 2



Application of surgical exsanguination tourniquet to the tapered thigh of the young child. Note the straps wrapped around the limb, preventing the ring from rolling back.

c. Postoperative deep vein thrombosis
d. Postoperative motor/sensory deficit
e. Compartment syndrome
f. Postoperative pain at tourniquet ring site
g. Abrasion, petechia, or chemical burn at tourniquet ring site.

Description of the S-MART surgical exsanguination tourniquet

The SET (S-MART; OHK Medical Devices; www.ohkmed.com) consists of a tension-calibrated elastic ring wrapped around by a cylindrical sleeve and pull-straps (Fig. 1). The toroid-shaped device is sterile and for single-patient use. It is placed on the fingers or toes of the patients and, when the straps are pulled, the SET rolls up the limb quickly and without effort. While rolling, the constricting elastic ring squeezes the blood from the vessels back into the central circulation, while blocking the re-entry of blood into the limb through the arteries. A third effect of rolling up the SET is the sterile sleeve that is left behind, coating the limb from distal to proximal, thereby providing a sterile field. The SET thus replaces the Esmarch bandage, the pneumatic tourniquet (plus controller) and the sterile stockinet. Two sizes of the S-MART were available to us during the study – a smaller device (S-MART/40) suitable for limbs with a circumference of 24–40 cm and a larger one (S-MART/60) used on limbs that are 30–60 cm in circumference. In two instances in which the limb circumference was smaller than 24 cm, we wrapped a sterile ace bandage around the limb at the site we wished the ring to be located, in order to build the circumference up to the minimum level recommended by the manufacturer [4].

Results

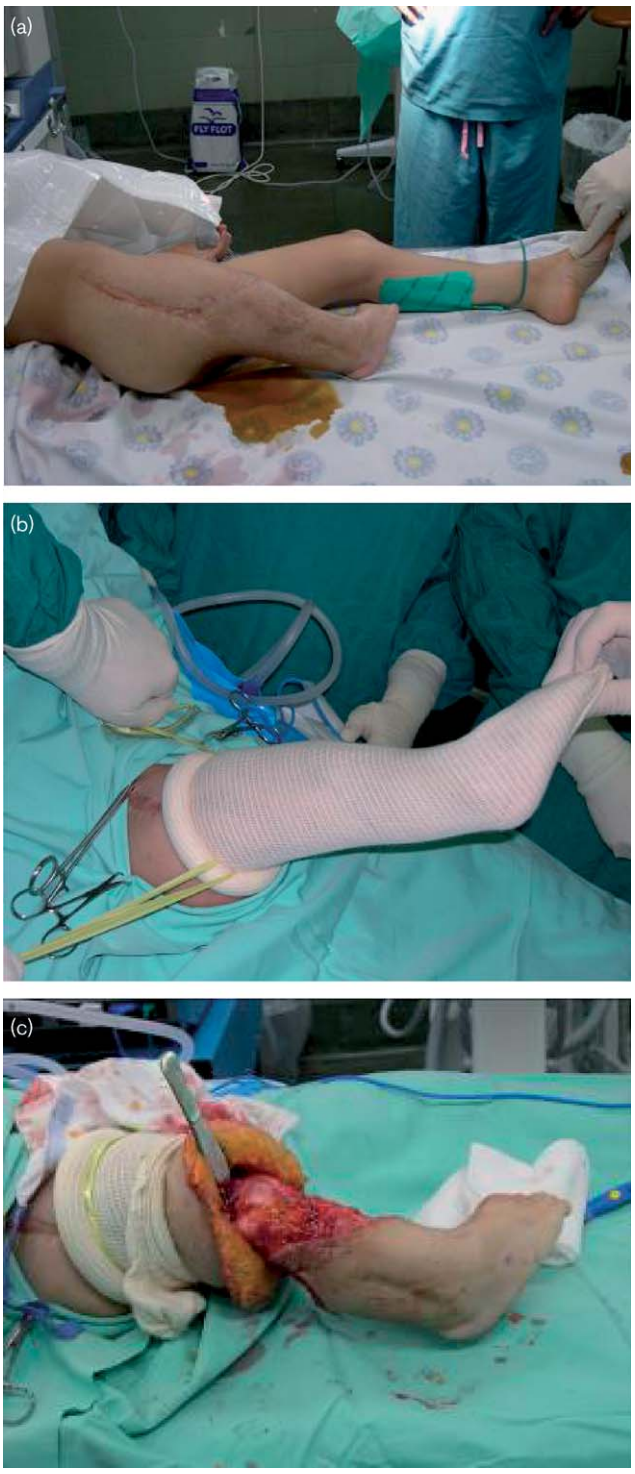
The SET was applied successfully on all the patients and generated a superior surgical field easily and effectively. Table 2 summarizes our observations for the entire group according to the evaluation criteria listed above. The average tourniquet time with the SET was 44 ± 17 min (mean ± SD; median = 40 min). The SET was placed at thigh level in 26 procedures, at the lower leg level in 18 procedures, at the upper arm level in four procedures and on the forearm in one procedure. No adverse effects were noted. The SET ring remained in place even on sharply

Table 2 Evaluation of the surgical exsanguination tourniquet (SET) per criteria

Criterion	Observation
Ease of application	Applying the SET was rated 'very easy' in all cases
Time of application	The SET was applied within 15 s
Tourniquet position on the limb	Upper arm Forearm Thigh Lower leg
Quality of exsanguination – bleeding upon first incision	The exsanguination quality was superior to conventional method. Essentially no bleeding was observed. Sponges or electro-coagulation were not used.
Prevention of subsequent bleeding – throughout the entire procedure	Bloodless field was sustained throughout the entire surgical procedure.
Interference with surgical site/procedure	The SET did not interfere with the surgical site.
Limb/joint mobility distal and proximal to the tourniquet ring	Limb mobility and joint flexibility distal and proximal to the tourniquet ring were rated 'very good'
Quality of stockinet cover	Stockinet is elastic and snug to the skin surface and therefore does not shift during the surgical procedure
Ease of removal	The SET is easily removed by cutting the elastic ring using a scalpel. A cutting card supplied with the device is inserted beneath the ring to prevent accidental nicking of the skin while cutting
Postoperative complications	
Surgical outcome	No adverse effects were observed in the study population
Infection	No surgical wound infections were found
Postoperative DVT	No postoperative DVT cases were seen
Postoperative motor/sensory deficit	No motor or sensory neurological deficits were observed in the operated limb
Compartment syndrome	No patients had compartment syndrome in the study population
Postoperative pain at tourniquet ring site	None of the patients complained postoperatively on pain at the site of the tourniquet ring
Abrasion, petechia, or chemical burn at tourniquet ring site	No signs of skin or tissue damage were observed in short and long-term follow-up

DVT, deep vein thrombosis.

Fig. 3



(a) Short limb through-knee amputation whereby the remaining length of the stump is too short for a conventional pneumatic tourniquet. (b) The surgical exsanguination tourniquet placed on the limb, preventing bleeding and facilitating a 'dry' surgical field (c).

tapered limbs (Fig. 2) and there was no loss of occlusion in any of the patients.

In several cases, the SET was found to be essential in facilitating a bloodless field in procedures that would otherwise have to be done in a non-bloodless fashion. These include, in particular, cases in which surgery was performed on a relatively proximal segment of the limb. An example is a case of congenital femoral deficiency and tibial hemimelia (Figs 3a–c).

Postoperatively, we examined all patients for dermal, vascular or neurological deficit. The clinical evaluation included observation of the skin, estimation of soft-tissue tenderness at the site of the SET ring, pulses and capillary filling, venous congestion or distal swelling, sensation and motor use of the limb. In none of the patients did we find signs or symptoms of soft-tissue damage, vascular occlusion, deep vein thrombosis, compartment syndrome or neurological deficit.

Table 3 Comparison between the surgical exsanguination tourniquet and traditional Esmarch/pneumatic tourniquet method

Property	New exsanguination tourniquet	Pneumatic tourniquet
Quality of exsanguination	Excellent	Pressure dependent
Sterility	Sterile, single patient use	Non-sterile, multi-use
Speed of application	Quick, 10–15 s	5–10 min
Application by:	Surgical team	Applied before the procedure
Site of application	Distal or proximal	Only proximal
Volume of ischemic tissue	Reduced for distal site	Entire limb
Compressed tissue volume	Reduced, only under ring	Larger, under entire cuff
Pressure selection	Three levels only, per systolic blood pressure	Continuous selection
Stability of occlusion	Stable	Occasional occlusion loss
Release	Ring cutting	Pressure release
Re-exsanguination	Not possible	Tourniquet re-pressurized
Skin at site of compression	No lesions	No lesions
Sizes	Adult sizes only (24–60 cm)	Pediatric size available

Discussion

In the present study, we report our experience using a new exsanguination tourniquet in pediatric orthopedics. Our overall rating of the new device is high and we feel that it is a very useful contribution to clinical practice. Table 3 summarizes the comparison between the SET and the traditional Esmarch/pneumatic tourniquet method. In particular, we found the new device to be indispensable in procedures that involve surgical incisions that are only a few centimeters from the axilla or the groin area, where the space is insufficient for using a pneumatic tourniquet. Another advantage that is unique to pediatric orthopedics practice is the new device's stability even on most tapered anatomy as often encountered in well-fed babies. This taper is often associated with distal 'migration' of the pneumatic tourniquet with reduction in cuff pressure which turns the arterial tourniquet into a venous occlusion device with flooding of the surgical field. Another occasional difficulty associated with this migration is the appearance of the non-sterile tourniquet in the surgical field. None of these problems were encountered with the SET.

Exsanguination and surgical field quality

The SET exsanguinates the blood from the limb very effectively, creating a superior quality surgical field that requires virtually no hemostasis during the surgical procedure [5]. In our hands, a drier surgical field facilitates more accurate dissection, better alignment of structures and more straightforward progress of the procedure.

Time saving

We estimate that the procedures done with the SET took less operating room time, required a shorter anesthesia time and had a shorter tourniquet time than with the standard Esmarch/pneumatic tourniquet method.

Safety and pressure

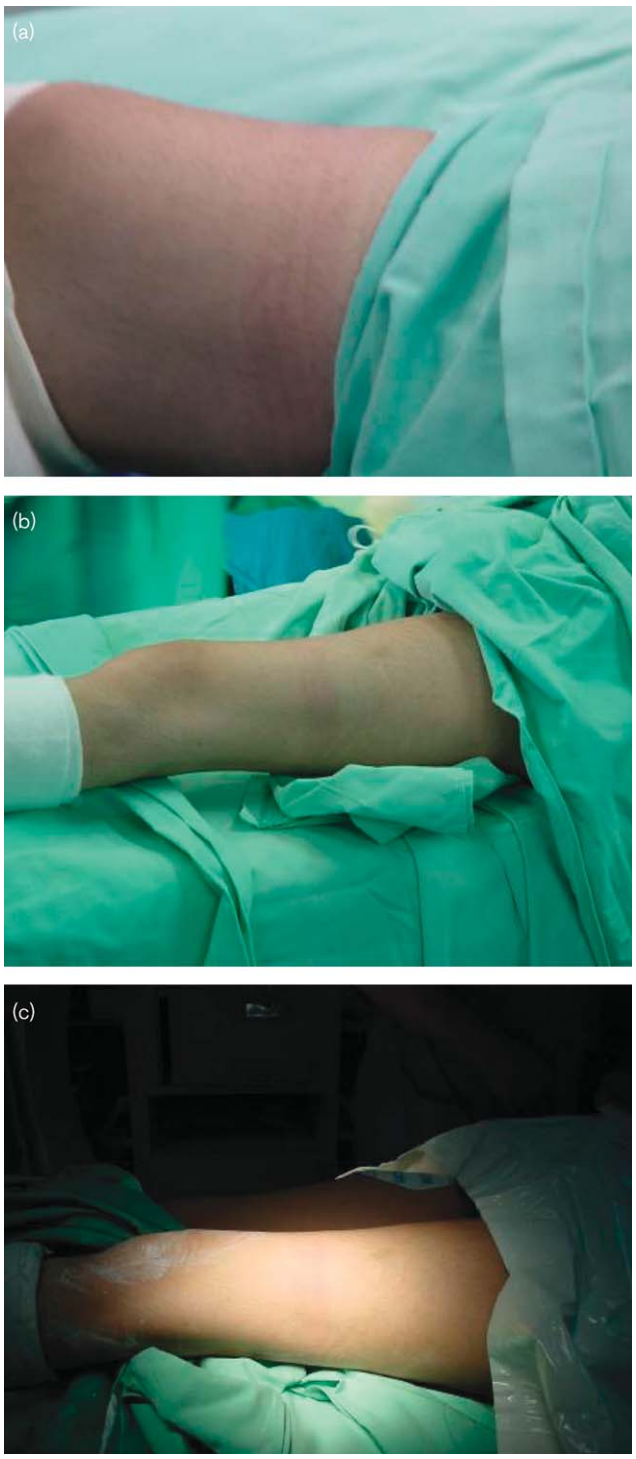
The SET differs from the pneumatic tourniquet in its mechanics. The constricting elastic ring is factory calibrated to provide a localized pressure that is sufficient to block the arterial flow into the limb without causing excessive tissue compression. In all patients, the SET provided continuous arterial occlusion for the entire duration of the procedure. The pressure range as reported by the manufacturer is 227 ± 37 mmHg (mean ± range) for the smaller SET (S-MART/40, yellow) and 246 ± 86 mmHg for the larger SET (S-MART/60, blue). These pressures are similar to the levels we usually use in pediatric orthopedics. We found no local adverse effects at the ring site postoperatively. We observed the skin condition immediately after removal of the SET and found very fine skin marks, similar to those seen on the ankle after wearing a sock. These marks disappeared within less than an hour after removal of the SET (Fig. 4a–c). Furthermore, there were no cutaneous adverse effects of the SET on subsequent postoperative follow-up. No signs of chemical burn, mechanical abrasions or micro/gross hematomas were observed at the site of the ring, as occasionally seen with the use of the pneumatic tourniquet [6].

The SET applies force on the skin surface that is distributed on a relatively small area, substantially smaller than the area beneath the pneumatic tourniquet, thereby minimizing the amount of tissue under compression. Despite other findings, the study by Ochoa *et al.* [7] clearly demonstrated the advantage of using a narrow cuff. Using electron microscopy, they showed that nerves compressed over a length elongate to cause intussusception (telescoping) of the nerve into itself at the nodes of Ranvier, leading to axonal disruption and damage. We did not observe any neural deficit or skin damage associated with the use of the SET.

Placement site and surgical exsanguination tourniquet dimensions

Another advantage of the SET's narrow profile and its non-migrating nature, together with its being sterile, is in situations in which surgery has to be performed in children in whom the limb length is shorter. The sterile

Fig. 4



The marks on the skin after removal of the surgical exsanguination tourniquet: (a) immediately after removal, (b) after 29 min, and (c) after 36 min. Note rapidly fading skin marks.

SET may be placed near the surgical incision with no concern of infection. Thus, when working on a distal structure (foot/ankle and wrist/hand), it was possible to place the SET ring just distal to the calf on the lower leg or on the mid-forearm.

Practicality of surgical exsanguination tourniquet use

SET directly replaces the Esmarch bandage, the sterile stockinet and the padding beneath the tourniquet. In addition, its use avoids the need for a sterile tourniquet, either *de novo* or by re-sterilization. As the SET is applied by the surgeon, its use obviates the need to wait for a technician to secure a tourniquet on a patient's limb and to calibrate and operate the controls of the regulator. The entire process of prepping the limb and applying the SET is substantially shorter than with the standard method. The time saved facilitates a shorter and thereby safer procedure and, in certain circumstances, may translate into cost saving.

Summary and conclusions

The SET is a new device for bloodless surgery that applies exsanguination, tourniquet and sterile stockinet in seconds. This report outlines the superior effectiveness of SET over the existing method, without adding any new safety concerns. A drier surgical field with no 'tourniquet failure', quicker application and the possibility of using it in situations in which pneumatic tourniquets are not feasible makes it particularly useful in pediatric orthopedics. We are satisfied that the new device is safe and free of soft-tissue, vascular or neurological side effects.

Acknowledgements

We gratefully acknowledge the co-operation of Ms Rachel Brandon of OHK Medical Devices and the free supply of some of the S-MART units used in this study.

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The use of sterile tourniquet in Paediatric Orthopaedics

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Abstract

Background: This prospective study was designed to highlight the pros and cons of the application of sterile tourniquet in children with congenital deformities, benign tumors or fractures of upper and lower limbs.

Material and Methods: From October 2007 to April 2008 this device was used in 40 children (23 boys and 17 girls), with an average of 5.6 years old (range from 6 months to 14 years), who were treated surgically in our Department. Twenty three operations affected the upper, and 23 the lower limbs. The effectiveness of this type of tourniquet was evaluated according to specific criteria and was compared to that of pneumatic tourniquet, not only during the operation, but also post-operatively.

Results: There was no failure of application or cutaneous complications after its removal and no complaints from the young patients at all as well.

Conclusions: Sterile tourniquet seems to advantage due to its ease of application, shortening of operative exsanguination time, success in retaining a sterile field and easy replacement in operations lasting over ninety minutes. Moreover, no skin plicas or necrosis can be found after its removal and the surgeon needs no help by the nurse to put it in place. Issues of concern are its operatively stable pressure (inability to up-or-down regulate), the contraindications of use in operations lasting more than ninety minutes and its insufficiency in unstable fractures or dislocations.

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Key words: *Bloodless operation, sterile tourniquet, childhood.*

INTRODUCTION

A bloodless technique in limb operations is the safest procedure applied in Paediatric Orthopaedics because it simplifies the surgeon's work and reassures parents' fears. The goal of a bloodless operation is traditionally achieved by the use of Esmarch exsanguination bandage and application of pneumatic tourniquet. However, in Paediatric Orthopaedics, one finds special circumstances that hinder the uneventful use of the traditional Esmarch bandage and may give negative results. For instance, the length of humerus and femur are so small that may make the use of pneumatic tourniquet, for the removal of an osteoid osteoma in humerus or a plastic restoration of quadriceps in a child with arthrogryposis and genu recurvatum, problematic (Figure 1). Moreover, femur's conical shape in overweight children allows the progressive sliding of the pneumatic tourniquet distal to its initial position during the operation, leading to loss of exsanguination and sterility in the surgical field.

Additional problems that are known to be associated with the use of pneumatic tourniquets are skin abrasions and chemical burns[1,2]. Not seldom we find that the wear due to the intensive use produces leaks in the elastic tubes or central apparatus resulting in reduction of the initial pressure. There are also cases where the pneumatic tourniquet was accused for cross-contamination[3].

We hereby report our experience with the use of a sterile tourniquet (S-MART, OHK Medical Devices) in order to analyze all the advantages and disadvantages of the method.

MATERIAL AND METHODS

In this prospective study we used the sterile tourniquet

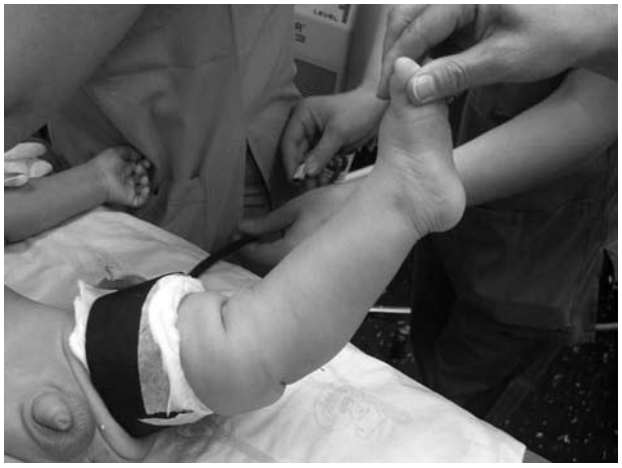

Figure 1. Femur's length is so small that makes the use of pneumatic tourniquet, for plastic restoration of quadriceps in a child with arthrogryposis and genu recurvatum, problematic.

in operations of upper and lower limbs in infants and children that were hospitalized in our Department from October 2007 to April 2008. Forty children (23 boys and 17 girls) suffering from congenital deformities, benign tumors or fractures in limbs were submitted into operation. Mean age of the patients was 5.6 years old (range from 6 months to 14 years). Twenty three operations in upper and 23 in lower limbs were conducted as we can see in Table 1. Exclusion criteria were unstable or particularly displaced fractures, dislocations, severe skin disorders and procedures with estimated surgical time more than 2 hours. Limb dimensions smaller than 24 centimeters in the site where the tourniquet was to be placed, did not discourage us despite the relevant references[1].

In order to completely evaluate our results from this method we used specific criteria in conjunction with its applicability and safety. These criteria were the following:

1. Ease of application
2. Time for application
3. Tourniquet position on the limb
4. Quality of exsanguination-bleeding upon first incision
5. Quality of exsanguination during the whole procedure
6. Interference with surgical field
7. Joint mobility distal and proximal to the tourniquet
8. Ease of removal
9. Scrub nurse's opinion
10. Postoperative complications

In postoperative complications we included infection, deep venous thrombosis, neurological deficits, compartment syndromes and postoperative pain, abrasions, petechias or chemical burns at tourniquet site[3-5]. The evaluation of all these complications was completed the first ten postoperative days.

The type of the tourniquet used was SET (Surgical Exsanguination Tourniquet), S-MART, OHK Medical Devices with the Israel (Haifa) being the country of origin. This type consists of

1) an elastic ring,
2) a cylindrical stockinet wrapped round the ring and
3) two pull straps.

The tourniquet device is sterile in its pack and for single use only. It is placed on the patient's fingers or toes, depending on the occasion, by the orthopaedic surgeon, in a previously appropriately prepared surgical field (Figure 2a). Pulling the straps vertically to the longitudinal axis of the limb the elastic ring rolls up the limb quickly and without effort until its end point of application (Figure 2b). While rolling the elastic ring squeezes the blood from the vessels back into the central circulation and simultaneously prevents the arterial inflow.

At that point the limb is covered by the sterile elastic stockinet at all its length. By this way the SET replaces the Esmarch bandage, the pneumatic tourniquet and the sterile stockinet. We open (or remove) with scissors the part of the stockinet that covers the incision site and now the operation can continue under sterile and bloodless conditions (Figure 2c). After the end of the operation the elastic ring can be cut with the use of a scalpel size no.21 with the help of a special plastic card (Figure 2d).

Three sizes of the S-MART were available to us during the study; the small device (for limbs with a circumference of 15-50cm) colored in pink, the medium size (suitable for limbs that are 20-80cm in circumference) colored in yellow, and the large size (for limbs with a circumference of 40-100cm) colored in blue. For the selection of the appropriate size for each occasion, we estimated the distance from the tip of toes or fingers to the position where the ring was to be placed and the circumference of the limb at the application site. With the use of tables we were choosing the size and knew the pressure applied.

RESULTS

The SET was applied successfully in all our cases despite our initial reservations. According to the criteria used concerning the applicability and safety of the method, we can make some remarks shown on Table 2. The use and final application of the device were judged as easy, after we had dealt with the initial difficulties consulting carefully the manufacturer's manual. The SET was kept in place and did not move, neither in children with small length of humerus or femur, nor in overweight children with conical shaped limb as we would expect to happen if pneumatic tourniquet was used.

The time required for its application was not longer than 60 seconds, in any occasion. The average tourniquet time with the SET was 47 minutes, with a range of 10 to 80 minutes. It was placed at the upper arm level in 23 cases and at in the thigh level at 23 procedures. We did not choose in any case the median part of forearm for

Table 1.

No.	Tourniquet Size		Area of application	Procedure time	Sex	Diagnosis	Age (years)
1	Pink	15′	Humerus	Opening a tendon sheath	M	Trigger thumb	2.3
2	Yellow	30′	Humerus	Excision	F	Wrist ganglion	4.2
3	Yellow	60′	Humerus	Finger separating	M	Hand Syndactyly	2.1
4	Yellow	30′	Humerus	Excision	F	Wrist ganglion	7.8
5	Yellow	60′	Humerus	Finger separating	M	Hand Syndactyly	2.5
6	Pink	10′	Humerus	Opening a tendon sheath	A	Trigger thumb	1.8
7	Yellow	45′	Humerus	ORIF	F	Medial epicondyle fracture	8.5
8	Yellow	60′	Humerus	ORIF	M	Olecranon fracture	10.2
9	Yellow	60′	Thigh	Broad syndesmolysis	M	Congenital Club foot	0.5
10	Pink	15′	Humerus	Opening a tendon sheath	F	Trigger thumb	2.2
11	Pink	12′	Humerus	Opening a tendon sheath	F	Trigger thumb	2.5
12	Yellow	60′	Thigh	Broad syndesmolysis	M	Congenital Club foot	0.7
13	Yellow	75′	Humerus	ORIF	F	Monteggia fracture	12.5
14	Pink	10′	Humerus	Opening a tendon sheath	F	Trigger thumb	3.2
15	Yellow	60′	Humerus	ORIF	F	Humeral condyle fracture	8.5
16	Yellow	70′	Humerus	ORIF	M	Forearm fracture	10
17	Blue	45′	Thigh	Excision of the exostosis	M	Tibial exostosis	11.9
18	Pink	15′	Humerus	Opening a tendon sheath	M	Trigger thumb	1.5
19	Yellow	60′	Thigh	Broad syndesmolysis	F	Congenital Club foot	0.6
20	Blue	80′	Thigh	Green-Grice arthrodesis	M	Flexible pes valgus	13.5
21	Yellow	60′	Humerus	ORIF	F	Radial head fracture	10.2
22	Pink	12′	Humerus	Opening a tendon sheath	M	Trigger thumb	2.8
23	Pink	20′	Humerus	Opening a tendon sheath	F	Trigger thumb	1.8
24	Yellow	60′	Thigh	Broad syndesmolysis	F	Congenital Club foot	0.7
25	Yellow	60′	Humerus	ORIF	F	Humeral condyle fracture	9.5
26	Yellow	75′	Humerus	ORIF	M	Monteggia fracture	13.8
27	Blue	45′	Thigh	Excision of the exostosis	F	Tibial exostosis	12.7

operations in the hand or the tibia, for operations in the foot. The exsanguination quality upon first skin incision was excellent, provided no need for hemostasis was apparent. But also during the whole operation the quality of exsanguination remained in the same excellent level provided the applied pressure was stable. The surgical field was not disturbed in any case from the presence of SET and the surgeon fulfilled his duty under absolute sterile and bloodless conditions. The mobility of the joints distal and proximal to the application site was kept free and the SET was removed without any problem. Scrub nurse's opinion was written down, something that is permanently omitted. She was complaining about the use of sterilized scissors to open the applied stockinet in the beginning of the operation (Figure 3) and was concerned about the presence of free particles of cut stockinet near the surgical field that are difficult removed (Figure 4).

As far the postoperative complications are concerned, we tried to find out which of them were attributed to the use of SET in the first 10 days following the operation. No signs of infection, deep vein thrombosis, neurological deficit, compartment syndrome or postoperative pain at application site were mentioned. In none of our patients did we find signs or symptoms of soft-tissue damage, petechias or chemical skin burns.

DISCUSSION

In this study, we report our experience using a new exsanguination tourniquet in infants and children suffering from congenital deformities, benign tumors or fractures of upper and lower limbs. Our impression is very favorable of the applicability and safety of this method in comparison with the use of traditional tourniquet method. It proved to be very useful in operations conducted only a few cm distally to the axilla or groin area, where the

Table 1. *(cont.)*

No.	Tourniquet		Area of	Procedure	Sex	Diagnosis	Age
Size	time		application				(years)
28	Pink	10′	Humerus	Opening a tendon sheath	F	Trigger thumb	3.8
29	Yellow	30′	Thigh	Finger excision	F	Foot polydactyly	1.4
30	Yellow	60′	Thigh	Bone grafts	M	Fibular aneurysmal cyst	5.5
31	Blue	45′	Thigh	Excision of the exostosis	F	Tibial exostosis	11.5
32	Pink	15′	Humerus	Opening a tendon sheath	M	Trigger thumb	3.8
33	Yellow	30′	Thigh	Cyst excision	F	Popliteal cyst	4.5
34	Yellow	60′	Thigh	Broad syndesmolysis	M	Congenital Club foot	0.6
35	Yellow	30′	Thigh	Finger excision	F	Foot polydactyly	1.2
36	Yellow	70′	Thigh	Quadriceps plastic restoration	M	Arthrogryposis	1.2
37	Yellow	75′	Thigh	Open reduction	F	Congenital vertical talus	1.5
38	Blue	60′	Thigh	Excision of the nidus	M	Osteoma of femoral condyle	14
39	Blue	45′	Thigh	Excision of the exostosis	F	Tibial exostosis	3.4
40	Blue	80′	Thigh	Green-Grice arthrodesis	M	Flexible pes valgus	13.8
41	Yellow	70′	Thigh	Quadriceps plastic restoration	M	Arthrogryposis	1.6
42	Yellow	75′	Thigh	Open reduction	F	Congenital Vertical Talus	1.6
43	Yellow	60′	Thigh	Broad syndesmolysis	M	Congenital Club foot	0.6
44	Blue	45′	Thigh	Removal of Nancy nails	M	Fracture of femur	12.2
45	Yellow	60′	Humerus	ORIF	F	Radial head fracture	8.2
46	Yellow	60′	Thigh	Broad syndesmolysis	M	Congenital Club foot	0.7

space is insufficient for the use of pneumatic tourniquet. Additionally, it proved to be particularly useful when the children's limbs are small and conical shaped leading the pneumatic tourniquet to migrate distally to its initial position causing loss of cuff pressure, loss of resultant exsanguination and contamination of the surgical field.

The achieved exsanguination was satisfying in such a degree that no major hemostasis was needed, reducing the amount of blood loss. It also helped the surgeon recognize the relevant anatomy especially in hand operations[6]. Application time was minimal (less than 60 seconds) contributing to anesthesiologist's work and to a more straightforward progress of the operation.

The pressure applied by the elastic ring was stable during the whole procedure and depended on the distance between the tip of fingers or toes and the application point, and the circumference at that point. Using tables we were choosing the size and knew the exact pressure applied. For example, in finger-application site distance of 15 to 50cm and circumferences in application point between 14 and 28cm, the pressure varied between 180 and 210mm Hg-pink colored tourniquet. For distances between 20 and 80cm and circumferences between 24 to 40cm the pressure varied between 230 and 260mm Hg (yellow color). For distances ranging from 40 to 100cm and for circumferences from 24 to 56cm the pressure varied between 260 and 330mmHg (blue color).These pressures while blocking blood flow in the limb, they do not suppress or contuse the tissues[1].

After the removal of the elastic ring no focal problems were found, such as bruises, petechias, chemical burns as in the use of pneumatic tourniquet[4]. We should mention the presence of minor skin signs resembling the signs that a stocking leaves in the skin, which disappear in less than an hour. The elastic tourniquet applies pressure to a small skin surface, apparently much smaller than the surface pressed by the pneumatic tourniquet. As a result of this, we did not find any neurological deficits described with the traditional method[5].

We preferred to use the ring at the upper arm level or at the thigh to avoid the possibility of postoperative infection from contamination of the surgical field. Some authors have accused pneumatic tourniquet for infection by methicillin resistant staphylococcus aureus (MRSA)

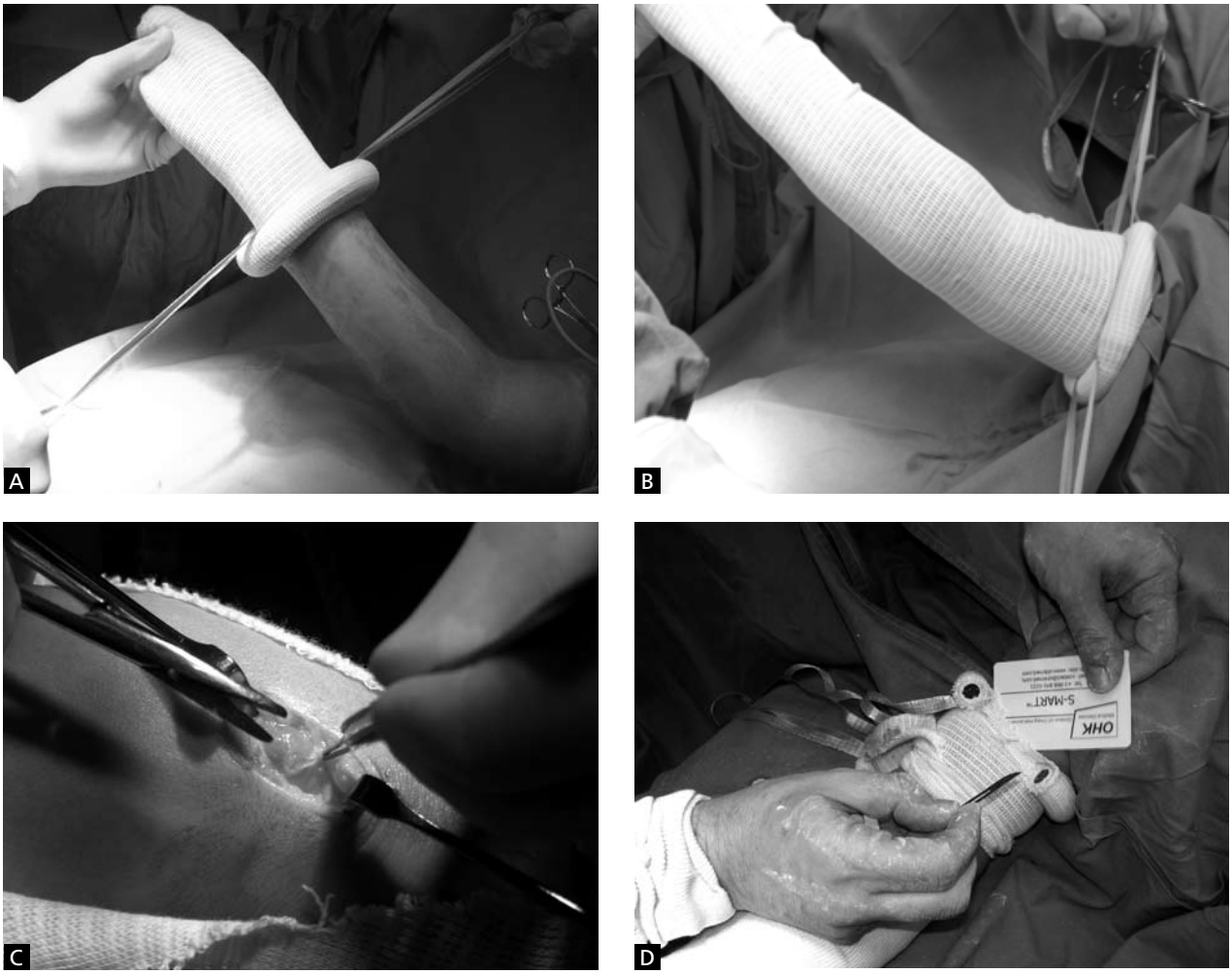

Figure 2. Application of the sterile tourniquet in an upper limb with a carpal ganglion. **A)** It is placed on the patient's fingers by the orthopaedic surgeon, with the surgical field being previously appropriately prepared. **B)** Pulling the straps vertically to the longitudinal axis of the limb, the elastic ring rolls up the limb quickly and without effort until its end point of application. **C)** We open (or remove) with scissors the part of the stockinet that covers the incision site. **D)** After the end of the operation the elastic ring can be cut with the use of a scalpel size no.21 with the help of a special plastic card.

due to its progressive migration during the operation[3,7,8]. No cases of deep venous thrombosis or compartment syndromes were found.

CONCLUSIONS

Sterile tourniquet bandage is a device that combines easy with quick application, decreases the exsanguination time, provides an excellent sterile surgical field and can be used in situations where pneumatic ones are not feasible. As it is applied by the surgeon, its use obviates the need for a technician to secure the tourniquet and make all the calibrations. It can be replaced easily when the operation lasts more than 90 minutes and is free of soft-tissue, vascular or neurological side effects. However its pressure remains stable (it can not be altered operatively) and can not be used in operations that last over 90 minutes with insufficiency in unstable fractures or dislocations. Summarizing, we could say that we report in this study the superior effectiveness of this device over the traditional method without posing additional problems.

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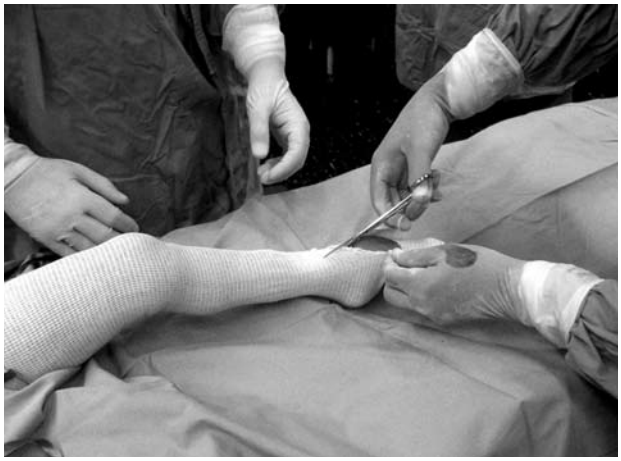

Figure 3. Scrub nurse was complaining about the use of the sterilized scissors to open the applied stockinet in the beginning of the operation.

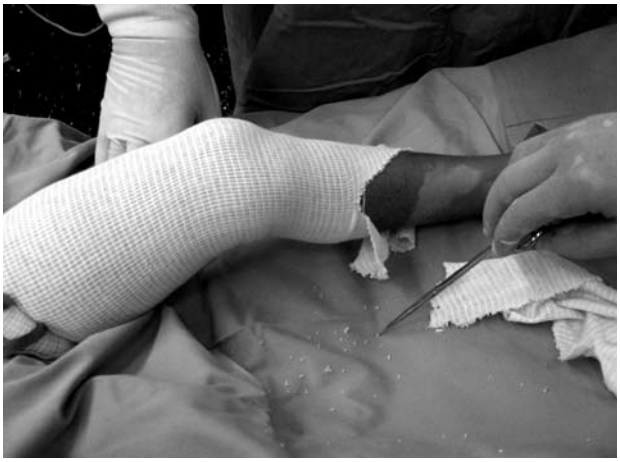

Figure 4. Scrub nurse was concerned about the presence of free particles of cut stockinet near the surgical field which were difficult removed.

Table 2.

Evaluation criteria	Result
1. Ease of application	very satisfying
2. Time for application	less than 60 seconds
3. Tourniquet position on the limb	proximal end of humerus or femur
4. Quality of exsanguination-bleeding upon first incision	Excellent
5. Quality of exsanguination during the whole procedure	Excellent
6. Interference with surgical field	not mentioned
7. Joint mobility distal and proximal to the tourniquet	Free
8. Ease of removal	very satisfying
9. Scrub nurse's opinion	Reserved
10. Postoperative complications	not mentioned

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Safety of using a novel device for creating a bloodless surgical field in pediatric limb fractures

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Introduction
The objective of the tourniquet is to provide a surgical field free of blood in order to reduce bleeding, easily identify anatomical structures and as a consequence reduce length of surgery. Additionally, exsanguination of the patient's limb reduces bleeding and improves the surgical field. In children the use of the tourniquet is as common as in adults but there are factors that preclude the use the standard pneumatic tourniquet, including the length of the limb and the conic shape of the child's thigh that causes distal sliding of the tourniquet. The SET (Surgical Exsanguination Tourniquet) is a new device made of a silicon ring wrapped with a sterile stockinet sleeve. The SET is placed on the operated limb and then rolled proximally, while the elastic sleeve is spread and a bloodless sterile field is formed.

Aims
The aims of the present study are (a) to investigate the safety and efficiency of a method of imaging-guided axial limb traction during SET placement for internal fixation of pediatric limb fractures, and (b) to formulate instructions for use and identify contraindications for the use of the SET with axial stretching.

Materials and Methods
Following authorization of the Ethics Committee we recruited 39 children and teenagers (3 - 18 years) that were admitted to the Pediatric Orthopedic Unit at Rambam Medical Center for surgery including open/closed reconstruction and internal fixation of limb fractures. 26 of the patients were operated on with SET and 13 without (control).

Results and discussion
No SET placement-related or pneumatic tourniquet complications were observed. The axial traction by two surgeons technique was applied with no difficulty. The surgical procedures were under excellent visibility conditions with the SET. The SET was found to be safe for use in trauma while performing the axial stretching technique under imaging control.

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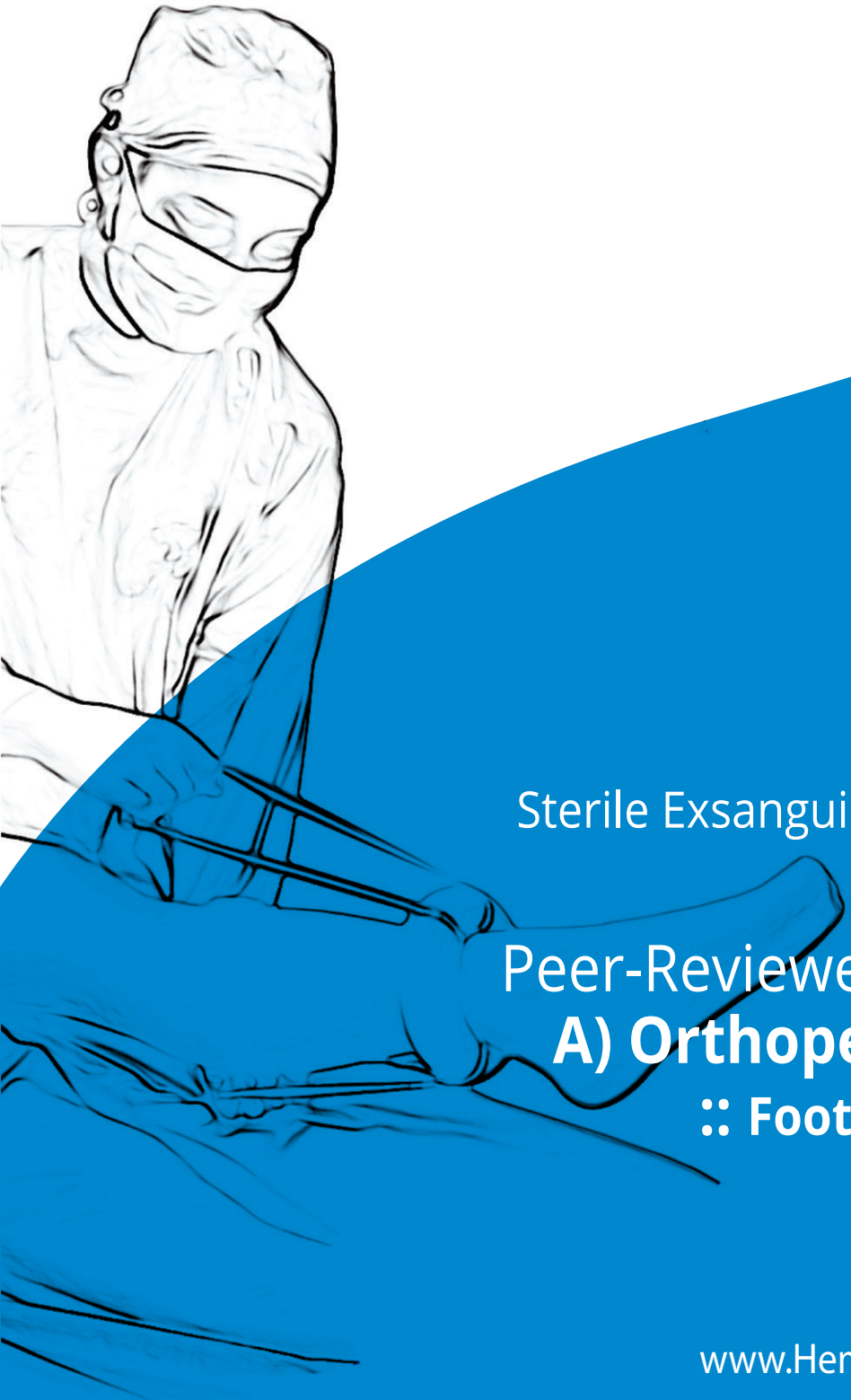

Sterile Exsanguination Tourniquet

Peer-Reviewed Publications
A) Orthopedic Surgery
:: Foot & Ankle

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S-MART and Pneumatic tourniquet in foot surgery -a randomized controlled study

Podium No: 257
Thursday, March 06, 2008
10:36 AM - 10:42 AM
Location: Moscone Convention Center
Room 250-262

Arvind Mohan, MBBS Epsom, Surrey United Kingdom
Palanisamy Ramesh, FRCS Orth Kingston Upon Thames United Kingdom
M J Curtis, FRCS Kingston United Kingdom

Moderator(s):
Steven L Haddad, MD Glenview IL
Charles L Saltzman, MD Salt Lake City UT

S-MART tourniquet is a good for foot surgery, provides a good operative field, is easy to apply and saves precious theatre-time and resources.

We undertook a prospective randomized study to assess the efficacy of the S-MART tourniquet in foot surgery as compared to the pneumatic tourniquet. A literature review confirms this is the first randomized controlled study objectively measuring the outcomes of this tourniquet system.

We included 60 consecutive patients who had foot surgery from May 2006 to November 2006. Informed consent with local medical ethical approval was obtained. We excluded patients with history of diabetes mellitus, deep vein thrombosis, fractures, and limb circumference more than 40 centimeters and smokers. The ease of application of tourniquet, intraoperative bloodless field and ease of removal was scored on a scale of 1-10. Patients were followed up at 2 weeks.

30 patients were randomized into group one with pneumatic tourniquet (average age 63.7) and 30 patients in group two with S-MARTTM tourniquet (average age 61.8). The average tourniquet placement time in-group one was 147.66 seconds as compared to 11.3 seconds in-group two (p value < 0.001 using unequal variance t-test). The mean ease of application scores was 4.30 in-group one as compared to 1.56 in-group two. Total tourniquet time was more in-group one. Intraoperative haemostasis was rated higher in-group two.

SMARTTM tourniquet provides a good intraoperative haemostasis and is easy to apply. The limitation is it cannot be reinflated and cannot be used in patients with fractures. S-MART tourniquet is a good for foot surgery, provides a good operative field, is easy to apply and saves precious theatre-time and resources.

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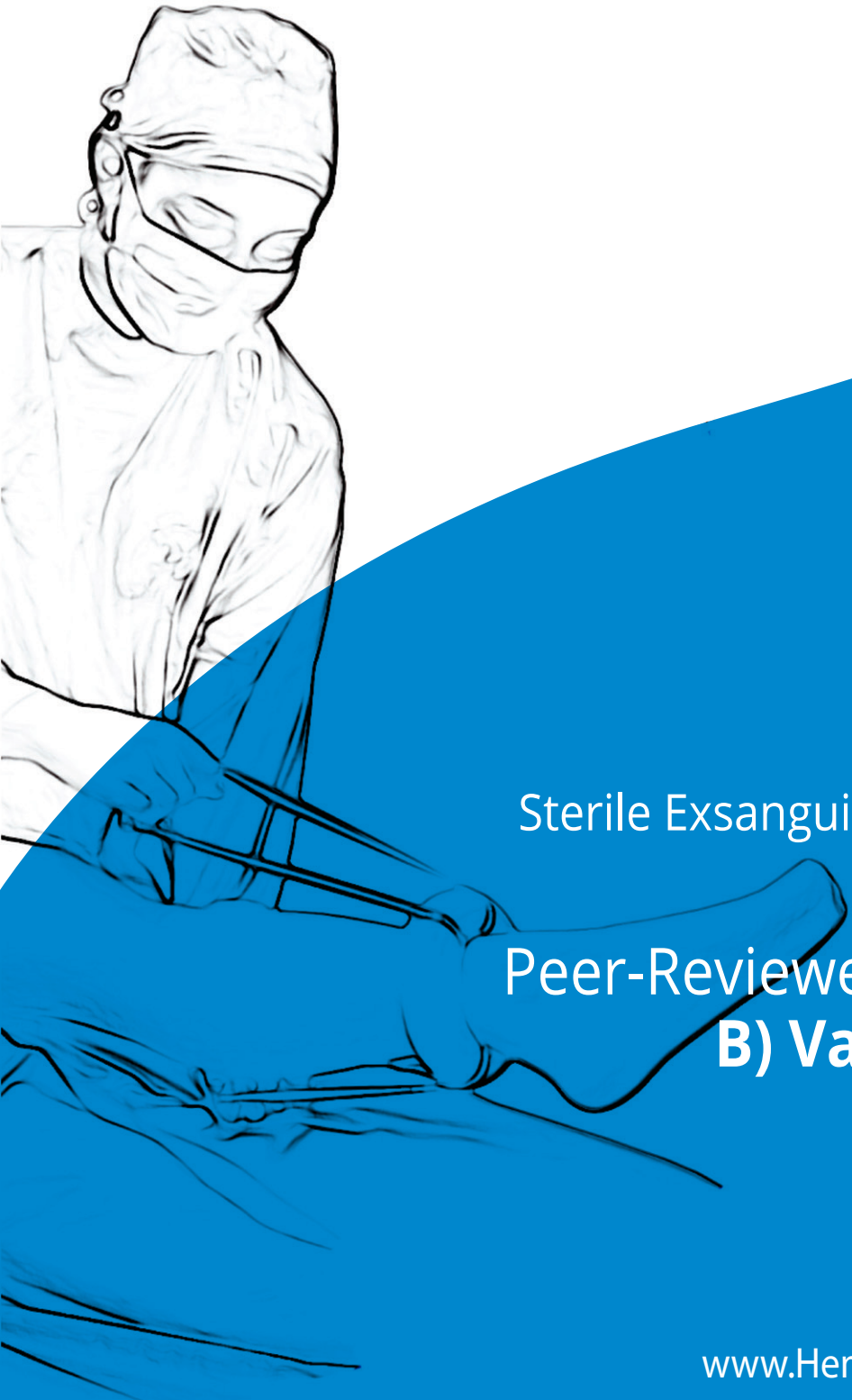

Sterile Exsanguination Tourniquet

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J Vasc Access 2012; 00 (00): 000-000
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ORIGINAL ARTICLE

A sterile elastic exsanguination tourniquet is effective in preventing blood loss during hemodialysis access surgery

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ABSTRACT

Purpose: **We report the first use of a sterile elastic exsanguination tourniquet (SET) in performing hemodialysis vascular access procedures in 27 patients. The main advantages of this tourniquet are the reduction of blood loss and need for possible transfusions. Additional benefits are the near-perfect exsanguination and excellent exposure of the operative field.**

Methods: **This SET is a sterile elastic stockinet device that rolls up the arm starting from the hand by pulling on two handles. The elastic silicone ring provides sufficient pressure (220 ± 30 mmHg) to block arterial flow into the limb. The stockinet can be cut to provide access to the incision area while providing an additional sterile cover over the rest of the limb.**

Results: **No transfusions were required in any patients. Minor adverse effects occurred in four patients, including a twisted vessel, a bleeding vascular branch, a tear in atrophic arm skin, and pain, all of which had resolved on subsequent follow-up. Operational recommendations to avoid these adverse effects are outlined.**

Conclusions: **We conclude that this sterile elastic exsanguination tourniquet is effective and safe in preventing bleeding during upper extremity hemodialysis vascular access procedures.**

Key words: Arteriovenous fistula, Dialysis access, Hemodialysis, Tourniquet use, Upper extremity

Accepted: August 11, 2012

INTRODUCTION

Pneumatic tourniquets have been reported to be useful during dialysis access surgery of the forearm (1). These tourniquets may reduce the duration of the surgery and the arterial spasm provoked by the dissection. Moreover, when microsurgical techniques and preventive hemostasis are used, it is possible to create fistulas even in very small children. However, when an arteriovenous fistula is created or revised in the upper arm, there is often not enough space for the pneumatic tourniquet between the axilla and the surgical incision. As such, these operations are performed without a tourniquet, leading to substantial blood loss and sometimes a transfusion. It is desirable to minimize the use of transfusion in all patients with end-stage renal failure because of the risks of viral transmission. In renal transplant candidates, it is particularly important to avoid transfusion because of risk associated with sensitization to human lymphocyte (HLA) antigens, known as the panel-reactive antibody (PRA), which may induce rejection (2,3).

Recently, we started using an ultra-narrow, non-pneumatic exsanguination tourniquet (HemaClear®, OHK Medical Devices, Haifa, Israel). This surgical exsanguination tourniquet (SET) is a sterile elastic stockinet device that rolls up the arm starting from the hand by pulling on two handles. The elastic silicone ring provides sufficient pressure (220 ± 30 mmHg) to block arterial flow into the limb. The stockinet can be cut to provide access to the incision area while providing an additional sterile cover over the rest of the limb. This tourniquet is being used extensively in orthopedic surgery for both upper and lower extremity procedures. The available sizes accommodate limb circumferences ranging from 14 - 90 cm. This report describes our experience with this device with special attention to several adverse effects we have encountered and specific recommendations for its safe use in dialysis access surgery. We believe this to be the first report of using this tourniquet in dialysis access surgery.

MATERIALS AND METHODS

Institutional Review Board/Ethics Committee approval was obtained for this study. Between August 1, 2011 to January 5, 2012, we utilized a SET in 27 dialysis access procedures – 17 in the forearm and 10 in the upper arm. The SET can be deployed quickly on the patient's arm and performs three functions: blood removal (exsanguination), arterial flow occlusion and automatic application of a sterile stockinet (4). Table I shows the types of procedures performed. After appropriate anesthesia is induced,

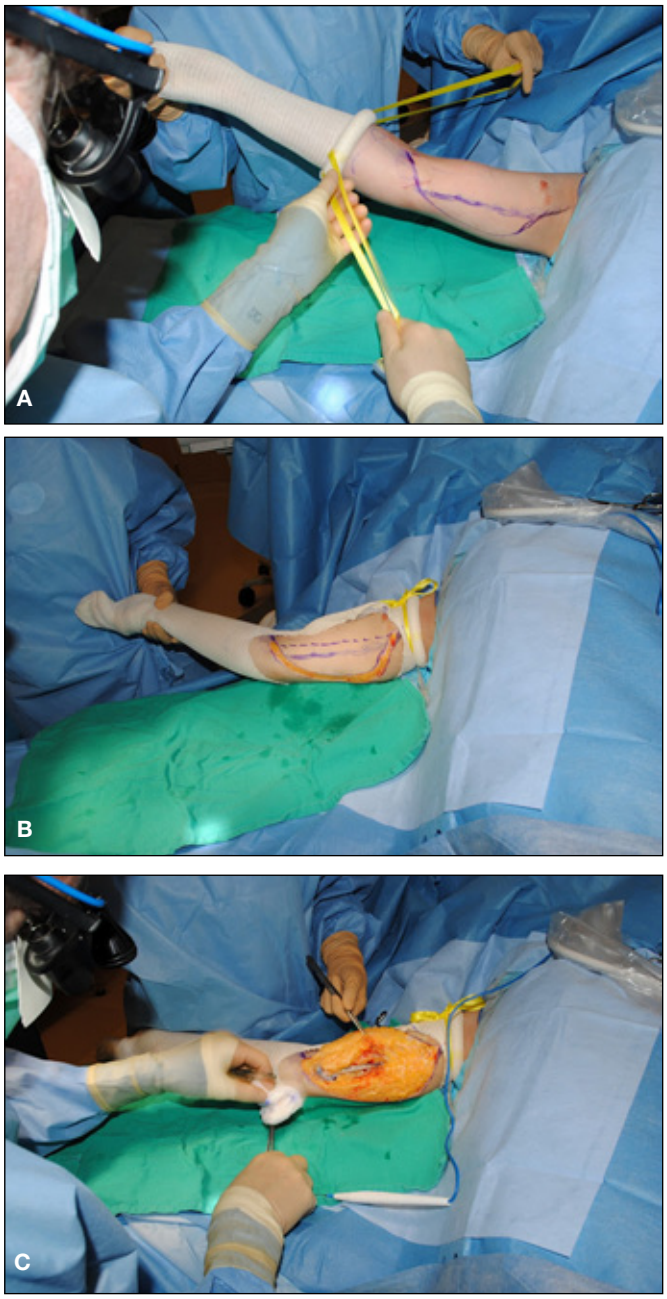

Fig. 1 - *A) The SET is applied to the patient's arm by pulling the straps. B) The SET is in place and the first incision has been made. C) The vessels are dissected bloodlessly.*

the SET is applied to the arm by pulling the straps and rolling the ring up the arm (Fig. 1a). With the SET in position with the ring just distal to the deltoid, the material is cut to provide wide surgical site exposure in the upper arm with no bleeding from the incision (Fig. 1b). The SET allows excellent visibility of the anatomic structures because of the near-perfect exsanguination with no residual blood in the arm (Fig. 1c). After the procedure is completed but before wound closure is commenced, the SET is removed by cutting the ring with a scalpel, with care taken to avoid inadvertent nicking of the skin.

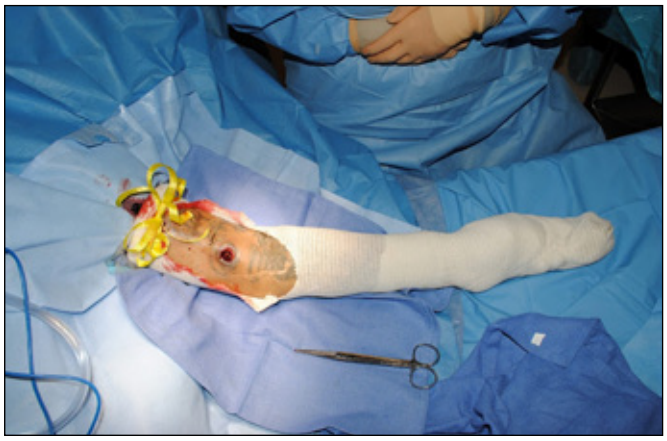

Fig. 2 - *The SET is applied over an ulceration requiring surgical removal.*

The SET is also effective in providing a bloodless operative field for dissection of an ulceration at the site of a dialysis vascular access fistula. The sterile SET is rolled over the lesion and the fabric of the stockinet cut to expose the surgical site (Fig. 2). The lesion can be dissected widely with essentially no blood loss. The wound is closed after the SET is removed.

RESULTS

The follow-up period ranged from 1 - 8 months (mean, 3.5 months). In all 27 cases, hemostasis and surgical exposure were excellent. The SET enables exposure, dissection and manipulation of upper arm blood vessels under tourniquet control. In all but one case, blood loss was < 20 mL. There were four adverse events that resolved (Tab. II).

TABLE I - TYPES OF PROCEDURES PERFORMED

Forearm	Cases (n)
Radiocephalic fistula	4
Brachiocephalic fistula (direct anastomosis)	8
Brachiobasilic stage 1 (direct anastomosis of brachial artery to basilic vein)	4
Removal of infected arteriovenous graft of the forearm	1
Upper arm	
Brachiocephalic fistula (extensive transposition)	2
Brachiobasilic stage 2 (extensive transposition of the basilic vein)	6
Removal of infected arteriovenous graft of the upper arm	2

TABLE II - SUMMARY OF FOUR ADVERSE EVENTS

Adverse Event	Outcome/Treatment
Skin Tear	Patient with edematous, atrophic skin had skin avulsion that healed without further surgery.
Post-operative hemorrhage	Wound closed before tourniquet was removed. Post-operative hemorrhage from unsecured brachial artery branch treated by reoperation.
Pain	Resolved with removal of the tourniquet.
Unrecognized twisted vein	Vein was harvested and tunneled under tourniquet control. Twisted vein was recognized only after tourniquet was removed.

DISCUSSION

An arteriovenous fistula (AVF) is the preferred access for performing hemodialysis. The AVF is a very high-flow reconstruction of the vascular system. Normal blood flow to the arm is 100 - 150 mL/min but the typical blood flow in an AVF is 600 mL/min and can be ≥ 2000 mL/min. Creation or revision of an AVF is sometimes associated with substantial blood loss. Despite the availability of erythropoiesis-stimulating agents, it is still not uncommon for patients with renal disease, even those awaiting transplant, to need and receive blood transfusion after AVF procedures. Transfusion is a leading cause of sensitization to HLA antigens (PRA) and the degree of sensitization is increased with more units transfused (3). It has also been shown that patients with high PRA levels wait longer for a transplant than patients with low PRA levels (3). Therefore, the ability to perform the required vascular access procedure with minimal blood loss is highly desirable.

The SET exerts pressure comparable to pneumatic tourniquets – approximately 200- 250 mm Hg for the upper and 300 - 350 mm Hg for the lower extremity. There are four sizes that can be used for limb circumference ranging from 14 - 90 cm limb circumference. The size for each patient is determined by measuring limb circumference at the required occlusion site and by the systolic blood pressure, according to a table provided with the device (5). In contrast to the traditional pneumatic cuff tourniquet, the SET's silicone ring applies a more narrow region of pressure. While there may be concern about possible tissue damage because of higher pressure applied to a narrow area, there have been no reports of tissue damage from use of this SET, in over 300 000 units sold (6). Furthermore, a recent study found that nerve injury was 12 times more prevalent with a traditional wide cuff pneumatic tourniquet than with the SET (7).

Another study compared the tolerance and recovery time of a pneumatic cuff tourniquet and a silicone ring tourniquet applied to the upper arm and thigh using healthy volunteer subjects (8). The subjects rated pain associated with the use of both tourniquet types using a visual analog scale; arterial blood pressure, pulse rate and oxygen saturation were also monitored. There were no statistically significant differences in tolerance time and recovery between the two tourniquets (8).

The traditional pneumatic tourniquet is of limited effectiveness in upper arm AVF surgery. The SET described in this report is much narrower than the pneumatic tourniquet and has enabled AVF and grafts to be performed in the upper arm. One excellent use of the roll-on SET is in the creation of the transposed brachiobasilic fistula. The basilic vein of the upper arm can be harvested readily through either long incisions or multiple small incisions with long skin bridges. When harvesting the basilic vein through long incisions, the SET limits blood loss. When harvesting the basilic vein through small incisions with long skin bridges, absolute hemostasis is essential for adequate exposure and visualization. Similarly, the SET has enabled extensive harvesting transposition of the cephalic vein of the upper arm to be performed almost bloodlessly. Additionally, one of the bloodiest procedures in dialysis access surgery is removal of the infected upper arm arteriovenous graft. With the SET rolled up to the junction of the axilla and the upper arm, the infected upper arm graft can be removed with very little blood loss.

There are some precautions to consider when using the SET inherent to its major effectiveness in interrupting blood flow. After harvesting the basilic or cephalic vein under tourniquet control, it is essential to remove the SET prior to tunneling the vein in order to be able to flush the vein with heparinized saline and verify that it is not twisted. If the tourniquet is left in place during the tunneling process, there will be some uncertainty as to whether the vein is twisted. A twisted vein will result in technical failure of the procedure. Thus, before tunneling, we recommend that the SET always be removed and that the vein be double-checked for twists.

Another pitfall that must be avoided is related to the high blood flow in the arm when an AVF is present. The SET must be removed and hemostasis verified prior to wound closure. If the tourniquet is left in place until after the wound is closed, tiny unligated branches of the fistula may cause very serious bleeding. If no fistula was present, the small venules would ordinarily create no problems for surgical hemostasis but in the renal patient with an AVF, the abnormally high blood flow and venous pressure will cause wound hematomas and complications unless extra attention is paid to final hemostasis. We recommend never closing the AVF surgical incision until after the SET has been removed.

Caution should be exercised in patients with very poor skin integrity. The process of rolling the tourniquet up the

arm applies some shear stress to the skin. Some patients with chronic renal disease have atrophic skin and edema that heightens their susceptibility to skin tears (1). In addition, the SET is sterilized with ethylene oxide, which could be an allergic concern for some hemodialysis patients (6).

Care must be taken to provide adequate analgesia or anesthesia, as the hemostatic force of the SET is concentrated into a narrower zone than a pneumatic tourniquet. If regional anesthesia is used, consider that the application zone of the SET at the junction of the axilla and upper arm is innervated by the intercostobrachial nerve, which can be missed during some brachial plexus nerve blocks. If local anesthesia is used, additional sedation may be needed (2).

CONCLUSIONS

We report what we believe to be the first successful use of a SET with a narrow footprint in 27 hemodialysis patients. The main advantage is the prevention of blood loss in upper arm procedures that would have otherwise been performed without a tourniquet and could have resulted in substantial bleeding and possible need for blood transfusion. No transfusion was required in this group. Additional benefits are the near-perfect exsanguination, excellent exposure and visibility and the avoidance of direct placement of vascular clamps on the blood vessels with the ensuing risk of spasm and intima shearing. We encountered adverse effects in four of the cases, including a twisted vessel, a bleeding vascular branch, a tear in atrophic arm skin and pain. Subsequent follow-up of these patients has not been associated with any adverse effects that could be attributed to the use of the SET. We conclude that the SET is effective and safe in preventing bleeding in upper extremity hemodialysis vascular procedures and, in particular, in reducing the need for blood transfusion.

Conflicts of interest: The authors were not remunerated nor do they have any financial association with the manufacturer of the HemaClear® tourniquet (www.hemaclear.com).

Meeting presentations: Poster presented (2nd place award) at the annual meeting of the American Society of Diagnostic and Interventional Nephrologists, Feb. 25, 2011, New Orleans, LA, USA.

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EDITORIAL

Narrow elastic disposable tourniquet (Hemaclear®) vs. traditional wide pneumatic tourniquet for creation or revision of hemodialysis angioaccesses

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ABSTRACT

Purpose: To choose the best arterial tourniquet for angioaccess surgery.
Methods: Preventive hemostasis with an arterial tourniquet prevents bleeding and provides better visualization. The surgeon may currently use a traditional wide nonsterile inflatable pneumatic cuff after exsanguination with an Esmarch bandage or a disposable sterile narrow elastic silicone ring (HemaClear®), available in different sizes according to the patient's limb circumference and blood pressure.
Results: The latter is easily rolled up the upper limb after surgical draping, to achieve exsanguination and occlusion of the proximal brachial artery, thus providing a wide sterile field that is most useful for upper arm vein superficialization or arteriovenous fistula (AVF) revision. Although rare, neurological complications must be prevented by limiting the compressive force applied to the tissues to occlude the arteries and the veins. Such tissues are almost non-compressible but deformable; thus, they may be elongated and damaged, mostly at both extremities of the tourniquet, especially the nerves. The compressive force (kg) applied to the limb by the cuff is the product of the cuff pressure (mm Hg) imposed and the surface (cm^2) of the skin in contact with the cuff. Reduction of the cuff surface results in reduction of the volume of tissue beneath the cuff and therefore in limitation of the compressive force.
Conclusions: From a theoretical point of view and from clinical data, it seems therefore reasonable to recommend the use of a narrower cuff size and, for practical reasons, the silicon ring.

Keywords: Arteriovenous fistula, Preemptive hemostasis, Tourniquet

Introduction

Preventive hemostasis is routinely used by the authors for every angioaccess procedure located at or below the mid upper arm. For arteriovenous fistula (AVF) creation (1), the main benefit of preventive hemostasis in association with microsurgery is improved visualization of anatomical details, allowing for creation of distal AVF in most patients, even in small children. The second benefit is the prevention of possible spasm of the radial artery, related to the surgical dissection and ligation of collaterals that are necessary when instrumental clamping is employed. For angioaccess revision procedures (2), one more benefit of preventive hemostasis is the total absence of blood loss, even during high flow access revision.

The device traditionally used is the pneumatic tourniquet, inflated after limb exsanguination using an Esmarch elastic bandage. Nevertheless, in a study published in 1974 (3) about half the surgeons were still using an Esmarch bandage as a tourniquet. This can produce extremely high tissue pressure, and a disproportionate number of complications may be related to such use.

An elastic, non-pneumatic narrow disposable silicone ring tourniquet (HemaClear®, OHK Medical Devices, Haifa, Israel) was introduced recently to clinical practice to achieve both exsanguination and occlusion of arterial flow.

The aims of this review are to compare the clinical use of the classical wide pneumatic tourniquet with the use of the narrow silicone elastic ring tourniquet, and to re-evaluate the risks and the theoretical basis of preventive hemostasis for surgical angioaccess procedures.

Tourniquets are used at both the upper and lower limbs. However, in the present paper we mainly describe and discuss their use in the creation or revision of angioaccesses in the upper limb.

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Clinical use of pneumatic tourniquets

Preventive hemostasis is implemented after completion of echo-guided regional anesthesia and intravenous administration of prophylactic antibiotics, before sterile surgical draping. The size of the tourniquet is chosen according to the caliber of the proximal part of the upper limb, traditionally using a wider tourniquet for obese patients. European and US guidelines recommend using a cuff with a width at least 0.3 times the limb circumference (4, 5). A wrinkle-less padding beneath the tourniquet is mandatory. Exsanguination must be as complete as possible using the Esmarch elastic bandage. For small children and for older patients with fragile skin, a narrow non-elastic bandage is more convenient for exsanguination. The tourniquet is then inflated to 50 mm Hg above the arterial systolic pressure. It is recommended not to exceed one hour before deflation. This is long enough for the creation of the fistula. After deflation of the tourniquet, the patency of the anastomosis should be checked by visible dilatation of the vein, thrill palpation or evidence of a permanent signal with systolic reinforcement on sterile Doppler examination, the latter two being positive signs of a well-functioning AVF. Finally, the hemostasis is completed and the incision closed.

In the case of incomplete exsanguination, any persistent bleeding or minimal leaking of plasma while suturing the anastomosis may be responsible for blood coagulation or deposits of fibrin, resulting in primary thrombosis. In such conditions, atraumatic clamps should be placed on both sides of the artery opening to stop any leakage.

The duration of tourniquet inflation is still a matter of debate. One hour is generally considered to be a safe limit, but on the basis of current data some authors consider two hours to be a widely accepted limit. One hour is in fact a sufficient amount of time for the vast majority of angioaccess creations but this may be too short for complex AVF revision.

The traditional pneumatic tourniquet is usually too wide to be used for access surgery above the lower third of the upper arm, i.e., the second stage of superficialization of the upper arm basilic or cephalic vein and brachio-axillary graft. Some other contraindications have been reported, most being only relative contraindications. In our experience, preventive hemostasis for AVF creation in patients with sickle cell disease for frequent exchange transfusions has been uneventful. In cases of highly calcified arteries, the tourniquet may be only partly effective. Finally, the use of a tourniquet is questionable for revision of angioaccesses associated with distal ischemia.

In cases of massive hemorrhage related to skin necrosis at the puncture site, immediate local finger pressure will easily stop the bleeding. A compression bandage (reinforced, if necessary, with a pneumatic arterial blood pressure cuff or better still an orthopedic surgery tourniquet) can then be applied to the bleeding site and the patient should be urgently transferred to the operating theatre. Surgical revision can then be performed, ideally using preventive hemostasis, but some upper arm lesions may be situated too high for proximal application of a pneumatic tourniquet.

One limitation of the traditional pneumatic tourniquet is the risk of infection. In the absence of ethylene oxide sterilization, significant contamination with bacteria commonly involved in surgical site infections may be found on most tourniquets and Esmarch bandages used in orthopedic theaters (6).

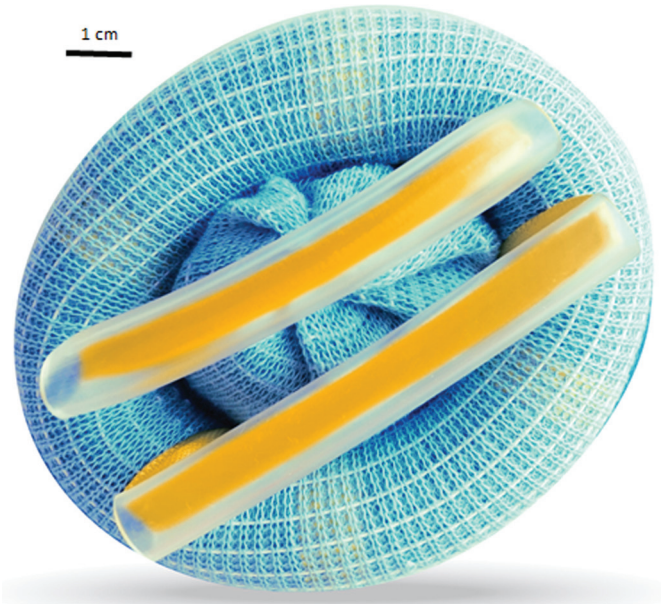

Fig. 1 - HemaClear®/40 yellow tourniquet.

Clinical use of elastic silicone ring tourniquets

The silicone ring device is made of a narrow, sterile, disposable, elastic ring, and pull straps wrapped in a stockinet sleeve. The size is determined after measuring the limb circumference of the patient at the required occlusion site. The full range of available sizes covers infants to obese adults for the upper extremity and for different blood pressures. The HemaClear®/40-yellow upper arm model (Fig. 1) is suitable for most adult patients with upper limb circumferences ranging from 24 to 40 cm and systolic arterial pressure of <190 mm Hg. After surgical sterile draping, the ring is easily and rapidly rolled up the upper limb by pulling the straps to produce exsanguination (>95% of the limb blood volume), up to the proximal part of the upper arm to occlude the brachial artery blood flow.

The main practical advantages of this device are usability, sterility and narrowness of the ring (<2 cm in width) allowing a large sterile field, and this is necessary for upper arm vein superficialization or AVF revision.

For a primary forearm or upper arm AVF, a protective card is placed underneath the silicone ring after completion of the anastomosis. The ring is then cut with a scalpel and removed, before final hemostasis and skin suture (Fig. 2). For superficialization of the cephalic vein by lipectomy (7), it is recommended to grasp and elevate a portion of the ring in front of the brachial artery with two forceps at the end of the procedure. This will momentarily release the compression of the artery in order to check the function of the angioaccess, before cutting the ring. The same maneuver is used after superficialization of

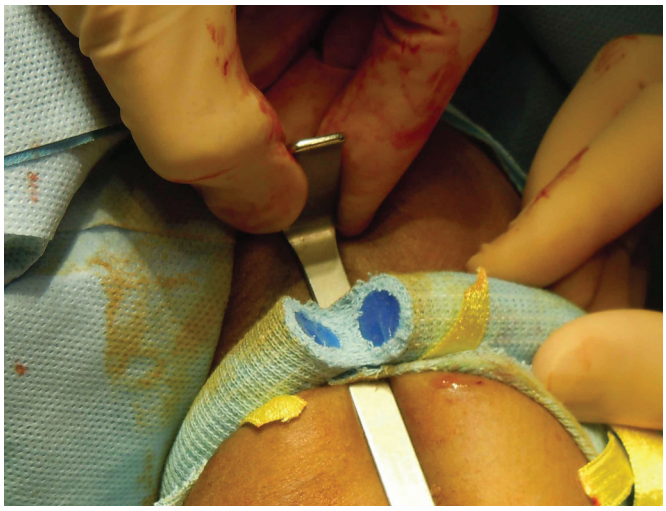

Fig. 2 - Section of the HemaClear® silicone ring after completion of the anastomosis. (photo by E.Molon).

the upper arm basilic vein in a subcutaneous tunnel. Alternatively, it has been recommended to remove the ring (8) after harvesting the basilic vein under tourniquet control and prior to tunneling the vein in order to be able to flush the vein with heparinized saline and verify that it is not twisted.

Use of the narrow elastic ring is possible in almost all re-interventions, including proximal skin necrosis at puncture sites of an upper arm angioaccess.

There are nevertheless some contraindications, related to mechanical exsanguination. Exsanguination by upper limb elevation and traditional pneumatic tourniquet is preferred in cases of significant skin lesions (skin disease, paper-thin skin, burns) and infection.

Nerve complications due to tourniquet application

Incidence

Pneumatic tourniquet

The incidence of neurological complication in Australia in the 1970s following use of a tourniquet was approximately one to 5000 applications on the upper limb. Thirty-three years later, in 2006, one severe neurological complication was reported in Norway for approximately every 6000 tourniquet applications to the upper limb. During that interval, in spite of modifications to the pneumatic tourniquet with lower and more controlled pressures, there has been no reduction in the total incidence of neurological complications following tourniquet application (3).

Elastic ring

Gavriely in 2010 (9) reported that the prevalence of nerve damage available to OHKMedical Devices following the use of its S-MART/ HemaClear® was 2/100,000. Now, with more than 800,000 applications worldwide, not one case of long-term tourniquet nerve injury has been reported (Gavriely, personal communication). Nerve complications were reported to have occurred only when the device was used beyond the recommended 120-minute time limit. In 2012 Reyenders (unpublished data) reported an overall 0.5% complication rate after 4870 HemaClear® applications (20% upper limb). These were: lung embolism 2 (lower limb), thigh pain 12, slight paresis 5, and imperfect visualization 12 (9 upper limb). In 2013 Drosos et al (10) reported no related complications in 536 orthopedic operations, including 219 upper limbs, but the tourniquet failed in 14 patients (2.6%), possibly related to unexpectedly elevated blood pressure or incorrect selection of HemaClear® type. In cases of tourniquet failure with persisting bleeding, it is urgent to remove the ring and restore circulation (11).

Etiology: ischemia or compression or both?

It is generally agreed that the incidence and severity of nerve complications is related to both excessive and prolonged pressure applied to nerves beneath the cuff, rather than to ischemia.

Ochoa et al (12) used a tourniquet to produce long-standing conduction blocking in the peripheral nerves of baboons. They found a characteristic lesion (lateral displacement of Ranvier's nodes with rupture of the stretched paranodal myelin) preceding paranodal demyelination. The anatomical features and distribution of this lesion (maximal at both edges of the cuff) suggest that the damage to the nerve fibers is a direct result of the pressure applied (force), and not a consequence of secondary ischemia. The consequences for the nerves are different according to the force of the compression: 1) Mild compression of the nerve fibers produces a physiological block which is reversed as soon as the compression pressure is released. 2) Severe compression may actually crush the fibers and leads to Wallerian degeneration; the response of the nerve distal to the lesion is then lost and possible recovery may take months. 3) Intermediate severe compression may result in a local lesion (modification of Ranvier's nodes) with preservation of distal conduction; this may take several weeks to recover.

Graham et al (13) experimented with pressure transducers placed adjacent to the radial, median and ulnar nerves in the upper extremities of six cadavers of average dimensions. His conclusions were: 1) the pressures applied to a normally sized arm by an externally applied tourniquet cuff are transmitted to underlying peripheral nerves with no significant attenuation in the intervening soft tissues (confirming and documenting the hypothesis of incompressible tissue), 2) the highest tissue pressures are manifested under the midpoint of the cuff and the lowest pressures are under the cuff edges, and 3) at higher levels of inflation the pressure gradient between areas under the edges and midpoint of the cuff may result in the creation of deleterious transverse shear forces applied to the nerves.

Discussion: wide or narrow tourniquets?

Mittal et al (14) noted that wider cuffs have been reported to cause reduced risk of tourniquet-induced injury to the underlying soft tissues than narrower cuffs due to the fact that lower occlusion pressures are caused by the former. To

address and investigate this question, conduction in the median nerve was measured proximal to the tourniquet as well as distal to the tourniquet, by Graham et al (15). Elastic cuffs 14 cm and 7 cm wide were applied to the upper extremities of 20 healthy, normotensive volunteers. Systolic blood pressure was first measured and the cuff was then inflated to 20-30 mm Hg above this and was kept inflated for 15 minutes. Recordings were made prior to the period of tourniquet inflation, and following release of the tourniquet. Nerve conduction velocity was more severely affected by the 14 cm cuff than by the 7 cm cuff. The conclusion was that wider cuffs resulted in more severe changes in the nerve.

The damage caused to the tissues and particularly to nerves beneath the cuff depends on several parameters, i.e., the duration of compression, the mechanical stress imposed on the nerves, and the volume of compressed tissues: for identical cuff pressure, the longer the length of nerve under the cuff, the greater the likelihood of nerve damage.

Moreover, the notion of mechanical stress requires more clarification. For an arm circumference of 35 cm and a cuff width of 14 cm (surface of the cuff-skin contact: 35 × 14 = 490 cm^2) inflated at 200 mm Hg (or 266 g/cm^2), the total force applied to the arm is 490 × 266 = 130 kg. For the identical inflation pressure (200 mm Hg), a 7 cm wide cuff positioned on the same arm (circumference 35 cm) will result in a total applied force of 7 × 35 × 266 = 65 kg. Using a 1.4 cm wide 259 mm Hg (or 344 g/cm^2) pre-calibrated compression pressure HemaClear® device, for the same 35 cm circumference arm, the total force applied would be 17 kg, i.e., about 4 and 8 times less than the forces calculated for the 7 and 14 cm wide pneumatic cuffs, respectively. Finally, with nearly the same pressures (mm Hg) and similar results for the arterial blood inflow (i.e., interruption), the total force applied (kg) to the arm of the patient is proportional to the width of the cuff.

This is in agreement with morphological measurements performed under experimental conditions: Kovar et al (16) assessed the morphological grade of median and radial nerve compression for 20 minutes with either a silicon ring or a pneumatic tourniquet placed on the upper non-dominant limb of 14 healthy human volunteers, visualized by 3 Tesla magnetic resonance imaging (MRI), using high-resolution (2.5 mm slice thickness) axial T2-weighted sequences. They could not detect any significant difference in the diameters of median and radial nerves between basal resting conditions, compression by HemaClear® and by the standard pneumatic tourniquet. Their previous hypothesis that a narrow silicone ring causes more pressure to the nerve compared to a wide tourniquet was not proven. Because tissues, and especially muscles, are basically uncompressible but deformable, any force applied to a limb area will produce their deformation and mobilization from that area to both upper and lower parts of the limb. Figure 3 shows MRI images of both left and right upper limbs at the cuff level of a pneumatic tourniquet (A, B) or HemaClear® device (C, D). The images clearly show that the muscular tissue volume was markedly reduced at the cuff level. It can be supposed that the muscle, and hence both vessels and nerves at this level, were stretched during compression. This longitudinal stretch may cause damage to the nervous tissue, as previously demonstrated by Ochoa et al (12).

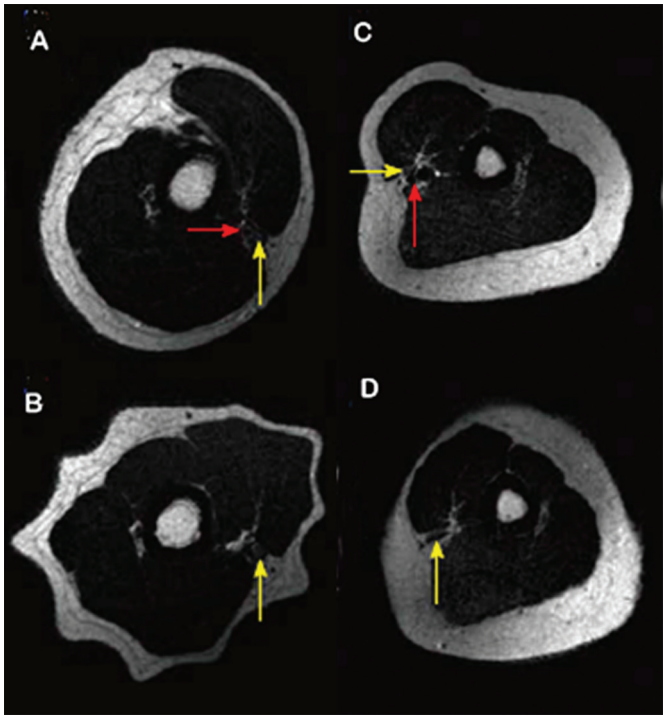

Fig. 3 - Magnetic resonance imaging (MRI) of upper limb before and during compression with a pneumatic tourniquet (**A**, **B**) or a HemaClear® device (**C**, **D**), respectively. Red arrow indicates open brachial artery, yellow arrow indicates median nerve demonstrating no differences in nerve size without and with compression in either group. From Kovar et al (16), with permission.

Finally, to minimize the deleterious effects of cuff pressure for vascular surgery of the limb, three parameters can be modified: the magnitude and the duration of the occluding pressure and the volume of the compressed tissues. The goal of pressure devices (pneumatic tourniquet or silicon ring) is the same, i.e. to transmit pressure to the underlying limb artery that is greater than the systolic arterial blood pressure. Actually, the wider the cuff, the greater the volume of the compressed tissues and the length of stretched nerves. We may therefore expect more severe nerve and tissue damage with wider cuff sizes. Doubling the cuff width will result in doubling the cuff-skin surface and hence the total force applied and the volume of the compressed tissues.

From a theoretical point of view and clinical data, it seems therefore reasonable to recommend the use of a narrower cuff size, and, for practical reasons the silicon ring.

Conclusion

Preventive hemostasis allows for better vision, limited dissection of vessels and complete absence of blood loss when creating or revising arteriovenous angioaccess shunts. Neurological complications related to tourniquet application are rare but may be dramatic

Both wide and narrow occluding tourniquets must be applied to the limb artery at a pressure higher than the systolic arterial pressure to result in arterial occlusion and thus cessation of bleeding. However, the total force applied to the

tissues, especially the nerves, and also the volume of compressed soft tissues, are far greater when wide size cuffs are used. Furthermore, a narrow elastic ring has several practical advantages for the surgeon. We therefore recommend the use of narrow silicon rings for angioaccess surgery, especially for arteriovenous fistulas.

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Disclosures

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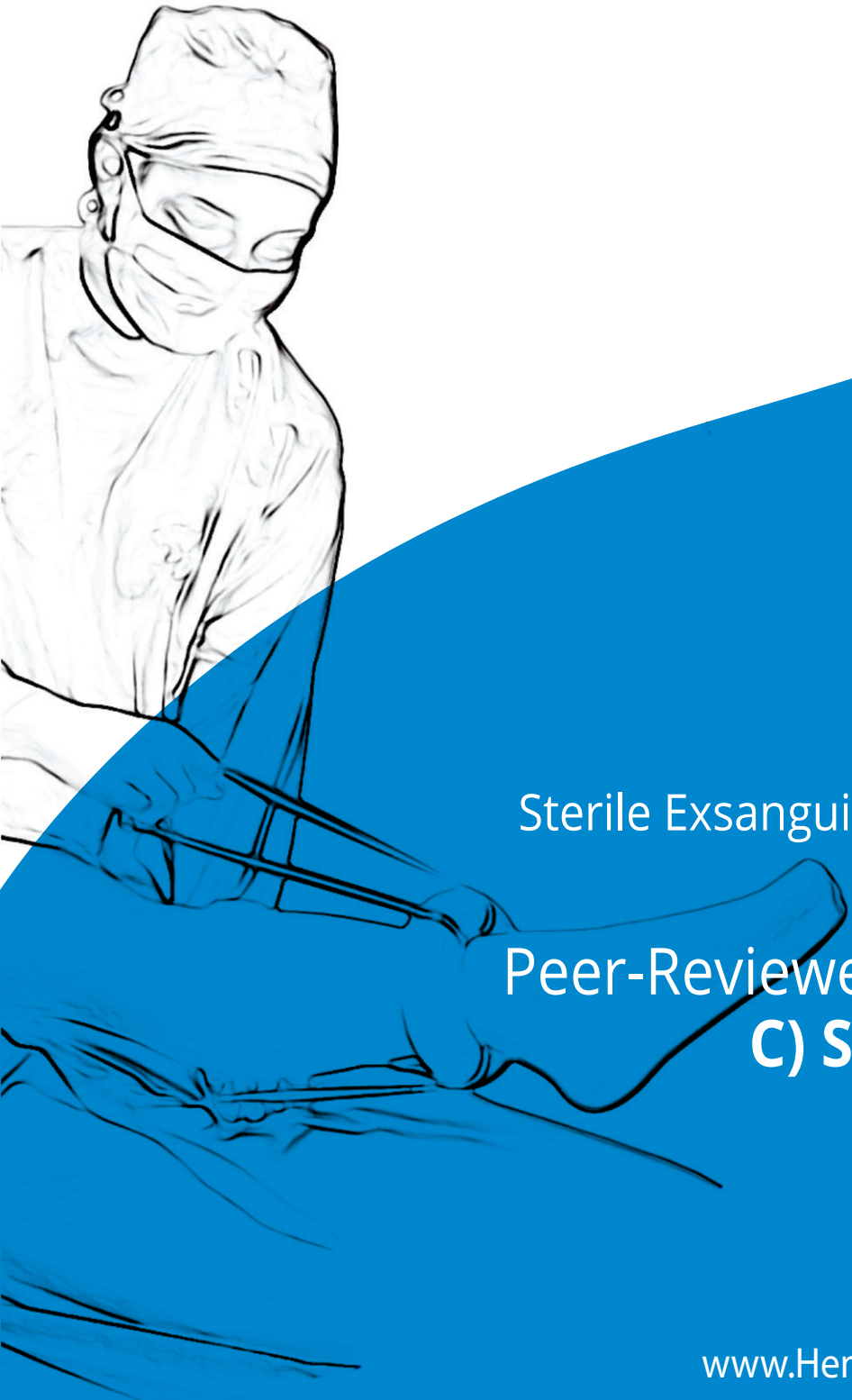

Sterile Exsanguination Tourniquet

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Pulmonary Embolism After Application of a Sterile Elastic Exsanguination Tourniquet

VIKTOR FELDMAN, MD; AHMAD BIADSI, MD; OMER SLAVIN, MD; BENJAMIN KISH, MD; ISRAEL TAUBER, MD; MEIR NYSKA, MD; YARON S. BRIN, MD

abstract

Sterile elastic exsanguination tourniquets (HemaClear; OHK Medical Devices, Haifa, Israel) are relatively new on the market but are widely used because of the ease and speed of their application. The sterile elastic exsanguination tourniquet consists of a silicon ring wrapped in a stockinet sleeve with pull straps. The physician places the ring on the patient's fingers or toes and then pulls the straps proximally. The silicon ring rolls up the limb, and the stockinet sleeve unrolls onto the limb. During proximal rolling, the device displaces blood out of the limb (exsanguination). When the elastic ring reaches the preferred occlusion location, the pulling motion is stopped. The ring exerts suprasystolic pressure on the limb, thereby blocking arterial blood flow into the limb and thus acts as a tourniquet. HemaClear tourniquets are thin and sterile and therefore provide a large operative field. The authors report 2 cases of pulmonary embolism after HemaClear tourniquet application in patients with traumatic injuries (fractures of the patella and tibial plateau). Exsanguination applies mechanical stress that might dislodge a preexisting deep venous thrombosis, leading to the serious complication of pulmonary embolism. The authors want to increase awareness of this possible fatal complication during procedures performed on the lower limbs, when the HemaClear tourniquet is used for exsanguination of the affected limb. Careful consideration should be given to the use of HemaClear tourniquets in high-risk patients and those with traumatic injuries, especially when there has been a delay in surgery. [*Orthopedics*. 2015; 38(12):e1160-e1163.]

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The modern tourniquet was introduced by Friedrich von Esmarch in 1873 using an elastic ("Esmarch") bandage that was improved in 1908 by Dr. Harvey Cushing with the introduction of the pneumatic tourniquet.

To achieve a bloodless surgical field and reduce intraoperative blood loss, the orthopedic surgeon can exsanguinate the limb (eg, elevate the limb before surgery), exsanguinate the limb and occlude blood flow to the limb with an Esmarch bandage, or only occlude blood flow to the limb with a pneumatic occlusive tourniquet.

Recently, the authors started to use a new sterile elastic exsanguination tourniquet (HemaClear; OHK Medical Devices, Haifa, Israel) for bloodless limb surgeries, traumatic injuries, and elective procedures. This device is meant to replace the traditional pneumatic tourniquet and has 3 functions: (1) it removes blood from the operated extremity (exsanguination); (2) it occludes arterial flow; and (3) it serves as a sterile stockinet.[1-4]

The sterile elastic exsanguination tourniquet is a silicone ring wrapped in a stockinet sleeve with 2 pull straps. The physician places the ring on the patient's fingers or toes and then pulls the straps proximally. The silicone ring rolls up the limb, and the stockinet sleeve unrolls onto the limb (**Figures 1-2**). During proximal rolling, the device displaces blood out of the limb. When the elastic ring reaches the preferred occlusion location, the pulling motion is stopped and the ring blocks arterial blood flow distally (**Figure 3**). The ring exerts suprasystolic pressure on the limb, blocking arterial blood flow into the limb, and thus acts as a tourniquet. During rolling of the ring, a stockinet sleeve unrolls onto the limb and covers it entirely up to the level of occlusion, thereby draping a sterile cover over the surgical field (**Figures 2-3**).

At the end of the procedure, the silicone ring is cut with a blade. The sterile stockinet is cut away with scissors, and the blood supply to the limb resumes.

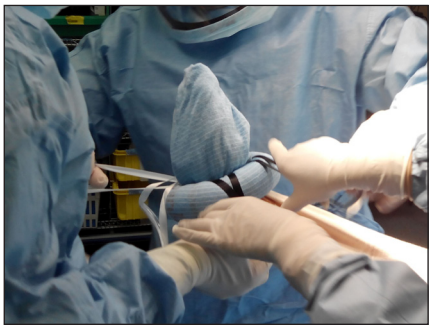

Figure 1: Photograph showing the physician placing the ring on the toes.

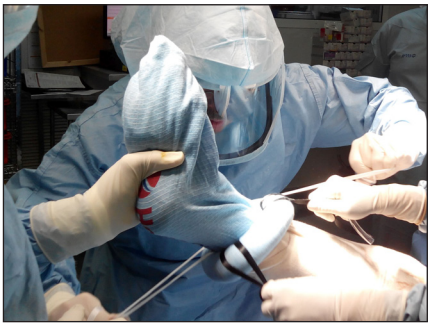

Figure 2: Photograph showing the physician pulling the silicone ring proximally.

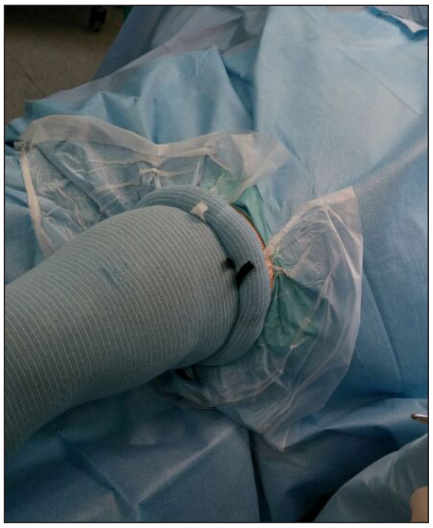

Figure 3: Photograph showing the stockinet sleeve unrolled on the limb and covering it entirely up to the level of the occlusion level, with a sterile drape covering the surgical field.

Many reports have been published on pulmonary embolism that occurs when an Esmarch bandage is applied to traumatized lower limbs.[5]

This serious and often fatal complication has not been reported with the use of the sterile elastic exsanguination tourniquet.

This article reports 2 such cases. To the best of the authors' knowledge, this is the first report of the association between pulmonary embolism and the use of this tourniquet.

Case Reports

Patient 1

A healthy 65-year-old woman was admitted to the authors' hospital after she had a patellar fracture of the left knee as a result of a motor vehicle accident. She had no other concomitant musculoskeletal injuries.

On admission, a thorough medical examination showed no obvious abnormalities. The patient's blood profile and coagulation status were normal. She was not overweight and did not smoke.

Initial management included immobilization of the fractured limb in a long cylindrical (tutor) cast. The patient was encouraged to be mobile in the ward; therefore, no anticoagulant therapy was administered.

The patient underwent fixation of the fracture 9 days after the injury. The anesthesiology team induced general anesthesia with intravenous midazolam and fentanyl, and tracheal intubation was facilitated by succinylcholine. A HemaClear tourniquet was then rolled onto the injured limb from the toes to the midthigh. Immediately, the patient became cyanotic and tachycardic, blood pressure dropped rapidly from 140/90 mm Hg to unmeasurable, heart rate increased from 40 beats/min to 120 beats/min, and end-tidal carbon dioxide partial pressure decreased to 17 mm Hg within 1 minute. Blood gas results showed serious respiratory acidosis. The tourniquet was immediately released, and the limb was immobilized in a cast. Computed tomography angiography showed bilateral pulmonary emboli. Intravenous heparin was administered, and

the patient was successfully extubated the next day. An inferior vena cava filter was implanted, and fixation of the patellar fracture was successfully performed a day later. The patient was discharged 7 days after surgery in good general condition.

Patient 2

A 53-year-old man with a history of untreated high blood pressure and chronic renal failure presented to the emergency department with an isolated right tibial plateau (Schatzker VI) fracture after a motorcycle accident.

On the day of admission, the fracture was stabilized with an external fixator. Definitive stabilization surgery was scheduled, and the patient was discharged from the department with no preventive anticoagulation treatment.

Twenty-six days after the accident, the patient was admitted for internal fixation of the fracture. Before surgery, he was in good general health and had normal vital signs, with oxygen saturation of 99%. During surgery, the HemaClear tourniquet was applied, and 1 minute later, oxygen saturation dropped suddenly to 90%.

The patient became tachycardic but was normotensive. Arterial blood gas values showed severe acidosis. A chest radiograph obtained in the operating room showed normal placement of the endotracheal tube. No atelectasis or edema was evident. The anesthesiologist could keep the oxygen saturation above 95% with 100% oxygen. After consultation with the anesthesiology team, a decision was made to proceed with surgery. The procedure was performed as quickly as possible and concluded after 90 minutes. Immediately after surgery, the patient underwent computed tomography arteriography, but shortly afterward, he had extreme bradycardia of 40 beats/min and the blood pressure dropped to 80/50 mm Hg. Resuscitation was immediately begun, but the patient's condition soon deteriorated to a state of pulseless electrical activity. Heart echocardiography showed a dilated right ventricle, with global dyskinesia and severe left ventricle dysfunction. Doppler ultrasound of the lower limb showed deep venous thrombosis (DVT) in the right femoral vein. Despite continuous resuscitation attempts, including full heparinization and thrombolysis therapy with tissue plasminogen activator, resuscitation efforts were unsuccessful. The patient could maintain normal blood pressure values only with the administration of inotropic drugs.

Two days later, the patient was declared brain dead and his family decided to discontinue mechanical ventilation. Postmortem examination showed that the cause of death was multiple pulmonary emboli in the right heart, completely blocking both of the pulmonary arteries.

Discussion

Sterile elastic exsanguination tourniquets are relatively new on the market but are widely used because of the ease and higher speed of application compared with pneumatic tourniquets. Another advantage of these tourniquets is the fact that they are thinner than most pneumatic tourniquets and, in contrast to pneumatic tourniquets, they are sterile and therefore can provide a larger sterile operative field.

An important advantage of the sterile tourniquet is that it squeezes the blood out of the extremity during the process of proximal rolling. When the tourniquet reaches a more proximal position on the limb that is wide enough to hold it, the tourniquet blocks arterial flow into the extremity.[6] The authors assume that in these patients the proximal rolling and squeezing created mechanical stress that suddenly accelerated venous flow and was the main cause of the release of a thrombus from its origin in the deep venous system of the lower extremity to the main circulatory system and from there to the pulmonary arteries.

Trauma, immobility, and surgery predispose patients to DVT. Although a thrombus can embolize spontaneously, the mechanical stress caused by an Esmarch bandage or a tourniquet is believed to cause a sudden increase in the velocity of venous flow and dislodge the preexisting thrombus, causing a pulmonary embolism. Some reports mentioned pulmonary emboli after the application of Esmarch bandages, and it is believed that a preexisting DVT is moved to the lungs by the centripetal direction of the blood flow. A number of cases in the literature have reported the association of pulmonary embolism with pneumatic tourniquets. In these cases, the pulmonary embolism episodes occurred immediately after inflation or deflation of the tourniquet. Pulmonary embolism occurring after inflation is explained by the increase in compartment pressure in the limb when the tourniquet is inflated, and this may be sufficient to dislodge the thrombus. When pulmonary embolism occurs after tourniquet deflation, the general assumption is that a period of venous stasis results in local thrombosis, with subsequent embolization once the tourniquet is deflated.[7]

Acute massive pulmonary embolism is a very serious condition; 50% of patients are expected to die within 15 minutes, and only 33% survive longer than 2 hours.[8,9]

When all reported cases of pulmonary embolism after Esmarch bandage application were compared, the most important parameter was a delay in surgical treatment of 5 days or more.[5]

Pulmonary embolism may have various manifestations under anesthesia, such as sudden onset of breathlessness, loss of consciousness, hypotension, and a decrease in end-tidal carbon dioxide. The usual electrocardiogram findings are ST-T changes seen on the right-sided leads, right bundle branch block, and electromechanical dissociation. Transesophageal echocardiography has high sensitivity and specificity in detecting pulmonary embolism and right ventricular dilation. Transthoracic echocardiography can show right ventricular hypokinesia and dilation,

but is not sensitive in identifying an embolus. An increase in the plasma level of D-dimer can help to correlate the diagnosis, even though it is not specific for DVT. Normal levels of D-dimer help to rule out DVT.[7]

Patient 1 had no predisposing factors for DVT, and her mobility was not restricted. Therefore, prophylactic anticoagulation treatment was not considered necessary.

Patient 2 was immobilized, but did not meet the criteria for anticoagulation treatment and therefore was not given anticoagulation treatment.[10]

Although it is customary to use a tourniquet to provide better visualization of the surgical field and decrease blood loss, there is no absolute indication for the use of a tourniquet when performing the procedures described in this article (patella and tibial plateau repair). Many reports have described safe application and possible adverse effects, but the decision to use a tourniquet is up to the surgeon. At the authors' institution, some surgeons use tourniquets, but others prefer to operate without them.[11]

Diagnostic tests for DVT are invasive, are not sensitive, and are expensive, making routine use difficult. Diagnostic workup should be considered in patients who are immobilized for more than a few days if use of a tourniquet is planned.[7]

Although the number of cases reported here is too limited to allow definitive conclusions, the authors recommend extreme caution and even suggest avoiding the use of an exsanguination tourniquet in patients undergoing elective surgery who have risk factors for DVT and in patients with traumatic injury of the extremities because these patients are at risk for DVT.[5]

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The effect of sterile versus non-sterile tourniquets on microbiological colonisation in lower limb surgery

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ABSTRACT

INTRODUCTION Surgical tourniquets are commonplace in lower limb surgery. Several studies have shown that tourniquets can be a potential source of microbial contamination but have not compared the use of sterile versus non-sterile tourniquets in the same procedures.

METHODS Patients undergoing elective orthopaedic lower limb surgery were randomised prospectively to use of non-sterile pneumatic tourniquet or sterile elastic exsanguination tourniquet (S-MART™, OHK Medical Devices, Haifa, Israel). Samples were taken from the ties of the non-sterile tourniquet prior to surgery and from the sterile tourniquets at the end of the operation in a sterile fashion. These were then sealed in universal containers and immediately analysed by the microbiology department on agar plates, cultured and incubated.

RESULTS Thirty-four non-sterile tourniquets were sampled prior to surgical application, twenty-three of which were contaminated with several different organisms including coagulase-negative *Staphylococcus* spp, *Staphylococcus aureus*, *Sphingomonas paucimobilis*, *Bacillus* spp, and coliforms. Thirty-six sterile tourniquets were used, with no associated contamination.

CONCLUSIONS There was significant contamination of 68% of orthopaedic surgical tourniquets. These are used regularly in procedures involving the placement of prosthesis and metalwork, and can act as a potential source of infection. We recommend the use of sterile single-use disposable tourniquets where possible. The availability of an alternative should now set the new standard of care and we recommend adopting this as a current NICE guideline for control of surgical site infection.

KEYWORDS

Tourniquet – Equipment contamination – Orthopedic equipment – Lower extremity – Agar plate

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Surgical tourniquets are commonplace in lower limb surgery as a bloodless field is necessary in many orthopaedic procedures. Previous studies have shown that tourniquets can be a potential source of microbial contamination but have not compared the use of sterile versus non-sterile tourniquets in the same procedures.[1] We hypothesised that tourniquets could be a cause of surgical site and prosthetic infection through microbial contamination.

Non-sterile medical equipment is used frequently in the sterile environment of the operating theatre. Studies have shown that medical equipment can be colonised and contaminated with bacteria that can be transferred to the operating room environment.[2–5] The tourniquets in theatre are very rarely cleaned according to the manufacturer's guidelines between cases. They are often stored in the pneumatic tourniquet box in close proximity to the ground, with parts in contact with the ground, other tourniquets or the Rhys-Davies exsanguinator (a common haven for bacteria).[6]

Surgical site infections (SSIs) place a huge financial burden on the healthcare system.[7] More importantly, SSIs confer a distinct disadvantage on the patient, who will invariably need to undergo further blood tests, intravenous antibiotic administration, prolonged exposure to radiology and possibly the need for revision surgery.[8]

Manufacturers offer orthopaedic tourniquets that are sterile and disposable, designed for use on one procedure only. Our trust uses both disposable sterile elastic exsanguination tourniquets (EETs) (S-MART™, OHK Medical Devices, Haifa, Israel) and re-usable non-sterile pneumatic tourniquets (OHK Medical Devices). The choice is down to the surgeon's preference. There is no NICE guidance on this issue although otherwise thorough guidelines on preventing SSIs have been published.[9]

Methods

This was a prospective randomised clinical trial where patients from two district general hospitals in one NHS trust were randomised to either sterile or non-sterile tourniquet groups. The patients were screened for methicillin-resistant *Staphylococcus aureus* (MRSA) prior to surgery in accordance with trust guidelines. All the procedures were commonplace elective knee procedures including arthroscopy and total knee arthroplasty undertaken in laminar flow theatres.

Samples were taken from the ties around the non-sterile tourniquet prior to surgery using an aseptic sterile technique. The areas sampled were not integral to the tourniquet function itself but were in contact with the patient throughout the procedure. A biopsy of the main body of the sterile tourniquet was taken at the end of the procedure in a sterile fashion using a new surgical blade and new surgical gloves and gown.

A total of 34 non-sterile and 36 sterile tourniquets were sampled. There were no complications with obtaining the specimens. Standardised conditions used throughout the study ensured that cross-contamination did not occur.

The specimens were sealed in universal containers and taken to the microbiological laboratories in the same trust. They were examined and tested by one biomedical scientist throughout who was blinded to the source of the tourniquet samples. The samples were placed onto whole Columbia blood agar plates and an aseptic technique was used to transfer both sides of the tourniquet to the agar. The plates were then incubated at 35°C for 48 hours in air. The agar was examined and bacterial type and colony count were recorded.

Results

In the non-sterile tourniquet group, 23 of 34 tourniquets (68%) were contaminated, whereas none of the 36 sterile tourniquets were colonised. This difference was statistically significant ($p<0.01$). Colony counts were low, ranging from 1 to >61, with some tourniquets yielding more than one bacterial species. Significant numbers of skin flora were identified but no MRSA was isolated.

The main bacterial species isolated was coagulase-negative *Staphylococcus* spp, which occurred in 11 of the 23 positive samples (32% of total). *Bacillus* spp was present on eight samples (24%), coliform species on three samples (9%) and *Sphingomonas paucimobilis* on one sample. *Staphylococcus aureus* was found with coagulase-negative *Staphylococcus* spp on two tourniquets.

Discussion

This study is the first to compare the bacterial load of non-sterile pneumatic versus sterile elastic exsanguination tourniquets (EETs) used for the control of bleeding in lower limb surgical procedures. The results show unequivocally that the sterile EET is growth-free, not only as it comes out of the package but also at the end of the procedure, whereas the non-sterile pneumatic tourniquet is contaminated in 23 of 34 of cases (68%). Reusing non-sterile tourniquets may therefore result in the transfer of bacteria between patients.

The bacterial species identified are commonly found on human skin or excretions including coagulase-negative *Staphylococcus* spp, the most common cause of joint infection in total knee replacement and arthroscopy.[10,11] Such infections develop in 1–3% of knee surgical procedures[10] and are associated with poor outcome and increased cost.[8] Although the colony counts were low, it is certainly possible that bacteria will move from the tourniquet to the surgical field during surgery or when dressing the wound.

When compared with recent work on the bacterial load in non-sterile tourniquets,[1,12] our study actually found a lesser degree of contamination. These other studies found 100% contamination of all non-sterile pneumatic tourniquets although one demonstrated that colonisation was reduced by 99.2% when cleaned in accordance with the manufacturer's guidelines.[1] This difference may be related to a higher level of overall infection control and cleanliness in the theatres we studied or a difference in sampling and culture technique. In any event, since the same technique was used for the non-sterile tourniquet and the EET, the difference in contamination in this study is significant and valid.

The logical conclusion may be that reducing bacterial load in close proximity to the surgical site will reduce SSIs. However, this is yet to be demonstrated by a prospective and blinded controlled study, and subsequent studies may go further than this one in following up the patients to determine if the organisms isolated caused SSIs. Our study did not address other differences between the two types of tourniquet such as ease of use and efficacy in terms of achieving a bloodless field. Anecdotally, the surgeons in this study preferred the sterile EET.

Conclusions

This study clearly documented the bacterial load of pneumatic tourniquets and presented the fact that an alternative EET is not contaminated. Putting all other considerations in favour of the use of EET aside, we conclude that using contaminated non-sterile tourniquets in surgical procedures that often involve insertion of foreign materials into the human body is not advisable. The availability of an alternative should now set the new standard of care and we recommend adopting this as a current NICE guideline for control of SSI.

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Pain and paraesthesia produced by silicone ring and pneumatic tourniquets

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Abstract
Twenty volunteers were recruited to compare a novel, silicone ring tourniquet (the Hemaclear® tourniquet) with a pneumatic tourniquet. After application of the tourniquets, the pain and paraesthesia experienced by the participants was scored at 1 minute, 5 minutes, and 10 minutes. This was repeated with the tourniquets on the forearm. On the upper arm, the silicone ring tourniquet was associated with a significantly lower pain score than the pneumatic tourniquet. The incidence of paraesthesia was also lower with the silicone ring tourniquet. When applied to the forearm, there was no statistically significant difference in pain scores between the two types of tourniquets. However the incidence of paraesthesia was again lower with the silicone ring tourniquet.

Keywords
Tourniquet, pain tolerance, paraesthesia

Introduction

Upper limb surgery is often done under local anaesthesia and the use of a tourniquet. Esmarch described the first use of his tourniquet in 1873 as a means of providing a bloodless field and the pneumatic tourniquet was introduced to limb surgery in 1904 by Harvey Cushing (Klenerman, 1962). Since then there have been many developments in the field of tourniquets, some of which have been influenced by military use (Welling et al., 2006).

One tourniquet system which has shown good results in upper limb surgery done under local anaesthesia is the Hemaclear® system (also known as S-MART™ and first developed in 1999 by OHK Medical Devices, Haifa, Israel) (Boiko and Roffman, 2004). The Hemaclear® system consists of a silicone ring (internal diameter 52 mm, external diameter 76 mm) wrapped within an elastic sleeve or 'stockinette' and with two straps attached to pull handles (Figures 1 and 2). It is applied by placing it on the patient's fingers and rolling it up the limb to the desired occlusion site by pulling on the straps (Figures 2 and 3).

The risks and benefits of using a tourniquet have been much discussed (Odinsson and Finsen, 2006). The new silicone ring tourniquet has shown good efficacy and safety (Boiko and Roffman, 2004; Eidelman et al., 2006; Norman et al., 2009). However, the pain tolerance in patients undergoing hand surgery with the use of this new tourniquet system has not been reported. We conducted a comparative study to assess the pain tolerance scores and paraesthesia experienced by patients when using the silicone ring tourniquet compared with a pneumatic tourniquet. We also compared upper arm and forearm tourniquets.

Methods

Twenty healthy volunteers comprising ten men and ten women aged between 23 and 55 years were recruited. The study was split into two parts to look at the upper arm and forearm separately. All 20 volunteers were included in both parts of the study. All the volunteers were from a non-medical background and were asked questions about any discomfort associated with the tourniquets, which were applied at the same time. The volunteers were blinded to the outcome.

In the first part, the pneumatic tourniquet was applied to one arm of the participant and the silicone ring tourniquet was applied to the other arm simultaneously. In the second part of the study, the pneumatic tourniquet was applied to one forearm of the participant and the silicone ring tourniquet was applied to the other forearm. Thus, each

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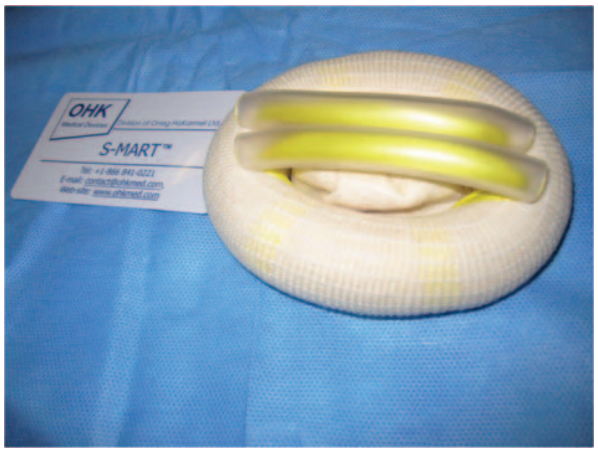

Figure 1. The 'Hemaclear®' or silicone ring tourniquet.

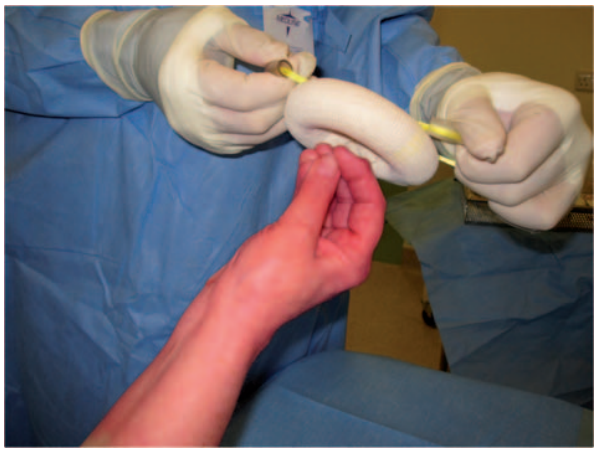

Figure 2. Holding the straps to position the tourniquet.

volunteer acted as his/her own control. The upper arm tourniquet was applied 10 cm above the medial epicondyle and the forearm tourniquet 10 cm below this point.

The pneumatic tourniquet (Oak Medical Services Ltd, North Lincolnshire, DN20 8PD) was placed over four layers of orthopaedic wool after exsanguination with a Rhys-Davies exsanguinator, and a size 45/9 pneumatic cuff was inflated to a pressure 100 mmHg above systolic blood pressure.

The silicone ring tourniquet was directly applied after skin preparation without the need for wool or exsanguination and the size was chosen according to the limb circumference and the systolic blood pressure of the patient.

After application of the tourniquet, pain experienced by the participants was scored out of 10 (with '0' being no pain and '10' being worst pain ever) at 1 minute, 5 minutes and 10 minutes in both

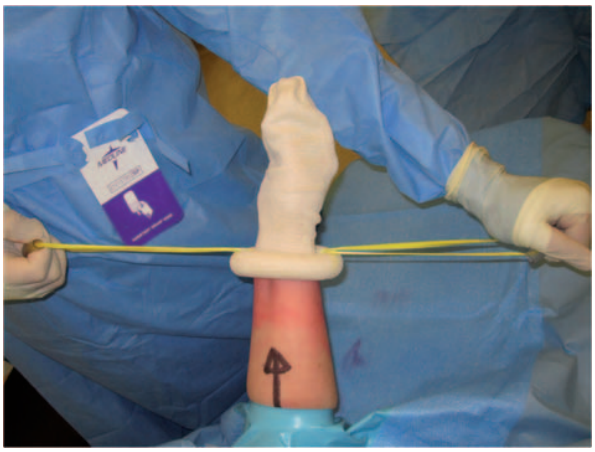

Figure 3. Rolling the silicone ring to the desired position.

parts of the study. Paraesthesia was scored '0' if there was no numbness or tingling at the site of or distal to the tourniquet, and '1' if either of these was experienced.

Each tourniquet was applied by the same investigator (A.M.). No actual surgical procedures were done and the tourniquets were removed after 10 minutes.

Once the data had been collected, two-tailed paired *t*-tests were used for statistical analysis. A *p*-value of <0.05 was considered statistically significant.

Results

The results are summarized in Table 1.

When the tourniquets were applied to the upper arm, the average pain score of the 20 participants after the first minute was similar for both the pneumatic and the silicone ring tourniquets. At 5 minutes, the average pain scores with the silicone ring tourniquet dropped below that experienced with the pneumatic tourniquet. Overall, it was found that in the upper arm, after 10 minutes, the silicone ring tourniquet was associated with a significantly lower pain score than with a pneumatic tourniquet.

When the tourniquets were applied to the upper arm, paraesthesia was more common with the pneumatic tourniquet than with the silicone ring tourniquet; six out of 20 participants experienced paraesthesia at 1 minute with the pneumatic tourniquet, compared with only one with the silicone ring tourniquet. By 10 minutes, 16 of the 20 participants wearing pneumatic tourniquets on the upper arm were experiencing paraesthesia. Of these, two were severe and three found the discomfort so unbearable that they had to have the tourniquet removed. In comparison, at 10 minutes, only four of the

Table 1. Pain scores and presence of paraesthesia, values are given as mean (SD)

	1 minute	5 minutes	10 minutes	*p*-value (10 mins)
Pain scores at upper arm				
Pneumatic tourniquet	4.0 (1.5)	4.3 (1.6)	5.7 (2.5)	<0.01
Silicone ring tourniquet	4.7 (1.6)	3.1 (1.6)	3.7 (2.3)	
Paraesthesia at upper arm				
Pneumatic tourniquet	0.3 (0.5)	1.2 (0.5)	3.2 (0.5)	<0.01
Silicone ring tourniquet	0.1 (0.22)	0.3 (0.2)	0.8 (0.4)	
Pain scores at forearm				
Pneumatic tourniquet	4.1 (1.6)	4.3 (1.7)	2.3 (1.7)	0.09
Silicone ring tourniquet	5.5 (1.1)	3.5 (1.5)	1.9 (1.2)	
Paraesthesia at forearm				
Pneumatic tourniquet	0.5 (0.5)	0.7 (0.5)	0.8 (0.4)	<0.01
Silicone ring tourniquet	0.1 (0.2)	0.2 (0.4)	0.2 (0.4)	

participants experienced paraesthesia with the silicone ring tourniquet. The paraesthesia was described as mild though one had to have the silicone ring tourniquet removed (this participant had to have the pneumatic tourniquet removed as well). Overall, it was found that in the upper arm, after 10 minutes, the silicone ring tourniquet was associated with a significantly lower incidence of paraesthesia than with a pneumatic tourniquet.

In the second part of the study with tourniquets applied to the forearm, pain scores with both types of tourniquet were lower than when placed on the upper arm. With the silicone ring tourniquet, the average pain score at 1 minute was again 5. However the pain scores decreased at both the 5 minute and 10 minute points. With the pneumatic tourniquet, pain scores were initially slightly lower. However, at 5 minutes, the pain scores increased then fell at 10 minutes. There was no statistically significant difference in pain scores between the two types of tourniquets when applied to the forearm.

With forearm tourniquets, only one participant wearing the silicone ring tourniquet experienced paraesthesia at 1 minute compared to eight of those wearing pneumatic tourniquets. At 10 minutes, only four of the participants wearing silicone ring tourniquets experienced paraesthesia compared to 15 participants wearing pneumatic tourniquets. There was significantly less paraesthesia at the forearm with the silicone ring tourniquet than with the pneumatic tourniquet.

Discussion

Our results have shown that the silicone ring tourniquet gives a lower pain score than the pneumatic tourniquet in the upper arm though pain scores appear to be fairly similar in the forearm. In terms of paraesthesia, the silicone ring tourniquet produces much less than the pneumatic tourniquet and as a result is better tolerated.

Any surgical procedure that is carried out under local or regional rather than general anaesthetic relies on maintaining the comfort of the patient to allow surgery to continue. We found that participants were able to tolerate the silicone ring tourniquet for longer, thereby providing a longer for surgical intervention. Furthermore, less discomfort experienced during surgery makes it more likely that patients will have a positive outcome (Kehlet and Wilmore, 2002). This, together with its speed and ease of draping suggest the silicone ring tourniquet may be a useful alternative to the pneumatic tourniquet.

On a biomechanical level, the difference between the two tourniquets is primarily due to the surface area occluded by each type. Animal studies using electron microscopy have shown that pneumatic tourniquets can cause compression of nerves that is sufficient to displace the nodes of Ranvier (Ochoa et al., 1972). The damage done by just 2 hours of tourniquet time can be detected for days and weeks afterwards. Unlike the pneumatic tourniquet, the silicone ring tourniquet does not use a wide cuff and the amount of nerve damage is thought to be much less. However, MRI or nerve conduction studies may be needed to assess this (Mittal et al., 2008).

We found that forearm tourniquets produced marginally more paraesthesia than upper arm tourniquets but due to the lower pain scores, no patients had to take them off. Maury and Roy (2002) in a study of 24 volunteers had similar findings and reported that a forearm tourniquet was tolerated for 7 minutes longer than an upper arm tourniquet.

Some participants had difficulty with all tourniquets and this may have affected the results.

However, if these participants had been excluded, this would have improved the scores obtained with the silicone ring tourniquet. In the clinical settings, such participants would be probably better suited to general rather than local anaesthesia.

Our results show that the most comfortable position to place a tourniquet is on the forearm. The most comfortable type of tourniquet to use is the silicone ring tourniquet. The improvement in comfort between the silicone ring tourniquet and pneumatic tourniquet is most evident when used on the upper arm. Patient comfort with any tourniquet system is largely related to the pain tolerance and paraesthesia associated with the tourniquet system.

Conflict of interests

None declared.

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ORTHOPAEDIC SURGERY

Silicone ring versus pneumatic cuff tourniquet: a comparative quantitative study in healthy individuals

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Abstract
Introduction The aim of the present study was to compare a new silicone ring tourniquet (SRT) with a classic pneumatic cuff tourniquet (PT) in terms of tolerance and recovery time following their use in healthy volunteers.
Methods Both tourniquets were applied in the arm and thigh of 15 healthy unmedicated volunteers. PT pressure was kept at 100 mmHg above the systolic blood pressure. The appropriate model of the SRT was used according to the systolic blood pressure. Pain was assessed by visual analogue scale and arterial blood pressure, pulse rate and oxygen saturation were monitored in all volunteers.
Results There was no statistically significant difference in tolerance time between SRT and PT in the arm (19.13 vs. 18.25 min) and thigh (21.52 vs. 21.39 min) nor in recovery time between the two devices.
Conclusion The SRT performed similarly to the classic PT in terms of tolerance and recovery time when applied in the arm and thigh of unmedicated healthy volunteers.

Keywords Tourniquet · Silicone ring tourniquet · Esmarch · Tourniquet pain

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Introduction

Tourniquet use is widespread in orthopaedic surgery to provide a bloodless operating field during surgical procedures involving the extremities and for intravenous regional anaesthesia. Pneumatic tourniquet (PT) is the most commonly used tourniquet since its introduction by Harvey Cushing in 1904 [1]. The Esmarch tourniquet is generally considered less safe than PTs, although some surgeons continue to use this device [2, 3].

Modern PTs are designed to minimize the incidence of complications [4], and recent prospective randomized clinical trials have shown no significant long-term deleterious effects of using PTs in extremity surgery [5–8].

Although serious complications of the use of a PT are rare, there is a definite morbidity [9–16] and even mortality [17].

Nowadays, it is generally accepted that wide-cuff PT systems inflated at low-pressure allow more predictable and precise pressure regulation at the site of application resulting in improved safety for extremity surgery [4]. Nevertheless, a recent survey shows that the incidence of tourniquet complications is still at least as high as that estimated in the 1970s [16].

In order to eliminate these complications, the PTs should be kept in good condition by routinely checking all valves and gauges, daily calibration checks, intraoperative frequent monitoring of tourniquet function and monthly performance-assurance tests. The tourniquet should be tested by inflation and then completely deflated before application and experienced personnel should apply the appropriated padding and the tourniquet cuff around the limb [1, 4].

While research continues regarding many aspects of PTs such as application, safety and sequela [18–23], a new devise has been introduced in clinical practice recently [24–26].

The silicone ring tourniquet (SRT) is a novel device (S-MART™, OHK Medical Devices, Haifa, Israel) consisting of a silicone ring wrapped within an elastic sleeve (stockinet) and two straps attached to pull handles. The device is inserted over the patient's fingers or toes and is then rolled proximally up the limb, compressing the limb and expelling the blood into the central circulation. The ring is positioned at the proximal occlusion location while the stockinet unfolds onto the limb to provide a sterile draping, as the entire device is sterile (Figs. 2, 3). The use of SRT avoids all time- and personnel-consuming procedures related to the maintenance and application, and it can be applied and removed easily and quickly by the surgeon alone, thereby eliminating the need for assistance from the operating room staff. The sterility of the device allows application after skin preparation and draping, thus shortening tourniquet time. On the other hand, the SRT has a preset applied pressure that cannot be changed and the limb circumference at the occlusion site should be in the range of 20–60 cm for the leg and 20–40 cm for the arm.

The aim of this study was to compare the classic PT with this new device designed for exsanguination and occlusion of the blood flow to the limb.

Materials and methods

Study design

Fifteen adult healthy unmedicated volunteers with no previous fracture or operation in the limbs or any type of anaemia participated in a four-test study. Data regarding volunteer's age, height, weight, sporting activity and smoking were recorded. A Hospital Ethics Committee approval for this study was obtained. The procedure was also described to each volunteer prior to obtaining written consent.

The two different tourniquets were applied on the dominant upper and lower limb of each volunteer, one each time, with a 2-day interval after each application. In half of the volunteers (every other volunteer) the PT was studied first and on the other half the SRT. Also in half of the volunteers the tourniquet was applied on the arm first and on the other half in the leg. The only variable in this study was the type of tourniquet used.

Tourniquet types

A standard PT with an 8-cm-wide cuff for the upper arm and a 14-cm-wide cuff for the thigh was used (Fig. 1). The SRT comes in two sizes; a small size for the arm (circumference of the limp at occlusion site up to 40 cm) and a large size for the leg (circumference of the limp at occlusion site up to 60 cm). Each size has three tension models, and for each patient the appropriate model is used according to the systolic blood pressure measured in the operating room before the placement of the device. The device is inserted over the patient's fingers or toes and is then rolled proximally up the limb, compressing the limb and expelling the blood into the central circulation. The ring is positioned at the proximal occlusion location while the stockinet unfolds onto the limb to provide a sterile draping, as the entire device is sterile (Fig. 2, 3).

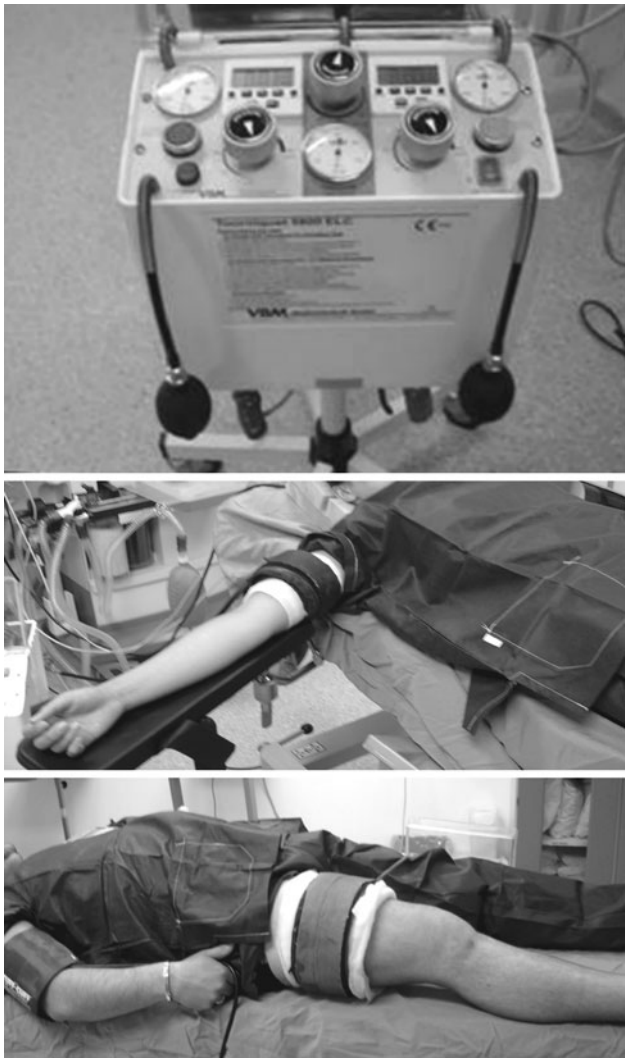

Fig. 1 Pneumatic tourniquet study with the cuff applied on the upper arm and thigh

Procedure

The procedure was explained to all participants. They also instructed how to use the Visual Analogue Scale for discomfort/pain, 0 = no discomfort/pain to 10 = the worst pain [27]. The volunteer was placed in a comfortable, supine

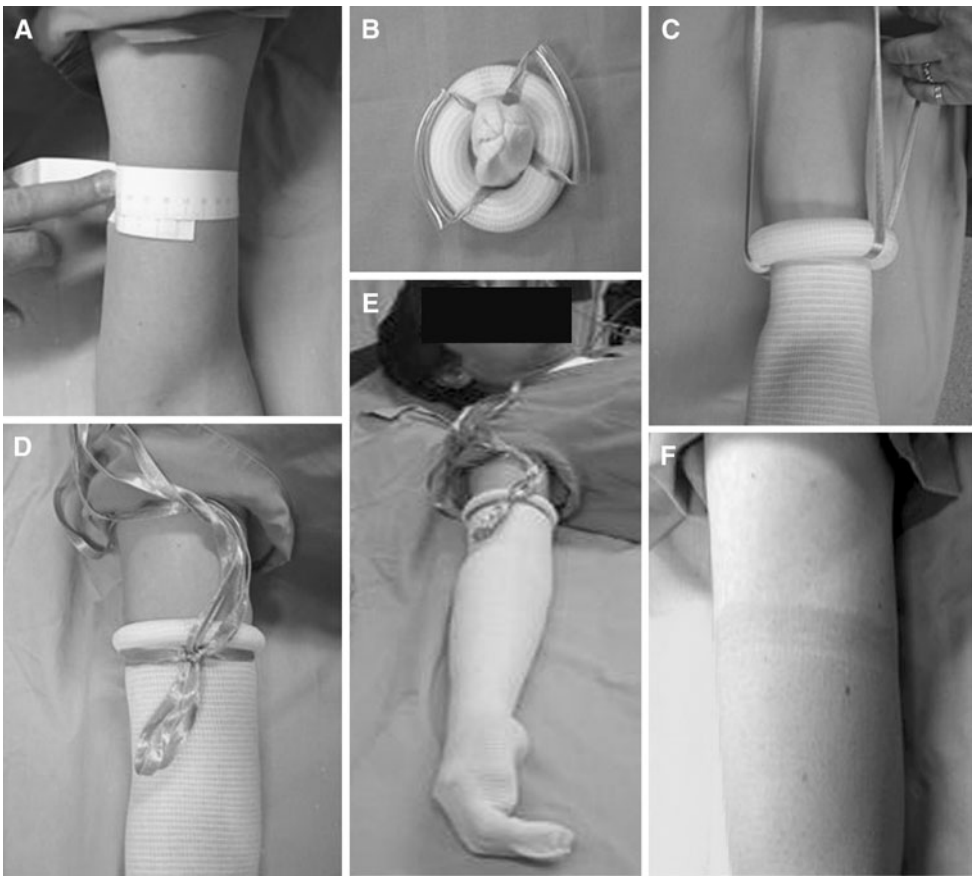

Fig. 2 Silicone Ring Tourniquet study on the arm. **a** Measurement of the upper arm circumference, **b** selection of the appropriate tension model, **c** the device is inserted over the patient's arm and is rolled proximally up the limb, **d** and **e** the tourniquet has been applied on the upper arm, **f** the arm after the tourniquet removal

position out of site of clocks or monitoring equipment. For ethical reasons it was decided to discontinue the study when the volunteers felt that pain at either the tourniquet application site or in the extremity distal to the tourniquet reached the VAS level of 8.

The circulatory variables of systolic and diastolic blood pressure, pulse rate, as well as PO_2, were monitored using a noninvasive monitor and cuff/cables were applied in the non-dominant upper limb. After a 15-min period to allow stabilization of all recorded variables, the values of these variables just before the tourniquet application were used as standards.

The PT cuff was applied over two thicknesses of smoothly applied cast padding. The limb elevated for 3 min before the tourniquet inflation. The PT inflation pressure was 100 mmHg above the standard systolic blood pressure. The appropriate model of SRT was selected according to the standard systolic blood pressure and applied as recommended by the manufacturer.

The circulatory variables, PO_2, and VAS levels for pain at the tourniquet application site as well as in the limb distal to the tourniquet were recorded (a) just after tourniquet application, (b) every 5 min during maintenance of the tourniquet on the limb, (c) just before the tourniquet removal (tolerance time), (d) every 5 min after the tourniquet removal, and (e) at the time of complete recovery from any symptoms (recovery time).

The primary outcome of concern was the tolerance time and recovery time for each tourniquet type. Secondary outcome was the changes of the systolic and diastolic blood pressure, pulse rate and PO_2 for each tourniquet type.

Statistical analysis

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS), version 11.0 (SPSS, Inc., Chicago, IL, USA). Continuous variables were expressed as mean ± standard deviation and categorical variables were expressed as frequencies and percentages. The normality of continuous variables was tested with Kolmogorov–Smirnov test. Student's *t* test was used to compare the pre-application values of the circulatory variables and PO_2 between PT and SRT devices, while paired samples *t* test was used to assess any device-related differences in the tolerance and recovery time. Repeated measures analysis of variance (ANOVA) was used to examine the changes of the circulatory variables and PO_2 throughout the application of the devices; post hoc analysis was performed using Bonferroni's correction. The interaction between the different devices and the change of all these

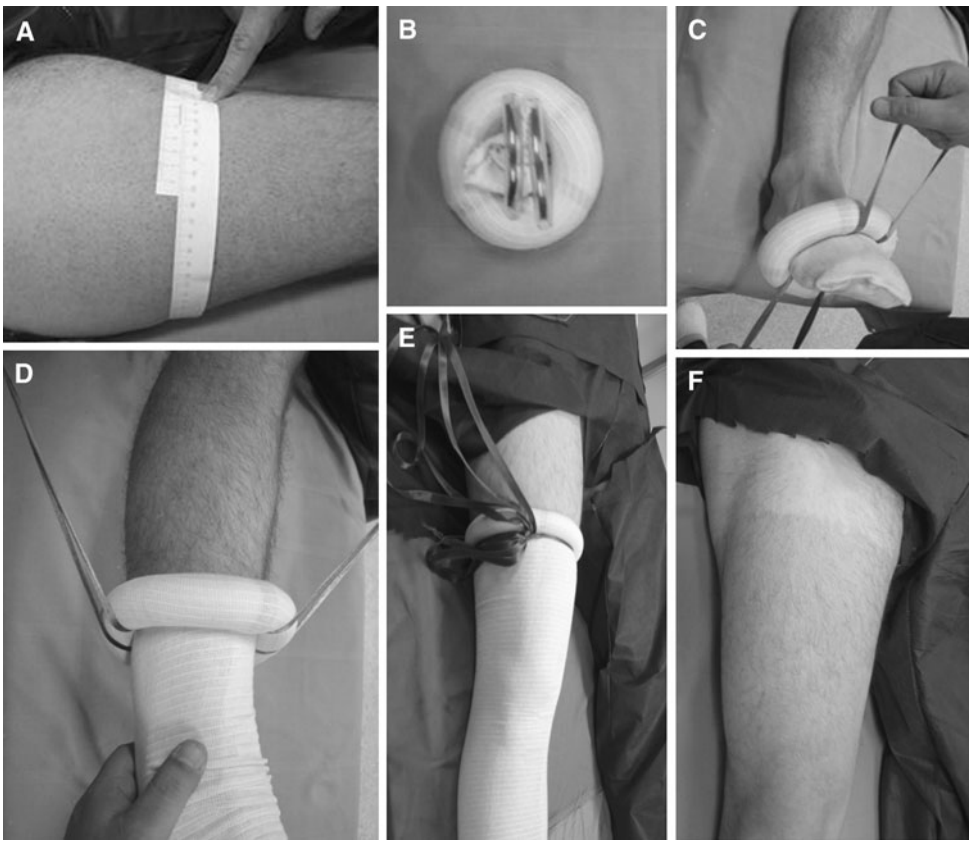

Fig. 3 Silicone Ring Tourniquet study on the arm. **a** Measurement of the thigh circumference, **b** selection of the appropriate tension model, **c** the device is inserted over the patient's foot, **d** the tourniquet is rolled proximally up the limb, **e** the tourniquet has been applied on the thigh, **f** the thigh after the tourniquet removal

variables over time was established by two-way ANOVA. One-way analysis of covariance (ANCOVA) was performed to investigate the effect of the devices on circulatory variables and PO_2 on each measurement, adjusting for pre-application values. All tests were two tailed and statistical significance was considered for p values less than 0.05.

Results

Patient data

The study population was comprised of 15 male volunteers, with a mean age of 32.80 ± 4.60 years (range 24–41 years), mean height of 178.07 ± 7.39 cm (range 165–192 cm) and mean weight of 84.47 ± 7.37 kg (range 72–97 kg). The majority of them were smokers (73.3%; 11 men), while 7 men (53.3%) indulged in sporting activities.

Pain and other symptoms

SRT application produced an immediate pain at the site of the tourniquet application, while in the PT study tourniquet inflation was followed by only some if any discomfort (a pressure sensation). In the SRT study, the pain partially subsided to a tolerable level within a few minutes, followed by numbness in the hand or foot and again gradually worsened as the time was passing. In the PT study, the pain levels at the site of the tourniquet application were low for the most part of the study, but were becoming worse gradually and further quickly just before the tolerance time.

After the application of the tourniquet the volunteers started feeling numbness in the hand or the foot at a variable interval time. The numbness was initially felt in the little finger (ulnar nerve distribution) or in the dorsal first web space (radial nerve distribution) of the hand, and in the medial side (saphenous nerve distribution), or in the dorsum of the foot (peroneal nerve distribution). This numbness gradually occupied the rest of the hand or foot, and while it was extending proximally, the hand or foot was becoming 'paralyzed'. Eventually, the volunteers were describing an 'aching abnormal feeling' of the limb distal to the tourniquet application site.

The tourniquets were removed when the pain reached the VAS level of 8 and this time was recorded as tolerance time. In both SRT and PT studies the volunteers requested to have tourniquet removed because of pain distal to the tourniquet despite the pain level at the tourniquet site being less than 8 of VAS.

After the tourniquet removal, an initial relief was followed by an unpleasant tingling which lasted for several

minutes. Subsequently the 'paralysis' disappeared followed by a gradual relief from numbness.

No difference in the sequence of these subjective feelings was noted between the two different tourniquets.

Tolerance and recovery time

The tolerance and recovery time for each device at the arm and thigh is shown in Table 1.

In the arm, the tolerance time of PT ranged from 9.58 to 29.15 min with a mean value of 18.25 ± 4.60 min, while the tolerance time of SRT ranged from 12.55 to 34.29 min with a mean value of 19.13 ± 5.73 min. Moreover, the recovery time of PT ranged from 3.40 to 15.03 min with a mean value of 7.74 ± 3.48 min, while the recovery time of SRT ranged from 4.00 to 15.00 min with a mean value of 8.52 ± 3.23 min. SRT device presented a 4.8% and a 10.1% elevation in the tolerance and recovery time, respectively, compared with PT device, but none of these differences reached statistical significance ($p = 0.220$ and $p = 0.339$, respectively).

In the thigh, the tolerance time of PT ranged from 13.00 to 34.54 min with a mean value of 21.39 ± 5.44 min, while the tolerance time of SRT ranged from 14.00 to 30.04 min with a mean value of 21.52 ± 5.28 min; the recovery time of PCT ranged from 5.00 to 12.00 min with a mean value of 7.64 ± 1.84 min, while the recovery time of SRT ranged from 4.50 to 12.00 min with a mean value of 7.62 ± 2.21 min. There were no statistically significant differences in the tolerance ($p = 0.928$) and recovery ($p = 0.959$) time between PT and SRT devices.

There was a marginal positive correlation between the tolerance time of the arm and the thigh ($r = 0.329$, $p = 0.076$), when the data from the two devices were combined; this association was more pronounced in PT ($r = 0.534$, $p = 0.040$) than in SRT ($r = 0.164$, $p = 0.559$) device.

On the contrary, a statistically significant positive correlation was found between the recovery time of the arm and the thigh in the combined group ($r = 0.511$, $p = 0.004$), in PT ($r = 0.513$, $p = 0.050$) and in SRT ($r = 0.526$, $p = 0.044$) device.

Among the combined group, there was a statistically significant positive correlation between the tolerance and recovery time in the arm ($r = 0.438$, $p = 0.015$), but not in the thigh ($r = 0.126$, $p = 0.509$).

Systolic blood pressure

The pre- and post-application mean systolic blood pressure for each device at the arm and thigh is shown in Tables 2 and 3. One-way repeated measures ANOVA showed statistically significant changes of mean systolic blood pressure over time (arm: $p < 0.001$ for PT and $p < 0.001$ for SRT; thigh: $p = 0.020$ for PT and $p < 0.001$ for SRT). The interaction between the two devices and the change of systolic blood pressure over time was not statistically significant ($p = 0.290$). Overall, SRT tourniquet demonstrated significantly higher values of systolic blood pressure on tolerance time ($p = 0.050$), as well as higher mean maximum ($p = 0.037$) values compared with patients' PT tourniquet.

Diastolic blood pressure

The pre- and post-application mean diastolic blood pressure for each device at the arm and thigh is shown in Tables 2 and 3. The interaction between the two devices and the change of diastolic blood pressure values over time was not statistically significant either ($p = 0.056$). At both sides, there was not any statistically significant tourniquet-related difference in the values of diastolic blood pressure on any of the five time frames or in the mean total and maximum diastolic blood pressure (Tables 2, 3).

Pulse rate

The pre- and post-application values of pulse rate for each device at the arm and thigh are shown in Tables 2 and 3. Overall, pulse rate fluctuated statistically significantly

Table 1 Tolerance and recovery time for arm and leg application of both tourniquets

	Device		*p* value	95% CI of difference
	PT Time in minutes (mean ± SD)	SRT Time in minutes (mean ± SD)		
Arm				
Tolerance time	18.25 ± 4.60	19.13 ± 5.73	0.220	−2.35 to 0.59
Recovery time	7.74 ± 3.48	8.52 ± 3.23	0.339	−2.44 to 0.90
Leg				
Tolerance time	21.39 ± 5.44	21.52 ± 5.28	0.928	−3.08 to 2.83
Recovery time	7.64 ± 1.84	7.62 ± 2.21	0.959	−0.85 to 0.89

Table 2 The pre- and post-application values of systolic BP, diastolic BP, pulse rate, and PO_2 for the arm

	PT	SMART	*p* value
Systolic BP (mmHg)			
Pre-operative	110.93 ± 7.64	114.27 ± 9.54	0.300
After application	113.00 ± 5.52	117.73 ± 12.60	0.387
Tolerance time	117.53 ± 6.96	126.00 ± 14.70	0.106
Removal	113.20 ± 8.37	119.40 ± 10.91	0.110
Final	111.07 ± 6.70	117.47 ± 10.88	0.032
Total	565.73 ± 32.98	594.87 ± 52.97	0.028
Maximum value	118.40 ± 7.77	128.13 ± 13.99	0.036
Diastolic BP (mmHg)			
Pre-operative	70.47 ± 6.08	73.67 ± 9.63	0.288
After application	72.60 ± 7.17	75.13 ± 9.66	0.837
Tolerance time	75.07 ± 7.01	82.27 ± 10.75	0.080
Removal	73.93 ± 7.07	80.53 ± 10.18	0.051
Final	72.27 ± 6.11	81.20 ± 10.21	0.007
Total	364.33 ± 30.87	392.80 ± 42.74	0.018
Maximum value	77.07 ± 7.97	87.53 ± 11.90	0.008
Pulse rate			
Pre-operative	70.87 ± 8.29	71.60 ± 7.65	0.803
After application	72.53 ± 8.63	73.20 ± 10.97	0.992
Tolerance time	72.00 ± 8.77	73.93 ± 7.90	0.376
Removal	69.93 ± 7.79	68.27 ± 8.03	0.138
Final	69.87 ± 8.76	69.67 ± 7.42	0.495
Total	355.20 ± 40.04	356.67 ± 38.48	0.685
Maximum value	74.80 ± 8.06	76.60 ± 9.76	0.541
PO_2			
Pre-operative	95.93 ± 2.40	95.73 ± 2.63	0.830
After application	96.07 ± 2.22	95.80 ± 2.60	0.797
Tolerance time	96.33 ± 2.23	96.47 ± 2.23	0.576
Removal	96.73 ± 2.19	96.00 ± 2.67	0.376
Final	96.13 ± 2.20	96.27 ± 2.40	0.498
Total	481.20 ± 10.22	480.27 ± 11.22	0.921
Maximum value	97.20 ± 2.18	97.07 ± 2.40	0.886

Table 3 The pre- and post-application values of systolic BP, diastolic BP, pulse rate, and PO_2 for the leg

	PT	SMART	*p* value
Systolic BP (mmHg)			
Pre-operative	117.67 ± 12.62	120.80 ± 11.09	0.476
After application	123.00 ± 10.95	128.67 ± 10.42	0.165
Tolerance time	122.47 ± 13.07	131.00 ± 11.92	0.050
Removal	123.60 ± 7.05	123.07 ± 13.42	0.276
Final	120.47 ± 9.16	121.47 ± 11.90	0.507
Total	607.20 ± 48.67	625.00 ± 52.14	0.395
Maximum value	127.93 ± 9.28	134.93 ± 10.01	0.037
Diastolic BP (mmHg)			
Pre-operative	74.00 ± 12.22	81.20 ± 14.08	0.146
After application	80.73 ± 8.45	83.80 ± 10.27	0.770
Tolerance time	78.93 ± 8.61	82.20 ± 10.16	0.709
Removal	81.13 ± 7.61	78.80 ± 6.16	0.084
Final	80.13 ± 6.44	79.60 ± 8.58	0.258
Total	394.93 ± 38.06	405.60 ± 37.19	0.624
Maximum value	83.00 ± 8.25	90.07 ± 12.67	0.309
Pulse rate			
Pre-operative	73.60 ± 10.07	76.87 ± 11.34	0.411
After application	74.93 ± 9.87	77.00 ± 10.76	0.867
Tolerance time	75.40 ± 9.63	79.13 ± 10.07	0.554
Removal	70.53 ± 9.75	72.07 ± 10.78	0.860
Final	71.07 ± 10.99	73.60 ± 11.44	0.974
Total	365.53 ± 45.24	378.67 ± 49.10	0.968
Maximum value	79.53 ± 9.69	82.33 ± 10.71	0.983
PO_2			
Pre-operative	95.80 ± 1.90	96.27 ± 1.49	0.460
After application	95.80 ± 2.57	96.80 ± 1.61	0.281
Tolerance time	96.07 ± 2.25	96.53 ± 1.96	0.988
Removal	96.33 ± 1.88	96.53 ± 1.81	0.636
Final	96.20 ± 2.04	96.20 ± 1.47	0.162
Total	480.20 ± 9.97	482.33 ± 7.53	0.938
Maximum value	96.93 ± 1.98	97.20 ± 1.70	0.547

throughout the application of the two devices at both sides (arm: $p = 0.063$ for PT and $p = 0.001$ for SRT; thigh: $p = 0.026$ for PT and $p = 0.004$ for SRT). Furthermore, at both sides, there was no statistically significant difference in pulse rate between the two devices on any of the five time frames; no significant differences were also found in the mean total or maximum pulse rate (Tables 2, 3).

PO_2

The pre- and post-application values of PO_2 for each device at the arm and thigh are also shown in Tables 2 and 3. The effect of the application of both tourniquets on the pulmonary function at any site (arm and thigh) was not significant (arm: $p = 0.272$ for PT and $p = 0.467$ for SRT; thigh: $p = 0.360$ for PT and $p = 0.297$ for SRT). The interaction between the two devices and the change of PO_2 values over time was not statistically significant either ($p = 0.586$ and $p = 0.220$ for arm and thigh, respectively). At both sides, there was not any statistically significant tourniquet-related difference in PO_2 values on any of the five time frames or in the mean total and maximum PO_2 value (Tables 2, 3).

Discussion

The main finding of this study was that there was no statistically significant difference in tolerance time and recovery

time between the two tourniquets. Although the difference was not statistically significant, volunteers could tolerate the SRT slightly longer than the PT. The recovery time was also longer for the SRT compared with PT. We believe that this is related to the longer tolerance time for SRT compared with PT, which implies that recovery of any symptoms will take more time.

There was a difference between PT and SRT in the initial sensation at the tourniquet application site. While SRT application produced an immediate pain at the site of the tourniquet application, tourniquet inflation in the PT study was followed by only some if any discomfort. The subjective descriptions by the volunteers ('feelings') produced by maintenance of tourniquet inflation on the extremity as well as after the tourniquet deflation and removal were consistent with previous published studies [28, 29] and similar in both SRT and PT studies. Therefore, apart from the initial difference after the SRT and PT application, no other difference in the sequence of the subjective feelings was noted between the two different tourniquets.

The aetiology and neural pathways involved in tourniquet pain remain controversial, but are probably multifactorial [30]. It is also not clear whether the mechanical pressure of the nerve or the nerve ischemia is the main factor responsible for the tourniquet induced nerve damage. The results of animal studies [31–33] and human volunteer studies [34–37] are controversial.

As far as the width of the tourniquet is concerned, it is known that wider cuffs require lower arterial flow occlusion pressure [38, 39] and thus it is accepted that the risk of tourniquet-induced injury to the underlying soft tissues is reduced. On the other hand, human volunteer studies have shown that wider tourniquets resulted in more pain and were tolerated for less time than narrow cuffs [28]. A more recent study found that this is true in higher pressures, but in lower pressures a wide tourniquet cuff is less painful than a narrow cuff [30]. Nerve conduction studies in volunteers have shown recently that wider cuffs resulted in more severe changes in the nerve than narrow cuffs inflated at the same pressure and time [40].

The observed changes in blood pressure are well known [41–44]. The so-called tourniquet hypertension was more pronounced in the SRT study and we think that this merits a further clinical investigation. If the SRT application itself results in higher values of blood pressure this should be considered from the anaesthetic point of view. An unexpected elevation of the systolic blood pressure above a certain value will result in SRT failure to occlude the blood circulation into the extremity.

A large inter-individual difference was noted in tourniquet tolerance time in our study similar to previous studies [29]. It has also been considered as an idiosyncratic response to tourniquet application [45]. Statistical analysis of the results of our study showed a marginal positive correlation between the tolerance time of the arm and the thigh and a statistically significant positive correlation between the recovery time of the arm and the thigh. Therefore, it seems that a volunteer who tolerates an arm tourniquet longer than another volunteer is likely to tolerate a thigh tourniquet for longer time as well.

The limitations of this study are (a) the volunteer group is not comparable to the standard orthopaedic patient undergoing surgery, where the orthopaedic problem (i.e. osteoarthritis) or other comorbidities and medications may alter the perception of pain and (b) this study describes the immediate effects of a new device and compares these effects to the standard PT. The clinical relevance of the results of this study is not clear. Comparative clinical studies are required and in fact two of these studies are under way in our department.

Nevertheless, several tourniquet studies in the past have used this study protocol (i.e. healthy volunteers) in order to compare tourniquets with different cuff width [28–30], different pressure [29] and application of the same tourniquet in different sites [29, 46–48].

In conclusion, this novel device, the SRT—with the advantages and disadvantages previously described—performed in a similar way to PT as far as the immediate effects are concerned in unmedicated healthy volunteers.

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ORIGINAL ARTICLE

Prospective Study

Nerve compression and pain in human volunteers with narrow *vs* wide tourniquets

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Author contributions: Kovar FM and Kasprian G contributed equally to this work; Jaindl M, Prayer D and Kutscha-Lissberg F designed the research; Kovar FM, Oberleitner G and Breitenseher J performed the research; Kovar FM and Endler G analyzed the data; Kovar FM and Jaindl M wrote the paper.
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Ethics approval: The study was reviewed and approved by the IRB, Medical University Vienna, EK-1042/2011.
Clinical trial registration: The study is registered under NCT02023476 at https://clinicaltrials.gov/ct2/show/NCT02023476?term=hemaclear&rank=1.
Informed consent: All study participants provided informed written consent prior to study enrillment.
Conflict-of-interest: The present paper was supported by different sources: Volunteers honorary in the amount of 3.000 USD was supported by private funds of Kovar FM; HemaClear™ devices were provided by OHK Medical Device, Haifa, Israel. An agreement with representatives auf Zimmer Inc. in Austria failed, for providing an A.T.S.® 3000 Automatic tourniquet system, as used by McEwen. We herby certify that there are no other actual or potential conflicts of interest for the authors of the present paper. There are no other undisclosed financial or personal relationships with other people or organizations that could inappropriately influence our work. All other authors do not have a conflict of interest.
Data sharing: Technical appendix, statistical code, and dataset available from the corresponding author.

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Abstract

AIM: To assess the clinical effects and the morphological grade of nerve compression.

METHODS: In a prospective single-center randomized, open study we assessed the clinical effects and the morphological grade of nerve compression during 20 min of either a silicon ring (group A) or pneumatic tourniquet (group B) placement variantly on the upper non-dominant limb in 14 healthy human volunteers. Before and during compression, the median and radial nerves were visualized in both groups by 3 Tesla MR imaging, using high resolutional (2.5 mm slice thickness) axial T2-weighted sequences.

RESULTS: In group A, Visual analog pain scale was 5.4 ± 2.2 compared to results of group B, 2.9 ± 2.5, showing a significant difference (P = 0.028). FPS levels in group A were 2.6 ± 0.9 compared to levels

in group B 1.6 ± 1, showing a significant difference (P = 0.039). Results related to measureable effect on median and radial nerve function were equal in both groups. No undue pressure signs on the skin, redness or nerve damage occurred in either group. There was no significant difference in the diameters of the nerves without and under compression in either group on T2 weighted images.

CONCLUSION: Based on our results, no differences between narrow and wide tourniquets were identified. Silicon ring tourniquets can be regarded as safe for short time application.

Key words: Nerve compression; Magnetic resnane iamge; Wide tourniquet; Narrow tourniquet; Human volunteers

Core tip: Nerve injury is a serious potential complication associated with clinical use of tourniquets in surgery. In a prospective single-center randomized, open study we assessed the clinical effects and the morphological grade of nerve compression during 20 min of either a silicon ring (group A) or pneumatic tourniquet (group B) placement variantly on the upper non-dominant limb, visualized by 3 Tesla magnetic resonance imaging, using high resolutional (2.5 mm slice thickness) axial T2-weighted sequences. Based on our results, no differences between narrow and wide tourniquets were identified. Silicon ring tourniquets can be regarded as safe for short time application.

Kovar FM, Jaindl M, Oberleitner G, Endler G, Breitenseher J, Prayer D, Kasprian G, Kutscha-Lissberg F. Nerve compression and pain in human volunteers with narrow *vs* wide tourniquets. *World J Orthop* 2015; 6(4): 394-399 Available from: URL: http://www.wjgnet.com/2218-5836/full/v6/i4/394.htm DOI: http://dx.doi.org/10.5312/wjo.v6.i4.394

INTRODUCTION

Nerve injury is a serious complication, associated with the clinical use of tourniquets, and influencing profoundly orthopedic surgery[1-3]. A bloodless operative field is considered mandatory for most surgical procedures on the upper and lower extremity, allowing surgical procedures to be performed with improved precision, safety and speed[1-7].

The invention by McEwen in 1981, a modern microcomputer-based tourniquet system can be seen as a modified version of this basic idea of Cushing[2]. Following a different approach, OHK Medical Devices Inc. launched an elastic rubber ring with a stockinet and gained common approval.

Several studies related to tourniquet use have investigated various complications, the most frequent one being nerve palsy[1-4,6,8,9]. In the current literature, the impact of the width of a tourniquet and as a consequence the pressure expansion, is discussed controversial[3,10-14].

To the best of our knowledge, none of them used magnetic resnane iamge (MRI) as a visualization model, in healthy human volunteers, wearing two different tourniquet devices. Therefore we conducted the present study, to investigate differences between HemaClear™ blood free device and a standard pneumatic tourniquet.

MATERIALS AND METHODS

We investigated 16 upper extremities in 16 volunteers during an eight months period in an IRB approved (EK 1042/2011) single centre randomized prospective, controlled study, by the standards of International Conference of Harmonisation and Good Clinical Practice. (Registered: NCT02023476) All individuals gave written consent to participate in the study. Two individuals, one male and one female, had to be exclude after study Day 1, due to the fact of violating the inclusion criteria between Day 1 and Day 2. In the remaining group of 14 volunteers, mean age was 24.3 years (range 22 to 28), 9 (64%) were males and 5 (36%) were females. All remaining individuals finished the study without nerve impairment or skin lesion.

Volunteers who meet the inclusion criteria and provide written informed consent were included. Main criteria for inclusion were the following: self defined Caucasian, clinically healthy, body mass index (BMI) of $\leqslant$ 30, a systolic arterial blood pressure $\leqslant$ 190 mmHg, no rash or dermatologic condition or tattoos which may interfere with the placement site and no neurovascular impairment or previous surgery on the investigated limb. Self-defined Caucasian was implemented to guarantee an equal evaluation of possible skin lesions.

HemaClear™ of OHK Medical Device (group A)

HemaClear™ consists of a silicon ring wrapped in a stockinet sleeve and pull straps (Figure 1). It performs three functions-blood removal (exsanguinations), arterial flow occlusion, and placement of sterile stockinet. The ring is placed on the extremity and then straps are pulled proximally. The silicone ring rolls up the limb and the stockinet sleeve unfolds onto the limb. During the rolling up process, the ring exerts pressure and squeezes the blood away from the limb. Pressure is exercised by only a single silicon ring, and therefore the profile is very small.

Standard pneumatic tourniquet (group B)

As standard pneumatic tourniquet system, we used the following setting: an inflatable cuff (Tourniquet Cuff REF 20-64-711, 35 cm/14 in., VBM Medical Technique), with a width of 8 cm/6.5 in. and an air compression unit (fine pressure actuator tube connector 645-1708.2, Synthes REF 520.95) using the inner hospital 5 bar pipeline system for inflating the tourniquet. Due to

Figure 1 Hemaclear consists of a silicon ring wrapped in a stockinet sleeve and pull straps.

the containing metal of the air compression unit, we connected it with the tourniquet in the MRI room, using a flexible tube (PVC Extension Tubing, VBM Medical Technique) of 20 meter/187.4 in. length.

Defining the appropriate inflating pressure of the pneumatic tourniquet: In a similar approach like McEwen[2], we detected the Limb Occlusion Pressure (LOP) with a handheld dopplers device (MD2/SD2, Dopplex® High Sensitivity Pocket Dopplers, Huntleigh Healthcare Limited, Cardiff United Kingdom). RTP (Recommended tissue pressure) feature was calculated as following: LOP + 40 mmHg if LOP < 130 mmHg, LOP + 60 mmHg if LOP 131-190 mmHg, and LOP + 80 mmHg if LOP > 190 mmHg. Calculated RTP was the pressure, used for inflating the pneumatic tourniquet.

MRI protocol

Subjects were examined by a clinical high field (3 Tesla) MR system (Philips Achieva, Best, The Netherlands) in supine position. A flex medium surface coil was consistently placed on the non-dominant upper arm, with the tourniquet centering the field of view. Before, 5 min after application of the tourniquet a T2-TSE (turbo spin-echo sequence: TR (repetition time) 4808 ms. TE (echo time) 90 ms, flip angle 90°, FOV 130 mm × 164 mm, acquisition data matrix 260 × 316, reconstruction image resolution 0.2 mm, slice thickness 2.5 mm, NEX 1; The total imaging was 6:25 min) was acquired in an axial plane, covering the region 3.7 proximally and 4.8 cm distally to the tourniquet and 6.7 proximally and 7 cm distally to the narrow tourniquet position.

Practical setting

The study was divided in three parts, screening visit (SV), study day 1 (Day 1) and study day 2 (Day 2). During SV, a physical examination, evaluation of the inclusion criteria and the device randomization (Group A-HemaClear™; Group B- standard pneumatic tourniquet) with a blinded envelope were performed. On Day 1, blood pressure, visual analog pain scale (VAS) and faces pain scale (FPS) baseline scores and pictures of the upper limb were performed. According to the randomization process to groups were formed for further proceedings.

In group A, the volunteer was placed in a supine position on the MRI, and the baseline MRI sequence was performed. Before starting the T2 sequence, the HemaClear™ device was placed on the non-dominant upper arm, using the same measurements criteria for exact placement. After finishing the T2 sequence, the tourniquet was removed immediately.

In group B, LOP and RTP detection were performed in a sitting position, and the volunteer was placed in a supine position on the MRI. Than, bating of three layers, and the standard pneumatic tourniquet were placed on the non-dominant upper arm. The exact position for the placement site was half the way of a drawn line between the greater tubercle and the lateral supercondylar ridge. A baseline MRI sequence was performed, and inflating to the calculated RTP was conducted, seconds before starting the T2 sequence, guaranteeing a full inflated tourniquet. After finishing the T2 sequence, the tourniquet was removed immediately.

Subsequently, the following procedures were performed in both groups: detecting the grade of muscle strength for the compressed upper extremity on a scale from 5 to 0, and evaluating VAS and FPS. Pictures of the device placement site were taken (iPhone 4, Apple Inc., Cupertiono, CA, United States) after the volunteer had left the MRI room. During a final check up, 30 min post removal, before the volunteer left the study site the following parameters were evaluated: blood pressure, VAS and FPS levels.

Day 2 was performed at least seven days after Day 1, but no longer than 2 wk after Day 1, with switched groups for each volunteer. At the end of Day 2 the volunteer was asked which device was more painful after all.

MRI measurements

The maximum and minimum diameter of the median and the radial nerve and the brachial artery were measured on three axial planes in the T2 weighted sequences: the plane of the compression by the HemaClear™, 4 cm proximal and 4 cm distal to that point. Since the radial nerve divides in several fascicles at the spiral groove, the maximum diameter could not be measured at this point. The cross sectional area of the nerves was calculated assuming that the shape of the nerve resembles an ellipse.

Statistical analysis

For statistical analysis we used the SPSS 16.0 software package (SPSS, Chicago, Ill., United States). Mean values and standard error of the mean are given unless otherwise indicated for continuous variables. Discrete data are presented as counts and percentages. To

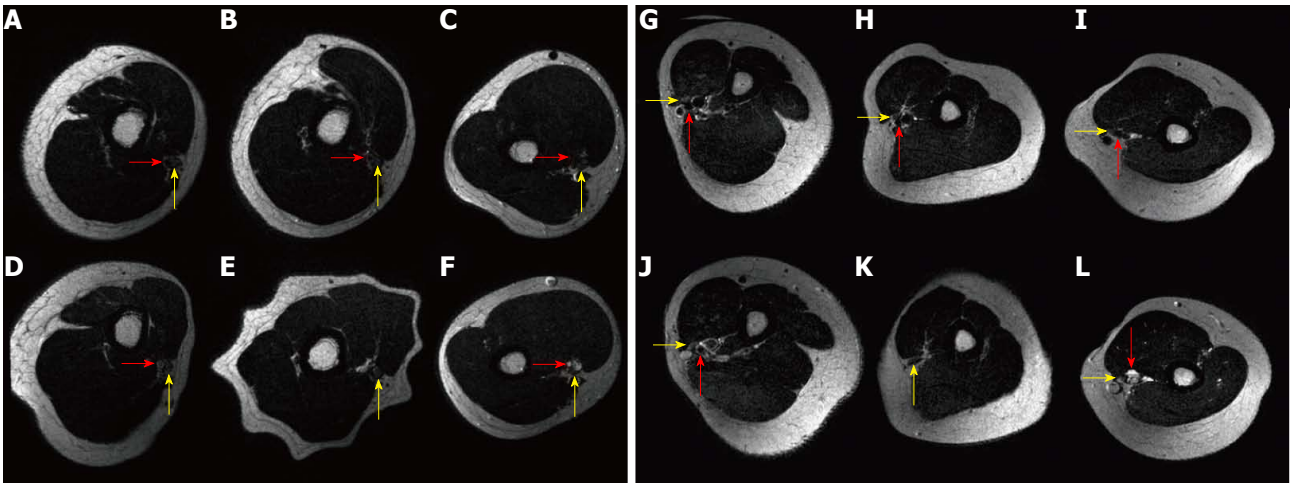

Figure 2 Red arrow indicates brachial artery, yellow arrow indicates median nerve. A-F: MRI imaging; A-C: Baseline imaging proximal, sulcus and distal humeral arm; D-F: Compression with the broad tourniquet proximal, sulcus and distal humeral arm; G-L: MRI imaging; G-I: Baseline imaging proximal, sulcus and distal humeral arm; J-L: Compression with the narrow tourniquet proximal, sulcus and distal humeral arm. MRI: Magnetic resonance imaging.

Table 1 Mean values of median nerve in mm without compression (NORM), with the Hemaclear device (HEM) and with a pneumatique tourniquet (PNEU)

	PROX	SULC	DIST
MIN[1]			
NORM	0.287	0.25	0.254
HEM	0.281	0.234	0.244
PNEU	0.275	0.253	0.285
MAX[1]			
NORM	0.396	0.403	0.376
HEM	0.384	0.415	0.381
PNEU	0.389	0.386	0.368

[1]All resilts are mean values in mm.

compare the two study groups we used a dependent sample student's *t*-test. A two-tailed *P* value less than 0.05 was considered statistically significant. Statistics was performed by GE, a biomedical statistican.

RESULTS

Fourteen subjects, nine males and five females with complete data participated in the present study. As a result we were able to acquire data from 14 placements of each device. For the HemaClear™, we used six Pink and eight Yellow devices. In the A group we used the same device in all patients, adapted to the circumference of the upper arm.

MRI measurements

Levels for compression of the median and radial nerve where almost similar in both groups (Figure 2A and B, Table 1). The brachial artery was compressed in all individuals by both tourniquets as a sign of adequate vessel compression. In one patient the compression of the HemaClear™ was 2 cm proximal of the beginning of the spiral groove, in all other volunteers the radial nerve was passing the spiral groove at the point of compression.

We could not detect a significant difference concerning the diameters or of the calculated area of the nerves between no compression, compression by HemaClear ™ and the standard pneumatic tourniquet.

Pain

VAS and FPS levels were evaluated at baseline, immediately after removal of the tourniquet device, and 30 min post removal. VAS and FPS levels at baseline were 0 in all volunteers. In group A, VAS was 5.4 ± 2.2 compared to results of group B, 2.9 ± 2.5, showing a significant difference (P = 0.028). FPS levels in group A were 2.6 ± 0.9 compared to levels in group B 1.6 ± 1, showing a significant difference (P = 0.039). VAS and FPS levels, post removal, were 1 and 1 in only two volunteers, both male and occurring after Day 1 with the HemaClear™ device.

Only two out of 14 volunteers described independent the pneumatic tourniquet as more painful. One volunteer was male, one female, both experienced the HemaClear™ device on Day 2. The reasons, given by the study subjects, why the HemaClear™ device was more painful were as following: the roll on process was described as uncomfortable, but the main pain was caused by the placement (silicon ring) at the upper arm, which was felt as a pulsing or throbbing sensation.

Nerve impairment

Levels (manual force grade) for both nerves were identical within the same group, but there was a slight difference between group A 4.5 ± 1.4 and group B 4.3 ± 1.1 (P = 0.098).

Application

Placement of the silicon ring device was more practicable, because of the simple roll up whereas for the broad pneumatic tourniquet, placement of the bating, LOP/RTP detection, and finally inflating was mandatory.

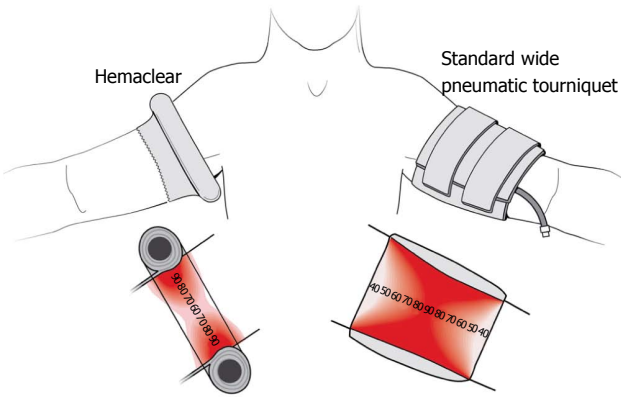

Figure 3 Detailed illustration of the different models of pressure application (reprinted with permission).

No other data than mentioned are available.

DISCUSSION

The primary aim of the present study was to investigate the differences between HemaClear™ blood free device and standard pneumatic tourniquet, concerning possible nerve damage in healthy volunteers. We also investigated the pain scale during compression with both devices.

Our first hypothesis that a narrow silicone ring causes more nerve compression compared to a wide tourniquet was disapproved. Our second hypothesis that a narrow silicone ring causes more pain compared to a wide tourniquet was approved.

The most gravid article concerning this topic, by Noordin *et al*[14], defaming the use of a HemaClear™ similar device, caused some controversial response. The substituted opinion by McEwen and his study group is in sharp contrast to findings of other various trials, and may be influenced by commercial interests[1,2,4,13-16].

A study of female baboons suggests that the damage to the nerve fibers is a direct result of the applied pressure, and not a consequence of secondary ischemia[17]. The same paper also showed that the pressure gradient was higher at the edges rather than in the middle of the tourniquet, a finding that also supports the idea of a narrow tourniquet[17]. Another trial concluded that a wider cuff would not be intrinsically safer than a regular cuff, a result that is contrary to Crenshaw's findings[18].

The relationship between tourniquet cuff width and the pressure that, last on the surface and the layers underneath it, is the core point in the current discussion. The fundamental difference is the technique, attaining the pressure and as a direct consequence fulfill the goal of exsanguination. In a narrow cuff the pressure is substantially diminished towards the middle of the limb, with a drop of 45%-55%, leading to a small gradients at the cuff's end and a short length of vessels and nerves under compression[18]. In contrast, in a wider cuff the nerves and vessels are exposed to a relatively high compression stress, because the high pressure is transmitted across the limb at the same level as in the cuff and leads to high shear forces at the edges[18]. The wide tourniquet applies the pressure over a wide surface, resulting in shear forces at both edges, squeezing the nerve at two points in an unnatural way, and not as suggested by many users over the whole length of the tourniquet[18].

Behind the HemaClear™ device, is a different model of pressure application, which is at the beginning confusing and controversial discussed in the literature[14] (Figure 3).

Contrary to Noordin's suggestions, narrow tourniquets can look back on a broad use in surgical settings in civilian hospitals and their safe use should not be reduced to military indications only[1,3,19]. Depending on the placement of the cuff, the occurrence of nerve related injuries has been experienced by 21%-28% of surgeons[5]. An experimental study in 20 healthy volunteers concluded that wider cuffs result in more severe changes in the nerve[3].

The experience of a novel elastic tourniquet in 43 pediatric patients was published, concluding that it is safe and valuable in clinical practice[1]. Another trial reports, that application of a silicon ring device is practical, provides bloodless field for a certain time, and does not increase the complication rate related with the pressure applied to underlying tissues, but is not appropriate for long surgical procedures[20].

Limitations of the study

First is the small number of volunteers (n = 16), due to the fact of limited financial and logistical feasibility. The limited number of tourniquet time is accidental by the local ethics commission, due to their concerns of pain and soft tissue damage. For ethical reasons, we were not allowed to use anesthesia. The time interval of 20 min of compression in this study can not be compared to a clinical setting with compression times over 60 min and longer. We also have to admit that we did not investigated the possible influence of secondary ischemic factors on our reported results.

Limitations of both devices

The HemaClear™ occupies only 2 cm on the limb after application and enables a wider limb surface compared to regular pneumatic tourniquets. But there are also disadvantages like the constant pressure, performed by the silicon ring, which cannot be changed during surgery. The use in open or dislocated fractures has to be seen limited because of the roll up mechanism and in limbs with applied external fixation devices it cannot be used.

In contrast to those findings, the broad pneumatic tourniquet can be used in open and dislocated fractures because of its different application technique. Inflation and deflation during surgery are possible and enable longer surgical procedures, because reperfusion is possible after 2 h. Despite the mentioned advantages,

the main disadvantages are the large surface the tourniquet occupies on the limb, the additional console to operate the tourniquet and to detect LOP and RTP.

To the best of our knowledge we are the first to have visualized nerve compression with MRI using two different devices of surgical tourniquets *in vivo* in healthy human volunteers. Application of both devices resulted in a similar degree of vascular- and nerve compression. There were no indirect MR imaging signs of nerve compression (change in nerve cross sectional area, increased T2-weighted signal intensity) noted. No patient related complications where observed.

ACKNOWLEDGMENTS

I want to give eminent credit for my parents and friends for their unlimited support for my research and when the sun was not shining. I also want to say thank you to the staff of the Department of Radiology for their easygoing collaboration and workflow during the study period. Special thanks to MJ and GK for their support, and to all volunteers, making this study possible.

COMMENTS

Background

Nerve injury is a serious potential complication associated with clinical use of tourniquets in surgery. Several studies related to tourniquet use have investigated various complications, the most frequent one being nerve palsy. In the current literature, the impact of the width of a tourniquet and as a consequence the pressure expansion, is discussed controversial.

Research frontiers

The invention by McEwen in 1981, a modern microcomputer-based tourniquet system can be seen as a modified version of this basic idea of Cushing. Following a different approach, OHK Medical Devices Inc. launched an elastic rubber ring with a stockinet and gained common approval.

Innovations and breakthroughs

Based on these results, no differences between narrow and wide tourniquets were identified.

Applications

Silicon ring tourniquets can be regarded as safe for short time application.

Terminology

HemaClear™ consists of a silicon ring wrapped in a stockinet sleeve and pull straps.

Peer-review

The authors describe a valuable study which is well conducted and gives important clinical conclusions which may influence surgical and ethical conduct of interested surgical specialties.

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Upper Extremity Nerve Function and Pain in Human Volunteers with Narrow versus Wide Tourniquets

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ABSTRACT: Nerve injury is a serious potential complication associated with clinical use of tourniquets during surgery. A novel narrow, single-use silicon ring tourniquet has been introduced, which may cause less nerve compression and provide a larger field of surgical exposure than standard wide tourniquets. We investigated both types of tourniquets in the non-dominant proximal upper arm of 15 healthy human volunteers. Pain and neurological effects were assessed during 15 minute trials with each tourniquet applied 1 week apart without anesthesia according to the manufacturers' recommendations. Median nerve function was studied using the pressure-specified sensory device, an instrumented two-point discriminator, and pain was assessed by two validated instruments. Skin sores, redness, nerve damage, or neurological complications did not occur in either group. Subjects reported more pain with the narrow tourniquet; however, measurable effect on median nerve function was the same in both groups. Tourniquet application with the narrow device was more efficient, the device was easier to use, and larger surgical field exposure was obtained. We conclude that the sensory deficit with the use of narrow tourniquets is not greater than that observed with pneumatic/wide tourniquets.

KEY WORDS: upper extremity surgery, tourniquet, pain, nerve function, silicone ring tourniquet, decreased bleeding, narrow versus wide

I. INTRODUCTION

A bloodless operative field for extremity surgery allows surgery to be performed with improved precision, safety, and speed and there is therefore a need for tourniquets during these procedures.[1–3] The first recorded use of tourniquet-like devices dates back to the second century AD.[4] In 1628, Jean Louis Petit designed the first "tourniquet" for surgery. In 1864, Esmarch developed a rubber bandage for the same purpose.[5–7] Cushing then invented the first modern pneumatic tourniquet in 1904. McEwen[8] updated the standard pneumatic tourniquet in 1981 by adding a microcomputer control system to regulate the pressure based on a measured arterial pressure. A novel tourniquet with a silicone ring and a rolled stockinet that both exsanguinates and applies compression was developed by OHK Medical Devices (Haifa, Israel) called the HemaClear®, which was known previously as the S-MART™ device (Fig. 1).[1,9] However, as first described by Volkmann in 1881, all tourniquets are not without potential complications and, of these, the most common is limb paralysis due to nerve injury.[6]

Nerve injury is a serious complication associated with clinical use of tourniquets, with severe consequences for the patient.[1,2,8,10,11] Furthermore, tourniquet-related risk for venous embolism has also been studied.[12–14] However, the most frequently investigated complication of tourniquet use is nerve palsy.[4,6,8,15–25] Moreover, it is easy to identify nerve palsy after tourniquet application, but the exact cause is unclear. It may be caused by nerve ischemia or physical deformation from direct tourniquet pressure.[26,27] In addition, multiple studies have investigated the relationship between tourniquet width and pressure required to terminate blood flow.[2,25,28–30] Interestingly, Noordin et al.[29] reported

FIG. 1: Hemaclear™ device half stripped to show the silicon ring underneath the stockinet. The measuring tape is used to size the device to the extremity (reprinted with permission from LifeBridge Health).

recently that a smaller-diameter cuff requires more pressure to cease blood flow, causing a higher risk of neurological injury.

The purpose of the present study was to investigate the differences between the narrow HemaClear® tourniquet system and a standard wide pneumatic tourniquet, the Zimmer A.T.S.® tourniquet system, especially with regard to possible nerve damage and pain level in healthy volunteers.

II. METHODS

A. Patients

After obtaining proper institutional review board approval in our institution, a total of 15 healthy volunteers (15 upper extremities) were included in our study. Volunteers who met the inclusion criteria and agreed to an informed consent were enrolled. The inclusion criteria were self-defined Caucasian, age between 18 and 45 years, clinically healthy, body mass index less than 30 kg/m^2, systolic blood pressure less than 190 mmHg, no rash or dermatologic condition or tattoos that could interfere with the placement site, and no neurovascular impairment. The study population was restricted to Caucasians to enable an assessment of device-related erythema or skin lesions.

Fifteen subjects, eight male and seven female, were entered and completed enrollment in the study. Application of both devices was performed according to the manufacturers' recommendations without anesthesia.

B. HemaClear® OHK Tourniquet

HemaClear, a U.S. Food and Drug Administration (FDA)-approved tourniquet, is a silicon ring wrapped in a stockinet sleeve with pull straps (Fig. 1). The device size is selected according to the circumference of the limb at the occlusion site. It performs three functions: blood removal (exsanguination), arterial flow occlusion, and placement of sterile stockinet.[31] The HemaClear® is placed on the fingers and its straps are pulled proximally. The silicone ring rolls up the limb as the stockinet sleeve unrolls. During the rolling up process, the silicon ring exerts pressure and exsanguinates, the application takes less than

30 seconds. The amount of pressure exerted is a function of the silicon ring and the thickness of the stockinet layers left on the silicone ring at the end of the roll-up procedure. The narrow ring width applies pressure over a smaller length of the nerves and other soft tissues. Theoretically, the pressure decreases beyond the proximal and distal boundaries of any tourniquet device, creating isobars with a pressure gradient at the two edges. In the narrow HemaClear® tourniquet, the isobars from either side overlap, causing less pressure in the central, deep section where the compression of the artery and nerve takes place. Skin pressure may be high, but the delicate neurovascular structures are subjected to lesser pressure, and over a shorter distance, with theoretically less damage potential.

C. Zimmer A.T.S.® 3000 Tourniquet

The A.T.S.® 3000 is an automatic wide tourniquet system with a limb occlusion pressure (LOP) feature. It is the latest innovation in tourniquet technology and has FDA approval. It was invented by McEwen[8] and the basic function has been described in several clinical trials and publications.[29] The main difference between this and standard pneumatic tourniquets is the LOP and the recommended tissue pressure (RTP) feature. These parameters are designed to optimize the pressure force on the tourniquet for each individual patient. The LOP is detected before inflating the tourniquet. The RTP is the LOP plus an additional amount of pressure to guarantee arterial flow occlusion and a blood free field. This theoretically uses the lowest effective pressure to occlude the limb, thus minimizing neurovascular damage.

D. Pressure-Specified Sensory Device (PSSD)

Quantitative sensory testing was performed with the use of a PSSD (NK Biotechnical, Minneapolis, MN; Fig. 2),[32] a computer-based, FDA-cleared device that functions as a quantitative two-point discriminator to determine moving or noncontinuous contact (Fig. 2). It is noninvasive and painless. Neurosensory testing studies with the PSSD have suggested that this device offers an effective way to identify sensory changes.[11,32] PSSD testing was conducted by two board-certified physical therapists well experienced in its use.

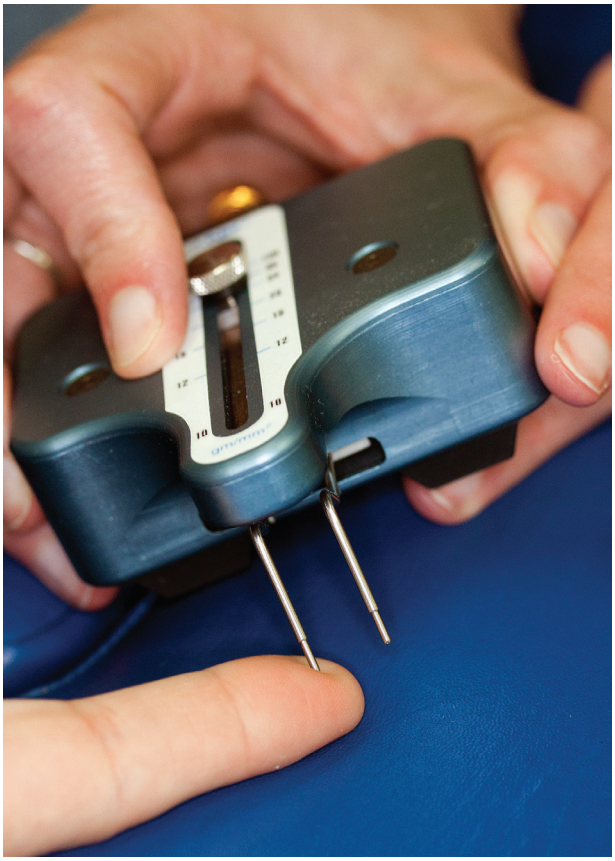

FIG. 2: The PSSD being used on the finger of a study subject to evaluate the possible influence on nerve function impairment (reprinted with permission from LifeBridge Health).

E. Practical Setting

Subjects were instructed that both tourniquets were going to be applied to the same arm (non-dominant) 1 week apart and they were randomized to receive each in a different order. During the initial screening visit, physical examination, evaluation of the inclusion criteria, and randomization to either one or another tourniquet were performed. On day one, a supine blood pressure measurement and a PSSD baseline were performed before the tourniquet was

applied. For patients who were randomized to the HemaClear® tourniquet, a roll-up technique was performed and the stockinet was cut off to detect the exsanguination. For the Zimmer A.T.S.® cohort, three layers of padding were applied before the tourniquet was placed. After calibration, LOP and RTP were detected. The recommended RTP was used and the tourniquet was inflated after exsanguination with an Esmarch bandage.

In both cohorts, the PSSD measurement and pain were evaluated at specific previously defined time points. For PSSD, the time points were baseline, 3, 6, 9, 15, and 25 minutes after device placement. The final PSSD measurement was taken 10 minutes after removal of the device to ensure a return to baseline. Pain evaluation was performed using the visual analog scale for detecting the pain at baseline, 2, 5, 8, 14, and 24 minutes after device placement.

The tourniquet devices were removed after 15 minutes of application. After a recovery period of 5 minutes, blood pressure measurements and neurological examination of both upper extremities were performed to ensure that there was no difference. Study subjects were observed for 30 minutes after the last procedure. This procedure was then repeated 1 week later with the other type of tourniquet.

F. Statistics

All statistical analyses we performed with the aid of statistical software (SPSS version 22.0, IBM, Armonk, NY). Mean values were reported unless otherwise indicated for continuous variables. All discrete data are presented as counts and percentages. The two groups were compared using a two-tailed *t* test and $p < 0.05$ was considered statistically significant.

III. RESULTS

A. PSSD

None of the collected PSSD values showed statistical significance when correlated to group affiliation, gender, or age ($p > 0.05$). The trend in collected values can be seen as comparable between both groups and did not show significant differences, as illustrated in Figure 3. In 10 out of 180 measurements, a result could not be detected, indicating that the subjects were numb and unable to discriminate a two-point sensation. This occurred while using the HemaClear® in 6 instances, 1 at the 9-minute mark and 5 at the 15-minute mark. When using the Zimmer A.T.S.® tourniquet, this occurred 4 times, all during the 15-minute mark.

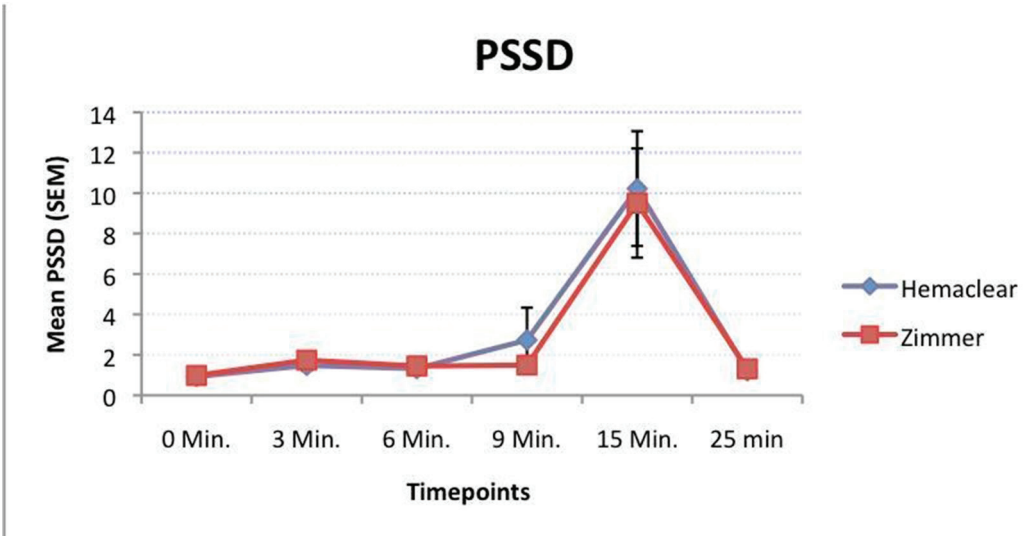

FIG. 3: Measured PSSD values (gm/mm^2) and the time course for both devices (reprinted with permission from LifeBridge Health).

B. Pain

There was a steady progression of pain intensity with a peak after 14 minutes in all study subjects in both groups. This finding reached significance at the following time points: 2, 5, 8, and 14. In addition, 14 subjects reported independently that the silicone ring tourniquet was more painful than the wide pneumatic tourniquet. They stated that the application process was uncomfortable and described it as a pulsing or throbbing sensation. However, 10 minutes after the device was removed, no significant difference was found between the cohorts ($p = 0.84$; Table 1).

IV. DISCUSSION

The primary aim of the present study was to investigate the differences between the HemaClear™ narrow tourniquet and the Zimmer A.T.S.® wide tourniquet system regarding possible nerve effect in healthy volunteers. Pain was also assessed at defined intervals during and after compression with both devices. Our first hypothesis, that a narrow silicone ring causes less or equal pain compared with a wide tourniquet, was disproved; however, when these devices are used clinically, the patients will be under anesthesia. The second hypothesis, that there is no difference in the sensory impairment between the two devices, was confirmed. However, both tested devices are the two most recent and controversial products on the market.[1,2,8,28,29,33–37]

This study had several limitations, one of which was that the tourniquets were only applied for 15 minutes. However, because patients were not anesthetized, longer exposure times may have been too painful for the test subjects. In addition, the small patient population of 15 patients limited the power of the study. However, due to the obtained results, we believe that performing similar studies in larger cohorts will have similar outcomes. All patients were healthy volunteers in which a tourniquet was applied without a surgical insult, controlled hypotension, or any other stress that can occur in the surgical setting, which may alter our results.

An anatomical change in peripheral nerves compressed by a pneumatic tourniquet was investigated by Ochoa et al.[17] In a study of female baboons, the anatomical features and distribution of lesions suggested that the damage to the nerve fibers was a direct result of the applied pressure, not a consequence of secondary ischemia.[38] The study also showed a higher pressure gradient at the edges rather than in the middle of the tourniquet, supporting the idea of a narrow tourniquet.[38] Hodgson stated that a wider cuff would not be intrinsically safer than a regular cuff, a result that is contrary to Crenshaw's findings.[39,40]

The relationship between tourniquet cuff width and the surface pressure versus deep pressure is germane to this discussion. The fundamental difference between the two devices is the way that they attain the pressure and fulfill the goal of

TABLE 1: Differences in VAS reported pain by device

Measurement Time Point	VAS (Silicone Ring)	VAS (Wide Pneumatic)	*p*-Value
Baseline	0	0	0.99
2 min	3.1	1.8	0.001
5 min	3.5	2.5	0.008
8 min	3.8	2.8	0.002
14 min	4.5	3.8	0.03
24 min (10 min after removal)	0.30	0.30	0.84

Reported pain was significantly higher in the HemaClear® device at the 2, 5, 8, and 14 minute time intervals. Pain was reduced to 0 in both devices 10 minutes after the tourniquet was removed (reprinted with permission from LifeBridge Health).

VAS, visual analog scale.

exsanguination. In a narrow cuff, the pressure is diminished substantially toward the middle of the limb, with a drop of 45–55%, leading to a small gradient at the cuff's distal and proximal ends and only a short length of vessels and nerves being under compression.[39,41] In contrast, in a wider cuff, the nerves and vessels are exposed to a relatively high compression stress because the high pressure is transmitted across the limb at the same level as in the cuff and leads to high sheer forces at the edges.[39,41] This is the main criticism of the pneumatic tourniquet because it leads to increased strain and stress on squeezing the nerve along its length and at its two end points. This is contrary to the suggestion by wide tourniquet manufacturers who claim that the pressure is spread evenly over the entire length of the tourniquet.[39,41] In fact, the pressure (which is force divided by contact area) is the same beneath the entire length of the pneumatic tourniquet so that the contact area is much larger, so the force applied must be much higher than with a narrow tourniquet. The HemaClear™ device uses a different model of pressure application, which was criticized by Noordin et al.[29] The pressure distribution diagrams (Fig. 4) simulating both devices suggest that wider tourniquets might not be safer after all.

Narrow tourniquets may have a broad potential for use that should not be considered only in emergency and military situations.[2,10,42,43] Many investigators have proposed that wider tourniquets may be associated with changes in nerve conduction; of these, a study by Mittal et al. studied different tourniquets in 20 healthy volunteers and concluded that wider cuffs result in more severe changes in nerve conduction.[2] Similarly, Guss and Bhattacharyya found that neural injuries are more common in obese orthopedic patients secondary to increased pressure on contact points and difficulty with safe positioning of the unconscious patient.[44] In these patients, the narrow silicon ring tourniquet may be advantageous and might lead to an increase in safety.

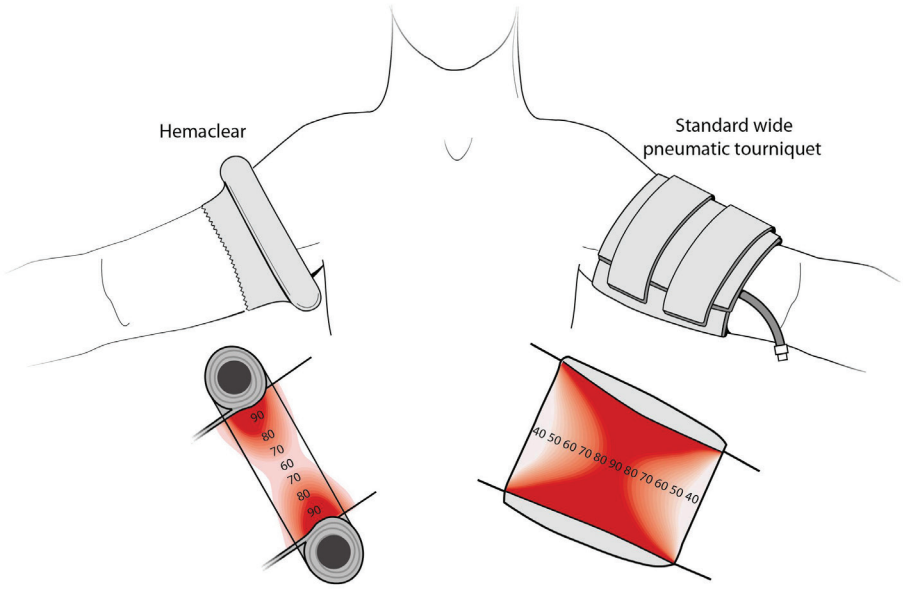

FIG. 4: Diagrammatic representation of the isobars of pressure from a wide versus a narrow tourniquet on the upper limb. Numbers represent the percentage of the pressure at the skin level just beneath the tourniquet/HemaClear™. Note that, with the wide cuff, the tissue pressure throughout the cross-section of the limb is the same as the cuff pressure (reprinted with permission from LifeBridge Health).[9]

In addition, pneumatic tourniquets may be overinflated when being used during surgery. A study by Olivecrona et al.[45] reported that a pressure greater than 225 mmHg was linked to wound complications at the time of discharge in 40 of 47 total knee arthroplasty patients. Similarly, Chalidis et al.[46] found that wider tourniquets, especially when inflated to high pressures (400 mmHg), resulted in skeletal muscle ischemia when studied in rabbits. However, by using silicone ring tourniquets, overinflation problems can be reduced.

Eidelman et al.[1] used the narrow HemaClear® tourniquet in 43 pediatric patients, concluding that it is safe and effective. Similarly, Orbay et al.[47] concluded that application of the silicon ring device is practical, provides a reliable bloodless field, and does not increase the complication rate. However, they are not appropriate for surgical procedures lasting more than 120 minutes.[47] In another study on healthy volunteers, the silicone ring tourniquet had comparatively better pain tolerance and produced less paresthesia over time when applied to the upper arm compared with a pneumatic tourniquet.[48]

A. Limitations of Both Devices

Both devices have advantages and disadvantages. The HemaClear® occupies only about 2 cm on the limb and thus enables a wider surgical area compared with regular pneumatic tourniquets. There are also disadvantages such as the constant pressure applied by the silicon ring, which cannot be modified during surgery. The use of HemaClear® in open or dislocated fractures may be a limiting factor because of the roll-up mechanism. Axial traction has been recommended to avoid buckling at the fracture. The HemaClear® cannot be used in limbs with external fixation devices in place. In contrast to the pneumatic tourniquet, the elastic silicone ring cannot be deflated and re-inflated for reperfusion during surgery. If re-perfusion is needed (e.g. in procedures lasting more than 2 hours), then the HemaClear® must be removed and a new one applied after a 20-minute interval.

In contrast, the broad pneumatic tourniquet can be used in open and dislocated fractures because of its application technique. Inflation and deflation during surgery are possible and enable longer surgical procedures because reperfusion is possible after 2 hours. However, applying a tourniquet without prior thorough exsanguination of the limb carries the risk of intravascular coagulation. These clots may travel to the pulmonary circulation upon tourniquet release and could cross to the systemic circulation if the foramen ovale is patent. The main disadvantages are the large surface the tourniquet occupies on the limb and the required additional control console used to operate the tourniquet and detect LOP and RTP.

B. Conclusion

Our study showed that both tourniquets temporarily impair nerve function, but do not cause any type of long-term nerve damage. Based on our results and the current literature, we suggest that both devices are safe for clinical use. However, both devices have potential advantages and disadvantages. When speed and larger surgical access are of paramount concern, the narrow tourniquet may have clear advantages; however, in longer surgical procedures, wide inflating tourniquets are a better alternative. Further studies with larger cohorts investigating these devices in surgical patients are required.

ACKNOWLEDGMENTS

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Surgical Tourniquets in Orthopaedics

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Complications of Titanium and Stainless Steel Elastic Nail Fixation of Pediatric Femoral Fractures

To The Editor:

I read the article "Complications of Titanium and Stainless Steel Elastic Nail Fixation of Pediatric Femoral Fractures" (2008;90:1305-13), by Wall et al., with great interest. It is an interesting observation, and we are also having the same experience in our practice. I would like to know from your data, which is not mentioned in your article:

1. How many patients had a mismatch in the diameter of the nails (titanium or stainless steel elastic) as seen in Fig. 2-B (the nails are of a different diameter)?

2. Did you use more than two nails in any single patient? We have found that a child who weighs >40 kg or is over eleven years old requires more than two nails; otherwise, malunion may occur.

3. In the case of breakage, was it breakage of both nails (all nails in a single patient) or just one of the nails and was there malunion in that patient? How much did that patient weigh?

4. You mentioned that the stainless steel nails were custom made to order. Which type of steel material was used: 316L or 316LVM? What were the mechanical properties in terms of ultimate tensile strength and percentage of elongation on tensile stress? Which company made the custom-made nails? Can you tell us whether the stainless steel nails were more flexible than the titanium nails supplied by Synthes (Paoli, Pennsylvania)?

Navin N. Thakkar

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E.J. Wall, V. Jain, V. Vora, C. Mehlman, and A.H. Crawford reply:

Thank you for your comments and the questions. Following are our answers to your questions:

1. *How many patients had a mismatch in the diameter of the nail (titanium or stainless steel elastic) as seen in Fig. 2-B (the nails are of a different diameter)?*

Except for the patient illustrated, none of the other fifteen patients with malunion had any mismatching of the nails. Overall, <5% of our patients had mismatched nail placement; the patients were evenly distributed among the stainless steel and titanium groups (three and two, respectively).

2. *Did you use more than two nails in any single patient? We have found that a child who weighs >40 kg or is over eleven years old requires more than two nails; otherwise, malunion may occur.*

We have not used more than two nails in any of our patients in the study except the two cases of implant breakage.

3. *In the case of breakage, was it breakage of both nails (all nails in a single patient) or just one of the nails and was there malunion in that patient? How much did that patient weigh?*

We had two cases of nail breakage. The nail breakage was seen in one patient with titanium nails with a resultant malunion. Only one nail was broken. This was treated by re-reduction and introduction of a third nail. The other patient had stainless steel nails, which did show breakage of one nail without malunion (according to our criteria) and was treated by insertion of a third nail.

4. *You mentioned that the stainless steel nails were custom made to order. Which type of steel material was used: 316L or 316LVM? What were the mechanical properties in terms of ultimate tensile strength and percentage of elongation on tensile stress? Which company made the custom-made nails? Can you tell us whether the stainless steel nails were more flexible than the titanium nails supplied by Synthes (Paoli, Pennsylvania)?*

Howmedica (Rutherford, New Jersey) was the supplier of the stainless steel nails. The company was integrated into Stryker in the year 1999. All of our stainless steel nails were 316LVM. Mechanical testing of these nails was not done for the present study. According to the surgeons' clinical experience, the titanium nail feels more flexible than the stainless steel nail[1-3].

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These letters originally appeared, in slightly different form, on jbjs.org. They are still available on the web site in conjunction with the article to which they refer.

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Surgical Tourniquets in Orthopaedics

To The Editor:

In a recent article, "Surgical Tourniquets in Orthopaedics" (2009;91:2958-67), by Noordin et al., the authors expressed highly critical opinions on the use of "a non-pneumatic elastic ring designed to combine exsanguination and tourniquet functions." The only commercial device that is currently available on the market and fits this description is the S-MART/HemaClear (www.hemaclear.com; www.ohkmed.com) manufactured by OHK Medical Devices (Newark, New Jersey). The authors confidently predict that "uncritical use and acceptance of non-pneumatic tourniquets for extended periods . . . may increase the incidence of

tourniquet-related adverse events, exposing patients and surgical staff in civilian settings to unnecessary risks." Clearly, if these presumed facts are substantiated, it is imperative that the use of the HemaClear is discontinued immediately and indefinitely. However, the excellent safety track record of the S-MART/HemaClear, as outlined below, is far from supporting the allegations by Noordin et al. As the developers, manufacturers, and distributors of HemaClear, we find it necessary to set the record clear on scientific as well as procedural levels.

Before getting into the physics and physiology of the subject matter, it is important to clarify the status of the authors and the motives that they may have had in publishing this supposedly objective scientific manuscript. It is unfortunate that the ethics rules of full disclosure have not been followed by at least one of the authors. Their disclosure statement says: "The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity." This statement is in fact false and misleading: The intensive commercial conflicts of interest of Dr. J.A. McEwen, the founder, inventor, and officer of several commercial entities in the field of pneumatic tourniquets (e.g., www.tourniquet.org), were withheld from *The Journal* and its readers. Clearly, since the S-MART/HemaClear has been gaining rapid popularity among leading orthopaedic surgeons in the United States and elsewhere, there potentially exists a commercial and financial interest in displacing such competition from the market.

It is within this context that we now wish to address some of the scientific aspects of this paper.

First, we address the safety track records of wide pneumatic tourniquets compared with the narrow elastic exsanguination-arterial blocker ring. In a recent paper referenced by the authors, Odinsson and Finsen[1] described the rate of complications using tourniquets in orthopaedic surgery in Norway. The authors found fifteen cases of neurological deficit in more than 60,000 applications of a tourniquet (a prevalence of approximately 24/100,000), the majority of which were in the lower extremity. This prevalence was no better than that reported twenty-five years earlier in Australia (Middleton and Varian[2]) and, in fact, was somewhat worse, despite the use of modern tourniquets (wide tourniquets with controlled pressure and monitoring) and use (i.e., with the pressure adjusted at approximately 100 mm Hg above systolic blood pressure) by the majority of the Norwegian surgeons. It is interesting to note that none of the neurological complications occurred among the 14% of the survey responders who routinely use an Esmarch bandage to control blood flow. Clearly, the one parameter that changed from Australia in 1974 to Norway in 1999 is the cuff width, which may have gotten bigger and may have been a contributing factor to the worsening of the data.

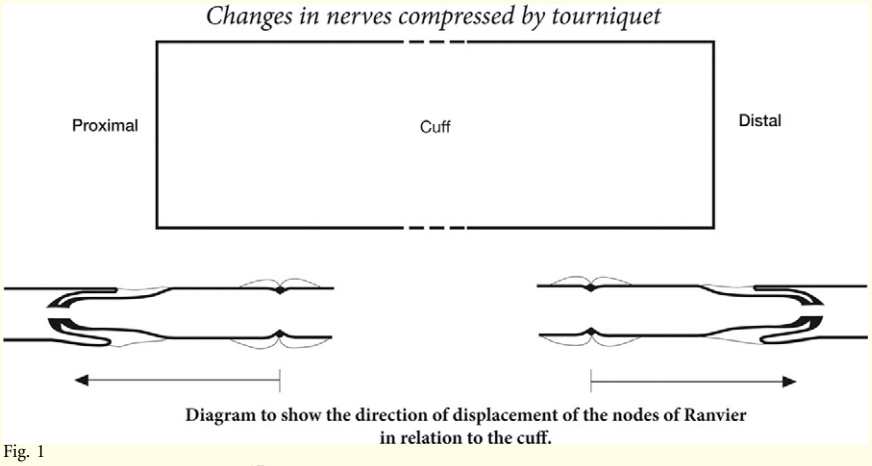

Fig. 1

Diagram from Ochoa et al.[17], showing the axially displaced elongated nerve due to the compression by the wide cuff used in their study. The telescoping damage was found at the proximal and distal edges of the cuff. (Reproduced, with permission, from: Ochoa J, Fowler TJ, Gilliatt RW. Anatomical changes in peripheral nerves compressed by a pneumatic tourniquet. J Anat. 1972;113(Pt 3):433-55.)

These numbers, while not high in and by themselves, are substantially higher than the data on possible nerve involvement available to OHK Medical Devices on the use of its S-MART/HemaClear in more than 150,000 cases worldwide (three cases of nerve involvement for a prevalence of 2/100,000, and all three occurred when the device was used beyond the recommended 120-minute time limit). This is despite the fact that the S-MART/HemaClear elastic ring is much narrower than the wide pneumatic tourniquet promoted by Dr. McEwen and his companies over the last twenty-five years (references related to the Noordin et al. study[3-13]). This obviously superior track record for safety is supported by a number of independent scientific studies that clearly provide the physical and physiological explanation to the observed difference in incidence. Examples include the following:

1. In a recent independent study of nerve conduction during application of narrow and wide pneumatic cuffs in volunteers, Mittal et al.[14] found significantly lesser subclinical, yet physiologically documentable, nerve conduction speed deficits with the narrow cuff than with the wide one.

2. In two independent studies by Drosos et al.[15] and by Mohan et al.[16], the tolerance of volunteers to the placement of a pneumatic tourniquet and the S-MART/HemaClear showed longer endurance with the S-MART/HemaClear, with a significant difference in the study by Mohan et al.

3. A study of the effects of a wide tourniquet on neuronal damage in experimental animals by Ochoa et al.[17], in 1972, revealed the nature of tourniquet-induced nerve injury. They clearly showed that axial displacement (elongation) of compressed nerves beneath a pressurized wide tourniquet causes the transmission disruption because of telescoping ("invagination") of the nerve into itself at the nodes of Ranvier near the edges of the tourniquet (Fig. 1). The contribution of the cuff width to the damage was clearly stated by Ochoa et al. in the Discussion section of their paper as shown in Figure 2.

4. In another independent study, published in 1993, in *Biomedical Instrumentation and Technology,* Hodgson[18] concluded:

Explanation by Ochoa et al.

"Why are the lesions concentrated under the edges of the cuff? This could be explained by the pressure gradient in the tissues between the parts under the cuff and those beyond its edge. With the relatively wide cuff we have used, the gradient would be maximal under the edges of the cuff and least under its centre. Without such a gradient one would not expect axoplasmic movement or displacement of the nodes of Ranvier to occur, even if the absolute pressure in the tissues were high."

Fig. 2

Excerpt from the discussion in the study by Ochoa et al.[17], in which the direct contribution of the cuff width is emphasized.

"Use of a wider cuff in and of itself will not reduce axial strain, so if the hypothesis is correct, a wider cuff would not be intrinsically safer than a regular cuff, a result that is contrary to current opinion."

Thus, there is a strong and well-documented body of evidence that is independent from any commercial interests to show that narrow tourniquets are actually better than wide pneumatic tourniquet cuffs. In fact, the evidence in support of using a wide cuff, outside of Dr. McEwen's own publications, is scant or nonexistent.

Second, we address the question: What is happening inside the limb when a tourniquet is applied? Pressure. It is rather regrettable that the authors failed to comprehend the fundamental aspects of the mechanics of tissue compression beneath surgical tourniquets (pneumatic or elastic ring). The first key parameter in preventing damage to the tissues *inside* the limb (e.g., nerves and blood vessels) is the pressure inside the limb rather than at the skin surface, as described by Noordin et al. in their Figure 5. In fact, in order to stop the arterial blood flow into a limb, all that is needed is to compress the artery over a few millimeters of its length by a pressure applied just outside the artery that is a few millimeters of mercury higher than the highest fluctuation of systolic blood pressure, e.g., 150 mm Hg if the patient's mean systolic blood pressure is 130 mm Hg.

When a wide tourniquet is used, the pressures outside the artery and the nerve are the same as those at the skin surface (i.e., approximately 100 mm Hg higher than the systolic blood pressure). This has to do with the fact that the pressure field (distribution) beneath a wide cuff is uniform, except toward the margins of the cuff. When applying the narrow cuff or the HemaClear elastic ring, the skin surface pressure dissipates when transmitted through the soft tissues (skin, fat layer, and muscle) to the level of the artery and the nerve (i.e., radial pressure gradient), so that even if the skin-surface pressure is high, the pressure at the nerve level is quite low. Actually, in most patients, the skin pressure is around 250 mm Hg when the HemaClear 40 is used on the arm and 300 to 350 mm Hg when the HemaClear 60 and HemaClear-90-Black and White are applied to the thigh (see HemaClear pressure charts at www.hemaclear.com) and not as illustrated in Figure 5 in Noordin et al.

Third, we address the pressure gradient. The second most important parameter with respect to nerve damage is the axial pressure gradients at the edges of the tourniquet. There is an across-the-board agreement that the higher this axial gradient at the level of the nerve, the higher the risk for shear stress and telescoping injury to the axons as documented by Ochoa et al.[17]. However, the notion that narrower cuffs and rings exert higher axial gradients than wide cuffs (as alluded to in the hypothetical graph shown in Figure 5 of Noordin et al.) is simply not true. In fact, the experimental data to date have

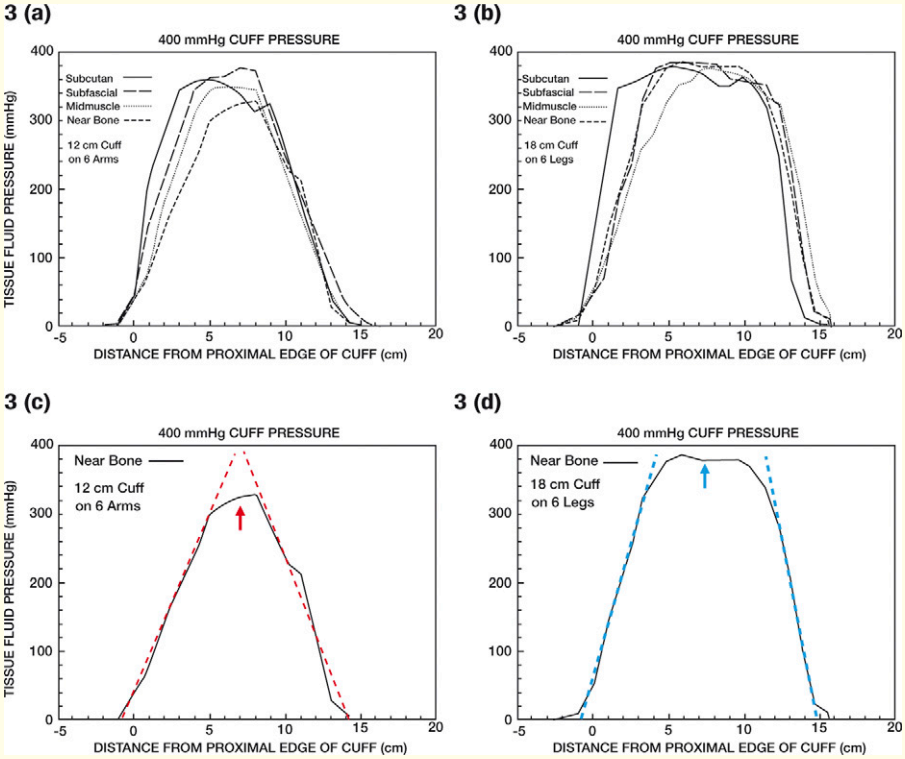

Fig. 3

Original data from Crenshaw et al.[19], showing the pressures measured inside a cadaver limb beneath a narrow (a and c) and wide (b and d) pneumatic tourniquet. Panels *a* and *b* are copies of the original figures. Panels *c* and *d* show only the corresponding ''Near Bone'' (innermost) pressure profiles with superimposed lines to indicate the steeper axial pressure gradient with the wide cuff. Arrows indicate that the peak pressure inside the limb is lower with the narrow cuff. The data in this classic paper clearly show that the shear strain and pressure stress at the inner part of the limb are higher with the wide cuff. (Reproduced, with modification, from: Crenshaw AG, Hargens AR, Gershuni DH, Rydevik B. Wide tourniquet cuffs more effective at lower inflation pressures. Acta Orthop Scand. 1988;59:447-51. Reproduced with permission.)

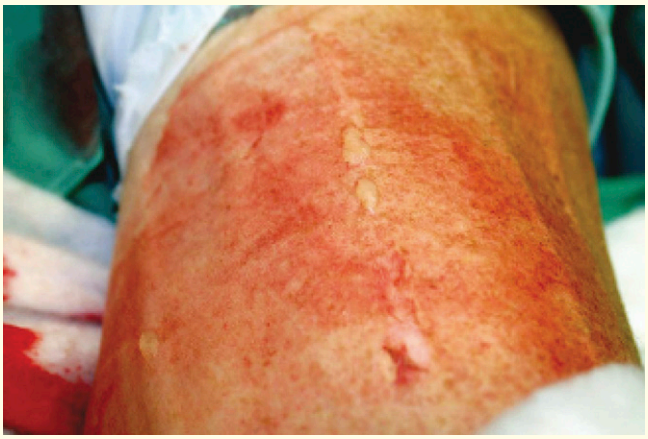

Fig. 4-A

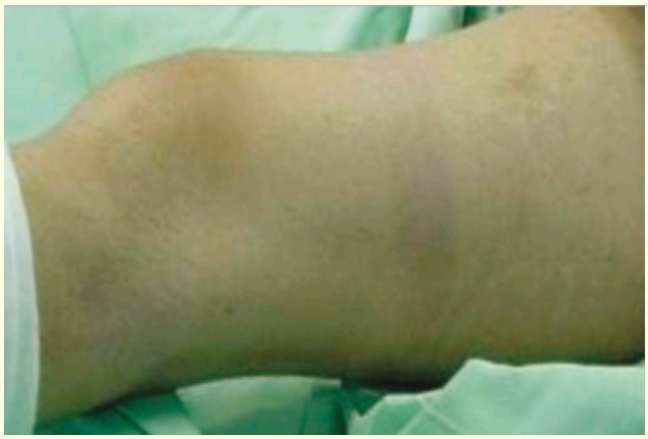

Fig. 4-B

Figs. 4-A and 4-B Skin condition following use of a wide pneumatic tourniquet (Fig. 4-A) and HemaClear (Fig. 4-B). Note the blisters at skin folds and hemorrhagic abrasions caused by the pneumatic tourniquet. The transient skin erythema at the HemaClear ring position faded over the subsequent forty-five minutes.

shown exactly the opposite. The figure shown here from the landmark 1988 study by Crenshaw et al.[19] clearly demonstrates it (Fig. 3). The graphs show the intralimb axial pressures at four radial locations with narrow (Fig. 3, *a* and *c*) and wide (Fig. 3, *b* and *d*) tourniquet cuffs inflated to 400 mm Hg. It is readily seen that the gradients with the narrow cuff (red lines in Fig. 3, *c*) are much less steep than with the wide cuff (blue lines in Fig. 3, *d*). Similar experimental data as well as computational models confirm this observation. The graphs also show that the actual pressure internally is lower with the narrow cuff.

Thus, with pressures at the nerve level that are lower with the narrow cuff and with gradients that are much less steep, it is not surprising that the incidence of nerve injury is higher with the wide cuff.

Fourth, we address the question: Is the higher pressure at the skin level with narrow cuffs or an elastic ring a cause for concern? The pressure exerted on the skin by the S-MART/HemaClear depends only on the limb circumference and the distance of the placed ring from the toes or fingers. This pressure is factory calibrated and cannot be exceeded. With pneumatic tourniquets, while the pressure used in the majority of patients is not more than 300 to 350 mm Hg, it is possible that if bleeding starts into the surgical field because of a sudden surge in arterial blood pressure, the surgeon will instruct to increase the pressure on the controller. Pneumatic tourniquet controllers can be dialed up to 475 mm Hg in the cuff, with a 700 mm Hg reservoir (e.g., ATS 2000; Zimmer, Warsaw, Indiana[20]). It is, however, more important to note the overall skin safety record of wide pneumatic tourniquets compared with the S-MART/HemaClear. The recent study by Din and Geddes[21] on skin complications following the use of a wide pneumatic tourniquet indicated a prevalence of 6%, even when adequate padding was used. This is far beyond the very few cases known to us from among the >150,000 patients managed with the HemaClear. This is attributed to the round contour of the ring-skin interface and the many layers of stockinette left around the elastic ring. Figures 4-A and 4-B show examples of skin conditions with a wide pneumatic tourniquet and the S-MART/HemaClear.

In summary, the data described above clearly document the superior safety track record of the elastic exsanguination tourniquet (S-MART/HemaClear) over the wide tourniquet promoted by Dr. McEwen and materially refute his unsubstantiated allegations. The smaller pressure inside the limb at the nerve level and the less steep internal axial pressure gradients are the underlying mechanisms of this improved patient outcome. The fact that the patient's skin tolerates the S-MART/HemaClear better than the wide tourniquet cuff has to do with specific design details. These features are accompanied by other advantages: the overall lower volume of tissue that is under compression conditions, the time needed for preparation and application, the fact that the S-MART/HemaClear exsanguination is superior, with an excellent surgical field and larger room for wider exposure because of the smaller footprint of the occluding ring, its usefulness both on the upper part of the limbs (arm and thigh) as well as on the tapered parts of the limb (calf and forearm), and its sterility all contribute to the popularity that this product is gaining.

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S. Noordin, J.A. McEwen, J.F. Kragh Jr., A. Eisen, and B.A. Masri reply:

We thank Dr. Gavriely for raising important questions that will serve to stimulate further thinking about current concepts relating to tourniquets in orthopaedics. His question about conflict of interest has been addressed directly with the Editor, and an erratum has been published.

We trust that this will not detract from consideration of some important questions raised by Dr. Gavriely's letter, which include the following:

1. What are the basic mechanisms of tourniquet-related injuries, as reported in the literature?

2. What is the relationship between tourniquet-related injuries and the levels and gradients of pressures applied to limbs by tourniquet cuffs?

3. Do narrower tourniquet cuffs, whether pneumatic or non-pneumatic, necessarily require higher pressures and higher pressure gradients to stop arterial blood flow?

4. What ranges of pressures may be produced by narrow, non-pneumatic tourniquet devices that are applied manually and in which applied pressures cannot be accurately monitored or regulated after application?

5. What is the reported incidence of tourniquet-related injuries, and what factors may affect their recognition and reporting?

In our manuscript, we attempted to analyze the pertinent literature relating to each of these questions, among others.

The literature on the mechanism of tourniquet injuries is clear and consistent and well established by many investigators over many years. There is a relationship between higher tourniquet pressures, higher pressure gradients, and a higher probability of injury.

Dr. Gavriely's main assertion is that narrow elastic tourniquet rings are superior to wider cuffs[1-6]. It appears to us that Dr. Gavriely has misunderstood or misinterpreted aspects of earlier peer-reviewed papers by Ochoa et al.[4], Hodgson[5], and Crenshaw et al.[6]. The important findings by Ochoa et al. about the mechanism of tourniquet-related injuries are accurately described in our manuscript (see Figure 3 and page 2959) and do not support Dr. Gavriely's assertion. Hodgson[5], in 1993, described an interesting biomechanical model and hypothesized, on the basis of that model, that wider tourniquet cuff designs having a gradual roll-off of pressure near the edges would be optimal in avoiding tourniquet-induced neuropathy; cuffs having such designs subsequently became available. Also, Dr. Gavriely may have misunderstood the importance of the results of Crenshaw et al.[6]: "The cuff pressure required to eliminate blood flow decreased as cuff width increased. . . . Thus, wide cuffs transmit a greater percentage of the applied tourniquet pressure to deeper tissues than conventional cuffs; accordingly, lower cuff pressures are required, which may minimize soft-tissue damage during extremity surgery." Dr. Gavriely may not have appreciated that if a lower tourniquet pressure can eliminate blood flow past a specific cuff, then the pressure gradients produced by that cuff will be correspondingly lower. Figure 4 in our study summarizes the relationship between tourniquet cuff width and limb occlusion pressure reported in the literature over many years. Nevertheless, we recognize there are circumstances, particularly certain military applications, when narrow, non-pneumatic tourniquets are appropriate and life-saving.

We find it necessary to correct Dr. Gavriely in his assertion regarding the data presented in Figure 5 in our study: these data were not hypothetical but were based on measurements. Dr. Gavriely suggested that different sizes of an elastic ring tourniquet could be matched to a limb location according to a look-up table able to produce a desired applied pressure. We were not able to find data or evidence of pressure measurements supporting the recommendations of a look-up table and the resultant pressures produced. Further, that suggestion raises safety concerns arising from an inadvertent mismatch between ring and limb size by a user if actual tourniquet pressure is not measured. In the study, we pointed out that the use of non-pneumatic tourniquet devices of current designs precludes accurate pressure measurement, pressure monitoring, and pressure control during use. A direct understanding of some of the relevant safety concerns can be gained by a reader by self-application of any of the tourniquet devices in Figure 5, by operating each as recommended to eliminate blood flow, and by comparing the relative levels of pain experienced. The variation in focal pressure concentration and pain perception is substantial.

We remind Dr. Gavriely of aspects of our brief historical review: narrow rubber bandages were used as tourniquets at the end of the nineteenth century, but their use in surgical, nonmilitary applications was quickly supplanted after Cushing introduced the pneumatic tourniquet in 1904, thereby reducing tourniquet-related injuries by permitting tourniquet pressure to be measured,

The Mechanical Response of Limbs to a Tourniquet Application

Preliminary Phase:

Axisymmetric and Plane-Strain Analysis

Prepared for:

OHK Medical Devices

Division of Oneg HaKarmel Ltd.

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April 2002

Introduction

Pneumatic tourniquets are routinely used in limb surgery to provide a bloodless operating field. The intent in preparing this paper was to obtain some insight and intuitive understanding with regard to the mechanical behavior of limbs (i.e. stresses, strains and deformations), when Tourniquet pressures are applied to them.

In this preliminary study, two simple cases were analyzed. For both, the limb components were modeled as linear elastic isotropic and homogeneous – and practically non-compressible "materials" (except blood vessels). The analysis was done utilizing a finite element (FE) program called PLAXIS, which is a special-purpose computer code for solving 2D problems in soil mechanics. However, due to the relative ease of creating a model within this program and the fact that elastic materials can be modeled - both in plain-strain and axisymmetric modes, it was used for this preliminary phase. It is clear that for more advanced phases of analysis, a full 3D modeling will be required. This will be accomplished by using either ANSYS or STRESS-CHECK (both use the FE method as well).

1. The Axisymmetric Model

For the axisymmetric model (see Figure 1), a uniform pressure distribution was applied (in the radial direction) to the circumference of a full-cylinder. The cylinder's radius is denoted by - R, with the longitudinal dimension being relatively large. The pressure was applied to the cylinder over a limited length – L.

Figure 2 depicts the typical manner in which the cylinder in Figure 1 deforms after the application of the external pressure. Since the problem has a longitudinal axis of symmetry, only the right side is shown. From the Figure it is seen that the radius of the cylinder under the load is reduced relative to its initial value, with the largest reduction being in the middle. At a certain distance away from the loading, the cylinder's radius is larger than its initial value due to the non-compressibility of the material. Further away from the loading, the radius of the cylinder is practically unaffected by the applied pressure (this cannot be seen in the Figure).

Figure 3 shows the pressure distribution inside the cylinder due to an applied external pressure of magnitude "–100", for four different L to R ratios: 1.0, 1.5, 2.0, and 3.0. From studying the Figure, several observations can be drawn:

a) Immediately under the applied pressure, the internal pressures in the cylinder are about the same in magnitude as the external pressure (slightly lower).
b) Deeper into the cylinder (in the radial direction), the internal pressures are lower in magnitude than the external pressure. This, however, is more pronounced for lower ratios of L/R. The highest internal pressure in the middle of the cylinder (on the axis of symmetry), is seen to be 50%, 70%, 75%, and 80% of the external pressure for (respectively) L/R=1.0, 1.5, 2.0, and 3.0.
c) Higher magnitudes of internal pressures, spread over longer lengths are "produced" under the loading when the ratios L/R are higher.
d) Internal pressure-gradients tend to develop near the edges of the applied loading. These are more severe for higher L/R ratios.

It is note-worthy that the pressure distribution shown in Figure 3 and the above observations are not affected or modified when the elastic modulus of the cylinder is changed.

The pressures shown in Figure 3 were calculated by averaging the three principal stresses at each point. For a plot of the distribution of the radial stresses inside the cylinder (for the four different L to R ratios), Refer to Figures 4 – 7. The Figures show the relative magnitudes & direction of the principal stresses and a plot of the radial tresses. From the Figures it is seen (particularly refer to Figure 6), that the length over which the magnitude of the radial stresses equals the magnitude of the loading (i.e., "-100"), decreases to a minimum at the axis of symmetry. Moreover, it was found that for L/R ratios of 1.0 and 1.5, the maximum radial stresses at the axis of symmetry were (respectively), 5% and 20% lower than the loading. For a L/R ratio of 0.5 (not shown in the Figures), the radial stresses at the axis of symmetry were found to be 50% lower than the radial external loading.

The displacement field inside the cylinder for the case of L/R=2 is shown in Figure 8. In this Figure, arrows are plotted, each representing the direction and relative

displacement-magnitude of a material point. Figure 9 is an enlargement of the arrow plot near the applied loading shown in Figure 8. It is interesting to note that points on the axis of symmetry are displaced in the vertical direction only, to opposite directions, producing internal tensile strains.

2. The Plane Strain Model

A plain-strain model (i.e., infinite in the perpendicular direction) was constructed for the problem by digitizing a typical thigh cross-section (see Figures 10 & 12). For the FE modeling, four different material properties were used: "Fat" with E & ν=0.5, "Muscle" with 2E & ν =0.5, "Bone" with 1000E & ν =0.4, and "Blood Vessels" with 0.001E & ν =0.1. After the application of the external pressure (with a magnitude of "-200"), a relatively uniform internal pressure distribution is formed (see Figure 11).

The displacement field is shown if Figures 12 & 13. The arrows in the Figures represent (as before), the direction and relative displacement-magnitudes of several material points. From these Figures it is seen that, since only the "blood vessels" where made "compressible" (ν <<0.5), they are closed when the external pressure is applied. However, the exact external pressure required for complete closure is geometry and material dependent.

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E. Levenberg

LIST OF FIGURES

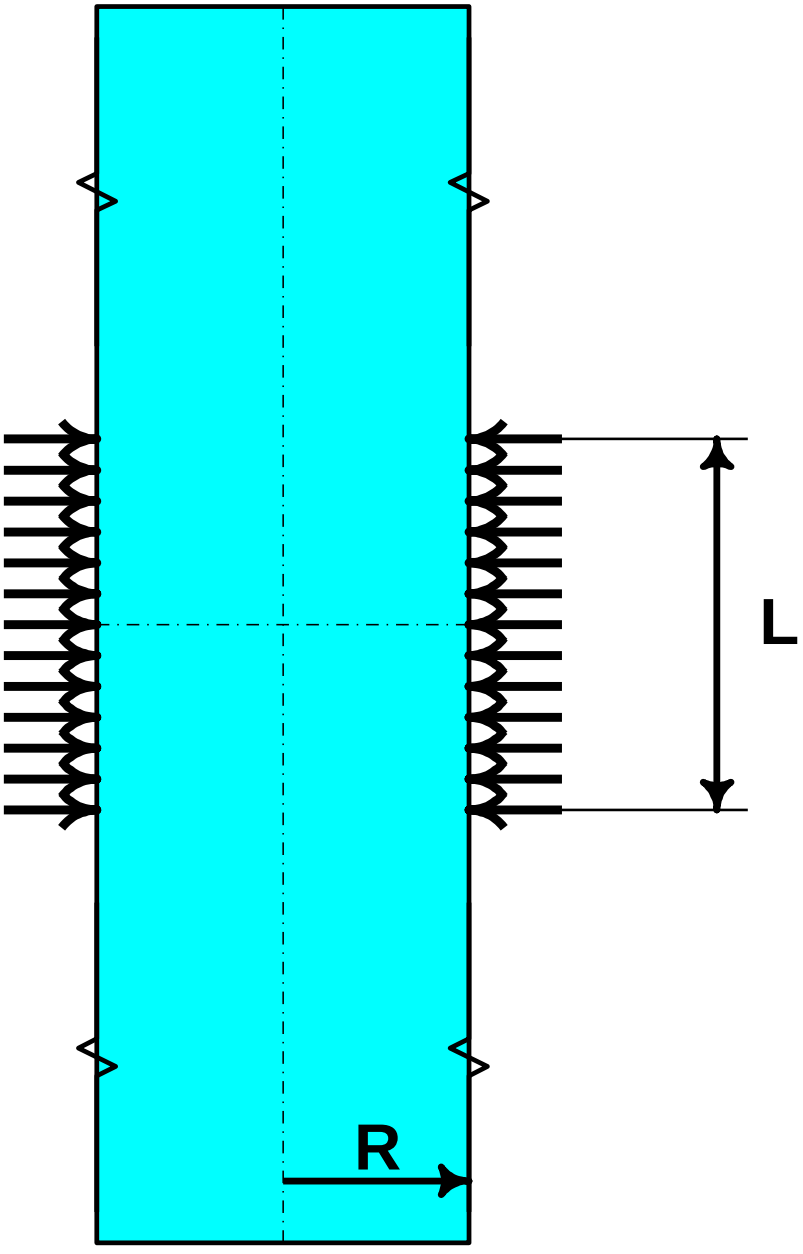

Figure 1: Pressure applied to a full-cylinder (axisymmetric model).

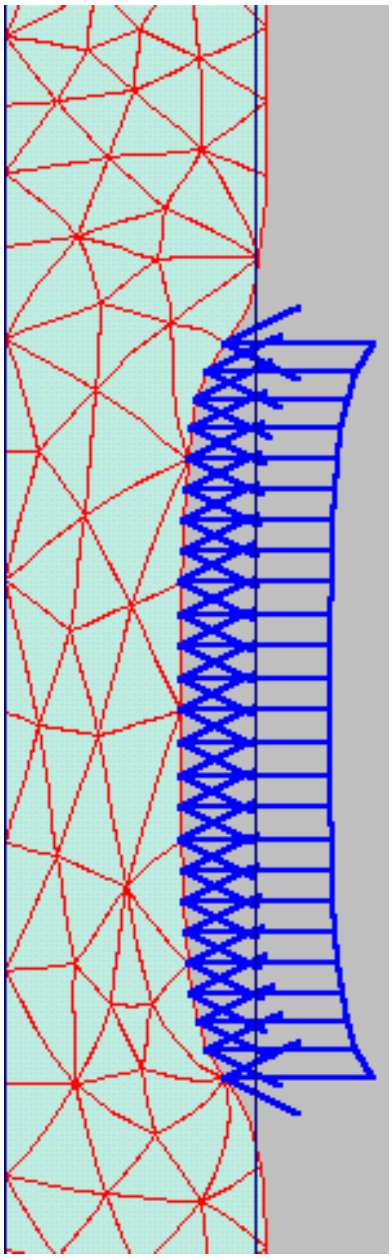

Figure 2: Deformation after pressure application (axisymmetric model).

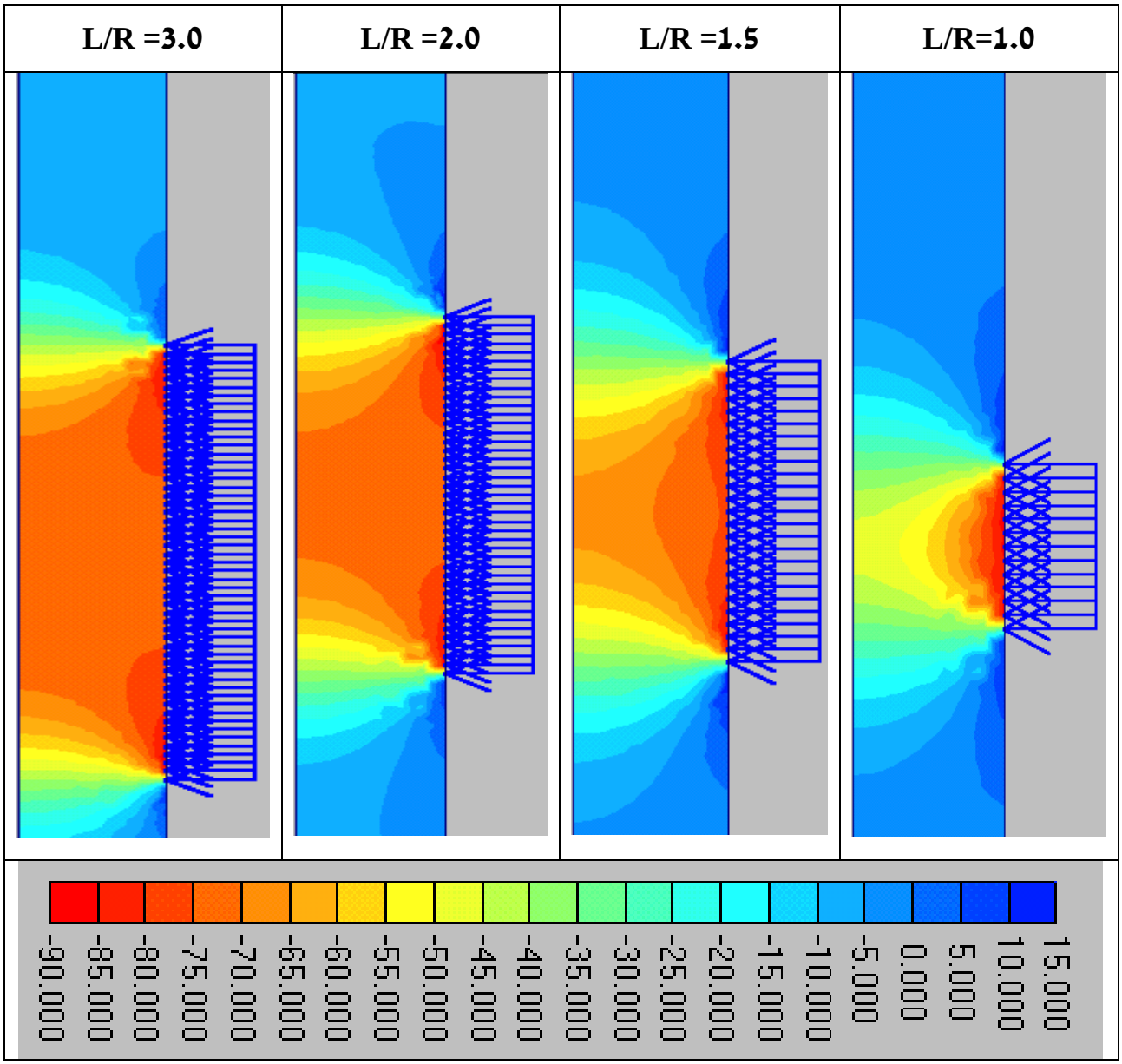

Figure 3: Internal pressure distribution for different L to R ratios (axisymmetric model).

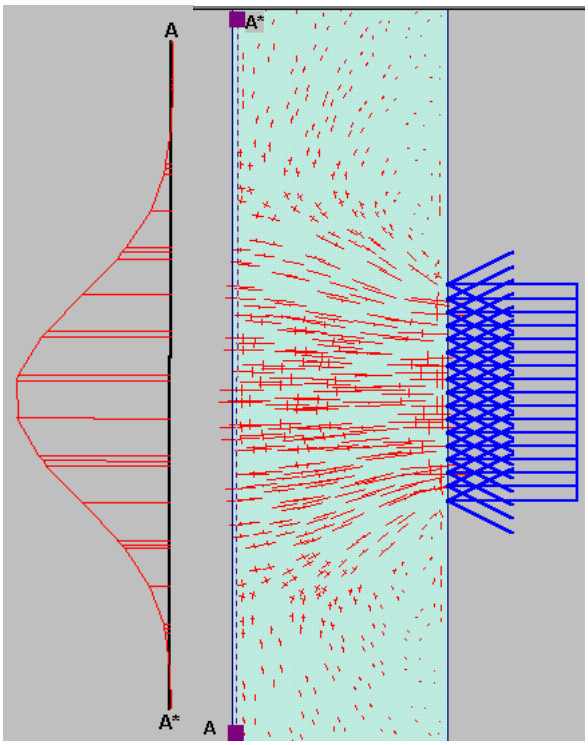

Figure 4: Distribution of principal stresses and a plot of the radial stresses at the axis of symmetry - maximum radial stress = 80%, L/R=1.

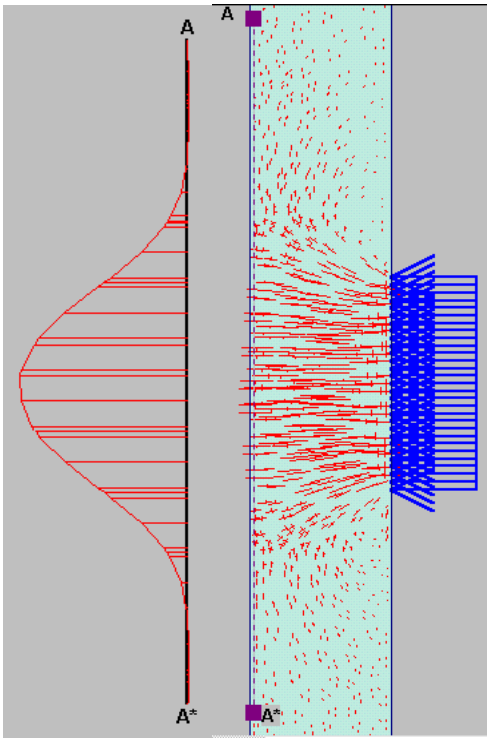

Figure 5: Distribution of principal stresses and a plot of the radial stresses at the axis of symmetry - maximum radial stress = 95%, L/R=1.5.

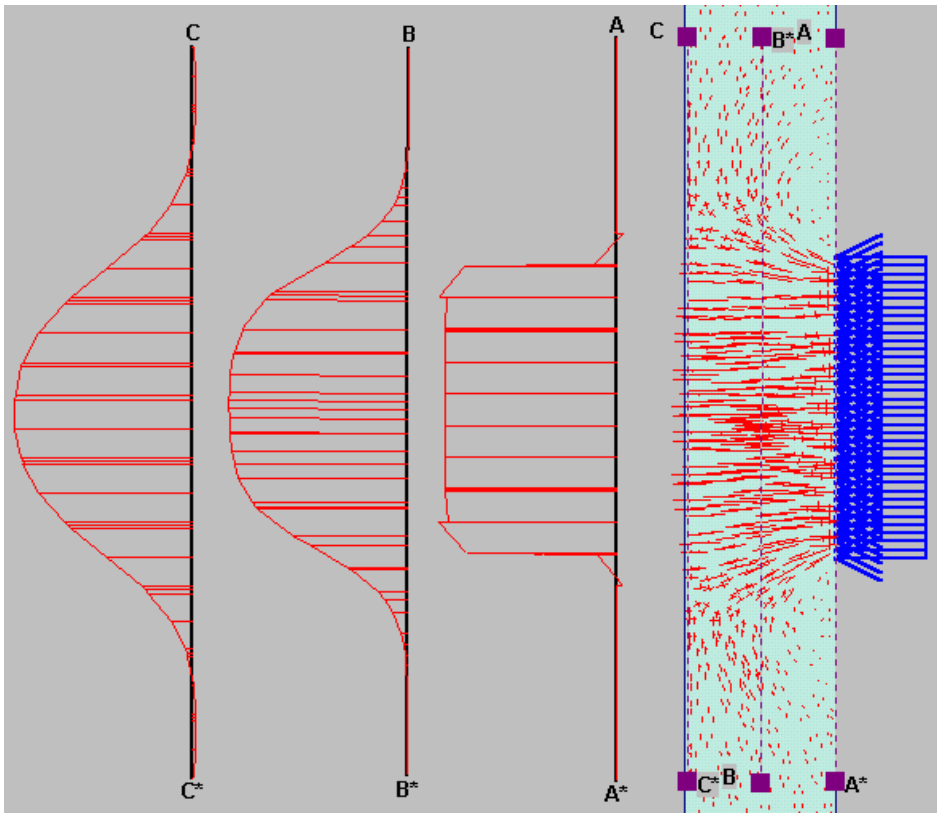

Figure 6: Distribution of principal stresses and a plot of the radial stresses at the several distances from the loading - maximum radial stress = 100% for all plots, L/R=2.

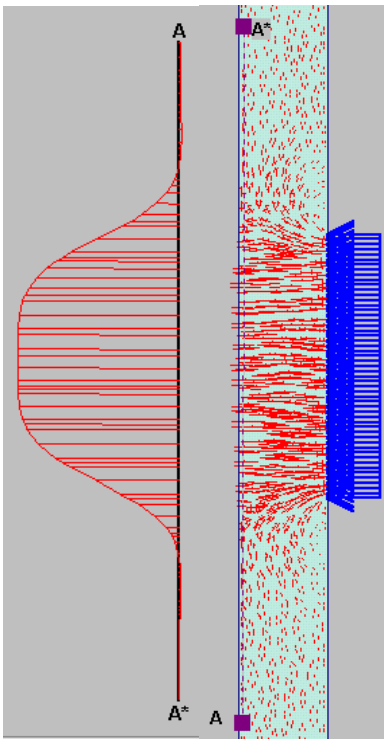

Figure 7: Distribution of principal stresses and a plot of the radial stresses at the axis of symmetry - maximum radial stress = 95%, L/R=3.0.

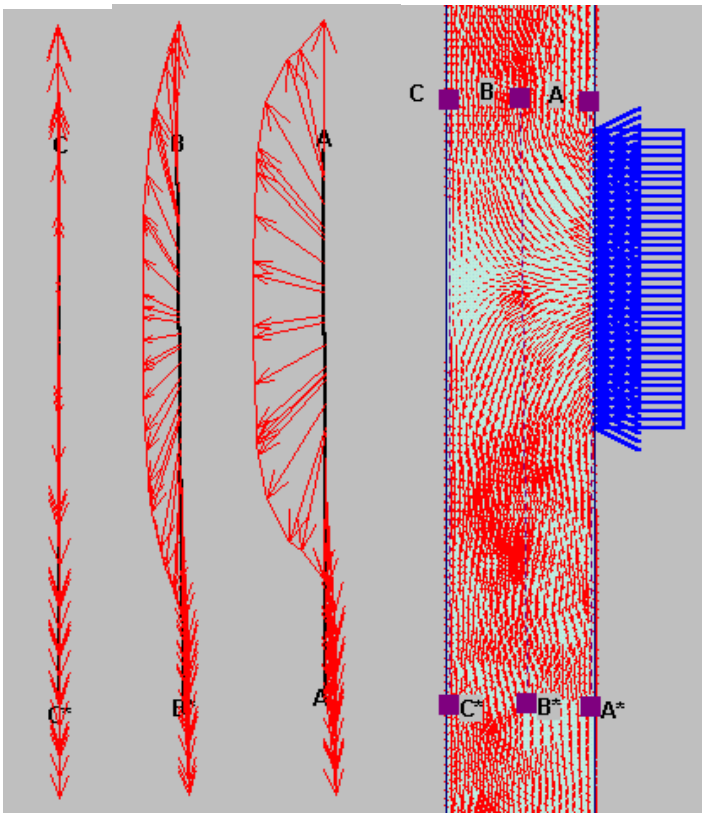

Figure 8: Arrow plot of the displacement field - L/R=2.0 (axisymmetric model).

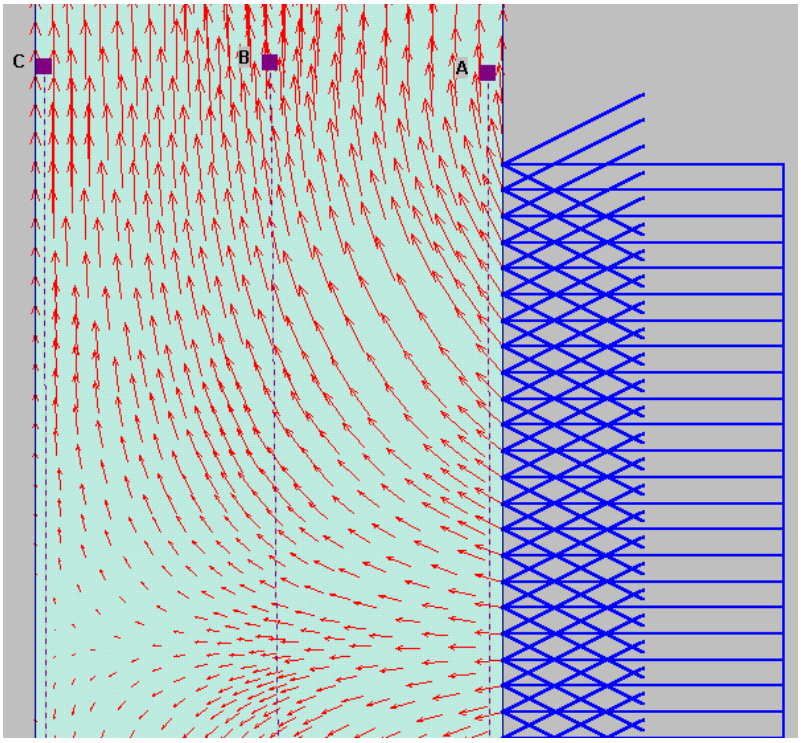

Figure 9: Arrow plot of the displacement field under to loading – L/R=2.0 (enlargement of Figure 8).

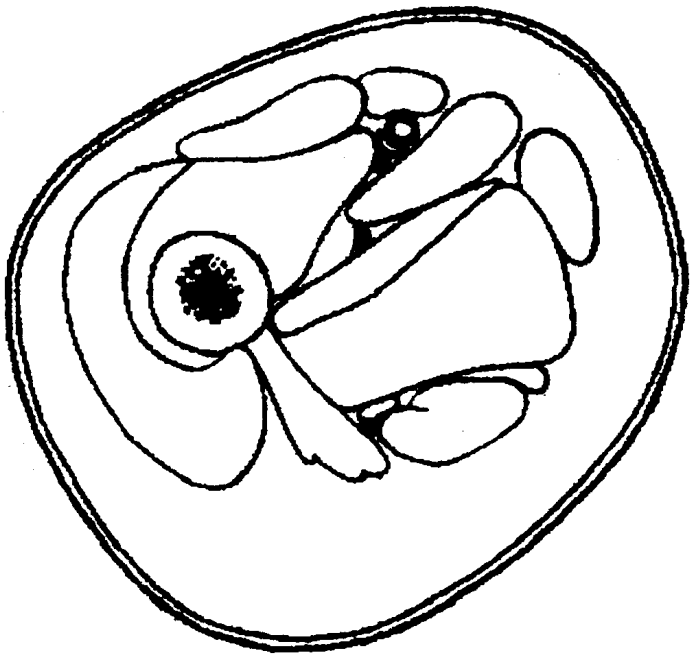

Figure 10: "Typical" cross section of a human thigh (Shaw and Murray, 1982).

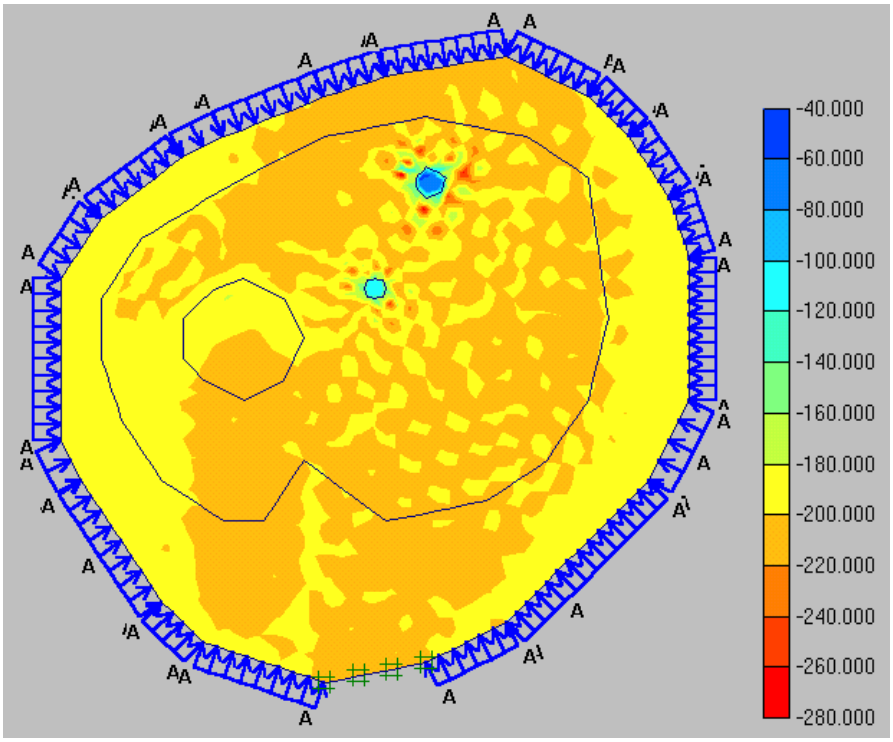

Figure 11: Internal pressure distribution (Plane-strain model).

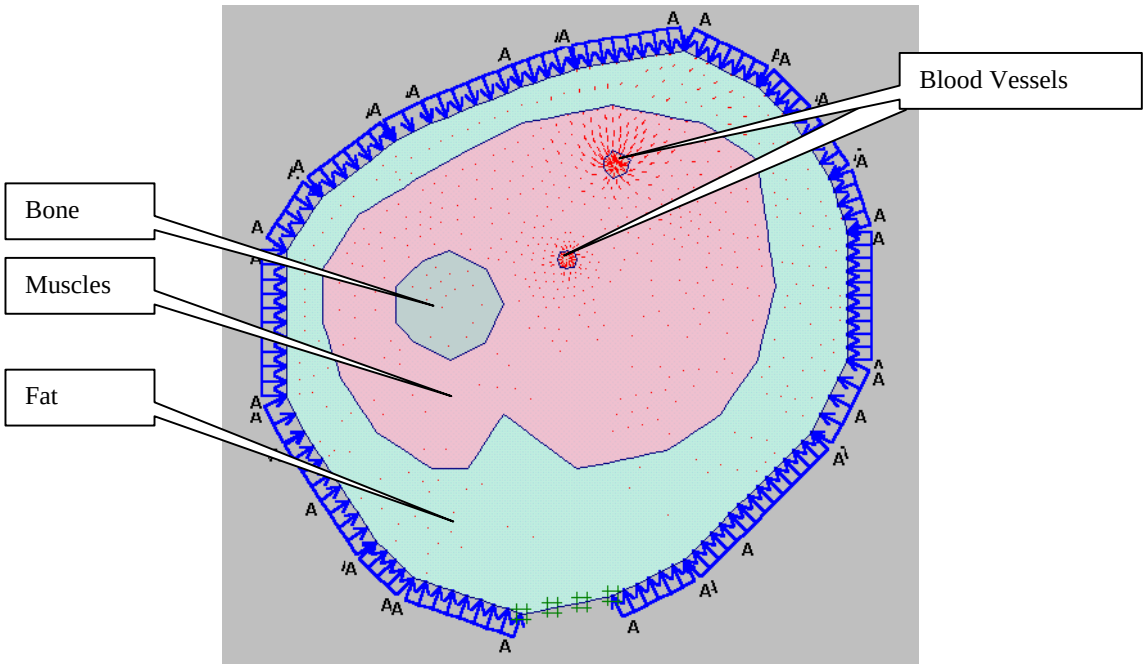

Figure 12: FE model of the thigh cross-section shown in Figure 10 (Plane-strain model).

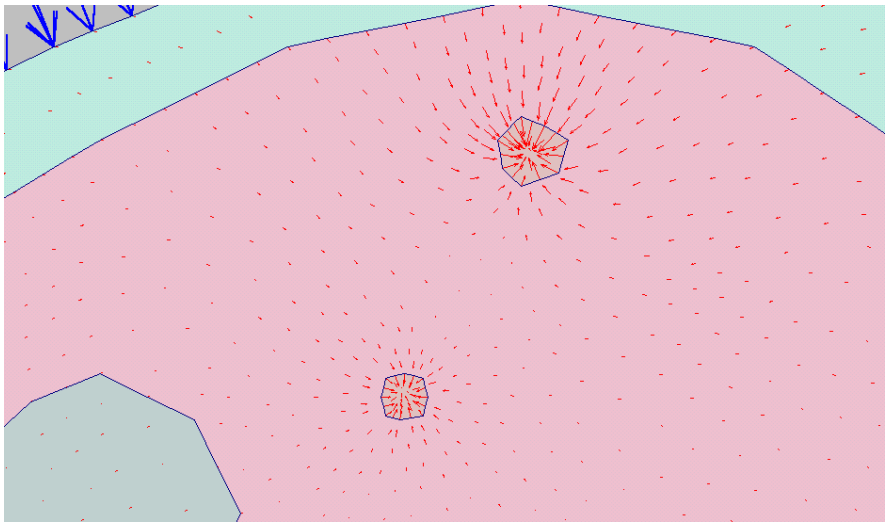

Figure 13: Displacement field and closure of "blood vessels" (plane-strain model).

The Mechanical Response of Limbs to a Tourniquet Application

Phase II:

A Study of the Interaction between the Auto-Transfusion Tourniquet and a Limb

Prepared for:

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Introduction

The Auto-Transfusion Tourniquet (ATT) is an elastic doughnut shaped device designed to expel the blood of human limbs into their central circulation. The ATT is stretched and forced over the limb (that has a larger radius), and then rolled over it from distal to proximal. The stretching produces a radial contact pressure on the circumference of the limb that compresses the tissues during the rolling operation, consequently "milking" the blood into the central circulation, and preventing it from re-entering the limb.

This report presents the development of a simple mechanical model prepared in order to simulate and analyze the interaction between the ATT and a limb during its application. The analysis is aimed at quantifying the pressure distribution exerted by the ATT at its contact with the limb, and the corresponding mechanical response of the limb. The final goal of the analysis is to provide a rational tool for reviewing and improving the design of the ATT.

1. The modeling scheme

In order to study the interaction between the ATT and a limb, a two-stage analysis is conducted. First, the contact stresses occurring when the ATT is pressed against the limb are calculated analytically (using the contact theory of Hertz). These are presented and discussed in section 3, and are supplemented by a computer disk containing an Excel spreadsheet in which the governing equations were programmed. Second, the mechanical response of the limb to the applied stresses is calculated utilizing a FE code. The results of this stage are presented and discussed in section 4.

The general view of the model is shown in Figures 1, 2, & 3, which also present the assignment of mechanical properties and geometric parameters. In these Figures the "limb" is shown (in blue) as a full cylinder with the following properties: Young's modulus: E_2, Poisson's ratio: υ_2, and external (initial) radius: R_2. The "ATT" (in yellow) is treated as an elastic "doughnut", characterized by: Young's modulus: E_1, Poisson's ratio: υ_1, initial internal radius: R_1, and a cross-sectional diameter: d.

Hence, the ATT and the limb are treated as linear-elastic, homogenous, and isotropic "materials". Moreover, it is assumed that the width of the contact area developed

between the ATT and the limb is relatively small with respect to the diameter of the limb ($2R_2$) and the ATT (d). Consequently, the contact theory of Hertz in applicable, and can be used for the first stage of the analysis.

2. Analytic calculations – basic and advanced models

The equations shown hereafter are aimed at calculating the width of the contact area that develops between the ATT and a limb. Two calculation models are presented: For the first, termed the "basic model", the calculations are done assuming that the final internal radius of the ATT (after its application) equals the initial external radius of the limb (i.e., R_2). This is, however, not entirely true since the contact stresses cause some reduction to the limb's external radius, which in-turn reduces the tension in the ATT, which in turn, causes some reduction in the contact stresses, which in-turn cause an increase to the limb's external radius. This process "continues" and converges into an equilibrium state. The second model, termed "advanced model", is developed accordingly, in order to account for this complex behavior. Both models were programmed into a Microsoft Excel spreadsheet (file name: ATT.xls), that is provided with this report.

3.1 Basic model calculations

The ATT has an (average) initial non-stretched length - l_0 , calculated by:

$$l_0 = 2\pi\left(R_1 + \frac{d}{2}\right) \tag{3.1}$$

By forcing the ATT to stretch to a larger internal radius (i.e., larger than R_1), which is equal to the limb's external radius - R_2 , the ATT's new (average) length becomes:

$$l_{new} = 2\pi\left(R_2 + \frac{d-\Delta d}{2}\right) \tag{3.2}$$

The term $d-\Delta d$ denotes the reduced ATT's diameter after the longitudinal stretching due to the Poisson's ratio effect. Δd is calculated according to the expression: $\Delta d = d\nu_1\varepsilon$, derived directly from Hook's Law (triaxial case), In which ε

is the longitudinal (or tangential) strain of the ATT, defined by the formula $\varepsilon = (l_{new} - l_0)/l_0$. Solving for ε using (3.1) and (3.2) yields:

$$\varepsilon = \frac{R_2 - R_1}{R_1 + \frac{d(1+\nu_1)}{2}} \tag{3.3}$$

Moreover, according to Hook's law, the longitudinal (tangential) stresses produced in the ATT (after stretching it to ε), are:

$$\sigma = E_1 \varepsilon \tag{3.4}$$

Thus, the tensile (tangential) force inside the ATT (due to the above stretching) can be calculated by combining (3.3) and (3.4) to yield:

$$T = A\sigma = AE_1\varepsilon = AE_1 \frac{R_2 - R_1}{R_1 + \frac{d(1+\nu_1)}{2}} \tag{3.5}$$

In equation (3.5), A denotes the cross-sectional area of the ATT after the stretching, i.e., $A = \pi(d - \Delta d)^2/4$.

Alternatively, if an internal (line-load) pressure of magnitude P (with dimensions of force per unit length), is applied internally (in the redial direction) to an ATT, such that its (new) internal radius becomes R_2 (with $R_2 > R_1$), a tensile (tangential) force is produced inside the ATT. This force can be calculated by the simple formula [1]:

$$T = PR_2 \tag{3.6}$$

Combining the results of (3.5) and (3.6) – i.e., equating T, we find a mathematical expression for the contact line-load pressure (P) exerted to the limb by the ATT:

$$P = AE_1 \frac{R_2 - R_1}{\left(R_1 + \frac{d(1+\nu_1)}{2}\right)R_2} \quad \text{or} \quad P = AE_1 \frac{1 - (R_1/R_2)}{\left(R_1 + \frac{d(1+\nu_1)}{2}\right)} \tag{3.7a,b}$$

It is important to note that equation (3.7) is based on equilibrium considerations, and is not restricted by any model assumptions. Moreover, it can be seen in (3.7b) that if

R_2 is much larger than R_1, the contact line-load pressure approaches a constant value. In this case, unless $\nu_1 = 0$, which means that A is unaffected by the ATT's longitudinal stretching, the value of P approaches zero. Some insight of this behavior is shown in Figure 4.

Additionally, according to Hertz [2, 3], the contact width (b) produced when a long cylinder of diameter $d - \Delta d$ is pressed against an elastic half-space by a line-load pressure P, is given by the formula:

$$b = \sqrt{\frac{8P(d-\Delta d)C_E}{\pi}} \tag{3.8}$$

with C_E given by [3]:

$$C_E = \frac{1-\upsilon_1{}^2}{E_1} + \frac{1-\upsilon_2{}^2}{E_2} \tag{3.9}$$

Moreover (according to Hertz), the contact-stress distribution- $\sigma(s)$, with dimensions of force per unit area, takes an elliptic form - given by the following formula (relate to Figure 5):

$$\sigma(s) = \sigma_0\sqrt{1-\left(\frac{2s}{b}\right)^2} \qquad For \quad |s| \le \frac{b}{2} \tag{3.10}$$

with the maximum contact-stress magnitude (σ_0), with dimensions of force per unit area (also called "Hertzian stress"), given by:

$$\sigma_0 = \sqrt{\frac{2P}{\pi(d-\Delta d)C_E}} \tag{3.11}$$

Although equations (3.8) – (3.11) were formulated (originally) for characterizing the contact between a cylinder and a half-space, they are applicable to our analysis provided that the limb's radius (R_2) is large relative to the contact width (b) – which is generally the case in our model. This applicability can be understood intuitively, and is also supported by calculations - which are presented later on.

3.2 Advanced model calculations

Instead of R_2 denoting the final ATT radius as was assumed in the above analysis, the final radius is smaller, due to the applied ATT pressure (P) and the corresponding radial deformation of the limb. Accordingly, a more accurate formula than (3.3) for calculating the longitudinal ATT strain (ε) would be:

$$\varepsilon(P) = \frac{R(P) - R_1}{\left(R_1 + \frac{d(1+\nu_1)}{2} \right)} \tag{4.1}$$

with the term $R(P)$ denoting the "final" Limb's radius. This "final" radius is decomposed into the initial limb's radius R_2 minus the radial deformation of the limb (ΔR_2), as follows:

$$R(P) = R_2 - \Delta R_2(P) \tag{4.2}$$

with [2]:

$$\Delta R_2(P) \cong P\left(\frac{1-\nu_2{}^2}{\pi E_2} \right)\left\{ 2\ln\left(\frac{4R_2}{b} \right) - \left(\frac{\nu_2}{1-\nu_2} \right) \right\} \tag{4.3}$$

Equation (4.3) is (originally) the maximum surface deformation of a half-space relative to a point at a depth R_2 below the surface, loaded by a Hertzian stress distribution (identical to that shown in Figure 5), with an equivalent line load pressure P. This expression was compared to the FE analysis in predicting the value of ΔR_2 and found accurate (for all practical purposes), provided that the L/R ratio (i.e., b/R_2) is less than 0.65 (see [4] for the definition of L/R ratio). The relative error trend between equation (4.3) and the FE analysis is shown in figure 6. It is noted that in our model, the value of b/R_2 is usually lower than 0.65, so that the use of (4.3) is valid in most cases. Moreover, the applicability of (4.3) provides "justification" for using equations (3.8) – (3.11) in the analysis (for both the "advanced model" and the "basic model").

Accordingly, for the "advanced" case, equations (3.7), (3.8), (3.10), and (3.11) are modified (respectively) to take the form:

$$P = A(P)E_1 \frac{R(P) - R_1}{\left(R_1 + \frac{d(1+\nu_1)}{2}\right)R(P)} \tag{4.4}$$

$$b(P) = \sqrt{\frac{8P[d - \Delta d(P)]C_E}{\pi}} \tag{4.5}$$

$$\sigma(s) = \sigma_0 \sqrt{1 - \left(\frac{2s}{b(P)}\right)^2} \qquad For \quad |s| \le \frac{b}{2} \tag{4.6}$$

$$\sigma_0 = \sqrt{\frac{2P}{\pi[d - \Delta d(P)]C_E}} \tag{4.7}$$

with: $A(P) = \pi[d - \Delta d(P)]^2 / 4$, $\Delta d(P) = d\nu_1\varepsilon(P)$, and C_E as defined in (3.9).

Solving for P equations (4.1) – (4.7) must be done numerically, since P cannot be analytically isolated. For this reason, a VBA-macro program was written (utilizing Newton's method) and embedded in the Excel sheet named "advanced model calculations". To run the program, it is only necessary to press the command button on the screen.

Finally, it is recommended that whenever the Hertzian approach results in a contact width (b) larger than $\alpha(d - \Delta d)$ with $\alpha = 0.90 \Leftrightarrow 0.95$ (i.e., close to the ATT's diameter), to set: $b = \alpha(d - \Delta d)$. In this case, assuming the Hertzian stress distribution (as shown in Figure 5) still applies, the maximum contact stress (σ_0) becomes (out of equilibrium considerations):

$$\sigma_0 = \frac{4P}{\pi(d - \Delta d)\alpha} \tag{4.8}$$

3. The FE analysis

Once the contact stresses between the ATT and the limb are determined from the analytic formulation (presented in previous section), they can be used in a FE code to analyze the mechanical response of the limb. In this section, mostly the case of $b/R_2 = 0.5$ is presented and discussed (except Figure 11).

Figure 7 depicts the typical manner in which the "limb" deforms under the application of the external Hertzian stress distribution. From the Figure it is seen that the radius of the "limb" under the load is reduced relative to its initial value, with the largest reduction being in the middle. This reduction was denoted in the previous section by ΔR_2 and its magnitude predicted by (4.3). The corresponding displacement field is shown as an "arrow-plot" in Figure 8. In this Figure, each arrow represents the direction and relative displacement-magnitude of a material point. The general trends in this plot are no different than those discussed in reference [4].

Figure 9 shows the relative magnitudes & direction of the principal stresses inside the limb, and Figure 10 plots the radial stresses (with magnitude relative to σ_0), for four different radial distances from the loading (the furthest coinciding with the axis of symmetry). As can be seen in the Figures, further away from the loading the maximum radial stress becomes smaller in magnitude. On the axis of symmetry the maximum radial stress equals $0.37 \cdot \sigma_0$. Figure 11 also plots the radial stresses (with magnitude relative to σ_0), for different radial distances from the loading. However, in this Figure, only the maximum radial stresses are shown – for different ratios of b/R_2: 0.4, 0.5, and 0.6. From the Figure it can be seen that the magnitude of the maximum radial stress decreases faster (as one looks deeper into the "limb"), when b/R_2 is smaller.

Figure 12 shows the pressure distribution inside the "limb" due to an applied Hertzian stress distribution of maximum magnitude "–1.0" (i.e., $\sigma_0 = -1.0$). The pressure at each point is calculated by averaging the principal stresses at the point. The general trends in this plot are very similar to those discussed in reference [4]. However, it appears that the pressure gradients, which develop on both sides of the loading, are less severe compared to larger L/R ratio's with uniform pressure distribution.

The longitudinal strains in the limb can be studied from Figures 13 and 14. These Figures show that the limb exhibits (mostly) internal tensile straining as a result of the applied compressive radial-stresses. The highest tensile strain is found at a certain distance from the loading, and not on the axis of symmetry. It is noted that the plot is material-dependent, i.e., changing the limb's modulus or Poisson's ratio results in a different longitudinal strain-field. The Figures were prepared for two values of ν_2: $\nu_2 = 0.3$, & $\nu_2 = 0.5$, and constant value of E_2: $E_2 = 5[kg/cm^2]$. It is noted that if E_2 was lower, higher tensile (positive) and compressive (negative) strain magnitudes would be produced (this is not shown in the Figures).

4. References

[1] Fung, Y. C. (1965), "Foundations of Solid Mechanics", Prentice-Hall, Inc.

[2] Johnson, K. L. (1985), "Contact Mechanics", Cambridge University Press.

[3] Roark, R. J. and Young, C. W. (1975), "Formulas for Stress and Strain", McGraw-Hill Kogakusha, Ltd., 5th Edition.

[4] Levenberg, E. (2002), "The Mechanical Response of Limbs to a Tourniquet Application – Preliminary Phase", Prepared for OHK Medical Devices.

E. Levenberg

FIGURES

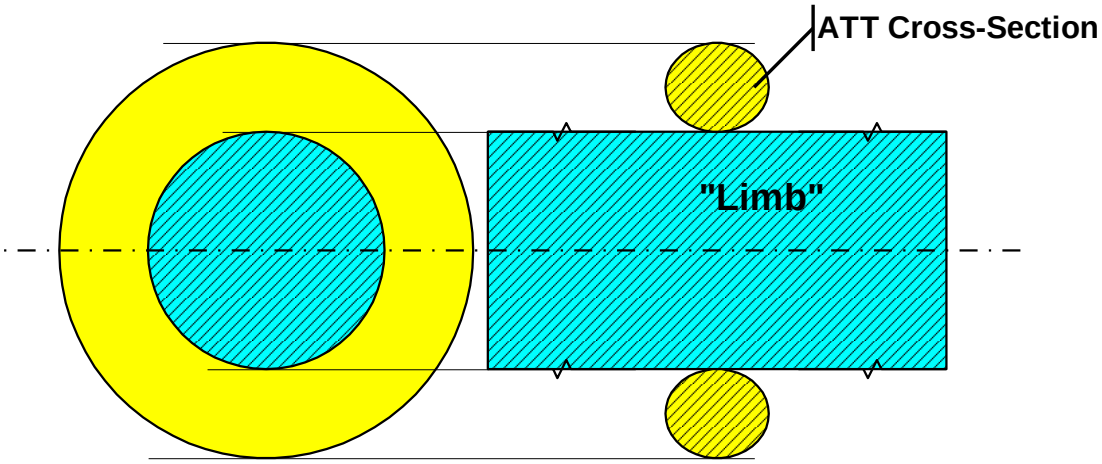

Figure 1: General view of the model.

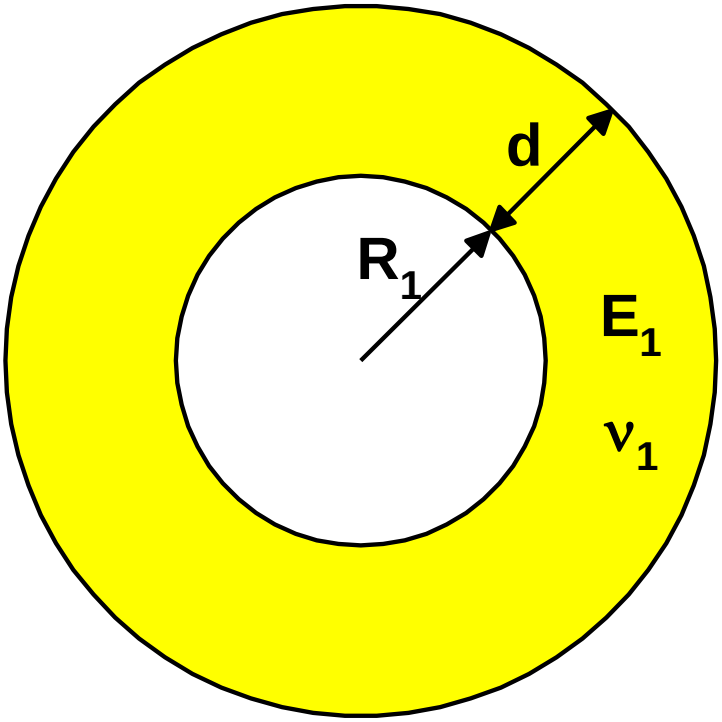

Figure 2: "ATT" model properties and parameters.

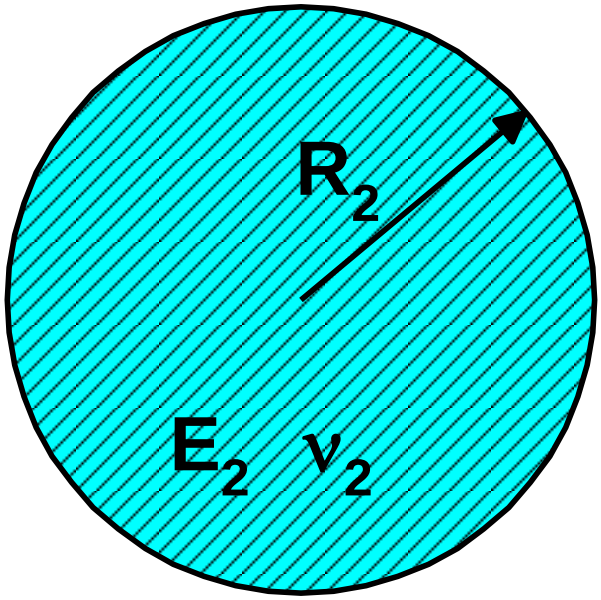

Figure 3: "Limb" model properties and parameters.

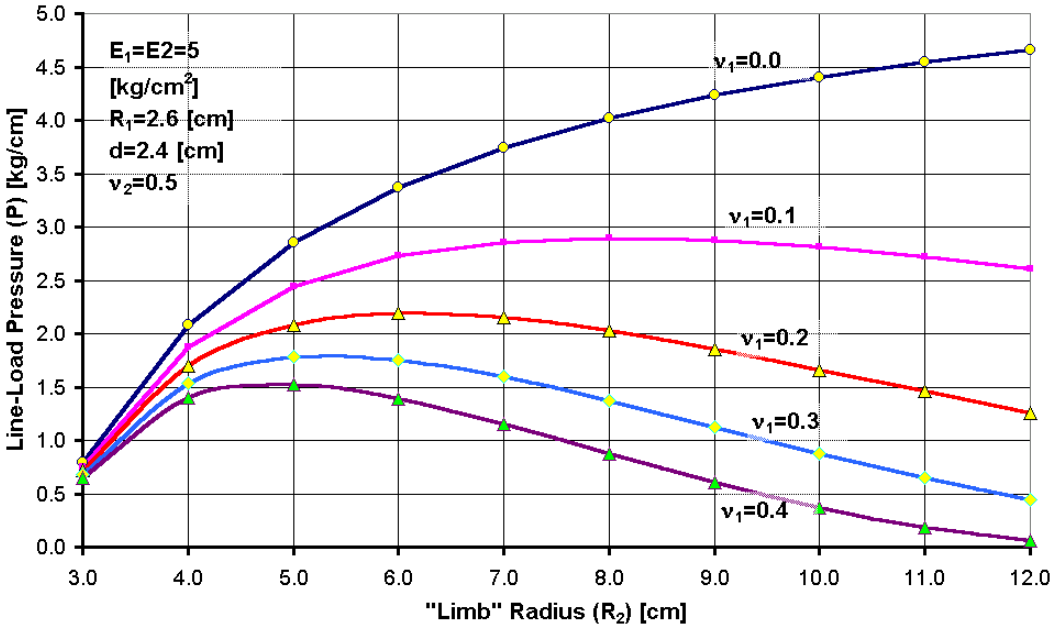

Figure 4: Line-load pressure for different "Limb" radii and ATT's Poisson's ratio (ν_1).

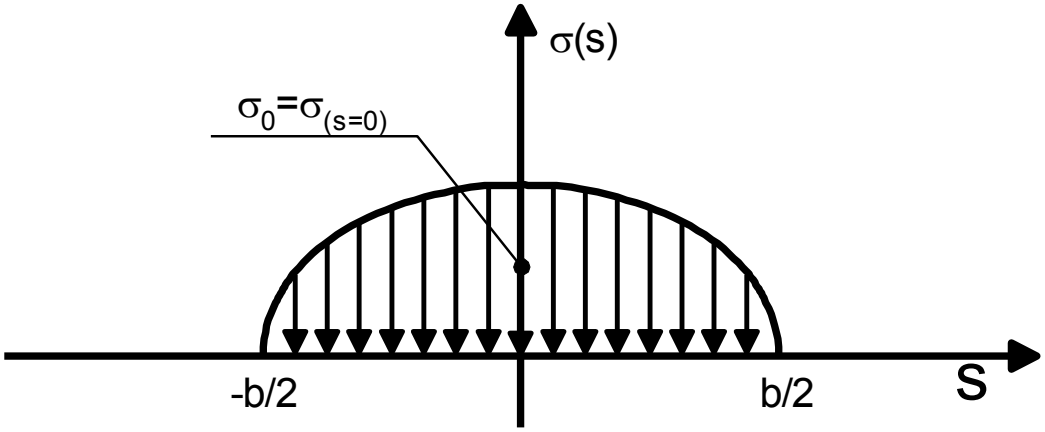

Figure 5: Hertzian contact-stress distribution.

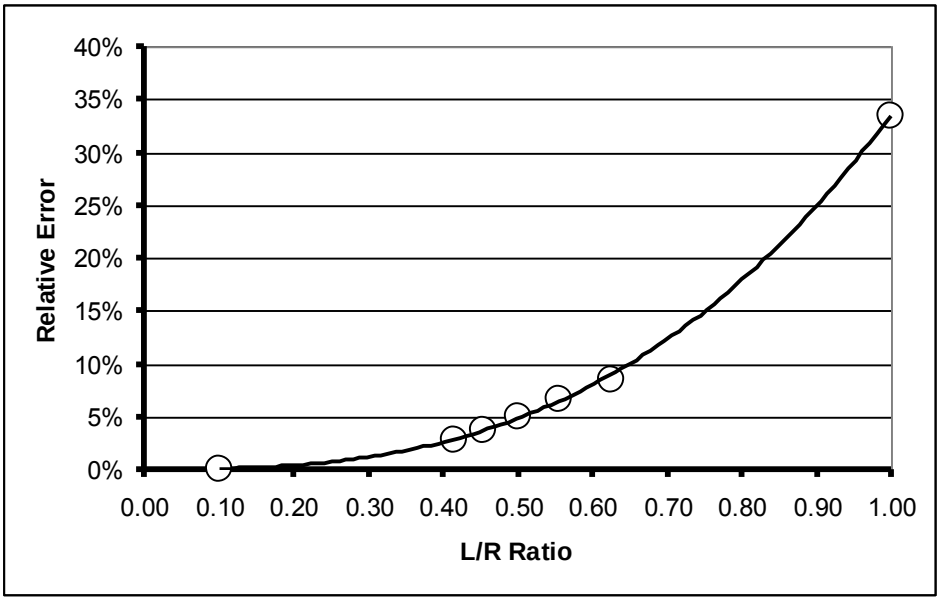

Figure 6: Relative error between the FE analysis and equation (4.3) for calculating ΔR_2.

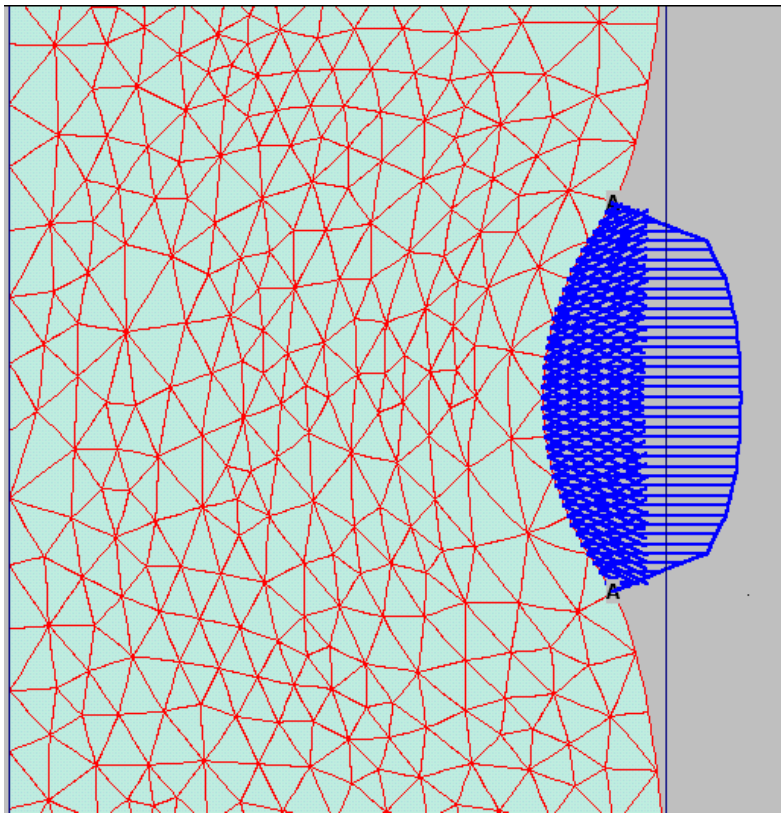

Figure 7: The deformed mesh (L/R=0.5).

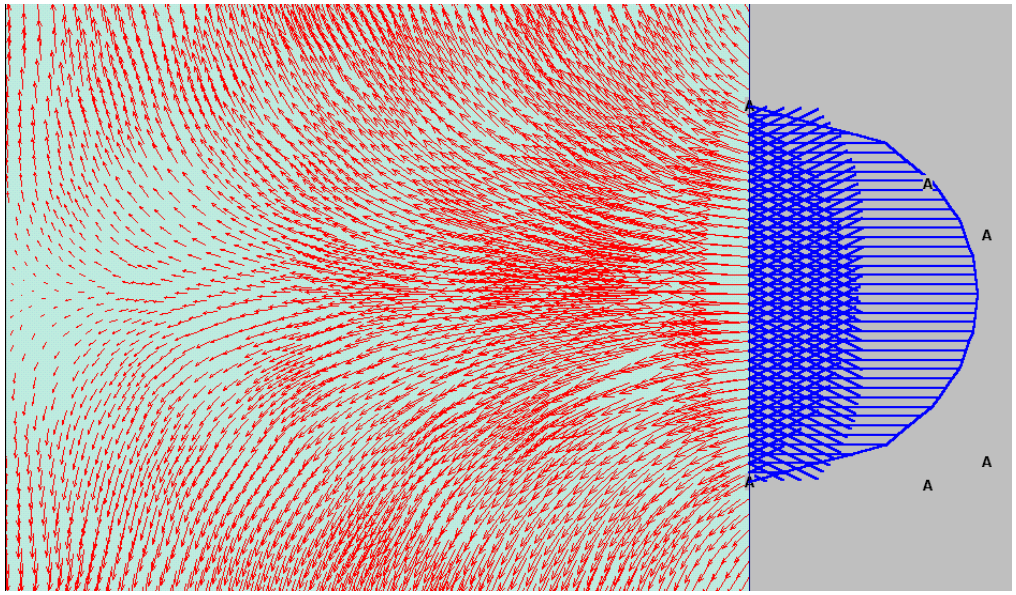

Figure 8: The displacement field under the loading (L/R=0.5).

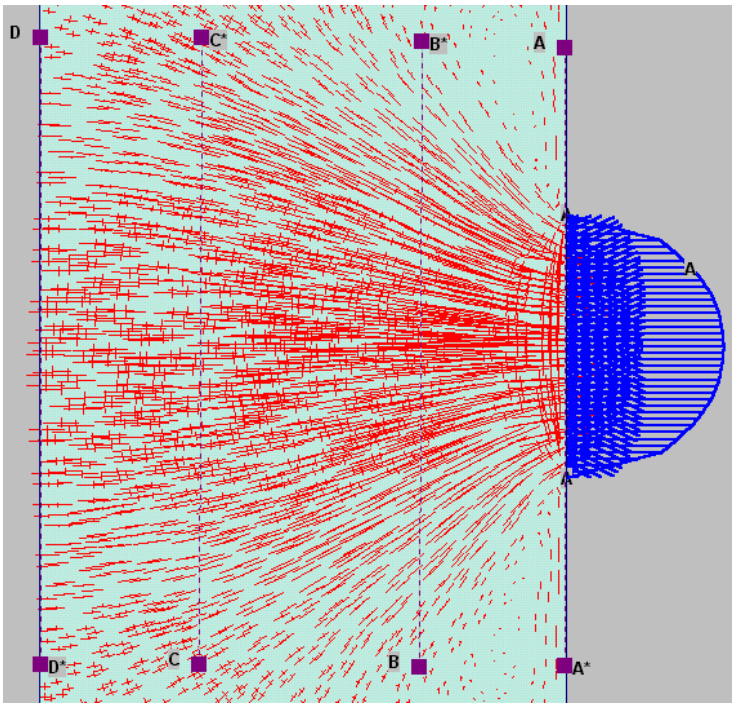

Figure 9: Principal stresses under the loading – maximum applied stress is - σ_0.

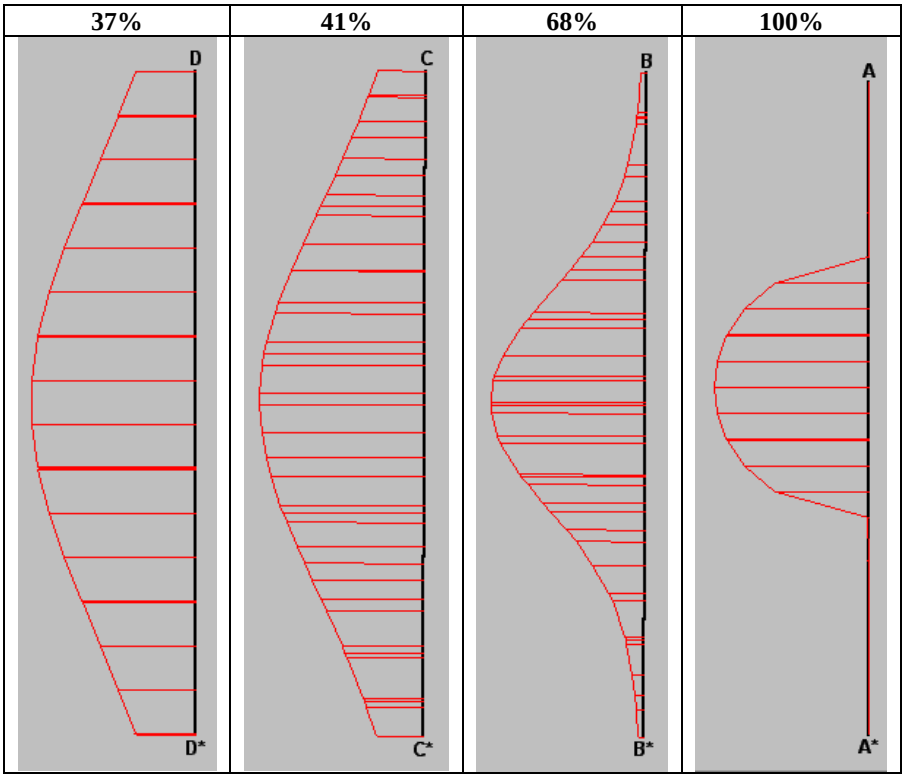

Figure 10: Radial stresses at several distances from the load (relate to Figure 9). Maximum stress values are indicated above relative to σ_0 ($b/R_2 = 0.5$).

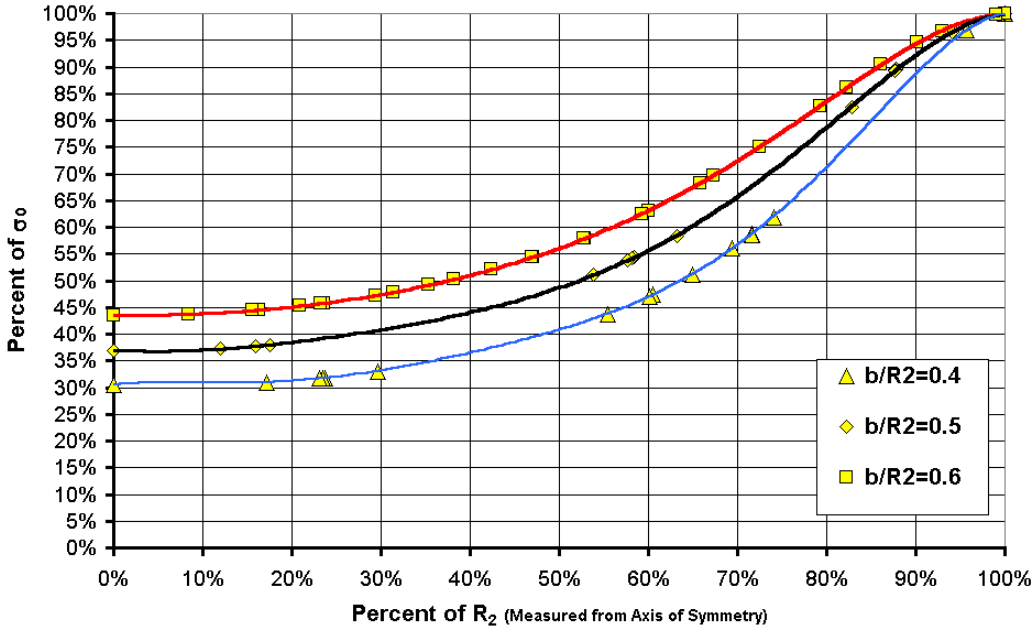

Figure 11: Radial stresses, directly under the middle of the stress distribution, at several distances from the load - for different ratios of b / R_2.

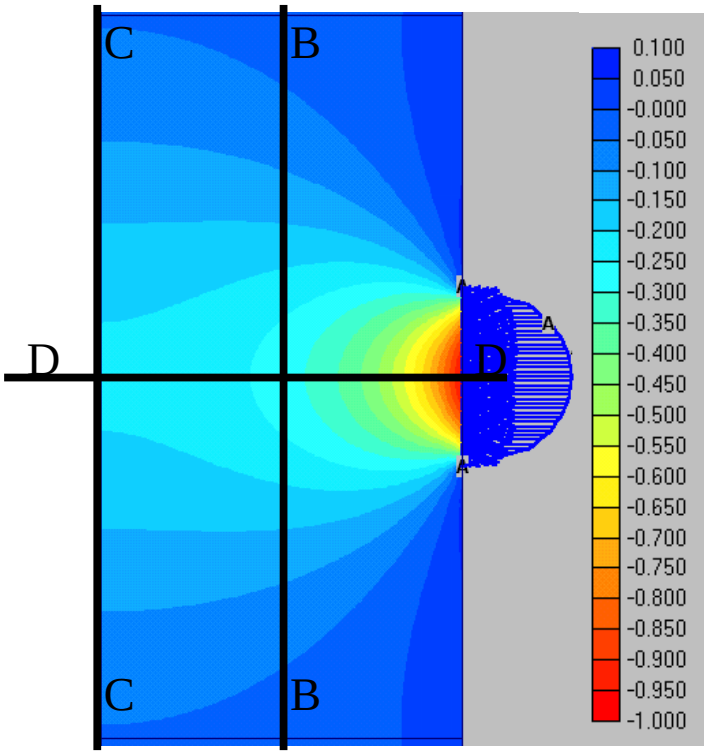

Figure 12: Pressure distribution inside the "limb" due to a Hertzian stress-distribution.

RESEARCH ARTICLE

The Effect of the Silicone Ring Tourniquet and Standard Pneumatic Tourniquet on the Motor Nerve Conduction, Pain and Grip Strength in Healthy Volunteers

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Abstract

Background: The pneumatic tourniquet (PT) is routinely used in upper and lower limb operations by most orthopaedic surgeons. The silicone ring tourniquet (SRT) was introduced in clinical practice the last decade. Clinical as well comparative studies in volunteers concerning its safety and efficacy have been published. The aim of this study was to investigate the postoperative effect of the silicone ring tourniquet (SRT), primarily on the motor nerve conduction, and secondarily on the pain and grip strength, in comparison to the effect of the pneumatic tourniquet (PT) in healthy volunteers.

Methods: Both tourniquets were applied in the forearm of the dominant arm in 20 healthy volunteers and were kept on for 10 minutes. Pain was measured using the visual analogue scale and grip strength was measured with a hand dynamometer. We evaluated the following parameters of median nerve conduction: motor conduction velocity (MCV), latency (LAT) and amplitude (AMP).

Results: Pain score at the time of tourniquet application was higher in SRT group but the alteration in pain scores in PT group was higher, with statistical significance (P<0.05). The grip strength was reduced by the application of both tourniquets; however there was a significantly higher reduction in the SRT group (P<0.05). The conduction impairment of the median nerve was worse in the PT group than in the SRT one, according to the changes in MCV (P<0.05).

Conclusion: Median nerve conduction was affected more after PT application as compared to the SRT. Nevertheless, the reduction of grip strength was higher after the SRT application.

Keywords: Cuff, Nerve conduction, Pain, Silicone ring tourniquet, Tourniquet

Introduction

The tourniquet is routinely used in upper and lower limb operations by most orthopaedic surgeons in order to achieve bloodless surgery, improve the identification of vital structures and expedite surgical procedures (1). Pneumatic tourniquet (PT) is the most commonly used device since its introduction by Harvey Cushing in 1904 and its use has become almost routine (1).

The mechanical pressure as well as ischemia-reperfusion injury are related to structural and functional changes to muscles and nerves as well as to skin and vessels. Apart from the amount of the applied pressure and the duration of application, the characteristics of the cuff (width and shape) are also important elements. Although lower arterial occlusion pressure is required using wider cuffs, human volunteer studies have shown that the wider cuffs resulted in more pain and were tolerated less than narrow cuffs (2-4). A more recent study found this to be true with higher pressures; however with lower pressures a wide tourniquet cuff is less painful than a

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narrow one (5). Nerve conduction studies in volunteers have recently shown that wider cuffs resulted in more severe changes of the nerve function than narrow cuffs, provided that they were inflated at the same pressure and for the same time (6).

The silicone ring tourniquet (SRT) was has been introduced in clinical practice during the last decade and both clinical and comparative studies in volunteers concerning its safety and efficacy have been published (7-15). The SRT is a narrow silicone ring applied at a predetermined pressure. This is determined by the selected tourniquet model, according to the patient's arterial blood pressure.

Pain intensity and tolerance time after SRT application in comparison to PT have been studied in healthy volunteers (11-13). However, the effect of this tourniquet on muscle strength and nerve function has not been studied yet, according to our knowledge.

The aim of this study was to investigate the effect of the SRT on the motor nerve conduction in comparison to that of a standard PT, in healthy volunteers. Secondarily, we assessed tourniquet pain and the effect of both tourniquets on the grip strength.

Material and Methods

Volunteers

Twenty healthy volunteers, on no medication and without previous operations or fractures in the limbs, participated in this study [Table 1]. The study was approved by the Ethics Committee (UGHE 50/3-7-2013), the procedure was explained to each volunteer and a written consent was obtained from all volunteers.

Tourniquets

Both tourniquets were applied on the dominant forearm, one after the other, with an at least 2-day interval. The SRT was studied firs in half of the volunteers and the PT on the other half (one alternating with the other). The volunteers were placed in a supine, comfortable position. The systolic blood pressure was measured in each one and was used as standard.

The appropriate model-size of the silicone ring tourniquet (HemaClear, OHK Medical Devices, Haifa, Israel) was used according to the standard systolic blood pressure. A standard PT with a 14-cm-wide cuff was also used and the cuff was applied over two layers of smoothly applied cast padding. The limb was elevated for 3 min before the tourniquet inflation, with the inflation pressure being 100 mmHg above the standard systolic blood pressure.

Table 1. Volunteers' characteristics

Number	20
Age (mean ± std)	35.45 ± 10.308
Gender (male)	14 (70%)
Height (mean±std)	1.735 ± 0.087
Weight (mean±std)	80.32 ± 15.576
BMI (mean±std)	26.612 ± 4.564
R-L (Right)	18 (90%)

Grip strength and pain measurement

Grip strength was evaluated with the Jamar dynamometer (FEI, Irvington, NY, USA) according to the protocol of the American Society of Hand Therapists (16). Volunteers performed three maximum attempts for each measurement, each arm alternatively. The results of these trials were recorded and the average value was used for analysis.

The volunteers were instructed how to use the Visual Analogue Scale (VAS) for pain measurement (0 = no pain to 10 = the worst pain) and how to use the hand dynamometer (17).

Median nerve conduction studies

Volunteers were resting in a supine, comfortable position. Motor nerve conduction velocity (MCV) (in m/sec), amplitude (AMP) (in mVolt) and latency (LAT) (in msec) measurements of the median nerve for each subject were carried out prior to the application of tourniquet to the forearm and the results were recorded.

Stimulating and recording electrodes were placed on the forearm of the dominant upper extremity for each subject to stimulate the median nerve. The skin below the electrodes was slightly abraded before placement to reduce impedance. A ground electrode was fastened to the non-dominant arm's forearm. The recording site was at the abductor policis brevis muscle. R1 and R2 electrodes were placed in such a way that R1 was placed over the muscle belly of the abductor brevis muscle and R2 over the first metacarpophalangeal joint. Stimulation sites were antecubital fossa proximally, and the wrist crease between the flexor carpi radialis and palmaris longus tendons distally.

The motor nerve conduction velocity before and following the application of the two cuffs was calculated by dividing the distance between the two stimulation sites by the difference in the onset latency proximal and distal to the cuff, i.e. CV (m/s) = distance (mm)/LATproxtocuff - LATdistaltocuff.

Procedure

Both tourniquets were applied in the forearm of the dominant arm and were kept on for 10 minutes.

The VAS score for pain was recorded (a) immediately

Table 2. Pain scores of both tourniquets

	PT [mean (sd)]	SRT [mean (sd)]	*P*-Value
T1	1.3 (1.2)	4.1±2.1	*0.0
T5	3.0 (2.2)	3.8±2.4	0.135
T10	3.6 (2.7)	4.5±2.5	0.138
T1-T5	1.7 (1) ^*P* =0.0, COT: 130%	-0.3 (0.3) ^*P* =0.433, COT; (-7.3%)	0.187
T5-T10	0.6 (0.5) ^*P* =0.008, COT: 20%	0.7 (0.1) ^*P* =0.024, COT: 18.4%	0.258
T1-T10	2.3 (1.5) ^*P* =0.0, COT: 176%	0.4 (0.4) ^*P* =0.631, COT: 9.7%	0.237

^ Significance over time. COT: Change over time. * *P* <0.05. Statistically significant difference

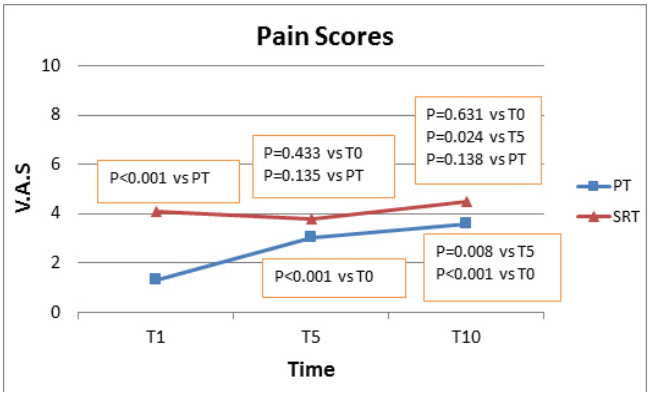

Figure 1. Pain scores.

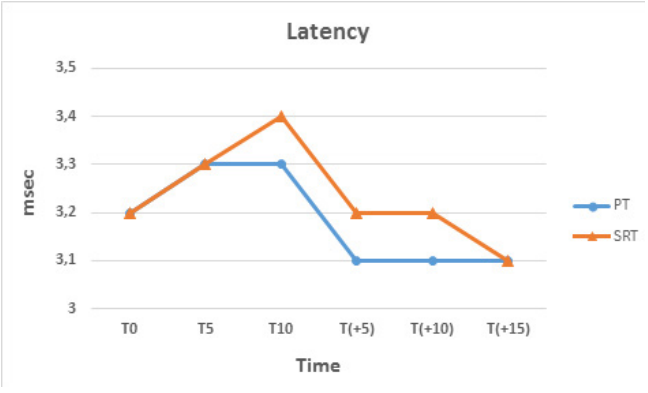

Figure 2. Changes in values of latency.

after tourniquet application (initial pain score, T1), (b) 5 minutes after the tourniquet application (T5), and (c) just before the tourniquet removal (final pain score, T10). Grip strength was measured prior to tourniquet application (T0) and 5 minutes after the removal of the tourniquet (T+5).

Nerve conduction measurements were done just before the tourniquet application (T0), after 5 and 10 minutes (T5 and T10) of tourniquet application, and following the tourniquet removal at 5,10 and 15 minutes (T+5, T+10 and T+15).

Statistics

Statistical Package for Social Sciences (SPSS), version 20 was used for the analysis of data. The quantitative parameters were expressed as mean ± std and the qualitative as frequencies and percentages. At the beginning of our statistical analysis, we used the Kolmogorov-Smirnov test to evaluate the normality of each parameter. The results showed that all parameters followed the normal distribution. As a consequence, we utilized the parametric one way repeated measures ANOVA tests, with the assistance of post hoc analysis (Bonferroni correction) as well as the paired T-test. All tests were two-tailed and statistical significance was considered for values less than 0.05.

Results

Twenty volunteers with a mean age of 35.5 years (range 25 to 45 years) participated in this study; their demographics are shown in Table 1.

Pain

Pain scores and changes over time are shown it Table 2 and Figure 1. In this study, the pain at the time of tourniquet application (T1) was higher in the SRT group than in PT one. One way repeated measures ANOVA showed significantly different pain scores between the two different tourniquets only at T1 (P=0.0).

The initial pain intensity during the SRT testing gradually subsided and increased again later, with a statistically significant difference identified only between T5 and T10 (F=4.142, P=0.024). On the contrary, the pain score changes during PT testing were significantly higher at all-time intervals, as it was shown by parametric statistics (from T1-T5, F=19.000, P=0.0, from T5 to T10, F=8.876, P=0.008, and from T1 to T10, F=21.891, P=0.0). Two way mixed ANOVA have shown a statistically significant correlation between the type of the tourniquet and the change in pain scores over time (F=4.478, P=0.005), meaning that the changes in pain scores with PT were more pronounced.

Grip strength in Dominant and Non-Dominant Arm

A reduction of grip strength was observed after the application of both tourniquets for 10 minutes [Table 3]. Paired T-test showed that the difference in average values before tourniquet application (T0) and after tourniquet removal (T+5) was marginally significant for the SRT test (P=0.049). As far as the values for the non-dominant arm is concerned, a statistically significant difference was also found during the SRT test (P=0.002).

Table 3. Grip strength values

		T0	T+5	Change	*P*-value
Dominant	PT [mean (std)]	37.8 (9.6)	36.7 (10.1)	-1.1 (0.5) [-2.96%]	P =0.183
	SRT [mean (std)]	39.3 (10.3)	37.0 (10.6)	-2.3 (0.3) [-5.7%]	P =0.049*
Non-Dominant	PT [mean (std)]	35.3 (8.3)	36.0 (9.0)	0.7 (0.7) [+0.83%]	P =0.405
	SRT [mean (std)]	38.7 (10.2)	36.3 (9.0)	-2.4 (1.2) [-3.88%]	P =0.002*

T0: Time 0. Grip strength measurement before the tourniquet application.
T5: Time 5. Grip strength measurement five (5) minutes after the tourniquet removal.
* P<0.05. Statistically significant difference

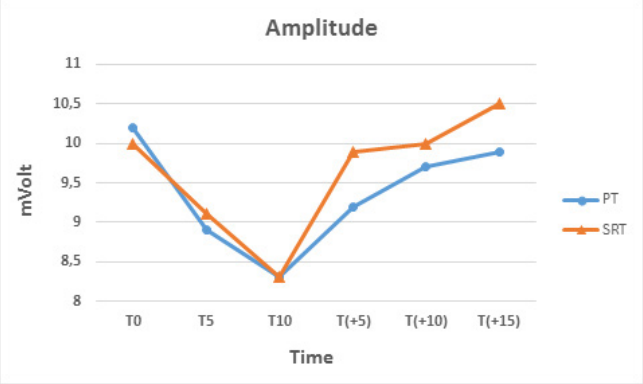

Figure 3. Changes in values of amplitude.

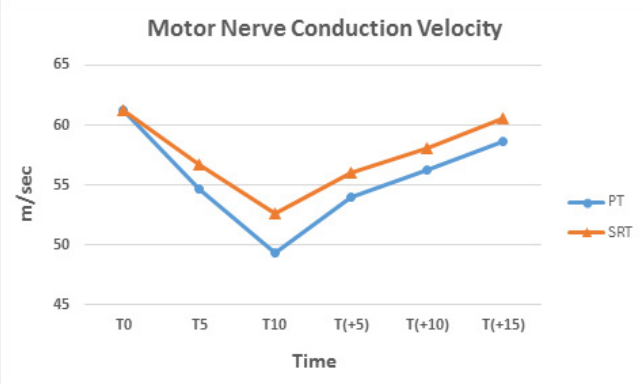

Figure 4. Changes in values of motor nerve conduction velocity.

Nerve conduction studies

The application of both tourniquets resulted in an increase of the latency up to T10, while the removal of the tourniquets was followed by a decrease of the latency [Table 4; Figure 2]. On the other hand, the amplitude and MCV values decreased after the tourniquet application and subsequently gradually increased following its the removal [Table 4; Figure 3; 4].

Overall, the changes of the values for the nerve conduction studies were more pronounced in the PT test, as compared with the SRT test, particularly in MCV, where the differences were found to be statistically

Table 4. Nerve conduction studies

	PT Mean (sd)	SRT Mean (sd)	RT versus SRT *P*-value
Latency			
T0	3.2 (0.5)	3.2 (0.5)	1.000
T5	3.3 (0.4)	3.3 (0.5)	0.670
T10	3.3 (0.4)	3.4 (0.6)	0.215
T(+5)	3.1 (0.5)	3.2 (0.5)	0.662
T(+10)	3.1 (0.5)	3.2 (0.4)	0.547
T(+15)	3.1 (0.4)	3.1 (0.5)	0.611
Amplitude			
T0	10.2 (3.6)	10 (3.7)	0.163
T5	8.9 (2.8)	9.1 (3.6)	0.776
T10	8.3 (2.8)	8.3 (4.3)	0.816
T(+5)	9.2 (2.6)	9.9 (3)	0.347
T(+10)	9.7 (2.6)	10 (2.9)	0.829
T(+15)	9.9 (2.4)	10.5 (1.9)	0.372
Motor Nerve Conduction Velocity			
T0	61.2 (5.4)	61.2 (5.4)	1.000
T5	54.7 (4.8)	56.7 (4.5)	0.003*
T10	49.3 (4.7)	52.6 (4)	0.000*
T(+5)	54 (4.7)	56 (4.2)	0.043*
T(+10)	56.2 (4.5)	58.1 (4.3)	0.014*
T(+15)	58.6 (4.7)	60.6 (4.7)	0.075

* <0.05. Statistically significant difference

significant. Furthermore, a return to the T0 values (before the tourniquet application) was noticed during the SRT test in 4 volunteers at T+10, while in PT test only in 1 volunteer at T+10 and another at T+15.

Discussion

This study showed that nerve conduction was impaired more severely in the PT group than in the SRT group, according to the changes in nerve amplitude; nevertheless, pain scores and reduction of grip strength were higher in the SRT testing. To our knowledge, this is the first study that investigated the effect of the Silicone Ring Tourniquet on motor nerve conduction in comparison to standard Pneumatic Tourniquet in healthy volunteers.

Pain

Tourniquet pain is related to local phenomena – compression and ischaemia- and there is evidence that more central mechanisms may also be involved (18, 19).

It is not clear whether compression of the skin, muscles and nerves, or ischaemia play the most important role in the etiology of tourniquet pain (20-23).

In our study, the pain score at the time of tourniquet application was higher in SRT group than in PT group. This high initial pain level during the SRT testing gradually subsided and later increased slowly, while the change in pain scores in PT testing was higher and statistically significant. These findings are in accordance to the findings of previous studies (11).

It is likely that the initial high level of pain with the SRT originates locally in skin and muscle, as the narrow size of the silicone ring exerts pressure over a small surface area (13).

Grip strength

The reduction of grip strength may be related to muscle functional changes and is due to muscle injury as well as to nerve conduction impairment (24, 25).

For the SRT test, the reduction of the grip strength was higher (marginally significant; P=0.049). It is possible that the initial changes caused by muscle compression and therefore the functional strength impairment, are more pronounced using the SRT, because the narrow silicone ring exerts the given pressure over a small area of the muscle. In the case of PT test these changes may take more time to be apparent because the given pressure is applied in a wider area.

The reduction of the grip strength in the contralateral upper limb, as was found in the previous study, has been attributed to changes of the sensitivity of neurons, or to very rapid cortical synaptic remodeling, or fast re-organisation of the synaptic system due to short-term deprivation of sensory input by ischaemic nerve block (24, 26-28).

In our study, there was no reduction of the grip strength of the contralateral (non-dominant) hand in the PT test, while in the SRT test this reduction was significant, although nerve conduction was more severely impaired in the PT group than in SRT one.

It is possible that the structural and functional changes of the nerve may be different –at least initially- following the application of these two different tourniquets. If this is the case, the application of the SRT may result in a more rapid deprivation of sensory input. This hypothesis needs to be supported by future studies.

Nerve conduction studies

The findings of this study suggest that the SRT application caused less impairment of the nerve function as compared with the PT. A complete recovery within 15 minutes after the tourniquet removal was found more frequently in volunteers than in the PT group.

In a previously reported study, nerve conduction studies were performed in 20 healthy volunteers after the application of two different pneumatic cuffs – a narrow of 7 cm length and a wide one of 14 cm (6). It was found that the impairment of the motor nerve conduction was greater with the wider cuff as compared with that of the narrow one, despite the fact that the amount of pressure required for occluding the blood supply for the wider cuff was lower. The authors hypothesized that anoxia of the larger area of the nerve could be a possible causal factor for the greater impairment of nerve conduction with the wider 14 cm cuff. This hypothesis is based on the findings of previous studies suggesting that nerve anoxia is more important than mechanical deformation from compression (29, 30).

Furthermore, according to these experimental findings it is not clear whether the damage occurs only to the section of nerve directly under and near the edges of the cuff or it extents more distal to it, with stretching of the paranodal myelin on one side of the node and invagination of the paranodal myelin on the other (22, 23).

According to the results of this study, the reduction of grip strength was higher after the SRT application; nevertheless, nerve conduction was impaired more severely in the PT group than in the SRT group, as this was shown by the changes in nerve conduction studies.

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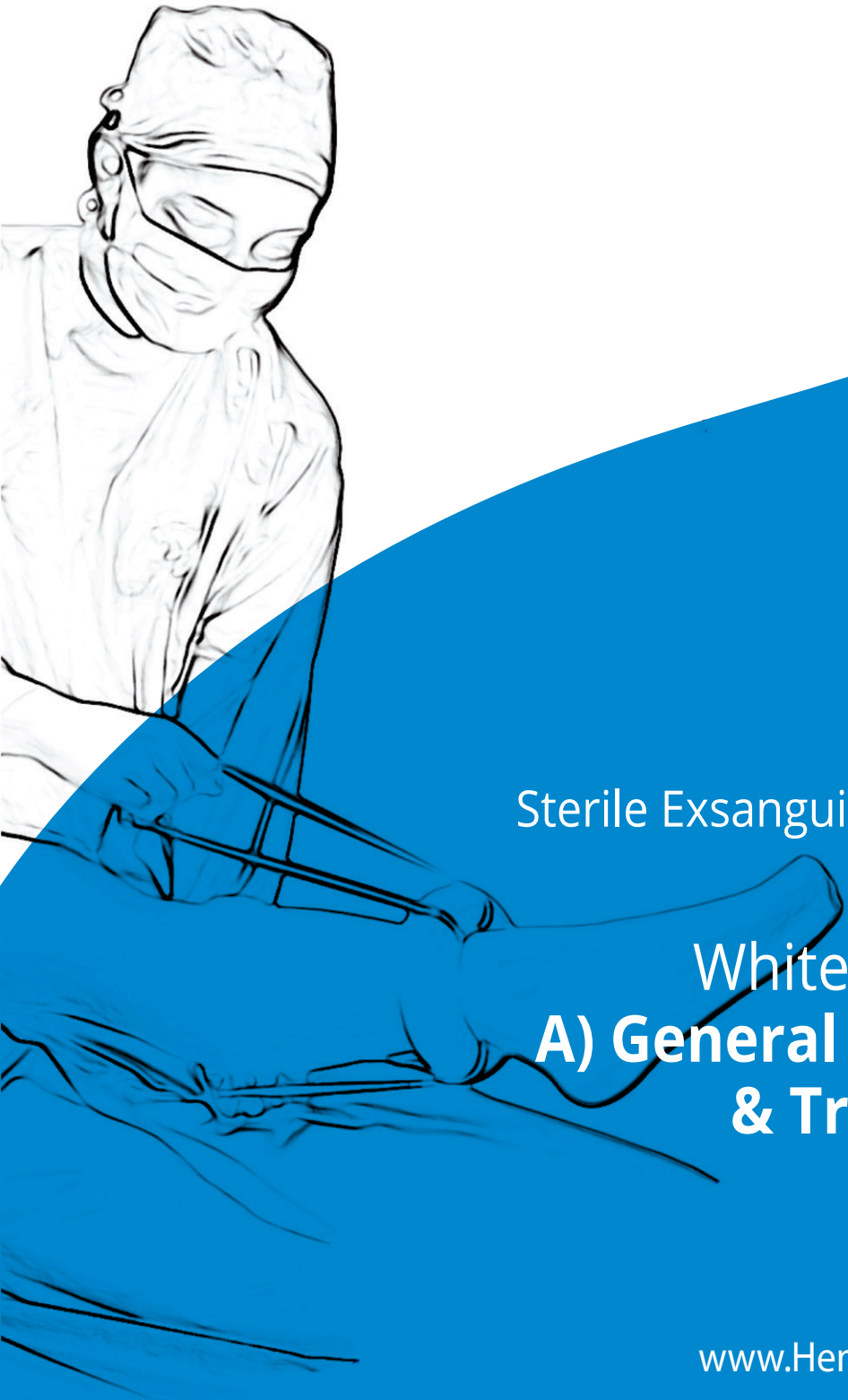

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Understanding and Mitigating Tourniquet Risks

(Tourniquet Pain, Skin Injury and Neuropraxia can be Mitigated by Using Sterile Silicone Exsanguination Tourniquet (SET))

March 2018

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Key words

Pneumatic Tourniquet, Esmarch bandage, exsanguination tourniquet, tourniquet-pain, tourniquet-burn, tourniquet-neuropraxia

Conflicts

The authors are executives and stakeholders in Oneg HaKarmel Ltd., manufacturer and distributor of HemaClear® (www.hemaclear.com).

Abstract

The majority of limb operations are performed with a bloodless surgical field, obtained by removing the blood from the limb (exsanguination) and blocking its re-entry (tourniquet). During the past 100+ years this has been achieved by using an elastic band (Esmarch bandage) and a wide cuff Pneumatic Tourniquet. This practice is associated with frequent and sometimes severe adverse effects. A recent JBJS (Am) study in 164 patients undergoing TKA using a Pneumatic Tourniquet (Zimmer, AST 4000) in Karolinska Institute (Stockholm, Sweden (6)), 20.7% of the patients had skin injuries at the tourniquet site on the thigh, 39.6% reported thigh pain on day 4 postop and 1 patient had tourniquet paralysis. Multiple other studies report similar results.

This review article analyzes the biomechanical processes leading to these adverse effects. In particular, (a) the effects of friction and pinching of skin folds by the inflating Pneumatic Cuff, leading to skin injuries and blisters; (b) the deformations and shear forces applied by a wide cuff on the muscles and specifically on the deep fascia where the pain slow C-fibers are located; and (c) the effect of nerve elongation and telescoping at the Nodes of Ranvier, leading to axonal disruption at the distal and/or proximal edges of the wide Pneumatic Tourniquet, causing nerve damage.

The article also discusses reasons why using the narrow elastic ring exsanguination tourniquet to achieve a bloodless field has not been associated with skin or nerve damage (0 cases in >1,100,000 uses) and significantly less post-op tourniquet pain. The narrow footprint, symmetric circumferential stretching when rolled up the limb, optimized subcutaneous pressure distribution and ability to place it at sites where there is less muscle and fascia, all contribute to its vastly improved safety track record.

When patient safety is of concern, it is apparent that using the sterile elastic exsanguination tourniquet is far safer than using the wide-cuff Pneumatic Tourniquet.

Introduction

The benefits of using a tourniquet during limb surgery are often offset by their adverse effects, namely tourniquet pain, tourniquet "burn" and less frequently tourniquet neuropraxia (2). Nevertheless, the majority of orthopedic surgeons use tourniquets during limb surgery to reduce intra-operative blood loss and in order to improve operative visibility, which lead to more accurate and shorter procedures. Studies and meta-analyses on the benefits and side effects of the use of tourniquets (1) show that their use reduces intra-operative blood loss, but overall hemoglobin levels drop and transfusion rate is not different, while post-operative tourniquet pain and skin damage are not seen when a tourniquet is not used. This essay explores the available data on the mechanisms of wide Pneumatic Tourniquet adverse effects and on the enhanced safety of using a Sterile Silicone Exsanguination Tourniquet – SET (HemaClear®, Oneg HaKarmel Ltd., Tirat Carmel, Israel) in upper and lower extremities surgery.

Tourniquet Pain – (TP)

There are two kinds of tourniquet pain (TP): intra-operative and post-operative. The intra-operative TP is described as an anesthesia challenge characterized by gradually increasing arterial blood pressure and heart rate that are poorly responsive to standard analgesics and anesthesia (2, 3, 4, 5). This kind of TP typically subsides upon release of tourniquet pressure. Speculations concerning the cause of intra-operative TP implicate nerve compression and ischemia that stimulate unmyelinated C-fibers. Their action potentials are perceived as pain. It is believed that slow conduction C-fibers, which are typically less responsive to local anesthetic blockade are the source of the pain. The pain increases over the first 45-60 minutes of tourniquet inflation so that regional blocks that are normally sufficient for surgical anesthesia for the surgical incision itself are not enough to block the tourniquet pain. Additional analgesia or even general anesthesia become necessary and even with those, sympathetic responses of blood pressure and heart rate may become excessive and require premature tourniquet pressure release.

Postoperative TP

Postoperative TP is pain experienced by the patient following the operation at the site where the tourniquet was placed. When Pneumatic Tourniquet is used this pain is in the quad muscles in the leg and on the biceps in the upper arm. The following paragraph was copied from a patients group blog (8) as is (including photograph). It best depicts the symptoms in a most authentic way:

"Tourniquet pain is a consequence of lower limb surgery that is not much talked about. It's a pain that occurs in the upper thigh because of the tourniquet the surgeon uses to both restrict blood loss and make the surgical field bloodless so he can carry out the procedure with greater accuracy and speed.

The tourniquet is usually pumped up to around [three] times the patient's blood pressure - 350mg/Hg for an adult leg. If this is maintained for a couple of hours, the patient may experience a burning pain for some hours or even days after the surgery. It can range from a slightly bruised feeling to an intense burning pain which restricts movement and makes it difficult to do straight leg raises and walking."

Figure 1 Pneumatic Tourniquet placed on a patient's thigh (8)

Several studies that looked into the incidence of postoperative tourniquet pain (6, 7, 9, 10, 11) have been published in recent years. The most focused one is the study by Olivecrona et Al from Karolinska Institute in Sweden, published in JBJS in 2012 (6). This study's primary outcome was the effect of tourniquet inflation pressure on postoperative tourniquet pain. Curved thigh Pneumatic Tourniquet (Zimmer) was applied on 161 patients who were divided into two groups, based on the method of pressure selection (Limb Occlusion Pressure method (LOP) and surgeon-determined pressure). The pain was assessed using a standardized questionnaire (WOMAC) on day 4 postoperatively. On that day, 20.7% of patients had developed blisters or other pressure-related injuries underneath the tourniquet cuff and 39.6% of patients reported they had pain in the quadriceps muscle beneath the tourniquet cuff. There were no differences between the two groups, ($p = 0.400$). All patients also received infiltration of local analgesic into the incision site at the end of the surgery by injecting it into the fascia, muscles, and subcutaneous tissue, regardless of whether they had spinal or general anesthesia. In 147 of the patients, a catheter was also inserted into the knee joint for post-op pain treatment with a local anesthetic. It was used during the day following the surgery and was then withdrawn.

This study clearly shows the discrepancy between the well-controlled incisional pain by the infiltration of long-acting local anesthetics vs. the extent of thigh muscle tourniquet pain. Other studies (7, 10, 11) also found that postoperative thigh pain was prevalent after TKA and often required parenteral narcotics (e.g. morphine).

Factors that Influence Pneumatic Tourniquet Pain and Other Adverse Effects

When compressive mechanical load is applied to a limb to block blood flow, the tissues beneath it are deformed macroscopically and microscopically. First off, the load has to be sufficient to collapse the arteries in order to stop

the circulation. This means that the pressure just outside of the artery must be greater than the highest intravascular pressure, namely the systolic blood pressure. The artery must be collapsed over a length of no more than a few millimeters in order to block it. The actual complete collapsing transmural pressure on the artery is a complex function of the systolic pressure and the arterial wall thickness and flexibility (http://www.academia.edu/13977055/General_Tube_Law_for_Collapsible_Thin_and_Thick-Wall_Tubes (Kozlovsky, P., et al., General tube law for collapsible thin and thick-wall tubes. Journal of Biomechanics (2014)). The applied external pressure must overcome the systolic blood pressure, as well as the mechanical resistance to complete folding of the arterial wall at the two edges of the buckled artery (Figure 2)

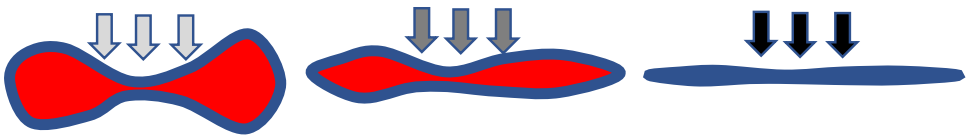


Figure 2 Left, low sub critical pressure causes partial collapse with significant side-lobes; Middle, higher pressure compresses the side-lobes, but closure is still incomplete; Right, the pressure needed to completely collapse the artery and block blood flow is somewhat higher than the systolic pressure. The extra pressure needed to completely fold the artery is small relative to the systolic blood pressure except in patients with arterial calcification and sclerosis.

To achieve the needed pressure just outside of the arterial wall the pressure applied by a tourniquet to the patient's skin should be at least as high. When a wide Pneumatic Cuff is used, such as when measuring blood pressure by the Riva Rocci sphygmomanometer the skin pressure and the internal pressure are identical. This is true also when applying a wide surgical Pneumatic Tourniquet to a limb. However, when the tourniquet is narrow relative to the limb diameter such as when a too narrow cuff is used to measure blood pressure or when the Silicone Exsanguination Tourniquet – SET (HemaClear®, Oneg HaKarmel Ltd., Tirat Carmel, Israel) is used to provide a bloodless surgical field, the tissue pressure outside the arterial wall is significantly less than the skin pressure.

When a wide Pneumatic Tourniquet cuff is applied to a limb, e.g. the thigh over the quadriceps or the upper arm over the biceps/triceps, in addition to the compression of the arteries, a large volume of soft tissue comes under stress and deformed. MRI images taken during tourniquet application (figure, 6 from Dr. Estebe Personal communication) show the deformed tissues and the extent of the deformation. Clearly the skin, subdermal tissues, the muscles and the deep fascia are deformed and displaced. The nerve(s) running along the limb are compressed and deformed as well.

The factors that play a role in this process are as follows:

1. Tourniquet skin pressure
2. The pressure field and distribution of pressure in the tissues
3. Tourniquet width which determine the volume of tissue and skin surface area beneath the tourniquet
4. Limb diameter and thickness of adipose layer

5. Duration of tourniquet application and patient-related factors (e.g. preoperative tissue oxygen storage, arterial stiffness, tissue vascularization etc.)
6. Location of tourniquet placement

The following chapters analyze the contribution of each factor to the risk of developing postoperative tourniquet pain.

Tourniquet Skin Pressure

There are many empiric clinical protocols to determine the skin pressure that will be sufficient to block the blood flow into a limb. The use of 200-250 mm Hg on the upper arm and 300-350 mm Hg for the thigh is common among surgeons and seem to work for the vast majority of patients, but may actually be excessive. Some researchers who felt that these pressure levels are too high and may be the cause of adverse effects sought to find a formula for "dialing in" tourniquet pressures that are tailored to the individual patient. They proposed using the patient's pre-operative systolic blood pressure and add a fixed value to it (e.g. 50 mm Hg for the arm and 100 mm Hg for the thigh). Another method is to determine the patient's pre-operative Limb Occlusion Pressure – LOP, which is the tourniquet pressure where pulsations in the toe/finger cease as determined by a photocell or a pulse oximeter. This value which is circa the systolic blood pressure is then used as basis for adding a fixed value. In both cases the reason for setting the tourniquet pressure higher than the pre-op systolic pressure/LOP is because blood pressure can rise during the operation. Most common reasons for this rise are (i) the shifting of blood from the limb (leg in particular) to the core during the pre-inflation limb exsanguination and (ii) surgical or tourniquet pain that is not countered sufficiently by analgesics. In a recent study (6) Olivecrona et Al suggested using 225 mm Hg as the highest tourniquet pressure in patients undergoing TKA who have a BMI not greater than 35. In a post-hoc analysis of their data they found a significantly lower rate of complications when tourniquet pressure was less than 225 mm Hg.

Pressure Distribution Inside a Limb

The origin of the Pneumatic Tourniquet is from the Riva-Rocci method of blood pressure measurement (Figure 3a) (http://en.wikipedia.org/wiki/Scipione_Riva-Rocci), or sphygmomanometer. The force applied to the soft tissues by a circumferential Pneumatic Cuff or tourniquet pressurizes and deforms the tissue. However, although the soft tissues of limbs (muscle, skin, fat) are elastic and flexible, they are not compressible. As a result, the applied forces cause elements of the tissue to move (displacement). Already in 1977, Alexander et Al calculated the pressure field within a limb model beneath a cuff and determined that in order for the pressure inside the limb at the middle of the width of a cuff to be equal to the cuff pressure throughout from the skin level to the center of the limb the cuff width must be 1.2 times larger than the diameter of the limb at the cuff site (Figure 3b). This is very important in order for blood pressure determination by the Riva-Rocci method to be accurate (red arrow). However, if the tourniquet is narrow (e.g. its width is only 0.5 (50%) of the limb diameter (green arrow), the tissue pressure at the midpoint of the tourniquet may be as low as 0.75 (75%) of the surface pressure (green arrow).

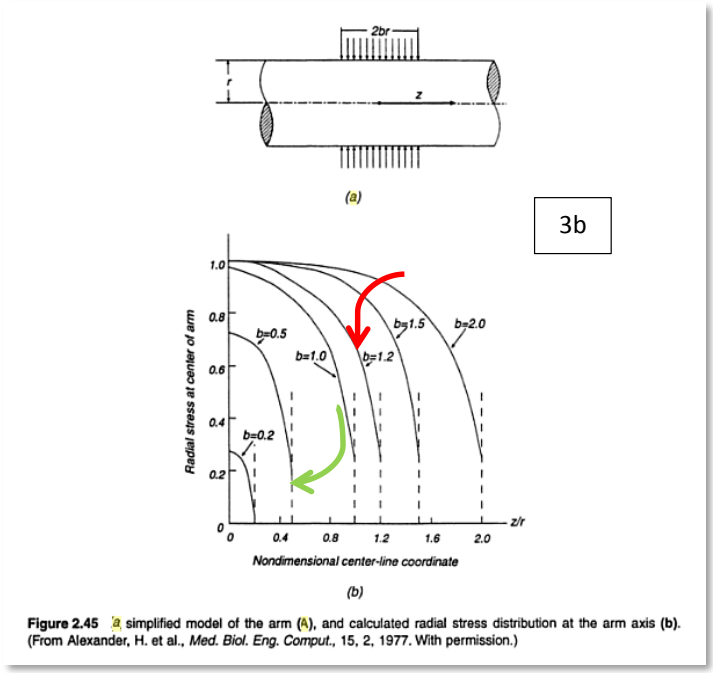


Figure 2.45 A simplified model of the arm (A), and calculated radial stress distribution at the arm axis (b). (From Alexander, H. et al., *Med. Biol. Eng. Comput.*, 15, 2, 1977. With permission.)

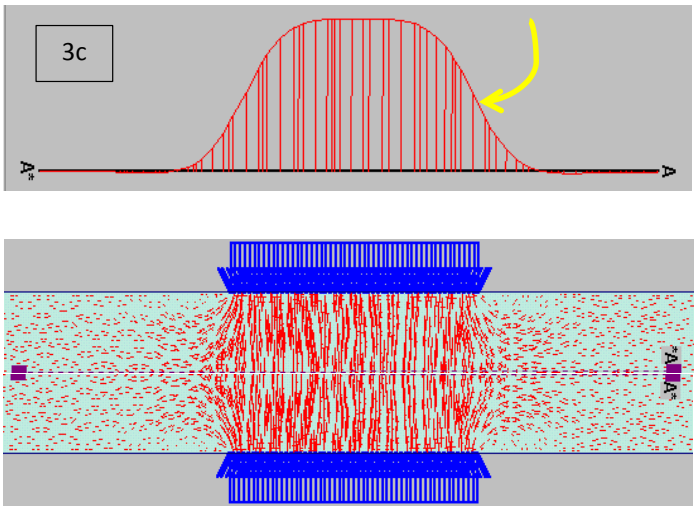


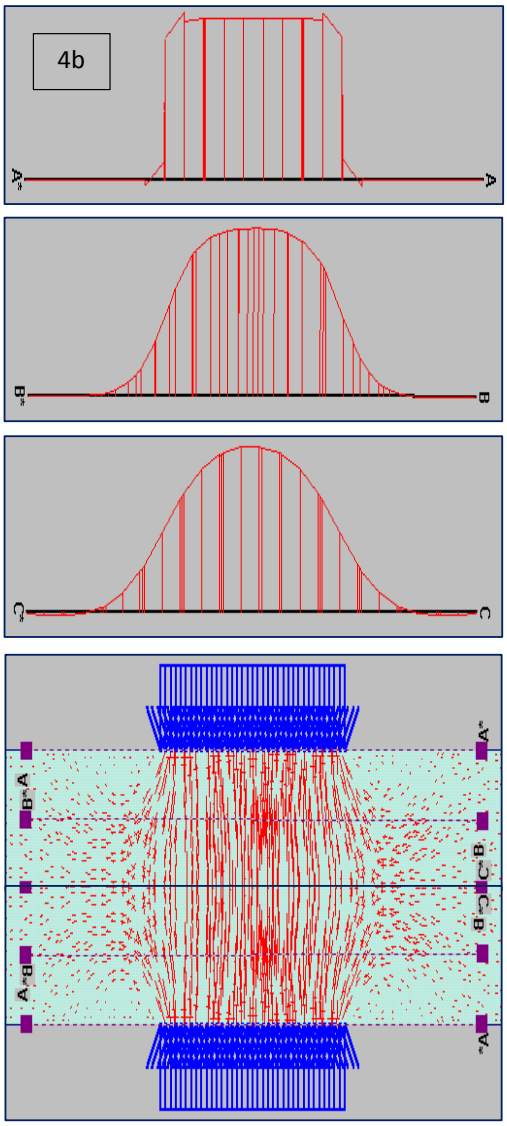
Figure 3a-c

3a. Top left: blood pressure measuring device (sphygmomanometer)

3b. Top right: Calculated radial stresses in a limb at its midline from Alexander et al, Med. Biol. Eng. Comput 1977. See text for explanation.

3c. Left: Distribution of principal stresses (pressure, lower panel) and a plot of the radial stresses at the axis of symmetry (upper panel) when a wide tourniquet (width = 1.5 X limb diameter) is applied [from Levenberg E. OHK Archives 2002].

Note the rather steep gradient of pressure drop along the axis of the limb at the edges of the tourniquet (yellow arrow).



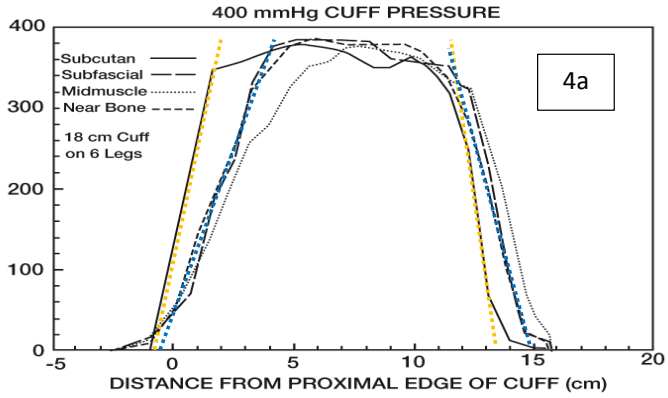


Figure 4a-b

4a. Top: Data from Crenshaw AG, Hargens AR, Gershuni DH, Rydevik B. Acta Orthop Scand 1988; 59(4): 447-451. **showing the pressures measured inside a cadaver limb beneath a cuff of a Pneumatic Tourniquet. The pressure profiles at four levels beneath the skin are shown. While the peak pressures in all the profiles are the same, it is possible to see that the subcutaneous profile is wider, nearly as wide as the cuff width, and the gradients at its two ends are very steep (orange dashed lines). The profiles deeper into the limb and near the bone are narrower and the gradients are less steep (blue dashed lines).**

4b. Left: Computational finite elements analysis of the same situation showing the limb model with the tourniquet (here the tourniquet width is the same as the limb diameter). Panel A is right under the cuff, panel B is half way to the midline and panel C is at the midline. Note that here also the peak pressure is nearly the same as the tourniquet pressure and that deeper into the limb the pressure gradients at the two ends become less sharp.

The similarity between the computational model results and the experimental data indicates a positive validation of the model.

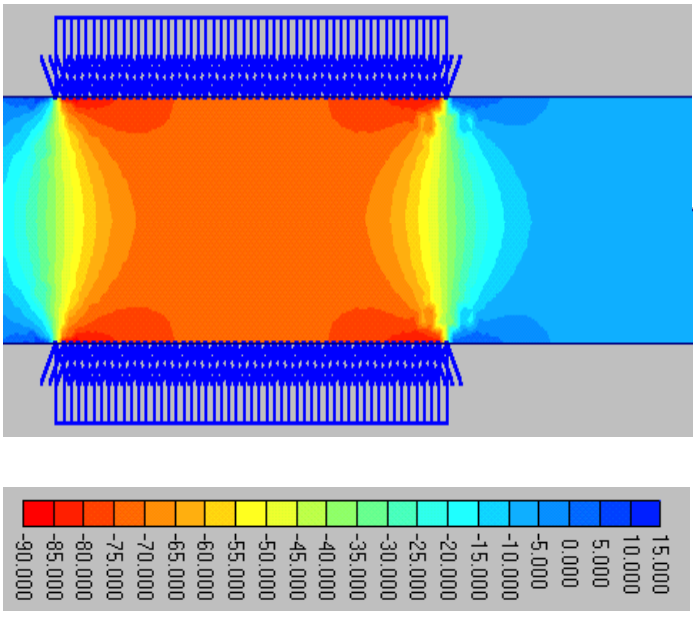
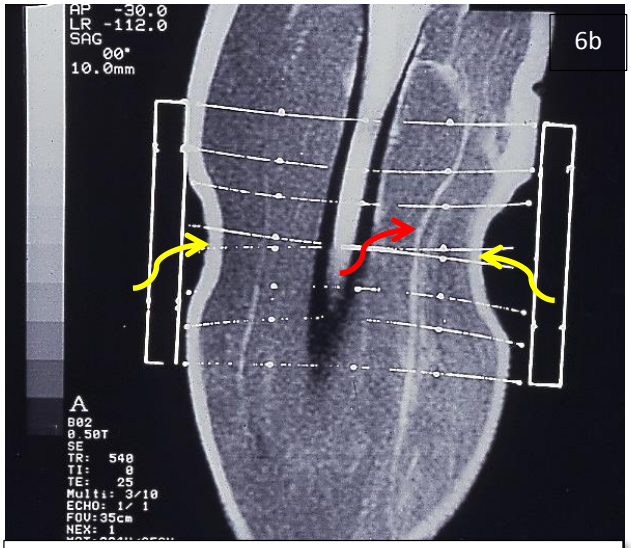


Figure 5

The pressure field inside the limb can also be shown as colored isobars (left). Isobars are areas where the pressure is about the same and are shown in percent of the skin pressure according to the color scale below. In this computational model of the pressures, it is possible to see that with a wide tourniquet (in this case the tourniquet width is X1.5 the limb diameter) the tissue pressure is uniform across the limb cross-section almost under the entire width of the tourniquet and is approximately equal to the tourniquet skin pressure. The gradient at the two ends of the tourniquets is steep, full scale over less than 0.5 limb diameter.

Soft Tissue Deformation Beneath a Cuff.

When a Pressure Cuff (tourniquet or sphygmomanometer) is pressurized around a limb, the soft tissues (skin, fat, muscle etc.) change their shape (deform). [Calling this deformation "compression" is incorrect since tissues, like solids and liquids are essentially incompressible materials. This is different from gases which can change their volume when pressurized and are therefore called "compressible"]. The MRI image on the right (Figure 6a) (courtesy of Prof. Estebe, Rennes, France, who had taken an MR image of his own thigh while a Pneumatic Tourniquet was inflated for 20 minutes) shows the deformation of the tissues. The cuff base is shown as two rectangles and the indentation of the skin (yellow arrows) is where the inflated bladder pushed and deformed the thigh. It is also possible to see that the muscle (gray) and the fascia (red arrow) are displaced, deformed and stretched.



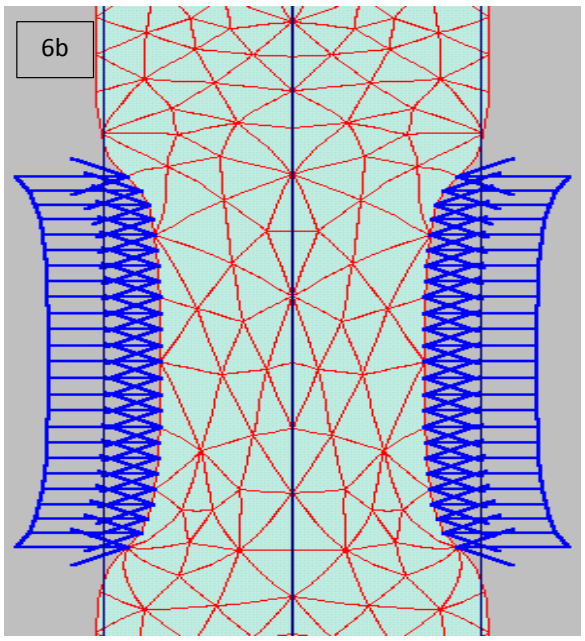


Figure 6a-b

6a. Top: MRI of the thigh under a pressurized Pneumatic Tourniquet (Estebe, personal communication, Rennes, France).

6b. Left: Computational finite elements analysis (red strings) showing the deformation (strain) of a limb under circumferential pressure by a Pneumatic Cuff. From Levenberg E. OHK Archives 2002.

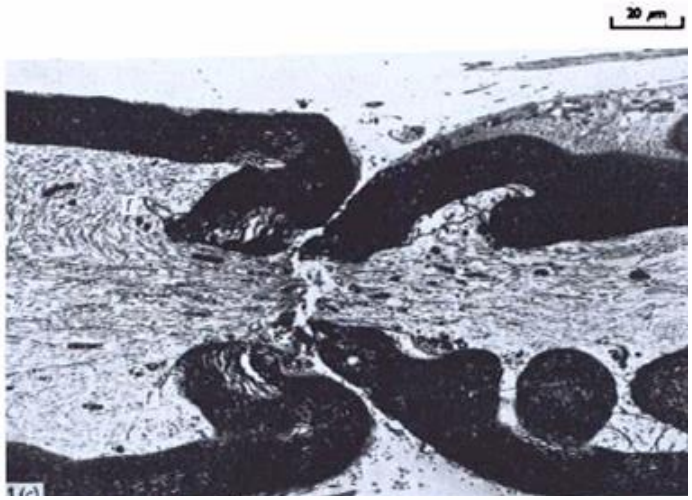
Note the similarities between the model results and the MR image of the limb above.

It is important to understand that the changes observed in the shape of the tissues are all related to motion or dispacement of tissue elements squeezed from the pressurized area beneath the cuff distally and proximally towards the un-pressurized areas. The only actual volume reduction is due to the closing shut of the blood vessels.

Consequences of Soft Tissue Deformation by a Tourniquet

Clearly, when circumferential force is applied to a limb, the resulting pressure field causes deformation and displacement of the soft tissues. The extent of deformation (or "strain") is not negligible and is different in various components of the tissue, depending on their elastic properties (also called the Young's Modulus). Fat is the softest element and muscle properties are different if deformed along the fibers or perpendicular to them. Fascia can be bent, but not shifted. A special case is the nerve, which, when compressed is elongated (see below). The difference in elasticity can cause adjacent tissues to move differently resulting in sheer forces between them, stretching beyond the elastic range and possible tears.

The radial forces that deform the limb radially cause longitudinal motion of tissues along the limb axis. This was noted already in the early 1970s by Ochoa et al who sought a mechanistic understanding of the cause of tourniquet-induced nerve damage ("tourniquet neurpraxia"). They applied pressurized Pneumatic Tourniquets to primates' limbs for several hours and after sacrificing the animals dissected the nerves for electron microscopy.



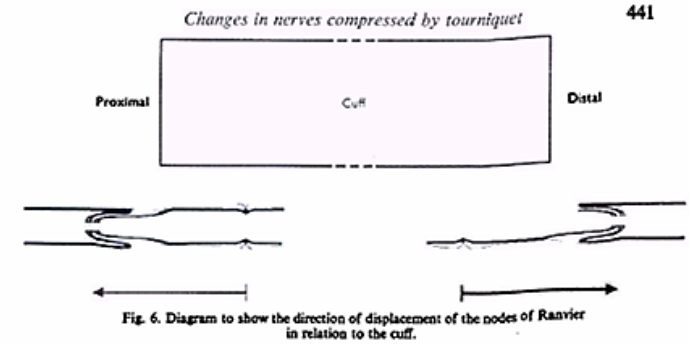


Fig. 6. Diagram to show the direction of displacement of the nodes of Ranvier in relation to the cuff.

They found that the nerves were damaged in a characteristic fashion – they telescoped into themselves at their weakest point, namely the Nodes of Ranvier (Figure 7). At these nodes the Schwan Cells sheet that envelopes the nerve is interrupted for a few microns so that only the axons are continued. The electron micrograph on the left shows an example with a disruption of the axons. To their surprise, the damaged nerves were only seen just proximal and just distal to the Pneumatic Tourniquet cuff as depicted on the two lower panels on the left.

The researchers concluded that the lateral compression of the nerve, which caused it to deform and elongate is the primary cause of the damage, rather than a direct effect of the pressure under the cuff.

The computational analysis by Levenberg depicted below (Figure 8) clearly shows the direction (arrows orientation) and the extent (arrows size) of tissue deformation caused by tourniquet pressure. Areas of excessive axial deformation just before and just after the edges of the tourniquet are marked by yellow arrows.

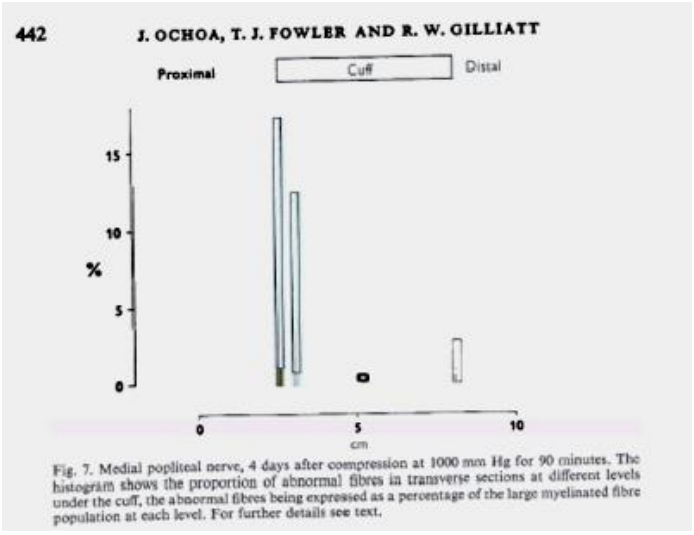
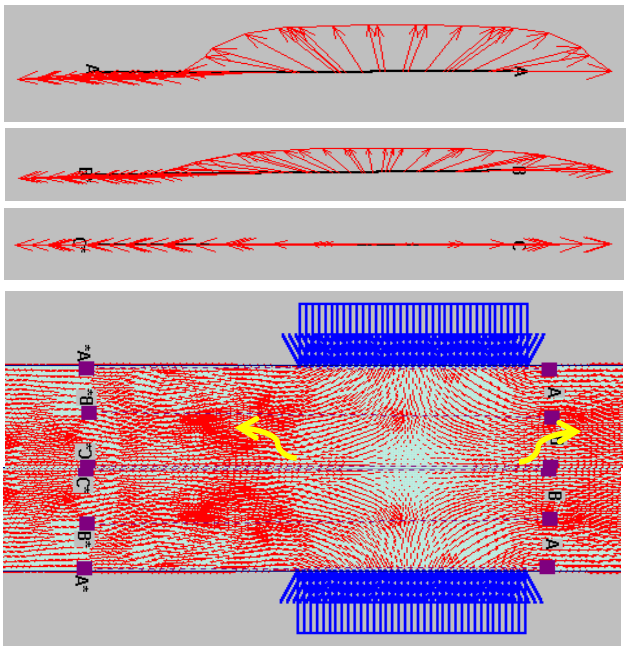


Fig. 7. Medial popliteal nerve, 4 days after compression at 1000 mm Hg for 90 minutes. The histogram shows the proportion of abnormal fibres in transverse sections at different levels under the cuff, the abnormal fibres being expressed as a percentage of the large myelinated fibre population at each level. For further details see text.



Additional Effects of Tissue Deformation

Two additional adverse effects of the use of wide Pneumatic Tourniquets are also related to tissue deformation, rather than to direct pressure effects or to ischemia. These are (A) skin injury, primarily in the form of blisters; and (B) tourniquet pain. In addition, tissue element motion is also responsible for the desired effect of using a tourniquet, namely the collapsing of the blood vessels beneath the cuff. Below are pictures that illustrate these effects and side effects as MRI (courtesy of Prof Estebe), photo of the skin of a patient who developed tourniquet-related blisters and a computational image showing the closure of the blood vessels by the applied tourniquet pressure.

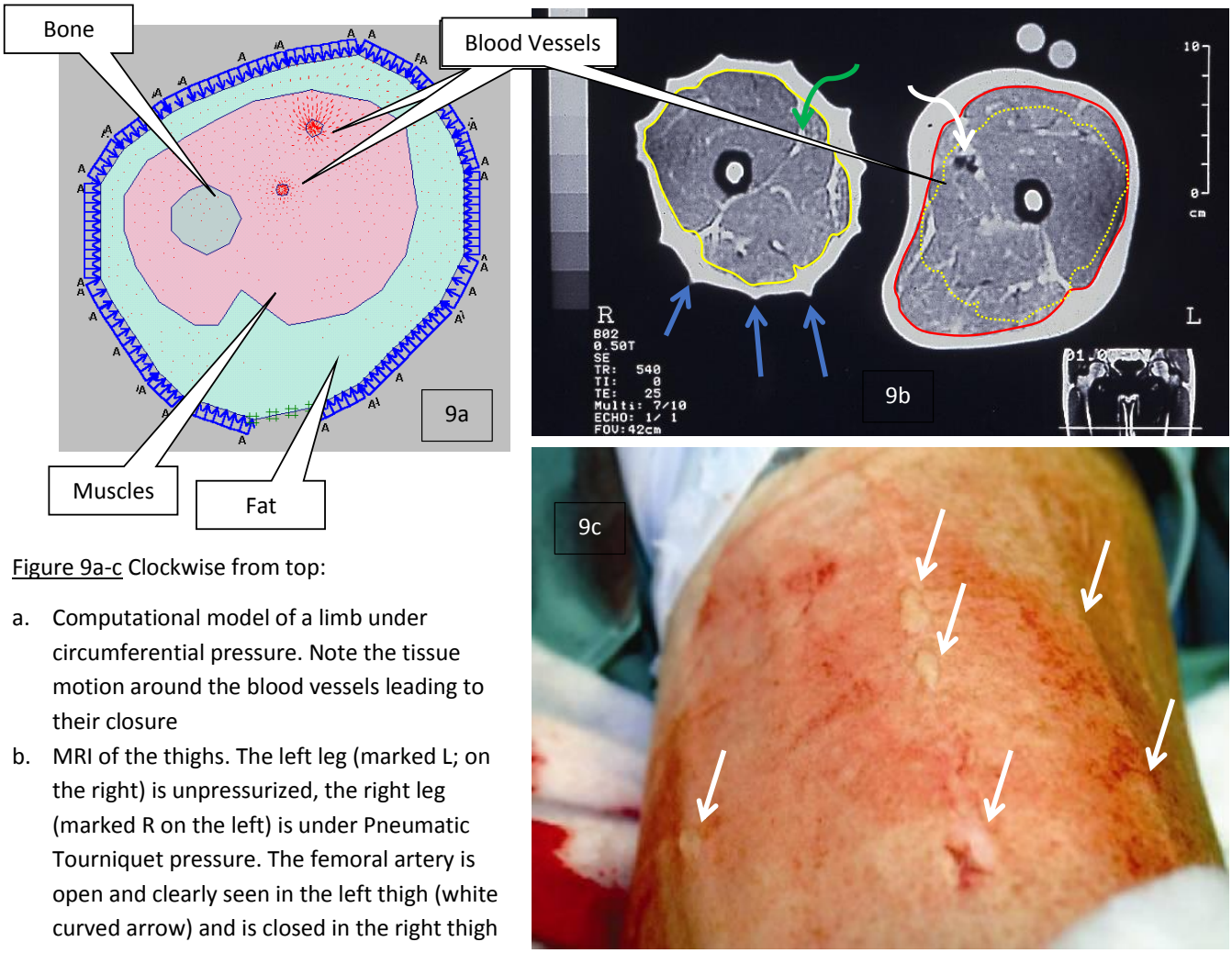


Figure 9a-c Clockwise from top:

a. Computational model of a limb under circumferential pressure. Note the tissue motion around the blood vessels leading to their closure
b. MRI of the thighs. The left leg (marked L; on the right) is unpressurized, the right leg (marked R on the left) is under Pneumatic Tourniquet pressure. The femoral artery is open and clearly seen in the left thigh (white curved arrow) and is closed in the right thigh (green arrow). The extent of deformation can be appreciated from the difference between the red and the dotted yellow perimeters. Note the creases of the skin where the inflated tourniquet pinched the excess skin (blue arrows).
c. These creases correspond to the longitudinal elevations and linear blisters seen in the photo of the post tourniquet skin damage (white arrows). These so called "tourniquet burn" have been attributed to chemicals used in disinfecting the skin. Obviously the main cause is mechanical and associated with the pinching of the skin by the inner surface of the Pneumatic Tourniquet.

Biomechanics of the Elastic Exsanguination Tourniquet

The Elastic Exsanguination tourniquet (HemaClear®, Oneg HaKarmel Ltd., Tirat Carmel, Israel is an elastic ring (torus) which, when stretched, applies circumferential tension around the limb that results in radial force and displacement of the tissue. The relationships between the circumferential force, the radial force and the tissue pressure are explained in Section 2.3.

Ring-induced pressure in the tissue

The Elastic Exsanguination Tourniquet exerts its maximal force on the skin surface where the force is perpendicular to the limb. Further into the limb the force (a vector) principal direction shifts a bit axially and as such the pressure becomes smaller. This results in two pressure gradients, one in the radial direction where the pressure becomes smaller deeper into the limb and the other is in the axial direction. In fact, in a thin limb (e.g. an arm) if the surface pressure is 250 mm Hg, the pressure near the artery may be less than 200 mm Hg. This radial gradient is even greater when the limb is wider (e.g. thigh) and the artery is further away from the skin surface.

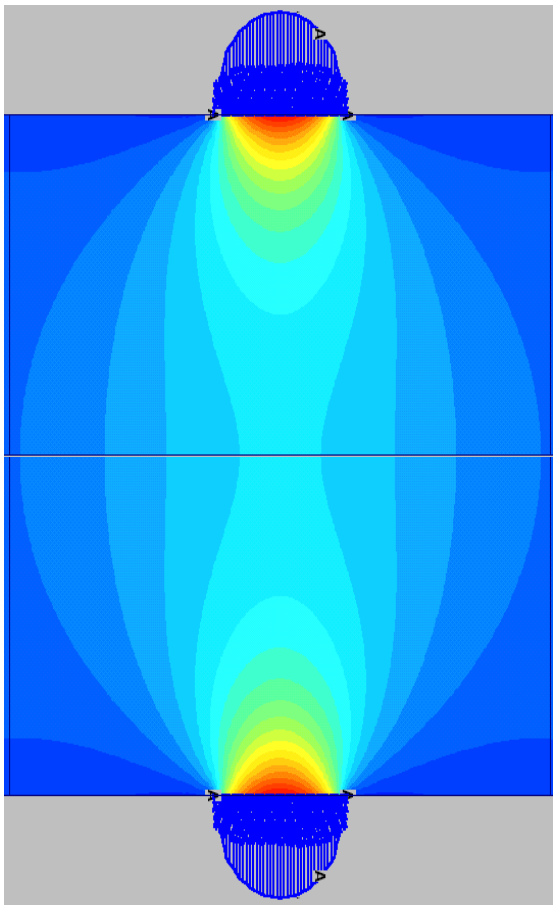
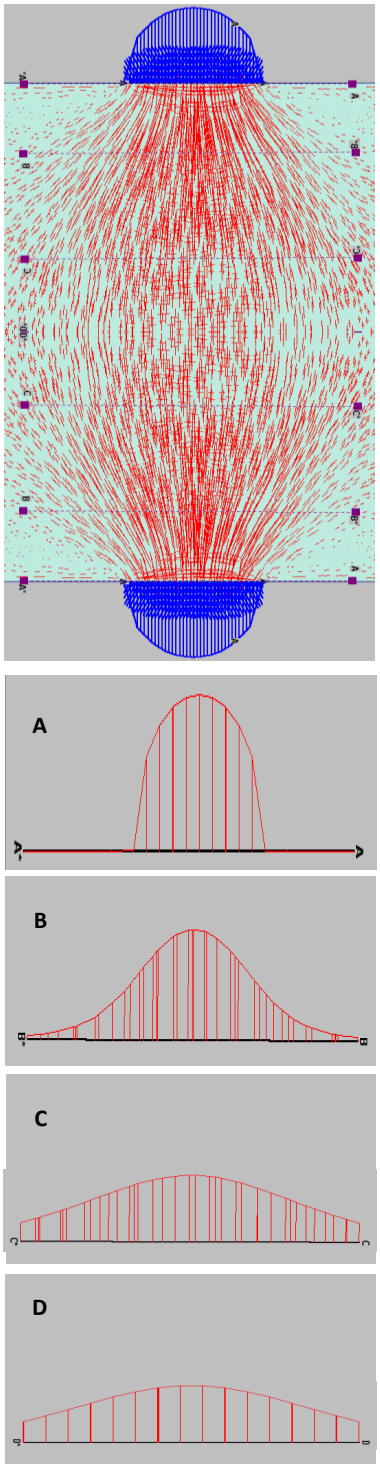


Figure 10

The figure on the right shows the pressure profiles at 4 levels: (A) immediately under the skin, (B) two thirds of the limb radius, (C) third of the limb radius, and (D) at the midline. Note that level B, which is about 68% of the maximum, represents a typical depth of the artery.

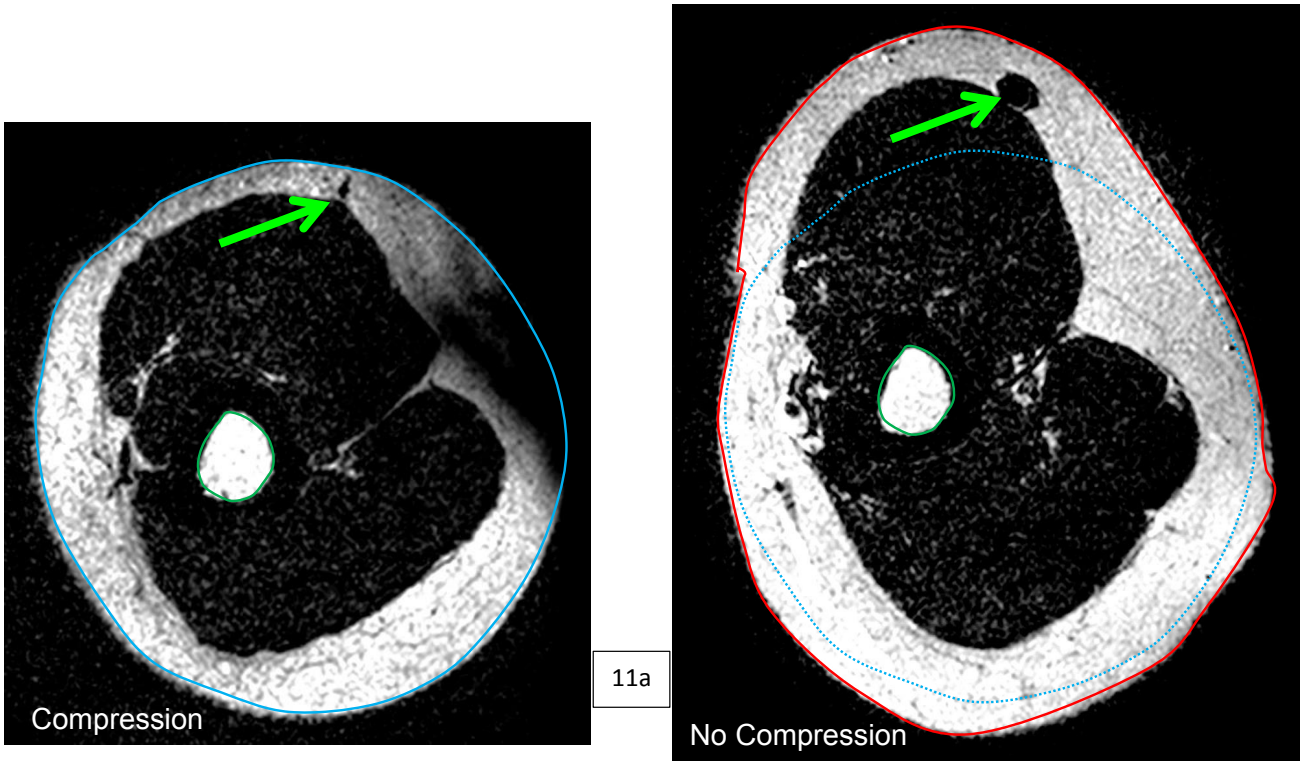
Note that the pressure dissipates beyond the width of the Elastic Exsanguination Tourniquet.



Soft Tissue Deformation by the Elastic Exsanguination Tourniquet

Applying equivalent radial force (stress) on the soft tissue of a limb by an Elastic Tourniquet causes approximately the same level of deformation or strain. This is so because the ratio of Stress/Strain is equal to the Young's modulus, which is a constant depending only on the properties of the tissue and not on the

mechanism by which the tissue is acted on. The images shown below for the Elastic Exsanguination Tourniquet should be compared to those for the Pneumatic Tourniquet shown in Sections 3.2 - 3.4.



11a

11b

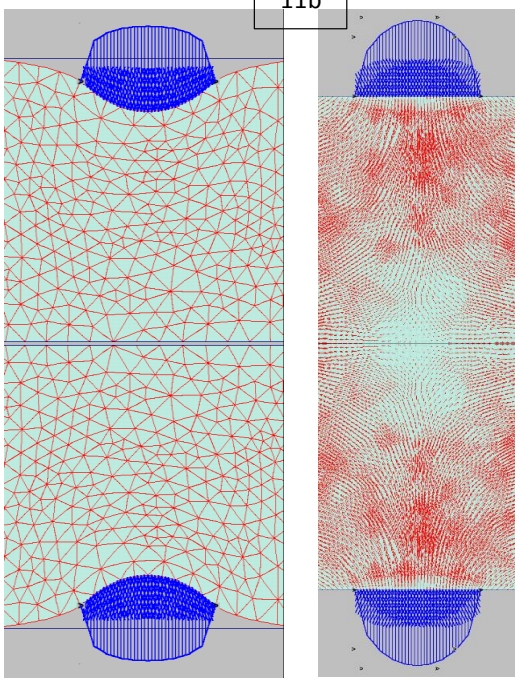


Figure 11 a-b

11a Top: MRI of an arm without (right) and with (left) an Elastic Exsanguination Tourniquet in place (courtesy of Dr. Kovar and Prof. Herzenberg, personal communication). The intra-medullary canal (white spot, perimeter marked in green) was used to verify dimensions. The elastic ring closed the blood vessels (green arrows) and deformed the muscles and fat. The extent of deformation is comparable to that by a Pneumatic Tourniquet, but into a smoothly rounded shape without the pinching side-lobes seen with the Pneumatic Tourniquet.

11b Right: Computational model of the tissue deformation beneath an Elastic ring. The extent of surface and elements deformation can be appreciated from the left-hand panel, while the extent actual motion can be seen in the direction and size of the small arrows shown in the right panel.

Tourniquet Width and the Volume and Surface Area of Tissue Under Compression Force Beneath the Tourniquet and the External Work Applied to the Tissue

We shall now calculate the volume and skin surface area beneath a tourniquet. If we call the cuff width "H" and the limb radius "R" than the volume of tissue beneath the tourniquet "V" can be calculated as

$$V = \Pi * R^2 * H$$

and the skin surface area beneath the tourniquet "A" is given by

$$A = 2\Pi * R * H$$

To calculate the Compression Force "F" we need to recall that the Tourniquet Skin Pressure "P" is given by the applied force divided by the surface area beneath the tourniquet:

$$P = F / A = F / (2\Pi * R * H)$$

This equation can be re-written as a calculation of Force for a given pressure and limb surface area:

$$F = P * A = P * (2\Pi * R * H)$$

When a tourniquet is placed on a limb, it compresses it and causes a change in volume ΔV. External work or applied energy "W" is defined as the product of the pressure applied and the displaced volume ΔV that can be estimated from the MRI images as $\Delta V = \Pi * R^2 * H - \Pi * (R- \Delta R)^2 * H \sim= 2\Pi * R * \Delta R * H$ so that:

$$W = P * \Delta V =\sim P * 2\Pi * R * \Delta R * H$$

Pneumatic Tourniquets cuffs widths vary between 75 mm ("narrow") to 120 mm ("dual bladder") and are typically 100 mm. The SET width is typically 15 mm. For this analysis we shall assume a normal adult upper thigh with a radius R = 100 mm (circumference of 62.8 cm). Table 1 shows the calculated V, A, F and W for a Pneumatic Tourniquet cuff and SET. Both with skin pressure of 250 mm Hg [= 0.33 atmosphere = 0.33 kg/ cm^2).

	Pneumatic Cuff	SET
Volume under constriction [ml]	$V = 3.14 * 10^2 * 10 =$ 3140 ml	$V = 3.14 * 10^2 * 1.5 =$ 471 ml
Skin area beneath tourniquet [cm^2]	$A = 6.28 * 10 * 10 =$ 628 cm^2	$A = 6.28 * 10 * 1.5 = 94$ cm^2
Force applied to the volume of tissue	F = 0.33 * 628 = 209 kg	F = 0.33 * 94 = 31 kg
External Work	W = 0.33 * 3.14 * 5 *1 * 10 = 50 Atm-cm^3	W = 0.33 * 3.14 * 5 * 1 * 1.5 = 7.5 Atm-cm^3 if we assume internal pressure is uniform. Since the internal pressure is lower than the skin-pressure, the external work is even smaller.

It is clear that the constricting force of over 200 kg applied by a Pneumatic Tourniquet on the volume of tissue beneath is excessive. This force has two direct effects: (A) it deforms the tissues beneath the tourniquet and given the fact that the soft tissues of the limbs are essentially non-compressible, the force is primarily causing the tissue to move and when possible to migrate away from the volume under force; and (B) the force is applied as nearly a step change at the two edges of the cuff, thereby creating a steep gradient, also called shear stress at the two edges of the cuff.

Another way to characterize the effect of applying a tourniquet to a limb is by determining the External Work into the tissue. External Work is force times displacement when applied in a unidirectional fashion (e.g. lifting a weight), or pressure time change in volume in three-dimensional compression as with the tourniquet. External Work is equivalent to energy input into the pressurized element and at ~50 Atm-cm is excessive.

The Effect of the Duration of Blood Flow Occlusion by a Tourniquet

When blood flow to a limb is stopped, the supply of oxygen and metabolite substrate (e.g. glucose) is stopped. This results in a quick drop in PO2 and the onset of consumption of alternative sources of ATP. Initially from the muscle stores of creatine phosphate, followed by onset of anaerobic metabolism that results in accumulation of its metabolites such as lactic acid. The graphs below show the kinetics of PO2 levels (top panels), quantity of anaerobic metabolites (e.g. lactate) in the intracellular compartment and the corresponding concentration. The occlusion of blood flow is indicated by the onset of PO2 drop.

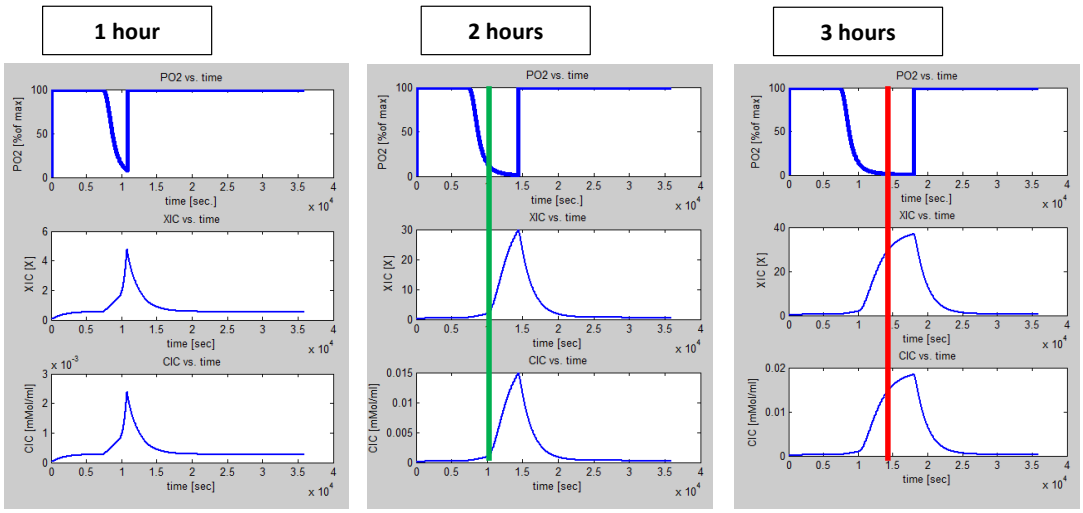


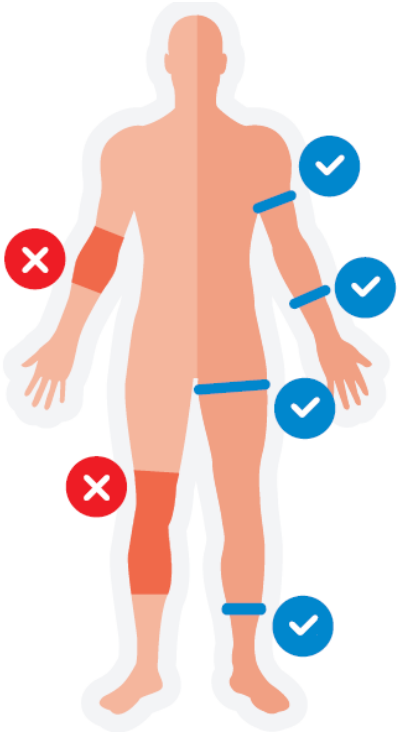
Figure 12 The effect of Tourniquet Time on PO2, quantity of metabolite (e.g. lactate) in the intra-cellular compartment (XIC) and its concentration (CIC). Left panel – 1-hour, Middle panel 2-hours, Right panel 3-hours. Note that the Y-axis is not the same in all the panels; time axis is in seconds X 10^4. (Gavriely, N. unpublished data)

In this example it is possible to see that when intracellular PO2 reaches a critically low level, the anaerobic metabolites start to accumulate (green vertical line). However, when the substrates for the anaerobic metabolism is depleted, the slope of the metabolites accumulation changes (red line). This is when ATP availability to the tissues becomes critically low and ischemic injury is imminent. In this model, the onset is at about 7000 sec after tourniquet onset =~ 2 hours. The situation is reversed when the blood flow occlusion is removed where PO2 returns to normal and the metabolites are washed out.

This model is helpful in pointing out the importance of pre-occlusion conditions and in particular the tissues oxygen levels and the stores of ATP and metabolic substrates. These are typically low in patients with co-morbidities such as peripheral vascular disease, cardio-pulmonary ailments and diabetes.

Location of Tourniquet Placement

An important factor in preventing tourniquet adverse effects is the locations where the tourniquet is placed. The options with the Pneumatic Tourniquet are limited to the thigh (mid or upper), or upper arm. Placing a Pneumatic Tourniquet on the wrist or on the ankle splints the ligaments and result in marked limitation of the motion of the fingers and toes, thereby interfering with the surgical procedures of hands and toes. These sites are associated with marked deformation of the underlying muscles and fascia and cause significant post-operative pain.



The SET, on the other hand, can be placed away from major muscle masses as shown in the diagram on the right (Figure 12). On the upper limb it is placed over the insertion of the deltoid, just above the biceps or on the wrist, 10 cm above the wrist skin fold. The wrist placement of the SET is possible because it does not splint the ligaments and allows full free passive and active motion of the fingers. The same is true when the SET is placed 10 cm above the lateral malleolus on the ankle. If on the upper leg, the SET should be placed at the groin level (i.e. where the leg connects to the pelvis). In all these sites the underlying muscles and fascia are the least and the result is much less post-op pain.

Summary and Conclusions

This manuscript reviews the biomechanics of tourniquets use and the known adverse effects of the wide Pneumatic Tourniquets including tourniquet neuropraxia, tourniquet pain and tourniquet-related skin injuries and blisters. It is apparent that all are attributed to the width of the tourniquet. An outcome of the analysis is the clarification that the wide tourniquet applies very large force and external work on a large volume the limb's tissues, which are unnecessary in order to occlude the blood flow. The superiority of the narrow elastic SET are brought to light with the markedly better safety track record – no neuropraxia, no skin damage and much less pain in more than 1.1 million cases, which are due to its narrow footprint, the uniform skin pressure, the optimized internal pressure and the ability to place it in optimal positions. The metabolic consequences of tourniquet use are briefly presented. Those are common to all tourniquets (wide, narrow or trauma types) and show the biochemical foundation for the empiric time limit of 120 minutes of continuous tourniquet use.

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Using HemaClear® on a Mono-trauma Left Knee-distal Femur: A Case Report

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A Twenty-three old women was involved in a road-traffic accident. She sustained a closed mono-trauma to her left knee-distal femur (according to AO it was classified as 33-C3 fracture).
Initial fixation was done with an external fixator (fig.1a&b)
We chose to use HemaClear® XL for this case as our exsaguination and occlusion method because it is sterile and has a narrow profile. Once in place, HemaClear allows access to the whole limb as opposed to classical pneumatic tourniquet, which due to its width, obstructs and diminishes the surgical field on the proximal thigh.
Applying HemaClear was simple even over the comminuted fractures. Three staff members were involved in the application process: one staff member held the limb and an elevated angel applying axial traction as the other two members pulled the device straps rolling it over the limb into the final occlusion location. HemaClear exsanguinates as it is rolled over the leg and exerts consistent pressure at the occlusion site occluding blood flow and eliminating the need for an Esmarch bandage, tourniquet machine and sterile stockinet (fig. 2a&b).
An open reduction and internal fixation was performed (fig. 3a&b&c&d)

Initial Fixation

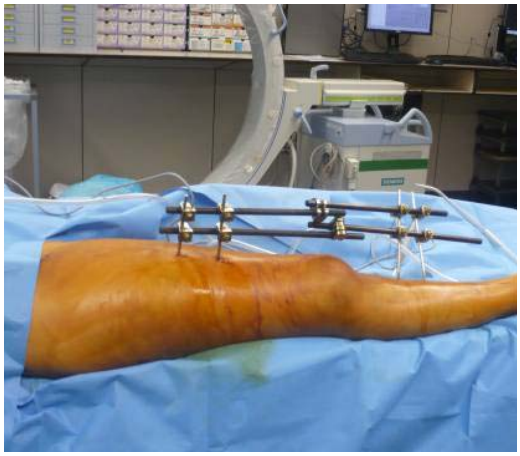


Fig. 1a

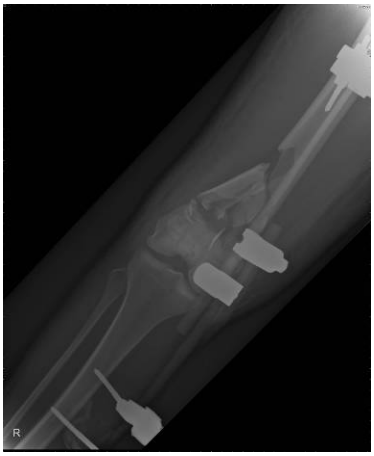


Fig. 1b

HemaClear® Application Technique – Axial Traction

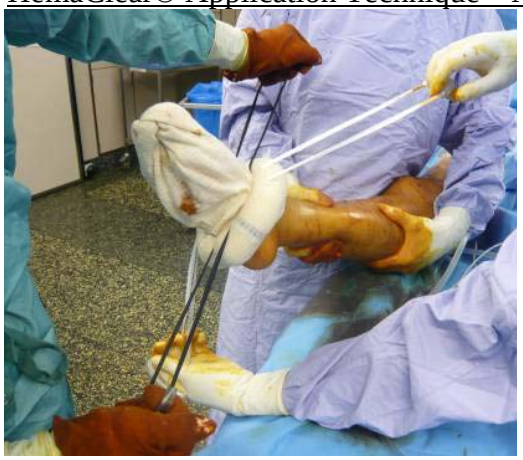


Fig. 2a

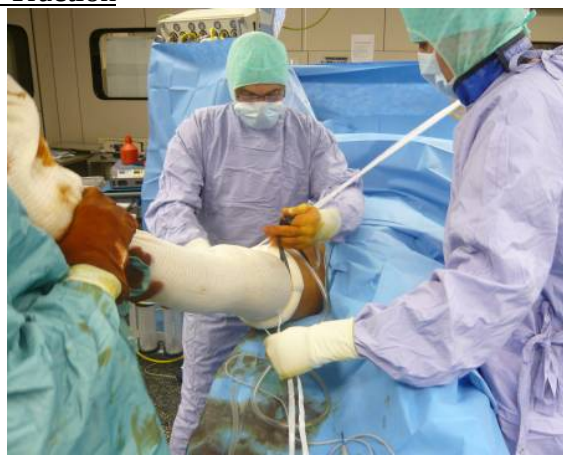


Fig. 2b

Complete Anatomical Access

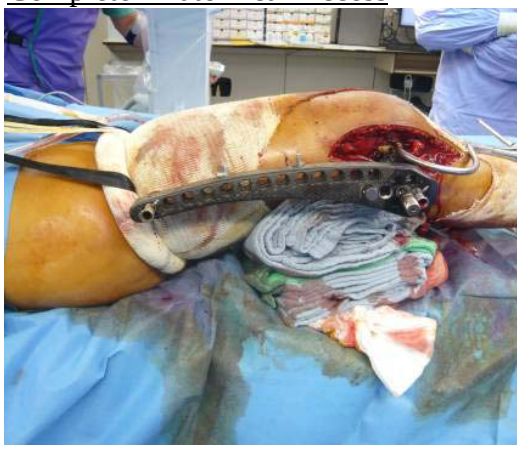


Fig. 3a

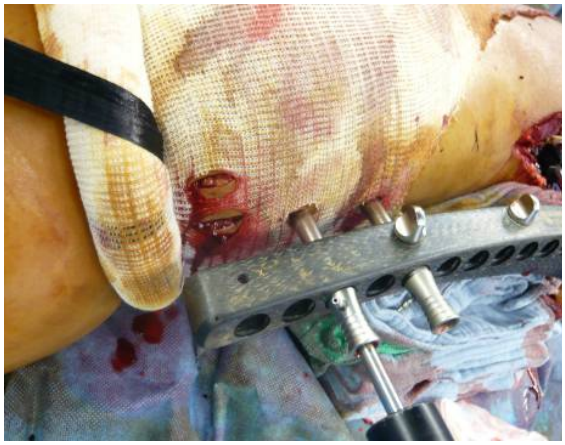


Fig. 3b

Results

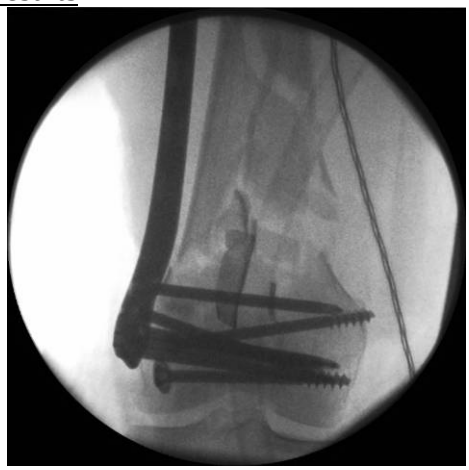


Fig. 3c

Fig. 3d

Moving to a new type of sterile and single use tourniquet for orthopaedic surgery

Author: Mr G P de Kiewiet, MBchB, FRCS, RCPS, FRCSEd, FRCSEd(Orth)

Introduction

Tourniquets are widely used in orthopaedic limb surgery in order to provide the surgeon with optimised visual capacity by creating a bloodless field followed by arterial occlusion proximal to the surgical site. We identified a number of potential patient risks in using the current methods, so, in order to reduce these risks, we felt the need to improve on our current bloodless surgery techniques. To help establish a mechanism for improving on our current methods, we evaluated a new type of sterile exsanguinating tourniquet called the S-MART, and found this, amongst other things, to reduce the preparation and tourniquet time, reduce cross infection risk and provide a first rate bloodless field in elective paediatric surgery.

In order to show the benefits of using this new device we need to consider the current methods of achieving exsanguination (removal of blood from a limb) and arterial occlusion, and the problems that can often arise with these methods.

How the current tourniquet method works

Historically tourniquets have been used routinely at Sunderland Royal Hospital in the Paediatric theatres. Development and implementation of tourniquet technology in limb surgery was established due to the need for a clear and bloodless field during the procedure. This is particularly relevant and important in paediatric cases as the type of surgery to which the tourniquet is applied, which is often intricate enough in adult cases, can increase in intricacy due to the smaller size of the patients' limbs. Further more the need to reduce blood loss is always important.

Traditionally, our method of achieving arterial occlusion was to apply a special, smaller, paediatric pressure cuff to the exsanguinated limb as a tourniquet. Exsanguination itself can be accomplished through various methods; limb elevation, Reece-Davis, Esmarch being the most popular techniques. At Sunderland Royal Infirmary, the preparation of the patient's limb generally takes place in the anaesthetic room prior to transfer into theatre.

This helps reduce the theatre time of the procedure but also leaves us with some more significant logistical problems that we felt could be avoided through the use of a different technique.

Disadvantages of the current method

In the paediatric cases, we usually start the patient's preparation by administering the anaesthetic. After the anaesthetic has been applied and the first preparatory stage of exsanguination has been performed, the pressure cuff must be inflated in order to occlude arterial flow and prevent blood from flowing back into the limb before surgery. We usually use tube or Reece Davis in order to achieve limb exsanguination and while this is being carried out, the pressure cuff is being prepared with its necessary padding and drapes, in order to provide as comfortable and aseptic field as possible. In most cases the patients are asleep on application and it is vital that all the necessary steps are taken to avoid the chances of skin burns from the fabric of the pressure cuff and contamination with the surgical prep fluids. Once the patient is padded and the surgical site protected from the chances of cross infection, inflation of the cuff concludes the initial preparation. After these activities, the limb is disinfected in the normal way prior to the first incision being made

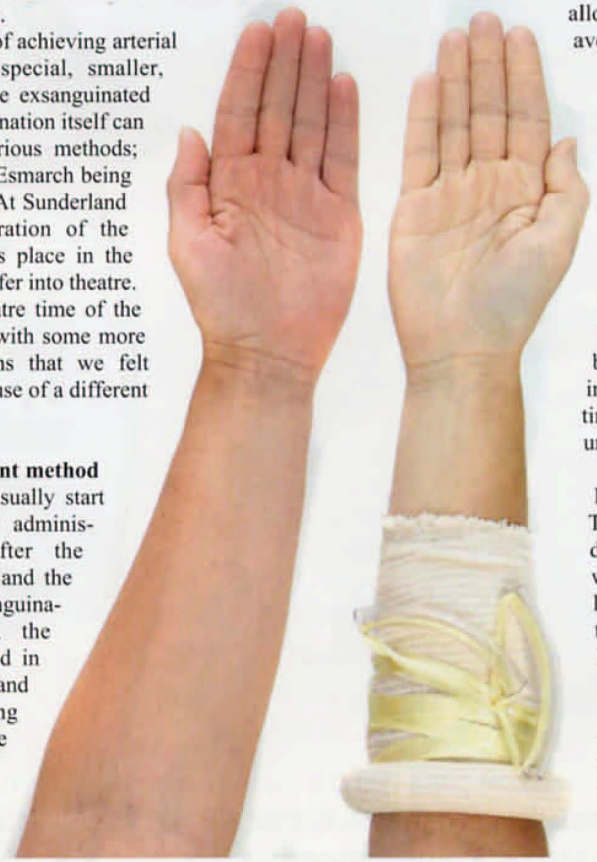
In this instance, the patient is under anaesthesia for the duration of the preparation. The same surgical and logistical result can be achieved by preparing the cuff before anaesthetic, in order to reduce the anaesthetic time. However, this results in an increase in the tourniquet time and means that the patient would feel the discomfort of the tourniquet for a short time while the anaesthetic was being administered and may also increase the risk of damage to internal structures. This is something we wanted to try and avoid, particularly in paediatrics. Application prior to anaesthesia will also increase the anxiety levels in this group of patients.

Avoiding increased anaesthetic and tourniquet time

Unfortunately, by using these methods, either the anaesthetic, or tourniquet time are extended, neither of which is particularly desirable but is, unfortunately, unavoidable when using a pressure cuff as a tourniquet.

However, with the S-MART™ exsanguinating tourniquet we have found an innovative yet simple solution that allows the tourniquet time to be reduced whilst avoiding an extension to the anaesthetic time.

In short, the traditional, separate methods of exsanguination, arterial occlusion and application of a sterile stockinette to the limb are encapsulated in the one device, which means that all of the required preparatory steps are achieved in one simple movement. However, adding to this is the fact that the device is sterile so it can be applied immediately after the disinfecting process. What this means is that the siting of the S-MART™ can be the last step before incision. It is by using this principle that we have been able to reduce the need for additional resource in the anaesthetic room and to reduce the tourniquet time whilst leaving the duration of anaesthesia unaffected.



Effective exsanguination and arterial occlusion

This device is relatively new in the UK and was discovered by members of our theatre nursing team whilst attending the AfPP Congress is Harrogate last year. The information with regards to the use of the device was brought back to Sunderland Royal Infirmary and we felt that this could be exactly the solution that we had been looking for.

Part of the initial attraction of the S-MART™ is its simple but innovative approach in finding a solution to the problems we face when using traditional tourniquet methods.

The device itself is comprised of a tensile silicone ring – the elasticity of which varies by

device type depending on what range of systolic pressures you wish to occlude - over which is rolled a long fabric stockinette. Into the stockinette is also rolled a set of straps with pull handles attached to the end. The idea is that fingers or toes of the patient are placed into the central hole of the device and, when in position, the straps are pulled, and the S-MART™ is rolled up the limb to the desired location. This process stretches the silicone ring, applying increasing pressure during lateral movement along the limb taper as the circumference of the limb increases. Blood is therefore squeezed from the limb to the point where the S-MART™ is sited. When the placement site is reached, the movement stops, resulting in a constant pressure, which ensures arterial occlusion.

As well as being sterile, the S-MART™ is much narrower than normal pressure cuffs which means that it can be placed closer to the surgical site without increasing the risk of cross infection. This is particularly useful when performing surgery on the elbow as the amount of room between the elbow and shoulder for pressure cuff placement is limited. It also means that there is less ischemic tissue as a lower volume of internal limb structure is under pressure with a narrower cuff.

Evaluation of new technique

Having considered the viability of this device for our paediatric cases, we first used the S-MART™ in November 2005. The decision was taken to evaluate in order to address some of the concerns that we had with pressure cuffs including the potential for abrasive skin burns and poor bloodless fields, although other benefits soon became apparent.

On the day that it was first evaluated, we had three paediatric cases. First, there was a 7 year-old boy who required a wrist tendon transfer, followed by an 11 year-old girl having a diagnostic knee arthroscopy and, finally, a 3 year-old boy for a flexor tenotomy of the foot.

There was, of course, quite a variation in limb size over the three cases but the manufacturers of the S-MART™ have developed a method of ensuring that there is an appropriate device available to cover all but the most extreme limb sizes. Traditionally, the same pressure cuff would be used on all limb sizes but with the S-MART™ you can choose the most appropriate device by measuring the circumference of the limb where the device is to be sited and then reading off supplied tables.

Which size of device you choose depends on the limb circumference and there are 4 sizes to choose from that range from S-MART Small (14-28cm circumference) to the S-MART™ XL (50-90cm circumference). In between there is the S-MART™ 40 (20-40cm circumference) and the S-MART™ 60 (30-60cm circumference). They also come in a range of colours which signify the range of systolic pressures that the S-MART will occlude so it is important to understand the systolic pressure of the patient before choosing the device. The necessary charts were supplied to us by the manufacturer and plenty of advice provided in order to ensure that the correct system was identified before use.

Appropriate device selection

As well as the device selection charts, we were also provided with tables which allowed us to understand the pressure at the limb surface for any given device. This figure is equivalent to the readout provided by the pressure cuff machine.

So, the circumference of the limb at the desired tourniquet site and the patient's systolic pressure are measured so that the right system can be identified. The device arrives sterile and is double wrapped for theatre, the packaging clearly showing the size and pressure capability of each individual system. The S-MART™ is handled using the normal theatre handling techniques to ensure aseptic delivery into the surgical field. Inside the pack there is a plastic "cutting card". This is required at the end of the surgery to aid the removal the S-MART™ and so needs to be retained.

Because the S-MART™ is sterile, the anaesthetic can be applied and the disinfecting preparations carried out before device placement. When preparations are complete and the first incision awaits, the S-MART™ should be applied.

In order to place the S-MART™, we cut off the closed end of the stockinette for the hand and foot procedures. For the arthroscopy case, access was gained through the stockinette at the surgical site. To remove the S-MART™, the plastic cutting card was placed proximal to the device and the device was rolled over the leading edge of the card. The S-MART™ ring was then cut with a scalpel and the device removed, allowing blood to flow back into the limb.

Excellent bloodless field

All three of the cases for which we evaluated the device were remarkably successful. After the S-

MART™ was rolled on to the limb of the first case and the first incision was made it was immediately apparent that the S-MART™ was going to provide us with exactly what we needed. Simply a visual examination of the skin surface was enough to show that exsanguination had been effective and, if that wasn't enough, the absence of any bleeding after the first incision confirmed it. Using the device was easy and placement was last minute, reducing tourniquet time but, most importantly of all, the surgical field was completely bloodless throughout, leaving a clear view which is ultimately important in delicate cases such as these.

Other areas of benefit

There was a lot of curiosity in the product when it arrived in theatre from all theatre personnel. It is an intriguing device at first sight, partly due to the various colours that represent the pressure range. We used two S-MART™ Small devices (pink), aimed specifically at paediatrics, on the tendon transfer and flexor tenotomy. These are applicable with systolic pressures up to 130mmHg. The arthroscopy case utilised the red device. This was an S-MART™ 40 applicable to medium systolic pressure ranges. The anaesthetists were particularly interested to find out how the S-MART™ coped with variations in systolic pressure as, at first glance, the devices seem to be quite similar. They were happy with the solution and the advice provided in choosing the appropriate system. We even had an ODP begin preparations in theatre for the placement of a sterile stockinette for the diagnostic arthroscopy. He was particularly surprised and pleased to hear that this would not be necessary as the S-MART™ applies a stockinette automatically during placement. He was subsequently able to turn his attention to other tasks which further demonstrated how the S-MART™ can also improve current use of theatre resources.

In all, the experience for the staff and the patients has been very positive and after such a resounding success in the initial evaluation phase we chose to continue the use of the product. To date, we have performed 20 operations ranging from flexor tenotomy to osteotomies and tendon transfers on patients with an age range of 14 years (Max 16, Min 2) and in all cases a clear and bloodless field has enabled us to perform the surgery with the accuracy and confidence required to ensure a positive clinical outcome.

Limitation of use

The one disadvantage of this technique is that if you remove the cuff to achieve haemostasis through the operation, you are unable then to re-inflate the cuff should this be desirable with certain procedures. Furthermore use of the cuff over fractured bones or open wounds would be undesirable and its main use therefore lies within the elective paediatric surgical field.

The future of S-MART™

With S-MART™, we now feel that we have found a suitable alternative to the pressure cuffs in paediatric and young adult cases and, as such, will no longer be commissioning the use of the pressure cuff tourniquets in these procedures. The S-MART™ is a very simple device which has provided us with a more effective tourniquet solution with regards to all aspects including ease of use, flexibility, time, resource and, of course, infection control and quality of the bloodless field, which needs to be second to none. Our intention is continue the use of the device and there may be future opportunities to expand the benefits of the device into other areas in the hospital such as day care.

Enquiry No 53

Tourniquet and the Obese Patient

White Paper

Prepared for OHK Medical Devices

By

Prof. Noam Gavriely
Scott Freer
Navit Suchard
Oren Gavriely

Abstract

More than a third of patients undergoing TKA have a BMI greater than 30 (obese) with many of these patients having a BMI that is greater than 40 (morbidly obese). Operating on these patients present the surgeon and the OR team with special problems all around, not the least of which is achieving and maintaining a blood-free surgical field. The problems include the need for larger and wider specialty (curved) cuffs thereby dangerously decreasing the distance from the distal edge of the tourniquet to the incision; tourniquets tend to slide distally when inflated due to the taper of the thigh; occlusion of arterial flow in the obese patient requires higher pressures, thereby causing more tissue compression (crush injury) and skin damage (1). Additionally, the obese patient is more vulnerable to infection if non-sterile tourniquets are used; the ability to expel the blood from the operated limb prior to tourniquet inflation is difficult in the obese patient, time consuming and tedious and often suboptimal, leaving substantial volume of blood in the vessels. This blood clots over the course of the tourniquet "up" period and when the tourniquet is deflated these clots travel to the pulmonary circulation (PE). The blood left behind also obstruct the surgical field visibility and the imperfect field requires additional OR time for hemostasis (2). Nevertheless, tourniquets are used in obese patients and the overall long term outcome of TKA in obese patients is as positive as in the normal BMI patients.

The HemaClear is a novel exsanguination tourniquet consisting of a rolling ring with an elastic stockinet and handles which can be applied quickly to the obese limb (picture). The HC90 is suitable for up to 90 cm of circumference which is suitable for most (but not all) obese patients. The HC provides a superior exsanguination, is a sterile, single patient use device and remains stable on the thigh (3). It applies safe levels of pressure to the limb and in more than 80,000 cases (all, not only obese) it has been used, proved to have an impeccable safety track record (no paralysis/paresis, no skin damage). The HC90 is a valuable addition to the tools designed to give the obese patient the same standard of care as the lean TKA recipient.

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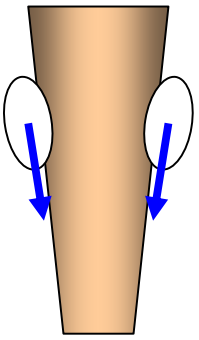
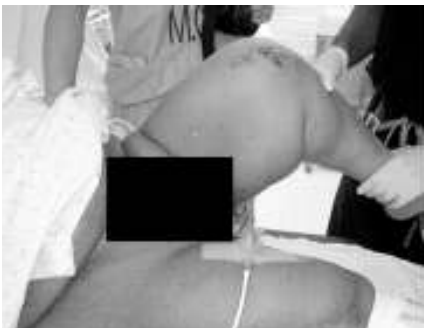
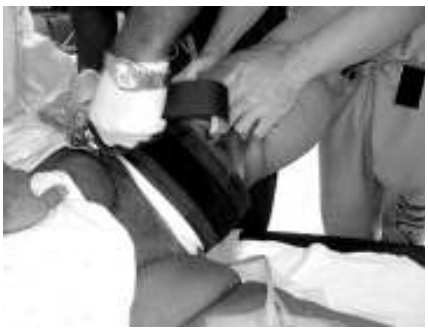
Adverse Effects of Pneumatic Tourniquet in Obese Patients.



Achieving blood-free surgical field in the obese patient undergoing TKA is a challenge. It requires experience and skill and some special tools, such as extra padding and special size and shape tourniquet. The obese thigh is typically very wide, acutely tapered, and relatively soft. The skin is loose and the distance to the groin is small relative to the circumference. These geometrical become obvious when Figure 1 is considered. The forces applied by the tourniquet on the tapered limb have, in addition to the desired radial component, an axial vector (arrow) that tends to slide the tourniquet distally towards the surgical incision site. The loose skin makes this sliding even easier with a tendency to pull some skin folds along (4).

In addition to the geometrical mechanics, the wider thigh requires a wider cuff thereby leaving less "real estate" for the surgical incision. The migration of the tourniquet occasionally brings it to an undesired proximity to the sterile field (5). The use of sterile tourniquets is therefore recommended in all obese patients. The rheology of the obese tissues is another factor that must be considered, namely the compressibility of the adipose tissue is such that higher pressures are needed in order to transmit the pressure from the skin surface beneath the tourniquet to the vicinity of the blood vessel. The higher pressures, particularly with a flat profile cuff, create higher shear forces at the proximal and distal edges of the tourniquet thereby increasing the risk of neural or vascular damage.





The obese patient often has delicate skin and poor peripheral circulation. It is essential to minimize tourniquet time and to apply tourniquets in a very even way. Attempts to squeeze skin folds and fat beneath a tourniquet that is not long enough can be detrimental. Case reports on pneumatic-tourniquet intduced rabdomyolysis in obese patients are indicative of this higher vulnerability (6).

In addition to the challenges of tourniquet placement and maintenance of arterial occlusion, it is known that effectively expelling the blood from the limb (exsanguination) is quite difficult in the obese. Limb elevation is ineffective (7-Blond et al) and Esmarch bandage placement is tedious in the obese patient. The blood left behind inside the blood vessels tends to clot during the course of the procedure. Once the tourniquet is released, many of these clots travel with the blood flow to the lungs (Micro Pulmonary Emboli) while those who stay behind can form seeds for further thrombus formation and post op DVT.

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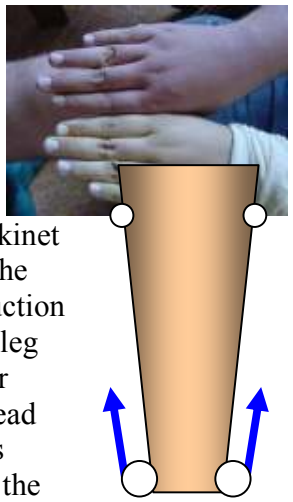
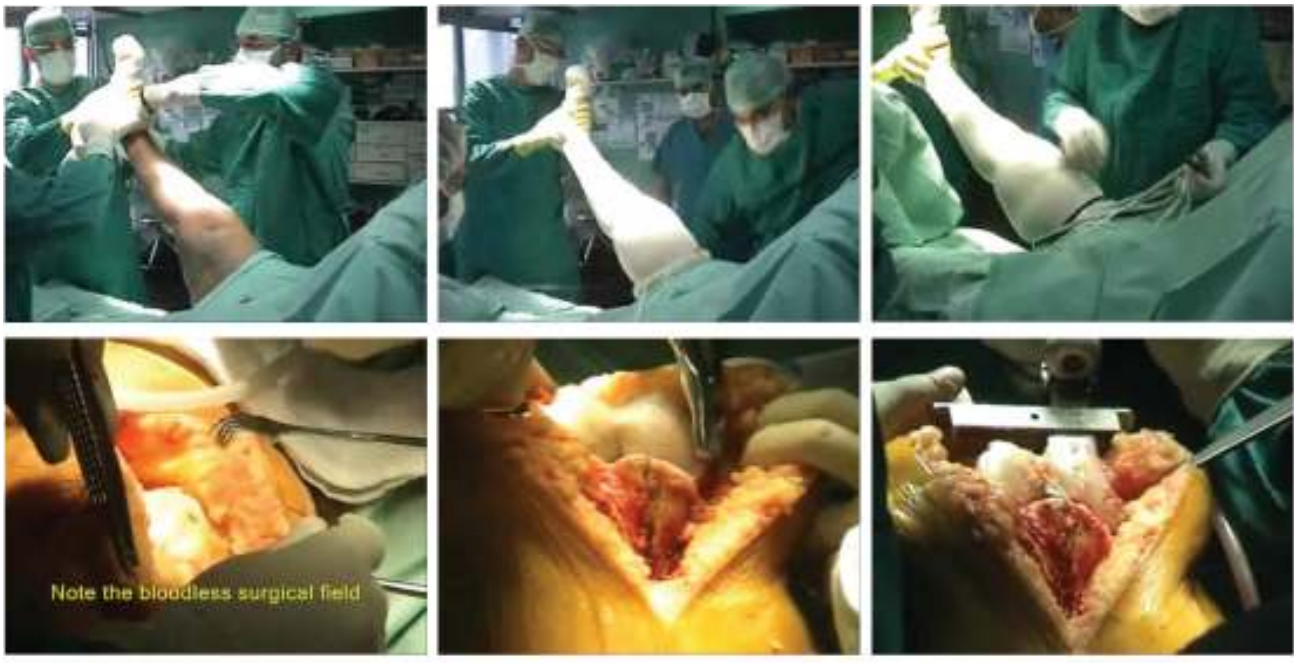
The HemaClear Solution



Recently, OHK Medical Devices (Haifa, Israel) brought to the orthopedic market a novel exsanguination tourniquet for limb blood-free surgery. The largest size of the series is the HC90, which was specifically designed for use on the obese patient. The HC technology consists of a highly calibrated elastic silicone ring with a latex-free stockinet wrapped around it. The HC90 also has 4 straps that when pulled along the axis of the limb cause the rolling of the ring along the limb. The construction of the HC90 is such that when it is placed on the distal-most part of the leg the annulus is thick and the hole in its middle is small to fit the narrower aspect of the leg. As the ring rolls up, the thick stockinet material is spread behind so that the annulus becomes narrower while the middle hole gets wider. The result is a uniformly applied pressure along the limb despite the widely changing circumference. The device is secured in place by wrapping the straps just distally to the ring so that it cannot roll back down despite motion of the knee and the underlying thigh tissues. At the end of surgery the HC ring is cut away by cutting the elastic ring. If there is a desire to minimize the drop of blood pressure after the release of the occlusion (due to the opening of the empty vascular bed in the leg) it is possible to leave the stockinet for a few additional minutes before cutting it away with scissors.

The HemaClear is applied quickly and easily on the prepped leg. It is applied immediately prior to the beginning of surgery thereby minimizing tourniquet time. The level of exsanguination is outstanding with a very dry field, despite the obesity (pictures).



The HC90 is sterile single-patient device and as such is suitable for use in the obese patient with its higher vulnerability to infection. The high exsanguination level also prevents leaving blood behind in the blood vessels, thereby reducing the likelihood of clotting and PE formation. The effect of the ring on the skin and the underlying tissues is

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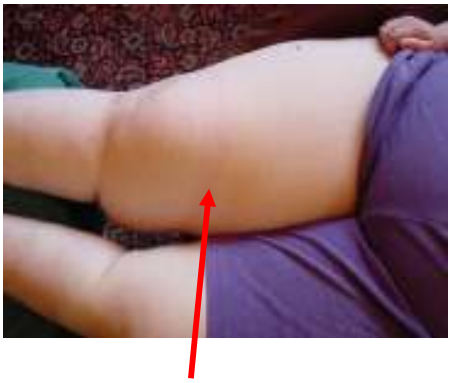
gentle (arrow in pictures) and no undesired effects (tourniquet paralysis, tourniquet "burn", tourniquet pain) have been reported in its frequent use in Europe and other countries.



Conclusions

The problems with pneumatic tourniquets in the obese patients drove some researchers to the conclusion that it is better to operate on these patients under non blood-free conditions. However, the majority of major joint surgeons continue to use exsanguination and tourniquet technique while struggling with the difficulties.

The data from large scale studies compiled by the CDC indicate that the overall satisfaction of obese patients with the outcome of TKA is as high as in non-obese patients(8). As such, it seems logical to conclude that they deserve the same level of quality care, including the details of the intra-operative process. The HC90, which was specifically designed to meet the needs of the very obese patient, is a useful addition to the care of these patients.

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the thigh and the surgeon reported excellent exsanguination.

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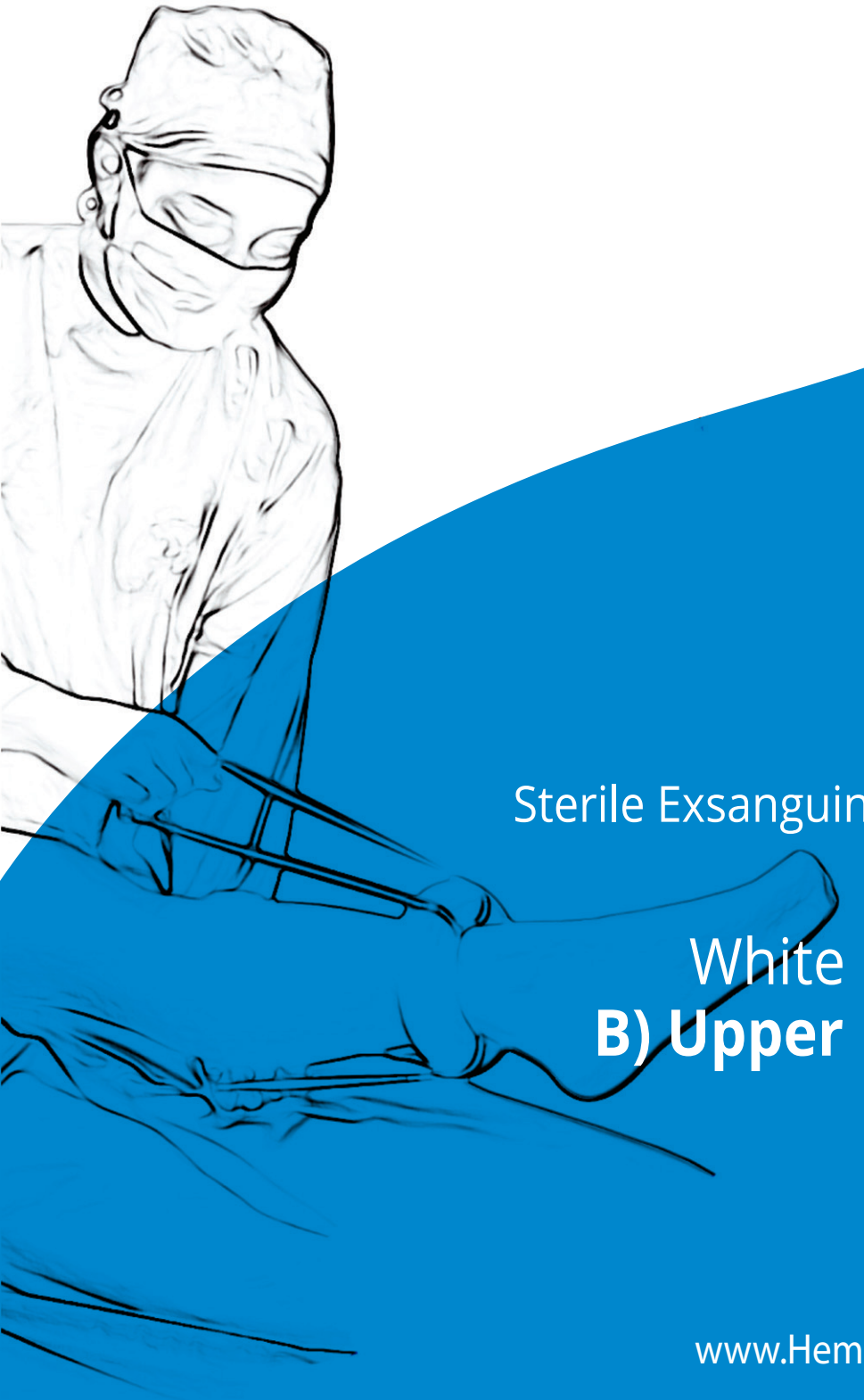

Sterile Exsanguination Tourniquet

White Papers
B) Upper Extremity

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Forearm Sterile Elastic Tourniquet – A Preferred Method For Carpal Tunnel Release (CTR)

Noam Gavriely, MD, DSc.

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Abstract

Carpal Tunnel Release (CTR) is one of the most common surgical procedures performed in the US. A key to a successful outcome of the procedure is good visibility. This is achieved by assuring a bloodless surgical field by applying an arterial tourniquet, or infiltrating the incision site with local anesthetics mixed with adrenalin. This paper describes the use of a sterile forearm elastic exsanguination tourniquet (FA-SET) as an alternative to the upper arm pneumatic cuff. The FA-SET is the superior choice in our view. It provides a sterile field, superior exsanguination and effective arterial blocking. The use of FA-SET should be the standard of care in small hand procedures and in particular when carpal tunnel release is performed.

Background

Carpal Tunnel Release (CTR) is one of the most common surgical procedures performed in the US. The incidence in 2000-2005 was 109 operations per 100,000 people each year (Gelfman, Neurology 2009), which translates to about 350,000 surgical procedures per year in the US. The direct cost of CTR was estimated in 2009 to be \$3068 $\pm$ \$983 or about \$1.1 Billion per year (Pomerance, J Hand Surg 2009). CTR is a safe procedure with minimal complications (Patterson and Simmons, Hand Clinics, 2002) and surgical site infection is relatively uncommon, estimated as <0.5% irrespective of perioperative use antibiotics (Harnes et al, J Hand Surg., 2010).

The CTR procedure is quick, taking 10-12 minutes or less. It requires a very simple set of instruments and minimal draping and is most often performed in an outpatient day-surgery setting. However, a key to successful outcome of the procedure is good visibility. This is achieved by assuring a bloodless surgical field by applying an arterial tourniquet, or infiltrating the incision site with local anesthetics mixed with adrenalin (Ralte et al, The Open Orthopaedics Journal, 2010). This paper describes the use of a sterile forearm elastic exsanguination tourniquet as an alternative to the upper arm pneumatic cuff.

Structure and Function of the Forearm Sterile Exsanguination Tourniquet (FA-SET)

The Forearm Sterile Exsanguination Tourniquet (HemaClear, OHK Medical Devices Ltd. Haifa Israel) consists of an elastic silicone ring wrapped around by tubular stockinet and four straps terminated by two handles (App. Figure 1a). The FA-SET is placed on a conical application cup that helps in its placement on the fingers and the initiation of its rolling up the hand. The FA-SET is sterile (Ethylene Oxide treatment) and comes double wrapped in individual packs. When the straps are pulled proximally along the axis of the arm, the ring rolls over the hand, wrist and forearm and the stockinet is released to cover the skin (App. Figure 1b). The final position of the FA-SET is 10-12 cm above the root of the palm (App. Figure 1c). The rolling applies uniform circumferential force on the tissues, translated into radial pressure that effectively squeezes the blood out (exsanguination) and blocks the arterial flow into the hand. The application of the FA-SET is quick and smooth, taking 3-5 seconds to apply.

Prepping and Draping

Disinfection is done in the usual manner up to, or beyond, the elbow. Draping for a CTR is done so that the edge of the drape is wrapped around the forearm about 5-8 cm above the root of the palm. As such, the FA-SET is rolled on top of the edge of the drape so that a continuity of draping is assured between the sterile stockinet of the device and the proximal drape. Exposure of the incision site can be done by cutting a window in the stockinet, or by folding the stockinet proximally thereby exposing the entire hand (App. Figures 1d, 1e).

At the end of the procedure the elastic ring is cut with a scalpel (scissors will not cut the silicone), after protecting the skin beneath the ring with the plastic card provided with the product (App. Figure 1f). It is important to also cut off the remnants of the stockinet to avoid venous occlusion and engorgement of the blood vessels. The cutting of the ring ("tourniquet down") can be done either prior to final hemostasis and suturing or after suturing and dressing of the incision site (see Discussion).

Experience with the FA-SET

We performed ___ CTR procedures with the FA-SET with no complications or side effects. The application of the device is quick and easy, and the exsanguination level is excellent. We usually cut the straps off, leaving about 10 cm of two of the straps to help pull and lift the ring for the placement of the protection card when cutting the ring. An important element in the process was the explanation to the patient of the importance of the use of the FA-SET to provide a bloodless field and optimal visibility. We described the constricting pressure of the tight ring and the discomfort to be expected. This was typically done while infiltrating the incision site with local anesthetics. In __% of the procedures the patient consented to the use of the device without forearm anesthesia. The device discomfort was tolerated well by the patients with a few words of encouragement from the team.

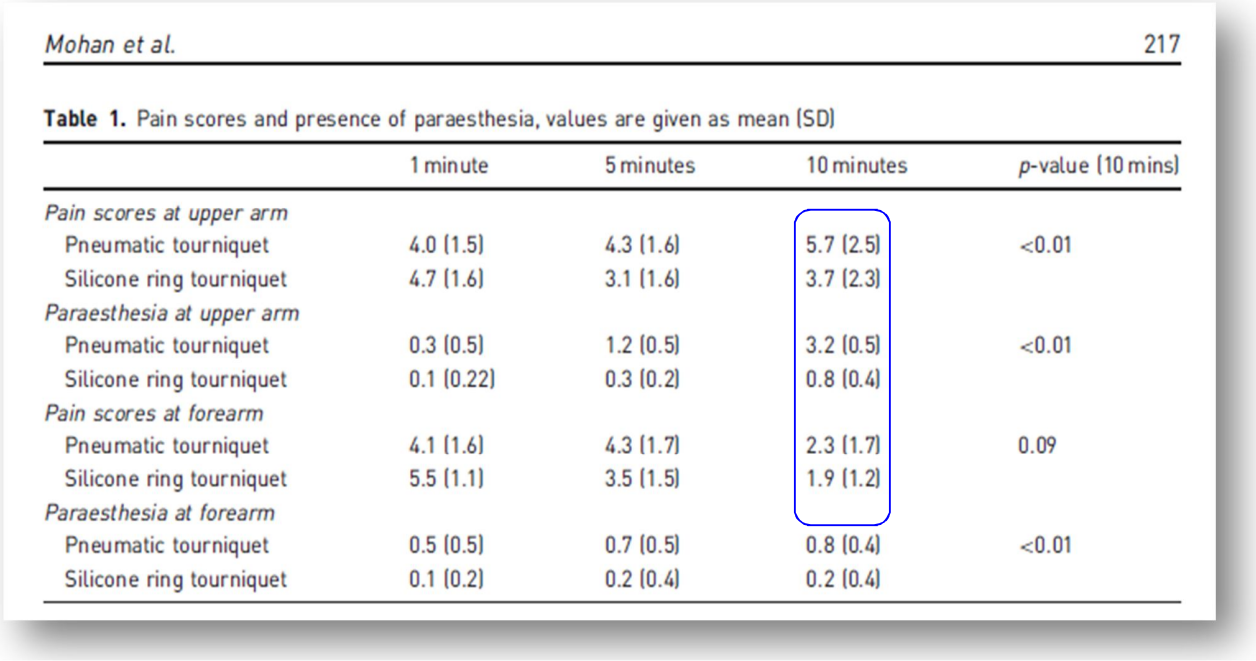
The Table below provides an item-by-item comparison between the pneumatic tourniquet and the FA-SET:

	Pneumatic Tourniquet	Forearm Sterile Exsanguination Tourniquet
OR Preparations	• Tourniquet cuff (select correct size) • Padding • Esmarch (if used) • Stockinet drape • Check pneumatic controller and tubing	• FA-SET (one size)
Preparation and application time	5-15 minutes	1-2 minutes
Capital equipment	Pneumatic controller	None
Pressure on tissue	As set by the user	225±25 mm Hg, factory set
Application by	OR Nurse/ technician	Surgeon
Sterility	Non-sterile or sterile	Sterile - single use
Tourniquet placement site	Upper arm if not sterile; upper arm or forearm if sterile	Forearm
Anesthesia	Local infiltration	Same
Procedure	Dissection of tunnel and cutting of transverse ligament	Same
Removal	Deflation of cuff	Cutting of ring

Discussion

The FA-SET is a sterile, single use item. As such, it can safely be used on the forearm about 10 cm (4") from the incision. The forearm positioning of a tourniquet has previously been shown to be tolerated much better by the patients when compared to the upper arm position (Hutchinson, J Hand Surg Am., 1993; Glynn, Ir Med J, 2005; Maury, J Hand Surg Br., 2002; Edwards, J Hand Surg Br, 2002; Yousif, J Hand Surg Br., 1993). These studies, performed with pneumatic tourniquets, were done in volunteers and in actual patients. The outcome of these studies clearly shows that a forearm tourniquet placement is safe, effective, and uniformly better tolerated by the patient.

When the SET (forearm or upper arm) was compared to the pneumatic tourniquet, "the silicone ring tourniquet (SET) was associated with a significantly lower pain score than the pneumatic tourniquet. The incidence of parasthesia was also lower with the silicone ring tourniquet. When applied to the forearm, there was no statitstically significant difference in pain scores between the two types of tourniquets. However, the incidence of parasthesia was lower with the silicone ring tourniquet" (Mohan, J Hand Surg Eur, 2011). However, when the upper arm pain and parasthesia scores at the 10 minutes mark are compared to the corresponding forearm scores, the differences are very large with the pain score of the silicone ring (SET) being 1.9±1.2 on the forearm vs. 3.7±2.3 on the upper arm, and 5.7±2.5 with the pneumatic tourniquet on the upper arm.



Mohan et al. 217

Table 1. Pain scores and presence of paraesthesia, values are given as mean (SD)

	1 minute	5 minutes	10 minutes	*p*-value (10 mins)
Pain scores at upper arm				
Pneumatic tourniquet	4.0 (1.5)	4.3 (1.6)	5.7 (2.5)	<0.01
Silicone ring tourniquet	4.7 (1.6)	3.1 (1.6)	3.7 (2.3)	
Paraesthesia at upper arm				
Pneumatic tourniquet	0.3 (0.5)	1.2 (0.5)	3.2 (0.5)	<0.01
Silicone ring tourniquet	0.1 (0.22)	0.3 (0.2)	0.8 (0.4)	
Pain scores at forearm				
Pneumatic tourniquet	4.1 (1.6)	4.3 (1.7)	2.3 (1.7)	0.09
Silicone ring tourniquet	5.5 (1.1)	3.5 (1.5)	1.9 (1.2)	
Paraesthesia at forearm				
Pneumatic tourniquet	0.5 (0.5)	0.7 (0.5)	0.8 (0.4)	<0.01
Silicone ring tourniquet	0.1 (0.2)	0.2 (0.4)	0.2 (0.4)	

In another study, the tolerance duration of the SET and pneumatic tourniquet, both placed on the upper arm, were compared (Drosos, Arch Orthop Traum Surg, 2011). There were no differences in duration tolerance between the wide pneumatic tourniquet and the narrow SET ring.

Another aspect that is readily observed when the FA-SET is used is its superior exsanguination. The surgical incision is completely bloodless. This is evident in the obviation of blood-stained "four-by-four" sponges. In fact, the use of the bipolar diathermia is almost eliminated when the FA-SET is used. The improved visibility of the dissected soft tissues of the palm seems to have a positive effect on the accuracy of the median nerve release and speeds up the process. It is not possible to perform a blinded study of the surgical duration, but our opinion is that the FA-SET facilitates shorter tourniquet time, skin incision-closure time and overall OR time.

The pertinent question is therefore why upper arm tourniquet is still in use? It is conceivable that in many hospitals, the tourniquets are not sterile and as such carry a heavy bacterial load with multiple pathogens). The negligible cost differential between a sterile and non-sterile tourniquet (i.e. not more than 1% of the overall cost of the procedure) seems to be the driving force. We feel that the presumed added cost is readily offset by the reduced perioperative logistics, increased OR throughput and the improved overall patient experience, particularly when the FA-SET is used.

Summary and Conclusions

The literature, as well as our own experience, clearly shows that forearm tourniquet position is the preferred site for short hand procedures done under local anesthesia. In order to do so without risk of contamination, the tourniquet must be sterile. The FA-SET is the superior choice in our view. It provides a sterile field, superior exsanguination and effective arterial blocking. It is tolerated well by most patients and is quick to apply. It is cost-effective compared to the sterile pneumatic tourniquet, particularly when the cost of the additional items needed when the pneumatic tourniquet is used is taken into account. The elimination of the capital cost and calibration requirements of the pneumatic controller are added benefits. The use of FA-SET should be the standard of care in small hand procedures and in particular when carpal tunnel release is performed.

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Appendix - Images

Figure 1a

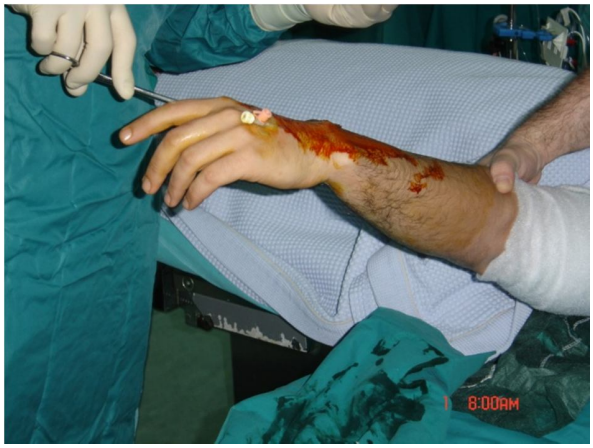


Figure 1b

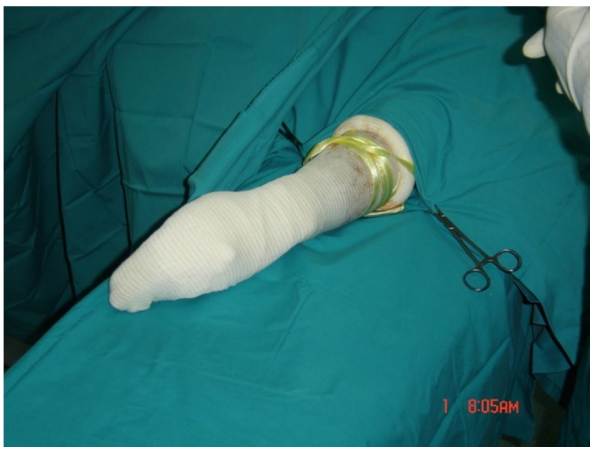


Figure 1c

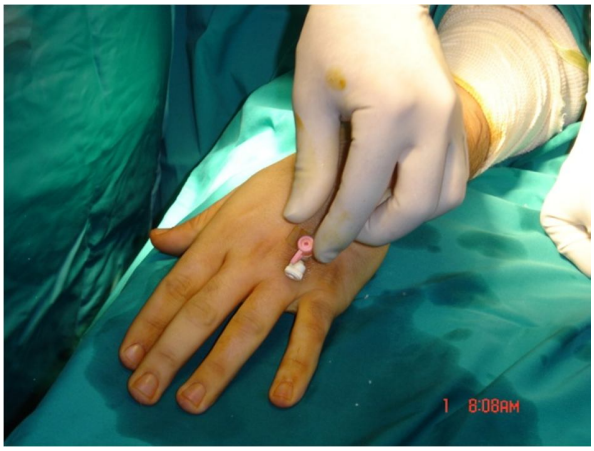


Figure 1d

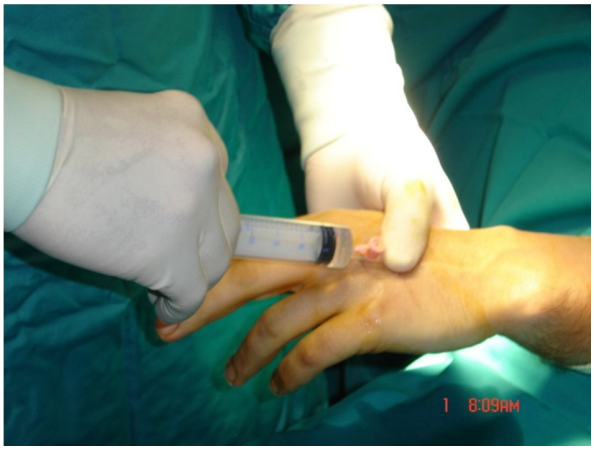


Figure 1e

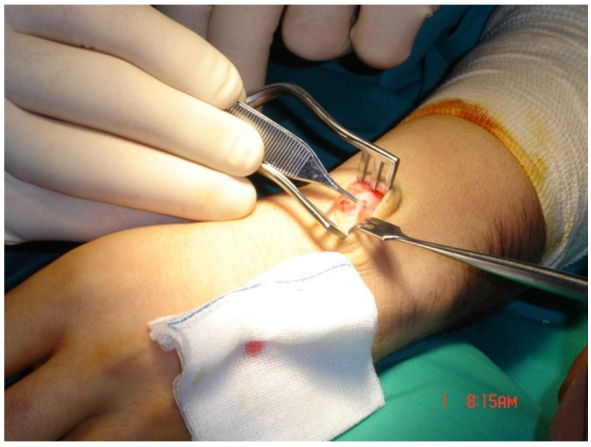
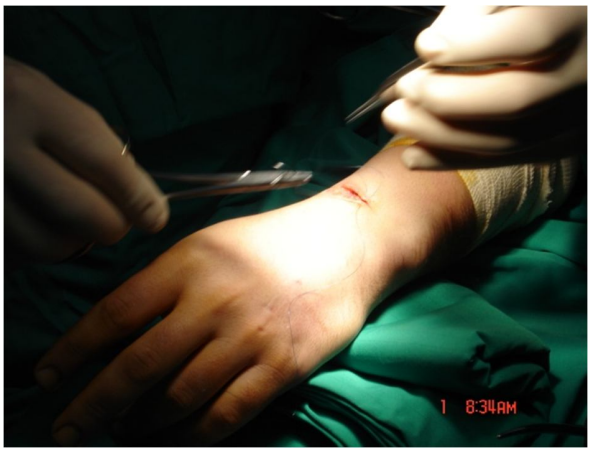


Figure 1f



Carpal Tunnel Syndrome: Background Information for HemaClear® Product Specialists

Edith R. Gavriely

Abstract

Carpal Tunnel Syndrome (CTS) is the most frequent nerve compression affecting 0.3% of the population of whom 1/3rd (0.1%) requiring surgical release – Carpal Tunnel Release (CTR) each year. It is caused by crowding the median nerve in its passageway into the hand at the base of the palm. The symptoms are numbness, pain of the thumb and the middle fingers and weakness of the muscle at the base of the thumb. While non-surgical treatment is often tried, about a third of the patients require surgery, which is most often performed as an outpatient procedure under bleeding-free conditions and local anesthesia. The sterile Forearm HemaClear® is a safe and effective device for achieving optimal bleeding-free surgical field.

Etiology

The carpal tunnel is a narrow passageway which encloses nine flexor tendons to the fingers and thumb and the median nerve, on the palm side of the wrist (5 Mayo p.1). The median nerve provides sensation to the first 3 ½ fingers (not the pinky) and motor function to hand muscles (thenar). There is minimal space to contain the median nerve and nine tendons (8 Solomon p.119) as they pass from the forearm into the hand (3 ASSH p.1). The specific cause of Carpal Tunnel Syndrome (CTS) is usually unknown (3 ASSH p.1).

Pathogenesis

Compression of the median nerve results in CTS. “In general, anything that crowds, irritates or compresses the median nerve in the carpal tunnel space can lead to carpal tunnel syndrome” (5 Mayo p. 2). As such CTS develops when pressure is placed on the median nerve. In laymen’s terminology – it is a pinched nerve in the wrist (5 Mayo p.1). Pressure is created in several ways: swelling of the lining of the flexor tendons (tenosynovitis), joint dislocations, fracture and arthritis, having a bent wrist for extended periods, fluid retention during pregnancy, thyroid conditions, rheumatoid arthritis, and diabetes. It may also result as a combination of causes (3 ASSH p.1). The anatomy of the wrist can also be a contributing factor; a smaller carpal tunnel has less room to accommodate any swelling (5 Mayo p. 2).

Risk Factors

Small anatomy may provide a predisposition to CTS, as there is little room to accommodate any swelling that may develop. Industrial – assembly line work - and cleaning employment with repeated movement of hand and/or vibration may cause trauma leading to CTS (2 Canale p.4285). It was believed that office workers were prone to CTS but this is “controversial and unresolved” (2 Canale p.4285). “In fact CTS is three times more common among

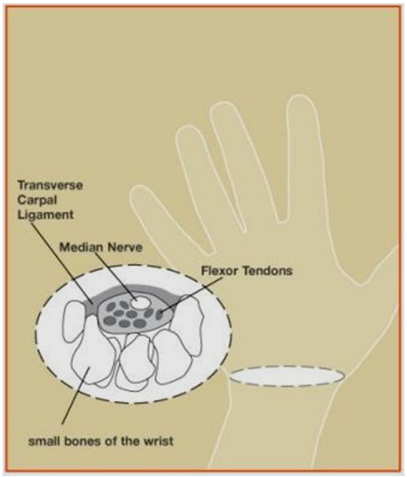


Figure 1. *The carpal tunnel is found at the base of the palm. It is formed by the bones of the wrist and the transverse carpal ligament. Increased*

assemblers than among data-entry personnel. A 2001 study by the Mayo Clinic found heavy computer use (up to 7 hours a day) did not increase a person's risk of developing carpal tunnel syndrome" (6 NINDS p. 2).

Epidemiology

CTS patients are usually between 30 – 60 years old and the syndrome is two to three times more prevalent in women than men (2 Canale p.4285). It may affect 1%-10% of the US population. (2 Canale p.4285). CTS is the most common peripheral neuropathy (4 SYMP p. 202).

Clinical Symptoms

CTS can be mild to very painful and usually presents every night, disturbing ability to sleep. The most frequent symptoms include pain and paresthesia - burning, numbness, tingling or a combination of the three in the median nerve distribution. Patients try to relieve the symptoms by shaking the arm or hanging it over the side of the bed (8 Solomon p.119). Pain usually does not keep the patient from falling asleep, but typically awakens him/her. Symptoms can also appear during the day and can effect ability to grip a cup or hold a telephone or newspaper, with a tendency to drop things (3 ASSH p. 1). Holding the wrist in a flexed position for an extended period of time can expedite the pain (7 Skinner p.560). The pain can radiate from the hand up the arm, to the shoulder or neck. If not treated, sensation and use of muscles at base of thumb can be permanently damaged (3 ASSH p1).

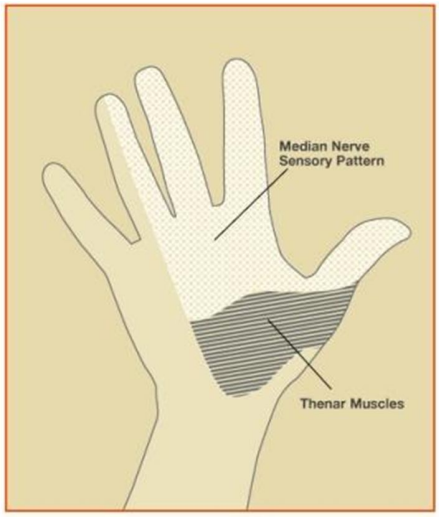


***Figure 2**. Aspects of median nerve function. (3)*

Diagnostics

Early diagnosis of CTS is vital to prevent permanent damage to the median nerve. The diagnosis is based on clinical and physical symptoms. The physical exam includes examination of hands, arms, shoulders and neck. "The wrist is examined for tenderness, swelling, warmth, and discoloration. Each finger should be tested for sensation, and muscles at the base of the hand should be examined for strength and signs of atrophy. Routine laboratory tests and X-rays can reveal diabetes, arthritis and fractures." X-rays can ascertain if there are other causes for the symptoms (6 NINDS p.2). Differential diagnosis is of utmost importance so as to eliminate other causes of similar symptoms. Diagnostics include provocation tests which try to reproduce the symptoms:

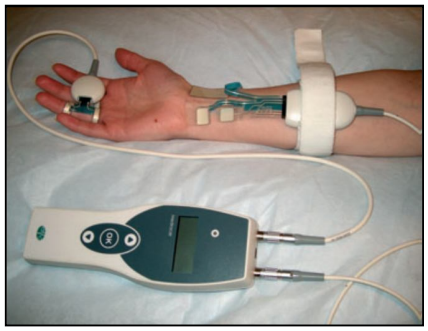


***Figure 3:** The handheld nerve conduction measuring device in use. (9)*

1 – Tinel nerve percussion over the median nerve;

2 – Phalen test – acute flexion of the wrist for sixty seconds;

3 – wrist compression test – pressure over the median nerve proximal to the wrist, to provoke symptoms within thirty seconds (2 Canale p. 4286);

4 – electrodiagnostic studies – NCV - nerve conduction velocity and EMG electromyogram;

5 – novel handheld nerve conduction measuring device – a new diagnostic device to accurately and objectively determine severity of CTS by measuring nerve conduction velocity. The results obtained in this manner also facilitate differential diagnosis (9 Tolonen p.390).

In cases with late diagnosis there is atrophy to median innervated thenar muscles, weakness of thumb abduction and sensory dulling in median nerve (8 Solomon p119) which may not be reversible.

Treatment

Treatment should begin as early as possible. Underlying causes should be treated, eg., diabetes and hypothyroidism. The affected wrist should be given at least two weeks of rest. Light splints may be worn to prevent wrist flexion, particularly for people who sleep with bent wrists. (8 Solomon p.119). Applying cold packs and rest breaks at work may reduce swelling and bring relief (5 Mayo p.4).

Nonsurgical Therapy

Drugs – Nonsteroidal anti-inflammatory drugs (NSAIDs) may help reduce swelling temporarily (2 Canale p. 4287). They may be effective short term but it has not been shown that they actually improve the carpal tunnel syndrome itself (5 Mayo p.5). Corticosteroids can be injected directly into the wrist to provide temporary relief. They reduce inflammation and swelling which in turn relieve pressure on the median nerve. Oral corticosteroids are not as effective as injection. Diuretics may also reduce swelling (5 Mayo p.5).

Exercise – Physical and occupational hand therapy with stretching and strengthening exercise, as well as changing pattern of hand use , may bring relief (3 ASSH p.1). High-intensity ultra sound may also provide relief by raising body temperature and promoting healing (5 Mayo p.6).

Alternative treatments – Acupuncture and chiropractic may be helpful but as yet their efficacy has not been proven. Additionally, “Yoga postures designed for strengthening, stretching and balancing each joint in the upper body, as well as the upper body itself, may help reduce the pain and improve the grip strength of people with CTS” (5Mayo p.6).

Surgery

CTS surgery is a very common procedure in the US. It is a very effective treatment for CTS (9 SYMP p. 201). If symptoms do not respond to non-surgical treatment, surgery is indicated (6 NINDS p.3). It is an ambulatory procedure under local anesthesia. The time at which to recommend surgery is still under debate. The Mayo Clinic staff claims that conservative treatment – non-surgical – may be effective if there are mild to moderate symptoms for less than ten months (5 Mayo p.4). According to the Symposium on the Wrist and Hand, surgery should be considered if conservative treatment of mild and moderate CTS do not bring relief within three months (4 SYMP p.202). The National Institute of Neurological Disorders recommends surgery if symptoms last for more than six months (6 NINDS p.3). Persons with severe symptoms should be referred to surgery immediately (4 SYMP p. 202).

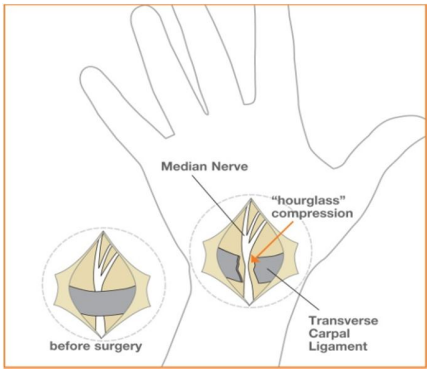


Figure 4: *The goal of surgery is to free the ligament to allow more room for the median nerve in the carpal tunnel. (3)*

Pressure on the median nerve is reduced by cutting the ligament that forms the roof of the tunnel on the palm side of the hand (3 ASSH

p.3). One option is standard open release surgery to divide the transverse carpal ligament at the wrist. A skin incision of up to two inches is made in order to identify and cut the carpal ligament and enlarge the carpal tunnel (6 NINDS p.3). It is done "under direct vision ensuring a safe and complete release. It is the oldest and most commonly used technique…and normally takes less than fifteen minutes." (4 SYMP p.201). Mini-open release surgery was developed to decrease problems of sensitivity following standard open release surgery (4 SYMP p.201). Endoscopic surgery is an alternative option. In this procedure the surgeon makes two incisions (about ½ inch each) in the wrist and palm, inserts a camera attached to a tube, observes the tissue on a screen and cuts the carpal ligament" (6 NINDS p.3). Post-operative recovery rehabilitation from the latter is quicker, but the surgery sometimes misses cutting the entire ligament due to poor visibility (4 SYMP p.201). Nearly all CTS release operations are performed with a tourniquet placed on the upper arm or on the forearm to prevent bleeding and improve visibility. The traditional pneumatic tourniquet is being replaced now by a new elastic exsanguination tourniquet (1 Boiko p.185) Hemaclear®, OHK Medical Devices, Ltd., Haifa, Israel, which is sterile and provides better visibility. Anesthesia is usually by local infiltration of Lydocaine or similar local anesthetics.

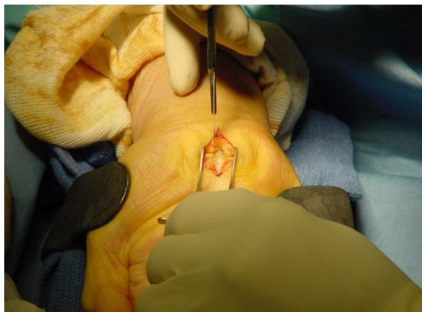


Figure 5. *Carpal Tunnel Release incision in an elderly woman. With permission OHK Medical Devices, Ltd.*

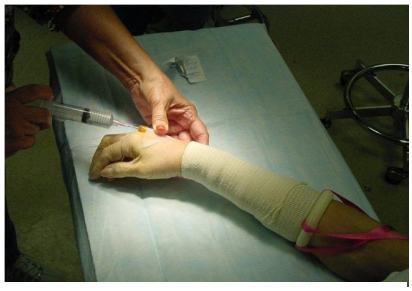


Figure 6. HemaClear® exsanguination tourniquet in use during CTR. With permission OHK Medical Devices, Ltd.

Prognosis

CTS symptoms are relieved after surgery, however full recovery can take months. Complications that may occur following CTS surgery include infection, nerve damage, stiffness, and pain at the scar. Occasionally the wrist loses strength. Recurrence is rare (6 NINDS p.3). Most patients (85%) benefit from surgery with lasting relief of CTS. However, patients over 70 years of age may not attain total relief (2 Canale p.4289).

Summary

In conclusion, CTS is a common neuropathy that affects women three times more than men. It can present with mild, medium or severe symptoms. The former may respond to conservative treatment; the latter necessitates surgical intervention. Not treating severe CTS may lead to irreversible thenar muscle atrophy.

Acknowledgement*: Prepared in partial fulfillment of requirements – Reidman Academy, Dr. Amit Hadari, supervisor.*

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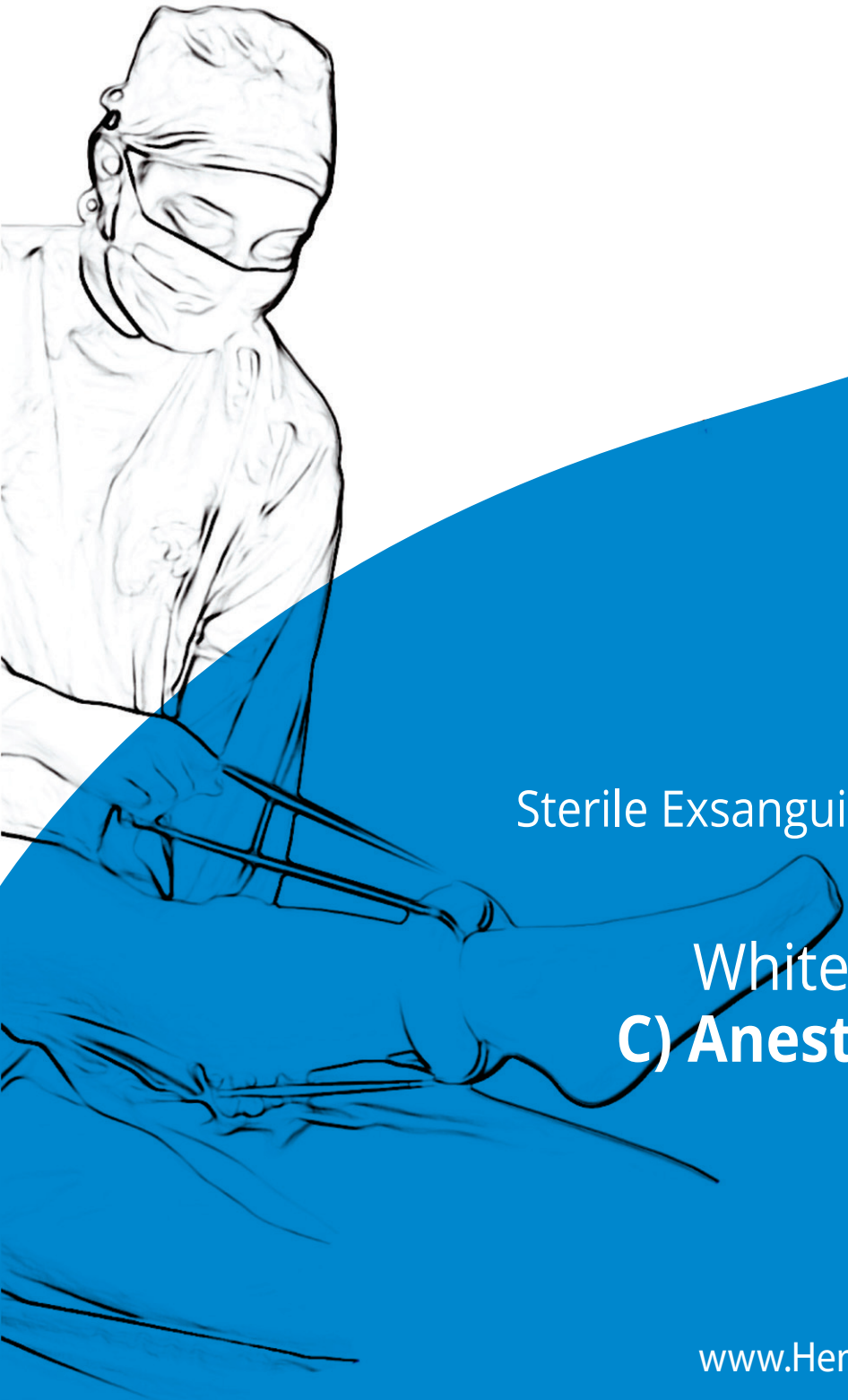

Sterile Exsanguination Tourniquet

White Papers
C) Anesthesiology

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Regional and Local Anesthesia of the Wrist and Hand Aided by a Forearm Sterile Elastic Exsanguination Tourniquet - A Review

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Keywords:

Intravenous regional anesthesia, IVRA, Carpal Tunnel Release, Hand surgery

Running Header:

Regional Anesthesia of the Hand with Forearm Sterile Exsanguination Tourniquet

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Conflicts of Interest:

Noam Gavriely is the founder, shareholder and salaried Chief Medical Officer of OHK Medical Devices Ltd., the manufacturer of the HemaClear® device used in this study.

Abstract

Hand and wrist procedures range in various lengths of time and are performed under bleeding-free conditions achieved by exsanguination and tourniquet. The purpose of this paper is to describe regional and local anesthesia options facilitated by the use of forearm tourniquet, in particular the forearm sterile elastic exsanguination tourniquet (FA-SET). The paper will focus on two main strategies: (i) Local incision-site infiltration while the FA-SET is tolerated by the patient without anesthesia or with additional topical anesthesia at the site of the tourniquet; and (ii) Intravenous regional anesthesia (IVRA – Bier Block) performed with the FA-SET in place. The conclusions from our experience is that (a) for short procedures local infiltration with FA-SET in place is well tolerated by the patient; and (b) the use of the FA-SET for IVRA is superior and safer over the traditional method of using an upper arm pneumatic tourniquet.

Introduction

Hand and wrist surgical procedures range from very short, such as carpal tunnel release (CTR), to medium (e.g. distal radius internal fixation), to long (e.g. multiple digital joint replacements). These procedures do have in common the need for effective anesthesia and in the majority of cases are performed under bleeding-free conditions achieved by some sort of exsanguination and tourniquet. The purpose of this paper is to describe regional and local anesthesia options facilitated by the use of the forearm tourniquet, in particular the forearm sterile elastic exsanguination tourniquet (FA-SET).

Our focus is on two main strategies: (i) Local incision site infiltration while the FA-SET is tolerated by the patient without or with additional topical anesthesia at the site of the tourniquet; and (ii) Intravenous regional anesthesia (IVRA – Bier Block) performed with the FA-SET in place. We hereby describe our experience with the FA-SET in both categories.

The Forearm Sterile Elastic Exsanguination Tourniquet

The FA-SET (HemaClear®, OHK Medical Devices Ltd. Haifa Israel) consists of an elastic silicone ring, wrapped around by a tubular stockinet and four straps terminated by two handles (App. Figure 1a). The FA-SET is placed on a conical application cup that helps in its placement on the fingers and the initiation of its rolling up the hand. The FA-SET is sterile (Ethylene Oxide sterilization) and comes double wrapped in individual packs. When the straps are pulled proximally along the axis of the arm, the ring rolls over the hand, wrist and forearm and the stockinet is released to cover the skin (App. Figure 1b). The final position of the FA-SET is 10-12 cm above the root of the palm. The rolling applies uniform circumferential force on the tissues, translated into radial pressure that effectively squeezes the blood out (exsanguination) and blocks the arterial flow into the hand. The application of the FA-SET is quick and smooth, taking 3-5 seconds.

Short procedures

Hand procedures that take no more than 15 minutes (e.g. Carpal Tunnel Release) may be performed with the FA-SET and local infiltration without any additional sedation or anesthesia. The patient should be alerted in advance about the discomfort associated with the compression of the FA-SET and should be verbally coached during the short duration of discomfort. For patients who are not in complete control of their faculties (i.e. cognitive dysfunction) or patients who seem very apprehensive, an alternative method should be offered (see below). Studies conducted with both pneumatic tourniquets and with the SET show significantly better tolerance of a tourniquet on the forearm as compared to the upper arm ( ).

When the patient, the surgeon, or the anesthesiologist determine that supplemental analgesia is needed to obviate tourniquet discomfort and pain, there are two techniques that are readily available:

1. Ring anesthesia – infiltration of the subcutaneous tissue in the area where the FA-SET will be placed with a local anesthetic (e.g. 50% diluted Citanest solution using 22 G × 3 1/2″ size spinal needle (Sujia®)); or
2. Circumferential spreading of a cream composed of 5% lidocaine and 5% prilocaine (Emla® Astra) on the skin over the area where the FA-SET will be placed.

In a prospective randomized study using a forearm pneumatic tourniquet, Inal, et al.(2009) found that anesthesia using Emla cream is equally effective and less disturbing than using the subcutaneous injection technique. They also commented that a tourniquet placed at the distal forearm is effective, safe, and a useful technique for hand surgery.

Longer procedures

Intravenous regional anesthesia (IVRA) or Bier Block becomes safer and more efficient when the FA-SET is used. This is primarily due to the smaller dose of lidocaine needed to effect surgical anesthesia of the hand. The following is a step-by-step annotated description of FA-SET – assisted IVRA:

1. An IV cannula is inserted and secured (App. Figure 1a). It is preferred to use a cannula with no side port (not as shown) which is flatter, but not a “butterfly”. The hand and forearm are disinfected. Securing the catheter in place can be done with a sterile bandage to prevent dislodgement when the FA-SET is applied.
2. The FA-SET is applied as usual (see description above) using the sterile technique. The optimal position is about 10-13 cm (4-5”) proximal to the root of the palm (App. Figure 1b).
3. The IV cannula is exposed (App. Figure 1c) and lidocaine 0.5% or another local anesthetic commonly used for IVRA is injected into the cannula (Figure 1d). We use 20-25 ml of the solution (100-125 mg). Given the fact that the veins are emptied, the intra-vascular pressure associated with the injection of such small volume is low, certainly under arterial pressure, thereby avoiding leakage of anesthetics beneath the FA-SET into the central circulation.
4. In our experience, the hand is fully under surgical anesthesia in 3-7 minutes, verified by pricking the skin with a sterile needle. The level of exsanguination is very good as seen by the minimal stain on the pad and the surgeon’s gloves (App. Figure 1e). In case the patient complains about tourniquet discomfort and pain, the FA-SET is simply moved distally a few centimeters by manually rolling it in the distal direction to a position that has already been anesthetized.

5. Suturing (App. Figure 1f) and compression dressing (App. Figure 1g) can be done before or after release of the FA-SET. Note that in view of the fact that the overall quantity of lidocaine is kept low (e.g. not more than 1.5 mg/kg) and within the therapeutic dose typically used for multiple PVCs, there is no risk associated with early release of the occlusion.
6. The removal of the FA-SET is done by cutting the ring with a scalpel (App. Figure 1h) and the fabric with scissors. App. Figure 1i shows the compression marks on the skin after the removal of the FA-SET ring.
7. The "dissected" FA-SET is shown in App. Figure 1j. The blue silicone ring is the elastic mechanism which applies calibrated pressure on the forearm.

It should be noted that performing IVRA with the FA-SET is tolerated well by the patients. It saves a few minutes of tourniquet time as the FA-SET can be removed as soon as the surgical procedure is completed, and it increases significantly the overall OR throughput. The fact that the FA-SET is sterile, as compared with the non-sterile and often dirty (App. Figure 2) pneumatic cuff, enhances the overall margin of safety.

The main differences from the traditional IVRA are the forearm placement of the FA-SET, its sterility, and the elimination of the pneumatic system from the process, notwithstanding the concern about sudden pressure loss or confusion between distal vs. proximal cuff inflation. In addition, while the IV cannula can be placed by the anesthesiologist or anesthesia nurse, the injection of the anesthetics is typically done by the surgeon, necessitating the drawing of the liquid into a sterile syringe.

Summary and conclusions

- The FA-SET is sterile and tolerated well by the patient. The forearm placement limits the volume of ischemic tissue to the minimum.
- Using the FA-SET for small hand/fingers procedures is logistically straight forward. It does not require capital equipment and calibration and the preparations for the case are simple (single item). As such, these cases can be performed in a procedure room with minimal support personnel, freeing the anesthesiologist for more complex cases.
- Subcutaneous infiltration of local anesthetics combined with the FA-SET is a safe, efficient and cost-effective way of optimizing the surgical field for short hand/fingers procedures. The addition of topical Emla® type cream can be applied in those patients where discomfort tolerance is low or unpredictable.
- Intravenous Regional Anesthesia with the FA-SET is safer than the traditional upper arm double cuff pneumatic tourniquet due to the fact that a much lower dose of local anesthetics

is required in order to obtain surgical anesthesia. It is also safer because there is no risk of sudden loss of tourniquet pressure.

The use of the FA-SET for IVRA is also logistically superior over the traditional methods. The elimination of the pneumatic system with only a single item needed for the blocking of blood flow into the hand and seepage of anesthetics into central circulation. The early release of the tourniquet allows for a more efficient use of OR facility and personnel. The FA-SET presents a useful option for effecting wrist, hand and finger surgical anesthesia. In our experience, the safety margin is better than the traditional use of upper-arm pneumatic tourniquet and should be considered as first choice in most hand cases.

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Appendix – Figures

Figure 1a

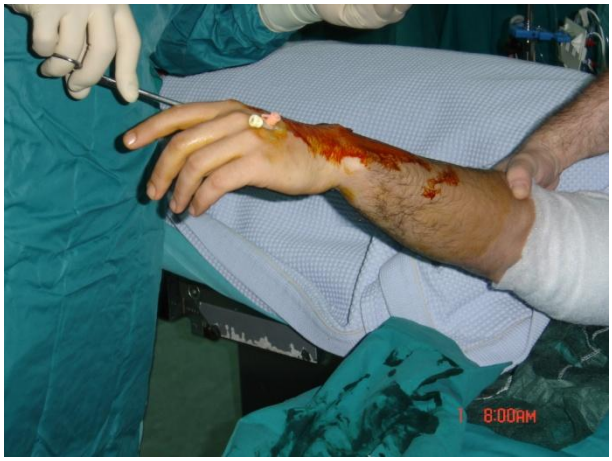
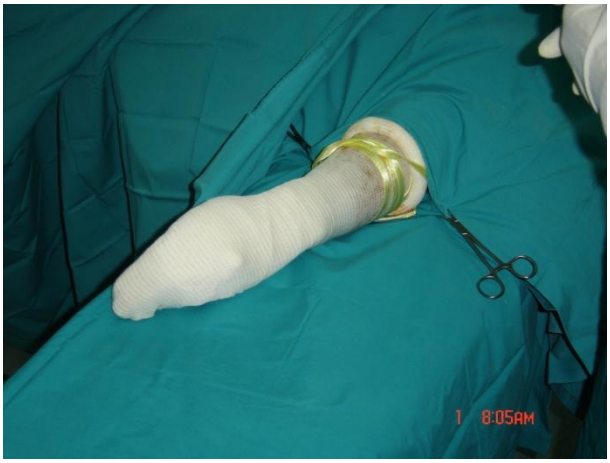


Figure 1b



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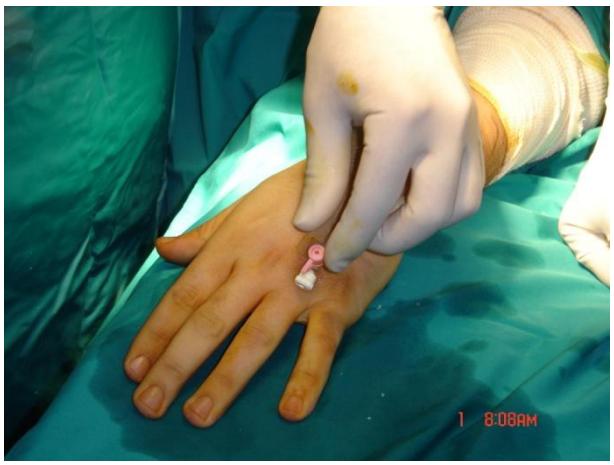

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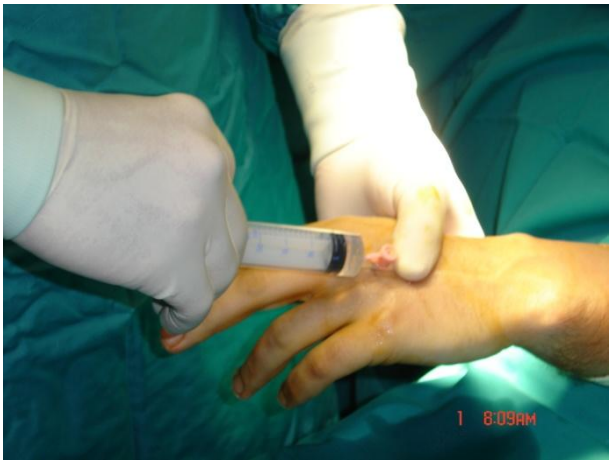


Figure 1e

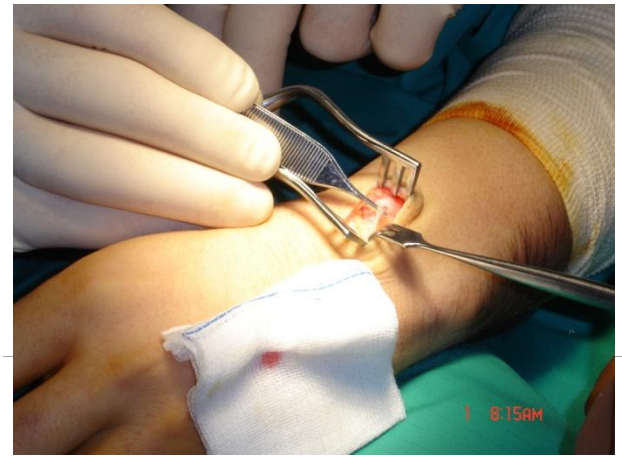
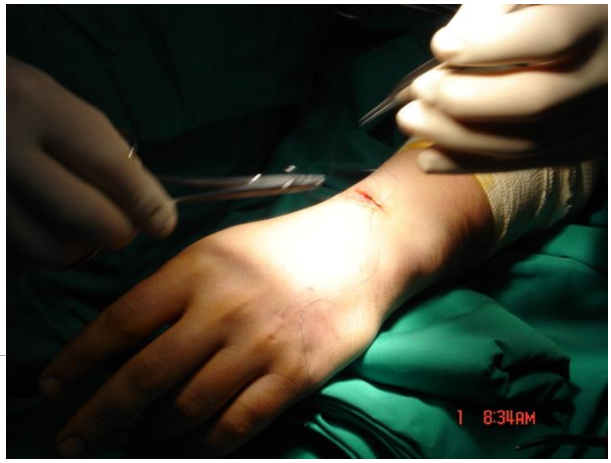


Figure 1f



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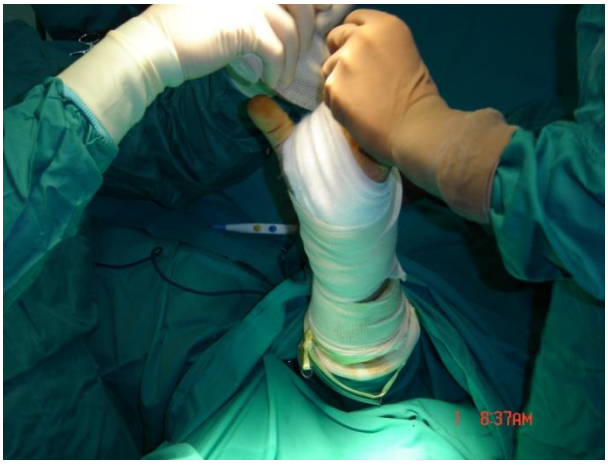


Figure 1h

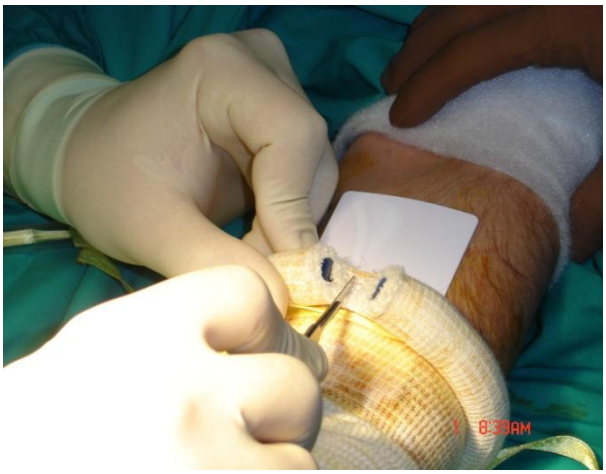
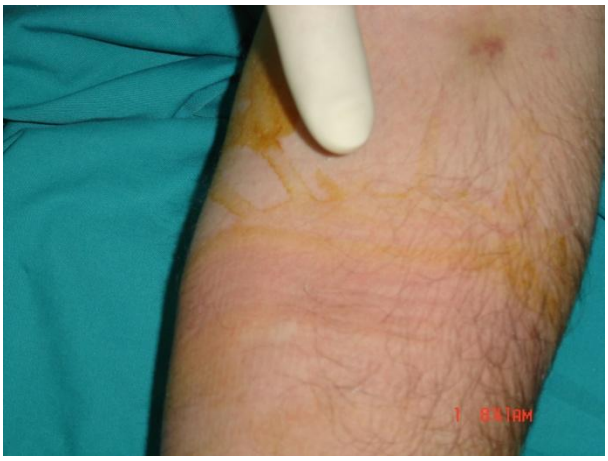


Figure 1i



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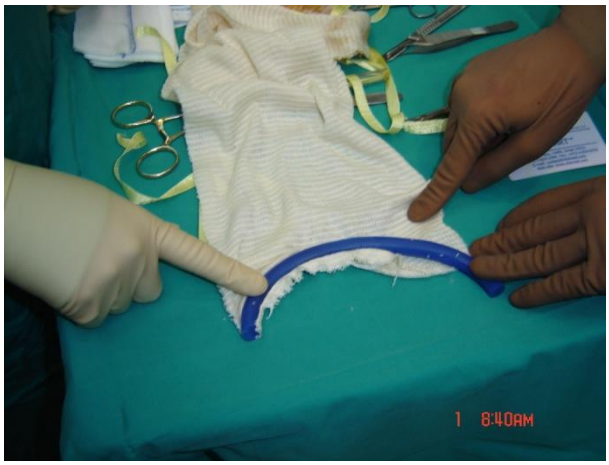

Figure 2

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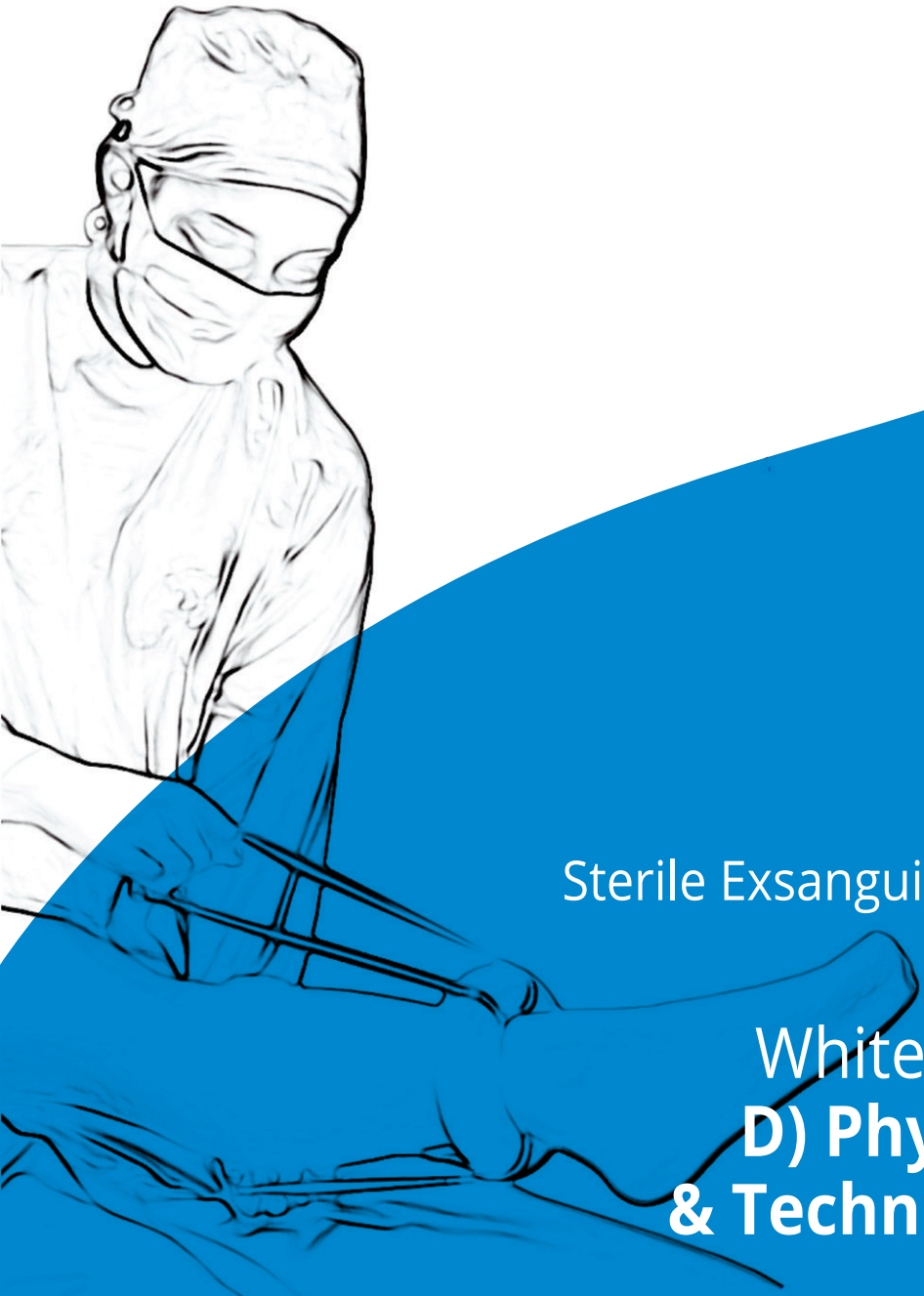

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Incomplete Leg Exsanguination: A Possible Cause of Post Total Knee Arthroplasty (TKA) Cognitive Deficit (CD)

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Abstract

Introduction & Aims: Mild to moderate CD after TKA is a common side-effect of an otherwise successful procedure. Despite improvement in the majority of the cases within weeks to a few months, this is a source of concern and disappointment. This analysis presents a possible mechanism for post-TKA cognitive changes.

Method: We reviewed the literature on the hemodynamic events around limb exsanguination, tourniquet placement and release during TKA. The majority of this literature is in anesthesia journals, with only a few in orthopedic journals (e.g., Berman, *JBJS*, 1998, 389-96). Once the data were collected, we scrutinized it for validity and in order to identify a plausible etiology that links between the TKA operating procedure and CD.

Results: Limb elevation, Esmarch bandage, or Rhys-Davis exsanguinators are used prior to tourniquet inflation. Blond et al, (*Acta Orthop Scand*. 2002; 73:89–92) showed that at best, 70% of the limb's blood was exsanguinated. Miller et al. (*Ann. Surg*. 1979; 190: 227-230) demonstrated that blood remaining inside the vessels of an occluded limb coagulates. Parmet et al (*Lancet*. 1993; 341:1057-8) observed a shower of echogenic material in the right atrium approximately 30 seconds after tourniquet release in ALL patients. Berman et al., (*JBJS*, 1998, 389-96) documented that this echogenic material consisted of fresh thrombi and not fat, bone marrow or cement. These thrombi partially occlude the pulmonary circulation, elevating the pressure in the right heart. As such, the blood pressure balance across the septum of the right atrium reverses. For patients with patent foramen ovale, blood flows from right to left. This brings echogenic material to the cerebral circulation in over 50% of TKA patients as detected by transcranial Doppler ~50 seconds after tourniquet release (Sulek, *Anesthesiology* 1999; 91:672–6). These cerebral emboli were associated with new brain infarcts detected by pre- and post-TKA MRI imaging (Koch, *J Neuroimaging*. 2007 17:332-5). The last step in this chain-of-evidence analysis is the statistics of CD post-TKA (Rodriguez, *J Arthroplasty.* 2005 20:763-71.)

Conclusions: The disproportionate prevalence of CD post-TKA as compared to other surgical procedures performed under similar types of anesthesia and in similar patients is worrisome. This hemodynamic analysis invokes a hypothesis that links incomplete limb exsanguination with cognitive dysfunction. Prospective studies where near-perfect exsanguination is applied in comparison with the current methods should be performed.

Bloodless Surgical Field

Most surgeons exsanguinate the leg and use a tourniquet to occlude blood flow as a routine method of maintaining a bloodless surgical field during total knee arthroplasty. Some prefer using it for the entire duration of the operation, while others only block the arterial flow into the leg for cementing of the implanted knee. In any event blood flow is stopped for anywhere between 30-120 minutes (maximum). This brief review is focused on the practice of limb exsanguination and the consequences of the incomplete removal of the blood from the vessels in the leg.

Exsanguination

The current methods of limb exsanguination before application of the tourniquet include the following methods:

1) Esmarch bandage wrapped tightly from distal to proximal;
2) Limb elevation;
3) Rhys-Davies exsanguinator (Woodville Polymer Engineering, Derbyshire, UK)[1] and the Pomidor roll-cuff (Pomidor AB, Varnamo, Sweden);
4) an elastic exsanguination tourniquet (HemaClear®, OHK Medical Devices, Haifa, Israel).[2]

In a series of studies, Blond et al.[3] used Tc99-tagged red blood cells to measure the extent of blood removal from a limb by applying each of the first three methods listed above.

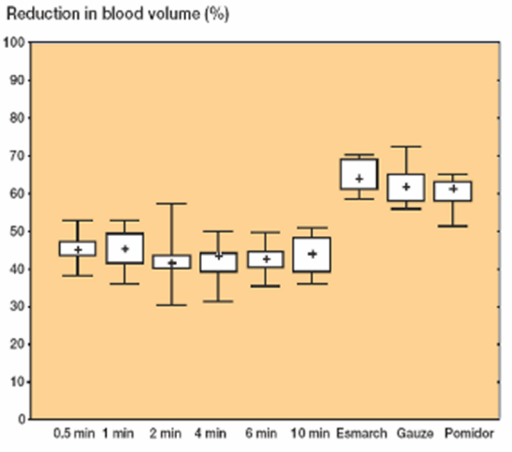

Figure 1. Results of various exsanguination methods in 12 subjects expressed as median (+), range and inter quartile percentage reduction in blood volume calculated from counts before and after exsanguination. Limb elevation achieved less than 50% count reduction. Esmarch about 65%.[4]

Figure 1 summarizes Blond's findings. They found that the best level of exsanguination was obtained with the Esmarch bandage. It was able to remove nearly 70% of the blood. The Pomidor, a device that is similar to, but smaller than the Rhys-Davies, was found to have removed slightly over 60% of the blood. Limb elevation was the least effective with no more than 45% of the blood was removed irrespective of the duration of holding the limb up.[5] As such, these studies clearly indicate that a substantial (eg. 30-55%) amount of the blood remains in the limb at the time the tourniquet is applied and blood flow ceases. No similar studies have been done so far with the elastic exsanguinating tourniquet, but multiple clinical studies have indicated that the exsanguination is near perfect (Fig. 2).[6]

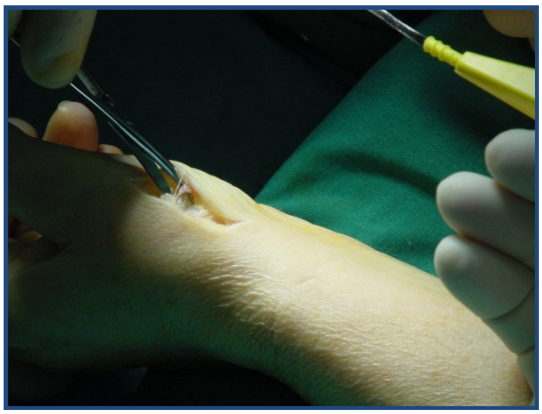

Figure 2. A nearly bloodless surgical field when using silicone exsanguinating ring.

Intravascular Coagulation

When blood stops flowing or becomes stagnant, it tends to coagulate and form fresh thrombi. Clot formation during tourniquet application has been demonstrated in 1979 in subhuman primates.[7] There are several factors that promote coagulation during total knee arthroplasty. These include reduced temperature, hypoxia and seepage of activated complement components from the incision site.

The time it takes for blood to coagulate from the onset of tourniquet application is under 6 minutes and is certainly less than 30 minutes[8]. With more than a pint of blood in the vessels of a normal sized leg. Incomplete exsanguination as outlined above will leave behind 120-250 mL of blood in the leg. When this residual blood clots, there is a certain degree of separation between the plasma and the clot so that the actual clot volume is probably 50-120 mL, depending on the pre-operative hematocrit.

The Events at Tourniquet Release

When tourniquet pressure is reduced ("tourniquet down"), blood floods into the limb first into the arterial side and shortly thereafter blood starts flowing in the veins. The blood flow sweeps with it the fresh thrombi from the

veins into the inferior vena cava and into the right atrium. Multiple studies where the right atrium was monitored with trans-esophageal Doppler have identified a shower of echogenic material in the atrium in all the patients. Several of these studies are worth mentioning more in detail. In 2002, Hirota et al.[9] did a quantitative analysis of the extent of the material traveling across the atrium. They found a peak density of about 20% of the atrium cross sectional area. This peak occurred approximately 30 seconds after the release of the tourniquet and gradually subsided over the next 10-15 minutes.

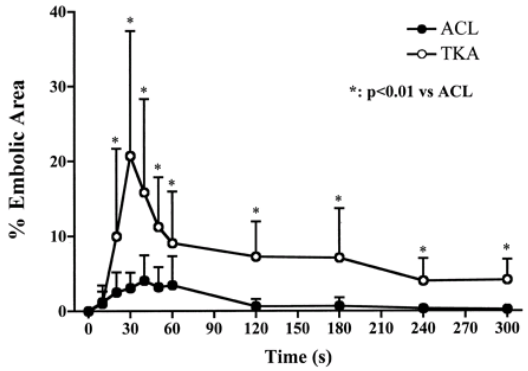

Figure 3. Time course of emboli formation in the right atrium (RA) after tourniquet release in the anterior cruciate ligament (ACL) and total knee arthroplasty (TKA) groups. *P < 0.01 versus ACL. All data are mean ± sd.

Another important publication is a study by Berman et al. in the JBJS in 1998.[10] In addition to documenting the fact that all the patients had echogenic material passing through their right atrium, they specifically evaluated the nature of the material. They inserted catheters into the femoral veins in the right atria in some of the patients that participated in the study, and aspirated blood immediately after the release of the pneumatic tourniquet. All the aspirates that contained solid material consisted of soft thrombus and did not contain fat, marrow, or cement material. The ongoing existing controversy on the nature of this echogenic material before the publication of this study was ended by these results.

Another study that shed light on this phenomenon was done by Parmet at al.[11] in 1998, where they compared the extent of the echogenic material in patients undergoing total knee arthroplasty with and without a pneumatic tourniquet. They found a 5.3 fold increase in the amount of material at the time of the tourniquet release in the tourniquet group compared to those patients where a tourniquet was not used. As such, it is clear from this study that the presence of thrombi is directly and unequivocally related to the stagnation of the blood in the leg.

Some of the studies attempted to correlate the duration of the application of the tourniquet with the extent of the thrombi recognized by the trans-esophageal Doppler. These studies did not show any statistically significant correlation. However, it should be noted that in all the studies tourniquet time was substantially greater than typical clotting time of blood. As such, one would not expect to see a correlation if in all patients clotting had already occurred. To date, no studies have yet been published on the extent of the echogenic material at the release of newer elastic exsanguination tourniquet.

Hemodynamic Effect of Thrombi Migration into the Right Heart

The clots that sweep through the right atrium continue into the right ventricle and the pulmonary arteries, and eventually lodge in the more distal arteries and arterioles in the pulmonary circulation. There they occlude the blood flow, thereby diverting the blood into other parts of the lung. Pulmonary vascular resistance goes up and the afterload of the right ventricle increases. In most normal patients the right ventricle reacts by increasing its end systolic pressure, as well as the end diastolic pressure. However, the pulmonary blood flow may be impeded to a degree, leading to a transient reduction in the venous return into the left atrium and ventricle. It is safe to assume that the Frank-Starling mechanism will reduce the left ventricular contractility and cardiac output. The negative inotropic effect is compounded

by the effect of the acidic blood coming from the legs' veins, which may also include high levels of carbon dioxide and potassium. During the period of occlusion of blood flow there is tissue hypoxia and a buildup vasodilator. These dilate the arterioles causing a decrease in vascular resistance. When tourniquet is released and perfusion is restored, blood flow is elevated leads to reactive hyperemia. The reactive hyperemia results in a washout of the acidic blood

The accumulated effect of these factors cause a sudden drop in systolic and diastolic blood pressure which is very familiar to anesthesiologists who care for patients undergoing TKA. The common practice is to infuse 560-1000 mL of fluids just prior to tourniquet release in anticipation of this pressure drop. As such, one may conclude that the effect of the pulmonary emboli at the time of the tourniquet release is not associated with the detrimental cardio pulmonary consequences of any lasting importance. However patients with preexisting conditions, such as pulmonary hypertension, COPD, congestive heart failure and related illnesses, should be given special attention to these effects.

Right-Left Shunt and Thrombi into the Arterial Circulation

In about 20%[12] of the population, the foramen ovale is closed by a detachable flap that prevents blood from moving from the higher pressure left atrium into the right atrium. This flap can open like a one way valve when the pressure in the right atrium rises above that on the left. This happens when emboli occlude the pulmonary circulation, as described in the previous section. This circumstance causes the right to left flow of blood which is saturated with thrombi from the limb clot. Once in the left side, the thrombi readily move into the left ventricle and are pumped into the arterial system. With the carotid arteries being the first branches out from the aortic arch in a straight line orientation, it is not surprising that at least some of these clots move into the cerebral circulation. This has been documented by trans-cranial Doppler in a number of studies that showed nearly 60% prevalence of echogenic material in the Circle of Willis with a peak at 50 seconds after the pneumatic tourniquet is released.[13] Other paths of the right-left shunt of blood and clots are through AV connections in the lungs that open up when pulmonary blood pressure rises.

Brain Infarcts Post Total Knee Arthroplasty

The first publication on cerebral emboli post TKA[14] failed to document cerebral infarcts by brain CT. However, a subsequent study by Monk et al[15] in 2005 clearly showed by MRI before and after TKA that 5 from 22 patients had new brain infarcts. The difference between the two papers is probably explained by the fact that small brain infarcts surrounded by edematous brain tissue are more readily detected by MRI than CT scan.

Post TKA Cognitive Dysfunction

The entity of reduced cognition after elective TKA is well known and well documented. The prevalence has been researched in a number of studies with observations that more than 40% of the patients have cognitive dysfunction seven days after surgery and more than 15% still had cognitive dysfunction 3 months after surgery. The percentages are much higher than observed in other procedures by general surgeons with similar types of anesthetics. As such, the notion that this cognitive dysfunction has to do with the performance of the anesthesiologist is not supported by the evidence. On the contrary, it is quite plausible and at least indirectly documented that these cognitive changes are the result of cerebral emboli infarction.

Summary

A flow diagram below summarizes the events leading from incomplete limb exsanguination to cognitive dysfunction during TKA.

Conclusions

Prevention of blood stagnation in the exsanguinated limb seems to be the critical element in this chain of events described above. This can be done by avoiding the use of the tourniquet all together or by using a technology that exsanguinates the blood better than with the current methods (Esmarch, limb elevation, Rhys-Davis). HemaClear® is one such device that exsanguinates the entire blood from the limb (except the blood within the bone marrow).

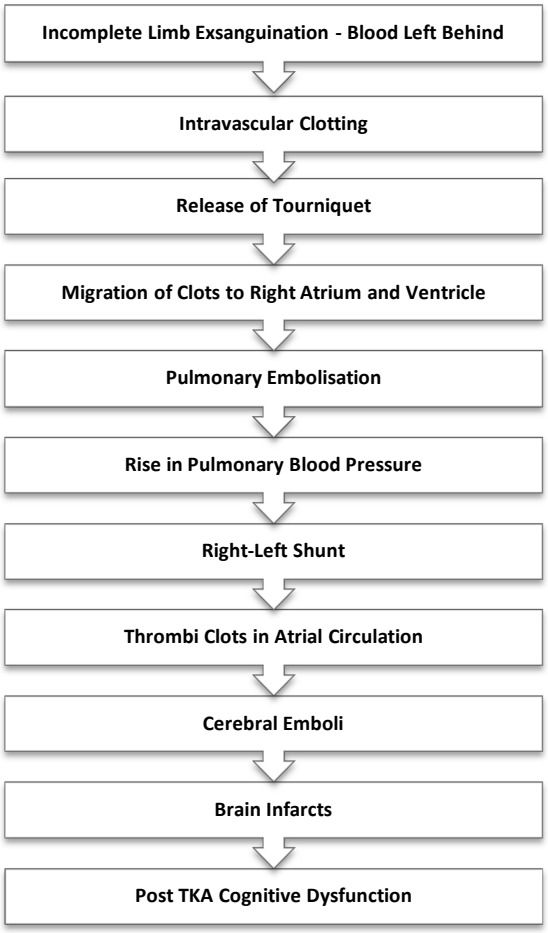

Figure 4. Cascade of events that link post TKA CD with incomplete leg exsanguination. See text for details.

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Pathophysiology and Prevention of HemaClear Tourniquet Failure

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Abstract

Tourniquet failure (TF) occurs when blood enters a limb beneath the tourniquet. This review analyzes the causes of primary TF – when the blood flow is not occluded a-priori, and secondary TF – when arterial flow is initially stopped, but resumes some time into the case. If TF occurs, the tourniquet must be removed to prevent venous engorgement, stagnation and clotting.

Arterial tourniquets are used to block the blood flow into a limb during surgery to achieve a blood-free surgical site. Tourniquet failure is defined as a condition whereby blood enters the limb beneath the occluding tourniquet. As such, the tourniquet becomes a venous occlusion device with blood accumulating in the vascular bed distal to the occlusion.

There are three factors that determine the ability of a tourniquet to block blood flow into a limb:

1. Arterial systolic blood pressure ($P_{systolic}$);
2. The pressure the tourniquet exerts right outside of the artery ($P_{tourniquet}$); and
3. The stiffness of the artery ($P_{buckling}$).

This can be expressed by a simple expression:

$$P_{tourniquet} - (P_{systolic} + P_{buckling}) > 0$$

Or, in other words, the pressure of the tourniquet on the artery must overcome the systolic blood pressure and the stiffness of the arterial wall.

In addition, it is imperative that the tourniquet is placed in the correct anatomical location.

We shall now evaluate each parameter with respect to the two types of tourniquet failure (TF) that one may encounter: (a) primary tourniquet failure (1^o TF), and (b) secondary tourniquet failure (2^o TF).

1^o TF

This is a condition where arterial blocking was never achieved and blood continues to flow into the limb right after the application of the tourniquet. This is an uncommon situation and there are three main conditions that lead to it:

1. **Calcified arteries.** This can be seen on x-ray of the limb and TF may be anticipated. It has been described with pneumatic tourniquets[1] and was recently encountered in Cardiff, Wales with the HemaClear (HC) tourniquet (Figure 1).

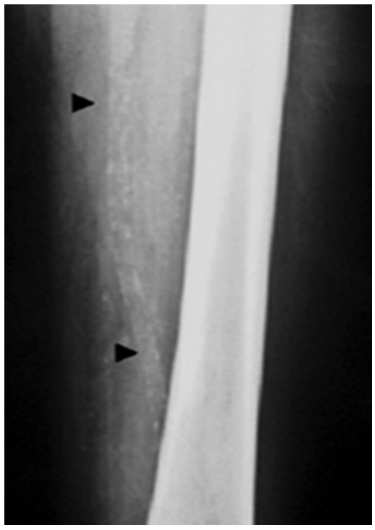

Figure 1. X-Ray of calcified arteries.

2. **A steep increase in arterial blood pressure (BP) immediately following the application of the HC on a leg.** This has particularly been observed in obese patients (Figure 2). The two lower images were taken just before and just after HC application on the obese leg shown in the top photo. Note the 40mmHg rise in systolic BP with virtually the same heart rate). The pathophysiology underlying this is the rapid shifting of blood from the leg into the central circulation. An adult leg holds about 500 ml of blood and in the obese person it can be as much as 750 ml. When HemaClear is applied, it exsanguinates the leg almost completely (~95%). This amount of blood is rapidly auto-transfused, and an elevation of BP is unavoidable. This is particularly so in patients who have a tendency for hypertension. As such, we currently recommend that when the HC-XL is used, the application is done in two steps. First, the device should be rolled up to the knee level, where a pause for 30-90 sec is taken. During this time, it is recommended that the anesthesiologist take a BP reading. If the systolic level approaches 160 mm Hg, it is suggested that hypotensive measures are taken (e.g. small dose of NTG be administered). Once the BP is back to normal levels (i.e. <140 mmHg), the HC can be brought up all the way to the groin. The above mentioned process will prevent this type of 1^{o} TF.

3. **Incorrect selection of HC type.** HC pressure is factory-set and cannot be changed. However, there are 4 HC sizes (Small, 40, 55 and XL) and from the 40 and 55 there are 3 pressure levels: 130 mmHg, 160 mmHg and 190 mmHg. The HC-SM is rated to 130 mm Hg and the HC-XL is rated to 160 mm Hg. Selecting an incorrect size (e.g. an HC-40 which is rated for 24-40 cm circumference for a 20 cm forearm) will result in a primary non-occlusion. Likewise, a selection of the incorrect pressure model (e.g. an HC-55 blue which is rated to 130 mm Hg for a hypertensive patient with a systolic blood pressure of 155 mm Hg) will result in primary TF.

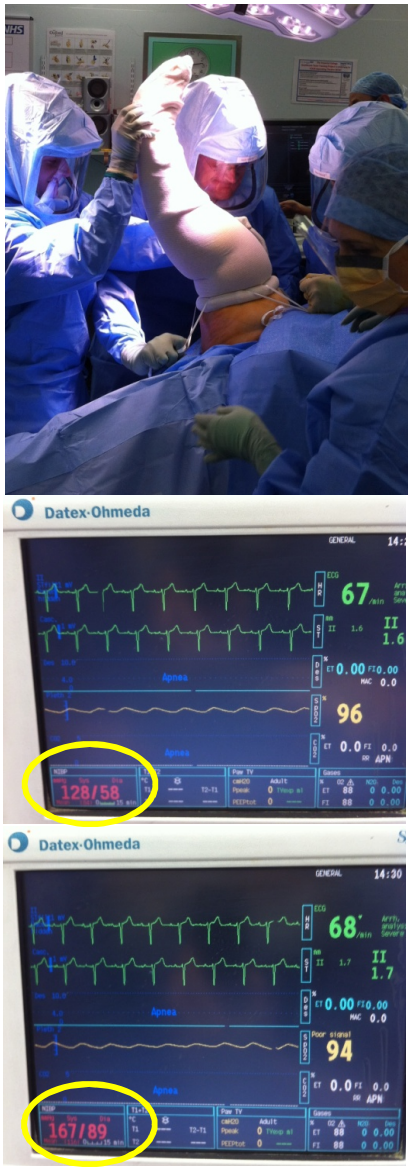

Figure 2. Surgical images from obese patient using HemaClear.

2^o TF

This is a situation where the blood flow into the limb is initially blocked and there is no bleeding at the beginning of the case, but blood appears in the surgical field later in the procedure. There are two main causes of 2^o TF:

1. **The rise in arterial blood pressure in the middle of the case.** As is well known to anesthesiologists, a rise of BP is almost always is due to the activation of the autonomic nervous system secondary to pain or anxiety. In a patient under general anesthesia, this is the result of inadequate analgesia. In a conscious patient managed with spinal or regional block, this is usually caused by anxiety, other stimulation from within, or from the environment. Either way, it is important to monitor BP closely in all patients where HC is used, particularly if there is a history of hypertension. This can be done by taking measurements frequently (e.g. every 5 minutes), especially at times during surgery where there could be increased pain or acoustic stimuli.

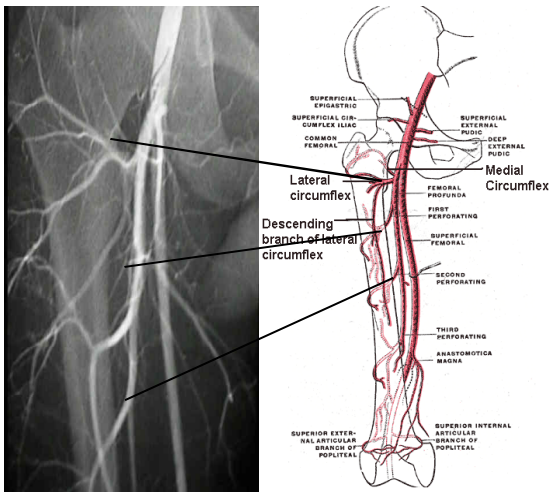

Figure 3. X-Ray & diagram of femoral artery.

2. **A special case of 2^o TF is when bleeding starts once the bone is being cut.** The cause of this is related to the arterial anatomy of the upper leg circulation (Figure 3). The femoral artery has three branches that feed the femur: the proximal, middle and distal femoris arteries. It is easy to see that if the HC is not placed high enough on the thigh, the proximal femoris artery will not be blocked and, as a result, the medulla of the femur will continue to receive blood supply. As such, if the bone is being cut, blood can seep through the trabecullae and the surgical field will fill with blood. This, of course, defeats the purpose of the arterial blocking, particularly at the cementing time when it is most desired.

Summary and Checklist

The above discussion clearly shows that TF can almost always be prevented and, in the case of calcification, at least anticipated. It is important to pay attention to the details of the product and anesthesia care. Below is a table that contains a checklist that can provide further assistance in the process.

It is important to note that if TF is encountered it is important to remove the tourniquet right away and restore circulation. This is needed in order to prevent intravascular clotting of the blood that entered the limb, even if active bleeding has stopped. Once the cause of the TF has been determined and corrected (e.g. lower BP, correct product selection, better HC position, etc.), a second HC can be used to exsanguinate the limb and block blood flow. The sterile HC can be safely rolled over the open incision.

Table – Summary and Checklist

	Condition	Action or reaction
Pre-op evaluation	Patient has calcified arteries on x-ray	Anticipate 1° TF. Evaluate arterial occlusion before making first incision. If bleed-through, remove HC and proceed without tourniquet.
	Patient has tendency for hypertension.	Alert anesthesiologist for need to monitor BP frequently and control systolic pressure. Use tightest HC model.
	HC model selection	Nurse/technician should measure circumference and prepare the correct HC size.
During surgery	Obese patient	Use the two-stage method. Coordinate with anesthesiologist with possible need for NTG. Secure HC in as proximal position near groin as possible.
	Anesthesia, analgesia and sedation	Patient's level of anesthesia should be monitored. Any rise in heart rate should be viewed as a potential sign of subconscious pain or, if under regional/spinal block - anxiety.
If bleed-through occurs	**Remove HC immediately**	**Even if bleeding has stopped**

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Use of HemaClear on the Lower Leg for Foot and Ankle Surgery

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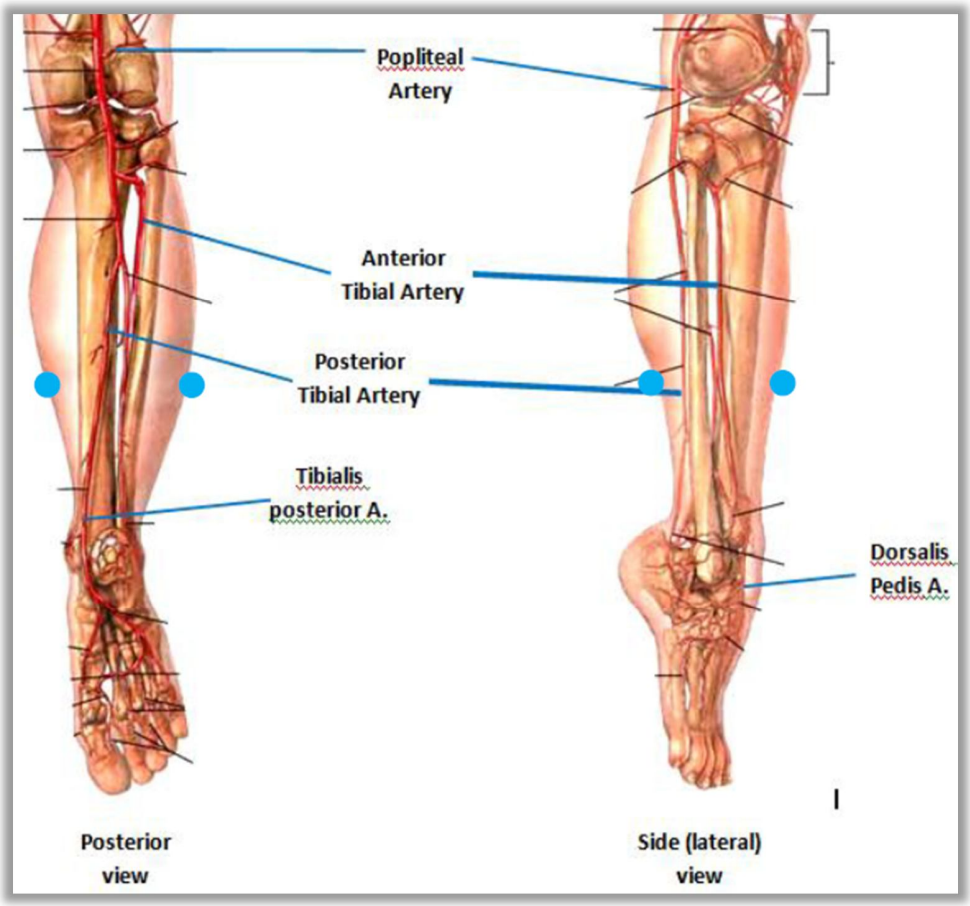
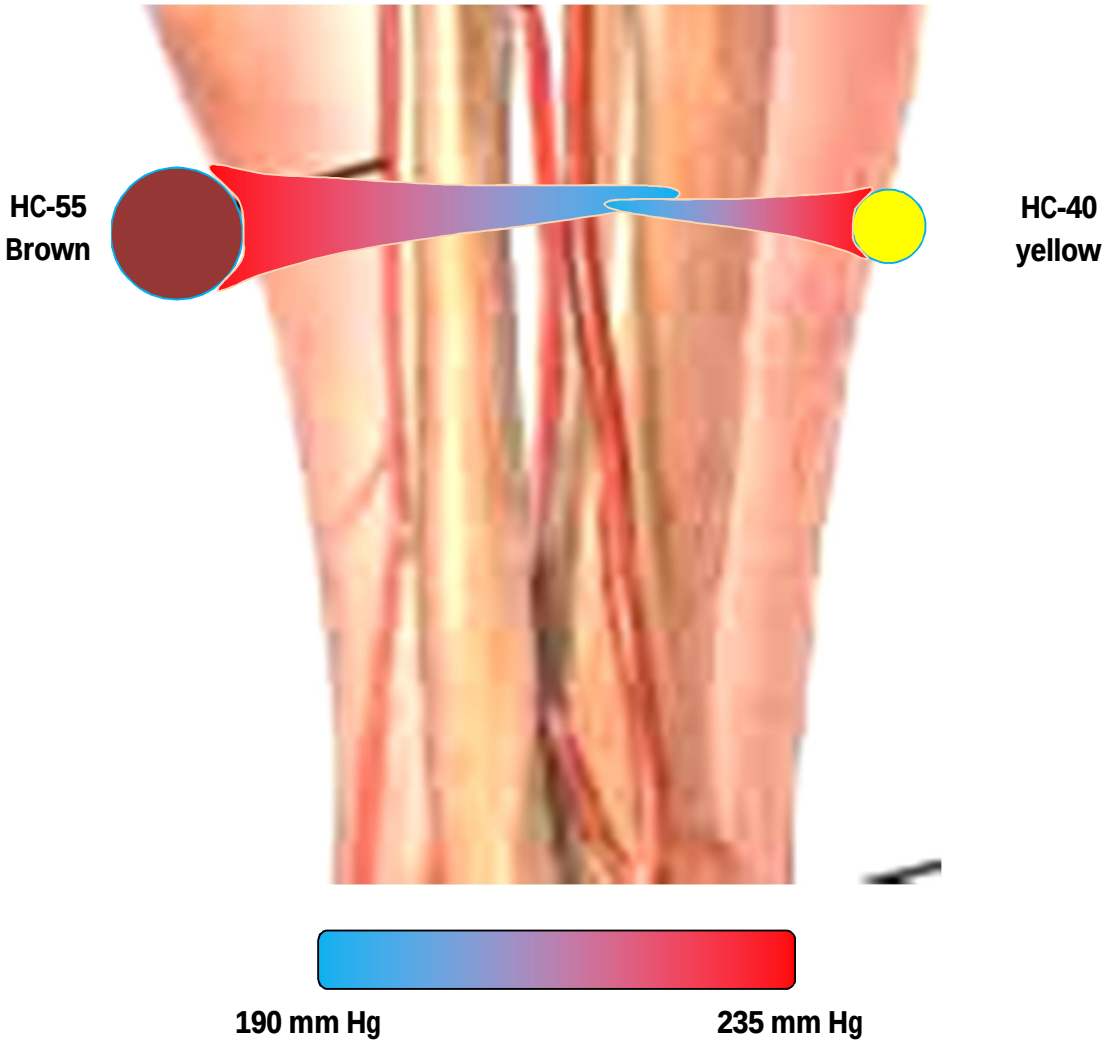
The HemaClear® is an excellent option for achieving a bleeding-free surgical field in Foot & Ankle procedures. The best choice for adults is the HC-55 (either Orange or Brown). This is better than using the HC-40 Yellow as is explained below using the charts that show the arteries of the lower leg.



The optimal position of the HemaClear® is just below the calf muscles as shown in the chart above. The circumference at the position is typically 30+4 cm. At this point, there are 3 main arteries that descend into the ankle: the Anterior and Posterior Tibial arteries and the Fibular (Peroneal) artery. The Anterior Tibial artery is passing forward in between the tibia and fibula and is therefore partially shielded from direct pressure. The diagram below shows why the thicker HC-55 is better suited for use in this position.

We do not recommend placing the HC directly on the calf muscles.



The diagram showing the distribution of pressure within the tissues of the lower leg, just distal to the calf muscles. The color-coded wedges indicate the pressure gradient from the skin to the inner aspect of the limb. The wider HC 55 applies essentially the same skin pressure, but because of the width, the pressure penetrates deeper to include the arteries within its effective range. Note that the narrower HC-40 may not exert enough pressure at the middle of the limb to block the arterial flow, even in normotensive patients.

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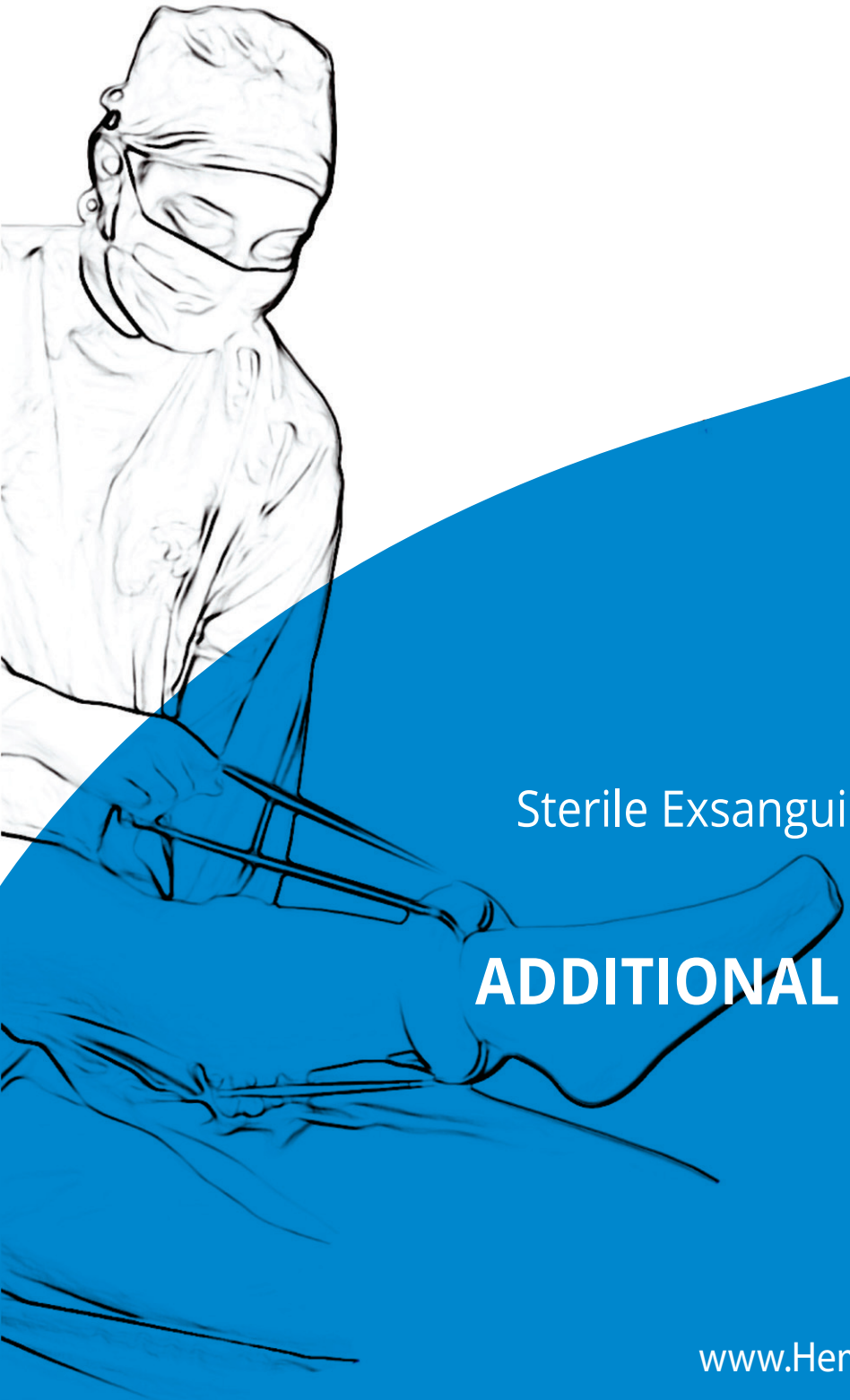

Sterile Exsanguination Tourniquet

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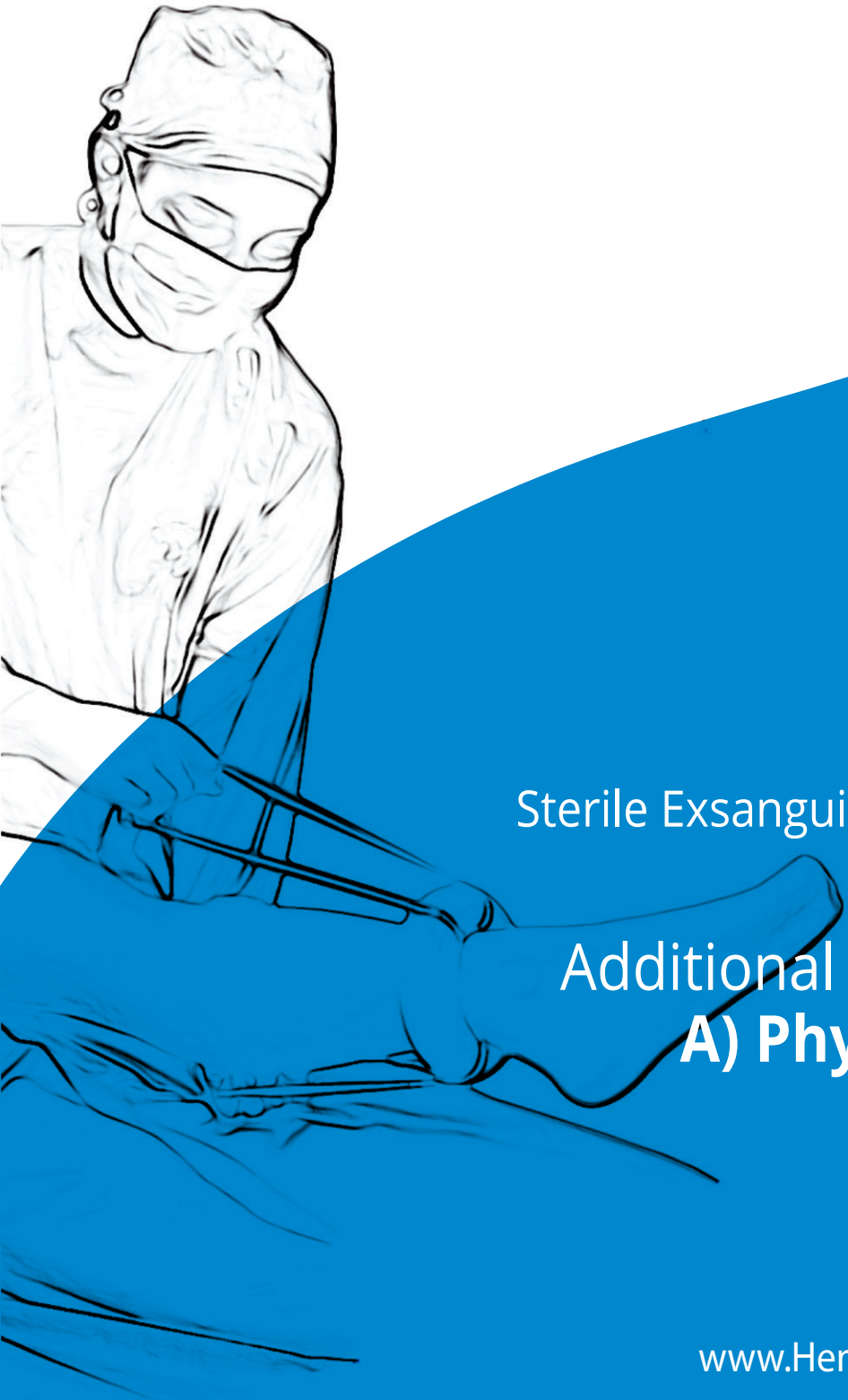

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Journal of Orthopaedic Surgery and Research

Research article

Effect of different cuff widths on the motor nerve conduction of the median nerve: an experimental study

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Abstract

Background: A bloodless operative field is considered mandatory for most surgical procedures on the upper and lower extremity. This is accomplished by using either an Esmarch bandage or a pneumatic tourniquet, but a number of complications are associated with both. Nerve palsy is one of the most frequently encountered complications of this procedure. Wider cuffs have been found to cause reduced risk of tourniquet induced injury to the underlying soft tissues than the narrower ones due to the fact that lower occlusion pressures are caused by the former. To address and investigate this question, conduction in the median nerve has been measured proximal to tourniquet as well as distal to the tourniquet. Parameters of nerve conduction measured are nerve conduction velocity, latency and amplitude.

Methods: Sphygmomanometer cuffs with widths 14 cm and 7 cm were applied to the upper extremities of 20 healthy, normotensive volunteers (9 males and 11 females with age ranging from 22 to 27). Systolic blood pressure was measured first and then the cuff was inflated to about 20–30 mm Hg above it and was kept inflated for 15 minutes. Recordings were done prior to, for the period of tourniquet inflation, and following release of the tourniquet.

Results: Nerve conduction was found to be more severely affected by the 14 cm cuff than the 7 cm cuff.

Conclusion: Wider cuffs resulted in more severe changes in the nerve. This brings us to the conclusion that though lower inflation pressures are required for the occlusion of the blood supply using wider cuffs, the nerve conduction is more severely affected by the wider ones. Both electrophysiological changes and occlusion pressure should be kept in mind while choosing the width of the cuff.

Background

Many studies related to tourniquet have been conducted till date. Some of these experiments have investigated the various complications associated with tourniquet [1-5]. No doubt tourniquets are advantageous in providing a clear operative field view but it is also true that they provide this advantage at the risk of many complications. Rorabeck [6] stated that, out of many complications, the most frequent one that should be wholly prevented are the nerve palsies arising from the use of tourniquets.

After a surgery, it is easy to identify nerve palsy but it is difficult to attribute it to a single defined cause. In tourniquet induced nerve palsies, a few studies have attributed it to ischemia [7] and others have attributed it to deformation following pressure [8]. The width of the tourniquet is also an important factor in deciding the extent of these injuries. Wider tourniquet cuffs can achieve an effective arrest of the regional arterial circulation at sub systolic pressures of inflation [9], so it could be assumed that these must cause less intense injury to the underlying soft tissue structures in comparison with the narrow ones. This is just an assumption and has not been proved till now.

This study is an attempt to shed some light on the electrophysiological changes in the motor nerve of the median nerve when the tourniquet of different widths is used.

Methods

The experimental protocol was reviewed and approved by the university research ethical committee. It was an experimental study with the same subject design {when one group of subjects is tested or measured on all the conditions and their performance compared it is known as Same Subject design, Related Subject design or Within Subject design} [10]. Subjects were thoroughly informed about the experiment and written informed consent was taken from them. Two sphygmomanometer cuffs of 7 cm and 14 cm width were used as tourniquet in the study. 20 normal subjects volunteered in the investigation, the purpose and procedure of which was explained to them in advance. There were 9 males and 11 females of age ranging from 22 to 27 [Mean age ± Standard Deviation [S.D.] = 24.45 ± 1.10].

After taking the blood pressure in a standard manner, the subject was placed in a supine position with the arm abducted to 90° and supported comfortably. Stimulating and recording electrodes were placed on the right upper extremity of each subject to stimulate the median nerve. Before placement, the skin below the electrodes was slightly abraded to reduce impedance. A ground electrode was fastened to a convenient site between the stimulating and recording electrode. The recording site was abductor policis brevis muscle. R1 and R2 electrodes were placed in such a way that R1 is placed over the muscle belly of abductor brevis muscle and R2 over the first metacarpophalngeal joint. Stimulation sites were axilla [proximal to tourniquet] and ante-cubital fossa [distal to tourniquet].

The resting motor nerve conduction velocity [MNCV], amplitude and latency measurements of the median nerve for each subject were carried out before the experiments. The decision to carry out the experiment at a particular time with either of the cuff was random and a gap of at least 24 hours was kept between the two experiments. The two cuffs were inflated to 20–30 mmHg above their respective systolic blood pressure ranging from 110 to 126 mmHg for 14 cm cuff and 140 to 166 mmHg for 7 cm cuff and were kept inflated for 15 minutes. An inflation pressure of 20–30 mmHg above the systolic blood pressure was used as the subjects included in the study were not anesthetized and the subjects would not have tolerated higher pressures than this. During this time period three recordings of the motor nerve conduction was taken by stimulating at both the axilla and the ante-cubital fossa. The first recording was done at 5th minute of inflation, the second one at 10th minute and the third at 15th minute. The cuff was then deflated and again recording of same parameters were taken at 1st minute, 2nd minute, 3rd minute, 4th minute, 15th minute and 30th minute of post deflation, stimulating the same points.

The motor nerve conduction velocity before and following the application of the two cuffs was calculated by dividing the distance between the two stimulation sites by the difference in the onset latency proximal and distal to the cuff i.e.

$$CV\ (m/s) = \text{distance (mm)}/LAT_{proxtocuff} - LAT_{distaltocuff}.$$

The percentage of MNCV, amplitude and latency was calculated using the formula i.e. [value of each parameter at different time durations/baseline value]*100

Throughout the experiment, the room temperature was maintained between 23°C and 26°C with the help of air conditioning. Paired t-test was used to compare the changes in the nerve conduction parameters with the application of 2 cuffs. All values which appear with the mean values are standard deviations [S.D.].

Results

The present study has demonstrated that the wider 14 cm cuff impairs conduction in the nerve more severely than the 7 cm cuff. Initially 2-way ANOVA with post hoc Tukey's Multiple Comparison test was applied to the obtained data. No statistically significant difference was obtained between the parameters compared for the two cuffs, so a more sensitive Paired t-test was applied and the results of the same are presented below.

Conduction Velocity

The decrease in MNCV was maximum with the 14 cm cuff. Though decrease in the conduction velocity occurred with both the 14 cm & the 7 cm cuff, the reduction was more with the former. After 5 minutes of inflation of the 14 cm cuff, MNCV was 93.01% ± 11.34 of its baseline value

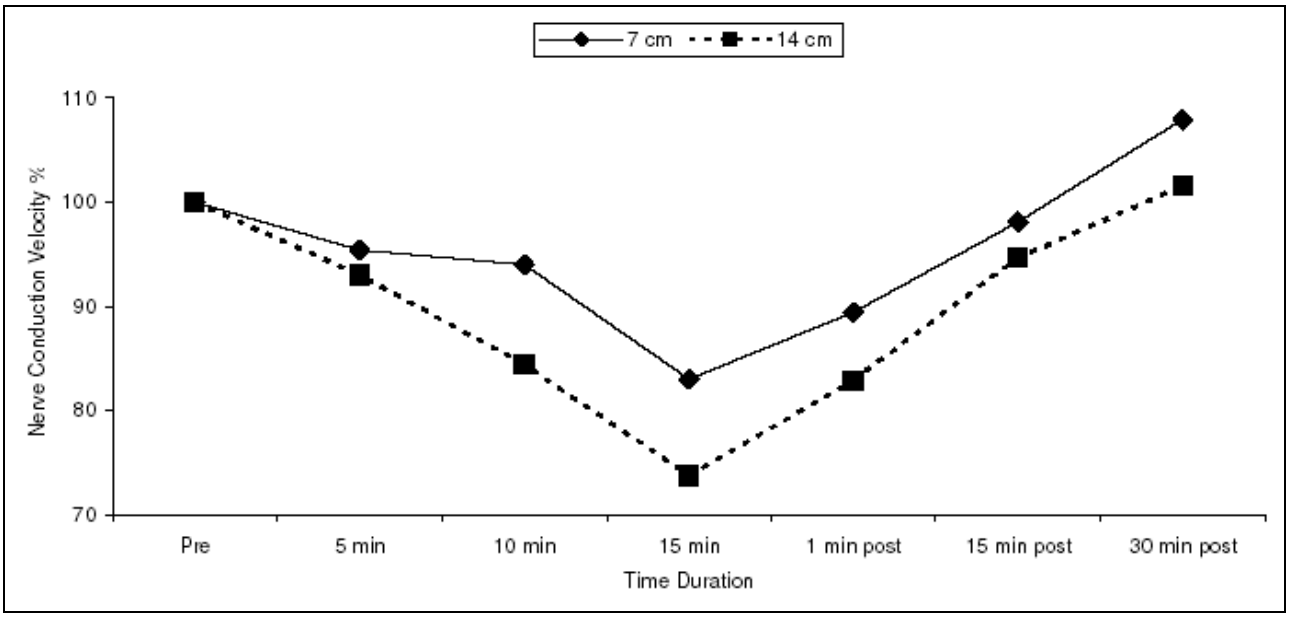

Figure 1
Mean values of the percentage MNCV at different time durations before and following the application of the 14 cm and 7 cm cuff. A decrease in MNCV is evident following application of both cuffs but as can be clearly seen that this decrease is more with the 14 cm cuff after 15 minutes of inflation of the cuff.

whereas with the 7 cm it was 95.40% ± 11.94. Though a decrease was evident, statistically this was not significant when the two tourniquets were compared. [Fig. 1]

The difference became statistically significant only after 10 minutes of inflation of the cuffs. At 10 minutes of inflation, when the percentage decrease in MNCV was compared for the two cuffs, a statistically significant difference was found with the p-value ≤ 0.03. With the 14 cm cuff the MNCV was 84.37% ± 10.15 of its baseline value after 10 minutes of inflation whereas with the 7 cm cuff the MNCV was 93.97% ± 16.10 of its baseline value. After 15 minutes of inflation also a significant difference was found in between the two cuffs with the significance level of $p \leq 0.04$. At this time the MNCV was 73.73% ± 12.06 of its baseline value for 14 cm cuff whereas it was 82.96% ± 16.33 for the 7 cm cuff.

The release of the tourniquet allowed these values to return to normal, the amount of time required for the same varied i.e. the conduction velocity took about 15 minutes to return to normal with the 7 cm cuff whereas with the 14 cm cuff it was 30 minutes.

Latency

As far as the onset latency is concerned, a prolongation in latency measured both distal & proximal to the tourniquet was found but the significant difference in this prolongation between the 2 cuffs was noted in the latency measured proximal to the cuff [Fig. 2]. A significant difference was obtained in the percentage latency measured proximally to the cuff at 15 minutes of inflation with $p \leq 0.02$, whereas in the latency measured distal to the cuff no significant difference was found between the 2 cuffs at any of the time duration.

As soon as the cuff was removed, the value of latency started returning to normal with no significant difference between the two cuffs at 15 minutes of removal of the cuff.

Amplitude

No significant difference was found in the percentage of amplitude, recorded either proximally or distally to the two cuffs, at different time durations with the 2 tourniquets. Also no defined pattern of increase or decrease in amplitude was found with the 2 cuffs [Fig. 3].

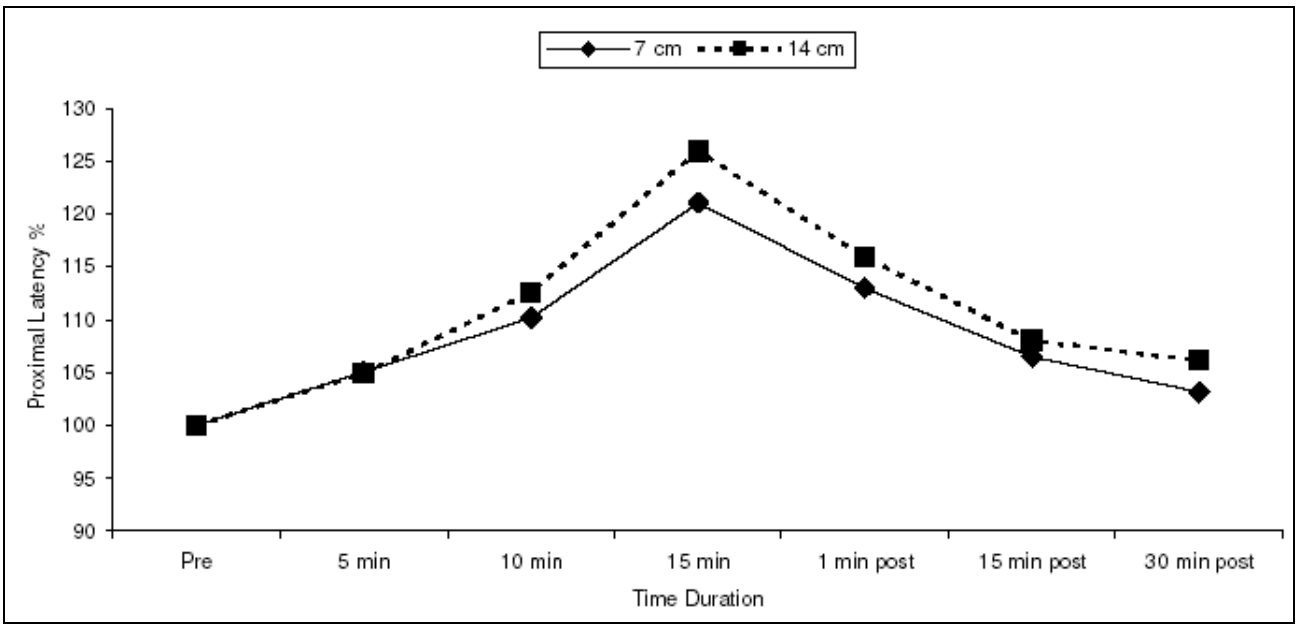

Figure 2
Plot of increase in the percentage latency measured proximal to the two cuffs with the wider cuff (14 cm) showing greater increase in the same during the 15 minutes of inflation of 14 cm cuff in comparison to the narrower one (7 cm).

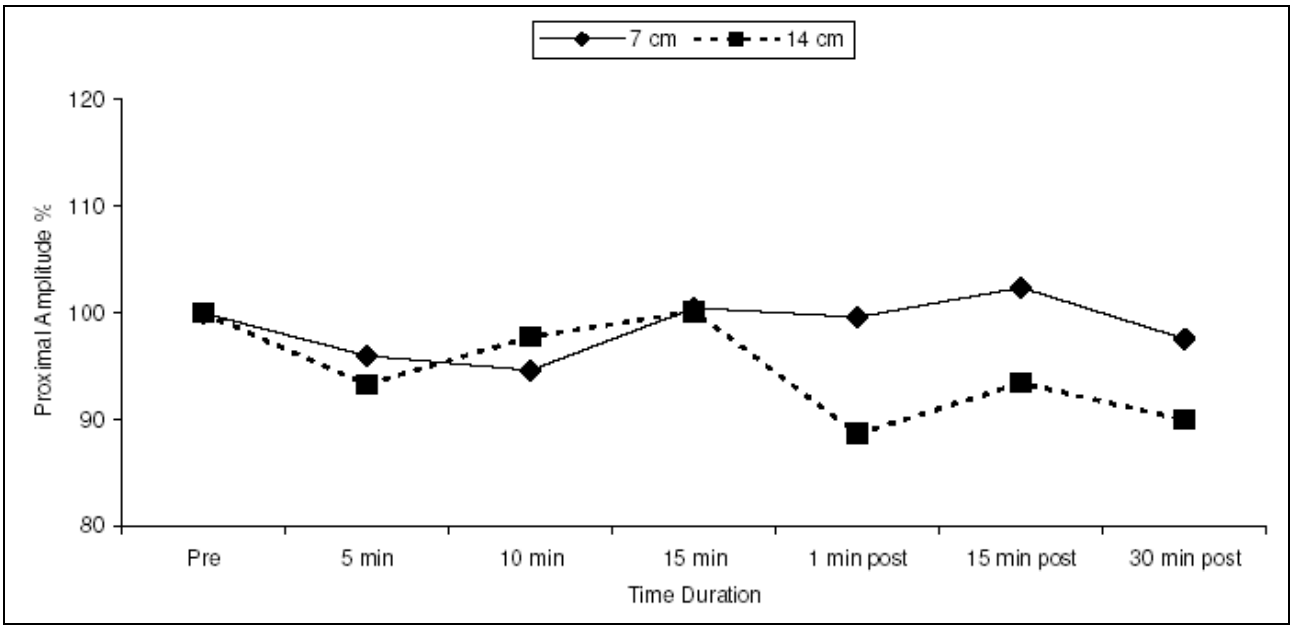

Figure 3
Figure showing the percentage amplitude change measured proximal to the two cuffs during the 15 minutes of inflation of the cuffs. The graph shows no definite pattern being followed by either of the two cuffs.

Discussion

The primary aim of the study was to investigate the effect of different width cuffs on the motor nerve conduction of the median nerve. Graham et al.[9] in their study found that wide cuffs can reduce the risk of tourniquet induced injury to the underlying soft tissues by lowering the inflation pressure required to secure a bloodless field. The results of the present study contradict these findings by the fact that even though the amount of pressure required for occluding the blood supply was less with the 14 cm cuff in comparison to the 7 cm cuff in the present study, the changes in the motor nerve conduction was greater with the former.

The possible causative factor that resulted in the present results could be the area of the nerve being compressed by the tourniquet. As the area of the nerve compressed under the 14 cm cuff is more, this could have resulted in more severe changes in nerve conduction by the same. Denny Brown & Brenner [11] while comparing the effect of localized direct pressure and the effect of application of the sphygmomanometer cuff to surface of the limb found that even when the external pressure exerted by the sphygmomanometer cuff was sufficiently high to cause an effective internal pressure, failure was more rapid than when a corresponding local compression with the mercury bag was used.

Different studies have identified one of the two causal factors i.e. ischemia and mechanical pressure as the main reason leading to an injury to the structures underlying the tourniquet following a surgery. A few studies have mentioned ischemia to be the cause of the impaired conduction in the nerve [7] whereas others have mentioned deformation resulting from the pressure as the causal factor [8]. If the clinical aspect is considered then it is clear that both time duration and the inflation pressure of tourniquet associated with the surgical procedures will play an important and decisive role.

Mechanical pressures could be an unlikely explanation as enormous pressures were necessary to abolish conduction in excised frog nerve enclosed in an oxygenated pressure chamber [12]. Usually such high pressures are not encountered in surgical procedures, so anoxia of the larger area of the nerve could be hypothesized as the possible causal factor for the more severe impairment of nerve conduction with the wider 14 cm cuff. Also the inconsistent results in the amplitude could be because of the short duration for which the tourniquet was kept inflated in the present study, as a complete cessation in the conduction has been found only after about 30 minutes of inflation of the cuff [13,14].

The results of the present study suggest that the inflation pressure for occlusion of blood supply should not be the only factor while considering the safety of the width of the cuff as electrophysiological changes are equally important in deciding the appropriate width of cuff. Thus while choosing the appropriate width of the cuff both occlusion pressure and electrophysiological changes in nerve should be kept in mind, so that least damage could occur to the underlying structures.

In the present study, subjects recruited were not anesthetized and also the amount of inflation pressure and the time duration for which the cuffs were applied was also small in comparison to what occurs in routine surgical procedures so there was no question of damage occurring to the underlying structures as is evident by the complete recovery that occurred after the cuff was removed. Thus to generalize the findings of the present study, further studies can be carried with more number of different cuff widths and also with the tourniquet inflation time and occlusion pressure simulating the time duration and occlusion pressure of surgical procedures.

Conclusion

Wider cuffs result in more severe changes in nerve conduction velocity than the narrow ones. This suggests that while choosing the appropriate width of the cuff, both occlusion pressure and electrophysiological changes in nerve should be kept in mind.

Authors' contributions

PM carried out the data collection and drafted the manuscript. SS and JSS were the co-investigators in the study.

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Exsanguination of lower limbs in healthy male subjects

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ABSTRACT – Gamma camera technique was used to assess the effectiveness of various exsanguination methods in 12 healthy male volunteers given an autologous injection of 99mTc-labeled erythrocytes. The methods used included elevation alone, Esmarch bandage, gauze bandage, and the Pomidor roll-cuff. The median times spent on use of these methods were: Esmarch 85 sec, gauze 104 sec, and Pomidor roll-cuff 18 sec. The various exsanguination methods caused a median percentage reduction in regional blood volume of the lower limbs: elevation 1/2 minute 45%, 1 minute 45%, 2 minutes 42%, 4 minutes 44%, 6 minutes 43%, 10 minutes 44%, Esmarch bandage 64%, gauze bandage 62%, and Pomidor roll-cuff 61%. No statistically significant differences were found between the elevation procedures. The external methods were more effective than elevation alone ($p < 0.001$).

Although exsanguination is a routine method in most orthopedic departments, only a few studies have dealt with this topic. Sir Lord Lister (1909) emphasized the importance of elevation and, after some observations, he recommended 4 minutes of elevation before applying of a tourniquet. However, DiStefano et al. (1974) in a plethysmographic study, noticed that a maximum reduction in blood volume after elevation seemed to occur even after 20 seconds with no noticeable change thereafter. Subsequently, in another plethysmographic study, Warren et al. (1992a) showed that optimal duration of elevation was 5 minutes. Apart from elevation, many methods for exsanguination have been suggested, all based on external compression (Esmarch 1873, Winnie and Ramamurthy 1970, Burchell and Stack 1973, Rhys-Davies and Stotter 1985, Colville and Small 1986, Löfqvist 1988).

The Esmarch bandage is generally thought to provide the most effective exsanguination (DiStefano et al. 1974, Rhys-Davies and Stotter 1985, Colville and Small 1986, Fancourt-Smith et al. 1990, Marshall et al. 1994). Previous studies on changes in local blood volumes in limbs have been based on plethysmographic methods . In this study, we used a new scintigraphic method to evaluate the effect of ordinary procedures for exsanguination of the lower limb before surgery (Blond and Madsen 2000).

Subjects and methods

12 healthy males subjects with a mean age of 29 (24–39) years, mean height of 179 (173–189) cm, and mean weights of 79 (61–91) kg participated in the study. All had normal blood pressure. The method for evaluating changes in blood volumes was based on the autologuous injection of 99mTc-radiolabeled erythrocytes and the use of a pneumatic tourniquet (Blond and Madsen 2000). The median radioactivity was 737 MBq. Each subject was placed supine on a horizontal inflexible bed with the lower leg aligned in a frame. Using gamma camera technique, a one-minute scintigram representing the lower leg and foot was taken before and after the exsanguination (Figure 1). To ensure reproducibility of the position of a region of interest (ROI) for subsequent integration of radioactivity, a 57Co source was placed 5 cm distal to the proximal demarcation of the right tibia. As ROI we used the smallest rectangle that included the

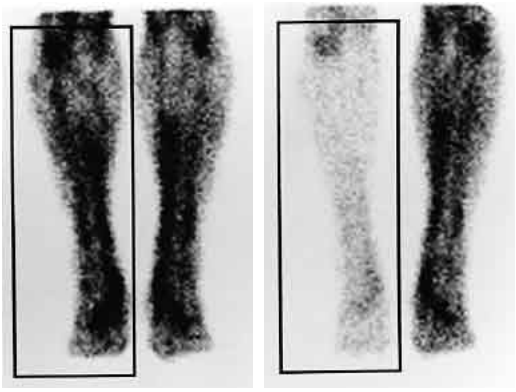

Figure 1. An example of a 1-minute scintigram of the lower limbs of a 25-year-old man obtained by 99mTc-radiolabeled erythrocytes showing the limbs from an anterior projection before and after an Esmarch exsanguination of the right limb. The frame represents the region of interest. The percentage reduction in blood volume, calculated from counts obtained before and after the exsanguination, was 61% here.

right foot and that part of the right crus distal to the marking. The same ROI was used for all measurements in each subject. The percentage reduction in blood volume was then calculated from counts obtained before and after the exsanguination.

The following exsanguination method were evaluated: elevation, Esmarch bandage, Pomidor roll-cuff (Pomidor AB, Varnamo, Sweden), and gauze bandage.

Elevation was done by the examiner who raised the limb to 60 degrees for half a minute, 1 minute, 2 minutes, 4 minutes, 6 minutes, and 10 minutes. The external methods were done with the limb raised to 60 degrees. After exsanguination, a 14 cm wide pneumatic cuff mounted on the thigh was inflated in a few seconds to 300 mm Hg. The pneumatic cuff was omitted when the Pomidor roll-cuff was used, because it also acts as a tourniquet when kept in place with two rubber wedges. The roll-cuff was used in accord with the recommendations of the manufacturer—i.e., the cuff size was chosen in relation to the circumference of the thigh and the cuff was inflated to a pressure of 120 mm Hg before use. Both the Esmarch and gauze bandages were applied using half of the width overlap. With the cuff inflated, the limb was realigned on the gamma camera and a one-minute scintigram was taken. The tourniquet was then deflated and in order to ensure that the phase of hyperemia was over, 12 one-minute scintigrams were taken before the next exsanguination. All 9 types of exsanguinations done in the 12 subjects were performed in random order, using the drawing lot principle. The time taken to apply and remove the external methods was noted.

Statistics

Friedman's test was used to compare the median values of the various exsanguination methods. A value of $p < 0.05$ was considered significant in all tests. Two-tailed tests were used. The data were analyzed with STATISTICA software package.

The local committee on ethics in Copenhagen approved the study. The subjects gave their written informed consent.

Results

The hyperemia phase lasted less than s4 minutes (median and quartiles 1.003 (0.963–1.057)) versus the opposite limb.

The median times for use of the exsanguination methods were: Esmarch 85 (81–94) sec, gauze 104 (90–107) sec, and Pomidor roll-cuff 18 (15–21) sec. The Pomidor roll-cuff took less time than the Esmarch bandage and gauze bandage ($p = 0.009$).

The various exsanguination methods resulted in the following median percentage reductions in regional blood volume in the lower limbs: elevation 1/2 minute 45%, Esmarch bandage 64%, gauze bandage 62%, and Pomidor roll-cuff 61%. For more details, see Figure 2.

As regards the results of elevation alone, no significant differences were found between the various durations of elevation ($p = 0.2$). All the external methods were more effective than half a minute of elevation ($p < 0.001$). No significant differences were found among the Esmarch bandage, gauze bandage and the Pomidor roll-cuff.

Discussion

The method we used with autologous injection of 99mTc-radiolabeled erythrocytes evaluated changes in blood volume in limbs (coefficient of variation: within subjects 6%, between subjects 14%) more

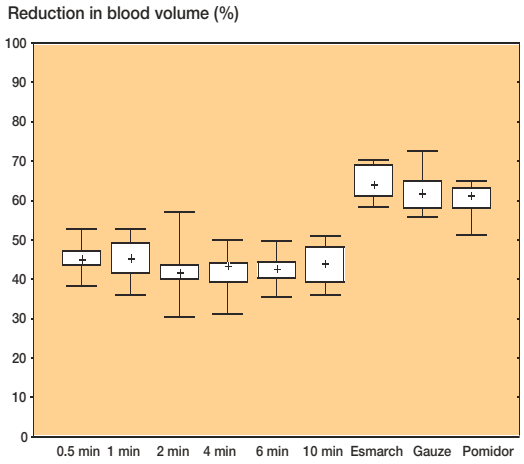

Figure 2. Results of various exsanguination methods in 12 subjects expressed as median (+), range and interquartil (box) percentage reduction in blood volume calculated from counts before and after the exsanguination.

precisely than other plethysmographic methods (Blond and Madsen 2000). It is also a more physiological approach for exsanguination.

We found that external methods induce more effective exsanguination than elevation alone, as reported by others (DiStefano et al. 1974, Rhys-Davies and Stotter 1985, Fancourt-Smith et al. 1990). As regards exsanguination with elevation alone, we found no significant difference between half a minute of elevation and a longer elevation time. This does not accord with Lister's (1909) and by Warren et al.'s (1992a, b) findings but is in the line with the observation of DiStefano et al. (1974) and Notcutt (1978). The discrepancy between ours and those of Warren et al. (1992a, b) may be methodological. Warren et al. (1992a, b) used a strain gauge plethysmographic method that indirectly estimates changes in blood volume since it measures only changes in the circumference of a limb. We believe that some of the interstitial fluid is drained when a limb is raised for more than a few seconds, and such drainage is probably the reason why the circumference of the leg continues to diminish for more than 5 minutes. The problem of stasis, which has previously been shown to occur when the lower limb is elevated to 90 degrees as a result of obstruction in the venous outflow (Warren et al. 1992b), does not seem to occur when using 60 degrees of elevation as in this study.

The oldest subject in our study was 39. To our knowledge no study has addressed the dynamic changes of the venous system in relation to age, gender or vascular diseases. However, it seems likely that some changes can occur, but how this may influence the exsanguination is unclear. Our subjects did not receive any anesthetic, which is common with the use of a bloodless field. We do not know whether this affected our findings.

We regret not to have included an elevation time shorter than half a minute in our study design, because it remains uncertain whether even shorter elevation times are sufficient for optimum exsanguination.

The fact that half a minute of elevation for exsanguination is as effective as longer elevation should change the practice in operating rooms when using elevation alone for exsanguination. A common practice is to inflate the tourniquet immediately after use of antiseptics, since the limb has just been raised for several minutes and has been regarded as optimally exsanguinated. We have learned that this is wrong and in order to minimize the tourniquet time, we believe that the inflation of the cuff should be postponed until the surgical cover has been applied and the surgeon is ready to exsanguinate. If a more effective exsanguination is required one of the external methods can also be used. The times taken for the various external methods differed. More than one minute was spent on putting on the Esmarch bandage, whereas the Pomidor roll-cuff may be putting on very quickly. The Esmarch and gauze bandages are not only time-consuming (O'Hara et al. 1991), but should not be used in the event of a fracture; they can damage the skin, because they induce torsional andlongitudinal shearing stresses (Hallet 1983, Marshall et al. 1994). However, none of the young healthy subjects in our experiment complained of pain when we used these bandages. Furthermore autoclaving the Esmarch bandage is troublesome (Asirvatham et al. 1990, O'Hara et al. 1991). In our experience, the Pomidor roll-cuff is easy to handle and gives fast, good, and constant exsanguination. It also allows placement of the surgical cover more proximal than normal, since the cuff is sterile, gives more freedom to move the leg and see the alignment. However, it has the disadvantage that when reperfusion is needed during an operation, the cuff must pass the operating field.

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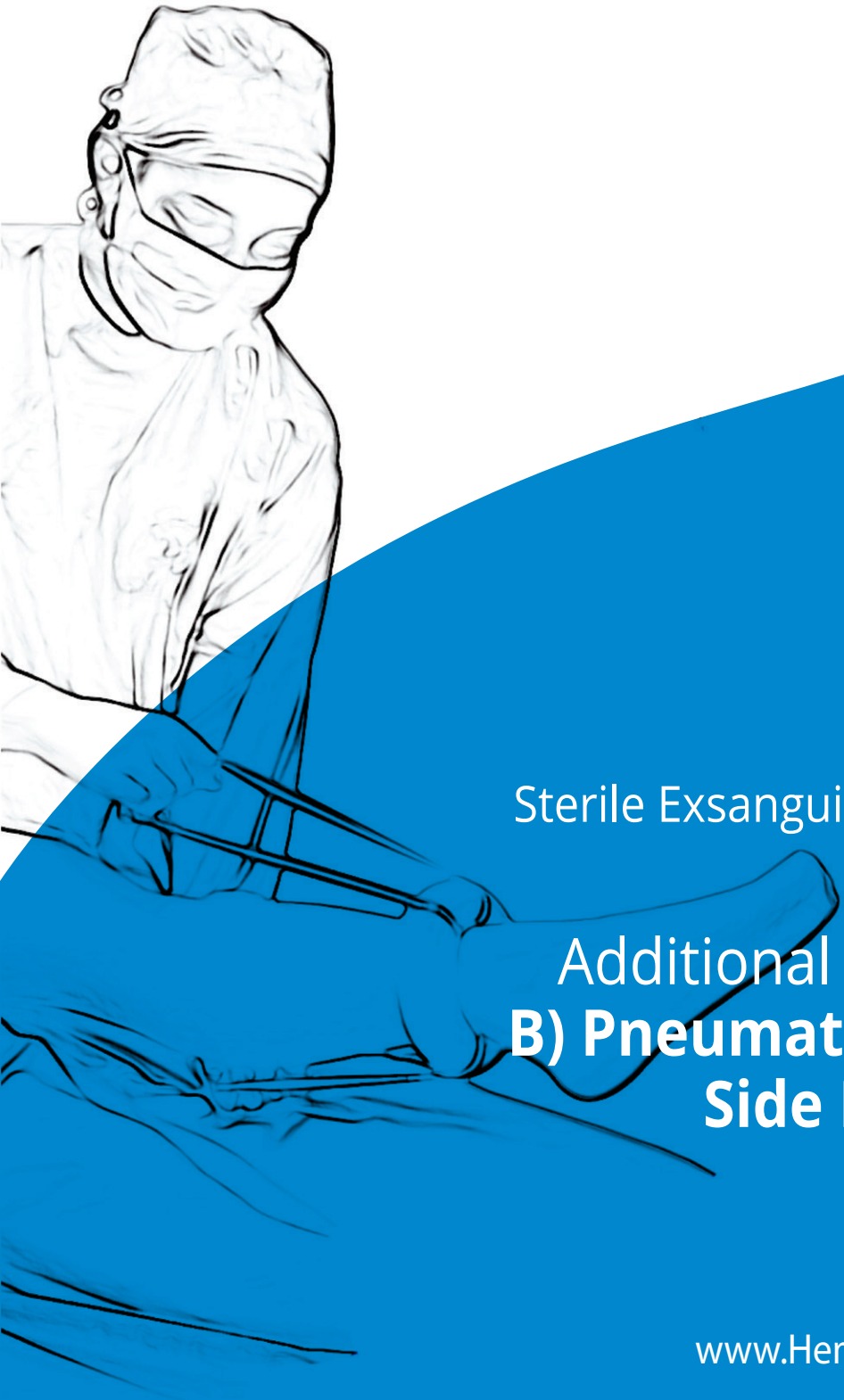

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Lower Tourniquet Cuff Pressure Reduces Postoperative Wound Complications After Total Knee Arthroplasty

A Randomized Controlled Study of 164 Patients

Charlotta Olivecrona, RN, Sari Ponzer, MD, PhD, Per Hamberg, MD, PhD, and Richard Blomfeldt, MD, PhD

Investigation performed at the Department of Orthopaedics, Södersjukhuset Karolinska Institutet, Stockholm, Sweden

Background: Measurement of limb occlusion pressure before surgery might lead to the use of a lower tourniquet cuff pressure during surgery and thereby reduce the risk of postoperative pain and complications. The primary aim of this study was to investigate whether the limb-occlusion-pressure method reduces the tourniquet cuff pressure used during total knee arthroplasty and if this leads to less postoperative pain compared with that experienced by patients on whom this method is not used. The secondary aim was to investigate whether there were any differences regarding the quality of the bloodless field, range of motion, and postoperative wound complications.

Methods: One hundred and sixty-four patients scheduled to be treated with a total knee arthroplasty were randomized to a control group or to undergo the intervention under study (the limb-occlusion-pressure [LOP] group). In the control group, the tourniquet cuff pressure was based on the patient's systolic blood pressure and a margin decided by the surgeon (the routine method). In the LOP group, the tourniquet cuff pressure was based on the measurement of the limb occlusion pressure. The primary outcome measure was postoperative pain, and the secondary outcome measures were the quality of the bloodless field, knee motion, and wound-related complications at discharge and two months after surgery.

Results: The tourniquet cuff pressure was significantly lower in the LOP group than in the control group ($p < 0.001$). We could not demonstrate any differences between the groups regarding postoperative pain or complications, although the number of postoperative complications was relatively high in both groups. However, at discharge forty of the forty-seven patients with a wound complication had had a cuff pressure above 225 mm Hg and at the two-month follow-up evaluation fourteen of the sixteen patients with a wound complication had had a cuff pressure above 225 mm Hg.

Conclusions: The limb-occlusion-pressure method reduces the cuff pressure without reducing the quality of the bloodless field, but there were no differences in outcomes between the groups. An important secondary finding was that patients with a cuff pressure of ≤225 mm Hg had no postoperative infections and a lower rate of wound complications.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

The use of a pneumatic tourniquet during a total knee arthroplasty improves visualization by preventing intraoperative bleeding. However, some studies have demonstrated lower rates of postoperative complications and better initial recovery of knee movement when the knee arthroplasty was performed without use of a pneumatic tourniquet[1-3]. When a tourniquet is used, the cuff pressure should be minimized to reduce the risk of tourniquet-related postoperative complications[2,4]. Setting the thigh tourniquet cuff pressure on the basis of the systolic blood pressure plus a margin of 100 mm Hg has been reported to reduce the cuff pressure and early postoperative pain[5]. According to another study, limb occlusion pressure and systolic blood pressure were not correlated well enough for the systolic blood pressure alone to be used to determine the optimal cuff

Disclosure: None of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of any aspect of this work. None of the authors, or their institution(s), have had any financial relationship, in the thirty-six months prior to submission of this work, with any entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. Also, no author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by authors are always provided with the online version of the article.

pressure[6]. Wide conical cuffs require a lower cuff pressure[7,8] and are less painful[7], although the authors of most published studies did not report whether a straight or a wider conical cuff had been used.

Measuring the limb occlusion pressure just before surgery by means of an automated photoplethysmographic sensor connected to a tourniquet apparatus takes into account such variables as the type and width of the cuff, the tightness of cuff application, the fit of the cuff to the limb, and the properties of the patient's soft tissues and vessels[6] and therefore has been suggested to result in a more optimal cuff pressure. However, automated measurement of limb occlusion pressure has been investigated in only a few clinical studies[6,9,10].

The primary aim of this study was to investigate whether the limb-occlusion-pressure method reduces the tourniquet cuff pressure used during surgery and if this leads to less postoperative pain. The secondary aim was to investigate whether there were any differences between the group treated with this method and a control group regarding the quality of the bloodless field, range of knee motion, and postoperative wound complications. We hypothesized that there would be no differences between the limb-occlusion-pressure measurement method and the control method.

Materials and Methods

This prospective randomized controlled clinical trial was performed from October 2008 to July 2010. Patients scheduled to be treated with a primary total knee arthroplasty, who were seventy-five years of age or younger, and who were classified as American Society of Anesthesiologists (ASA) 1, 2, or 3 were considered eligible for inclusion[11,12]. Patients who were unable to read and understand Swedish, had a systolic blood pressure of >200 mm Hg, or had a thigh girth of >78 cm were excluded.

All patients gave their informed consent to participate and were randomized preoperatively to a control or intervention (limb-occlusion-pressure [LOP]) group with use of opaque sealed envelopes.

The study was conducted according to the principles of the Helsinki Declaration and was approved by the Ethics Committee of Karolinska Institutet (Ref. No. 2007/757-31/1-4), Stockholm. It was registered at ClinicalTrials.gov (NCT01442298).

The standard method at our department was used for the patients in the control group. The tourniquet cuff pressure was based on the patient's systolic blood pressure and a margin that was decided by the surgeon. In the LOP group, the tourniquet cuff pressure was decided by measuring the limb occlusion pressure with use of an automated photoplethysmographic sensor connected to an ATS 3000 tourniquet apparatus (Zimmer Sweden, Sävedalen, Sweden). The recommended tourniquet pressure was defined as the limb occlusion pressure plus a safety margin of 50 mm Hg for those with a limb occlusion pressure of ≤130 mm Hg, 75 mm Hg for those with a pressure between 131 and 190 mm Hg, and 100 mm Hg for those with a pressure of >190 mm Hg. These recommended margins were higher than those reported earlier[4,6], but were the preadjustable margins indicated by the manufacturer (Zimmer Sweden).

The limb underneath the tourniquet cuff was protected by a two-layer elastic stockinette[13]. The operating room nurse applied a standard 140-mm-wide contour thigh cuff for all but seven patients (three in the control group and four in the LOP group), for whom the operating room nurse selected a 100-mm-wide cylindrical cuff because of difficulties in positioning the contour cuff due to a short lower limb or a very straight thigh.

The operating room nurse chose the tourniquet cuff and measured the limb occlusion pressure. Before starting the surgery, the surgeon determined the tourniquet cuff pressure according to the standard method. The operating room personnel applied this pressure if the patient had been randomized to the control group. If the patient had been randomized to the LOP group, they applied the pressure suggested by the limb-occlusion-pressure method. The surgeon was blinded to the randomization and was not told which tourniquet pressure was applied.The surgery was performed according to the routine at our department.

The surgeon used a midline skin incision with a medial parapatellar capsular incision of the joint, and all patients received a cemented NexGen Cruciate Retaining total knee arthroplasty (Zimmer Sweden).

All patients received perioperative antibiotics (cloxacillin, 2 g × 3) and low-molecular-weight heparin (dalteparin). All patients also received a local infiltration analgesic (300 mg of ropivacaine/0.5 mg of epinephrine/30 mg of ketorolac) at the end of the surgery by infiltration into the fascia, muscles, and subcutaneous tissue, regardless of whether they had had spinal or general anesthesia. In 147 patients, a catheter was also inserted into the knee joint for pain treatment with a local anesthetic (150 mg of ropivacain/30 mg of ketorolac). It was used during the day after the surgery and was then withdrawn[14].

After the surgery was completed, the surgeon was asked to rate the quality of the bloodless field on a visual analog scale (VAS), with 1 indicating the worst possible rating and 10, the most optimal. The surgeon was also asked to rate whether any technical difficulties had been encountered due to the quality of the bloodless field (1 indicating no difficulties and 10, extreme difficulties).

The skin underneath the tourniquet was inspected immediately after the surgery and on day four, when a ward nurse also performed a wound check. The functional assessment was done on the third postoperative day by an independent physiotherapist and included measurement of knee motion (with the patient lying down and sitting up) and a straight-leg lifting test (with a 1-kg weight). Furthermore, the patients filled out the modified Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire daily during their hospital stay. The WOMAC is a self-administered, well-validated health status instrument with three domains: pain, physical function, and stiffness[15,16].

All patients were followed at two months postoperatively (with inspection of the wound, measurement of knee motion, and completion of the WOMAC questionnaire). The medical records were scanned for complications such as nerve injury and deep venous thrombosis. The orthopaedic surgeon in charge and all staff at the department, except the operating room personnel who measured the limb occlusion pressure, were blinded to the allocation group during the hospital stay and at the follow-up evaluations.

Power Analysis

The sample size was calculated to detect a difference of 5 points (standard deviation [SD], 10 points) in the WOMAC pain score between the control and LOP groups on day four. A total of sixty-four patients in each group (128 patients in the series) were required to detect this difference with an 80% power at the 5% significance level, two-tailed. As we anticipated a drop-out rate of about 25%, the recruitment goal was determined to be 164 patients. When we were planning for this study, we knew of no earlier randomized study with cuff pressure as the outcome, so our sample size was calculated for detecting differences in postoperative pain.

Statistical Methods

Categorical variables were presented as absolute and relative frequencies and tested for differences between randomization groups with the chi-square test. Continuous variables were presented throughout as the mean and SD and tested with the Mann-Whitney U test. The nonparametric test was used because it was deemed more appropriate for the subjective scale variables, and for the remaining continuous variables the assumption of normality was not satisfied. Cuff pressure was partly analyzed as a continuous variable and partly as a categorical variable, whereby the cutoffs of 225 and 260 mm Hg were chosen on the basis of their clinical relevance. The results were regarded as significant if p was < 0.05 (two-tailed).

All analyses were performed according to the intention-to-treat principle.

Source of Funding

The authors did not receive any external funding or grants in support of their research for this work.

Results

Three patients were excluded after inclusion: one because of a change to a unicompartmental knee arthroplasty, one because of a change to a high-flex prosthesis, and one who was scheduled

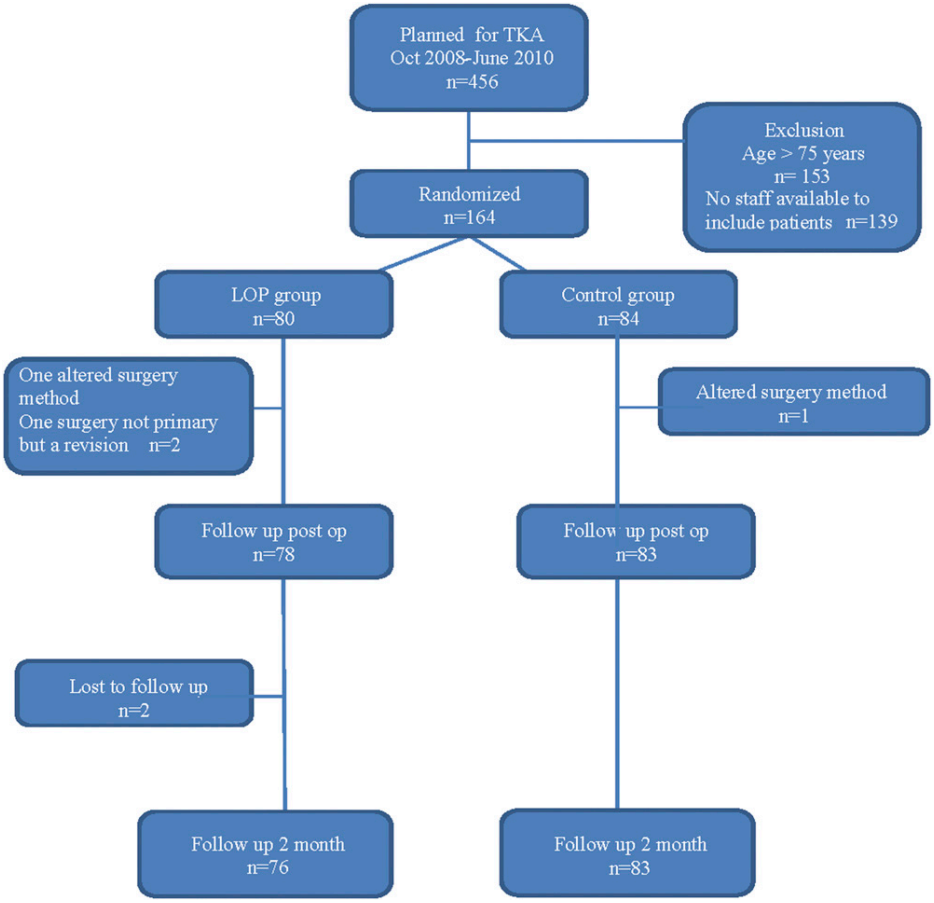

Fig. 1
CONSORT (Consolidated Standards of Reporting Trials) diagram. TKA = total knee arthroplasty.

for revision surgery and thus had been incorrectly included in the study. In total, 161 patients—eighty-three in the control group and seventy-eight in the LOP group—were included in the analysis. Two patients were lost to follow-up at two months (Fig. 1).

There were no differences between the LOP group and the control group regarding sex, age, ASA class, body mass index (BMI), preoperative systolic blood pressure, or the bloodless-field time during surgery (see Appendix). Systolic blood pressure, measured on the arm routinely at the start of surgery, was a mean (and SD) of 122 ± 20 mm Hg in the LOP group compared with 119 ± 19 mm Hg in the control group (difference not significant). The mean limb occlusion pressure (measured on the thigh in the LOP group) was 169 ± 34 mm Hg.

As shown in Table I, a tourniquet cuff pressure of ≤225 mm Hg was found more often in the LOP group than in the control group ($p < 0.001$). The mean tourniquet cuff pressure was also generally lower in the patients in the LOP group, but this difference was not significant ($p = 0.362$). No significant difference between the groups could be detected regarding the quality of the bloodless field or the technical difficulties as judged by the surgeon (Table I). There were incidents of break-through bleeding in three cases. In one of these cases, the tourniquet was deflated after only three minutes and the surgery was performed without a bloodless field.

Ratings of postoperative pain on the self-administered WOMAC questionnaire during hospitalization did not differ between the randomization groups, but the patients in the LOP group reported significantly less stiffness in the knee on day four ($p = 0.020$) (see Appendix). The range of motion of the knee on postoperative day three and the ability to do a straight-leg lift did not differ between the groups (see Appendix).

Three patients (out of 131 available) had blisters underneath the tourniquet cuff immediately after surgery, but there was no difference between the LOP group and the control group ($p = 0.227$). All three patients had had a cuff pressure of ≥260 mm Hg.

On day four, eight patients (out of the 111 available) had developed blisters or other pressure-related injuries underneath the tourniquet cuff and sixty-five patients reported that they had pain in the quadriceps muscle underneath the tourniquet cuff (no differences between the groups, $p = 0.400$).

At the time of discharge, forty-seven patients (30% of the 158 available) had developed a surgical wound complication such as blisters, oozing from the wound, or signs of infection. As shown in Table II, forty of these forty-seven patients had had a cuff pressure of >225 mm Hg during surgery. None of the patients with a cuff pressure of ≤225 mm Hg had any signs of wound secretion or infection, but seven patients had blisters

TABLE I Cuff Pressures and Ratings by the Surgeon Regarding the Quality of the Bloodless Field and Technical Difficulties

	Control Group (N = 83)	LOP Group (N = 78)	P Value
Cuff pressure *(no. [%] of patients)*			<0.001
≤225 mm Hg	7 (8)	26 (33)	
226-259 mm Hg	45 (54)	22 (28)	
≥260 mm Hg	31 (37)	30 (38)	
Mean cuff pressure (±SD) *(mm Hg)*	252 ± 17*	246 ± 45†	0.362
Mean preanesthetic systolic blood pressure (±SD) *(mm Hg)*	154 ± 18	155 ± 21	0.426
Mean preoperative systolic blood pressure/limb occlusion pressure (±SD) *(mm Hg)*	119 ± 19‡	169 ± 34§	
Mean VAS score (±SD) for quality of bloodless field	9.4 ± 1.3	8.7 ± 2.4	0.364
Mean VAS score (±SD) for technical difficulties	1.4 ± 1.3	2.04 ± 2.3	0.307

*Chosen by the surgeon. †Recommended by the apparatus. ‡Preoperative systolic blood pressure measured on the arm, immediately before the tourniquet was applied and the skin incision was made, for determination of the cuff pressure by the surgeon. §Limb occlusion pressure measured on the thigh by the limb-occlusion-pressure apparatus.

TABLE II Results of Wound Check on Postoperative Day Four, According to Group and Cuff Pressure, for the 158 Patients Available*

	Control Group			LOP Group		
	≤225 mm Hg (N = 7)	226-259 mm Hg (N = 45)	≥260 mm Hg (N = 31)	≤225 mm Hg (N = 24)	226-259 mm Hg (N = 22)	≥260 mm Hg (N = 29)
No wound complication	5	31	24	19	15	17
Blisters	2	8	4	5	5	10
Oozing from the wound	0	5	3	0	1	1
Signs of infection	0	1	0	0	1	1

*The values are given as the number of patients. P = 0.149 for the difference between the LOP and the control groups.

TABLE III Results of Wound Check at Two-Month Follow-up Visit for the 156 Patients Available*

	Control Group			LOP Group		
	≤225 mm Hg (N = 7)	226-259 mm Hg (N = 44)	≥260 mm Hg (N = 30)	≤225 mm Hg (N = 25)	226-259 mm Hg (N = 21)	≥260 mm Hg (N = 29)
No wound complications	7	39	27	23	19	25
Blisters	0	0	0	0	0	0
Delayed wound-healing	0	3	1	2	1	2
Wound infection	0	2	2	0	1	2

*The values are given as the number of patients. P = 0.869 for the difference between the LOP and the control groups.

around the knee. There were no significant differences between the LOP and the control groups (p = 0.149).

At the time of follow-up two months after surgery, seven patients (4%) had a postoperative wound infection and nine patients (6%) were recorded as having delayed wound-healing. Four of these patients had developed a deep wound infection after they were discharged from the ward and had been rehospitalized and reoperated on. Of the sixteen patients with a surgical wound complication at the two-month follow-up visit, fourteen had had a cuff pressure of >225 mm Hg. Two patients who had had a cuff pressure of ≤225 mm Hg had delayed wound-healing (Table III). There were no differences between the LOP group and the control group (p = 0.869).

Six of the seven patients who had a postoperative wound infection and all four patients who had a deep wound infection were men. We found no difference in cuff pressures between men and women, but men had significantly longer bloodless-field times (mean, eighty-nine minutes compared with seventy-three minutes for women; p = 0.027).

Two patients had a deep venous thrombosis, and one patient had a nerve injury. There were no differences between the LOP group and the control group (p = 0.752), but the patient with a nerve injury had had a cuff pressure >260 mm Hg.

At the two-month follow-up visit, knee motion, assessed by a blinded orthopaedic surgeon, did not differ between the groups. No difference in any of the three domains of the self-administered WOMAC questionnaire was detected between the LOP group and the control group (data not shown).

Discussion

This study shows that the limb-occlusion-pressure measuring technique reduces the tourniquet cuff pressures in patients undergoing a total knee arthroplasty, but we could not demonstrate any differences in postoperative pain between our LOP and control groups.

The generally lower cuff pressure in the LOP group provided a good-quality bloodless field but did not have any impact on the risk of developing a postoperative wound complication or on the range of motion, although the patients in the LOP group reported less stiffness of the knee on postoperative day four.

An important secondary finding was that, regardless of the randomization group, patients with a cuff pressure of ≤225 mm Hg had no postoperative infections and a lower rate of wound complications at discharge and at the two-month follow-up evaluation.

In contrast to the reports by Reilly et al.[9] and Younger et al.[6,10], we could not demonstrate any significant differences in the mean cuff pressures between the LOP group and the control group. The chosen cuff pressure depends on such factors as the experience of the surgeon as well as on local traditions. The surgeons in our study generally used a rather low cuff pressure, with a mean of 252 mm Hg in the control group, compared with surgeons in other published studies, in which cuff pressures of 300 to 350 mm Hg have been reported[2,4,6,17,18]. However, the limb-occlusion-pressure method led to more individual cuff pressures among our patients, since the pressures ranged from 150 to 300 mm Hg (SD, ±45) in the LOP group compared with 200 to 300 mm Hg (SD, ±17) in the control group. The mean measured limb occlusion pressure in our study was 169 mm Hg, which is higher than the mean of 142 mm Hg in the study by Younger et al.[6]. Our tourniquet apparatus also had a higher preadjustable margin from the manufacturer than earlier described[6,9,10], which resulted in higher recommended tourniquet pressures and therefore also higher mean values—246 mm Hg in our study compared with 202 mm Hg in the study by Younger et al. and 198 mm Hg in the study by Reilly et al. Nevertheless, the limb-occlusion-pressure measuring technique led to lower margins: 77 mm Hg in the LOP group compared with 133 mm Hg in the control group.

All of our patients received local infiltration analgesia at the end of surgery, and most of them received it the next day as well. This was a rather new routine at our department and was effective for treatment of postoperative pain. The fact that postoperative pain treatment was good in all patients could be one of the reasons why we could not demonstrate any differences in postoperative pain between groups. Another reason could be that the WOMAC questionnaire might not be sensitive enough to capture relatively small differences in postoperative pain ratings.

We could not demonstrate any differences in knee motion between the groups. All patients achieved good knee flexion as early as on day three: the mean was 78° in the control group and 77° in the LOP group, compared with 47° on day three after total knee arthroplasty done with a tourniquet in the study by Li et al.[3]. Earlier studies comparing knee or ankle surgery with and without a tourniquet have shown significantly better knee flexion after surgery without a tourniquet[3,17,19]. The authors suggested that the swelling of the limb after use of a tourniquet might be an explanation. Tourniquet release is known to be associated with an immediate 10% increase in limb girth[20], which was reported to increase up to 50% over the first postoperative day[17].

There was a rather large number of wound complications in our study. One reason could be that we did not exclude patients with diabetes, as has been done in other studies[1,3,17,19]. In our study, even patients classified as ASA 3, and some later classified as ASA 4, were included. However, no patient in our study who had a cuff pressure of ≤225 mm Hg developed a postoperative wound infection. This finding is in accordance with the report by Clarke et al.[2], who studied the pattern of postoperative wound hypoxia seven days after knee surgery and found that a tourniquet cuff pressure of about 225 mm Hg yielded a significantly better return of the oxygen levels compared with cuff pressures of 350 mm Hg.

Butt et al.[21] demonstrated a significant association between increased tourniquet time and wound oozing after total knee arthroplasty. They had a mean tourniquet time of eighty-three minutes with a range of thirty-eight to 125 minutes. In our study, the mean tourniquet time was eighty-seven minutes. Six of the seven patients who had a postoperative wound infection in our study were men. We found no other differences between men and women other than a significantly longer bloodless-field time for men. In this study, we focused on cuff pressures and complications; however, the duration of the bloodless field is probably another important factor that requires further investigation.

The strength of this study is that it was a randomized controlled trial of a "nonselected" study population, with few exclusion criteria. A limitation might be that we used the WOMAC questionnaire as the primary outcome measure

since it may not be reliable enough to capture the small differences regarding postoperative pain. Another limitation of our study is that very few of our patients had a BMI of >35 kg/m^2 and therefore our results may not be valid for that patient group.

In conclusion, the generally lower tourniquet cuff pressure in the LOP group did not decrease the postoperative pain or other outcomes in our patients. However, patients who had undergone total knee arthroplasty in a bloodless field with a cuff pressure of ≤225 mm Hg had a lower rate of wound complications such as delayed healing and infections.

The limb-occlusion-pressure measuring technique can help the surgeon to choose more individual, often lower, cuff pressures. However, if the surgeon carefully chooses an optimal and not too high cuff pressure and considers the type and width of the cuff, the circumference of the limb, and the patient's individual vessel characteristics, both methods appear to yield a good outcome in terms of postoperative complications.

Appendix

eA Tables showing demographic baseline data and the duration of the bloodless field as well as the results of the WOMAC, range of motion, and straight-leg lifting are available with the online version of this article as a data supplement at jbjs.org. ■

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Tourniquet associated chemical burn

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Abstract

Chemical burn under pneumatic tourniquet is an iatrogenic preventable injury and is rarely reported in the literature. The two important mechanisms are maceration (friction) and wetness underneath the tourniquent. In this report, our experience with two illustrative patients who presented with iatrogenic tourniquet associated burn is described.

Keywords: Chemical burn, irritation, maceration, tourniquet

INTRODUCTION

Pneumatic tourniquets have been commonly utilized during orthopedic extremity surgeries to attain a bloodless field facilitating operative procedures. Although tourniquet associated complications including postoperative swelling, delay of recovery of muscle power, compression neuropraxia, wound hematoma with the potential for infection, vascular injury, tissue necrosis, compartment syndrome, and systemic complications have been reported in the literature, the iatrogenic chemical burn during pneumatic tourniquet use has been rarely reported.[1–4] Here, we report two cases of chemical burn to sensitize the orthopaedic surgeons about its possible occurrence.

CASE REPORTS

Case 1

A 24 year old male underwent lateral meniscus allograft transplantation on his left knee. The patient did not have thin skin and any underlying skin disease and allergies. The patient's operation was performed under tourniquet control. The tourniquet cuff used was a standard leg tourniquet (18 cm) and was applied with four layers of adequate wool padding. The skin preparation used was a 10% povidone-iodine (betadine) solution. The set pressure was 250 mmHg which was about 100 mmHg higher than the patient's systolic pressure. The tourniquet compression time was 2 h (total operation time=3 h). When the tourniquet was removed after operation, the burn was seen on the medial aspect of thigh [Figure 1a]. While inspecting the padding where the burn was present, the drape preparation seemed to have run down the patient's thigh during painting and had been left in wet condition underneath the tourniquet. The wound was of intermediate to deep second degree burn with blisters of size about 5 × 6 cm. The patient was treated conservatively with a furazone gauze occlusive dressing

and was discharged from orthopedic department without skin grafting. However, he underwent multiple treatments with the dermatologist for complete healing which took almost 12 months [Figure 1b]. Even to this time (2 years postoperation), the patient continuously complains of hypersensitivity on the scar area, which aggravates during normal gait.

Case 2

A 65 year old female patient, underwent elective unicompartmental knee arthroplasty for medial compartment osteoarthritis of the knee. The patient was free of chronic underlying diseases and had moderate skin thickness. The tourniquet cuff used was a standard leg tourniquet and was applied with four layers of adequate wool padding. The skin preparation used was a 10% povidone-iodine (betadine) solution. The set pressure was 250 mmHg which was about 100 mmHg higher than the patient's systolic pressure. The tourniquet compression time was 1.5 h (total operation time=2 h). When the tourniquet was removed, the burn was seen on the medial aspect of thigh. The burn was also of intermediate to deep second degree with dermis involvement. Betadine soaked padding was also observed at the site of burn. One week postoperatively, blisters and crusts were found roughly at the proximal margin of tourniquet [Figure 2a]. Local furazone gauze was applied for dressing and complete healing needed almost 1 year after operation. During this followup period, analgesics were continuously prescribed for the irritating, hypersensitive scar. Scar revision excising this hypersensitive, hypertrophic scar was needed after 1 year 4 months postoperatively [Figure 2b].

DISCUSSION

The chemical burn resulting from tourniquet application cause more in-depth injury to the skin than the abrasion wound because there is greater time exposure and the anesthesia prevents the patient from reacting to the noxious burn stimulus.[5] Consequently, multiple debridement, skin graft, and even flap surgeries may be needed in such injuries with prolonged treatment period. Both of our cases had intermediate to deep second degree burn extending into deep dermis. Not only a long duration of healing time (up to 1 year postoperatively) was needed, but also hypersensitive and painful scar remained thereafter. The iatrogenic chemical burn induced by tourniquet application can have an impact on surgeon patient relationship.

Tourniquet associated chemical burns have been reported previously also. Dickinson and Bailey[1] reported four burns beneath the cuffs of pneumatic tourniquets. In all cases, the burns were seen when the tourniquet was removed. In two cases, the area of iodine staining corresponded exactly with the area of the burn, while in the other two cases the burns were smaller. All burns were of partial thickness and healed within 4 weeks, leaving minimal scarring. Nahlieli *et al*.[2] reported three adult cases. One of these patients had a partial thickness burn under the tourniquet cuff, after a 2-h surgery on his right palm. Similar experiences were reported by other authors.[3,6] The scars described in these reports seem to have healed without much complications. Unlike the previous reported cases, our cases required prolonged healing time and patients continuously complained discomfort in the scar area. The basic mechanism of tourniquet induced chemical burn involves irritation by antiseptics[2,4,7,8] coupled with maceration,[9–11] compression pressure,[12–14] duration of compression,[13,14] and wetness underneath the tourniquet.[15,16] Polyvinylpyrrolidone-iodine (PI) is a widely used antiseptic which was introduced by Shelanski and Shelanski in 1965.[17] It is a water-soluble compound that results from the combination of molecular iodine and polyvinylpyrrolidone. The preparations of commercially available PI are povidone-iodine (betadine) solution, scrub, ointment, tincture, and foam; of these, the solution is the most commonly used. The 10% PI solution generally contains 90% water, 8.5% polyvinylpyrrolidone, and 1% available iodine and iodide (pH 4.5–5.5). Although uncommon, chemical burns have been reported with this solution.[2,5,18–21] Alcohol (70%), which is used for draping, may also cause hypersensitivity.[2,4,7] By using alcohol, the epidermal

lipid barrier acting to the skin may be decreased by de-esterification.

To prevent tourniquet associated chemical burn, two important points should be noted. First, friction between the skin and the tourniquet should be avoided because macerated skin becomes more permeable to PI which may become prone for damage. Movement of tourniquet during draping and compression should also be prevented. An elastic stockinette is known to be effective in preventing the development of maceration induced blisters.[22] The shape mismatch between the tourniquet and the thigh should be considered when applying tourniquet to minimize friction. Very muscular or obese patients tend to have conical shaped thigh.[14] Even distribution moving the skin and the soft tissues distally underneath the tourniquet may overcome this mismatch. Second, emphasis should be made on some form of barrier occluding the tourniquet, preventing wool soaking from antiseptics.[15,16] In addition to a number of commercial covers, a variety of simple, non commercial alternatives have been proposed. Sarkhel and Stride[15] suggested using the disposable reservoir bag from a single use anesthetic circuit, while the use of surgical glove was proposed by Tomlinson and Harries.[16] Our department has been using adhesive plaster (Sinsin Pharm Co. Ltd., Korea) and antimicrobial incise drape (Ioban™ 2®, 3M Health care, USA) for mechanical barrier [Figure 3a and b]. On taking these precautions, further occurrence of tourniquet associated chemical burns was prevented.

The chemical burn due to pneumatic tourniquet is a relatively under-reported problem which may be more frequent than believed. The PI related chemical burn in tourniquet use may be prevented by understanding the mechanism of occurrence of this complication to prevent this devastating iatrogenic injury.

Footnotes

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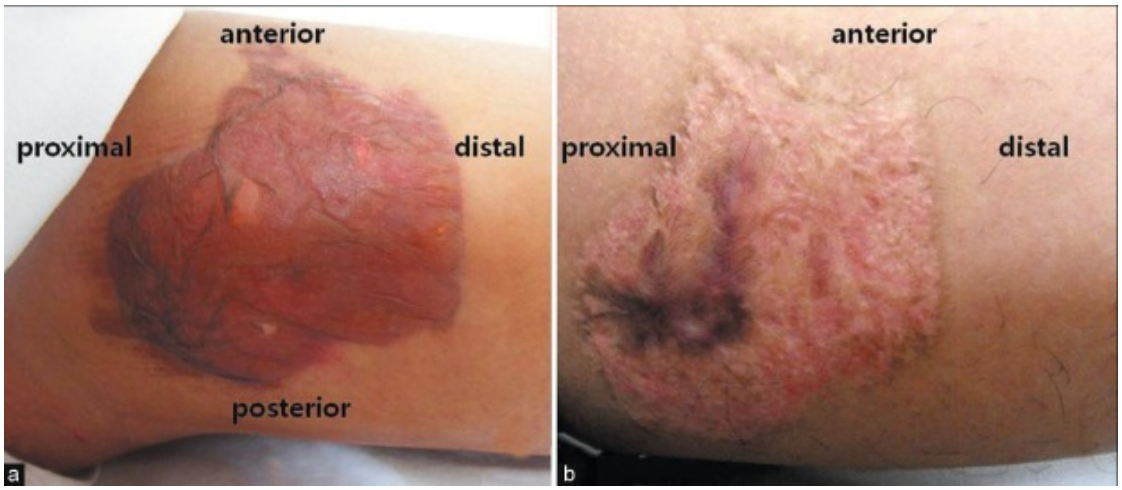
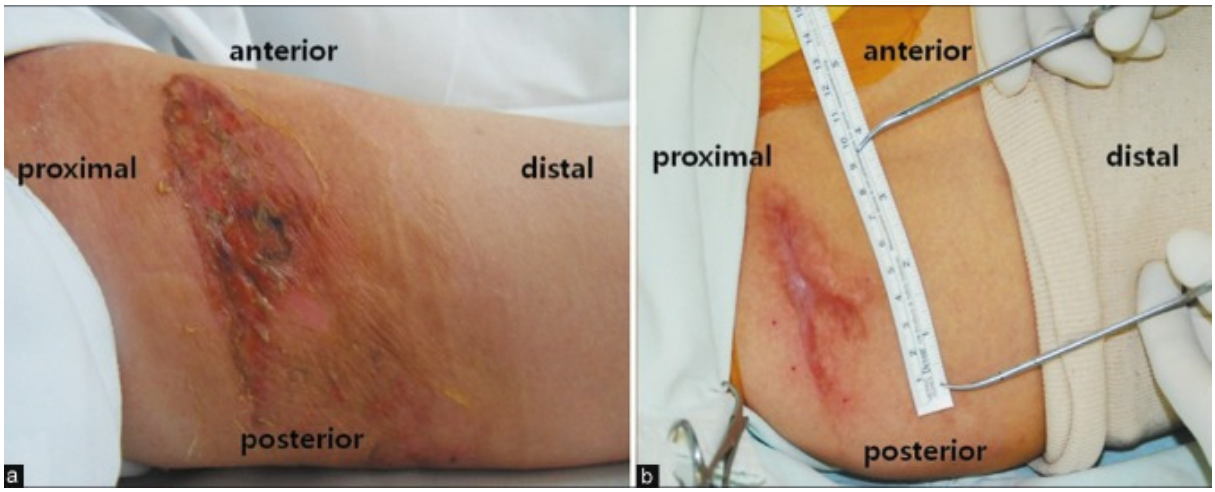
Figures and Tables

Figure 1



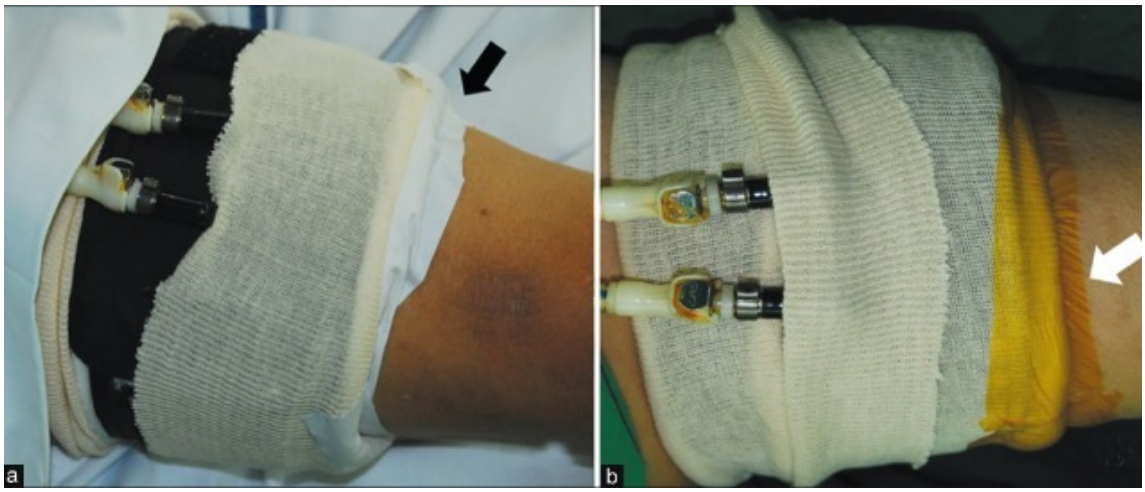
Case 1. Tourniquet-associated chemical burn developed on medial aspect of thigh: (a) immediate postoperative; (b) 1year and 9 months postoperative

Figure 2



Case 2. Tourniquet-associated chemical burn developed on medial aspect of thigh: (a) 1 week postoperative; (b) 1 year and 4 months postoperative (just prior to scar excision)

Figure 3



Suggested method for tourniquet application with elastic stockinette and wool padding. Note the adhesive plaster (black arrow) (a) and antimicrobial incise drape (white arrow) (b) used for mechanical barrier

Tourniquet use and its complications in Norway

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Over a two-year period, 265 Norwegian orthopaedic surgeons working at 71 institutions performed 63 484 operations under a tourniquet. Their replies to a questionnaire revealed that they mostly followed modern guidelines in their use of the tourniquet. Most felt that the tourniquet could be left on for two hours, and that it could be re-applied after 15 minutes. A total of 26 complications (one in 2442 operations) that might have been due to the tourniquet were reported, of which 15 were neurological. Three were in the upper limb (one in 6155 operations) and 12 in the lower limb (one in 3752 operations). Two were permanent (one in 31742 operations), but the remainder resolved within six months. One permanent and one transient complication occurred after tourniquet times of three hours. The incidence of tourniquet complications is still at least as high as that estimated in the 1970s.

The pneumatic tourniquet was introduced by Harvey Cushing in 1904 and is widely used in orthopaedic surgery to create a bloodless field in limb surgery. It allows meticulous surgical dissection and causes less morbidity than when an Esmarch bandage is used as a tourniquet.[1] Nonetheless, complications still occur, of which nerve damage causing paralysis is the most feared.

Middleton and Varian[2] reported that the incidence of tourniquet complications in Australia in the 1970s was approximately one in 5000 applications on the upper limb and one in 13 000 on the lower limb. Since then the design of the pneumatic tourniquet has been improved. It has been made wider, and the most recent models are conical to give a better fit. These changes reduce the pressure needed to stop arterial flow, thereby minimising the pressure on the compromised peripheral nerves, given that pressure and the duration of nerve ischaemia are the two main factors causing nerve injury.[3-5]

The purpose of this study was to survey how the tourniquet is used in clinical practice in Norway and to estimate the incidence and nature of complications of its use.

Method

A questionnaire was sent to all members of the Norwegian Orthopaedic Society enquiring about their use of the tourniquet. Specific questions were asked about the type of tourniquet, pressure, location, and time limits. Respondents were asked whether they released the tourniquet temporarily during long operations, how long they felt the interval should be, and for how long they could keep it inflated afterwards. They were also asked to report any complications at their hospital due to tourniquet use during the previous two years (1998 and 1999). If a complication had been reported, the hospital was contacted again two years later and details were obtained about the operation and its outcome.

In order to establish the incidence of complications, we obtained from the Norwegian patient register the total number of operations that had probably been performed in a bloodless field during the same two-year period. We only included hospitals from which a surgeon had replied to the questionnaire.

Results

Tourniquet use. A total of 265 of 398 (67%) orthopaedic surgeons from 71 hospitals replied to the questionnaire. The estimated number of operations carried out using a tourniquet at these hospitals during this two-year period was 63 484.

Many surgeons reported that they varied in their individual practice, using either a fixed tourniquet pressure or a pressure related to the patient's systolic blood pressure. The most common method was to apply a pressure of 100 mmHg above the systolic blood pressure

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Table I. The number of surgeons using tourniquet pressure in relation to the patient's systolic blood pressure, and the pressures above systolic blood pressure employed

	Upper arm	Forearm	Thigh	Calf	Ankle
Number of surgeons	113	46	106	54	59
Median pressure (mmHg)	100	100	110	100	100
10th percentile	50	50	100	100	75
90th percentile	120	120	200	150	150

Table II. The number of surgeons using fixed tourniquet pressure and the pressures employed

	Upper arm	Forearm	Thigh	Calf	Ankle
Number of surgeons	78	20	84	28	28
Median pressure (mmHg)	250	210	300	250	250
10th percentile	200	200	250	200	200
90th percentile	300	250	350	300	300

Table III. Surgeons' responses regarding maximum permitted tourniquet time in minutes, interval length and maximum tourniquet time after interval

	Maximum tourniquet time	Interval length	Operation time after interval
Median (minutes)	120	15	60
10th percentile	90	10	30
90th percentile	120	30	120

Table IV. The most usual placement of tourniquets

	Upper arm	Forearm	Wrist	Thigh	Calf	Ankle
Number of surgeons	172	35	26	176	58	99

(Table I). If a fixed pressure was used, it was usually 250 mmHg on the upper arm and 300 mmHg on the thigh (Table II).

There were 108 surgeons who stated that one should use a lower tourniquet pressure for children, and 40 felt that the pressure could be reduced with a wider cuff. Five surgeons reported that they took account of the circumference of the extremity when deciding on tourniquet pressure, and one used a lower tourniquet pressure with general anaesthesia than with a local anaesthetic.

Most respondents felt that they could operate safely for two hours with the tourniquet inflated (Table III). When asked if they released the tourniquet for a while if the operation lasted longer than two hours, 80% answered yes, 13% no, and 7% that their operations never exceeded two hours. The median deflation time was 15 minutes and median permitted operation time after re-inflation was 60 minutes.

A pneumatic tourniquet was used by 72%, 14% used the Esmarch bandage as a tourniquet, and the remaining 14% did not reply to this question. The tourniquet was most frequently placed on the upper arm or the thigh, whether fixed or systolic-related tourniquet pressures were used (Table IV).

Complications. Over the two-year period 26 complications were reported to have occurred. Six were compartment syndrome or deep-vein thrombosis, which were thought more likely to be a complication of the injury or the operation than due to the use of a tourniquet. It was not possible to obtain further information on two complications, as neither the surgeon who had reported them nor anyone else on the medical staff could remember them. They were therefore excluded from the study. The remaining 18 complications consisted of three cases of blistering and skin necrosis, and 15 nerve complications, only two of which were permanent. Both were a paresis, one of the extensors of the wrist and hand, leading to a wrist drop, and the other of the peroneal nerve causing a foot drop. The remaining 13 nerve complications resolved spontaneously within six months of surgery. These included one patient with a complete sensory and motor palsy in the arm, six patients with a paresis and six with sensory disturbance. Most of the complications occurred after the tourniquet had been inflated for less than two hours at a pressure of 300 mmHg or less. The permanent wrist drop, however, occurred after a tourniquet time of 130 minutes and a pressure of 300 mmHg in an otherwise healthy 55-year-old man. The patient with a temporary but complete sensory and motor palsy in the arm had a tourniquet time of 180 minutes at a pressure of 250 mmHg.

Only three of the nerve complications (one in 6155 operations) were in the arm, the other 12 (one in 3752 operations) were in the lower limb. The overall incidence of neurological complications was 0.024% (one in 4232 operations; 15 in 63 484) and of permanent injury 0.032% (one in 31 742; 2 in 63 484). If the skin complications are included, the overall incidence of tourniquet complications was 0.028% (one in 3526), and if the two possible complications where data were lacking are also included, the incidence was 0.032% (one in 3174).

Discussion

Complications of tourniquet use are fortunately very rare, although this inevitably makes an exact estimate of their incidence difficult.

For this study, in order to estimate the total number of operations carried out, we had to make the assumption that all operations that are usually performed in a bloodless field required the use of a tourniquet.

Of all Norwegian orthopaedic surgeons, two-thirds took part in the study. Our findings, therefore, probably reflect the use of the tourniquet in Norway fairly accurately. It appears that most surgeons follow modern recommendations regarding cuff pressures and ischaemia time. The most frequent cause of blistering of the skin is seepage of antiseptic solution into the padding beneath the cuff during skin preparation, resulting in a chemical burn. This is easily prevented by wrapping a plastic drape around the distal edge of the cuff. A median time of 15 minutes' reperfusion in our study is somewhat short. The recommended time

according to Wilgis[6] is 15 to 20 minutes after two hours' inflation.

The maximum permitted tourniquet time has been the subject of much debate. Klenerman[7] concluded that three hours' ischaemia is well within the timescale likely to produce irreversible muscle damage. Korthals, Maki and Gieron[8] showed that nerves in ischaemic limbs in cats undergo mild necrotic changes after five hours, and moderate to severe changes after eight hours. Paletta, Willman and Ship[9] showed that the tourniquet time could be prolonged considerably by cooling the limb and by giving heparin pre-operatively or just before releasing the tourniquet.

Klenerman[7] has pointed out that the usual cause of nerve damage in clinical practice is an abnormally high cuff pressure. Neimkin and Smith[10] developed a method using double tourniquet cuffs which they alternated at one-hour intervals, thereby preventing continued compression of a localised segment of the limb. This, however, does not reduce the total pressure on the arm, which can only be achieved by using a wider tourniquet.[11]

Our findings of a neurological complication for approximately every 6000 tourniquets on the upper limb and one for approximately every 3700 on the lower limb are similar to those of Middleton and Varian[2] for the upper limb, but much higher than the one in 13 000 they estimated for the lower limb. The total incidence in our study was one in 4200, compared with one in 8000 in Middleton and Varian's report.[2] In spite of increased awareness of the potential for nerve damage when using the tourniquet, and modifications to the tourniquet which allow lower and more controlled pressures, there has been no reduction in the total incidence of neurological tourniquet complications. On the contrary, in our study the incidence seems to be higher. In Middleton and Varian's study,[2] about half the surgeons used an Esmarch bandage as a tourniquet on the lower limb. This can produce extremely high pressures, and a disproportionate number of their complications occurred after such use.[2] We were, therefore, expecting a lower complication rate in our study, but in the event found it to be higher. A possible explanation for this is that in our estimate of the number of operations performed we may be closer to the true number than were Middleton and Varian,[2] who simply estimated that each surgeon had performed 200 operations.

A few Norwegian surgeons still use the Esmarch bandage as a tourniquet. However, none of the complications occured among these patients. Two of the major complications occurred with tourniquet times of 130 and 180 minutes and with acceptable pressures of 250 and 300 mmHg, suggesting that the ischaemia time is an important factor.

Bushell et al[12,13] found that, in rats, a preliminary period of ischaemia of five minutes, followed by reperfusion for five minutes before the main period of ischaemia, seemed to have a protective effect on the skeletal musculature. This may have an application in clinical practice.

Much effort has gone into reducing the required tourniquet pressure by changing the cuff size and design.[4,10,11,14,15] Until further design improvements are made, possibly in the form of double tourniquets with alternating inflation, or cuffs incorporating a cooling system, it would seem appropriate to observe the common recommendation of a maximum of two hours' ischaemia time in order to reduce the occurrence of permanent nerve damage.

Supplementary Material

A further opinion by Professor Leslie Klenerman is available with the electronic version of this paper on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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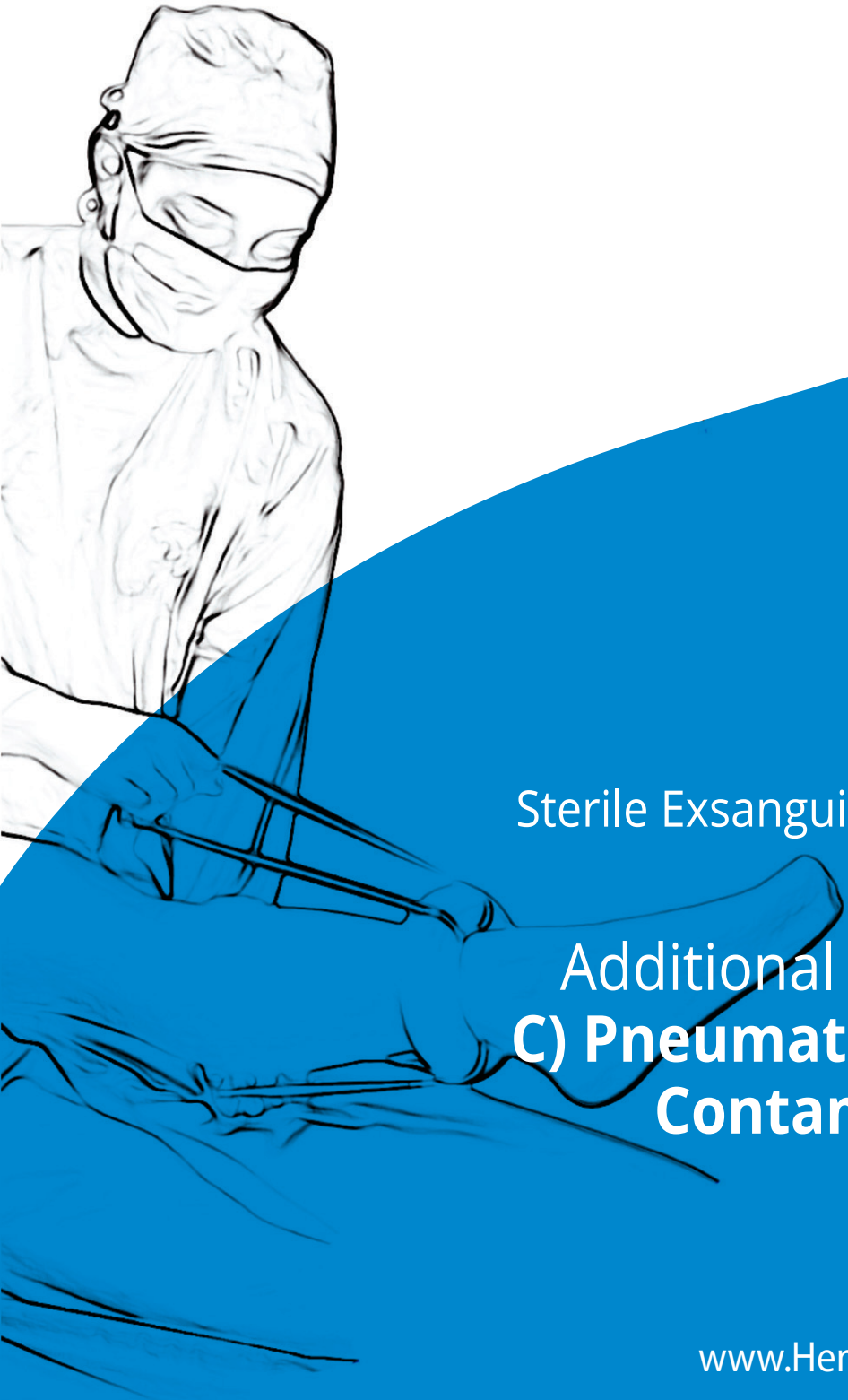

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Microbial Colonization of Tourniquets Used in Orthopedic Surgery

By Eric F. Walsh, MD; Debby Ben-David, MD; Mark Ritter, MD; Anthony P. Mechrefe, MD; Leonard A. Mermel, DO, ScM; Christopher W. DiGiovanni, MD
ORTHOPEDICS 2006; 29:709

August 2006

Abstract

This study analyzed tourniquets used for orthopedic surgery in our hospital to determine the frequency and type of microbial contamination. Group A tourniquets were from our main operating room, Group B tourniquets were from our ambulatory surgicenter, Group C tourniquets were unused, prepackaged, sterile tourniquets from our main operating room, and Group D tourniquets were sterilely packed tourniquets from our ambulatory surgicenter. Tourniquets from Groups A, B, C, and D had 100%, 40%, 0%, and 0% microbial growth, respectively. For Group A tourniquets, coagulase-negative staphylococci, *Bacillus*, and *Staphylococcus aureus* were present in 100%, 60%, and 20% of tourniquets, respectively. Twenty percent were contaminated either with *Streptococcus sanguis*, *Aerococcus viridans*, or *Cornyebacterium* species. Coagulase-negative staphylococci and *Bacillus* were present in 40% and 30% of Group B tourniquets, respectively. Tourniquet contamination may be a risk factor for the development of surgical site infection in orthopedic surgery.

Nonsterile tourniquets are routinely used in orthopedic surgery. Because there are no published recommendations specifically regarding sterility of tourniquets used in surgical cases, we aimed to define the microbial status of nonsterile tourniquets used in our operating rooms. This is particularly important given the fact that, currently, the same tourniquets routinely are used on patients with both clean and contaminated wounds, without standardized policies for tourniquet disinfection between cases.

Portable medical equipment such as stethoscopes, otoscopes, and blood pressure cuffs become contaminated during routine use, and may result in transmission of antimicrobial-resistant pathogens.[1-3] Reusable tourniquets also have been demonstrated to be contaminated with microbial pathogens.[3-6] To our knowledge, few hospitals require sterile tourniquet use for orthopedic surgery. We hypothesized that nonsterile tourniquets ready for use in orthopedic surgery may be contaminated with microbial skin flora since they are not routinely disinfected between cases.

Materials and Methods

We analyzed 30 tourniquets at our institution in July 2003. The tourniquets were of variable sizes, ranging from 42 to 62 inches in length. The tourniquets were manufactured by Zimmer (Warsaw, Ind), DePuy (Warsaw, Ind), and Smith and Nephew (Memphis, Tenn) (Figure 1). Groups A and B were nonsterile, repetitively used tourniquets from the main operating room and the ambulatory surgicenter operating room, respectively. Groups C and D tourniquets were re-packaged, sterilized tourniquets from the ambulatory surgicenter operating room and sterile, never used, and pre-packaged from the main operating room, respectively.

Figure 1: Modern tourniquet cuffs: reusable single bladder standard rectangular cuff (top left), reusable contour lower leg cuff (center), sterile disposable single bladder cuff (lower right), and reusable pediatric cuff (bottom center) (A). Pictures of various types and sizes of tourniquets used at our institution and the exact same kind of tourniquets tested for bacteria in our study (B).

Ten tourniquets from Group A were randomly selected for testing. They are used in major trauma and reconstructive procedures at our hospital, which is a Level 1 trauma center. These tourniquets are used repetitively and often sequentially in elective cases involving total joint replacement, arthroscopy, contaminated open fracture care, and irrigation and debridement of infected wounds.

All Group A and B tourniquets are located in a basket in each operating room. Surgeons choose an appropriate tourniquet length and place it on the operative limb of the patient (Figure 2). This is routinely done without gloves, prior to hand hygiene, and after anesthesia induction. The limb of a patient then is prepped to the level of the tourniquet, and draped with sterile sheets beyond the level of the tourniquet so it is not in the sterile

field. Occasionally, the surgeon may opt to not use or apply a nonsterile tourniquet at the beginning of the case. If the surgeon later required the use of a tourniquet for hemostasis in the operative field, a Group C or D tourniquet would be applied.

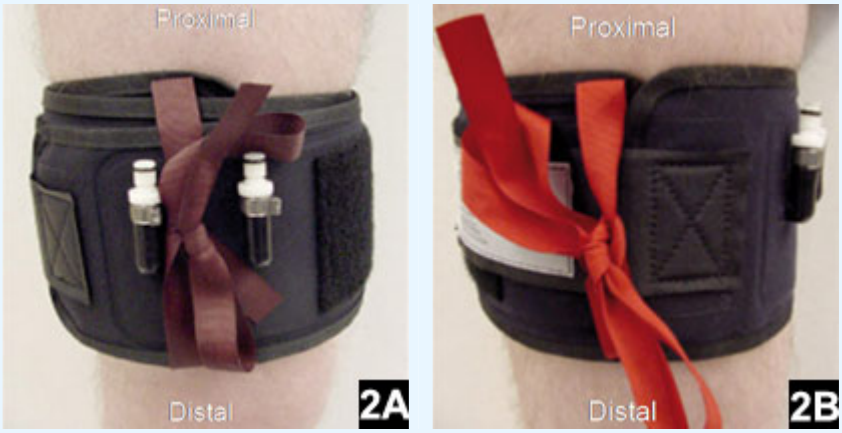

Figure 2: Proper placement of the tourniquets on the upper leg (A) and upper arm (B). Note the orientation of the tourniquets with the pneumatic hose connector pointing proximally. These are the areas most often handled by the surgeon and the areas tested in our study.

After each case, the limb is dressed, sterile sheets are removed, and the tourniquets subsequently removed and placed back in their respective bins for later use. Group A tourniquets from the main operating room routinely are not cleansed before reuse. The decision to send a tourniquet to central processing for cleaning is at the discretion of the scrub technician or circulating registered nurse in the operating room, as there is no written protocol for reuse, reprocessing, or decontamination of our nonsterile tourniquets. Once sent for disinfection, these tourniquets are washed by hand with Manu-Klenz instrument detergent (Sterris Corp, Mentor, Ohio).

Ten tourniquets in Group B from the ambulatory surgicenter operating room were randomly selected for testing. These are not cleaned between cases. They are discarded or changed only when they wear out or malfunction, also at the discretion of the operating room nursing staff. Group B tourniquets are used mainly for elective, clean surgery and are only rarely used for cases involving septic joints or open wounds. Five Group C tourniquets from the ambulatory surgicenter operating room were randomly selected for testing after being sterilized in central processing and repackaged for reuse. Five Group D tourniquets were similarly selected from the main operating room to be tested and represented unused, prepackaged tourniquets made available by the manufacturer.

Using aseptic technique, approximately 5 cm of each tourniquet from the four groups was cultured from four sites. Both sides of each tourniquet were pressed on blood agar plates and labeled as “internal proximal” and “internal distal.” These areas come in direct contact with patient skin during routine use. The external proximal and distal sides of each tourniquet also were cultured (Figures 3 and 4). A 5-cm area from each tourniquet

was pressed onto the trypticase-soy agar plates with 5% sheep blood. Plates were incubated at 37° C for 48 hours. Colonies were identified and antimicrobial susceptibilities determined using NCCLS (National College of Clinical Lab Sciences) criteria. All values from sampling each tourniquet were compared using Chi-square tests for categorical variables. Statistical analysis was performed using student *t* tests, and *P* values <.05 were considered significant. Odds ratios and 95% confidence intervals were determined using EpiInfo (Center for Disease Control and Prevention, Atlanta, Ga).

Figure 3: The area of the outer part of the tourniquet tested in our study. The yellow ring marks the proximal edge and the blue ring marks the distal edge.

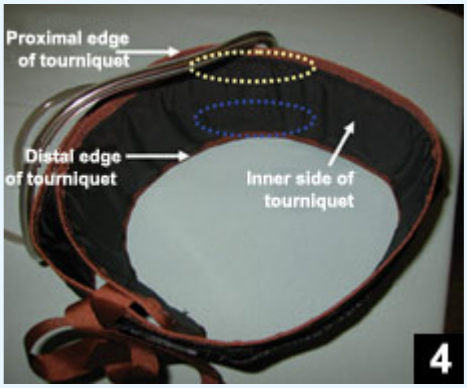

Figure 4: The area of the inner part of the tourniquet tested in our study. The yellow ring marks the proximal edge and the blue ring marks the distal edge.

Finally, we also queried five other New England teaching hospitals regarding their policies for routine disinfection of orthopedic operative tourniquets between cases, and recorded our results.

Results

One hundred percent (10/10) and 40% (4/10) of tourniquets in Groups A and B, respectively, demonstrated microbial growth. No growth was noted for any of the tourniquets cultured in Groups C and D (the sterilized tourniquets). For Group A, 10 of 10 tourniquets were contaminated with coagulase-negative staphylococci, including 35 (88%) of 40 agar plates. Six of 10 tourniquets (10 of 40 agar plates) were contaminated with *Bacillus* species. Two of 10 tourniquets (4 of 40 agar plates) were contaminated with *Staphylococcus aureus* and 2 of 10 (3 of 40 agar plates) each were contaminated with one of the following: *Streptococcus sanguis*, *Aerococcus viridans*, or *Corynebacterium* species. For Group B tourniquets, 4 of 10 had contamination with coagulase-negative staphylococci, including 10 of 40 agar plates, and 3 of 10 tourniquets (5 of 40 agar plates) were contaminated with *Bacillus* species. Overall, 70% of all nonsterile (Group A and B) tourniquets were contaminated with coagulase-negative staphylococci, 45% were contaminated with *Bacillus* species, and 10% were contaminated with *S aureus*. None of the coagulase-negative staphylococci or *S aureus* were methicillin-resistant. Antimicrobial susceptibility patterns are listed in the Table.

Contamination of Group A tourniquets was found to be significantly greater than those in Group B (*P*=.018).

Table

Percentage of Cultures Positive for Microbial Organisms Found on Tourniquets

	No. (%)				
	Staphylococcus Coagulase Negative	*Bacillus*	*Staphylococcus Aureus*	Other	No Growth
Group A					
Plates	35/40 (87.5)	10/40 (25)	4/40 (10)*	3/40 (7.5)	2/40 (5)
Tourniquets	10/10 (100)	6/10 (60)	2/10 (20)	2/10 (20)	0/10 (0)
Group B					
Plates	10/40 (25)	5/40 (12.5)	0/40 (0)	0/40 (0)	25/40 (62.5)
Tourniquets	4/10 (40)	3/10 (30)	0/10 (0)	0/10 (0)	4/10 (40)
Group C (Main)					
Plates	0/40 (0)	0/40 (0)	0/40 (0)	0/40 (0)	40/40 (100)
Group D (ASC)					
Plates	0/40 (0)	0/40 (0)	0/40 (0)	0/40 (0)	40/40 (100)
Groups A & B					
Plates	45/80 (56.3)	15/80 (18.8)	4/80 (5)*	3/80 (3.8)	27/80 (33.8)
Tourniquets	14/20 (70)	9/20 (45)	2/40 (5)	2/20 (10)	4/20 (20)
Groups C & D)					
Tourniquets	0/80 (0)	0/80 (0)	0/80 (0)	0/80 (0)	0/80 (0)

**Represent positive cultures for Staphylococcus aureus that on subsequent testing were determined to not to be methicillin-resistant.*

After we reviewed our results with the department of infection control and the operating room staff, policies were written and approved for routine disinfection of tourniquets between cases. Of the five New England teaching hospitals we queried regarding their policies for routine disinfection of orthopedic operative tourniquets between cases, four lacked standardized policies for routine tourniquet disinfection, and one required sterile tourniquet use for orthopedic surgical procedures. We also identified significant variability in how each institution used their tourniquets. For instance, the hospital that uses only sterile tourniquets opens and places them on the nonsterile extremity while another sends the nonsterile tourniquets after each case to be “cleaned” and packaged but not sterilized.

Discussion

As perioperative infection control becomes an increasingly scrutinized issue because of increasing antimicrobial resistance and the associated adverse outcomes, minimizing surgical field contamination is paramount.[7] This changing pattern of bacterial flora is supported by the observations of our own orthopedic department and has prompted us to find new ways of decreasing exposure and risk to surgical infection.

Operative tourniquets used by orthopedic surgeons often are nonsterile. Cultures of tourniquets at our institution demonstrated 80% of nonsterile, ready-for-use tourniquets were colonized with bacteria. The results of our data prompted our hospital to institute a

new policy for routine disinfection prior to reuse of any surgical tourniquet. Types of tourniquet care and cleaning protocols are presented in the Sidebar.[8]

Methicillin-susceptible coagulase-negative staphylococci were the predominant microbes contaminating tourniquets. While the majority of contaminants isolated are considered normal skin flora, many of these are prevalent offenders in orthopedic surgical site infections, particularly infections involving prosthetic joints and other hardware. Recent studies have reported an increasing incidence of orthopedic surgical site infections caused by coagulase-negative staphylococci that have led to delayed diagnosis and increased morbidity.[9]

If tourniquet application or use plays a role in potential contamination of the surgical field, certainly this would lend greater concern towards proper tourniquet disinfection when considering the implications on patient outcome and treatment. Results from our data have resulted in the institution of a new policy for tourniquet handling that we consider to be an important step in potential prevention of any tourniquet contamination of the surgical field. It remains unclear, however, if such contamination is a risk factor for orthopedic surgical site infections since these tourniquets are handled by the orthopedic surgeons prior to hand hygiene and they are not in the sterile field. Nevertheless, a solution to this unproven but potential problem, is of low cost and easy to implement. We recommend that hospitals institute a policy of either tourniquet sterilization between cases or the use of only prepackaged sterile tourniquets in the operating room. Beyond the concerns raised by our data, the need for such a recommendation also is supported by the fact that only one of the five other New England institutions we investigated had any protocol in place for disinfection of potentially contaminated tourniquets prior to reuse.

More About Tourniquet Cuffs

Disposable Versus Reusable Cuffs

- Sterile, disposable cuffs are available for situations that require placement of a sterile tourniquet near the operative site, or for use in contaminated surgical cases.
- The design and materials of disposable cuffs are suitable for a single sterilization cycle and must not be resterilized or reused.
- Disposable cuffs must be discarded at the end of the procedure.
- Reusable cuffs are not designed to be sterilized and must be used with sufficient sterile draping to isolate the cuff from the sterile field.

Care and Handling of Pneumatic Tourniquet Cuffs

- Various types of microorganisms are commonly found on contact closure–covered tourniquets and on Penrose drains. The tourniquet cuff, which is placed near the patient's axilla or groin, may be a

source of pathogenic microorganisms. After each use, it is important to decontaminate the tourniquet components, by following the manufacturer's recommended cleaning procedures. The following cleaning procedure is presented as an example only:

If the tourniquet cuff is adequately protected during surgery, hand washing of the cuff and bladder in lukewarm water is the only decontamination procedure indicated. If the bladder and plastic liner are removable, wash them as separate items. Do not immerse the bladder unless the connectors are sealed; if fluid enters the bladder, mildew may form, or subsequent deflation of a wet bladder during use may cause minute droplets of water to be forced back into the tourniquet regulating mechanism. Prevent rapid deterioration, shrinkage, and fading of the cuff fabric by avoiding hot water, harsh detergents, or bleaches.

- If blood or other body fluid comes in contact with these items, add an enzymatic detergent to the wash water to remove blood components from the fabric and rubber.
- If necessary, use a hand brush to remove encrusted material.
- If loose fibers are present in the contact closure straps, it may be possible to remove them using a nonmetallic brush or a comb in a side-to-side manner.
- Rinse the cuff and bladder thoroughly; detergent residue increases the chances for allergic reactions and may decrease the life of the cuff.
- Carefully follow manufacturer's instructions for drying. As a rule, air-dry the cuff and bladder flat, at room temperature, in their original shapes. Drip drying over a rack may stretch the cuff over time.
- Clean the exterior of the cuff hoses using a mild detergent solution, or a disinfectant that is not deleterious to rubber or polyethylene.
- After each use, decontaminate the exterior of the tourniquet instrument by wiping it with a cloth that has been dampened (not dripping) with a mild detergent.
- Avoid storing the cuff tightly rolled up to a small diameter as this may cause permanent kinking and ridging of the stiffened inner structure of the cuff. If possible, store the cuff rolled loosely to approximately its normal in-use diameter.

Conclusion

Standard, nonsterile tourniquets used in orthopedic surgery are contaminated with *Staphylococcus*, *Bacillus*, and occasionally other bacteria. Greater contamination of tourniquets from our main operating room may be due to tourniquet use in the

contaminated trauma and infected wound or joint cases that are more commonly performed. Tourniquet contamination may be a risk factor for the development of surgical site infection in orthopedic surgery.

What is already known on this topic
• Studies have analyzed the flora on other types of tourniquets routinely used in medicine (ie, phlebotomy); however, no studies exist regarding surgical tourniquets.
What this article adds
• Microbial colonization status can be found on tourniquets routinely used in repeated surgeries. Tourniquets should be routinely checked for possible dirt and contamination. • We continue to identify possible sources of microbial contamination in orthopedic surgical cases to improve the outcomes of our patients undergoing surgery.

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BMC Proceedings

POSTER PRESENTATION Open Access

Reusable tourniquets. An underestimated means for patient transfer of multi-resistant bacteria

T Gottlieb*, T Phan, EYL Cheong, G Sala, S Siarakas, A Pinto

From International Conference on Prevention & Infection Control (ICPIC 2011)
Geneva, Switzerland. 29 June – 2 July 2011

Introduction / objectives

We sought to investigate the use of reusable tourniquets as potential sources of MRO transmission.

Methods

100 reusable tourniquets were collected over 10 weeks in a 503-bed Sydney teaching hospital. Tourniquets were incubated overnight in BHI enrichment broth and subcultured.

Results

The colonisation rate was 78% (78/100). Ten grew non multi-resistant Gram- positives - MSSA (1) and Enterococcus species (9), 17 grew commensals. Non multi-resistant Gram-negatives grew in 38 specimens: Pseudomonas species (13) and 'coliforms' (26). MROs were found on 25% of tourniquets, including 3 from MRO isolation rooms. An IMP-4 positive *E. cloacae* and an ESBL *E. cloacae* were isolated from a single tourniquet each. MRSA was isolated from 14; vanB *E. faecium* was isolated from 18 and vanA *E. faecalis* from a single tourniquet. MRSA and VRE were isolated together from nine tourniquets, and 24 tourniquets grew either one. Van B positive *E.faecium* were typed using DiversiLab rep-PCR system This revealed five clusters without adominant clone. Six of 9 tourniquets from ICU grew at least one MRO. MROs were isolated throughout the 10 week period from a wide variety of locations including general wards, ICU, Burns, theatre anaesthetic bay and the blood collection unit.

Conclusion

Reusable tourniquets are frequently colonised with MROs and may be a potential source of cross-transmission. Using broth enrichment, 24% harboured either MRSA or VRE. Astourniquets are carried from ward to ward by hospital staff and used repeatedly, they may become a 'sleeper' mechanism for unrecognised hospital MRO transmission. They are also a surrogate marker for environmental colonisation and deficiencies in hospital cleaning. Continued use of reusable tourniquets may not be justified in the current hospital setting.

Disclosure of interest

None declared.

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Position Paper

On

The Use of Non-Sterile Pneumatic Tourniquets in Limb Operations

Submitted by

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OHK Medical Devices Ltd.

Synopsis

Despite multiple peer-reviewed clinical studies showing 100% of non-sterile reusable pneumatic tourniquet cuffs being contaminated with the same pathogens that cause surgical site infection (SSI), many hospitals and surgical centers continue to use them. The purpose of this position paper is to review the literature and set the stage for a mid-term change in the AORN Standards of Care recommendation on the use of tourniquets to mandate that all tourniquets used on patients for limb surgery be sterile.

Conflicts of Interest:

Both authors are employees and stakeholders of OHK Medical Devices, the manufacturer of HemaClear Exsanguination Tourniquet (www.hemaclear.com).

Background

Devices to exsanguinate a limb and block the re-entry of blood into it have been in routine use for >140 years. Initially it was the Esmarch bandage, originally described by Friedrich von Esmarch in 1873, used alone to both exsanguinate the limb and for arterial blocking. The pneumatic tourniquet followed shortly thereafter with its invention by Harvey Cushing in 1908. Both devices are still in broad use in the operating theatre. Since 2003 the sterile elastic exsanguination tourniquet (HemaClear®) is being used in hospitals in the US and around the world.

Data

Starting in 2006 a series of papers appeared in the peer-reviewed literature where bacterial colonization of non-sterile pneumatic tourniquets had been analyzed. Table 1 shows the main findings of each of these studies.

Title	Authors	Journal	Date and page	Main findings	Authors Comment
Microbial colonization of tourniquets used in orthopedic surgery.	Walsh EF[1], Ben-David D, Ritter M, Mechrefe A, Mermel LA, DiGiovanni C.	Orthopedics.	2006 Aug; 29(8):709-13.	coagulase-negative staphylococci, Bacillus, and Staphylococcus aureus were present in 100%, of non-sterile OR tourniquets,	Tourniquet contamination may be a risk factor for the development of surgical site infection in orthopedic surgery.
A study of microbial colonisation of orthopaedic tourniquets.	Ahmed SM[1], Ahmad R, Case R, Spencer RF.	Ann R Coll Surg Engl.	2009 Mar;91(2): 131-4	All sampled (n=20) tourniquets were contaminated with colony counts varying from 9 to > 385. Coagulase-negative Staphylococcus spp. were the most commonly grown organisms from the tourniquets (96%). Some tourniquets had growths of important pathogens including methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas spp., and S. aureus.	In addition to the manufacturers' guidelines, we recommend the cleaning of tourniquets with a disinfectant wipe before every case.

Tourniquets and exsanguinators: a potential source of infection in the orthopedic operating theater?	Brennan SA[1], Walls RJ, Smyth E, Al Mulla T, O'Byrne JM.	Acta Orthop.	2009 Apr; 80(2):251-5.	Bacteria commonly implicated in surgical site infections such as coagulase-negative staphylococci, Staphylococcus aureus and Proteus spp. were prevalent. We also found a resistant strain of Acinetobacter and Candida.	Infectious organisms reside on the tourniquets and exsanguinators presently used in the orthopedic theater. These fomites may possibly be a source of surgical site infection.
The effect of sterile versus non-sterile tourniquets on microbiological colonisation in lower limb surgery.	SM Thompson, M Middleton, M Farook, A Cameron-Smith, S Bone, and A Hassan	Ann R Coll Surg Engl.	2011 Nov; 93(8): 589–590.	Thirty-four (34) non-sterile tourniquets were sampled prior to surgical application, twenty-three of which were contaminated with several different organisms including coagulase-negative *Staphylococcus* spp, *Staphylococcus aureus*, *Sphingomonas paucimobilis*, *Bacillus* spp, and coliforms. Thirty-six sterile tourniquets were used, with no associated contamination.	There was significant contamination of 68% of orthopaedic surgical tourniquets. These are used regularly in procedures involving the placement of prosthesis and metalwork, and can act as a potential source of infection. We recommend the use of sterile single-use disposable tourniquets where possible. The availability of an alternative should now set the new standard of care and we recommend adopting this as a current NICE guideline for control of surgical site infection.

Microbial colonisation of orthopaedic tourniquets: A potential risk for surgical site infection.	SK Sahu[1], B Tudu[2], PK Mall[2]	Indian J Med Microbiol	2015: 33: 115-118	It was observed that the tourniquets were colonised with coagulase-negative staphylococci, *Staphylococcus aureus, Bacillus,* diphtheroids, *Pseudomonas, Acinetobacter,* enterococci, enterobacteria, and *Candida*	All the tourniquets were colonised with microorganisms. Colony counts from different spots of the untreated tourniquets ranged from 15 to 68 colonies per spot. The inner surfaces of the tourniquets were more contaminated than the outer surfaces (1459 against 1030 colony counts). Proximal aspects were more contaminated than the distal aspects (1382 against 1107 colony counts).

It is clear from the above literature review that nearly all non-sterile tourniquets are contaminated with pathogens.

Methods that are currently used to mitigate the risk of contaminating the surgical site

The most commonly used method is to place the pneumatic tourniquet as far away as possible from the incision site. For example, the tourniquet is placed on the thigh for a foot case or on the upper arm for a hand case. The tourniquet is wrapped or covered by a sterile drape which creates a bacterial barrier when intact. The recommendation to clean the tourniquet between cases with a bacteriocydic solution is seldom adhered to in most ORs.

Methods to avoid transmission of pathogens from one patient to another

Reusable pneumatic cuffs are padded with an absorptive soft material (e.g. Web Roll) and/or cuff covers. No data are available on the effectiveness of such pads in blocking the spread of pathogens from one patient to another.

Methods to protect the OR staff against contamination by tourniquets.

Given the fact that almost all non-sterile pneumatic tourniquets are contaminated and typically stored in an open basket (photo), it is advisable that the OR personnel handling them and place them on the patient will do so with sufficient protection. Unfortunately, this is not always the case.

Critique and Discussion

The incidence of Surgical Site Infection continues to be high, ranging from 0.72% to 1.4% in 3 recent clinical-epidemiological studies of SSI in TKA ( ). This translates to between 7 and 14 deep SSI cases per thousand TKA patients. Unfortunately there are no studies that looked at the incidence of SSI post TKA with sterile vs. non-sterile tourniquets. There is one study in bilateral TKA (Demirkale et Al, J. Arthroplasty, 2014 Volume 29, Issue 5, Pages 993–997) that showed a drop from 1.3% to 0.4% in post TKA Deep SSI (p=0.11) when non-sterile pneumatic tourniquet was replaced by a sterile elastic exsanguination tourniquet. Clearly, additional studies are needed in order to determine if using non-sterile pneumatic tourniquets are safe to use.

SSI is debilitating and very expensive with the cost coming to be $50,000 - $70,000 per patient. If the incidence of SSI is reduced by only one case per 1000, it is easy to see that the saving can be $50 - $70 per case which is roughly the cost of each sterile single-patient use tourniquet.

Conclusion

Based on the literature published in the last few years reusable pneumatic tourniquets are contaminated with pathogens which may cause surgical site infection. These publications are not cited in the current AORN Guidelines on safe tourniquet use and should be considered new evidence that justify a mid-term evaluation of the subject matter. We recommend that the committee will act to consider these new evidence-based data and move to amend its guidelines to include a requirement that tourniquets used in the OR for limb surgical procedures will always be **sterile**.

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