



Sterile Exsanguination Tourniquet

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TOTAL KNEE ARTHROPLASTY
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Total Knee Arthroplasty

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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.

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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, preoper-

ative 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 osteoarthritis. Institutional review board approval was obtained. Of these patients, comorbidities which can alter the rates of postoperative bleeding or infection rate such as inflammatory arthritis ($n = 31$), 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



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 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.

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 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.

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 $\pm$ 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

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.

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.

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 $(7.2 - 6.5) / 6.5 \times 5000 \text{ ml} = \sim 540 \text{ ml}$. 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.

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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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 ($3.8 \pm 1.9 \text{ d}$) in comparison to the control group ($5.4 \pm 2.8 \text{ d}$) ($p = 0.05$). 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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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.

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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.

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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 ± 54 mmHg for the large size, and 326 ± 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 BiovacTM 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 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.

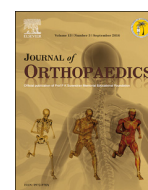
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Original Article

Silicone ring tourniquet versus pneumatic cuff tourniquet in total knee arthroplasty surgery: A randomised comparative study

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ABSTRACT

Introduction: The aim of the present study was to compare a silicone ring tourniquet (SRT) and a classic pneumatic cuff tourniquet (PT) in patients undergoing total knee replacement. We have compared the impact on the glycolytic activity caused by the ischaemia applied to the limb during the surgery.**Material and methods:** 140 patients that underwent total knee arthroplasty (TKA) were randomised in two groups. Serum lactate determination was made by reactive strips of enzymatic-amperometric detection, 5 min before tourniquet application and 5 min after tourniquet removal.**Results:** The mean tourniquet time was similar for both groups ($p = 0.13$). Postoperative serum lactate levels were higher with statistical significance than the preoperative levels and with a positive Pearson's correlation in the overall cases. The postoperative serum lactate levels were higher in the PT group (4.097 ± 2.248 mmol/L) than the SRT group (3.499 ± 1.566 mmol/L). There was no significant difference ($p = 0.07$) to be able to affirm that there was a difference of the anaerobic metabolism according to the tourniquet system used.**Discussion:** Ischaemia applied to the lower extremity during knee replacement surgery can produce tissue injury. Serum lactate determination allows comparison of the ischaemic changes during TKA surgery caused by two different tourniquet systems.**Conclusions:** SRT may be not disadvantageous compared to the classic PT from the impact on the glycolytic activity caused by the ischaemia.

Level of evidence II.

1. Introduction

Currently, pneumatic tourniquet has been widely used in orthopaedic surgery due to its multiple advantages, but remains controversial during total knee arthroplasty (TKA).^{1,2} Documented advantages of the use of tourniquet are a bloodless operative field, less intra-operative blood loss, and a better cement penetration.^{3,4} However, the use of pneumatic tourniquet may be also associated with potential complications, such as more postoperative blood loss, a greater occurrence of venous thrombosis, neuromuscular or cutaneous damage, and delayed rehabilitation. Tourniquet time over 120 min increases the risk of complications after knee arthroplasty surgery and special attention is advocated to reduce the tourniquet time,^{5,6} although there is no sufficient evidence to absolutely contraindicate prolonging the ischaemia time until 3 h.

Tolerance to ischaemia is variable, depending on the different

tissues. Different critical ischaemia times (maximum ischaemia time at ambient temperature that each tissue can tolerate, remaining viable after reperfusion) have been established. In the extremities, the muscular tissue is the most sensitive and presents a critical ischaemia time of 4 h. Other tissues present longer critical ischaemia times, for example the peripheral nerve (8 h), fat (13 h), skin (24 h) or the bone tissue (4 days).⁷ On the other hand, satisfactory outcomes have been observed after TKA implanted without tourniquet.⁸

Use of a silicone ring tourniquet (SRT) was introduced into clinical practice as an alternative to the standard pneumatic tourniquet.⁹ This 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 has been designed for exsanguination and occlusion of the blood flow to the limb. The entire device is sterile and comes in different sizes. There are three tension models for the medium and large sizes (systolic blood

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pressure ≤ 130 mmHg < 160 mmHg and < 190 mmHg), 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. 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. This device has been compared to the pneumatic tourniquet in healthy volunteers and in clinical studies of patients that underwent upper extremity operations.^{10,11} This device has the advantage of being applied in sterile conditions and being able to be located at a greater distance from the surgical field than conventional tourniquets.

The aim of our study was to compare the SRT and the conventional PT in patients undergoing total knee replacement. We have compared the impact on the glycolytic activity caused by the ischaemia applied to the limb during the surgery.

2. Material and methods

The study was monocentric and prospective. The study group involved 140 patients operated between January 2013 and June 2015 that underwent TKA. Patients were randomly assigned using a random number online generator. Our study followed the ethical standards of the World Medical Association Declaration of Helsinki, as revised in 2013, and was accepted by the institutional ethical committee. All patients gave their informed consent for the study.

2.1. Patient population

There were 110 women (78.6%) and 30 men (21.4%), with a mean age of 74 years (± 6) and a mean BMI of 32.1 kg/m^2 (± 4.2). According to the ASA physical status classification system, updated in 2014 by the American Society of Anaesthesiologists, 4 patients (2.9%) have been considered by the Anaesthesiology and Reanimation Service of our Centre, ASA I, 109 patients (77.8%) ASA II and 27 patients (19.3%) ASA III. Additional demographic information is presented in Table 1.

Patients were randomised in two groups (a standard PT was used in 70 patients and a SRT in the other 70). Inclusion criterion was implantation of a TKA for knee osteoarthritis with intraoperative use of tourniquet. Exclusion criteria included the presence of a contraindication to the use of tourniquet, severe hypertension, recent traumatic history, rheumatoid arthritis, diabetes, other conditions that could produce hypoxia of the tissues, acid-base imbalances or disorders or increased lactate production, patients undergoing anaesthesia other than spinal anaesthesia, prior knee surgery and bilateral TKA procedures in one time.

Table 1

Patients characteristics in the two study groups. F: female, M: male, BMI: Body Mass Index, ASA: American Society of Anaesthesiologists. (ASA I - normal healthy patient, ASA II - patient with mild systemic disease and ASA III - patient with severe systemic disease). Quantitative variables were expressed as the mean $\pm$ standard deviation, while qualitative variables were expressed as frequencies (and percentages).

	Standard Pneumatic Tourniquet	Silicone Ring Tourniquet
Gender	53 F (75.7%) - 17 M (24.3%)	57 F (81.4%) - 13 M (18.6%)
Age (years)	73.6 ± 5.9	74.4 ± 6.6
BMI (kg/m^2)	32.4 ± 4.4	31.7 ± 3.9
ASA Classification	ASA I 1 (1.4%) ASA II 55 (78.6%) ASA III 14 (20%)	ASA I 3 (4.3%) ASA II 54 (77.1%) ASA III 13 (18.6%)

2.2. Intervention

In all the cases, the TKA surgery was performed using a CT-based patient-specific cutting block technique (MyKnee®, Medacta International S.A., Castel San Pietro, Switzerland) with the same type of cemented fixed bearing knee prosthesis (GMK®, Medacta International S.A., Castel San Pietro, Switzerland). All patients were operated by the same knee surgery staff, integrated by two senior surgeons.

An inferior limb tourniquet was applied in all the cases. A standard PT was used in 70 patients. We have employed the A.T.S. 3000 (Automatic Tourniquet System by Zimmer) with a standard 76-by-10-centimetre cuff and a standard pressure of 350 mmHg. The standard PT was applied by the operating nurse around the upper thigh before draping. Exsanguination was performed by the surgical team employing a sterile Esmarch elastic bandage and the tourniquet was inflated just prior to skin incision. The tourniquet was deflated after completely dressing application. An SRT, the S-MART™ or HemaClear® system (OHK Medical Devices, Haifa, Israel) was used in the other 70 patients. In all the cases, size L or XL was used according to the circumference of the thigh of the limb to be operated (with a pressure provided by the manufacturer of 286 ± 54 mmHg for size L and 321 ± 21 mmHg for size XL). The SRT was applied by the operating team after draping, just prior to skin incision. The ring was sectioned after completely dressing application. All patients followed the same regimen of preoperative, intraoperative and postoperative drugs.

Serum lactate determination was made by reactive strips of enzymatic-amperometric detection, 5 min before tourniquet application and 5 min after tourniquet removal. The Lactate Scout+ analyser (SensLab GmbH, Leipzig, Germany) was used. The measuring range of this device is estimated from 0.5 to 25.0 mmol/L and it requires a volume of blood 0.2 microlitres for its analytical process. According to the manufacturer's specifications, the Lactate Scout+ has a coefficient of variation of $\pm 3\%$ (minimal standard deviation: ± 0.2 mmol/L) within the haematocrit range of 35–50% and $\pm 4\%$ (minimal standard deviation: ± 0.3 mmol/L) within the extended haematocrit range. Similar results have been published by independent authors.¹²

2.3. Statistical plan

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS), version 24 for Windows (SPSS, Inc., Chicago, IL, USA). All quantitative variables were expressed as the mean $\pm$ standard deviation, while qualitative variables were expressed as frequencies (and percentages). The normality of the quantitative variables was tested with the Kolmogorov-Smirnov test. The Student's *t*-test for paired and independent samples was used. Bivariate correlations have been used with the Pearson's correlation coefficient as a measure of linear association between two variables. Statistical significance was considered for *p* values of less than 0.05.

3. Results

There was no statistical significant difference in patient demographics between both study groups: mean age for the PT group 73.6 ± 5.9 years and for the SRT group 74.4 ± 6.6 years (*p* 0.47). Mean BMI for the PT group $32.4 \pm 4.4 \text{ kg/m}^2$ and for the SRT group $31.7 \pm 3.9 \text{ kg/m}^2$ (*p* 0.32). The mean tourniquet time was similar for both groups: PT group 98.16 ± 16.5 min and SRT group 102.5 ± 17.3 min (*p* 0.13). Also the surgical time (skin-to-skin time) was similar for both groups: PT group 79.64 ± 12.2 min and SRT group 77.12 ± 10.6 min. Postoperative serum lactate levels (3.798 ± 1.954 mmol/L) were higher with statistical significance (*p* 0.009) than the preoperative levels (2.316 ± 1.043 mmol/L) and with a weak positive linear correlation in the overall cases (Pearson's correlation coefficient 0.220, *p*-value 0.01). We also observed pre- and postoperative weak positive linear correlation in the PT group

(preoperative 2.254 ± 1.177 mmol/L and postoperative 4.097 ± 2.248 mmol/L, Pearson's correlation coefficient 0.246, *p*-value 0.05), but not in the SRT group (preoperative 2.377 ± 0.894 mmol/L and postoperative 3.499 ± 1.566 mmol/L, Pearson's correlation coefficient 0.209). The postoperative serum lactate levels were higher in the PT group (4.097 ± 2.248 mmol/L) than the SRT group (3.499 ± 1.566 mmol/L). There was no significant difference (*p*-value 0.07) to be able to affirm that there was a difference of the anaerobic metabolism according to the tourniquet system used.

4. Discussion

Ischaemia applied to the lower extremity during knee replacement surgery can produce tissue injury through a triple mechanism: mechanical injury due to the compression exerted by the tourniquet applied to maintain the ischaemia, anoxia injury and the inflammatory and oxidative lesion of the tissues after the reperfusion.^{5,7} During ischaemia, the cell's energy stores are depleted in an attempt to maintain homeostatic functions. Long periods of ischaemia lead to the decrease in the capacity to regenerate adenosine triphosphate through the aerobic systems. As a consequence, skeletal muscle cells must alter from oxidative phosphorylation to anaerobic glycolysis for energy production, causing a rise in lactic acid production. In our study we have used serum lactate levels as a marker of the increase of anaerobic glycolysis secondary to ischaemia. Jawhar et al¹³ found in a randomised, controlled, monocentric trial of muscle biopsies obtained from vastus medialis immediately after performing the surgical approach and exactly 60 min later, that tourniquet application did not affect the free/conjugated ubiquitin as well as total ubiquitin-protein ligase activity significantly. The proteasome-dependent peptidase activities were significantly upregulated during tourniquet application, suggesting an increase in protein degradation, which in turn might explain the skeletal muscle atrophy occurring after TKA.

Ejaz et al¹⁴ observed, using microdialysis, that performing TKA with tourniquet is associated with increased ischaemia. This affects all metabolites (including the lactate levels) but the changes are normalised after 5 h. Previously, Östman et al¹⁵ evaluated microdialysis as an *in vivo* method to characterise the time-course and relative kinetics of pyruvate, glucose, lactate, glycerol, hypoxanthine, uric acid, and urea, in skeletal muscles, exposed to prolonged ischaemia and 2 h of reperfusion, in patients having elective arthroscopic assisted anterior cruciate ligament reconstruction. To our knowledge, our study is the first to assess, without an invasive technique, the ischaemic changes during TKA surgery caused by two different tourniquet systems in a randomised setup.

Only few papers have been published about SRT. Drosos et al⁹ reported the use of SRT in 362 elective operations and 174 trauma cases. Pereira et al¹⁶ reported no clinically significant advantage in a retrospective comparison of carpal tunnel syndrome cases operated using a SRT versus a PT. However, Drosos et al¹¹ in a prospective randomised study of carpal tunnel syndrome cases, observed a significant decrease in pain evaluation, suggesting less soft tissue damage. To our knowledge, previous to our study, only two evaluations of the SRT during TKA have been reported. Brin et al¹⁷ observed that patients operated with SRT had a smaller decrease in haemoglobin on postoperative days one and three, and the amount of blood collected from drains at 24 h was significantly lower, in comparison with the patients operated with conventional pneumatic tourniquet. In the opposite way, Jenny et al¹⁸ reported that the calculated blood loss and the need for allogeneic transfusion were not significantly decreased by the use of SRT and it cannot be considered as an advantage of this device. These authors postulate however, that a significant decrease in operating time and a significant decrease in complication rate warrants further investigation.

In the present study, the mean tourniquet time was similar for both groups. In our study, we found no statistical significant difference in postoperative serum lactate levels between the patients operated with

standard PT and the patients operated with SRT, although postoperative serum lactate levels were discreetly higher in the PT group than the SRT group. We cannot affirm that there was a difference of the anaerobic metabolism according to the tourniquet system used. Therefore, it seems that SRT may be not disadvantageous compared to the classic pneumatic tourniquet from the impact on the glycolytic activity caused by the ischaemia.

The present study has several limitations. We do not have a serum lactate baseline determination of the patients, but the aim of our experience was not to demonstrate an increase in lactate values compared to basal lactate, but to target the increase from the moment just before the application of ischemia to the moment just after release. It should be noted that the patients in our study presented abnormally high values of serum lactate, also preoperatively. We think this elevation just before the intervention may be due to the metabolic alteration as a response to the patient's stress before the operation. In addition, there is no consensus regarding the validity of capillary lactate measurements using enzymatic-amperometric reactive strips. Bouzat et al¹⁹ conducted a prospective observational study in one level I trauma centre and tested the agreement between capillary lactate and blood lactate concentrations using Bland and Altman analysis. Although a significant association between point of care lactate concentration and transfusion requirements was found, the diagnostic performance of capillary lactate measurements was poor. Due to large disagreement between capillary lactate and blood lactate, the authors think that capillary lactate cannot be considered in the clinical setting. In the opposite direction, Purcarea et al²⁰ analysed in a prospective, observational, monocentric study point of care measurements of baseline capillary and venous lactate levels and compared them with the blood samples that were analysed in the central laboratory. They conclude that capillary lactate levels could be a more sensitive method than the classical lactate measurement for predicting the outcomes of acute conditions, especially infections. Recently, Baig et al²¹ examined the accuracy and timesaving effect of a handheld point of care lactate device for the measurement of fingertip and whole blood lactate and compared it with the reference laboratory blood testing in a sample of adult emergency department patients and conclude that fingertip point of care lactate measurement is an accurate method to determine lactate levels in septic adult emergency department patients. On the other hand, no portable device is absolutely accurate for the analysis of serum lactate levels, but it has been estimated that such devices are reliable enough for the determination of serum lactate levels.^{12,22}

5. Conclusion

In this randomised trial, the SRT may be not disadvantageous compared to the classic PT from the point of view of the glycolytic activity caused by the ischaemia. The results of this evaluation have led the authors towards a systematic use of the silicone ring tourniquet in primary TKA, since this device offers the advantage of being applied in sterile conditions and being able to be located at a greater distance from the surgical field than conventional tourniquets. Further studies are required to continue explorations in this direction and/or strengthen our conclusions.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Conflict of interest

None of the other authors have any conflict of interest or any financial or non-financial competing interests to declare with regard to this paper. No benefits or funds were received in support of the study.

Authors' contributions

VL made substantial contributions to the conception and the design of the work, to the analysis and interpretation of data for the work, performed the statistical analysis and drafted the manuscript. AL participated in the design of the study, helped to draft the manuscript and revised it critically for important intellectual content. CH participated in the design of the study, revised critically the manuscript and made substantial contributions to the analysis and interpretation of data for the work. ML conceived of the study and participated in its design and coordination, helped to draft the manuscript, revised critically the manuscript and made substantial contributions to the analysis and interpretation of data and performed the statistical analysis. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethical guidelines

The Institutional Review Board of Hospital General Universitario José María Morales Meseguer (of which the Hospital de la Vega Lorenzo Guirao is dependent) approved the study.

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Comparison of local pain and tissue reaction between conventional pneumatic tourniquet and disposable silicone ring tourniquet during Total Knee Arthroplasty

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ABSTRACT

Background: To study the comparison of conventional pneumatic and disposable silicone ring tourniquet in Total Knee Arthroplasty.

Material and methods: This is a prospective randomized control trial. We used conventional pneumatic tourniquet on one side of leg and disposable silicone ring tourniquet on the other side in consecutive 50 simultaneous bilateral TKR patients. Patients having peripheral vascular disease of the lower limb were excluded from the study. The patient demographics & characteristics are identical being the same patient with two different legs. We started the study with null hypothesis. An independent observer assessed the local tourniquet site pain (VAS score 1–10) and local tourniquet site skin reaction at 24 h and 48 h after the TKA. P value < 0.05 was considered significant.

Results: There were no local skin complication with disposable tourniquet (0%). 8 out of 50 patients in whom the conventional tourniquet was applied showed local bruising, and two patients had blister formation making the local skin site complication rate 20% (statistically significant, p value 0.0196, chi-squared test). The VAS score at 24 h was 4.3 ± 1.5 for disposable tourniquet group as against 5.6 ± 2.1 for conventional tourniquet group (statistically significant, p value = 0.0152, t statistic test for comparison of means). The VAS score at 48 h was 2.1 ± 1.5 and 3.3 ± 1.2 for disposable tourniquet group and conventional tourniquet group respectively (statistically significant p value = 0.003, student's t-test).

Conclusion: Use of disposable tourniquet has better outcome than the conventional tourniquet with minimal or no local complications. The advantages of the disposable tourniquet are: 1. less local pain, 2. no local skin problems, 3. accurate tourniquet pressure at the application site, 4.0% local contamination. Hence, we recommend use of the disposable tourniquet during the Total Knee Arthroplasty.

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1. Introduction

Use of a tourniquet remains controversial during Total Knee Arthroplasty (TKA).^{1–3} No use of tourniquet has also showed satisfactory outcomes.⁴ Documented advantages of using the tourniquet are a bloodless operative field,⁵ less intra-operative blood loss,⁶ and a better cement penetration.⁷ Perceived disadvantages are more postoperative blood loss,² a greater occurrence of venous thrombosis,³ neuromuscular⁸ or cutaneous⁹ damage,

and delayed rehabilitation.¹⁰ To minimize the tourniquet complications, the tourniquet time should be < 100 min.¹¹ Consequently, alternate procedures have been suggested. The half-course tourniquet strategy¹² 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. The various types of tourniquet used in TKA are 1. conventional pneumatic tourniquet, 2. Disposable silicone ring tourniquet. They both have their set of advantages and disadvantages. The advantages of conventional pneumatic tourniquet are it is economical, it can be deflated and re inflated anytime during the TKA procedure. The disadvantages of the conventional pneumatic tourniquet are it has to be calibrated frequently for the accuracy, it is not sterile and hence requires additional draping during the TKA procedure and it tends to produce uniform pressure over the application area. The advantages of disposable silicone ring tourniquet are, it is sterile and hence no additional draping is required during the TKA thereby increasing the operative

Abbreviations: Total Knee Arthroplasty, TKA; Visual Analog Score, VAS.

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field, it offers uniform pressure on the application site thereby minimizing the chances of local skin complications. It also produces accurate pressure and there is no need of frequent calibration. The disadvantages of the disposable silicone ring tourniquet are it is expensive; it cannot be deflated and reinflated during the TKA procedure. The aim of the present study is to compare the local pain and tissue reaction between conventional pneumatic tourniquet and disposable silicone ring tourniquet during Total Knee Arthroplasty. We started the present study with the null hypothesis, i.e. no difference exists as regards the local pain and tissue reaction between the conventional pneumatic tourniquet and disposable silicone ring tourniquet.

2. Material and Methods

This study is a prospective randomized control trial. Sample size was estimated to be 45 in each group (conventional and disposable tourniquet during TKR) with alpha error of 0.05, beta error of 0.1 and power of 0.90. Considering drop outs the number was rounded to 50. Local ethics committee approval and written informed consent of all the patients was obtained. We used conventional pneumatic tourniquet on one side of leg and silicone ring disposable tourniquet (Heamclear®/S-MART™, OHK Medical Devices, Haifa, Israel) on the other side in consecutive 50 simultaneous bilateral TKR patients. The patients were randomized to undergo TKA either with conventional pneumatic tourniquet on right and silicone ring disposable tourniquet on the left leg or silicone ring disposable tourniquet on the right and conventional pneumatic tourniquet on the left leg by the use of computer-generated random numbers. The randomization envelope was opened in the operating room. Patients having peripheral vascular disease of the lower limb were excluded from the study. The patient demographics & characteristics are identical being the same patient with two different legs (Table 1).

2.1. Disposable tourniquet application technique

The disposable tourniquet (Heamclear, OHK Medical Services, Haifa, Israel) consists of a silicon ring wrapped in a stockinet sleeve and pull straps. They are available in four sizes with specific color coding as shown in Table 2. The appropriate size tourniquet is determined by measuring the thigh circumference at the proposed site of application prior to surgery. The surgeon 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. 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

Table 2
Silicone ring tourniquet sizing guide.

Sr.	Size and color code	Circumference (cms)	Systolic blood pressure limit
1.	X-Large (Black and white)	50–85	<160 mmHg
2.	Large (Brown)	30–55	<190 mmHg
3.	Medium (Yellow)	24–40	<190 mmHg
4.	Small (Pink)	14–28	<130 mmHg

the preferred occlusion location, the pulling motion is stopped. The ring exerts supra systolic pressure on the limb thereby blocking arterial blood flow into the limb and thus acts as a 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. At the end of the procedure, the ring is cut with a blade. The sterile stockinet is cut away with scissors, and the blood supply to the limb is resumed.¹³ In all patients, the sterile elastic tourniquet provided continuous arterial occlusion for the entire duration of the procedure. As all the patients were females so large (brown) size tourniquet was used. The occlusion pressures were similar to the levels we usually use with the pneumatic tourniquet.

We started the study with null hypothesis. An independent observer assessed the local tourniquet site pain (VAS score 1–10) and local tourniquet site skin reaction at 24 h and 48 h after the TKA. The post operative blood loss was also documented. The continuous data was checked for normality and the statistical tests employed were chi-squared test and t-statistics test. MedCalc software version 19.4.1 was used for statistical analysis. P value < 0.05 was considered significant.

3. Results

There was no local skin complication with disposable tourniquet (0%). 8 out of 50 knees in whom the pneumatic tourniquet was applied showed local bruising, and two patient had blister formation with superficial skin necrosis (Fig. 1). The local skin site complication rate with the pneumatic tourniquet group was 20% (statistically significant, p value 0.0196, chi-squared test). The VAS score at 24 h was 4.3 ± 1.5 for disposable tourniquet group as against 5.6 ± 2.1 for conventional tourniquet group (statistically significant, p value = 0.0152, t statistic test for comparison of means). The VAS score at 48 h was 2.1 ± 1.5 and 3.3 ± 1.2 for disposable tourniquet group and conventional tourniquet group respectively (statistically significant p value = 0.003). Thus, the null hypothesis is rejected.

Table 1
Preoperative patient characteristics between Pneumatic and Disposable Tourniquet TKR group.

Parameters	Pneumatic Tourniquet TKR Group	Disposable Tourniquet TKR Group	p value
Number of patients (n)	n = 50	n = 50	
Mean Age (yrs)	68.5 ± 7.8 (58–82)	68.5 ± 7.8 (58–82)	
Mean BMI (kg/m ²)	29.6 ± 6.8	29.6 ± 6.8	
Gender			
Male	n = 0 (0%)	n = 0 (0%)	
Female	n = 50 (100%)	n = 50 (100%)	
ASA Grade			
Grade 1	n = 12	n = 12	
Grade 2	n = 34	n = 34	
Grade 3	n = 4	n = 4	
Preoperative clinical diagnosis			
OA (Grade 4, bone on bone)	n = 50 (100%)	n = 50 (100%)	
RA	n = 0 (0%)	n = 0 (0%)	
Mean operative time (minutes)	81.5 ± 14.5	84.2 ± 13.6	0.3392



Fig. 1. Blister formation and superficial skin necrosis with conventional pneumatic tourniquet.

blood loss was 185.6 ± 26.5 with the conventional pneumatic tourniquet and 180.4 ± 28.2 with the sterile disposable tourniquet. The mean operating time for pneumatic tourniquet group was 81.5 ± 14.5 min and that for disposable silicon ring tourniquet group was 84.2 ± 13.6 min (p value = 0.3392) (Table 3). The mean operating time and the mean tourniquet time in 10 knees where the local skin complications occurred was 84.6 ± 12.7 (statistically not significant, p value = 0.5150, t-statistics test). The mean operating time and the mean tourniquet time is same because the tourniquet was released at the end of the TKA procedure.

4. Discussion

In our study the local complications rate in the pneumatic tourniquet group was 20%. 8 out of 50 patients had local bruising at the site of application of the tourniquet. 2 patients had local blister formation and superficial skin necrosis necessitating prolonged wound dressing (Fig. 1). This resulted in tremendous discomfort and mental anxiety to the patients. Also, the VAS score at the site of application of the tourniquet at 24 and 48 h showed less pain with the use of silicone ring disposable tourniquet.

Few papers have been published about disposable tourniquet. Pereira et al.¹⁴ in a retrospective comparative study reported no clinically significant advantage. However, Drosos et al.¹⁵ in a prospective randomized study, observed a significant decrease in local pain, suggesting less soft tissue damage. Brin YS et al.¹⁶ showed that pneumatic tourniquets could be contaminated. Two more studies by Walsh et al. and Ahmad et al. have demonstrated 100% contamination among the tourniquets they had sampled.^{17,18} The bacteria collected included: *Staphylococcus coagulase negative*, *Staphylococcus aureus*, Methicillin Resistant *Staphylococcus Aureus* and *Pseudomonas aeruginosa*.^{17,18} The contamination problem is further compounded by the fact that most institutes do not have a standard protocol for cleaning tourniquets after the use.¹⁹ Thompson et al.²⁰ compared the bacterial load of non-sterile pneumatic vs. sterile elastic tourniquets. Their 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%). Ved et al.²¹ recommended that sterile tourniquet use is safe and is a useful tool facilitating ease of revision knee surgery for surgeons. They observed that the colonization rate of pneumatic re-useable devices reported to be 68–78%. Sterile single use tourniquets devices (Heamclear®/S-MART™, OHK Medical Devices, Haifa, Israel) have colonization rates of 0%. This study assessed the operative field clearance between the two devices and discussed the potential benefits for reducing infection in revision knee surgery. Their conclusion was that the average operative field space increase using a sterile single use tourniquet compared to a multi-use pneumatic device was 8.98 cm. León-Muñoz et al.²² in their study found no statistical significant difference in postoperative serum lactate levels between the patients operated with stan-

dard pneumatic tourniquet and the patients operated with silicone ring tourniquet. Jenny JY et al.²³ in their study showed no significant difference in the post operative blood loss and hemoglobin drop between the two groups (one with pneumatic tourniquet and other with disposable silicone tourniquet). In our study, there was a significant decrease of local skin complication rate in the disposable silicone tourniquet group. One main disadvantage of using the disposable tourniquet is that they are expensive. The cost per unit of disposable silicone ring tourniquet is 4200 rupees (approximately 55 US \$). This additional cost is justified on the cost benefit analysis as the financial, psychological and physical cost of managing the local skin complication (especially local skin abrasion and superficial skin necrosis) is too high. The abrasion or superficial skin necrosis in the groin area is extremely painful and requires multiple dressings. We believe the higher cost of disposable tourniquet will be offset by cost savings due to fewer local skin complications and improved patient well-being.

The strength of our study is that the patient demographics and characteristics are exactly the same being the same patient had different tourniquets on two limbs. There are certain limitations of our study. First limitation is our study had only female patients. This is not unusual as numerous studies have shown that women are more prone to have advanced symptomatic osteoarthritis.^{24–26} Second limitation is we only included advanced grade 4 Osteoarthritis patients and rheumatoid arthritis patients were excluded from the study. Further research is warranted to study efficacy of disposable tourniquet in rheumatoid arthritis patients. Third limitation is as the both types of tourniquets were used in the same patient, VAS score is likely to be affected (as pain also has a psychological component); compared to the hypothetical situation where different types of tourniquets are used on different patients. However, this limitation is offset by the fact that the VAS score comparison holds true for bilateral TKA situation which is the case in present study. Also, the patients were not aware about which type of tourniquet was used on the left or right leg thereby minimizing the psychological component.

5. Conclusion

Use of disposable tourniquet has better outcome than the conventional tourniquet with minimal or no local complications. The advantages of the disposable tourniquet are less local pain, no local skin problems and accurate tourniquet pressure at the application site. Hence, we recommend use of the disposable tourniquet during the TKA.

Declarations: Ethics approval and consent to participate

Local ethics committee approval was obtained before the study. Also all patients were consented.

Consent for publication: We hereby give our consent for publication.

Availability of data and materials

Not Applicable.

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Authors' contributions

All authors have contributed significantly to the preparation of manuscript.

Declaration of competing interest

The author does not have any conflict of interest related to this work.

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Table 3
Variables used in the study.

Variables	Conventional tourniquet	Disposable tourniquet	P value
Local bruising	8	0	0.0196
Blister formation	2	0	
VAS score 24 h	5.6 ± 2.1	4.3 ± 1.5	0.0152
VAS score 48 h	3.3 ± 1.2	2.1 ± 1.5	0.003
Post operative blood	185.6 ± 26.5	180.4 ± 28.2	0.3444

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A comparison of operative field space between sterile single use and re-useable pneumatic tourniquets in revision total knee arthroplasty

Ved A, Kempshall PJ, Sharma H, Morgan-Jones RL

Abstract

Adequate operative field space minimises potential complications during revision knee arthroplasty. The colonisation rate of pneumatic re-useable devices reported to be 68-78%, other devices should be considered in the revision knee surgery setting.

Sterile single use tourniquets devices (Heamclear® /S-MART™, OHK Medical Devices, Haifa, Israel) have colonisation rates of 0%. This study assesses the operative field clearance between the two devices and discusses the potential benefits for reducing infection in revision knee surgery.

At the time of revision knee replacement, the operative field space was measured using both pneumatic and sterile single use tourniquets. The measurements were taken once the components had been explanted. The average operative field space increase using a sterile single use tourniquet compared to a multi-use pneumatic device was 8.98 cm [CI95% 7.1-10.8 cm], $p < 0.001$ ($p = 0.00034$).

It is recommended that sterile single use tourniquets are safe and are a useful tool for surgeons facilitating ease of revision knee surgery.

Keywords: Tourniquet, Revision Knee surgery, Sterile single use tourniquet, Infection, Pneumatic tourniquet, operative field.

1. Introduction

The use of tourniquets for both upper and lower limb surgery has become common practice since its introduction in 1864 by Joseph Lister, for procedures other than amputation, where the concept of bloodless surgery was first applied [1].

The use of tourniquets for surgery has been accompanied by reports of complications such as nerve damage [2, 3] and cross infection [4, 5]. Though the problems of nerve injuries has been addressed in recent years with use of wider cuffs and reducing duration and pressure of these pneumatic devices [6, 7], the issues with cross infection still remain a problem with lack of strict compliance to manufacturer cleaning protocols in most of hospitals [5].

In a climate of 'super-bug' fear, a lot of emphasis has been made by the Department of Health on preventing cross infection between patients, on the ward and in the theatre setting. This has manifested in the introduction of uniforms and 'bare below elbow' guidelines for doctors and nursing staff [9]. Studies have reported colonisation rates of 68-78% on reusable pneumatic tourniquets compared to 0% on sterile single use brands [5, 8]. It is imperative to look for and reduce obvious sources of cross infection, especially in the operative theatre setting where the risk and cost of cross infection could have disastrous consequences.

The size of the sterile operative field facilitates ease of surgery. Ease of exposure has a potential effect on the complication rate by reducing operating time. A larger sterile field minimises the risk of contamination from extensile exposures needed for revision arthroplasty when the incision can be extended near to the limit of the sterile field. This study aims to compare the length of sterile operative field in Revision Total Knee Replacement (TKR) with use of conventional pneumatic devices and a single use, non pneumatic elastic ring tourniquet.

2. Material and Methods

Between March 2011 and December 2011, twenty consecutive patients listed for single stage, first time revision knee surgery were included in the study. After consent was obtained, a pneumatic multi used tourniquet was applied by the hospital operating department practitioner, and checked by the senior author. The distal extent of the tourniquet was marked with a skin

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marker pen and the tourniquet removed. The side support was applied to the operating table at the level required, but then rotated proximally out of the way for surgical preparation. The patients were then prepared for surgery with the use of a limb isolator sterile drape. The haemaclear® sterile single use tourniquet applied to the sterile field. Application consists of unrolling the device onto the leg. This has the effect of exsanguination of the limb. Once adequate surgical exposure was made to achieve explanation of the components, the proximal end of the incision was measured to the pre applied skin mark and to the single use tourniquets distal extent. The measurements were recorded in centimetre (Figs 1 and 2).



Fig 1: Haemaclear® Sterile single use tourniquet. Application following surgical preparation of the limb

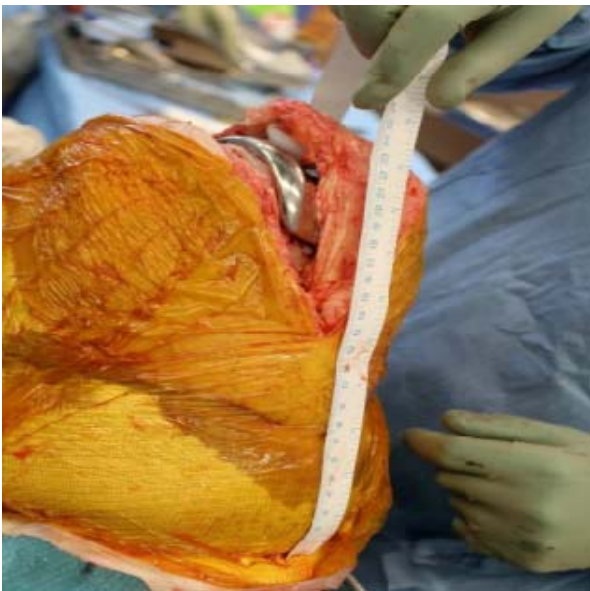


Fig 2: Measurement using sterile tape measure of the proximal extent of the wound to the distal extent of the tourniquet

3. Statistical Analysis

Statistical testing was performed using SPSS v18.0 (SPSS Inc., Chicago, Illinois) with significance defined as a p-value < 0.05. Significance testing was performed using Student's t-test when making comparisons between the operative field space available between the two devices.

4. Results

Of the 20 patients, 11 were female and 9 were male. The average age was 62 years. The average BMI was 36. The average sterile operative free space with standard pneumatic device was 5.5 cm (range 3.0-8.0 cm) while with single use

non-pneumatic device was 14.4 cm (range 9.0-21.0 m). [Fig 3] The average increase in operative field space was 8.98 cm (CI95% 7.1-10.8 cm) with the sterile single use tourniquet. Using the student's t-test this difference was found to be significant. [$p < 0.001$, $p = 0.00034$].

There was no incidence of ischemic injury and no nerve palsies in post-operative period in any of the cases. One patient was investigated for a deep vein thrombosis but was Doppler negative. There were no postoperative wound infections and all knees were aseptic at the last follow up. In all cases the increased surgical field facilitated the operative procedure; this was especially true in obese patients.

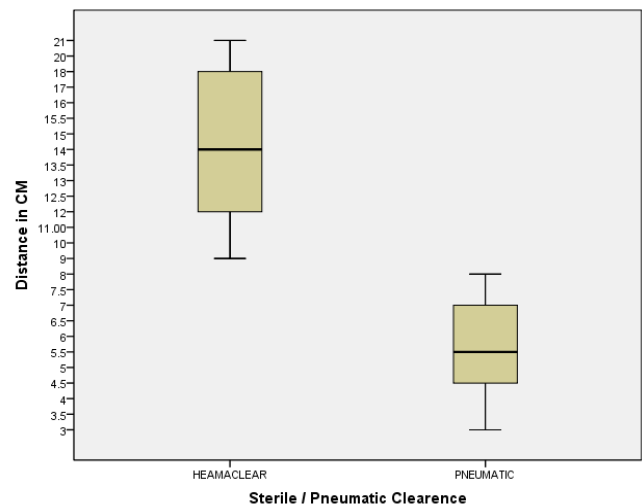


Fig 3: Box plot of the clearance of the two devices

5. Discussion

There has been a steady rise in the volume of revision Total Knee Arthroplasty (TKA) procedures in recent years and estimates suggest the number of revision TKA procedures is expected to increase. Revision knee replacement is a more technically and economically demanding procedure [12].

Improving a complicated procedure relies on the breakdown and analysis of the multiple procedural steps involved i.e. adequate pre-operative planning, adequate exposure and adherence to principles of revision arthroplasty [13, 14]. A wide exposure must be achieved to allow component removal, soft-tissue balancing, management of bone loss, reimplantation and importantly to minimise complications [13, 15].

This study adds to current literature for revision total knee replacement as there is currently no published data on operative field space associated with tourniquet type. Although a logical conclusion that if a smaller tourniquet is used operative space is increased, there is no evidence base to the statement.

Surgical factors play a role in the outcome of revision TKR. We feel that by increasing the operative field available to the surgeon during the revision, the procedure is simplified, and minimises the 'struggle' with difficult exposures. Minimising 'struggling' with an operation decreases the complications associated with exposure. It also minimises the operative time, minimises the tourniquet time and therefore and may improve outcome.

Outcome in revision TKR varies on a case by case basis and is multifactorial. Although it is not possible to singularly quantify the improvement in outcome from such a change in device, the potential gain to the operating surgeon in terms of ease of the procedure cannot be overlooked.

Recent literature has shown that infection is the single most

important predictor of outcome following revision [16, 17, 18]. Therefore every emphasis should be made on reducing the risk of infection in these patients. There are many ways that a surgeon can reduce infection including minimising operative time, minimising tissue ischemic time and giving adequate clearance from tourniquets colonised by pathogenic organisms. Hence it becomes especially significant during time of surgery to have maximum sterile operative length for adequate exposure. The sterile single use device also seals the operative field from the positive pressure from the patient warming device, where warm air could be blown into the operative field, another potential advantage.

Studies have also clearly emphasized the lack of cleaning of reusable tourniquet and hence risk of cross infection [5]. Despite all of the literature against the use of re-useable pneumatic devices they remain the most commonly used tourniquets in UK [4-6, 8].

This study is the first to compare sterile operative length of non-sterile pneumatic versus single use non pneumatic tourniquet devices. Our study clearly demonstrates the benefit of using single use non-pneumatic devices as tourniquets as it provides increased sterile operative clear space for adequate exposure as well makes operation much easier and it does not interfere with the side support. There was no post-operative complication in our study.

One limitation of the study was the small number of patients in the study group. Analysis of infection rate with newer device is therefore not possible, but it would be a logical conclusion that reducing bacterial load in close proximity to surgical site would reduce risk of infection. As far as efficacy and effect of both these devices are concerned there is enough evidence to comprehend that both have equal efficacy and safety and both have comparable effects on underlying soft tissue physiology [19, 20, 21].

6. Conclusion

It is evident from this study that that the non-pneumatic single use tourniquets provide the surgeon with much larger sterile operative field minimises potential complications with exposure and infection and therefore should be recommended for revision total knee replacement.

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Clinical Efficacy of Sterile Exsanguination Silicone Tourniquets on Primary Total Knee Arthroplasty

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Abstract

Objective

To compare the clinical efficacy on the accelerated recovery of postoperative patients in Primary TKA with pneumatic tourniquet and a sterile exsanguination silicone tourniquet.

Methods

In total 50 patients undergoing primary total knee arthroplasty were retrospectively studied from April to October in 2020. With the design of sequential trial, in total 25 patients (20 cases of single knee, 5 cases of double knee, a total of 30 knees) qualified were assigned to group sterile exsanguination silicone tourniquet from April to July; total 27 patients (24 cases of single knee, 3 cases of double knee, a total of 30 knees) were included into the group of pneumatic tourniquets. Intraoperative blood loss before releasing tourniquet, total blood loss, surgical time, tourniquet use time, allogeneic blood transfusion rates, incidence of deep venous thrombosis and knee active range of motion (ROM) were summarized. Visual clarity of surgical field, thigh pain and knee pain were measured by the Visual Analog Scale. Lovett muscle strength classification standard was adopted to evaluate quadriceps strength.

Results

Compared to pneumatic tourniquet, the sterile exsanguination silicone tourniquet group could obviously decrease the blood loss before releasing tourniquet ($P < 0.001$). Meanwhile, the excellent visual clarity of surgery field could be acquired in sterile exsanguination silicone tourniquet group with Score ($P < 0.001$). However, there is no significant difference in total blood loss between the two groups ($P = 0.67$). In sterile exsanguination silicone tourniquet group, tourniquet use time (64.10 ± 4.98) min, operation time (73.03 ± 6.11) min, the incidence of deep vein thrombosis was 13.33%. In pneumatic tourniquet group, tourniquet use time (70.73 ± 13.13) min, operation time (79.33 ± 14.57) min, the incidence of deep vein thrombosis was 36.67%. The difference between the two groups was statistically significant ($P = 0.01$, $P = 0.04$, $P = 0.04$). In the postoperative early stage, the thigh VAS score, knee VAS score, quadriceps strength and knee active range of motion in sterile exsanguination silicone tourniquet group were much better than those in pneumatic tourniquet group. There was no significant difference for allogeneic blood transfusion rates and tramadol demand rate between groups.

Conclusion

A sterile exsanguination silicone tourniquet is an effective method to reduce intraoperative blood loss and provide much visual clarity of surgery field, which is beneficial to improve surgical efficiency and decrease tourniquet use time and and surgical time. In the postoperative early stage, compared to pneumatic tourniquet, sterile exsanguination silicone tourniquet could reduce the crush injury and thigh pain of tourniquet, improve quadriceps strength and knee active range of motion, which is beneficial to faster recovery for patient as well as increasing patient satisfactions.

Key words

Total knee arthroplasty; sterile exsanguination silicone tourniquet; pneumatic tourniquet

Total knee arthroplasty (TKA) is one of the most common operations on the knee joint. It is used to treat end-stage arthritis and other related knee joint diseases, which can quickly and effectively improve joint function and improve the quality of life of patients[1]. With the application of the concept of accelerated rehabilitation, clinical practice has gradually focused on surgical safety, recovery speed and patient satisfaction [2,3]. Tourniquets are widely used for intraoperative hemostasis and improvement of surgical vision, which can create a clean osteotomy surface environment, which is conducive to the fixation of bone surface-bone cement-prosthesis [4]. There are still some disadvantages in the use of Pneumatic tourniquets, such as thigh swelling, skin blisters, muscle atrophy,

nerve damage, deep vein thrombosis, which delays the recovery process and reduces patient satisfaction [5]. The fine management of the perioperative period puts forward higher requirements for the use of tourniquets. Whether tourniquet should be used in TKA, how tourniquet should be used, safety pressure and time limit are still controversial, and the impact on postoperative rehabilitation still needs further study.

The sterile exsanguination silicone tourniquet (produced in Israel) has a good exsanguination and tourniquet effect. As a new concept and technology, it has been widely used abroad in trauma orthopedics, knee arthroplasty, hand and foot surgery, limb vascular Surgery and neurosurgery [6, 7], and has been gradually applied to the domestic orthopedics clinic.

This article retrospectively reviews patients who underwent first total knee arthroplasty in our hospital from April 2020 to October 2020 from the aspects of perioperative blood loss and surgical field clarity, postoperative pain, functional rehabilitation and complications. Analyze the clinical effects of Pneumatic tourniquet and sterile exsanguination silicone tourniquet to provide references for the selection and application of tourniquets in knee arthroplasty surgery.

1 Materials and methods

1.1 General information

A total of 52 patients were enrolled, including 7 males and 44 females; they were 50-75 years old. Divided into two groups according to the sequence study method, of which 25 cases (20 cases of one knee, 5 cases of double knees, a total of 30 knees) used sterile exsanguination silicone tourniquet, 27 cases (24 cases of one knee, 3 cases of double knees, A total of 30 knees) Use pneumatic tourniquet. There was no statistically significant difference in general information between the two groups before operation ($P>0.05$, see Table 1).

Inclusion criteria: (1) Age 50-75 years; (2) Unilateral total knee arthroplasty or bilateral knee arthroplasty for the first time, such as bilateral knee arthroplasty surgery, the same method of exsanguination and tourniquet was used for both operations, and the interval between two operations is 10 days.

Exclusion criteria: (1) history of knee surgery; (2) open trauma of lower extremities; (3) abnormal blood coagulation or long-term use of anticoagulant drugs, blood system diseases; (4) deep vein thrombosis of lower extremities, pulmonary embolism, cerebral embolism, Myocardial infarction, cerebral infarction, etc.; (5) Limb infection or malignant transformation or edema; (6) History of peripheral nerve and vascular disease; (7) Third-grade hypertension, which cannot be effectively controlled.

Table 1 Comparison of general information of the two groups of patients

Group	n	Number of TKA (cases)		Gender (cases)		Age (years)	BMI (kg/m ²)	HCT (%)	Preoperative hemoglobin (g/L)
		Bilate ral	Unilat eral	M	F				
Sterile elastic tourniquet	25	5	20	3	21	65.36±4.92	28.02±4.05	38.31±3.55	128.12±11.72
Pneumatic tourniquet	27	3	24	4	23	65.26±6.48	26.22±2.95	36.93±2.95	122.26±10.70
t value /X ² value		0.79		0.11		0.06	1.55	1.53	1.88
P value		0.38		0.74		0.95	0.13	0.13	0.07

1.2 Surgical methods

All patients received the same perioperative treatment strategy: primary total knee arthroplasty, pain control and rehabilitation exercises. The operation was performed under general anesthesia under tracheal intubation and was completed by the same chief surgeon. The bone cement artificial joint prosthesis was used, the knee joint was approached centrally, and the patella was routinely preserved. For patients who need bilateral knee arthroplasty surgery, they usually perform rehabilitation exercises for 10 days after the surgery on one knee joint, and perform the surgery on the contralateral knee joint.

Multimodal analgesia was used: celecoxib (200 mg, Bid) was taken orally 2 days before surgery, and femoral nerve block (0.2% ropivacaine, 20 mL) was preoperatively guided by ultrasound. The application of hemostatic drug tranexamic acid: 30 minutes before cutting the skin, intravenous infusion of tranexamic acid 1.0g (0.25g/5mL); when the joint capsule is sutured, the joint cavity is infused with tranexamic acid solution (tranexamic acid 1.0 g + Ropivacaine 20mL+Methylprednisolone sodium succinate 40mg for injection, diluted with normal saline for a total of 100mL); while closing the incision, intravenous infusion of tranexamic acid 1.0 g. Antibacterial drugs were routinely given to prevent infection.

In the exsanguination silicone tourniquet group, the model and specification of the silicone tourniquet should be selected according to the patient's blood pressure, the length of the affected limb (the length from the toe or finger to the placement), and the limb circumference of the placement before the operation. After disinfection and draping, open the double-layer sterile packaging (ethylene oxide sterilization), take out the sterile exsanguination silicone tourniquet, put it in from the toe, pulling the rope slowly upwards along the direction of the limb to the placement (near the groin). In the pneumatic tourniquet group, the pneumatic tourniquet is tied to the upper 1/3 of the thigh. Before the tourniquet is inflated, raise the affected limb or use an elastic bandage to exsanguination. The tourniquet pressure is 280~300mmHg, and the cuff width is about 11cm. In all operations, the intraoperative systolic blood pressure is controlled at 100~120mmHg, and the average arterial pressure is 70~80mmHg. The tourniquet was applied before the skin incision. After the joint capsule was sutured and the joint cavity was infused with tranexamic acid solution, the tourniquet was released and sutured layer by layer to close the incision. The drainage tube was placed according to the clinical situation, and the elastic bandage was used to compress the foot to the thigh after the operation.

1.3 Postoperative treatment

Postoperative ECG monitoring, oxygen inhalation for 6 hours, air pressure adjuvant therapy on both sides of the calf, anticoagulant therapy was started 6-8 hours postoperatively, and antibiotics were given to prevent infection within 24 hours postoperatively. Self-controlled analgesia pump (100mL, drip rate 2mL/h) was used in the first 2 days after surgery, and intravenous or oral non-steroidal drugs and weak opioids were continuously administered for analgesia until discharge. Daily local physical cooling of the wound, infrared therapy, quadriceps isometric contraction exercise, ankle dorsiflexion and toe flexion exercises. On the second day after the operation, they started walking exercises with weight-bearing activities, as well as knee extension and knee bending exercises with full joint range of motion.

1.4 Evaluation Index

The basic data of all patients, such as gender, age, body mass index (BMI), were recorded. According to the weight change of the gauze piece during the operation and the volume change of the flushing bottle, the apparent blood loss was calculated. Detect the hemoglobin level and hematocrit of the patients before and after the operation, and calculate the red blood cell volume and total blood loss according to the Gross[8] linear equation and the Nadler formula[9].

Main indicators: Record intraoperative blood loss before the tourniquet relaxes, total blood loss, intraoperative visual field clarity VAS score [10], tourniquet use time and operation time.

Secondary indicators: (1) The visual analogue scale (VAS) was used to evaluate the muscle pain and knee joint pain at the tourniquet area; (2) The Lovett muscle strength grading standard was used to evaluate the postoperative muscle strength; (3) The patient was in Measure the range of motion (ROM) of knee joint in the supine position;

(4) Other indicators, such as the incidence of deep vein thrombosis, the demand of weak opioid (tramadol) and blood transfusion; (5) Record complications Such as skin damage at tourniquet site, swelling, nerve damage, incision swelling, incidence of infection, etc.

VAS score of Clarity (full score 10 points, 1 point poor field of view, 10 points best field of view), the scoring rules are as follows:

1-2 points: bleeding during skin incision, obvious bleeding throughout the operation; 3-4 points: significant blood oozing in the tissue, significant blood accumulation in the joint cavity; 5-6 points: tissue oozing blood, slight blood accumulation in the joint cavity, fuzzy and difficult to distinguish the structure of tissues such as muscle and fat; 7-8 points: blood in the joint cavity but no blood accumulation, tissue structure such as muscle and fat are visible, and blood oozing on the osteotomy surface; 9-10 points: no obvious bleeding during the whole operation. The tissue structure such as muscle and fat is clear and identifiable, and the osteotomy surface is clean.

1.5 Statistical processing

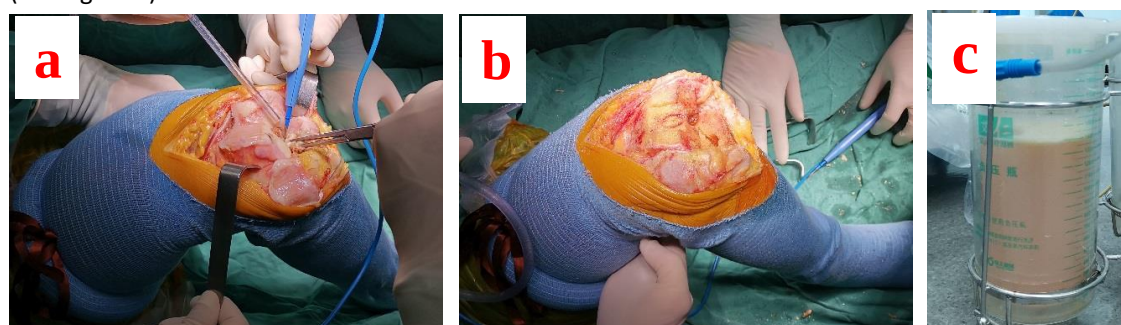
SPSS 21.0 software was used for statistical analysis. Measurement data were expressed as ($\bar{x} \pm s$), and independent sample Student's-t test was used; count data was expressed by rate, and χ^2 test was selected. $P < 0.05$ is considered statistically significant.

2 Results

2.1 Intraoperative application of tourniquet

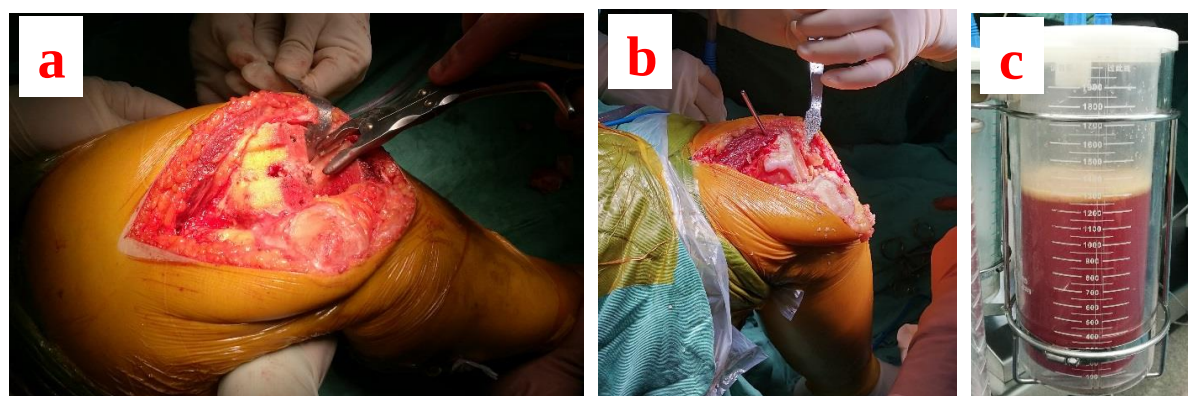
There were 25 cases (30 knees) in the sterile exsanguination silicone tourniquet group. The models were Large Orange 3 knees, Large Brown 5 knees, and X-Large black & white 22 knees (see Figure 1).

In the Pneumatic tourniquet group, there were 27 cases (30 knees). Because of its wide cuff and narrow operation area, the movement of the limbs is limited during the operation, and blood stains in the incision tissue are obvious (see Figure 2).



a) Open the joint capsule b) Osteotomy surface before flushing c) Flushing fluid after installing the prosthesis

Figure 1. Intraoperative situation with the use of sterile exsanguination silicone tourniquet



a) Open the joint capsule b) Osteotomy surface before flushing c) Flushing fluid after installing the prosthesis

Figure 2. Intraoperative situation with pneumatic tourniquet

2.2 Blood loss and clarity of vision

The statistical results of operation time, tourniquet usage time, intraoperative blood loss before tourniquet relaxation, total blood loss and hemoglobin reduction are shown in Table 2. In the exsanguination silicone tourniquet group, the application time of the tourniquet was (64.10±4.98) min, and the operation time was (73.03±6.11) min. These two indexes were significantly less than those of the pneumatic tourniquet group (the application time of the tourniquet was (70.73±13.13) min ($P=0.01$), the operation time was (79.33±14.57) min ($P=0.04$)). The intraoperative visual field clarity VAS score was (8.90±0.66) points in the exsanguination silicone tourniquet group, which was better than the Pneumatic tourniquet group (7.27±0.78) points ($P<0.01$). Comparing the blood loss before the tourniquet was released, the blood loss of the exsanguination silicone tourniquet group was (15.27±6.75) mL, which was significantly lower than that of the pneumatic tourniquet group (76.48±22.10) mL, $P<0.01$. There was no significant difference in the total blood loss, the hemoglobin level on the first and the third day after the operation, and the maximum reduction of hemoglobin between the two groups.

Table 2 Intraoperative clarity and blood loss

Group	Tourniquet time (min)	Operation time (min)	Surgical field clarity VAS score (points)	Blood loss before releasing the tourniquet (mL)	Hemoglo bin on 1st day post-op (g/L)	Hemoglo bin on 3rd day post-op (g/L)	Maximum hemoglobin reduction (g/L)	Total blood loss (mL)
Sterile elastic tourniquet	64.10±4.98	73.03±6.11	8.90±0.66	15.27±6.75	110.53±	100.87±	23.70±9.20	752.59±
					12.51	10.52		333.01
Pneumatic tourniquet	70.73±13.13	79.33±14.57	7.27±0.78	76.48±22.10	107.87±	98.37±1	22.30±9.53	788.98±
					10.87	1.19		329.98
t value / χ^2 value	-2.59	-2.18	8.71	-14.51	0.88	0.89	0.58	-0.43
P value	0.01	0.04	<0.01	<0.01	0.38	0.38	0.57	0.67

2.3 Pain score

2.3.1 Muscle pain score at the site of hemostasis

VAS scores were used to evaluate the muscle pain at the hemostatic site on the 1st, 2nd, 3rd, 5th day after operation and at the time of discharge. In the first 3 days after the operation, the thigh pain score of the hemostatic site in the exsanguination silicone tourniquet group was lower than that in the Pneumatic tourniquet group, and the difference was statistically significant (see Table 3).

Table 3 Comparison of the VAS scores of thigh muscle pain at the hemostatic site between the two groups ($\bar{x} \pm s$, points)

Group	1st day post-op	2nd day post-op	3rd day post-op	5th day post-op	On discharge
Sterile elastic tourniquet	2.23±0.73	1.73±0.58	1.23±0.77	1.03±0.76	0.73±0.83
Pneumatic tourniquet	2.70±0.70	2.03±0.49	1.63±0.72	1.10±0.40	0.73±0.78
t value	-2.53	-2.16	-2.08	-0.42	0.00

<i>P</i> value	0.01	0.04	0.04	0.68	1.00
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2.3.2 Knee pain score

In the first 3 days after operation, the pain VAS score of the exsanguination silicone tourniquet group was better than that of the Pneumatic tourniquet group, and the difference was statistically significant (see Table 4).

Table 4 Comparison of the VAS scores of knee joint pain between the two groups ($\bar{x} \pm s$, points)

Group	1st day post-op	2nd day post-op	3rd day post-op	5th day post-op	On discharge
Sterile elastic tourniquet	4.17 $\pm$ 0.70	3.67 $\pm$ 0.80	2.83 $\pm$ 0.53	2.34 $\pm$ 0.48	2.20 $\pm$ 0.41
Pneumatic tourniquet	4.67 $\pm$ 0.92	4.10 $\pm$ 0.76	3.27 $\pm$ 0.87	2.53 $\pm$ 0.57	2.30 $\pm$ 0.47
<i>t</i> value	-2.37	-2.15	-2.33	-1.37	-0.89
<i>P</i> value	0.02	0.04	0.02	0.18	0.38

2.4 Quadriceps muscle strength score

The Lovett score was used to evaluate quadriceps muscle strength. The quadriceps muscle strength scores in the exsanguination silicone tourniquet group were better than the Pneumatic tourniquet group in the first 3 days after operation, and the difference was statistically significant (see Table 5).

Table 5 Comparison of Lovett muscle strength scores between the two groups ($\bar{x} \pm s$, points)

Group	1st day post-op	2nd day post-op	3rd day post-op	5th day post-op	On discharge
Sterile elastic tourniquet	2.53 $\pm$ 0.63	2.97 $\pm$ 0.61	3.60 $\pm$ 0.50	4.31 $\pm$ 0.47	4.80 $\pm$ 0.41
Pneumatic tourniquet	2.07 $\pm$ 0.78	2.57 $\pm$ 0.57	3.30 $\pm$ 0.53	4.17 $\pm$ 0.46	4.57 $\pm$ 0.50
<i>t</i> value	2.54	2.60	2.25	1.18	1.97
<i>P</i> value	0.01	0.01	0.03	0.24	0.05

2.5 Knee joint range of motion

The patient was in the supine position, and the long-arm goniometer was used to measure the range of motion of the knee joint. In the first 3 days after the operation, the performance of the range of motion of the knee joint in the exsanguination silicone tourniquet group was better than that in the pneumatic tourniquet group (see Table 6).

Table 6 Comparison of knee joint range of motion between the two groups ($\bar{x} \pm s$, °)

Group	1st day post-op	2nd day post-op	3rd day post-op	5th day post-op	On discharge
Sterile elastic tourniquet	65.53 $\pm$ 18.47	76.30 $\pm$ 18.54	84.67 $\pm$ 18.29	92.76 $\pm$ 13.13	99.73 $\pm$ 10.05
Pneumatic tourniquet	57.07 $\pm$ 10.50	68.27 $\pm$ 10.14	77.03 $\pm$ 8.07	89.27 $\pm$ 11.25	97.50 $\pm$ 9.04
<i>t</i> value	2.18	2.08	2.09	1.10	0.91
<i>P</i> value	0.03	0.04	0.04	0.28	0.37

2.6 Postoperative complications

The incisions healed well in all patients, no infection and loosening of the prosthesis were found, and no skin damage was found at the hemostatic site. As the patient got out of bed, the affected limb often showed slight swelling, and no malignant swelling was found. The results of arteriovenous ultrasound of both lower extremities showed that deep vein thrombosis of lower extremity was mostly muscular calf vein thrombosis (MCVT). The incidence of exsanguination silicone tourniquet group was significantly lower than that of Pneumatic tourniquet group ($P=0.04$, see Table 7).

Table 7 Comparison of clinical indicators between the two groups [Example (%)]

Group	Intermuscular vein thrombosis	Postoperative blood transfusion	The need for tramadol after surgery
Sterile elastic tourniquet	4 (13.33)	1 (3.33)	9 (30.00)
Pneumatic tourniquet	11 (36.67)	1 (3.33)	11 (36.67)
X^2 value	2.80	0.00	0.30
P value	0.04	1.00	0.58

3 Discussion

The optimized application of tourniquet in TKA is an important part of perioperative management. As a new type of tourniquet, the sterile exsanguination silicone tourniquet has excellent exsanguination and hemostatic performance, and has a variety of models and specifications, which can meet the clinical needs of the personalized application of tourniquet. This article compares the clinical effects of Pneumatic tourniquet and exsanguination silicone tourniquet from the aspects of perioperative exsanguination and hemostatic performance, surgical field clarity, functional rehabilitation, complications, and provides strategies for the selection and optimization of tourniquets in TKA.

In terms of the clarity of the visual field during the operation, the joint capsule was opened during the operation of the exsanguination silicone tourniquet group, the worn cartilage is clearly visible, the muscle and fat tissue is dry, no blood stains, the osteotomy surface is dry during the operation, and there is no blood exudation, the blood color of the drainage bottle after the operation is lighter, and the blood loss is less throughout the operation. In the Pneumatic tourniquet group, the osteotomy surface oozes blood, the operation space is narrow and the tissue around the joint capsule is full of blood stains, the blood of the drainage bottle after the operation is darker, and there is more blood loss throughout the operation. From the intraoperative photos, it can be seen directly that the exsanguination and hemostatic performance of the exsanguination silicone tourniquet group is better than that of the Pneumatic tourniquet group. In this study, the VAS score was used to evaluate the clarity of the visual field during the operation of the two groups. The exsanguination silicone tourniquet group was better than the Pneumatic tourniquet group and the difference was statistically significant. The exsanguination silicone tourniquet has good exsanguination and hemostatic performance, and can provide a good operating environment for the surgeon. In order to further investigate the performance of exsanguination and hemostatic, we statistically analyzed the amount of blood loss before the intraoperative tourniquet was released. The exsanguination silicone tourniquet group was significantly less than the Pneumatic tourniquet group, and the difference was statistically significant, which can significantly reduce the intraoperative blood loss, which is helpful for intraoperative blood management. Blond et al. [11] thought that when elastic bandage or raising the affected limb to expel blood, the maximum amount of expelling blood was about 67%. Demirakale et al. [12] studies have shown that in TKA, The amount of blood expelled by the exsanguination silicone tourniquet reached 95%, which can reduce the blood transfusion rate and blood loss. In this study, the difference in total blood loss and blood transfusion rate between the two groups was not statistically significant, which may be related to the timing of the release of the tourniquet during surgery.

In terms of operation time, although it mainly relies on the surgeon's surgical skills, a good surgical field of vision can also help to improve the efficiency of the operation and save operation time [13, 14]. This study investigated

the use time of the tourniquet and the operation time, and the results showed that the exsanguination silicone tourniquet group was better than the Pneumatic tourniquet group, and the difference was statistically significant. The use of tourniquet has a certain impact on postoperative rehabilitation. It directly or indirectly affects the soft tissues of the lower limbs, such as nerves, blood vessels and muscles. And it ultimately affects the functional recovery of the affected limbs. Among them, pain is one of the common symptoms after TKA, the skin and deep tissues can be squeezed to cause limb pain, and tourniquet-induced ischemia/reperfusion injury, which will aggravate limb pain and swelling. Liao Yunjian et al. [15] showed that the duration of tourniquet compression is the determinant of the degree of muscle and soft tissue damage, rather than ischemia-reperfusion injury. The results of this study showed that the VAS score of thigh pain at the tourniquet site in the first 3 days after the operation of the exsanguination silicone tourniquet group was significantly lower than that of the Pneumatic tourniquet group, and the difference was statistically significant. Demirakale et al. [12] showed that in terms of the incidence of pain and analgesia requirements after TKA, the exsanguination silicone tourniquet is better than the Pneumatic tourniquet. The wider the tourniquet cuff and the higher the pressure, the more the tourniquet damages the limbs and the more significant the pain [16, 17]. The wider the cuff can easily cause myofascial deformation and cause pain. The narrow exsanguination silicone tourniquet can be worn to the groin, which can reduce the squeeze of the myofascial membrane, thereby reducing pain.

The damage of the tourniquet to the soft tissues of the lower limbs is also manifested as an impact on the function of the quadriceps muscle, which will affect the early recovery after the operation. The influence of tourniquet on postoperative muscle strength has not yet reached a consistent conclusion. Studies have shown that within 3 months after TKA, the quadriceps muscle strength of the group without tourniquet is better than that of the group with tourniquet [18]. However, Sun Xiao et al. [19] measured quadriceps muscle strength by muscle strength level, and did not find that the use of tourniquets would have an effect on muscle strength after TKA. In this study, the Lovett muscle strength score was used to measure the strength of the quadriceps muscle. The results showed that the quadriceps muscle strength of the exsanguination silicone tourniquet group was better than the pneumatic tourniquet group on the first 1, 2 and 3 days after the operation, and the difference was statistically significant. In TKA surgery, the weakening of quadriceps muscle strength is multifactorial, which may be due to direct compression injury of the tourniquet or ischemia/reperfusion [14, 20]. The recovery of quadriceps muscle strength after surgery is conducive to the early recovery of knee joint function after surgery, and can also be used as an index to predict long-term joint function. In the early postoperative period, the mobility of the knee joint in the exsanguination silicone tourniquet group was better than that in the Pneumatic group, which was closely related to the quadriceps muscle strength after the operation. In the first month after surgery, the tourniquet has a greater impact on the range of motion of the knee joint, but it cannot affect the long-term range of motion of the knee joint after the operation [21].

With the popularization of the concept of accelerated rehabilitation and everyone's attention to the prevention of venous thrombosis after orthopedic surgery, the current incidence of deep vein thrombosis in the lower extremities after TKA has been greatly reduced, and the incidence of symptomatic deep vein thrombosis in the lower extremities is 3.36% [22]. In this study, the incidence of muscular calf vein thrombosis in the exsanguination silicone tourniquet group was significantly lower than that in the Pneumatic tourniquet group ($p < 0.05$). Any cause of venous injury, venous blood flow stagnation, and hypercoagulable state of blood are risk factors for venous thromboembolism. TKA surgery does not completely expel blood, which can easily cause blood stasis in the lower limbs, which can induce thrombosis [11]. When the traditional elastic bandage is used to expel blood, the blood is not completely expelled and the blood is stagnant. At the same time, the calf gastrocnemius muscle is squeezed unevenly by the expelling bandage, which causes venous damage and further aggravates the formation of thrombosis in the lower limbs. The exsanguination silicone tourniquet has a better hemostatic effect, and there is less residual blood in the lower limbs, which is not easy to cause blood stasis, thereby reducing the incidence of thrombosis. This study is consistent with the report of Demirakale et al. [12] that the exsanguination silicone

tourniquet can reduce the incidence of thrombosis after TKA.

In terms of preventing infection, this study did not find any cases of infection. However, studies have shown [12, 23] that the exsanguination silicone tourniquet can reduce the infection rate after TKA. The possible reason is that the exsanguination silicone tourniquet is a sterile product (ethylene oxide disinfection), and the Pneumatic tourniquet is non-sterile, and can be used repeatedly. Thompson et al. [24] and other studies have shown that the Pneumatic tourniquet has microbial colonization, and bacteria can easily reach the wound through the sterile textile, increasing the risk of infection.

In total knee arthroplasty surgery, compared with the Pneumatic tourniquet, the exsanguination silicone tourniquet is more adequate to dispel blood, which can obtain a clear surgical field of vision, reduce blood loss, improve surgical efficiency, and shorten surgical time. In the early postoperative period, the exsanguination silicone tourniquet can reduce the crushing injury to the limbs, reduce the pain of the thigh, help the recovery of quadriceps muscle strength and knee joint mobility, accelerate the rehabilitation of patients, and improve patient satisfaction. The shortcomings of this study are that it is only limited to the follow-up of patients during hospitalization, and the lack of long-term follow-up data after surgery, which needs further study..

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驱血止血弹性束紧套环在初次全膝关节置换术中应用的疗效

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摘要:目的 对比驱血止血弹性束紧套环与气囊止血带在初次全膝关节置换术中的临床疗效以及对术后康复的影响。方法 回顾2020年4月至2020年10月于我科行初次全膝关节置换的52例患者,并采用序列研究方法分为两组。4~7月符合条件的25例患者(20例单膝,5例双膝,共30膝)纳入驱血止血弹性束紧套环组,8~10月符合条件的27例患者(24例单膝,3例双膝,共30膝)纳入气囊止血带组。统计术中止血带放松前失血量、总失血量、手术时间、止血带使用时间、输血率、曲马多需求比率、血栓发生率与膝关节活动度。疼痛视觉模拟评分法(visual analogue scale, VAS)用于评价术中视野清晰度、术后大腿疼痛与膝关节疼痛,采用Lovett评分评价股四头肌肌力。结果 相较于气囊止血带,驱血止血环可降低术中止血带放松前的失血量($P < 0.01$),提供良好的视野清晰度($P < 0.01$),但两组总失血量比较差异无统计学意义($P = 0.67$)。驱血止血环组止血带使用时间(64.10 ± 4.98)min,手术时间(73.03 ± 6.11)min,深静脉血栓发生率13.33%;气囊止血带组止血带使用时间(70.73 ± 13.13)min,手术时间(79.33 ± 14.57)min,深静脉血栓发生率36.67%,两组比较差异有统计学意义($P = 0.01, P = 0.04, P = 0.04$)。术后早期,对于止血部位大腿疼痛、膝关节疼痛、股四头肌肌力与膝关节活动度等方面,驱血止血环具有一定临床优势。其他指标如输血率、曲马多需求比率均没有差异。结论 驱血止血环可减少术中失血量,提供清晰的手术视野,缩短止血带使用时间与手术时间,提升手术效率。术后早期,驱血止血环可减少对肢体的挤压损伤,降低大腿疼痛,利于股四头肌肌力与膝关节活动度的恢复,加速患者康复,提升患者满意度。

关键词:全膝关节置换;驱血止血弹性束紧套环;气囊止血带

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Clinical Efficacy of Sterile Exsanguination Silicone Tourniquets on Primary Total Knee Arthroplasty

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Abstract: Objective To compare the clinical efficacy on the accelerated recovery of postoperative patients in Primary TKA with pneumatic tourniquet and a sterile exsanguination silicone tourniquet. **Methods** In total 50 patients undergoing primary total knee arthroplasty were retrospectively studied from April to October in 2020. With the design of sequential trial, in total 25 patients (20 cases of single knee, 5 cases of double knee, a total of 30 knees) qualified were assigned to group sterile exsanguination silicone tourniquet from April to July; total 27 patients (24 cases of single knee, 3 cases of double knees, a total of 30 knees) were included into the group of pneumatic tourniquets. Intraoperative blood loss before releasing tourniquet, total blood loss, surgical time, tourniquet use time, allogeneic blood transfusion rates, incidence of deep venous thrombosis and knee active range of motion (ROM) were summarized. Visual clarity of surgical field, thigh pain and knee pain were measured by the Visual Analog Scale. Lovett muscle strength classification standard was adopted to evaluate quadriceps strength. **Results** Compared to pneumatic tourniquet, the sterile exsanguination silicone tourniquet group could obviously decrease the blood loss before releasing tourniquet ($P < 0.01$). Meanwhile, the excellent visual clarity of surgery field could be acquired in sterile exsanguination silicone tourniquet group with Score ($P < 0.01$). However, there is no significant difference in total blood loss between the two groups ($P = 0.67$). In sterile exsanguination silicone tourniquet group, tourniquet use time (64.10 ± 4.98) min, operation time (73.03 ± 6.11) min, the incidence of deep vein thrombosis was 13.33%. In pneumatic tourniquet group, tourniquet use time (70.73 ± 13.13) min, operation time (79.33 ± 14.57) min, the incidence of deep vein thrombosis was 36.67%. The difference between the two groups was statistically significant ($P = 0.01, P = 0.04, P = 0.04$). In the postoperative early stage, the thigh VAS score, knee VAS score, quadriceps strength and knee active range of motion in sterile exsanguination silicone tourniquet group were much better than those in pneumatic tourniquet group. There was no significant difference for allogeneic blood transfusion rates and tramadol demand rate between groups. **Conclusion** A sterile

孙永强,刘国杰,李帅垒,等.驱血止血弹性束紧套环在初次全膝关节置换术中应用的疗效[J].实用骨科杂志,2021,27(3):199-204.

exsanguination silicone tourniquet is an effective method to reduce intraoperative blood loss and provide much visual clarity of surgery field, which is beneficial to improve surgical efficiency and decrease tourniquet use time and and surgical time. In the postoperative early stage, compared to pneumatic tourniquet, sterile exsanguination silicone tourniquet could reduce the crush injury and thigh pain of tourniquet, improve quadriceps strength and knee active range of motion, which is beneficial to faster recovery for patient as well as increasing patient satisfactions.

Key words: total knee arthroplasty; sterile exsanguination silicone tourniquet; pneumatic tourniquet

全膝关节置换术(total knee arthroplasty, TKA)是膝关节最常见手术之一,用于治疗终末期关节炎以及其他相关膝关节疾病,可快速、有效改善关节功能,提高患者生活质量^[1]。随着加速康复理念的应用,临床逐渐注重手术安全性、康复速度与患者满意度^[2-3]。止血带广泛用于术中止血及改善手术视野,可创造干净的截骨面环境,利于骨面-骨水泥-假体的固定^[4]。气囊止血带的使用仍存在一些弊端,如大腿肿胀、皮肤水疱、肌肉萎缩、神经损伤、深静脉血栓,延缓了康复过程,降低了患者满意度等^[5]。围手术期的精细化管理对止血带的使用提出了更高的要求。TKA术中是否使用止血带、止血带的使用方式、安全压力与时限等问题仍存在争议,且对术后康复情况的影响仍需进一步研究。驱血止血弹性束紧套环(以色列生产),具有良好的驱血与止血功能,作为一种新理念与技术被提出,在国外已广泛用于创伤骨科、膝关节置换、手足外科、四肢血管外科与神经外科等^[6-7],现已逐步应用至国内骨科临床。

本文从围手术期失血情况与术野清晰度、术后疼痛、功能康复及并发症等方面,回顾性回顾2020年4月至2020年10月于我院行初次全膝关节置换术的患者,分析气囊止血带与驱血止血弹性束紧套环的临床疗效,为膝关节置换手术中止血带的选择与应用提供参考。

1 资料与方法

1.1 一般资料 共纳入患者52例,男7例,女44例;年龄50~75岁。按序列研究法分为两组,其中25例(20例单膝,5例双膝,共30膝)使用驱血止血弹性束紧套环,27例(24例单膝,3例双膝,共30膝)使用气囊止血带。术前两组一般资料比较,差异无统计学意义($P>0.05$,见表1)。

纳入标准:(1)年龄50~75岁;(2)首次行单侧全膝关节置换术或双侧膝关节置换术,如双侧膝关节手术,两次手术均使用相同的驱血止血方式,且两次手术间隔期为10 d。排

除标准:(1)膝关节手术史;(2)下肢开放性外伤;(3)凝血功能异常或长期服用抗凝药物,血液系统疾病;(4)下肢深静脉血栓,肺栓塞、脑栓塞,心梗、脑梗等;(5)肢体感染或恶变或水肿;(6)有周围神经、血管疾病史;(7)三级高血压,未能有效控制。

1.2 手术方法 所有患者接受相同的围手术期治疗策略:初次全膝关节置换术、疼痛控制和康复锻炼。手术在气管插管下全麻进行,由同一主任医生完成,采用骨水泥型人工关节假体,膝关节正中入路,髌骨常规保留。对于需接受双侧膝关节置换的患者,通常在—侧膝关节手术后,康复锻炼10 d,接受对侧膝关节手术。

采用多模式镇痛:术前2 d口服塞来昔布(200 mg, Bid),术前超声引导下股神经阻滞(0.2%罗哌卡因, 20 mL)。止血药物氨甲环酸的应用:切皮前30 min静脉滴注氨甲环酸1.0 g(0.25 g/5 mL);关节囊缝合时,关节腔灌注氨甲环酸溶液(氨甲环酸1.0 g+罗哌卡因20 mL+注射用甲泼尼龙琥珀酸钠40 mg,用生理盐水稀释共100 mL);关闭切口时,静脉滴注氨甲环酸1.0 g。常规给予抗菌药物预防感染。

驱血止血环组,术前根据患者血压、患肢长度(脚趾或手指至阻断部位的长度)、阻断部位肢体周长,选择合适的驱血止血环型号与规格。在消毒与铺巾后,打开双层无菌包装的驱血止血弹性束紧套环(环氧乙烷灭菌),从脚趾套入,用拉绳沿着肢体方向(轴向牵引)缓慢向上拉伸直至止血部位(腹股沟附近)。气囊止血带组,气囊止血带绑缚在大腿上上1/3处,止血带充气前抬高患肢或用弹力绷带驱血,止血带压力280~300 mm Hg,袖带宽度约11 cm。所有手术,术中收缩压控制在100~120 mm Hg,平均动脉压70~80 mm Hg。止血带从切皮前开始应用,直至关节囊缝合并关节腔内灌注氨甲环酸溶液后释放,然后逐层缝合关闭切口。根据临床情况放置引流管,术毕自足部至大腿使用弹力绷带加压包扎。

表1 两组患者一般资料比较

组别	n	TKA数(例)		性别(例)		年龄(岁)	BMI(kg/m ²)	HCT(%)	术前血红蛋白(g/L)
		双膝	单膝	男	女				
驱血止血环组	25	5	20	3	21	65.36±4.92	28.02±4.05	38.31±3.55	128.12±11.72
气囊止血带组	27	3	24	4	23	65.26±6.48	26.22±2.95	36.93±2.95	122.26±10.70
t值/χ ² 值		0.79		0.11		0.06	1.55	1.53	1.88
P值		0.38		0.74		0.95	0.13	0.13	0.07

1.3 术后处理 术后心电监护,氧气吸入6 h,双侧小腿气压辅助治疗,术后6~8 h开始给予抗凝药物治疗,术后24 h内给予抗菌药物预防感染。术后前2天自控式镇痛泵(100 mL,滴速2 mL/h)及持续给予静脉或口服非甾体药物、弱阿片类药物镇痛直至出院。每日伤口局部物理降温、红外治疗,股四头肌等长收缩锻炼、踝关节背伸与趾屈锻炼,次日开始下地负重活动行走锻炼,以及全关节活动度的伸膝、屈膝锻炼。

1.4 评价指标 记录所有患者基本资料,如性别、年龄、身体质量指数(body mass index, BMI)等。根据术中纱布块的重量变化、冲洗瓶体积变化计算术中显性失血量。检测患者术前与术后血红蛋白水平、红细胞比容,根据 Gross^[8]线性方程和 Nadler 公式^[9]计算红细胞容量及总失血量。

主要指标:记录术中止血带放松前失血量、总失血量、术中视野清晰度 VAS 评分^[10]、止血带使用时间、手术时间次级指标:(1)采用疼痛视觉模拟评分法(visual analogue scale, VAS)评价止血带部位肌肉疼痛、膝关节疼痛;(2)应用 Lovett 肌力分级标准评价术后肌力;(3)患者于仰卧位测量膝关节活动度(range of motion, ROM);(4)其他指标,如深静脉血栓及发生率、弱阿片类药物(曲马多)的需求、输血情况;(5)记录并发症如止血部位皮肤损伤、肿胀、神经损伤、切口红肿、感染发生率等。

清晰度 VAS 评分(满分为10分,1分视野差,10分视野

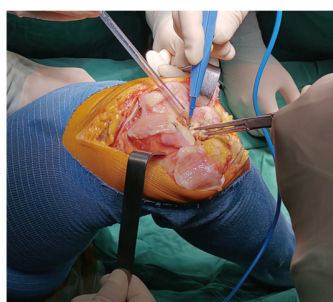
最优),评分细则如下:1~2分,皮肤切开时出血,手术全程出血明显;3~4分,组织显著渗血,关节腔内显著积血;5~6分,组织渗血,关节腔内轻微积血,肌肉、脂肪等组织结构模糊;7~8分,关节腔内渗血但无积血,肌肉、脂肪等组织结构可见,截骨面渗血;9~10分,手术全程无明显渗血,肌肉、脂肪等组织结构清晰可辨,截骨面干净。

1.5 统计学处理 统计分析使用 SPSS 21.0 软件,计量资料采用 $(\bar{x} \pm s)$ 表示,采用独立样本 Student's *t* 检验;计数资料用率表示,选择 χ^2 检验, $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 止血带的术中应用 驱血止血环组共25例30膝,驱血止血环型号:大号橙色3膝,大号棕色5膝,加大号黑白色22膝(见图1)。气囊止血带组27例30膝,由于其袖带较宽,手术区域较窄,术中肢体活动度受限,切口组织血渍明显(见图2)。

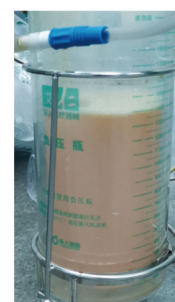
2.2 失血量与视野清晰度 手术时间、止血带使用时间、术中止血带放松前失血量、总失血量与血红蛋白减少值等统计结果见表2。驱血止血环组止血带应用时间(64.10 ± 4.98) min 与手术时间(73.03 ± 6.11) min 明显少于气囊止血带组的止血带应用时间(70.73 ± 13.13) min ($P = 0.01$)与手术时间(79.33 ± 14.57) min ($P = 0.04$)。术中视野清晰度 VAS 比较,驱血止血环组(8.90 ± 6.11)分,优于气囊止血带组(7.27 ± 0.78)分 ($P < 0.01$)。止血带放松前失血量比较,驱血止血环



a 穿戴驱血止血环后,打开关节囊

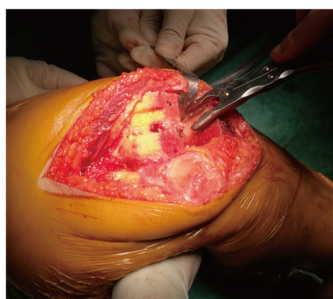


b 冲洗前的截骨面



c 安装假体后冲洗液

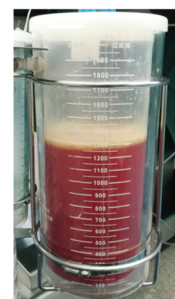
图1 驱血止血环术中应用情况



a 气囊止血带下打开关节囊



b 冲洗前切口组织血渍明显



c 安装假体后冲洗液

图2 气囊止血带术中应用情况

组(15.27 ± 6.75)mL,显著少于气囊组的(76.48 ± 9.53)mL, $P < 0.01$ 。两组总失血量、术后第1天与第3天血红蛋白水平,以及血红蛋白最大减少值的比较,差异均无统计学差异。

2.3 疼痛评分

2.3.1 止血部位肌肉疼痛评分 分别于术后第1天、2天、3天、5天与出院时,采用VAS评分评价止血部位肌肉疼痛。术后前3天,驱血止血环组止血部位大腿疼痛评分低于气囊止血带组,且差异具有统计学意义(见表3)。

2.3.2 膝关节疼痛评分 术后前3天,驱血止血环组的疼痛VAS评分优于气囊组,且差异具有统计学意义(见表4)。

2.4 股四头肌肌力评分 采用Lovett评分评价股四头肌肌

力,术后前3天驱血止血环组股四头肌肌力评分优于气囊止血带组,且差异具有统计学意义(见表5)。

2.5 膝关节活动度 患者于仰卧位,采用长臂测角器测量膝关节活动度,术后前3天驱血止血环组较膝关节活动度表现良好(见表6)。

2.6 术后并发症发生情况 患者术后切口均愈合良好,未发现感染及假体松动,止血部位未发现皮肤损伤等。随着患者下床活动,患肢常出现轻微肿胀,均未发现恶性肿瘤。双下肢动静脉超声结果表明,下肢深静脉血栓多为肌间静脉血栓。驱血止血环组发生率显著低于气囊止血带组($P = 0.04$, 见表7)。

表2 两组术中清晰度与失血情况比较($\bar{x} \pm s$)

组别	止血带时间 (min)	手术时间 (min)	术野清晰度 VAS评分 (分)	松开止血带 前失血量 (mL)	术后第1天 血红蛋白 (g/L)	术后第3天 血红蛋白 (g/L)	血红蛋白 最大减少值 (g/L)	总失血量 (mL)
驱血止血环组	64.10 ± 4.98	73.03 ± 6.11	8.90 ± 0.66	15.27 ± 6.75	110.53 ± 12.51	100.87 ± 10.52	23.70 ± 9.20	752.59 ± 333.01
气囊止血带组	70.73 ± 13.13	79.33 ± 14.57	7.27 ± 0.78	76.48 ± 22.10	107.87 ± 10.87	98.37 ± 11.19	22.30 ± 9.53	788.98 ± 329.98
t 值/ χ^2 值	-2.59	-2.18	8.71	-14.51	0.88	0.89	0.58	-0.43
P 值	0.01	0.04	<0.01	<0.01	0.38	0.38	0.57	0.67

表3 两组止血部位大腿肌肉疼痛 VAS 评分比较($\bar{x} \pm s$, 分)

组别	术后第1天	术后第2天	术后第3天	术后第5天	出院时
驱血止血环组	2.23 ± 0.73	1.73 ± 0.58	1.23 ± 0.77	1.03 ± 0.76	0.73 ± 0.83
气囊止血带组	2.70 ± 0.70	2.03 ± 0.49	1.63 ± 0.72	1.10 ± 0.40	0.73 ± 0.78
t 值	-2.53	-2.16	-2.08	-0.42	0.00
P 值	0.01	0.04	0.04	0.68	1.00

表4 两组膝关节疼痛 VAS 评分比较($\bar{x} \pm s$, 分)

组别	术后第1天	术后第2天	术后第3天	术后第5天	出院时
驱血止血环组	4.17 ± 0.70	3.67 ± 0.80	2.83 ± 0.53	2.34 ± 0.48	2.20 ± 0.41
气囊止血带组	4.67 ± 0.92	4.10 ± 0.76	3.27 ± 0.87	2.53 ± 0.57	2.30 ± 0.47
t 值	-2.37	-2.15	-2.33	-1.37	-0.89
P 值	0.02	0.04	0.02	0.18	0.38

表5 两组 Lovett 肌力评分比较($\bar{x} \pm s$, 分)

组别	术后第1天	术后第2天	术后第3天	术后第5天	出院时
驱血止血环组	2.53 ± 0.63	2.97 ± 0.61	3.60 ± 0.50	4.31 ± 0.47	4.80 ± 0.41
气囊止血带组	2.07 ± 0.78	2.57 ± 0.57	3.30 ± 0.53	4.17 ± 0.46	4.57 ± 0.50
t 值	2.54	2.60	2.25	1.18	1.97
P 值	0.01	0.01	0.03	0.24	0.05

表6 两组膝关节活动度比较($\bar{x} \pm s$, °)

组别	术后第1天	术后第2天	术后第3天	术后第5天	出院时
驱血止血环组	65.53 ± 18.47	76.30 ± 18.54	84.67 ± 18.29	92.76 ± 13.13	99.73 ± 10.05
气囊止血带组	57.07 ± 10.50	68.27 ± 10.14	77.03 ± 8.07	89.27 ± 11.25	97.50 ± 9.04
t 值	2.18	2.08	2.09	1.10	0.91
P 值	0.03	0.04	0.04	0.28	0.37

表7 两组临床指标比较[例(%)]

组别	肌间静脉血栓	术后输血情况	术后对曲马多的需求
驱血止血环组	4(13.33)	1(3.33)	9(30.00)
气囊止血带组	11(36.67)	1(3.33)	11(36.67)
χ^2 值	2.80	0.00	0.30
P 值	0.04	1.00	0.58

3 讨 论

TKA术中止血带的优化应用,是围手术期管理的一项重要内容。驱血止血弹性束紧套环作为一种新型驱血止血工具,具有无菌性、卓越的驱血与止血性能,且有多种型号与规格,可满足临床对止血带个性化应用的需求。本文从围手术期驱血与止血性能、术野清晰度、功能康复、并发症等方面,对比研究气囊止血带与驱血止血环的临床疗效,为TKA术中止血带的选择与优化提供策略。

在术中视野清晰度方面,驱血止血环组术中打开关节囊,磨损软骨清晰可见,肌肉脂肪组织干燥,无血渍;术中截骨面干燥、无血液渗出;术后引流瓶冲洗液血色较淡,手术全程失血较少。气囊止血带组,截骨面渗血,手术空间较窄且关节囊周围组织充满血渍;术后引流瓶血液颜色较深,手术全程失血较多。从术中照片可直观看出驱血止血环组的驱血止血性能优于气囊止血带组。本研究同时采用VAS评分评价两组术中视野清晰度,驱血止血环组优于气囊止血带组且差异具有统计学意义。驱血止血环驱血与止血性能较好,可为术者提供良好的手术环境。为进一步考察驱血与止血性能,我们统计分析了术中止血带放松前的失血量,驱血止血环组显著少于气囊组,且差异具有统计学意义,可显著降低术中失血量,有助于术中血液管理。Blond等^[11]认为弹力绷带或抬高患肢驱血时,最大驱血量约为67%。Demirkale等^[12]研究表明,在TKA术中,驱血止血环驱血量达到95%,可降低输血量及失血量。本研究中两组的总失血量与输血量差异均没有统计学意义,可能与手术中止血带释放的时机有一定关系。

在手术时间方面,虽然主要依赖医生的手术技巧,但良好的手术视野,也有助于提升手术效率,可节约手术时间^[13-14]。本研究考察了手术中止血带使用时间与手术时间,结果表明驱血止血环组均优于气囊止血带组,且差异具有统计学意义。止血带的使用对术后康复存在一定影响,通过直接或间接作用对下肢神经、血管、肌肉等软组织产生影响,最终影响术后患肢的功能恢复。其中,疼痛是TKA术后常见的症状之一,皮肤和深部组织受到挤压后均可导致肢体疼痛,以及止血带引起的缺血/再灌注损伤,则会加重肢体疼痛

与肿胀。廖云健等^[15]研究表明,止血带压迫时长是肌肉软组织损伤程度的决定因素,而非缺血再灌注损伤。本研究结果显示,驱血止血环组术后前3天止血带部位大腿疼痛VAS评分明显低于气囊止血带组,且差异具有统计学意义。Demirkale等^[12]研究表明TKA术后疼痛发生率及镇痛需求方面,驱血止血环优于气囊止血带。止血带袖带越宽且压强越高,止血带对肢体损伤越大,疼痛越显著^[16-17],袖带较宽,易引起肌筋膜形变,引发疼痛。驱血止血环较窄可穿戴至腹股沟处,可减少对肌筋膜的挤压,从而减少疼痛。

止血带对下肢软组织的损伤还表现为对股四头肌功能的影响,将影响术后早期康复。止血带对术后肌力的影响,尚未得到一致结论。有研究表明,TKA术后3个月内,不使用止血带组股四头肌肌力优于使用止血带组^[18]。但孙啸等^[19]通过肌力等级来衡量股四头肌肌力,没有发现止血带的使用会对TKA术后肌力产生影响。本研究采用Lovett肌力评分衡量股四头肌肌力,结果显示术后第1、2与3天,驱血止血环组股四头肌肌力优于气囊止血带组,且差异具有统计学意义。在TKA手术中,股四头肌肌力减弱是多因素的,其中可能因为止血带的直接挤压损伤或缺血/再灌注^[14,20]。术后股四头肌力的恢复有利于术后早期膝关节功能恢复,也可作为预测长期关节功能的指标。术后早期,驱血止血环组膝关节活动度优于气囊组,其与术后股四头肌肌力有很大关联。在术后早期1个月内,止血带对膝关节活动度有较大影响,但不会长期影响术后膝关节活动度^[21]。

随着加速康复理念的普及以及大家对骨科手术后静脉血栓预防的重视,目前TKA术后下肢深静脉血栓发生率已大大降低,有症状的下肢深静脉血栓发生率为3.36%^[22]。本研究中驱血止血环组肌间静脉血栓发生率显著低于气囊止血带组($P<0.05$)。任何引起静脉损伤、静脉血流停滞及血液高凝状态的原因都是静脉血栓栓塞症的危险因素。TKA手术驱血不彻底,极易引起下肢血液瘀滞,从而诱发血栓形成^[11]。采用传统弹力绷带驱血时,驱血不彻底,血液瘀滞,同时小腿腓肠肌受驱血绷带挤压力不均匀,引发静脉损伤,则进一步加剧下肢血栓的形成。驱血止血环驱血效果较好,下肢残留血液较少,不易引起血液瘀滞,从而可降低血栓发生率。本研究与Demirkale等^[12]报道一致,驱血止血环可降低TKA术后血栓发生率。

在预防感染方面,本研究虽没有发现感染病例。但有研究表明^[12,23],驱血止血环可降低TKA术后感染率,可能因为驱血止血环为无菌产品(环氧乙烷消毒),而气囊止血带是非无菌的,且反复使用。Thompson等^[24]研究表明气囊止血带存在微生物定植,细菌很容易通过无菌纺织物达到伤

口,增加感染风险。

在人工膝关节置换术中,相较于气囊止血带,驱血止血环驱血更充分,可获得清晰的手术视野,降低血液损失,提高手术效率,缩短手术时间。术后早期,驱血止血环可减少对肢体的挤压损伤,降低大腿疼痛,利于股四头肌肌力与膝关节活动度的恢复,加速患者康复,提升患者满意度。本研究的不足之处在于仅局限于患者住院期间的随访,缺乏术后长期随访的数据,需进一步研究。

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The effect of tourniquet type and thigh conicity on the length of hamstring autograft

Mehmet Faruk Çatma¹ and Alper Öztürk¹

Abstract

Purpose: We studied the effect of using wide contoured pneumatic tourniquet (PT) versus ultra-narrow sterile exsanguination tourniquet (SET) on the length of hamstring autograft for anterior cruciate ligament (ACL) reconstruction in patients with tubular and conical thighs. **Methods:** Fifty-eight patients undergoing ACL reconstruction between 2012 and 2013 were assigned to either SET or PT groups. We measured the tendon graft length and width as well as the patients' height, weight, and thigh circumference of 10 cm proximal to the patella and the distance from the anterior–superior iliac spine to the medial malleolus (ASIS-MM). We defined the ratio between the ASIS-MM and the thigh circumference as the conicity index (CI). All grafts were measured after folding into half, and the found value was recorded as functional graft length (FGL). Tendon graft dimensions were correlated with the individual anthropometric data and with CI in each of the groups. **Results:** PT was used in 34 patients and SET on 24 patients. FGL was 12.7 ± 0.84 mean + standard deviation for the SET group versus 11.5 ± 1.61 for the PT group ($p = 0.0011$) with a strong positive correlation between FGL and CI for the PT group ($R^2 = 0.625$; $p = 2.6 \times 10^{-8}$) but nonsignificant correlation for the SET ($R^2 = 0.222$). Graft thickness was correlated with the patient age ($R^2 = 0.450$) but not with CI or type of tourniquet used. We found the CI to be a better measure of thigh conicity than thigh circumference, length, height, weight, or body mass index individually. **Conclusion:** We conclude that using the SET which occupies less space on the thigh yielded significantly longer hamstring autologous ACL graft compared to the PT and the FGL became essentially independent from the CI when the SET was used.

Keywords

anterior cruciate ligament, autograft, hamstring, knee

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Introduction

Anterior cruciate ligament (ACL) is the second-most injured structure of the knee joint, preceded by the meniscal cartilage. Hamstring or patellar tendon autografts and allografts are currently used, and various fixation practices are performed for ACL reconstruction. Hamstring autografts can easily be harvested from their insertion at the proximal tibia by a tendon stripper when anatomical details of fascial attachments at the distal portion of both tendons are well recognized.¹ Also, as described by Solman and Pagnani, when harvesting the gracilis tendon, the stripper is aimed toward the ipsilateral lesser trochanter; when harvesting the

semitendinosus, the stripper is aimed toward the ipsilateral ischial tuberosity.² Diverting the stripper away from its natural course may cause early strike off, affecting the length of the harvested graft. The tissue pressure exerted

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by the tourniquet may affect such diversion. Although there are many reports about graft length required for ACL reconstruction in literature, there is no consensus about exact graft length needed. At least 22-cm graft (11 cm as folded) is advised for appropriate ACL reconstruction.^{3,4}

Harvesting longer graft may allow doubling of the graft with an increased diameter, providing enough length for adequate graft within the femoral tunnel and for the fixation of the graft outside the tibial tunnel.⁵ Furthermore, a longer graft can also enable reconstructing the ACL with only semitendinosus as reported by Kyung et al. before.^{6,7}

A bloodless field is generally preferred by many surgeons at the time of ACL reconstruction. Tourniquet use facilitates both graft harvesting procedure and arthroscopic reconstruction of the ACL with or without intra-articular pathology management. To date, the effect of tourniquets on thigh structures was evaluated, but the actual effect of the tourniquet type on the graft length especially for patients with tapered and short thigh and overweight patients is not available in the literature.^{8–11}

The purposes of the current study were to investigate the effect of the type of tourniquet used during ACL reconstruction with autologous harvested hamstring ligaments and to correlate the results with anthropometric measurements of the patients and the extent of taper of their thighs. We hypothesized that pneumatic tourniquet (PT) prevents harvesting a longer ligament on tapered limbs so sterile exsanguination tourniquet (SET) can be an alternative to overcome this. PT when used on tapered limbs may cause early strike off the tendon grafts and this can be prevented with the use of SET with a diameter of 3 cm.

Methods

The trial was approved by the appropriate Ethics Committee of the hospital. Fifty-eight consecutive patients undergoing ACL reconstruction using hamstring autograft tendons between 2012 and 2013 were included in the study. Preoperative physical examination was performed; Lachman and pivot shift tests were used to assess the integrity of the ACL. The diagnosis was confirmed by magnetic resonance imaging. The same surgical team implementing the same procedure for all cases carried out all ACL reconstruction operations. Patients received written information about the trial. Before randomization, informed consent was obtained from each patient. Each patient received numbered and blinded randomization envelopes and data on all ACL reconstruction patients were prospectively recorded on a structured pro forma by independent data clerks.

SET (HemaClear®; OHK Medical Devices Ltd, Haifa, Israel) and wide contoured PT (A.T.S®; Zimmer Ltd, Warsaw, Indiana, USA) were applied on the patients' thighs to facilitate bleeding-free surgical field during the operation. The applied PT was a contoured cuff with a width of 14 cm. The tourniquet cuff was placed as described by Genuario

et al. at the most proximal point of the limb, while both the knee and hip joints were flexed.¹² The SET was advanced to the most proximal point of the thigh and its width was 3 cm.

Before reconstructing the ACL, arthroscopy of the knee was performed to detect any coexisting additional pathology; if found, these pathologies were first repaired. ACL of all the patients was reconstructed using autologous hamstring tendon grafts harvested with a tendon stripper. This was followed by a longitudinal incision made at the medial proximal tibial metaphysis and distal part of the graft was fixed to the tibia with a bioabsorbable screw.

The semitendinosus and gracilis tendons were harvested from all of the patients and were folded into half; then their length was measured. This length was named as "functional length." Additionally, the width of the four-strand autografts was recorded. Patients' height, weight, anterior–superior iliac spine to the medial malleolus (ASIS-MM) distance, the thigh circumference, and their body mass index were recorded preoperatively. The circumference of the thigh was measured 10 cm proximal to the upper pole of the patella. The duration of surgery was measured starting from the onset of tourniquet pressure (PT or SET) administration and ended at the end of the procedure.

The use of straight tourniquets on conical thighs should be avoided, especially in extremely muscular or obese individuals.^{13,14} As noted by Schwartzberg et al., there is no broadly accepted criterion to characterize the shape of a conical thigh.⁵ Neither Pedowitz nor Schwartzberg reported an objective criterion for describing the conicity of the thigh. In our study, we used the ratio between the ASIS-MM distance and the thigh circumference as conicity index (CI) to describe the conicity.

Linear regression analysis (MS Excel 2010 add-in statistical tools) was used to determine the slope, intercept, regression coefficient (R^2), confidence intervals, and p value of the correlations, when $p < 0.05$ was accepted as statistically significant. κ -Coefficients were also calculated for determining the agreement levels between observers regarding all measurements including tendon length and width and patients' demographics.

Results

The mean age of the study population was 30.7 ± 7.7 years (range, 18–46 years). Study groups in Table 1 show demographics and measurements of the study population. The groups' demographics were not statistically different. PT was applied to 34 patients (58.6%) and SET to 24 patients (41.4%). The κ -coefficient for tendon length and width assessments was 0.731 and 0.840, respectively, for patients' demographics assessments, and both assessments had a p -value of <0.001 .

The graft width and the functional graft length (FGL) values of the two groups are shown in Table 2. There was no significant difference in the graft width among the

Table 1. Patients' demographics by groups.

	SET		PT		<i>p</i>	Comments
	Average	SD	Average	SD		
<i>n</i>	24		34			
Left knee	11		17		NS	Rest were right knee
General anesthesia	13		14		NS	Rest had spinal anesthesia
Age (years)	31.5	7.2	30.3	8.1	NS	
Height (cm)	175.0	4.8	174.9	6.3	NS	
Weight (kg)	83.2	8.9	82.2	8.9	NS	
BMI	27.2	2.9	26.9	3.1	NS	

SD: standard deviation; SET: sterile exsanguination tourniquet; PT: pneumatic tourniquet; BMI: body mass index.

Table 2. Leg length, thigh circumference, and CI as well as graft width and length are shown by tourniquet groups.^a

	SET		PT		<i>p</i>
	Average	SD	Average	SD	
Leg length (cm; ASIS-MM)	84.4	7.1	86.6	7.5	NS
Thigh circumference (cm)	46.5	4.7	46.9	4.4	NS
Conicity index (ASIS-MM/thigh circumference)	1.8	0.3	1.9	0.2	NS
Graft width (mm)	9.0	0.6	8.9	0.6	NS
Graft functional length (cm)	12.7	0.8	11.5	1.6	0.0011

FGL: functional graft length; CI: conicity index; SET: sterile exsanguination tourniquet; PT: pneumatic tourniquet; SD: standard deviation; ASIS-MM: anterior-superior iliac spine to the medial malleolus.

^aNote that the FGL was significantly longer by 1.3 cm in the SET group.

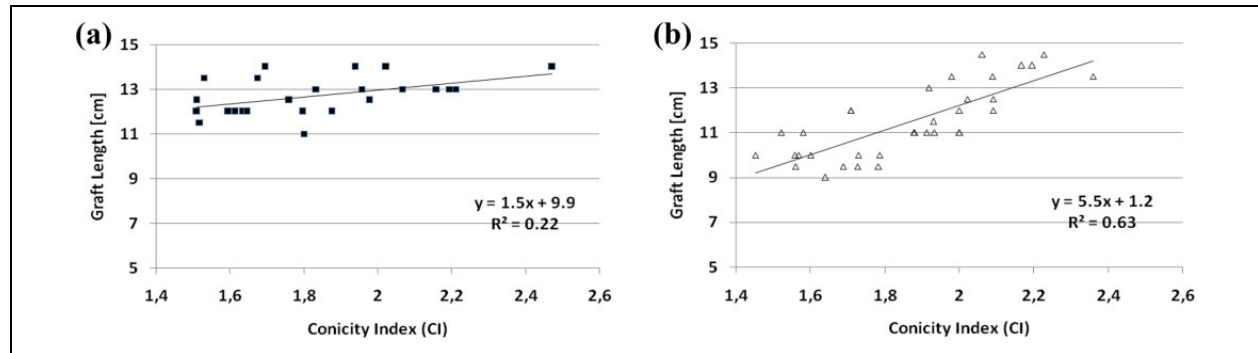


Figure 1. FGL versus CI in the SET group (a) and the PT group (b). Note that in the PT group, 18 of 34 patients had a length of 11 cm or less, whereas in the SET group, there was only one patient with 11-cm graft (none with less). Also, note the strong dependence of the FGL on CI in the PT group, but not in the SET group. FGL: functional graft length; CI: conicity index; SET: sterile exsanguination tourniquet; PT: pneumatic tourniquet.

groups, but there was a substantial (12 mm) and highly significant difference ($p = 0.0011$) in the FGL between the SET and the PT groups. Besides, finding the variability of FGL (i.e. the standard deviation) was twice as high in the PT group compared to the SET group.

Mean ASIS-MM distances by groups, thigh circumference values, and CI defined as the ratio between the two are shown in Table 2. There were no significant differences in these anthropometric measurements between the groups. Figure 1 shows the relationship between FGL and CI in the SET group (A) and in the PT group (B). In the PT

group, 18 of the 34 patients had an FGL of 11 cm or less. This was particularly noticed in patients who had a CI that was less than 2.0 (i.e. short leg and/or large circumference), so that there was a strong influence of CI on the FGL ($R^2 = 0.63$; $p < 0.0001$). In the SET group, all the patients except one had an FGL that was longer than 11 cm and there was only a weak correlation between the FGL and CI in the SET group ($R^2 = 0.22$; $p = 0.02$).

Surgical time was 90.6 ± 21.1 min with the PT and 80.9 ± 20.7 min with the SET ($p = 0.085$) with mean time for the entire population being 84.9 ± 21.2 (range 45–125)

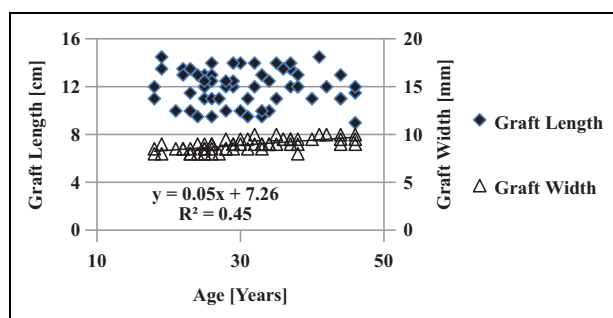


Figure 2. Correlation between FGL and width with the patients' age. Note the linear increase in graft width with age, but no correlation of graft length. FGL: functional graft length.

min. The type of anesthesia (general or spinal) and age did not affect the graft length. However, graft width positively correlated with the patients' age (Figure 2). This observation is in agreement with the findings presented by Melville at the American Orthopaedic Society for Sports Medicine 2011 Annual Meeting who reported that younger patients had narrower hamstring graft.¹⁵

Discussion

In this study, we compared a group of patients undergoing ACL autologous reconstruction using a wide contoured PT cuff (A.T.S; Zimmer Ltd) with a similar group undergoing the procedure with an ultra-narrow surgical exsanguination tourniquet (HemaClear; OHK Medical Devices Ltd). The wide contoured tourniquet cuff, recommended for tapered limbs of shorter and overweight patients by McEwen et al., occupies an area that is 14-cm wide on the thigh, while the SET occupies about 3 cm.¹⁶ The main finding in the present study is that when using the SET, the length of the harvested graft was significantly longer than with the PT. Perhaps, more important is the observation that in patients with low CI (i.e. more tapered thigh), the use of the PT resulted in an FGL that was exceedingly short—11 cm or less as shown in Figure 1. When the SET was used, the dependence of the FGL on CI was substantially less than with the PT (slope of 1.5 vs. 5.5). In addition, all grafts were more than 11-cm long except in one patient whose FGL was 11 cm (Figure 1). The fact that the SET can be placed higher on the thigh thereby providing more space for stripping the ligament without the compression effect of the tourniquet as shown in Figure 3 may play an important effect in this outcome.

In fact, in autologous ACL reconstruction, tendon graft length is as important as its width. A longer graft may allow doubling of the graft into half with an increased diameter and enable reconstructing the ACL with only semitendinosus as reported before.⁶ And also a longer tendon-bone contact can be achieved with a longer harvested graft in femoral tunnel. Fixation techniques outside of the tibial tunnel such as staples and some other proprietary fixation

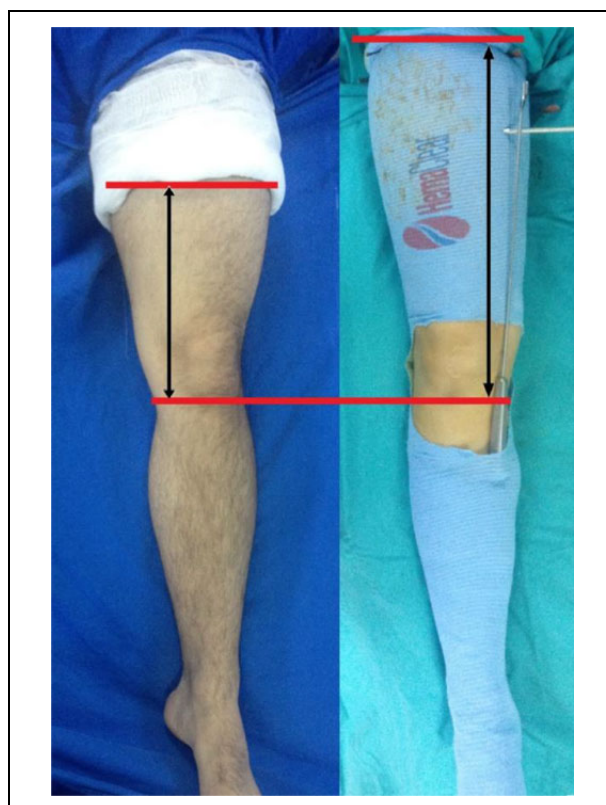


Figure 3. Space to the distal end of the patella from the distal end of the PT (left panel) and the distal end of the SET (right panel). Note the substantially greater free field when both devices are positioned near the groin. SET: sterile exsanguination tourniquet; PT: pneumatic tourniquet.

devices require that the grafts exit the tibial tunnels for a certain minimal distance.⁵ On the basis of the report of the second ESSKA scientific workshop concerning reconstruction of the cruciate ligament held in 1996, it was noted that choosing different graft tunnel positions affected the graft length.¹⁷

Recent studies showed that hamstring autograft ACL reconstruction was associated with more satisfactory results especially on the patients aged 40 and over.¹⁸ American Orthopaedic Society for Sports Medicine argued that the underlying reason was that younger patients had narrower graft size.¹⁵ A positive correlation between graft width and patients age is defined in the literature and this was confirmed by our study. Yet no relationship was detected between graft length and patients age (Figure 2). So other factors must be considered to achieve a longer graft for the patients at any age, for example, tourniquet type as stated in this study.

A limitation of the study is lack of preoperative magnetic resonance imaging of the cross-sectional area of the interested tendons for their length and width. Although it seems better to predict the structural properties of the tendons preoperatively by such techniques, measuring leg

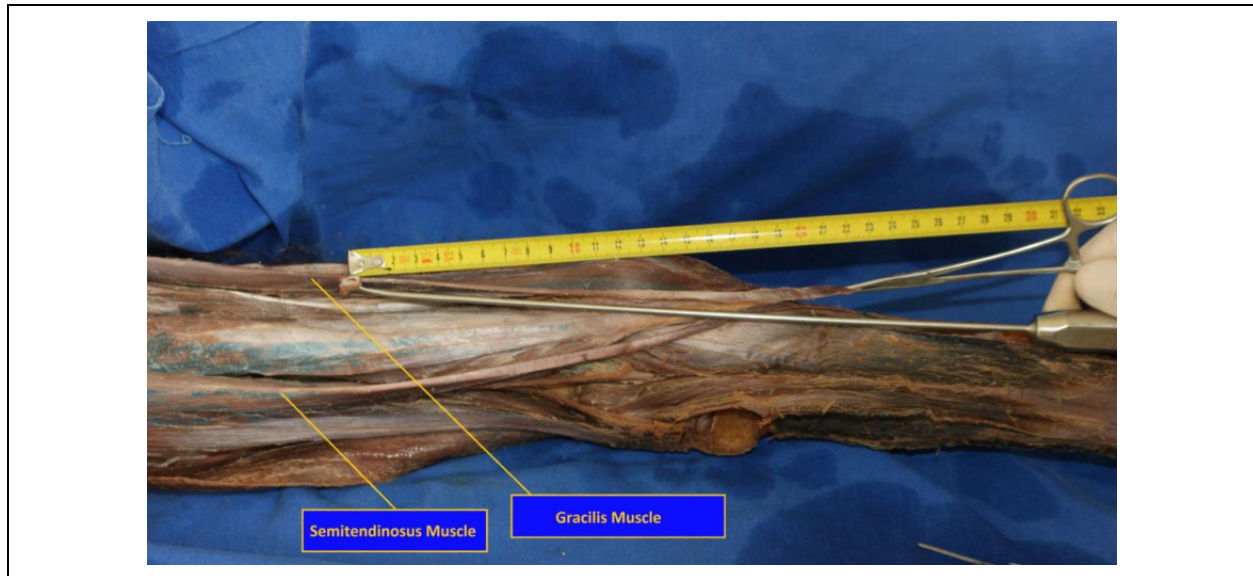


Figure 4. The dissection of a cadaver featuring gracilis and semitendinosus ligaments.

length and body weight can do a simpler way of prediction. However, this is not always the case, as we showed the inverse effect of the PT on the length of the grafts obtained by the stripper. There is no data in literature about incidence of harvesting short hamstring autografts due to the PTs, but this study demonstrated that autograft lengths may vary via tourniquet types. We speculate that the wide contoured pneumatic cuff when used on tapered limbs caused the tendon stripper to divert from the natural course of the tendon resulting in an early cut, possibly due to the cuff pressure compression of the muscles with migration of some of the muscle mass toward the distal thigh. The results of this study indicate that this is not the case when the SET is used, possibly because there is much less shifting of compressed muscles distally. The strengths of this study are prospective data collection and being the first comparative study evaluating the two different tourniquets on proper graft derivation.

In a study published by Apostolopoulos et al., including 72 patients, it was reported that the length of the hamstring autograft ranged from 11 cm to 13.5 cm and the diameter from 7 mm to 9 mm.¹⁹ In our study, the length of the autologous hamstring tendon ranged from 9.5 cm to 14.5 cm and the diameter from 8 mm to 10 mm. The failure to harvest long enough tendon graft may lead to the use of alternative graft sources. Schwartzberg et al. questioned whether common anthropometric measurements in patients undergoing ACL reconstruction with autologous hamstring tendon graft could predict autograft length and diameter. They found that doubled semitendinosus and gracilis graft length for ACL reconstruction was strongly associated with leg length.⁵

Although it is not statistically significant, SET provided quite shorter surgery time in this study. This situation can

be explained by the easiness of the SET application. The application of PT is more complex in terms of need for elevation, Esmarch bandage usage, or pressure adjustment according to arterial blood pressure level.

The most prominent factor influencing the length of the hamstring autograft is surgical technique. While harvesting the gracilis and semitendinosus tendons, all fascial branches of the tendon need to be freed so that the body of the tendon is not amputated in mid-substance before the entire muscle is stripped. Incomplete removal may cause the tendon stripper to follow one of the branches and prematurely amputate the tendon.²⁰ When harvesting the gracilis tendon, the stripper is aimed toward the ipsilateral lesser trochanter; when harvesting the semitendinosus, the stripper is aimed toward the ipsilateral ischial tuberosity.² Figure 4 shows the dissection of a cadaver featuring the linear course of the gracilis tendon and its muscular portion, which is longer than the semitendinosus tendon. Previous studies that established a link between early cut of hamstring tendon autograft and fascial branches also correlate shorter tendon grafts with lower extremity length.

Conclusions

We conclude that the use of SET provides a longer autologous graft for ACL reconstruction. This was particularly prominent in patients having lower CI value (more tapered).

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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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.



Sterile Exsanguination Tourniquet

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Use of the S-MART Tourniquet in Total Elbow Arthroplasty

Presented in 25th EFORT. Vienna, Austria. 2009.

Mr Arvind Mohan, Mr Mark Middleton and Mr Mark Flannery
Department of Orthopaedic Surgery
The Royal Surrey County Hospital NHS Trust, Egerton Road, Guildford, GU2 7XX

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.

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).

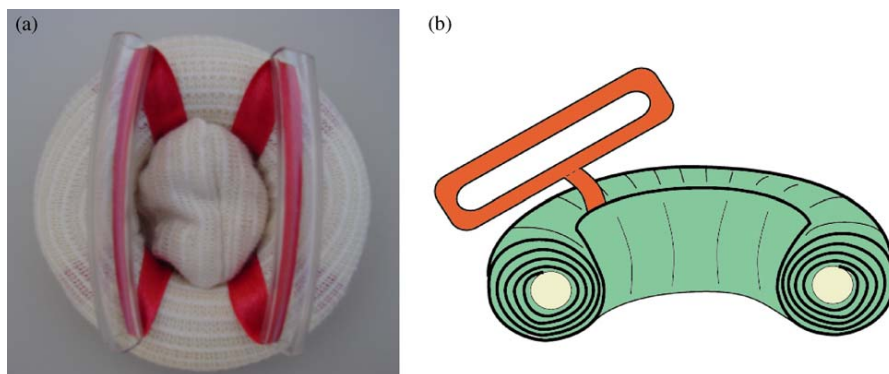


Fig 1 S-MART:arm.



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).

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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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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

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 device has been introduced in clinical practice recently [24–26].

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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 limb at occlusion site up to 40 cm) and a large size for the leg (circumference of the limb at



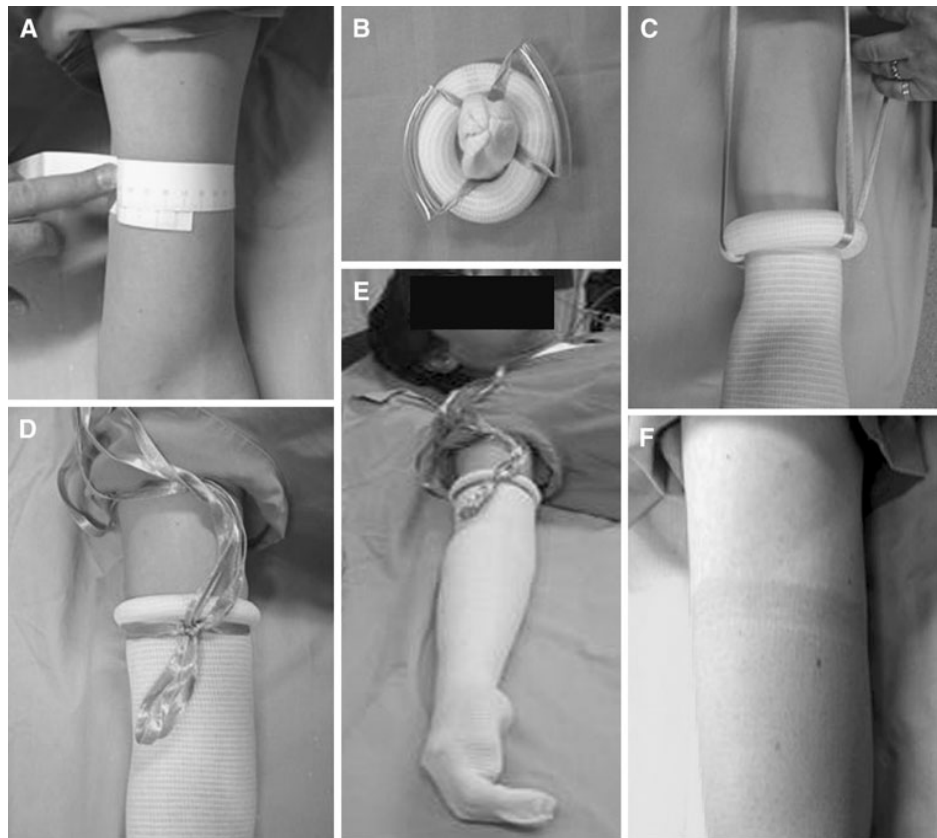
Fig. 1 Pneumatic tourniquet study with the cuff applied on the upper arm and thigh

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).

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

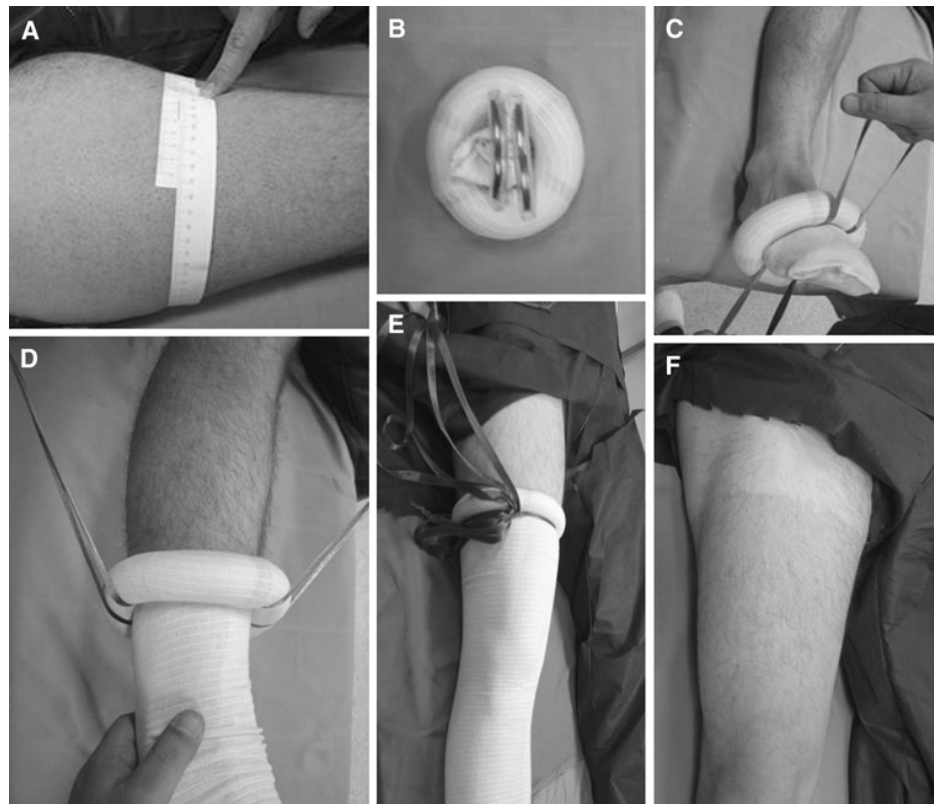
removal, and (e) at the time of complete recovery from any symptoms (recovery time).

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 $\pm$ 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		<i>p</i> 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	<i>p</i> 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

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

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

	PT	SMART	<i>p</i> 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

(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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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		

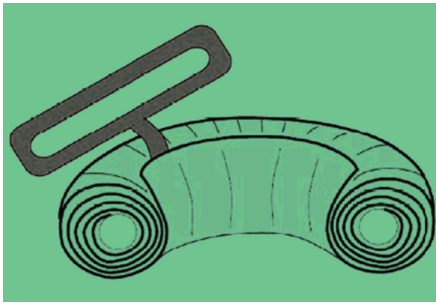


FIGURE 1: Cross section of the S-MART tourniquet.



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

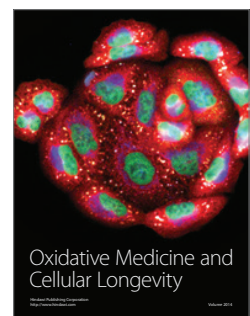
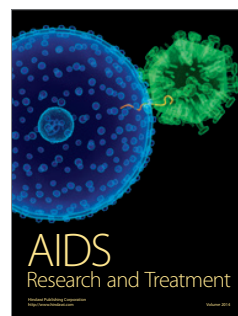
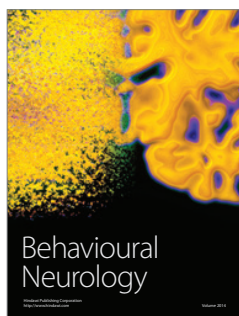
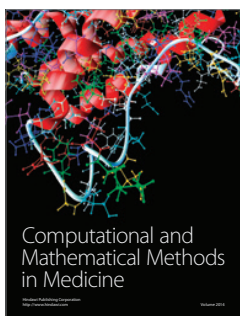
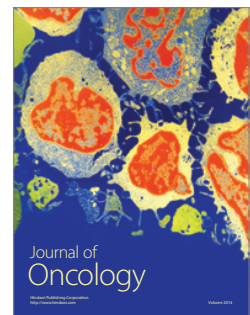
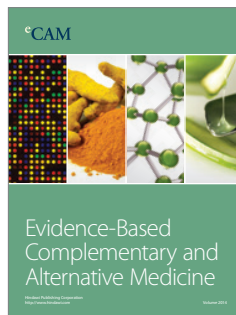
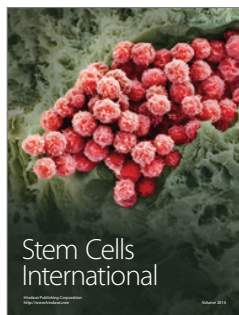
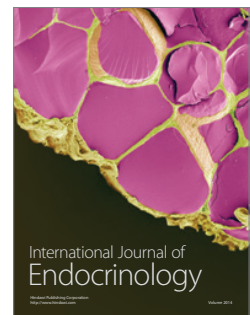
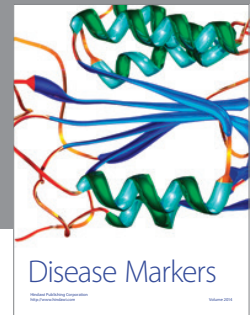
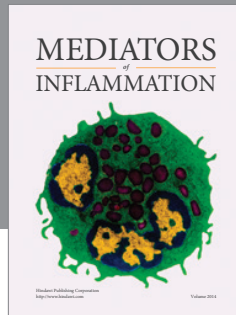
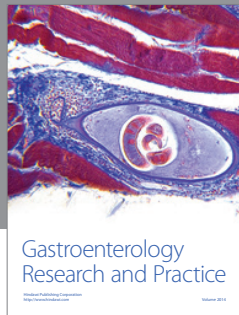
In our experience, the use of the S-MART exsanguination tourniquet is an effective and safe way to provide a bloodless field in hand and wrist surgery. Its use in our department in 250 cases did not indicate a higher tourniquet-related complication rate when compared to the use of a pneumatic tourniquet 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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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 $\pm$ 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

Demographics, diagnoses and procedures of the patients

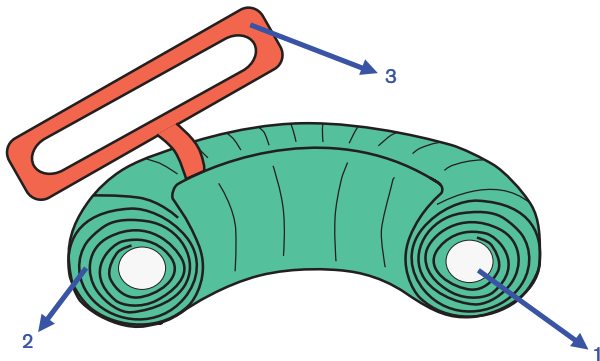
No.	Model	Tourniquet time (min)	Area of application	Procedure	Sex	Diagnosis	Side	Age (years)
1	Yellow	50	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Left	4
2	Blue	30	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	14
3	Blue	30	Mid thigh	Hamstrings 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	Subungual 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	Naviclectomy	M	Vertical talus	Left	4
52	Yellow	30	Mid forearm	Excisional biopsy	F	Wrist ganglion	Left	12

DVT, deep vein thrombosis.

Fig. 1



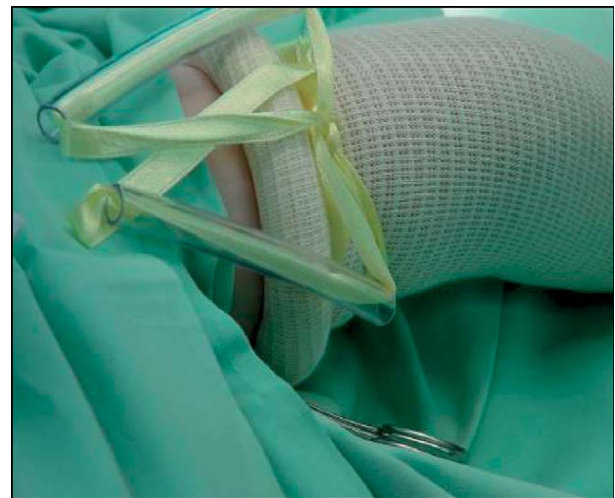
Schematics of the surgical exsanguination tourniquet showing the inner elastic ring (1), the stockinet wrapped around it (2), and the straps with pull handles (3).

- 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

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.

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 $\pm$ 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 post-operatively 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.

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

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).

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

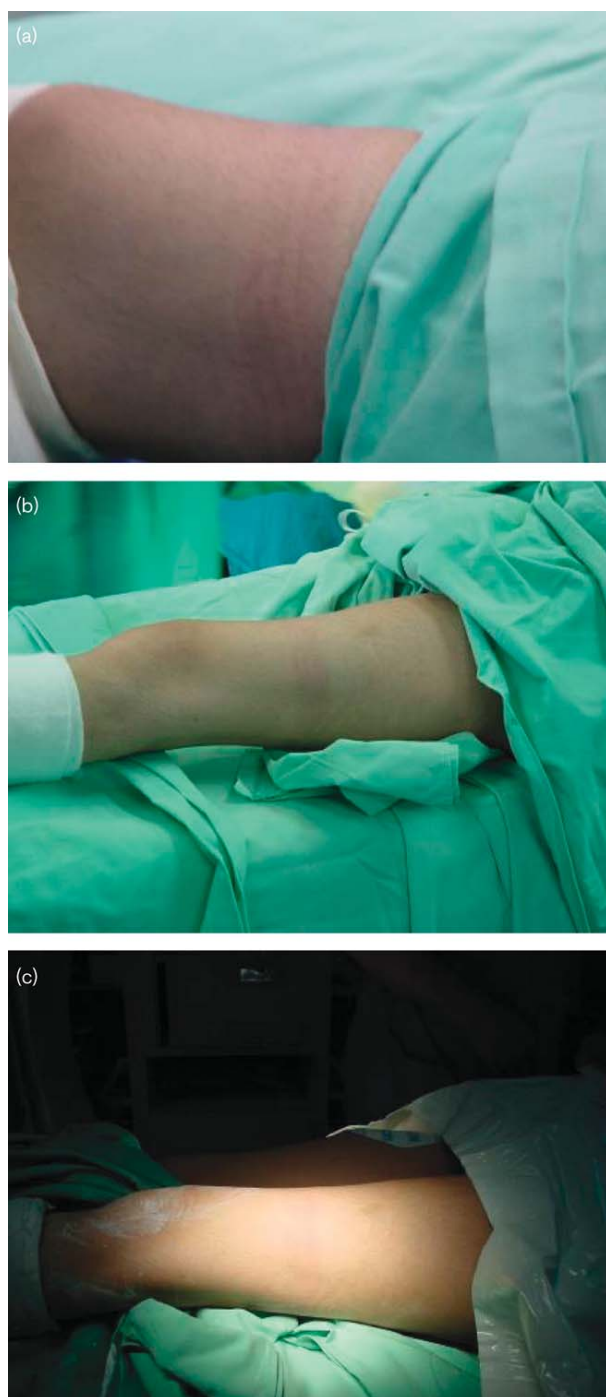
calibrated to provide a localized pressure that is sufficient to block the arterial flow into the limb without causing excessive tissue compression. In all patients, the SET provided continuous arterial occlusion for the entire duration of the procedure. The pressure range as reported by the manufacturer is 227 ± 37 mmHg (mean $\pm$ 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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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.

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.

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-contamination³.

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

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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 references¹.

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 site³⁻⁵. The evaluation of all these complications was completed the first ten postoperative days.

The type of the tourniquet used was SET (Surgical Ex-

sanguination 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 the thigh level at 23 procedures. We did not choose in any case the median part of forearm for

Table 1.

No.	Tourniquet	Area of application	Procedure	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. Size	Tourniquet time	Area of application	Procedure	Sex	Diagnosis	Age (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 operations⁶. 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 tissues¹.

After the removal of the elastic ring no focal problems were found, such as bruises, petechias, chemical burns as in the use of pneumatic tourniquet⁴. 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 method⁵.

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)

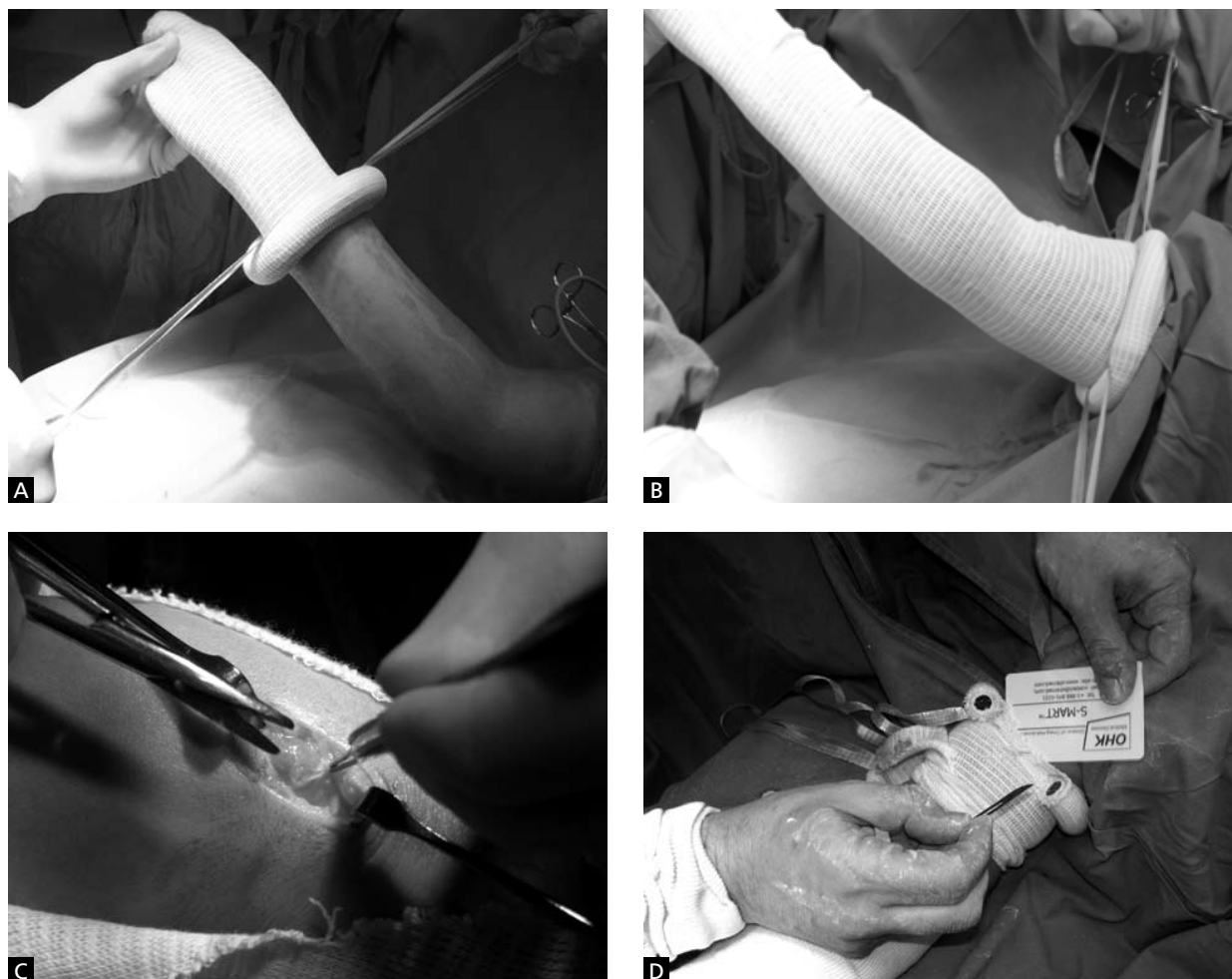


Figure 2. Application of the sterile tourniquet in an upper limb with a carpal ganglion. **A)** It is placed on the patient's fingers by the orthopaedic surgeon, with the surgical field being previously appropriately prepared. **B)** Pulling the straps vertically to the longitudinal axis of the limb, 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

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

Result

very satisfying
less than 60 seconds
proximal end of humerus or femur
Excellent
Excellent
not mentioned
Free
very satisfying
Reserved
not mentioned

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Sterile Exsanguination Tourniquet

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Skinny wire and locking plate fixation for comminuted intra-articular distal humerus fractures: a technical trick and case series



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Introduction: Intra-articular distal humerus fractures present a challenge to orthopedic surgeons. Stable fixation is difficult to achieve in fractures with articular and metaphyseal comminution and osteoporotic bone. Hence, these fractures are more commonly being managed with total elbow arthroplasty. We describe a novel surgical technique that confers stable fixation, allowing for early range of motion resulting in a high rate of union, a functional range of motion, and excellent patient reported outcome scores without the activity restrictions of total elbow arthroplasty.

Methods: Retrospective case series of 30 patients with AO/OTA type B and C intra-articular distal humerus fractures who underwent ORIF from 2014–2019 utilizing a novel surgical technique that focuses on reconstructing a comminuted articular surface through meticulous, transverse fixation of the tiny articular fragments with long, thin Kirchner wires, which are then bent over and trapped under locking compression plates to create a fixed angle support to the metadiaphysis.

Results: Patient mean age of 59 (19–90) years and 61% were female. Median follow up was 1.2 years. Twenty-seven (87%) were type C fractures and 3 (13%) were type B. Five patients (16%) suffered a concurrent ipsilateral upper extremity injury and four (13%) had an open fracture. Two were polytrauma patients. All fractures healed with an average time to union of 11 weeks. Over 80% patients reported no or mild pain at final follow up. Mean arc of elbow motion was 102 degrees, mean QuickDASH score 25.2. Post-operative complications included ulnar nerve paresthesias (38%), wound infection (3.2%), heterotopic ossification (3.2%), and olecranon nonunion (3.2%). Eight patients underwent secondary procedures: 7 (23%) removal hardware, 3(9.6%) capsular release, 2 (6.4%) ulnar nerve transpositions, and 1 (3.2%) total elbow arthroplasty.

Conclusion: We describe a novel surgical technique that we believe results in strong, stable fixation of complex intra-articular distal humerus fractures irrespective of bone quality. In our series, all fractures healed and post-operatively patients reported low levels of pain, achieved excellent elbow range of motion, high patient reported outcome scores. Patients should be counseled about high rates of post-operative ulnar nerve paresthesias that can be expected to improve over time and high reoperation rates for symptomatic hardware.

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Distal humerus fractures are 2%–7% of all adult fractures and 30% of elbow fractures.^{4,21} Intra-articular distal humerus fractures specifically pose a challenging problem for treating orthopedic surgeons. Most commonly, these fractures result from high-energy injuries in young adults or low-energy falls in the elderly. Reconstruction of the articular surface is often technically difficult owing to poor bone quality, limited cancellous bone to

support fixation, and multiple articular and metaphyseal fragments in severely comminuted fractures. The advent of locking plates placed orthogonally or in parallel have resulted in better fixation and improved clinical outcomes,^{2,10,20} but there remains a small subset of patients with poor bone quality and highly comminuted, AO/OTA type C distal humerus fractures which are challenging to treat, with difficulty achieving bony union and attaining a functionally acceptable extremity. Recently, there has been a trend toward treating these patients with total elbow arthroplasty (TEA), but in practice, this solution is often

Partners Human Research approved this study (Protocol #: 1999P008705).

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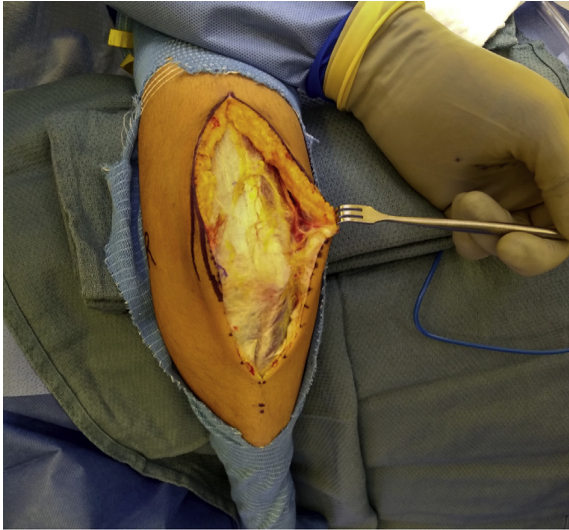


Figure 1 Posterior approach to the elbow. Medial and lateral skin flaps are created and the ulnar nerve is identified.

complicated by infection and mechanical failure. Even a successful total elbow entails strict, permanent activity restrictions which may require an active older patient to significantly change their lifestyle.^{14–16} We describe a novel surgical technique which we have found produces high rates of union, functional range of motion, and excellent clinical outcomes as defined by QuickDASH and PROMIS scores in even the most fragile, comminuted distal humerus fractures.

Surgical technique

Indications

The primary indication for this operative technique were patients who presented with AO/OTA type B or C distal humerus fractures with significant articular and metaphyseal comminution and an arguably unreconstructible articular surface as determined by the treating surgeon.

Operative technique

Patients are positioned in the lateral decubitus position with the operative arm at 90 degrees of shoulder abduction and elbow at 90 degrees flexion, supported by a firm bump. A sterile, self-contained low-profile tourniquet (HemaClear, OHK Medical Devices, Grandville, MI) is used to limit blood loss. All patients receive perioperative antibiotics (cephalexin or appropriate alternative) before incision. A direct posterior incision is used and dissection is carried out down to the triceps fascia (Fig. 1). Medial and lateral skin flaps are elevated and the ulnar nerve is identified medially and released along the cubital tunnel from the proximal mid-arm down to the two heads of the flexor carpi ulnaris and is tagged with a vessel loop for protection and handling (Fig. 2). In most cases, an olecranon Chevron osteotomy is used to obtain adequate exposure to the articular surface of the distal humerus (Fig. 2). A paratricipital approach may be used if adequate exposure of the articular surface can be achieved without osteotomy. The articular fragments are then identified, aligned anatomically and clamped in

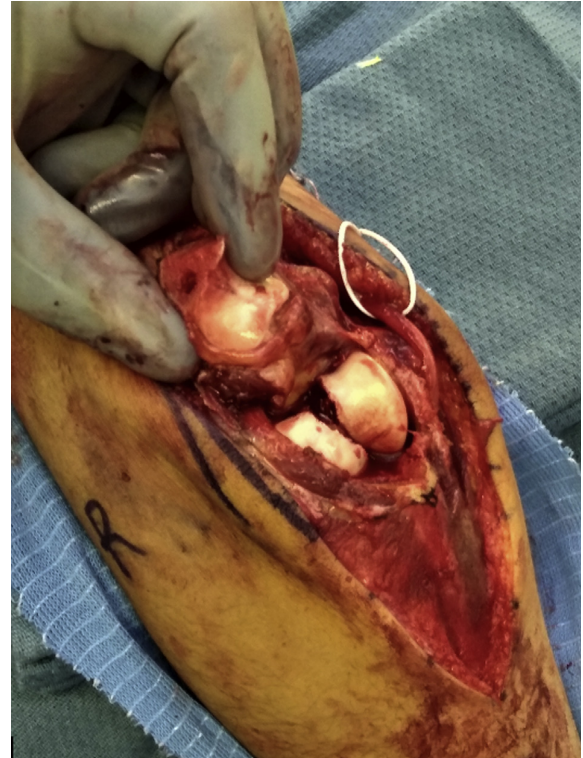


Figure 2 A Chevron olecranon osteotomy is used to gain adequate exposure to the articular surface in severely comminuted, complete articular fractures.

compression with reduction forceps. The fragments are then secured utilizing numerous 1.25-mm Kirschner wires passing transversely from the lateral to medial column, creating a rigid articular block with a reconstructed joint surface (Fig. 3). Rather than cutting them off, the long wires are bent 90 degrees proximally and molded to the shaft so they become a critical part of the definitive fixation. The metaphyseal fragments are realigned and fixed provisionally, thereby linking the articular segment and distal humeral shaft (Fig. 3). Polyaxial locking, anatomically contoured distal humerus plate(s) are subsequently utilized to create the final construct (Table 1). Before plate application, the long, skinny wires used for the articular block are cut flush along the medial column, bent over the lateral column, and trapped beneath the lateral column plate to prevent migration and effectively to unify them into a fixed-angle fixation device (Fig. 4). If the sharp ends poke out medially, they are cut flush. The plate(s) are then fixed first proximally to the humeral shaft, clamped in compression from medial to lateral to the articular block, and then fixed to the articular segment distally with combination of locking and nonlocking screws. Polyaxial distal locking screws allow for intentional interference placement of screws with the wires, maximizing fixation in the distal articular segment. In no case was there difficulty placing screws due to the existing presence of the wires. Attention is then turned back to the olecranon osteotomy, which is repaired by any appropriate method (tension band wire, an intramedullary screw, or a plate). In our series, a 7.3-mm cannulated screw was used for fixation most often (Table 1). Before closure, in 19 (61%) of the previous cases, the ulnar nerve was transposed subcutaneously to avoid contact with the medial plate;

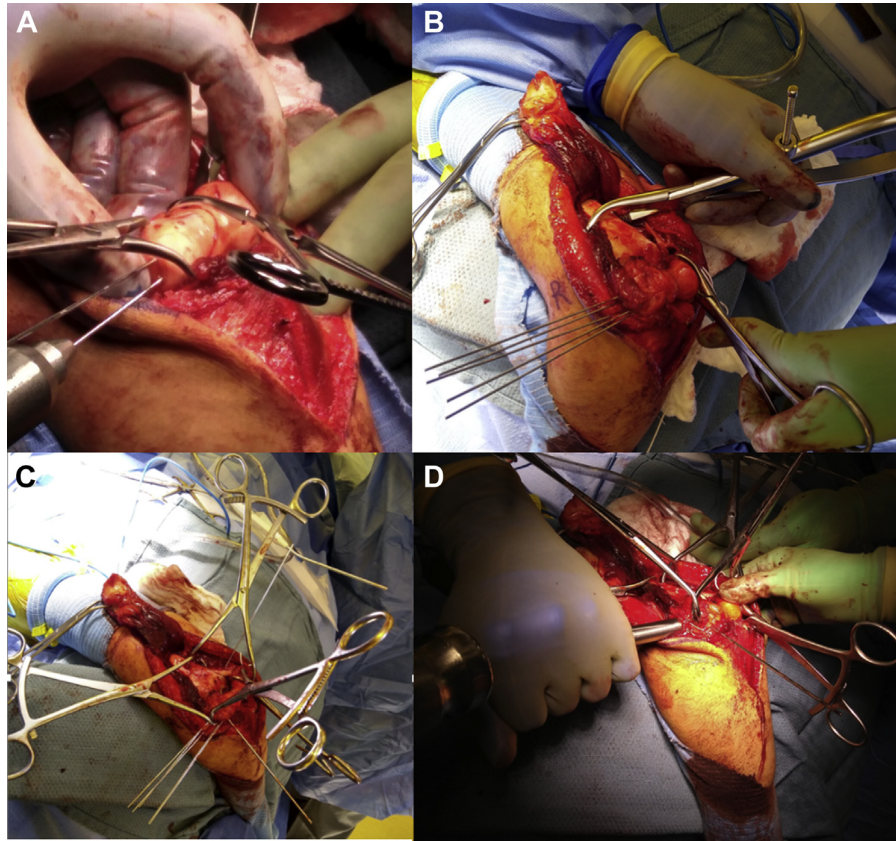


Figure 3 (A) Articular fragments are clamped in compression, then transversely fixed utilizing small, nonthreaded K-wires. (B) The metadiaphysis is then clamped to the reconstructed articular block. (C) Multiple reduction clamps are used for reduction of metaphyseal comminution. (D) A wire bender is used to bend the long K-wires over the lateral column.

Table 1
Details of procedure and surgical fixation.

Mean time to ORIF (range)	3.5 (0–29) days
ASA score	
2	17 (55%)
3	14 (45%)
Mean (range) operative time (min)	162 (55–390)*
Mean (range) EBL (cc)	108 (10–400)*
Mean (range) length of stay (days)	2.2 (0–8)
Olecranon osteotomy + fixation	26 (84%)
7.3 mm partially threaded screw	21 (81%)
Olecranon plate	4 (15%)
Tension band wiring	1 (4%)
ORIF construct (+ skinny wires)	
Lateral column plate	3 (10%)
Bicolumnar plate	24 (81%)
Bicolumnar + posterolateral plate	2 (9%)

ORIF, open reduction internal fixation; ASA, American Society of Anesthesiologists; EBL, estimated blood loss.

* One case combined with ORIF proximal humerus.

the remainder were left decompressed in situ. The wound is then irrigated and closed in standard fashion.

Postoperative protocol and follow-up

Patients are splinted in a posterior slab splint postoperatively allowing for 10–14 days of soft tissue rest. Patients do not routinely receive radiation therapy or nonsteroidal anti-inflammatory

medication for heterotopic ossification prophylaxis post-operatively. At their two-week visit, early, unlimited range of motion with limited weight-bearing is initiated. No splint, sling, or other orthosis is used beyond two weeks. Range of motion is measured at occupational therapy sessions or postoperative visits using a goniometer. Postoperative radiographs are used to assess healing of the fracture and the osteotomy site. Fig. 5 shows an example of a typical type C distal humerus fracture with significant articular comminution fixed with this technique. Fig. 6 shows the fracture healing with a reconstructed joint surface at three months postoperatively. Fracture healing is assessed by appearance of bridging callus or resolution of radiolucent fracture line combined with clinical assessment of functional pain at the site of the fracture. Patient-reported outcomes (QuickDASH and PROMIS Global 10 Mental and Physical Health scores) are collected prospectively in during clinic visits.

Results

Thirty-two patients with intra-articular distal humerus fractures treated with this novel surgical technique between 2014 and 2019 were retrospectively reviewed. Patients with minimum one year of follow-up were included. Two patients were excluded: one for inadequate follow-up (<3 months) and one for a devastating open injury with significant articular bone loss requiring trochlear interposition arthroplasty. Thirty patients were included in the final analysis. Results are presented as mean (range) or median

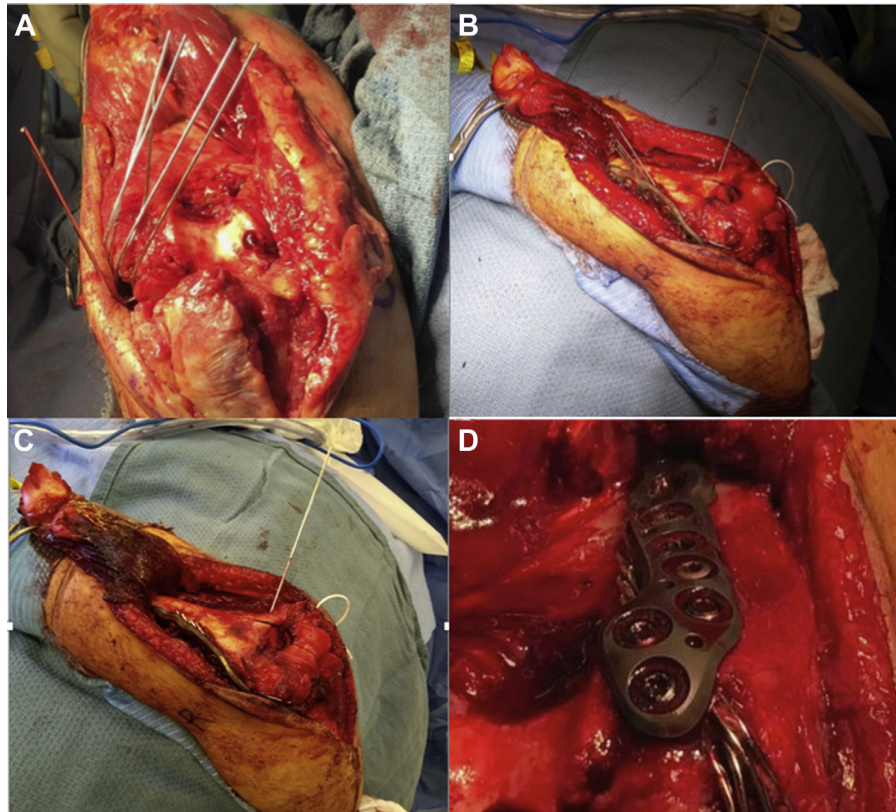


Figure 4 (A) K-wires bent over lateral column are shown. (B) Lateral column plate is applied, trapping the K-wires deep to the plate, preventing retrograde wire migration. (C) The wires are cut flush along the lateral column, avoiding prominent hardware. (D) Upclose view of final construct demonstrating wires secured deep to plate.

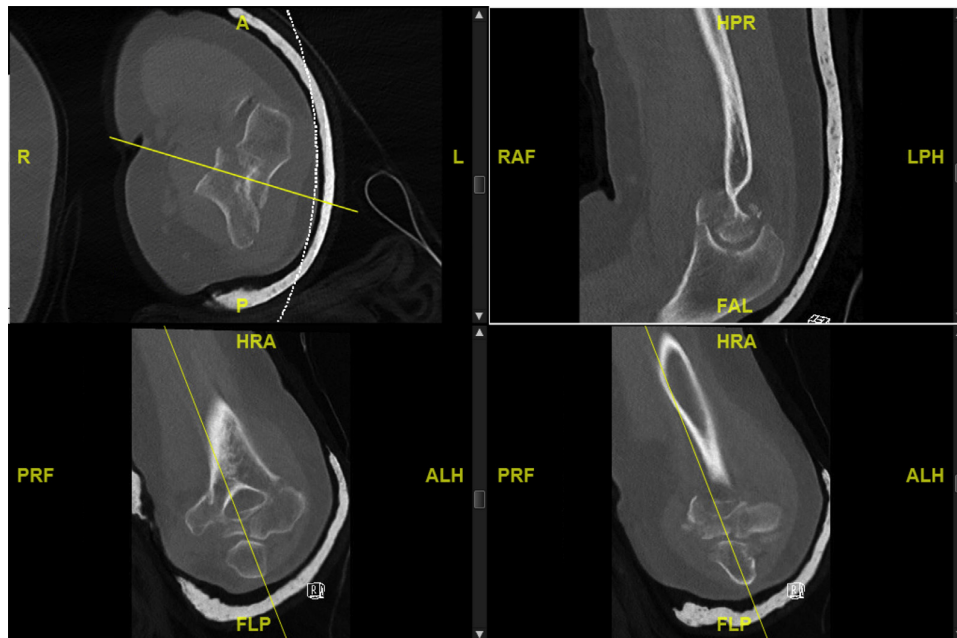


Figure 5 Midsagittal CT scan of a typical type C distal humerus fracture with significant articular comminution.

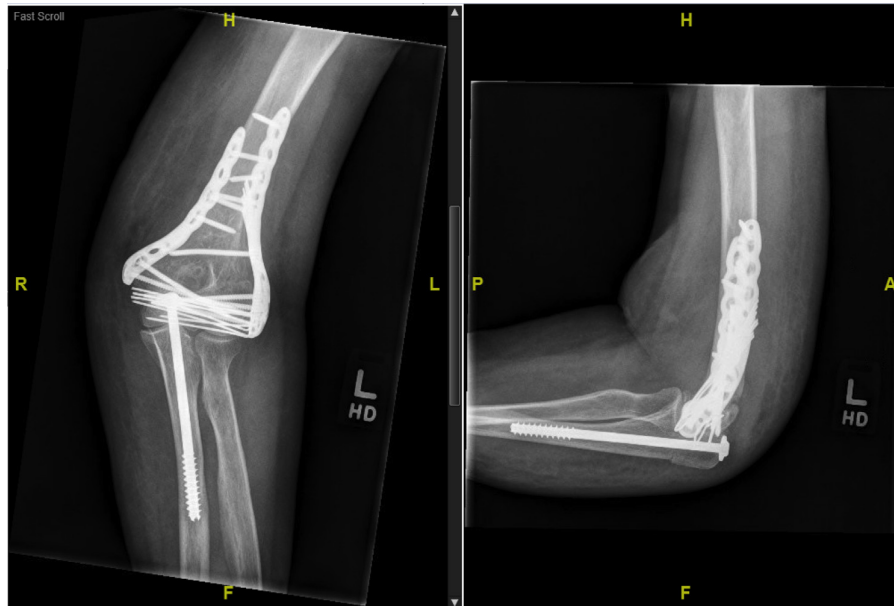


Figure 6 Three month postoperative radiographs demonstrating a healing fracture after utilizing multiple small K-wires to reconstruct the comminuted articular surface and locking plate fixation.

Table II
Injury and fracture characteristics.

Mechanism of injury	
Fall—standing	21 (70%)
Fall—height	5 (17%)
Motorcycle crash	3 (10%)
Gunshot wound	1 (3%)
High energy	10 (33%)
Polytrauma	2 (7%)
Ipsilateral upper extremity injury	5 (16%)
AO/OTA classification	
A type	0 (0%)
B type	3 (10%)
C type	27 (90%)
Affected extremity (% left)	21 (68%)
Open fracture (Gustilo-Anderson)	4 (13%)
1	3 (10%)
2	1 (3%)
3A	0
3B	0
3C	0
Primary nerve palsy	2 (7%)
Brachial plexopathy*	1 (3%)
Ulnar nerve	1 (3%)
Arterial injury	0 (0%)
Compartment syndrome	1 (4%)

* Patient sustained an ipsilateral proximal humerus fracture/dislocation.

(interquartile range) for continuous variables and as percentages for categorical data. Statistical analysis was performed using SPSS software (version 22.0; IBM, Armonk, NY, USA). The patient cohort had a mean age of 59 (19–90) years and a median follow-up of 1.5 (1.1–2.5) years. Sixty-one percent of patients were women and patients had an average BMI of 27.4 (19–49). Smoking and alcohol use were documented in 9.7% and 16.1% of patients, respectively. Medical comorbidities were reported in 74% of patients with osteoporosis (26%), diabetes mellitus (16.1%), chronic immunosuppression (12.9%), coronary artery disease (6.5%), and chronic liver disease (6.5%) the most common. Sixty-four percent of

Table III
Summary of postoperative outcomes and reported complications.

Fracture union	30 (100%)
Mean time to union	11.1 weeks
Ulnar nerve neuropraxia	12 (38%)
Paresthesias	12 (38%)
Motor deficit	1 (4%)
Nerve recovery	10 (83%)
Wound infection	1 (3%)
Heterotopic ossification	1 (3%)
Olecranon nonunion	1 (3%)
Secondary procedures	11 (35%)
Removal hardware	8 (26%)
Capsular release	3 (10%)
Ulnar nerve transposition	2 (6%)
Excision heterotopic ossification	2 (6%)
Total elbow arthroplasty	1 (3%)

Table IV
Functional and patient-reported outcomes.

Pain (NRS)	
None (0)	17 (54.8%)
Mild (1–3)	10 (32.3%)
Moderate (4–6)	4 (12.9%)
Severe (7–10)	0 (0%)
Range of motion	
Arc of motion	104 (45–140) degrees
Flexion	125 (90–160) degrees
Extension	–18 (–45 to 0)
Mean (SD) QuickDASH	24.0 (20.2)
Mean (SD) PROMIS (Global 10)	
Mental	53.8 (8.9)
Physical	49.6 (7.8)
Return to work/activity	
Retired—ADLs only (n = 9)	9 (100%)
Laboring occupation (n = 12)	10 (83%)
Office worker (n = 8)	8 (100%)
Physical activity (n = 2)	2 (100%)

NRS, numerical rating scale; SD, standard deviation; ADLs, activities of daily living.

patients were working at the time of injury, 38% in laboring professions. The remainder were retired or unemployed.

Most patients fractured their distal humerus as a result of a ground level fall. The remainder were high-energy mechanisms of injury. Table II presents details on fracture classification, injury mechanisms, concurrent injuries, classification of open fractures, and relevant nerve and vascular injuries. Three patients had extraordinary circumstances. One patient sustained severe poly-trauma as a result of a motorcycle crash. His injury burden included renal contusion, transverse process fractures, contralateral intertrochanteric femur and distal radius fractures, an ipsilateral tibial plateau fracture, and an ipsilateral proximal humerus fracture-dislocation resulting in a brachial plexus injury. A second patient sustained a Gustilo-Anderson grade 3A open fracture which required three irrigation and débridement procedures before definitive fixation, which involved interposition arthroplasty of the trochlea using triceps tendon autograft due to significant bone loss. Finally, a third patient sustained an ipsilateral both bone forearm fracture and underwent fasciotomy for evolving symptoms of compartment syndrome. In all 31 cases, fractures healed at mean time of 11 weeks. At final follow-up, most patients reported low levels of pain, a functional arc of motion, excellent PROMs, and high rate of return to work or activity in both laboring (ie, fire fighter, security guard, operating room technician, construction, gymnastics coach) work and activities (ie, kayaking, yoga, weightlifting) as detailed in Table III. There was a 38% postoperative complication rate and 35% reoperation rate, details of which are presented in Table IV. Transient ulnar neuropathy occurred at a rate of 38.7% and was higher when the ulnar nerve was transposed (52.6 vs. 16.7%, $P = .045$).

Discussion

For extra-articular or simple intra-articular distal humerus fractures in patients with good bone mineral density, conventional plating techniques alone are a good option. Union rates of 92–100% with good to excellent range of motion, low pain, and good functional outcome scores have been achieved in multiple studies looking at modern techniques with both parallel and orthogonal configurations of plates and screws—precontoured, locking, or nonlocking.^{1,2,4-7,9,10,12,20}

However, in low intercondylar fractures with a high degree of comminution in osteoporotic bone, engaging the small articular fragments with distal screws is challenging. More recently, surgeons have foregone fixation for total elbow arthroplasty (TEA) given the challenging nature of reconstructing the articular surface in these fragile, comminuted fractures. Frankle et al demonstrated superior clinical outcomes and significantly less revision surgery with total elbow arthroplasty compared to ORIF in women older than 65 with intra-articular distal humerus fractures.³ However, there is a high-rate infection and revision with total elbow arthroplasty. Prasad et al reported a 31% rate of aseptic loosening, although only two patients were symptomatic and required revision surgery¹⁶ and Peretta et al reported a 57% revision rate when total elbow was indicated for trauma. Survival was 75% at five years and 55% at 10 years for all total elbows.¹⁵ TEA is far from the perfect solution for low, comminuted intra-articular distal humerus fractures. It serves most appropriately for low-demand patients who can better tolerate the activity restrictions imposed on them by a total elbow arthroplasty procedure.

Here, we describe a technique that offers patients with highly comminuted fractures and poor bone quality a potentially better option than TEA. In our study, 100% of fractures healed at mean time of 11 weeks. This construct withstood an early active range of motion

protocol, resulting in a functional mean arc of motion of 102 degrees. Our surgical technique focuses on first achieving direct anatomic reduction of the articular surface, clamping the spool in compression, and capturing the small articular fragments using multiple Kirschner wires. This first creates a solid articular block, and by bending these wires and unifying them to the shaft, it effectively makes them into a fixed angle construct. Pin pull out is nearly impossible as our wires are left long, bent over the lateral column, and secured deep to the lateral column plate. Although we developed this independently, we note that in 2012, Kamrani et al described a similar “pin and plate” technique using articular wires. However, they secured their wires proximally in one spot with a 3-hole recon plate, risking wire migration distally at the bone/wire interface.⁸ They reported a high union rate with good ROM and DASH scores. However, they could not attribute all of their success to their technique as it was used in combination with Herbert screws and tension band wiring in multiple cases. In our study, the same technique was used in all patients. We report a mean arc of motion of 104 degrees, low pain score, and excellent QuickDASH and PROMIS scores. Even the oldest and most osteoporotic patients have been able to return to their normal activities of daily living. Younger ones have returned to laboring and physically demanding jobs, and activities they enjoy, without restriction.

This technique has its complications, as does any way of managing these challenging injuries. Rates of postoperative complications after distal humerus fixation are reported as high as 44–53%.^{12,17-20} Nonunion, hardware failure, heterotopic ossification, ulnar nerve paresthesias, and symptomatic hardware are the most common. Olecranon nonunion is a potential problem when osteotomy is used to access the articular surface. Nonunion rates following ORIF of distal humerus fractures are reported to be between 2 and 10%.^{18,21} In the present study, there were zero nonunions of the distal humerus, similar to results of more recent published series of simpler fractures.²¹ Heterotopic ossification (7–9%) is a significant problem after ORIF of distal humerus fractures, causing stiffness and pain which calls for reoperation.^{5,12,18,19,21,23} In our series, one patient formed heterotopic bone requiring excision with subsequent improvement in motion. Infection rates are reported from 6 to 15% based on two large systematic reviews of distal humerus fractures.^{18,21} Ulnar nerve paresthesias are very common after ORIF with rates ranging from 0 to 51%.^{2,11,13,18,21,22} A recent meta-analysis published in 2018 found the rate ulnar nerve injury after distal humerus fixation to be 19.3%.¹⁹ In our study, we report a 38% rate of postoperative ulnar nerve paresthesias although 10 of 12 (83%) experience improvement by the final follow-up. There was a higher rate of postoperative paresthesias when ulnar nerve transposition was used (53% vs. 17%, $P = .045$). One patient developed ulnar nerve motor weakness and intrinsic wasting which did not recover. Symptomatic hardware was also common in our practice with 26% of patients undergoing hardware removal. Recent studies have reported similar rates of hardware removal between 12 and 31%.^{2,10,20}

We acknowledge the limitations to our study and surgical technique. All these surgeries were performed by a single orthopedic surgeon whose practice is mostly complex upper limb trauma, and thus it may not be generalizable to all treating orthopedic surgeons. The surgical technique is associated with a high rate of secondary procedure, particularly removal of hardware. Elbow range of motion was functional, but still limited. There was a high rate of ulnar paresthesias, particularly when the ulnar nerve was transposed. It is unclear how much is attributable to initial nerve injury in the setting of severe soft tissue trauma, and how much from the technique itself. Our study is retrospective and some data are inconsistently reported or incomplete in the electronic

medical records. Physical examinations were not standardized with the goal of collecting data for research purposes. However, the most important clinical data were captured consistently including elbow ROM, functional scores, and patient-reported outcome scores. As with most trauma studies, follow-up is short. It is our practice to obtain radiographs only until the fracture unites, unless there is a clinical reason for more. Because 100% of fractures healed, this leaves the possibility of missing radiographic evidence of asymptomatic post-traumatic arthritis. Furthermore, given the short duration of follow-up, it is possible more patients will request hardware removal at a later date. It is also possible that patients who later develop post-traumatic arthritis would report greater pain and lower functional outcome score. QuickDASH and PROMIS scores could worsen with longer follow-up.

Conclusion

We describe a novel surgical technique that addresses the problem of achieving adequate fixation in very distal articular humerus fractures with significant comminution and poor bone quality. We believe our method of fixation may spare patients the need for a total elbow arthroplasty, providing good to excellent clinical outcomes without activity restriction. Further comparative study comparing the two groups directly would be helpful in drawing a more substantiated conclusion. In our series, we achieved 100% union rate in all patients with minimum one year of follow-up. Patients reported low levels of postoperative pain, achieved reasonable elbow range of motion, and had excellent patient-reported outcome scores at the final follow-up. They were permitted any degree of motion and weight-bearing after healing and many returned to physical work (eg, construction, fire-fighting, demolitions), or high-demand leisure activity (eg, kayaking, yoga, rock-climbing). Complication and reoperation rates remain high but comparable with other techniques used to treat these injuries. Patients should be counseled preoperatively about the risk of ulnar nerve paresthesias that should be expected to recover and symptomatic hardware that may warrant a second procedure.

Conflicts of interest

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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Use of the HemaClear™ elastic tourniquet reduces blood loss in operative treatment of humeral shaft fractures

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ABSTRACT

Background: To determine if the use of a narrower elastic tourniquet compared to a standard pneumatic tourniquet reduces operative blood loss in the operative fixation of humeral shaft fractures.

Methods: This retrospective cohort study was performed at a level I trauma center and included 134 patients, aged 18 to 90 years, with a humeral shaft fracture treated with open reduction internal fixation (ORIF) from January 2007 through June 2018. The primary variable of interest was the application of a HemaClear™ elastic tourniquet versus a standard pneumatic tourniquet during the fixation of a humeral shaft fracture. The primary outcome was estimated blood loss (EBL) during the humerus ORIF surgery as recorded in the operative record. The secondary outcomes were total tourniquet time and operative time. The primary purpose of the study was to compare the above outcomes between the two tourniquet types.

Results: Estimated blood loss was 42% lower (95% CI: 11% to 73%, $p < 0.01$) in the elastic tourniquet group when compared to the standard pneumatic tourniquet group. The use of the elastic tourniquet was also associated with a 67% increase (95% CI: 35% to 100%, $p < 0.01$) in tourniquet time compared to the standard pneumatic tourniquet. No difference in the total operative time between the two groups (difference, -3%; 95% CI: -21 to 14, $p = 0.72$) was observed.

Conclusion: Elastic tourniquet use was associated with 42% less blood loss in the fixation of humeral shaft fractures compared to use of a traditional pneumatic tourniquet, although this may be of unclear clinical importance given the relatively low estimated blood loss in this cohort. The potential benefit of reduced blood loss associated with the narrower elastic tourniquet is likely caused by the increased tourniquet time, without a change in overall operative time.

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Introduction

Open reduction internal fixation (ORIF) of the humeral shaft has been associated with clinically significant bleeding caused by the vascular nature and large exposures [1,2]. Tourniquets are one approach to reduce blood loss; however, tourniquets can increase the difficulty of the surgical procedure impeding the desired surgical outcome. The footprint of the commonly used pneumatic tourniquet is substantial and, therefore, often interferes with the proximal extent of the surgical incision. This limitation is especially true in proximal fractures using the anterolateral approach.

An alternative to the traditional pneumatic tourniquet is the elastic tourniquet. The elastic tourniquet works by unrolling a tightly wrapped cloth around a plastic tube. It requires no pneumatic device and is single use. One potential advantage is that the tourniquet is narrower than traditional pneumatic tourniquets. This type of tourniquet has been found to be an effective tourniquet for the treatment of distal radius fractures, carpal tunnel releases, total knee arthroplasty, and in the setting of hemodialysis angioaccess [3–7]. As such, it is possible that this type of tourniquet could reduce blood loss in humeral shaft fracture ORIF by being able to be used for a larger proportion of the surgical case, particularly in more proximal fractures.

Our primary purpose was to determine the association between the tourniquet type and estimated blood loss (EBL), tourniquet time, and operative time. We hypothesized the elastic tourniquet would be associated with less EBL than a traditional pneumatic tourniquet. Our secondary hypothesis was the elastic tourniquet

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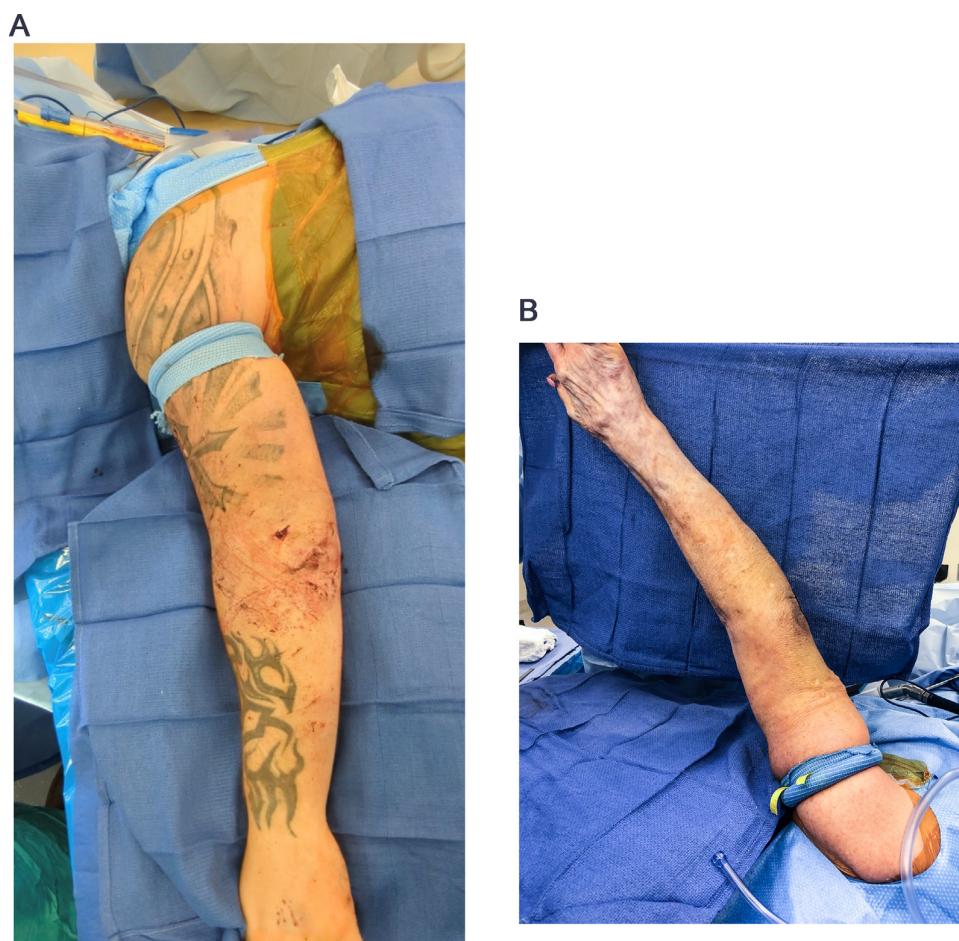


Fig. 1. (A, B) Two examples of HemaClear™ tourniquets placed in the sterile field on different patients.

would be associated with increased tourniquet time without increasing the overall surgical time. We also explored variations in outcomes based on surgeon volume, fracture location, and surgical approach.

Patients and methods

Study setting

This retrospective cohort study was conducted at a university-affiliated level I trauma center after receiving institutional review board approval. Patients were identified using an institutional database of billed Current Procedural Terminology (CPT) codes (24,515, 24,516) from January 2007 through June 2018. Patients treated by all institution-associated surgeons were included during the respective timeframe.

Study participants

We included patients between the ages of 18 to 90 years who underwent ORIF of an acute humeral shaft fracture. Patients with concurrent orthopedic or non-orthopedic operations, ipsilateral forearm fractures, or no blood loss reported were excluded. Fractures were excluded if a tourniquet was not used for the procedure or if the fracture lines extended into the proximal or distal joint.

Variables of interest

The primary variable of interest was tourniquet type. The elastic tourniquet (HemaClear™, OHK Medical Devices Inc., Grandville, MI) was compared to a traditional pneumatic tourniquet (Fig. 1). All elastic tourniquets were of medium size with a length less than 80 cm and a circumference between 24 cm to 40 cm. The elastic tourniquets were sized and applied per manufacturers guidelines. The pneumatic tourniquet used was either an 18 cm or 24 cm standard pneumatic tourniquet (Fig. 2). The tourniquet type used was at the discretion of the attending surgeon. Fifteen different surgeons performed the surgical treatments included in the study. Four surgeons contributed five or more patients and used both elastic and pneumatic tourniquets during the study period. Two of the four surgeons treated 72% of the included patients. All surgeons were fellowship-trained orthopedic trauma or hand surgeons. All cases were done either with an anterolateral or posterolateral approach in the lateral position.

We collected patient characteristics from institutional electronic medical records, including age, sex, body mass index (BMI), and laterality. Fracture characteristics, such as open versus closed, radial nerve injury, and polytrauma injuries, were recorded. The fracture location was determined by dividing the humeral shaft into three equal length segments: proximal, middle, and distal. The main fracture line or main point of comminution determined the fracture segment.

Table 1
Patient characteristics.

Characteristic	Elastic Tourniquet (n = 75)	Pneumatic Tourniquet (n = 59)	P
Age, years, mean (SD)	42.8 (21.1)	37.0 (17.0)	0.08
Sex, male, n (%)	44 (58.7)	41 (69.5)	0.20
Body mass index, kg/m ² , mean (SD)	27.8 (5.2)	28.5 (7.4)	0.51
Fracture location, n (%)			
Distal third	19 (25.3)	21 (35.6)	0.28
Middle third	48 (64.0)	35 (59.3)	
Proximal third	8 (10.7)	3 (5.1)	
Open fracture, n (%)	23 (30.7)	16 (27.1)	0.65
Radial nerve injury, n (%)	21 (28.0)	20 (33.9)	0.46
Polytrauma injury, n (%)	31 (42.5)	21 (35.6)	0.42
Approach, n (%)			
Anterior/deltpectoral	33 (44.0)	11 (18.6)	<0.01
Posterior	42 (56.0)	48 (81.4)	

**Fig. 2.** A pneumatic tourniquet placed in the sterile field.

Study outcomes

The primary outcome was EBL during the humerus ORIF surgery as recorded in the operative record. The secondary outcomes were total tourniquet time and operative time. Both tourniquet time and operative time were available as part of the standard nursing documentation. The operative time was defined as the time from skin incision to skin closure in the nursing documentation.

Statistical analysis

Assuming a baseline EBL of 200 mL with a standard deviation of 100 mL, a sample of 128 patients would provide 80% power to detect a 25% reduction in EBL caused by the elastic tourniquet with an alpha of 0.05.

Patient characteristics were described using means with standard deviations for continuous data and counts with proportions for categorical data. *Student t* tests and chi-squared tests were used for bivariate comparisons of the patient characteristics and the tourniquet type. The primary analysis tested the association between EBL and tourniquet type. The secondary analyses tested the association between tourniquet time and operative time with tourniquet type. The analyses were performed using mixed effects models, with each surgeon uniquely coded and included as a random effect in the model. Given the highly skewed distribution of

the EBL, tourniquet time, and operative time, the variables were log transformed. The effect of the elastic tourniquet is reported in reference to the standard pneumatic tourniquet in the regression models and can be interpreted as the percent change in the outcome. We conditioned these models based on the surgical approach and fracture segment.

We performed three subgroup analyses, stratifying the sample based on surgical volume among the participating surgeons (≥ 5 patients treated versus < 5 patients treated), the surgical approach (posterior versus anterior/deltpectoral), and fracture segment (proximal third versus middle third versus distal third). All statistical analyses were performed using JMP Pro-Version 14 (Cary, NC), and statistical significance was set to $\alpha = 0.05$.

Results

Of the 134 patients included in the study, the mean age was 40.2 years (SD: 19.5) and 63% were male ($n = 85$). Patients most commonly had fractures in the middle one-third of the humerus (62%). No significant differences were observed between the two groups regarding patient age, sex, BMI, incidence of polytrauma, proportion of open fractures, or incidence of radial nerve palsy (Table 1). The location of the fractures treated were similar between the two groups. The pneumatic tourniquet was used more commonly in fractures treated with a posterior approach ($p < 0.01$).

The median EBL was 175 mL (IQR: 100 to 300). Patients treated with the elastic tourniquet had 42% less blood loss than patients treated with the pneumatic tourniquets (95% confidence interval [CI]: -73% to -11% , $p < 0.01$) (Table 2). The median tourniquet time was 36 min (IQR: 19 to 80). Elastic tourniquets were applied for 67% longer than the pneumatic tourniquets (95% CI: 35% to 100%, $p < 0.01$). The median operative time was 180 min (IQR: 147 to 224). No difference in operative time between the two groups (difference, 3%; 95% CI: -21% to 15% ; $p = 0.72$) was observed.

In the subgroup analyses, all results favored the elastic tourniquet over the pneumatic tourniquet (Fig. 3). When we stratified the sample based on surgeon volume, the elastic tourniquet was associated with reduced EBL by 130% (95% CI: -228 to 31 , $p = 0.02$) in the low volume surgeons. However, no association was found between tourniquet type and EBL for high volume surgeons (difference, -25% ; 95% CI: -66 to 14 ; $p = 0.20$). Elastic tourniquets were associated with increased tourniquet time for fractures in the distal segment (difference, 81%; 95% CI: 28% to 133%; $p < 0.01$) and middle segment (difference, 76%; 95% CI: 32% to 121%; $p < 0.01$) but were not associated with change in the tourniquet time for fractures in the proximal segment (difference, 7%; 95% CI: -148 to 177 ; $p = 0.84$). Elastic tourniquets were associated with increased tourniquet time for fractures treated with the posterior approach

Table 2
Association between tourniquet type and estimated blood loss, tourniquet time, and operative time.

	Median (IQR)	Adjusted Percent Change	95% Confidence Interval	P
Estimated blood loss, mL				
Elastic tourniquet	150 (100 to 300)	−42.2	−73.2 to −11.2	<0.01
Pneumatic tourniquet	200 (100 to 300)	Ref (0.0)	Ref (0.0)	Ref (0.0)
Tourniquet time, minutes				
Elastic tourniquet	51 (25 to 89)	67.4	34.8 to 1.00	<0.01
Pneumatic tourniquet	29 (14 to 53)	Ref (0.0)	Ref (0.0)	Ref (0.0)
Operative time, minutes				
Elastic tourniquet	180 (141 to 221)	−3.1	−20.7 to 14.6	0.72
Pneumatic tourniquet	180 (155 to 228)	Ref (0.0)	Ref (0.0)	Ref (0.0)

Models were adjusted based on the surgical approach and fracture segment as fixed effects and the surgeon as a random effect.

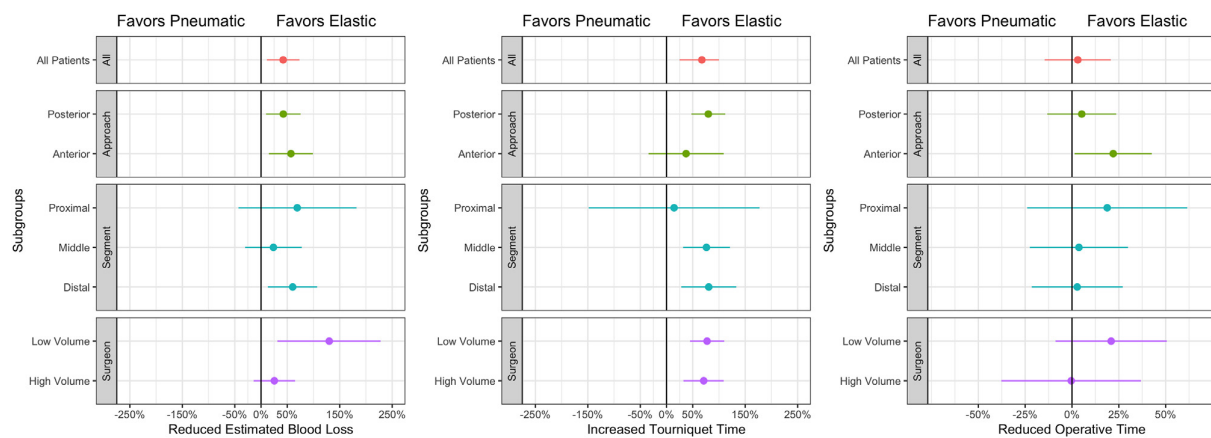


Fig. 3. Heterogeneity of tourniquet effect based on surgeon volume, fracture segment, and surgical approach.

(difference, 80%; 95% CI: 47 to 112; $p < 0.01$) but were not associated with change in the tourniquet time for fractures treated with the anterior/deltoidpectoral approach (difference, 37%; 95% CI: −34 to 110; $p = 0.30$). The use of an elastic tourniquet was associated with reduced operative time for fractures treated with the anterior/deltoidpectoral approach (difference, −22%; 95% CI: −42 to −1; $p = 0.04$) but was not associated with change in operative time of fractures treated with the posterior approach (difference, −5; 95% CI: −24 to 13; $p = 0.58$).

Discussion

Patients whose fractures were treated using the elastic tourniquets had significantly less blood loss and increased tourniquet time than patients treated with the pneumatic tourniquet. The magnitude of the blood loss difference is of unlikely clinical significance as it is only 50 cc; however, the ability to keep the tourniquet for a longer time period may be of more clinical importance. However, we observed no difference in operative time between the two groups. Elastic tourniquets were more commonly used in fractures treated with an anterolateral approach. This approach and the fractures commonly fixed using this approach highlight the limitations of a wider pneumatic tourniquet.

Our subgroup analyses suggest that the benefits of elastic tourniquets are greatest for surgeons that treat a low volume of humeral shaft fractures. While the reason for this is not immediately clear, we suspect that operative familiarity and experience play a role in decreased blood loss. Fracture location is a major determinate of the approach [8,9]. Our results suggest that the shorter tourniquet time benefits of the elastic tourniquet were

greatest in fractures treated with the posterior approach, and for fractures in the middle or distal third of the humeral shaft.

Reducing blood loss in humeral shaft fractures might be clinically important particularly in polytrauma patients. These patients are also the most vulnerable to blood loss [10]. Thus, it is important to optimize modalities that can control blood loss. Although we excluded patients who had other surgeries during the same setting, patients treated with humerus ORIF often have other injuries for which plating the humerus is thought to increase mobility by allowing crutch weight bearing. It is in this setting where the reduced blood loss can be particularly advantageous.

The strengths of the study include the novelty of this finding. To our knowledge, the effect of tourniquet type on EBL of humerus ORIF has not been reported previously and is likely to be of interest to surgeons operating on humeral shaft fractures. The vast majority of cases were performed by surgeons who used both types of tourniquets and both surgical approaches. We used mixed effects statistical models to account for confounders and surgeon variation, and the outcome variables were consistently reported.

Limitations to the study include the retrospective, nonrandomized nature of the study. Some inherent inaccuracy with reported EBL taken from the operative record can be expected. Although the two comparison groups differed in terms of surgical approach, we did account for this difference in our models. Further, the use of the elastic tourniquet became more common over time, so EBL might have reduced as surgeons became more experienced. However, this effect seems unlikely considering the experience level of the surgeons in this cohort. These data are from a single, level I center, so generalizability to other centers and patients is unknown. Finally, our primary outcome variable of EBL has the inherent issue of being an “estimated” value. However, it is highly

unlikely that the surgical team would have a bias leading them to preferentially underestimate blood loss in the elastic group for any reason.

Conclusion

Use of an elastic tourniquet was significantly associated with less blood loss compared to use of a traditional pneumatic tourniquet in the treatment of humeral shaft fractures (41% reduction, $p < 0.01$). This finding may be of unclear clinical importance given the relatively low estimated blood loss in this cohort. No difference in operative time was found. The intrinsic narrower design of an elastic tourniquet appears to allow for longer use, thus decreasing overall blood loss. Subjectively, the use of a tourniquet with a smaller footprint has changed surgical practice for surgeons at the institution where this study was undertaken.

Declaration of interests

C. Domes serves as a paid consultant for Johnson and Johnson: Synthes, unrelated to this study.

N. N. O'Hara receives stock options from Arbutus Medical Inc., unrelated to the study.

R. V. O'Toole serves as a paid consultant for Stryker, receives stock options from Imagen, and receives royalties from Lincotek, all unrelated to this study. The remaining authors report no conflicts.

Acknowledgement

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TECHNIQUE

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).

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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.

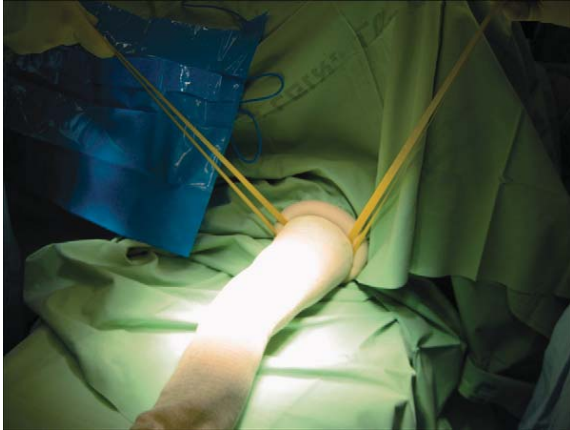


FIGURE 3. Straps are pulled proximally and the sterile stockinette unrolls onto the limb.

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.



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

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					
		20-30	30-40	40-50	50-60	60-70	70-80
LIMB CIRCUMFERENCE (cm) AT OCCLUSION LOCATION	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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Using HemaClear® on a Mono-trauma Left Knee-distal Femur: A Case Report

Peter Reynders MD PhD,

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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 exsanguination 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

 Case Report

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.

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

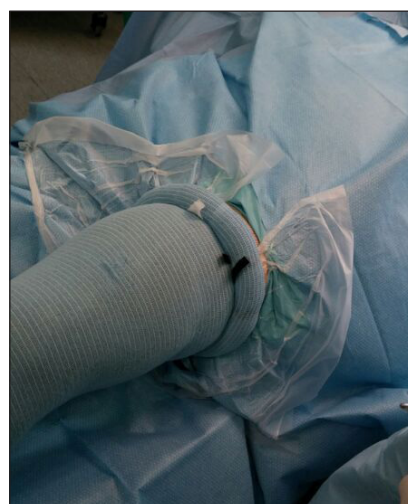


Figure 3: Photograph showing the stockinet sleeve unrolled on the limb and covering it entirely up to the level of the occlusion level, with a sterile drape covering the surgical field.

fentanyl, and tracheal intubation was facilitated by succinylcholine. A HemaClear tourniquet was then rolled onto the injured limb from the toes to the mid thigh. 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

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, mak-

ing routine use difficult. Diagnostic work-up 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 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 1904¹; 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 sequelae,⁵ and although serious



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

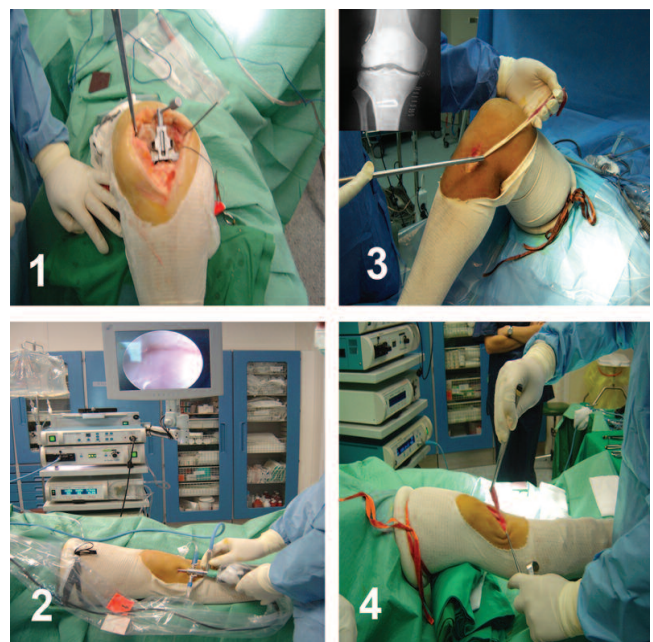


Figure 2. Above knee application of a silicone ring tourniquet in elective cases. (1) Total knee replacement, (2) knee arthroscopy, (3) ACL reconstruction with hamstrings graft, (4) ACL reconstruction with patellar tendon graft.

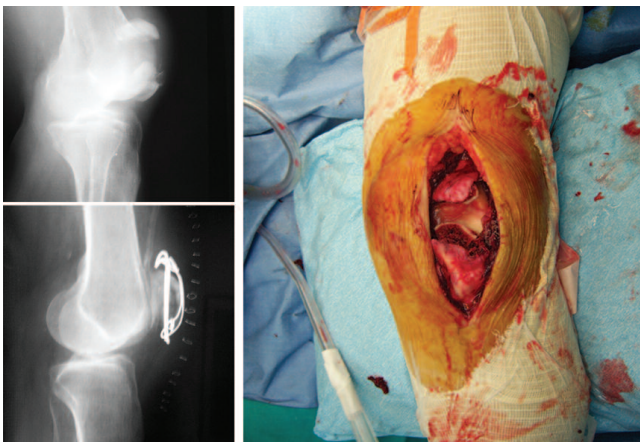


Figure 3. Open reduction and internal fixation of a patellar fracture using a femoral silicone ring tourniquet.

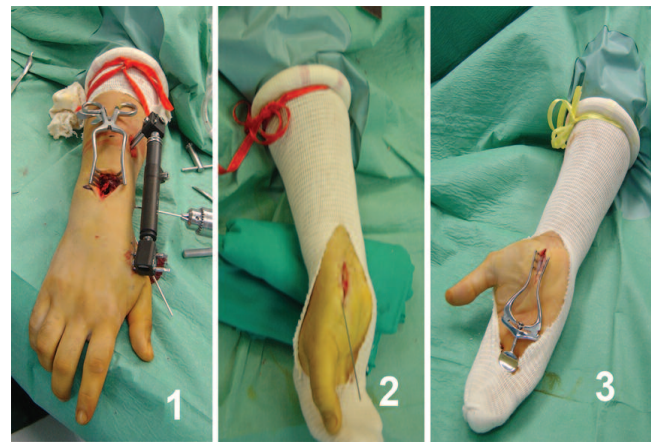


Figure 4. Forearm application of a silicone ring tourniquet. (1) Fixation of a distal radial fracture, (2) scaphoid fracture fixation, (3) carpal tunnel release.

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 pre-set. 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

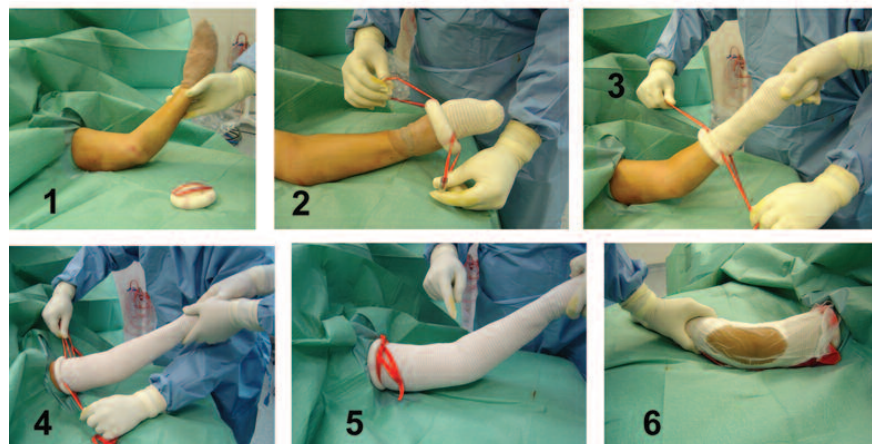


Figure 5. Humeral application of a silicone ring tourniquet.

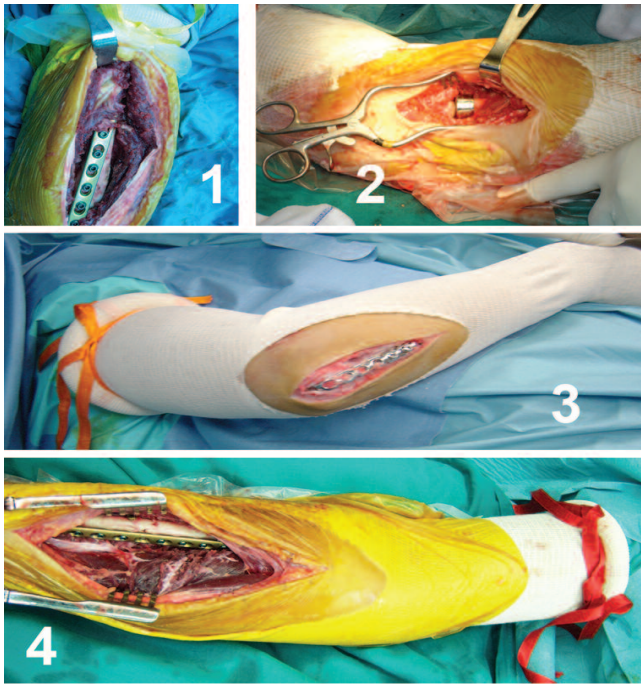


Figure 6. Humeral application of a silicone ring tourniquet. (1) Internal fixation of a humeral shaft fracture, (2) radial head replacement, (3) removal of ulnar plate, (4) internal fixation of a radial fracture.



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 record-

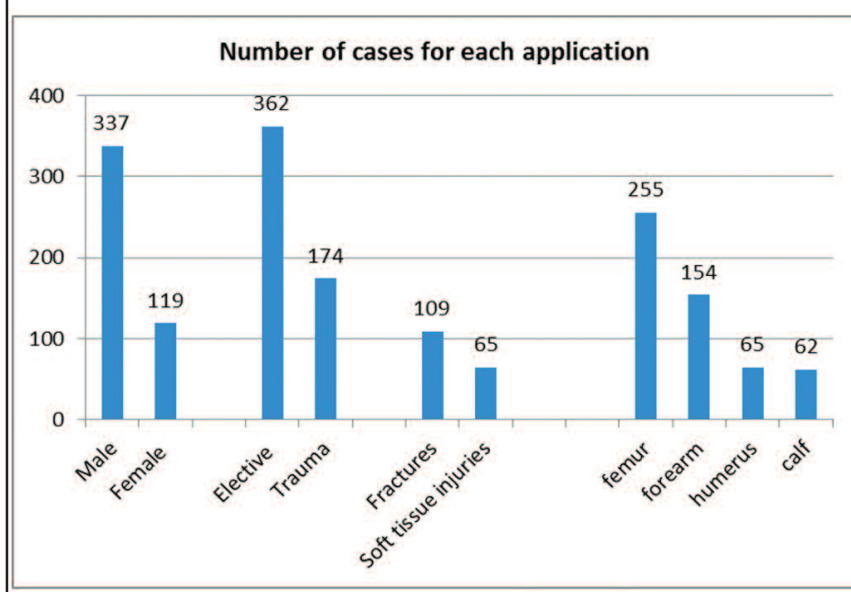
ed, and these included: (a) skin injuries underneath the tourniquet, (b) post-tourniquet syndrome, (c) nerve paralysis that was followed by either complete recovery (neurapraxia) or permanent nerve damage (paralysis), and (d) any other immediate intraoperative or post-operative complication that may 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.

RESULTS

Table I
Results of the Data Collection



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

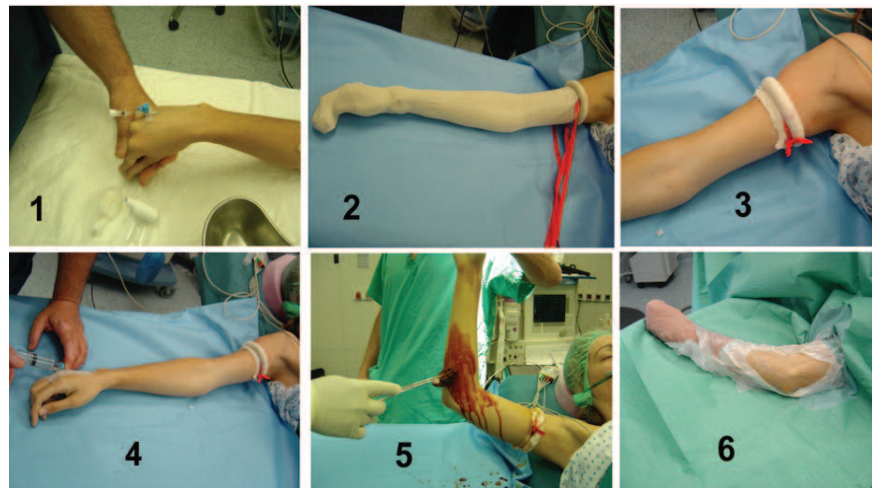


Figure 8. Bier's block using a humeral silicone ring tourniquet.

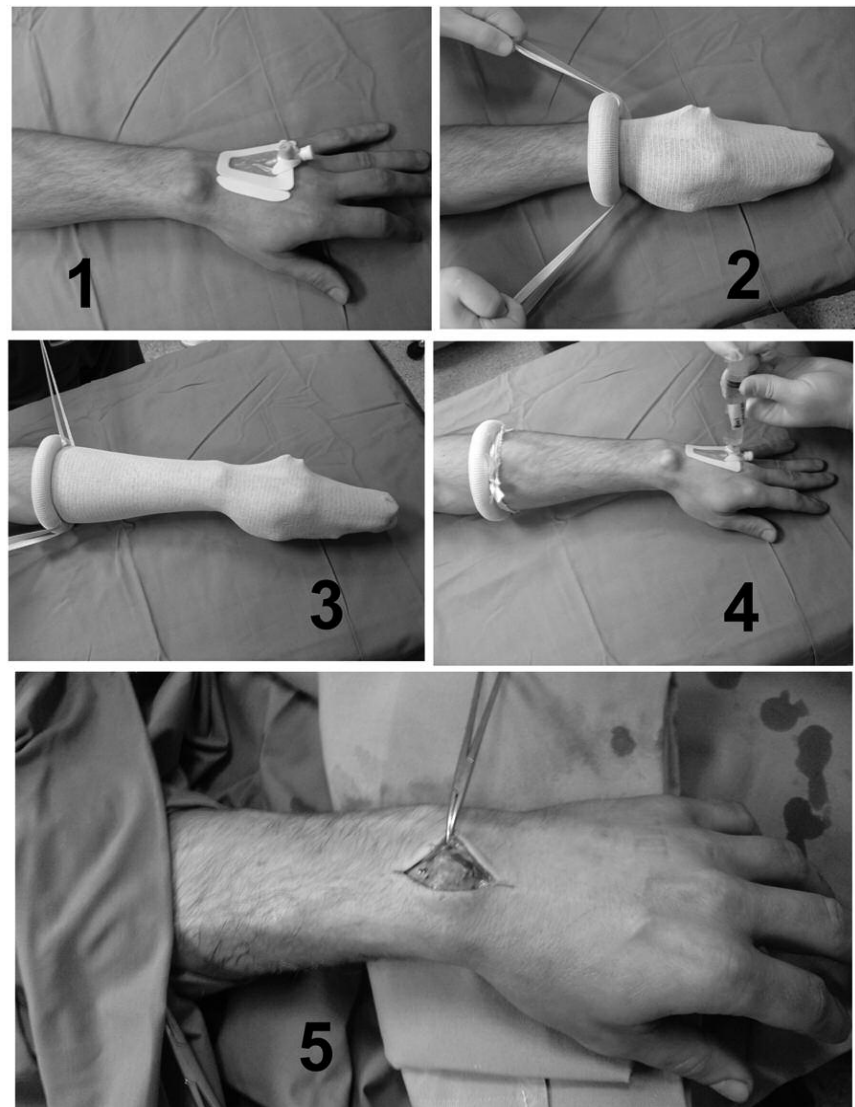


Figure 9. (1-4) Bier's block using a forearm silicone ring tourniquet and (5) removal of a ganglion cyst.

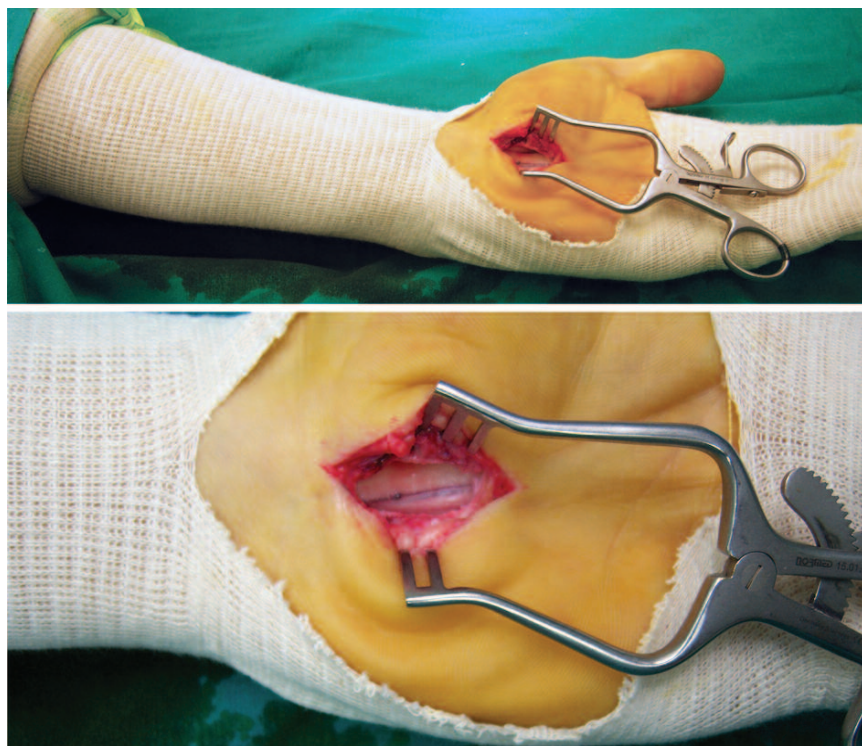


Figure 10. Carpal tunnel release. Excellent exsanguination of the hand using a forearm silicone ring tourniquet.

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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Sterile Exsanguination Tourniquet

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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 (cm²) 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

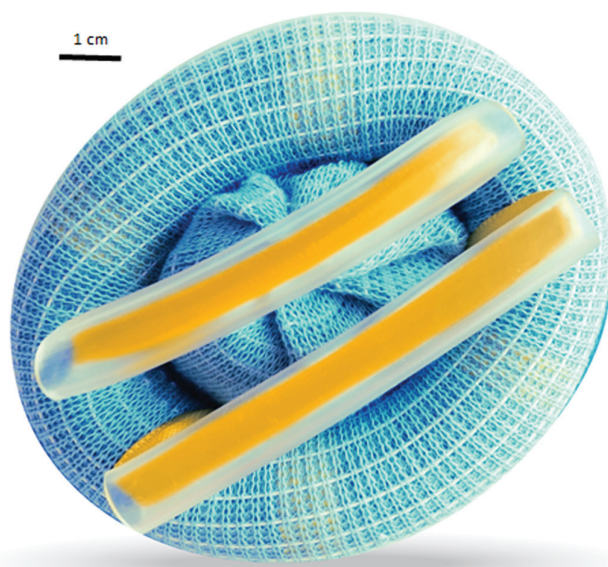


Fig. 1 - HemaClear®/40 yellow tourniquet.

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).

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 Reynders (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: $35 \times 14 = 490 \text{ cm}^2$) inflated at 200 mm Hg (or 266 g/cm^2), the total force applied to the arm is $490 \times 266 = 130 \text{ kg}$. 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 $7 \times 35 \times 266 = 65 \text{ kg}$. 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 incompressible 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).

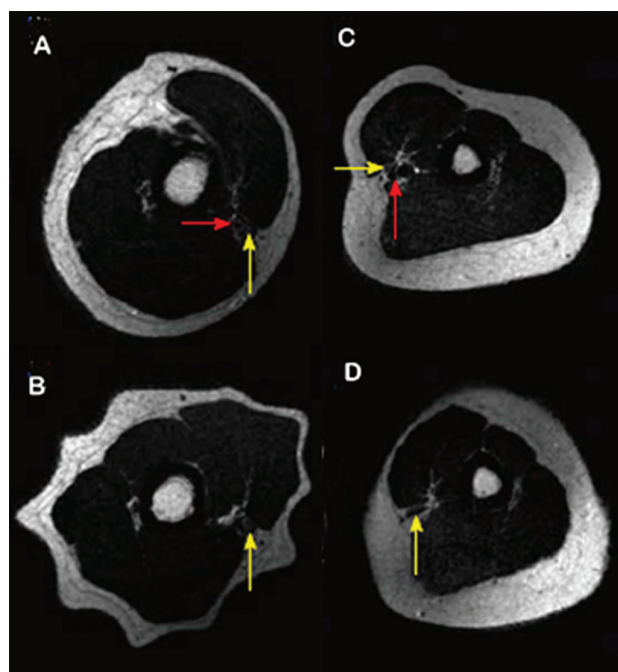


Fig. 3 - Magnetic resonance imaging (MRI) of upper limb before and during compression with a pneumatic tourniquet (A, B) or a HemaClear® device (C, D), respectively. Red arrow indicates open brachial artery, yellow arrow indicates median nerve demonstrating no differences in nerve size without and with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

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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,

Exsanguination tourniquet can be used in hemodialysis access surgery

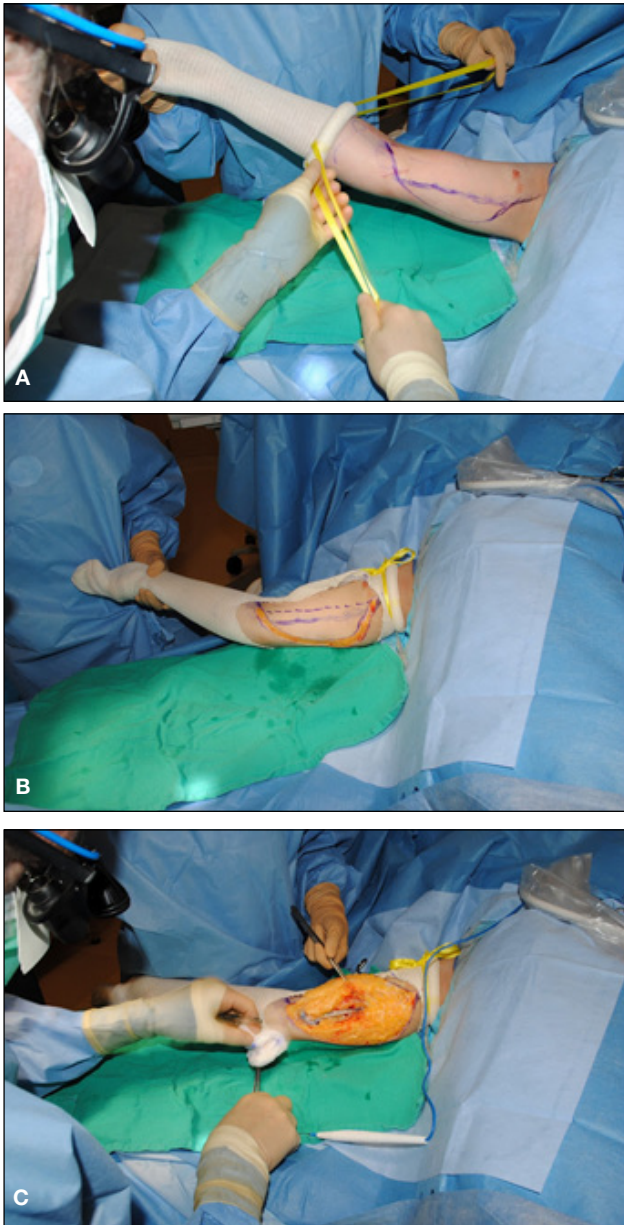


Fig. 1 - A) The SET is applied to the patient's arm by pulling the straps. **B)** The SET is in place and the first incision has been made. **C)** The vessels are dissected bloodlessly.

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



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

commenced, the SET is removed by cutting the ring with a scalpel, with care taken to avoid inadvertent nicking of the skin.

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 recov-

ery 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 brachio basilic 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

Exsanguination tourniquet can be used in hemodialysis access surgery

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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Surgical Tourniquets in Orthopaedics

Noam Gavriely

J Bone Joint Surg Am. 2010;92:1318-1322.

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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 nail¹⁻³.

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These letters originally appeared, in slightly different form, on jbs.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 Noordijn 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, Odinson and Finsen¹ 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

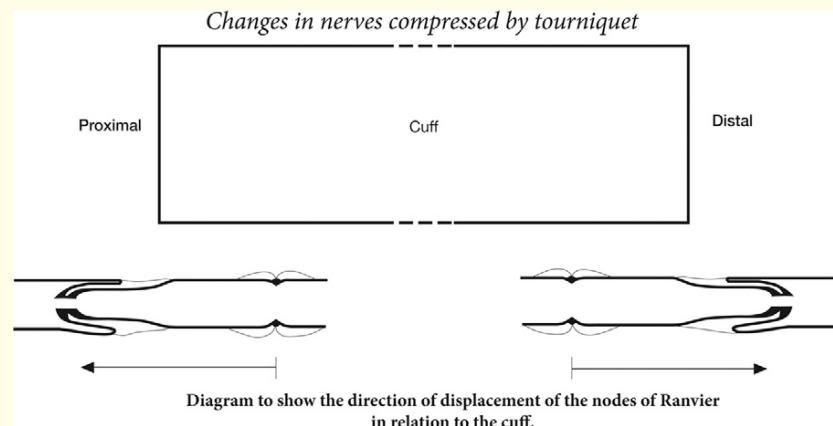


Fig. 1

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.)

(Middleton and Varian²) 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.

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 Noordijn et al. study³⁻¹³). 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*, Hodgson¹⁸ 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

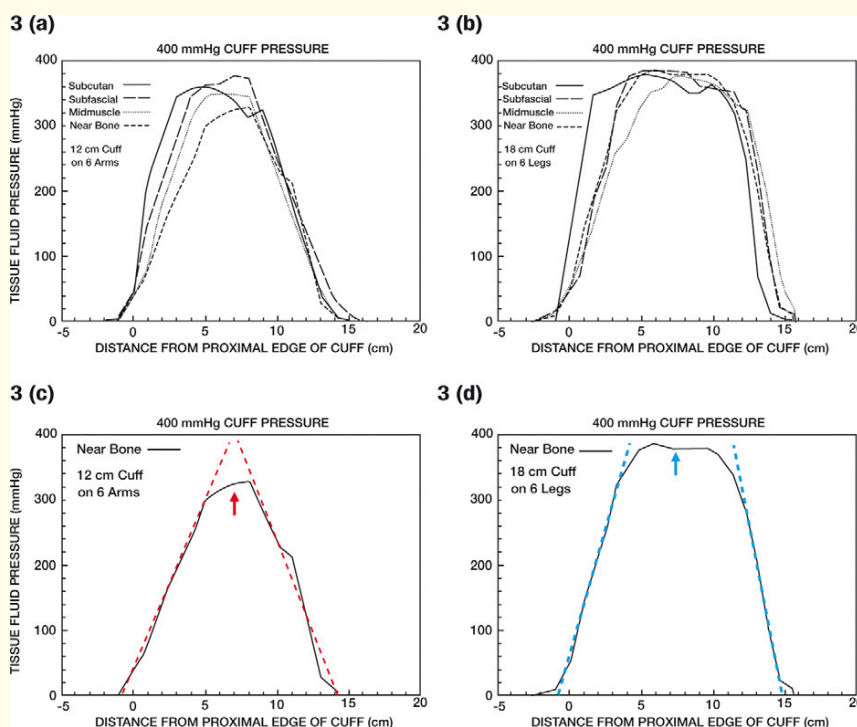


Fig. 3

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, Indiana²⁰). 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 Geddes²¹ 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 cuffs¹⁻⁶. It appears to us that Dr. Gavriely has misunderstood or misinterpreted aspects of earlier peer-reviewed papers by Ochoa et al.⁴, Hodgson⁵, 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. Hodgson⁵, 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 stresses. 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 & $\nu=0.5$, “Muscle” with $2E$ & $\nu=0.5$, “Bone” with $1000E$ & $\nu=0.4$, and “Blood Vessels” with $0.001E$ & $\nu=0.1$. 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 in 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” were made “compressible” ($\nu \ll 0.5$), 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

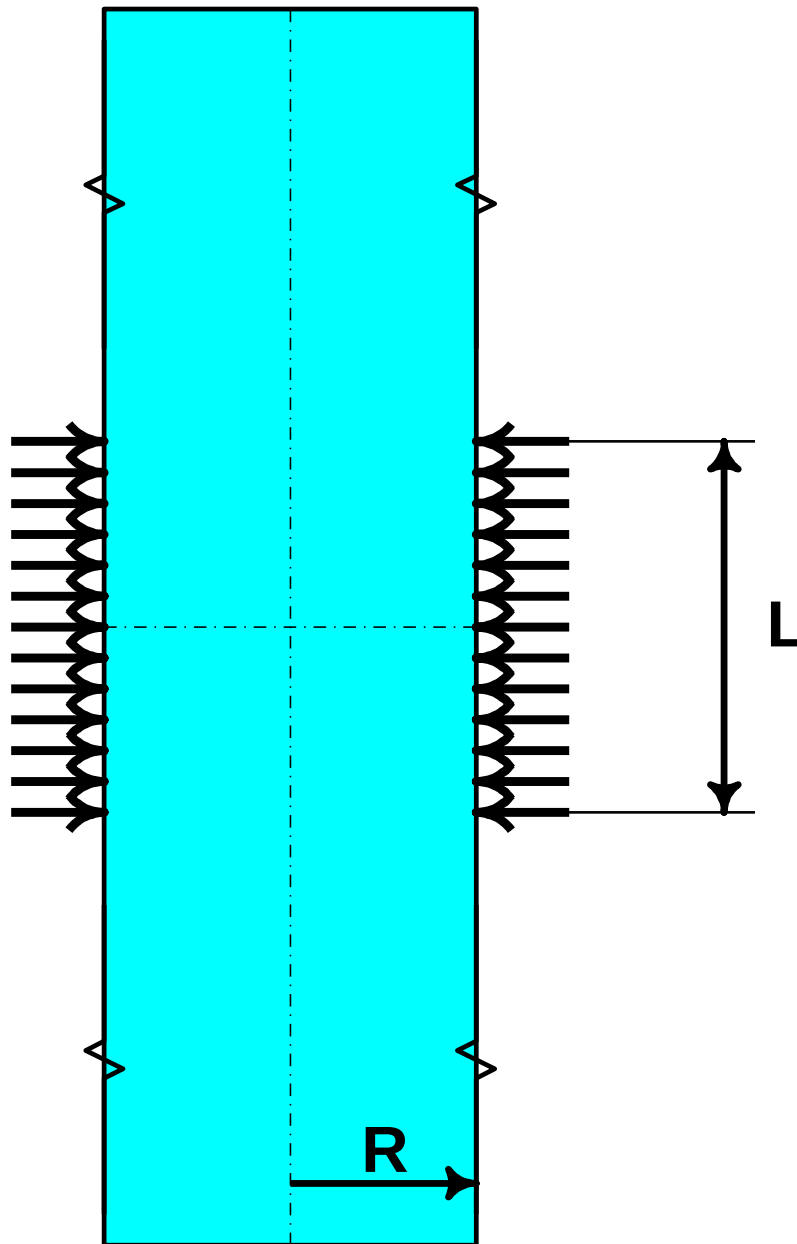


Figure 1: Pressure applied to a full-cylinder (axisymmetric model).

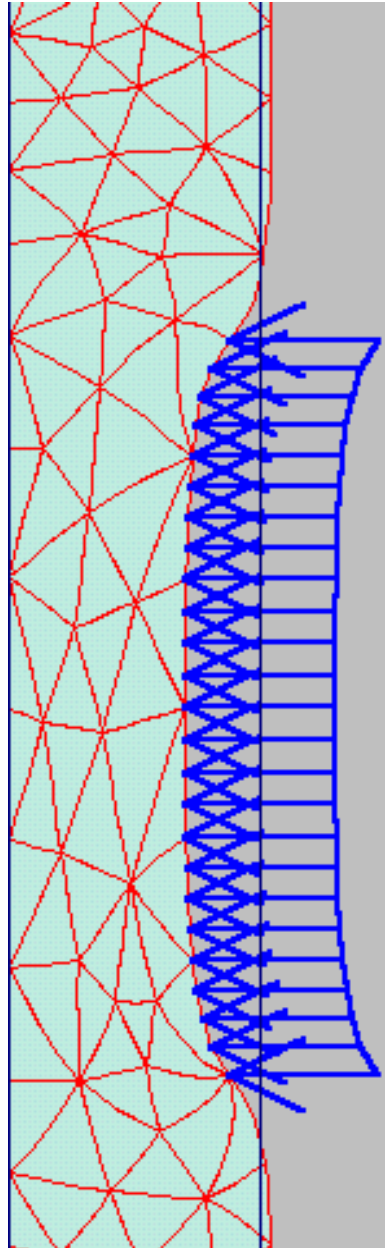


Figure 2: Deformation after pressure application (axisymmetric model).

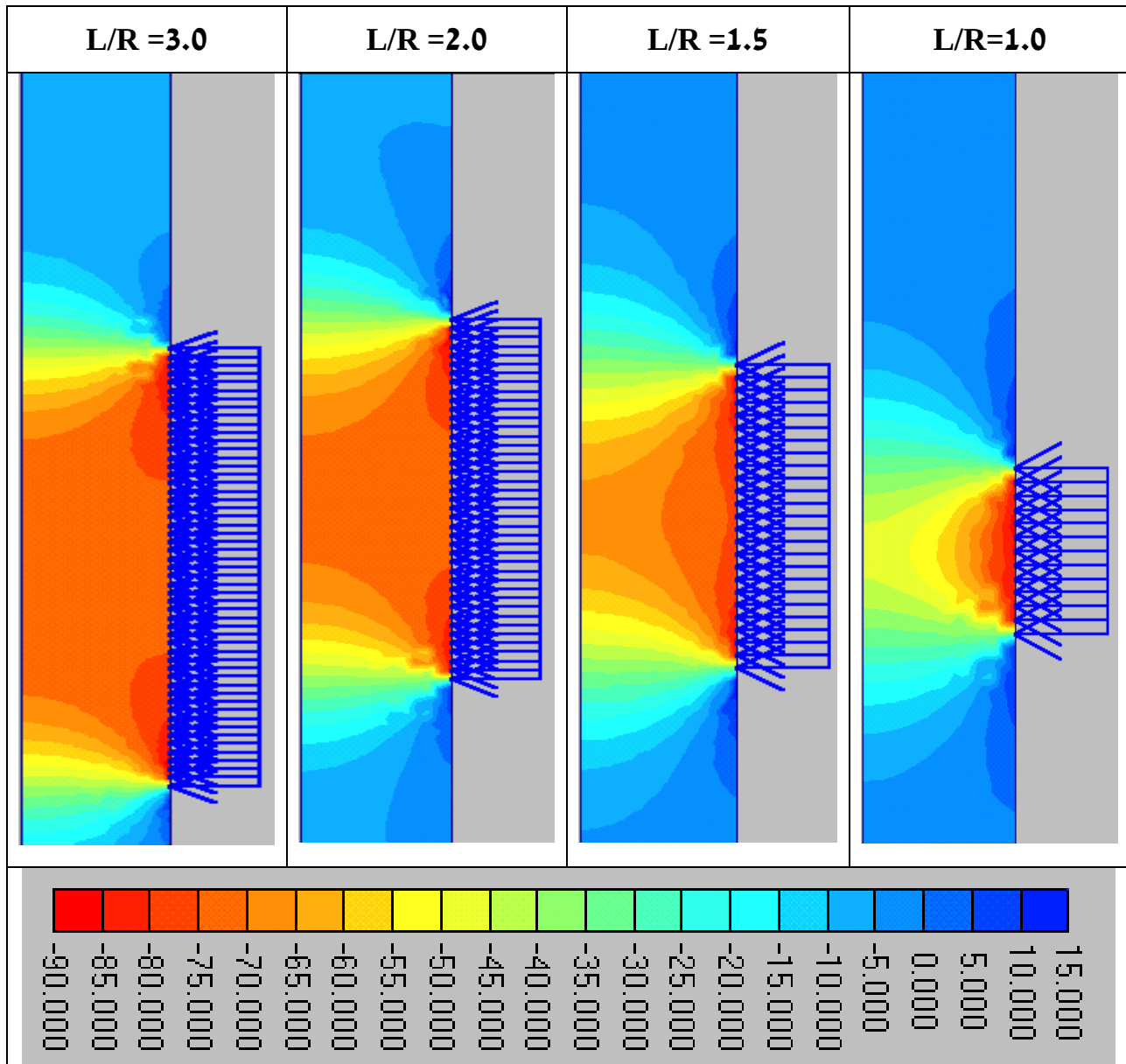


Figure 3: Internal pressure distribution for different L to R ratios (axisymmetric model).

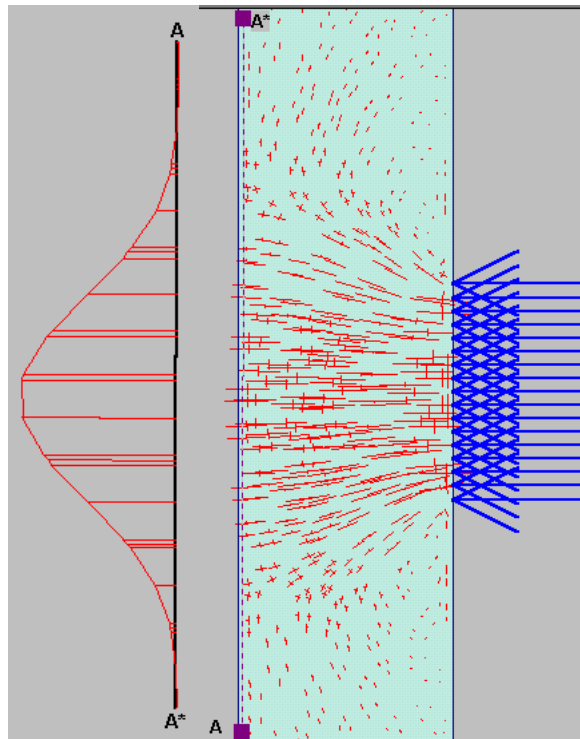


Figure 4: Distribution of principal stresses and a plot of the radial stresses at the axis of symmetry - maximum radial stress = 80%, $L/R=1$.

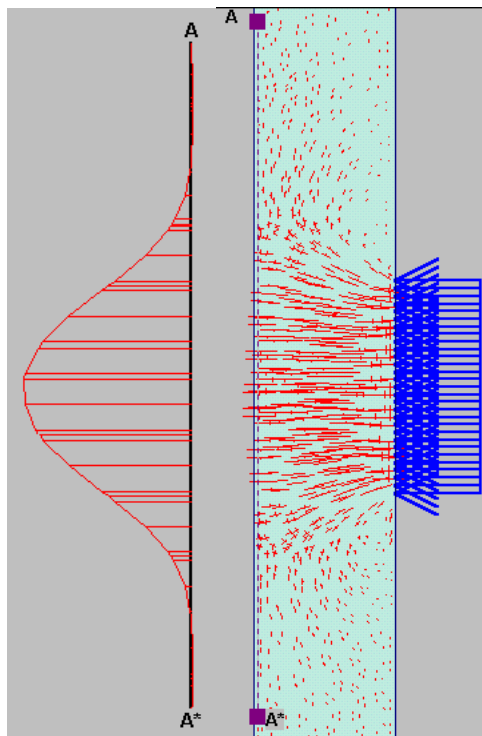


Figure 5: Distribution of principal stresses and a plot of the radial stresses at the axis of symmetry - maximum radial stress = 95%, $L/R=1.5$.

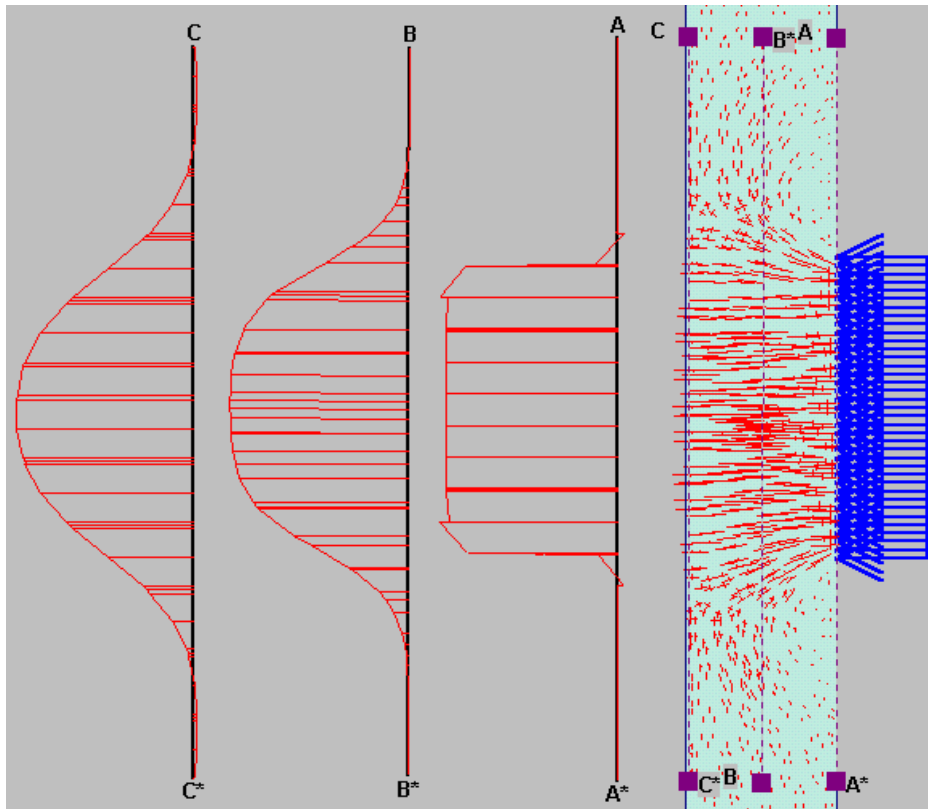


Figure 6: Distribution of principal stresses and a plot of the radial stresses at the several distances from the loading - maximum radial stress = 100% for all plots, $L/R=2$.

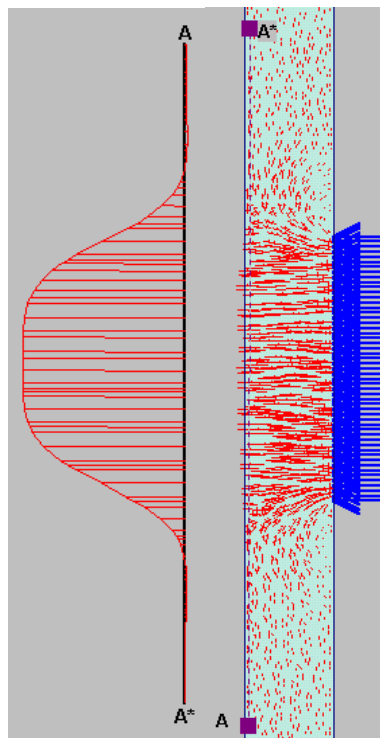


Figure 7: Distribution of principal stresses and a plot of the radial stresses at the axis of symmetry - maximum radial stress = 95%, $L/R=3.0$.

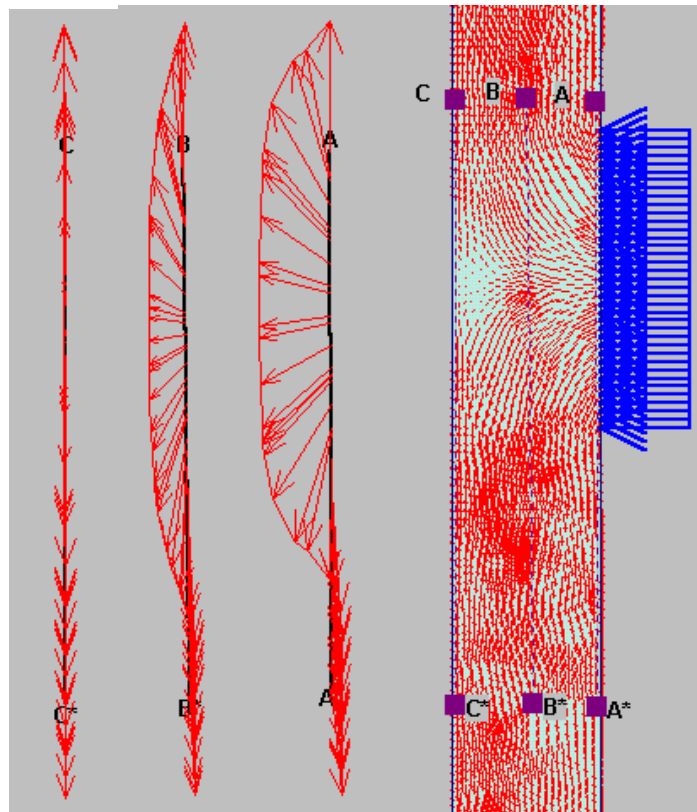


Figure 8: Arrow plot of the displacement field - $L/R=2.0$ (axisymmetric model).

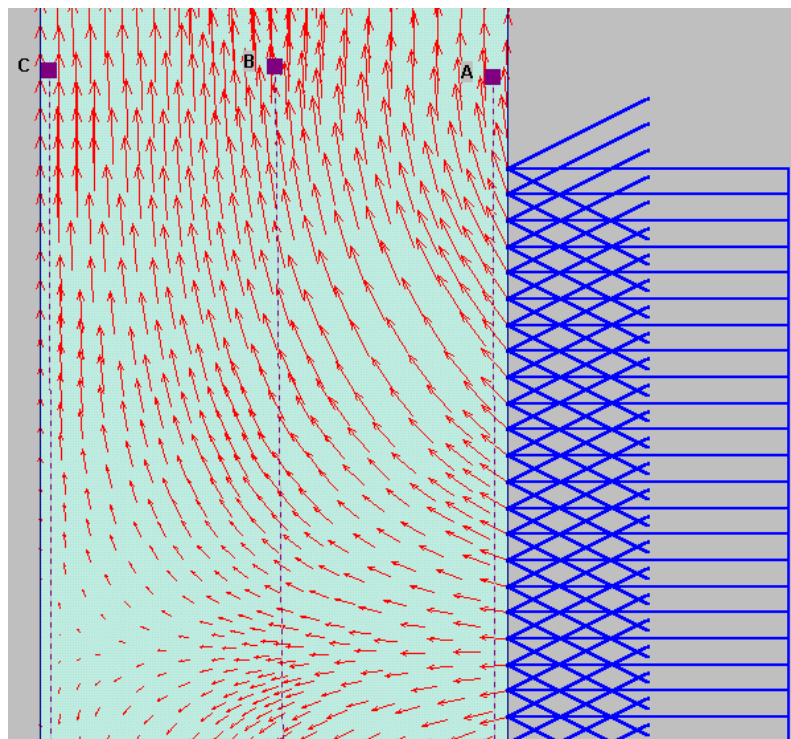


Figure 9: Arrow plot of the displacement field under to loading - $L/R=2.0$ (enlargement of Figure 8).

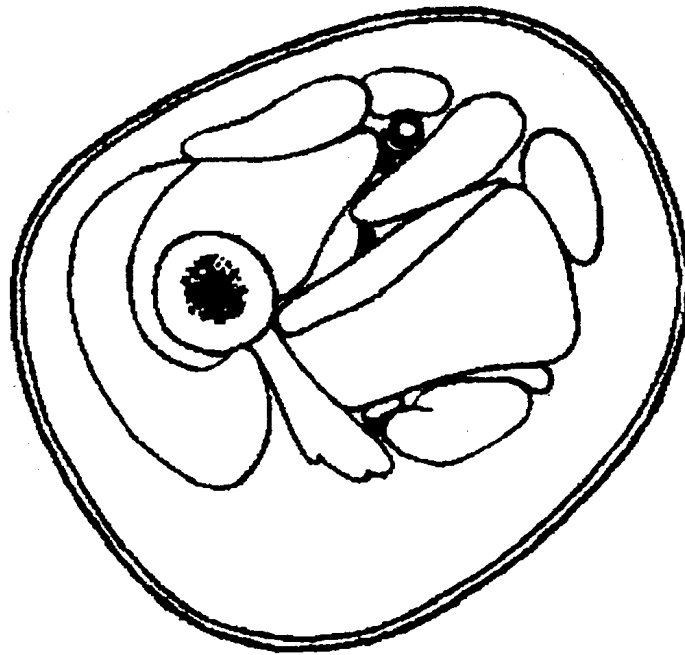


Figure 10: “Typical” cross section of a human thigh (Shaw and Murray, 1982).

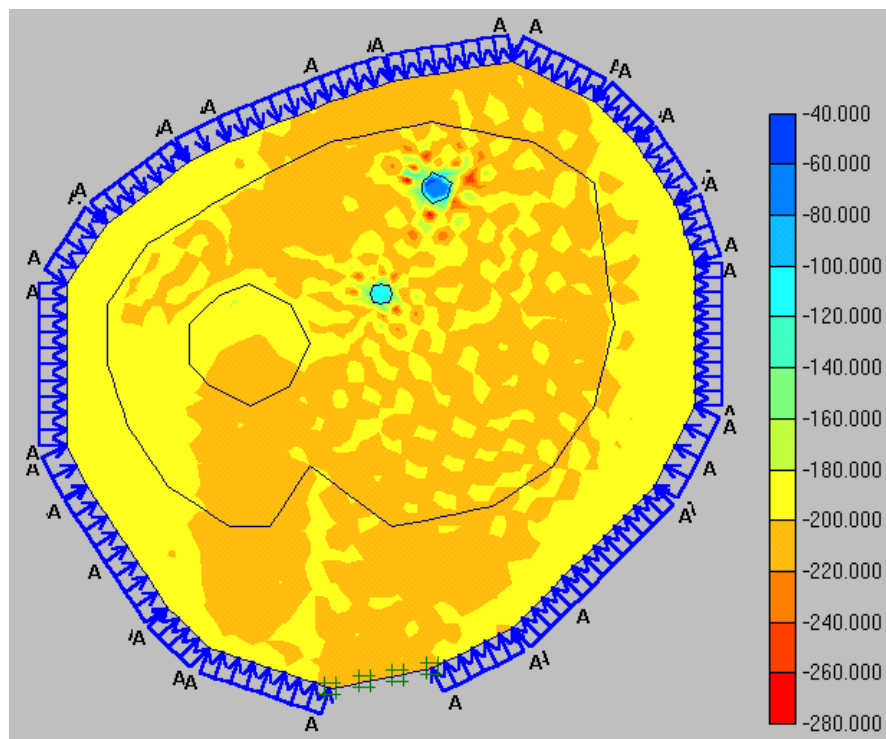


Figure 11: Internal pressure distribution (Plane-strain model).

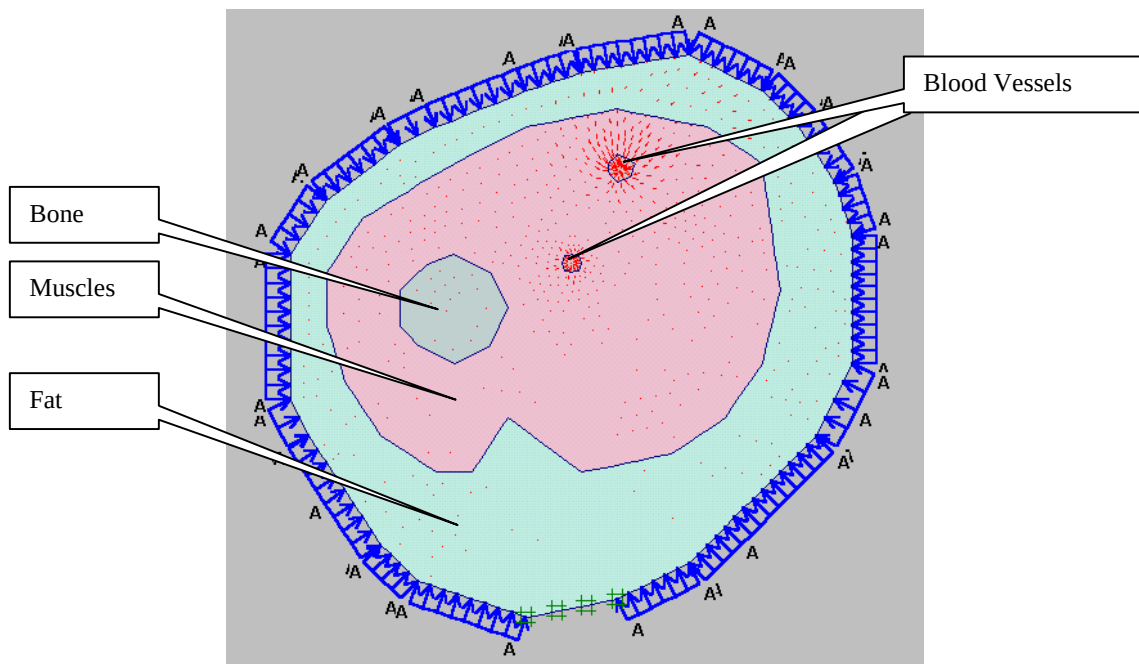


Figure 12: FE model of the thigh cross-section shown in Figure 10 (Plane-strain model).

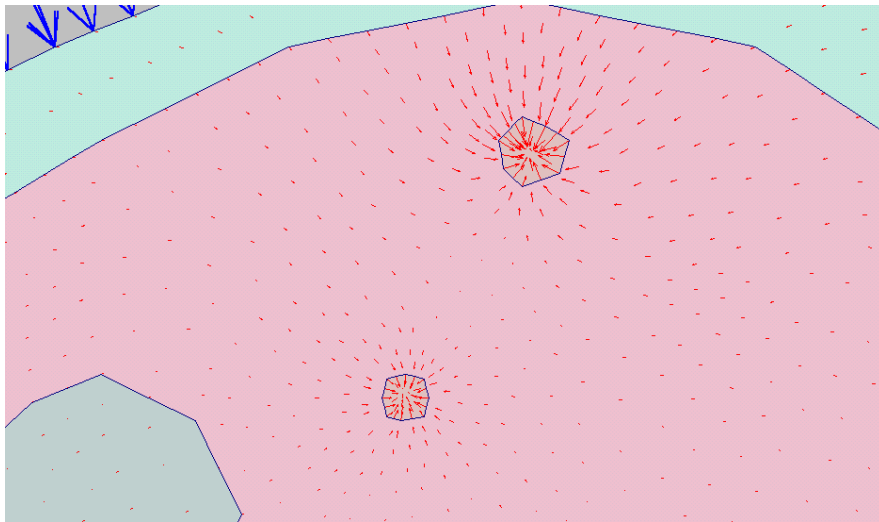


Figure 13: Displacement field and closure of "blood vessels" (plane-strain model).



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:

OHK Medical Devices

Division of Oneg HaKarmel Ltd.

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May 2002



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: ν_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: ν_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 is 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:

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

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:

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

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:

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

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

$$\sigma = E_1 \varepsilon \quad (3.4)$$

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:

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

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 radial 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]:

$$T = PR_2 \quad (3.6)$$

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:

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

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:

$$b = \sqrt{\frac{8P(d - \Delta d)C_E}{\pi}} \quad (3.8)$$

with C_E given by [3]:

$$C_E = \frac{1 - \nu_1^2}{E_1} + \frac{1 - \nu_2^2}{E_2} \quad (3.9)$$

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):

$$\sigma(s) = \sigma_0 \sqrt{1 - \left(\frac{2s}{b}\right)^2} \quad \text{For } |s| \leq \frac{b}{2} \quad (3.10)$$

with the maximum contact-stress magnitude (σ_0), with dimensions of force per unit area (also called “Hertzian stress”), given by:

$$\sigma_0 = \sqrt{\frac{2P}{\pi(d - \Delta d)C_E}} \quad (3.11)$$

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:

$$\varepsilon(P) = \frac{R(P) - R_1}{\left(R_1 + \frac{d(1+\nu_1)}{2} \right)} \quad (4.1)$$

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:

$$R(P) = R_2 - \Delta R_2(P) \quad (4.2)$$

with [2]:

$$\Delta R_2(P) \cong P \left(\frac{1-\nu_2^2}{\pi E_2} \right) \left\{ 2 \ln \left(\frac{4R_2}{b} \right) - \left(\frac{\nu_2}{1-\nu_2} \right) \right\} \quad (4.3)$$

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:

$$P = A(P)E_1 \frac{R(P) - R_1}{\left(R_1 + \frac{d(1+\nu_1)}{2}\right)R(P)} \quad (4.4)$$

$$b(P) = \sqrt{\frac{8P[d - \Delta d(P)]C_E}{\pi}} \quad (4.5)$$

$$\sigma(s) = \sigma_0 \sqrt{1 - \left(\frac{2s}{b(P)}\right)^2} \quad \text{For } |s| \leq \frac{b}{2} \quad (4.6)$$

$$\sigma_0 = \sqrt{\frac{2P}{\pi[d - \Delta d(P)]C_E}} \quad (4.7)$$

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):

$$\sigma_0 = \frac{4P}{\pi(d - \Delta d)\alpha} \quad (4.8)$$



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).

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E. Levenberg



FIGURES

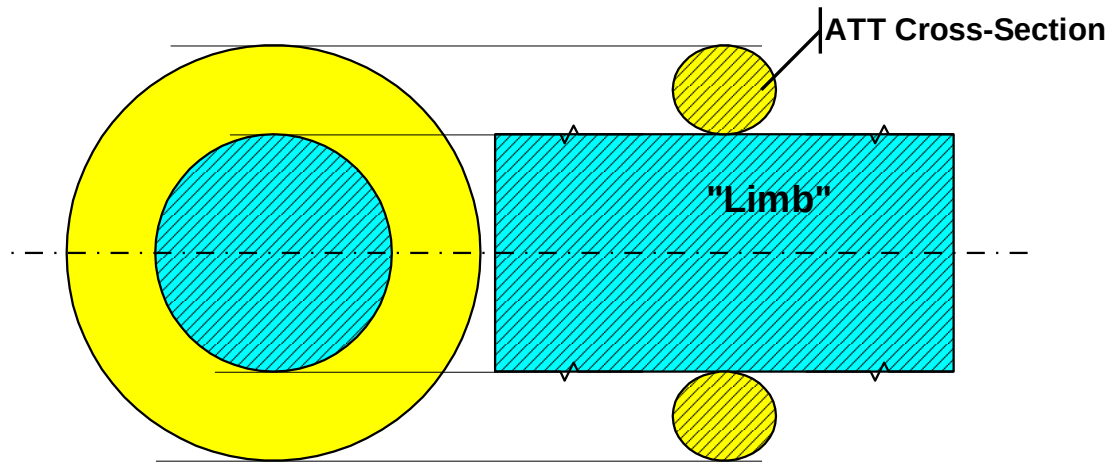


Figure 1: General view of the model.

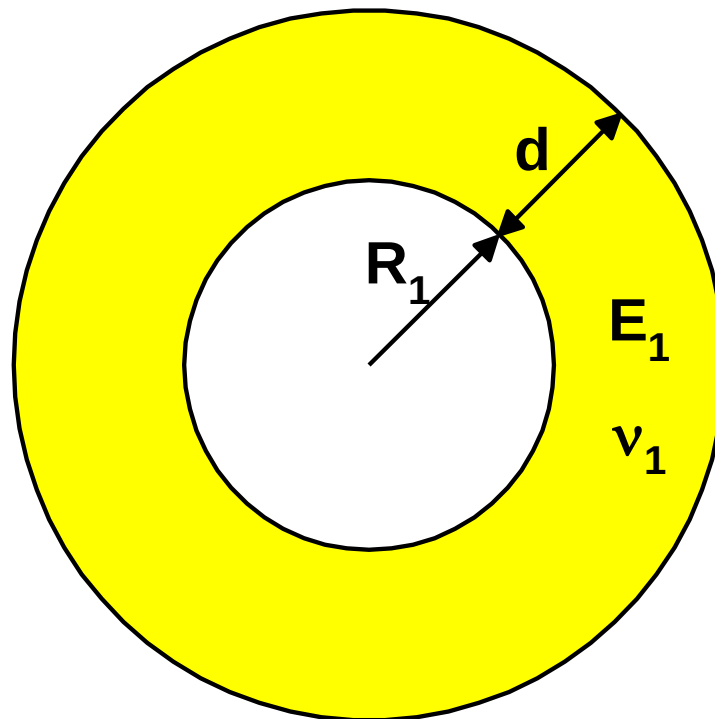


Figure 2: "ATT" model properties and parameters.

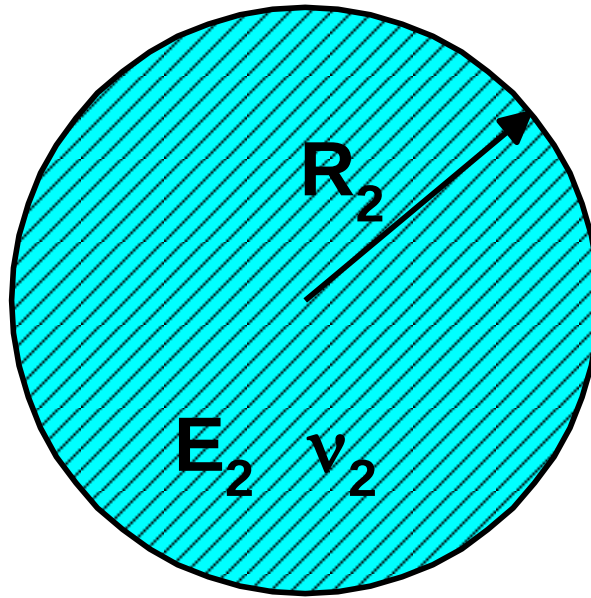


Figure 3: “Limb” model properties and parameters.

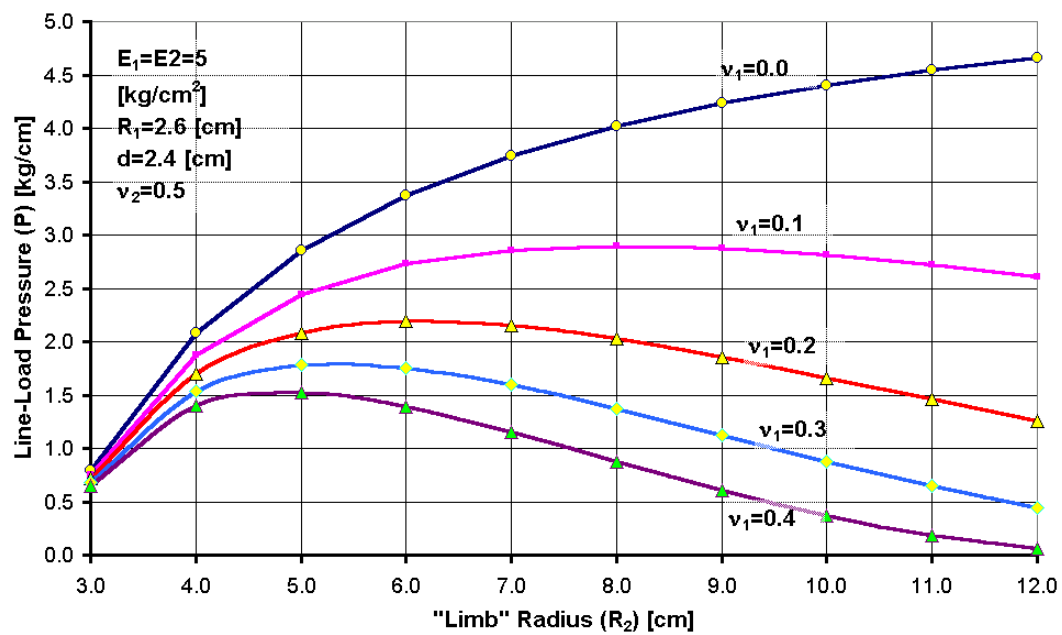


Figure 4: Line-load pressure for different “Limb” radii and ATT’s Poisson’s ratio (v_1).

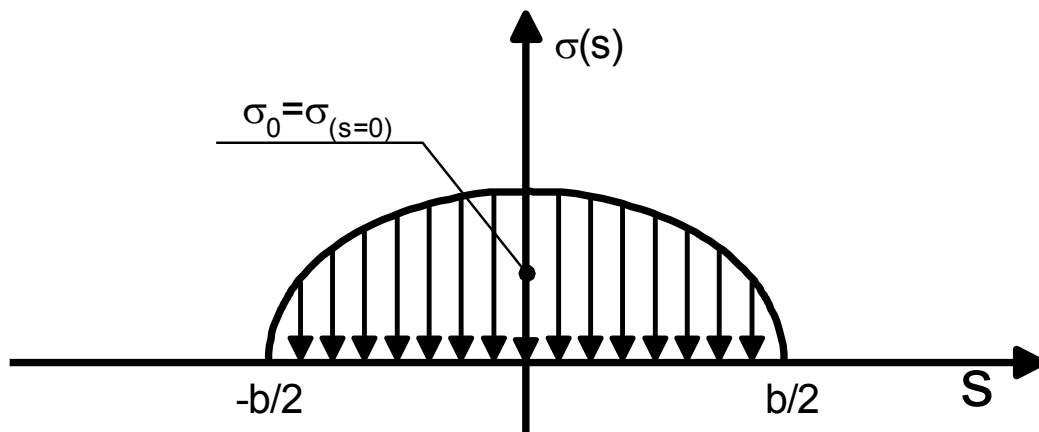


Figure 5: Hertzian contact-stress distribution.

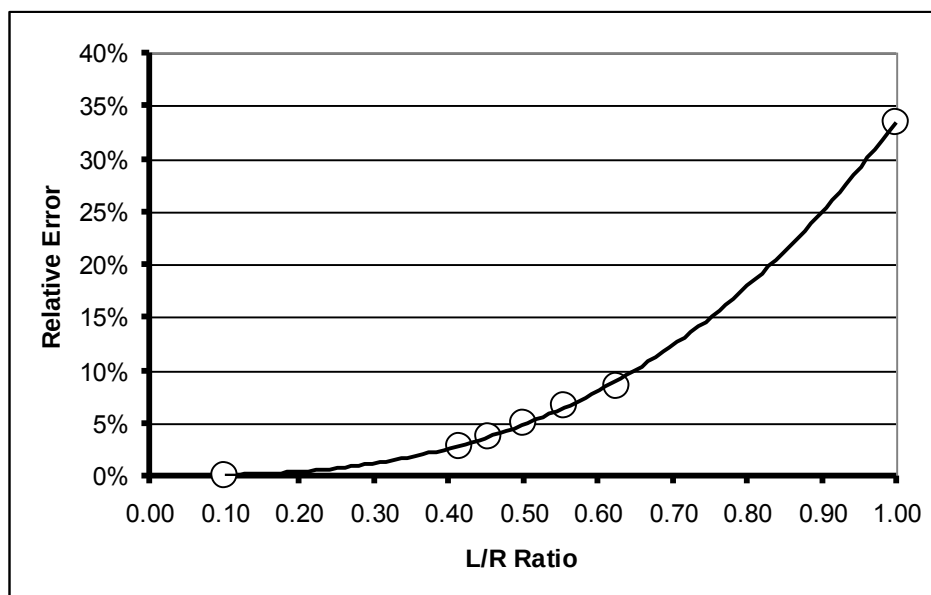


Figure 6: Relative error between the FE analysis and equation (4.3) for calculating ΔR_2 .

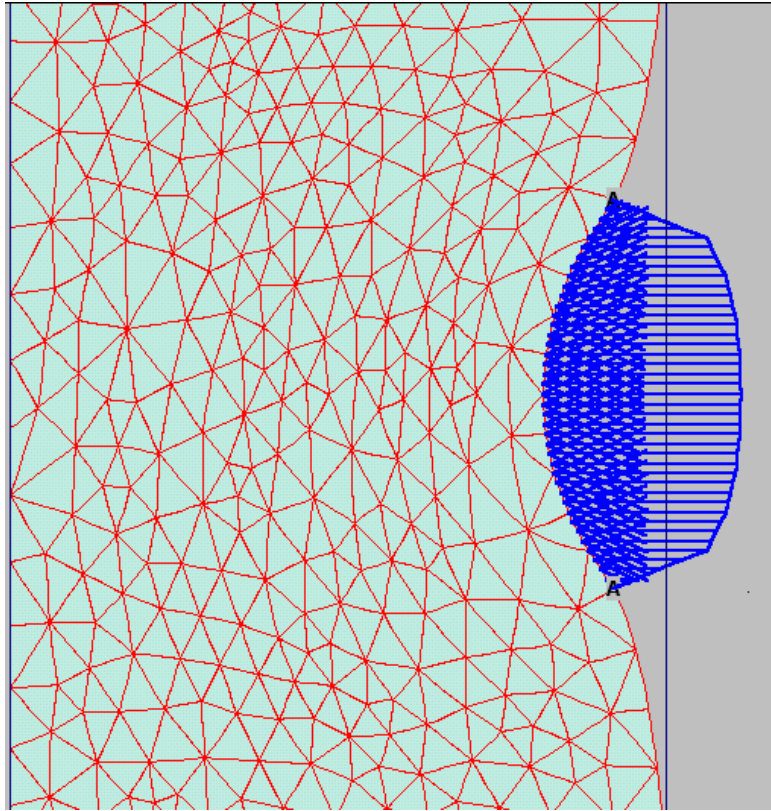


Figure 7: The deformed mesh ($L/R=0.5$).

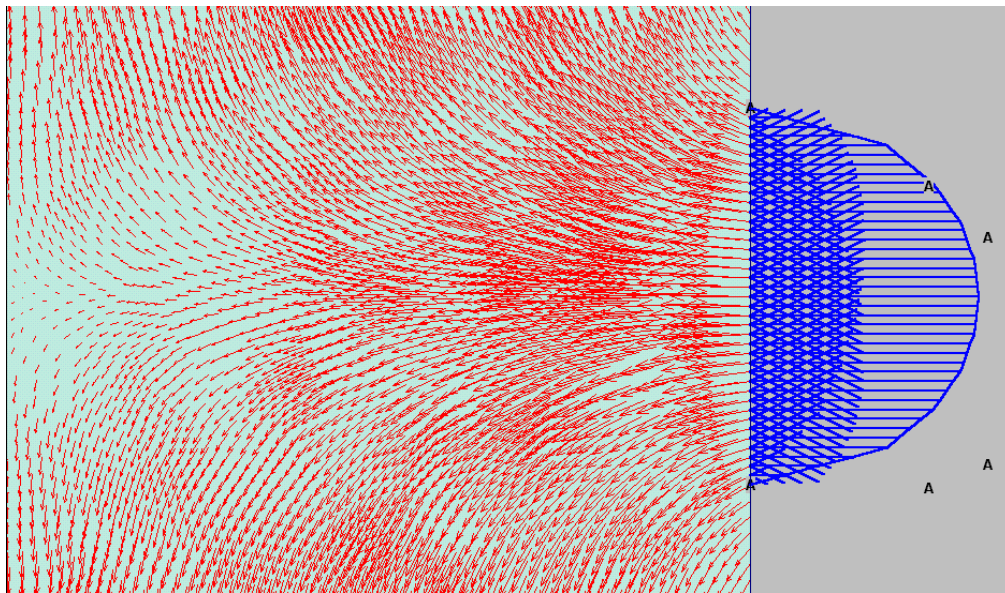


Figure 8: The displacement field under the loading ($L/R=0.5$).

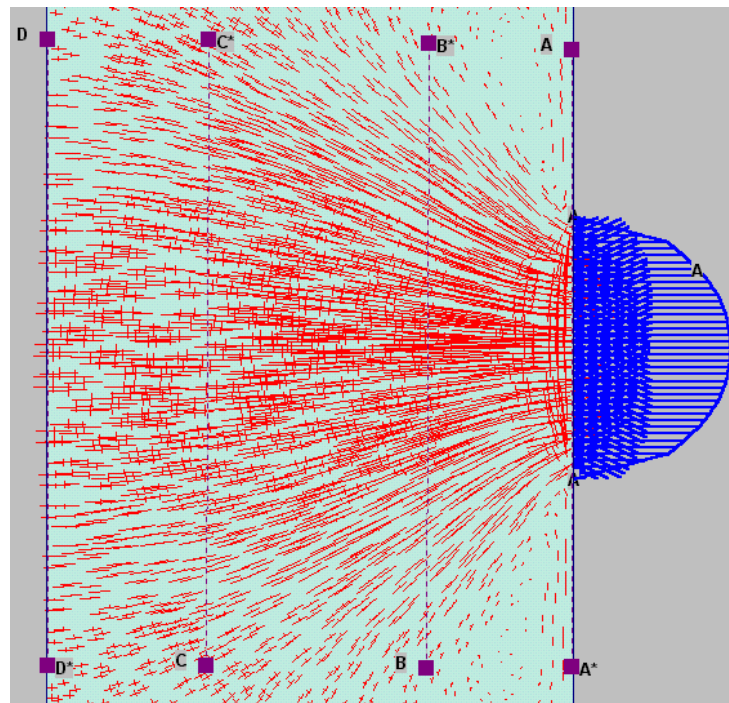


Figure 9: Principal stresses under the loading – maximum applied stress is $-\sigma_0$.

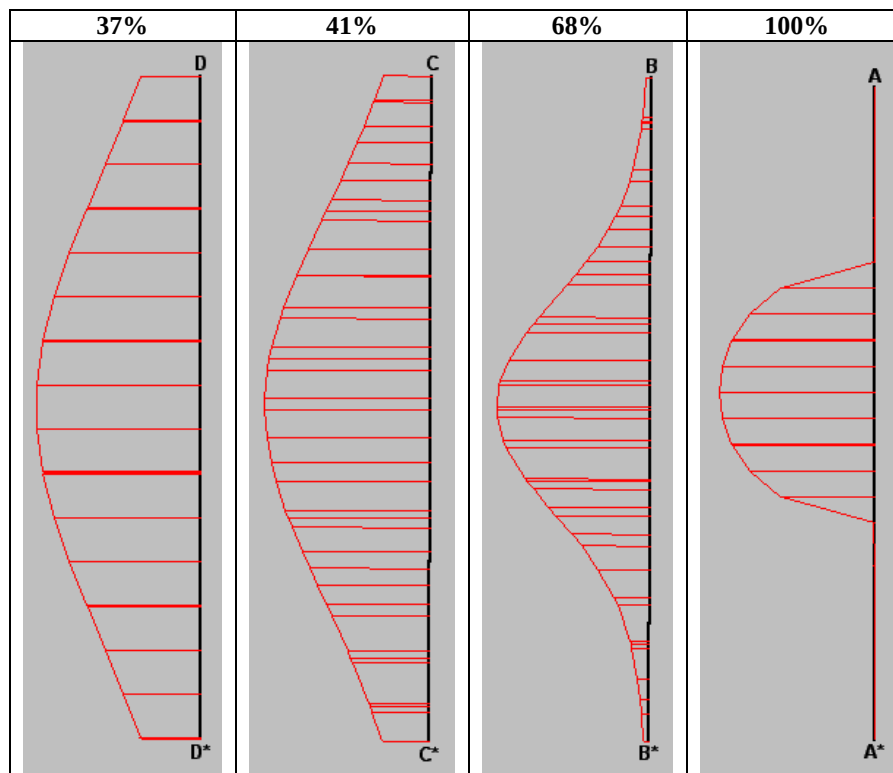


Figure 10: Radial stresses at several distances from the load (relate to Figure 9).

Maximum stress values are indicated above relative to σ_0

($b/R_2 = 0.5$).

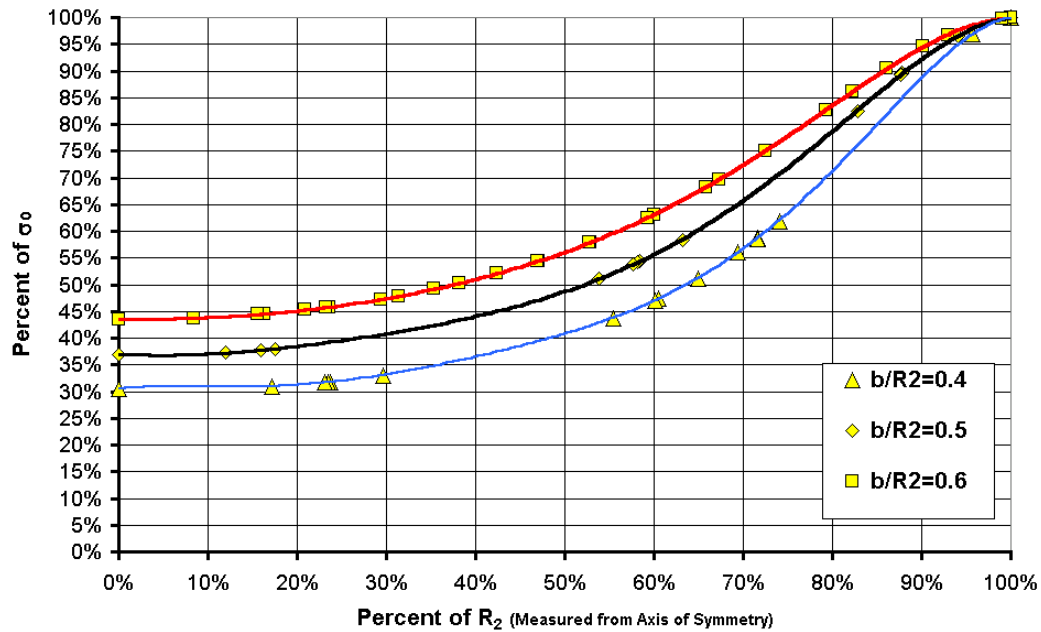


Figure 11: Radial stresses, directly under the middle of the stress distribution, at several distances from the load - for different ratios of b/R_2 .

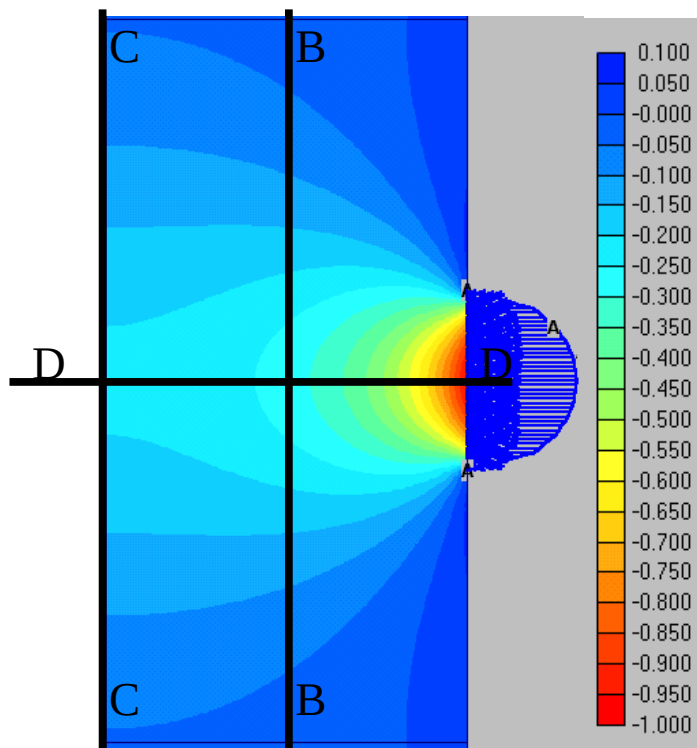


Figure 12: Pressure distribution inside the "limb" due to a Hertzian stress-distribution.

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) 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. Secondly, 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 first 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 (FEL, 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 pollicis 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 ante-cubital 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. $CV (m/s) = \text{distance (mm)} / \text{LATprox} - \text{LATdistal}$.

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

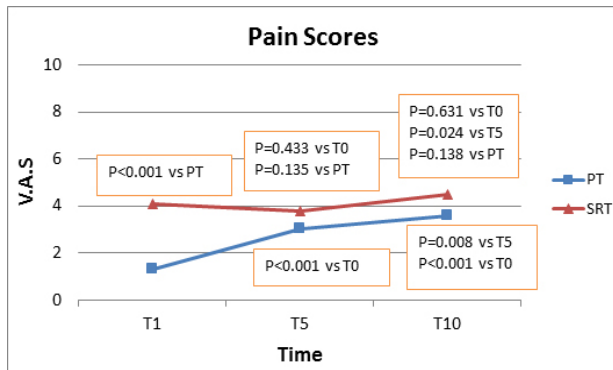


Figure 1. Pain scores.

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 $\pm$ 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.

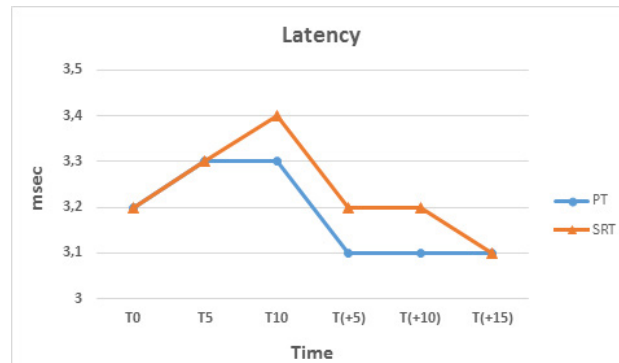


Figure 2. Changes in values of latency.

Pain

Pain scores and changes over time are shown in 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

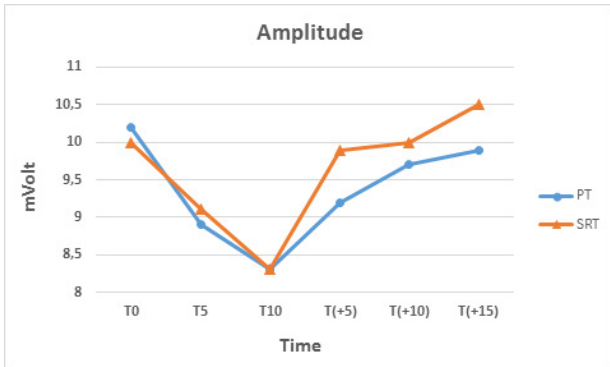


Figure 3. Changes in values of amplitude.

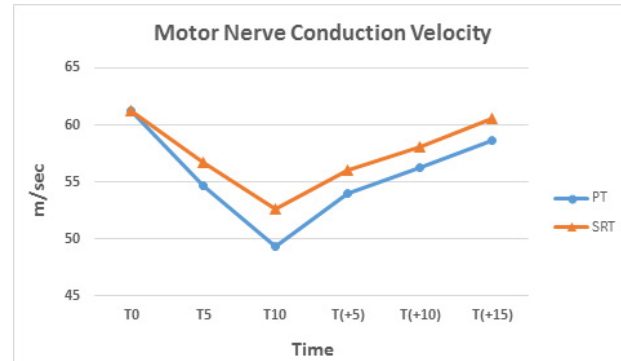


Figure 4. Changes in values of motor nerve conduction velocity.

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 extends 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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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. McEwen⁸ 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/m², 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 silicone 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 McEwen⁸ 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

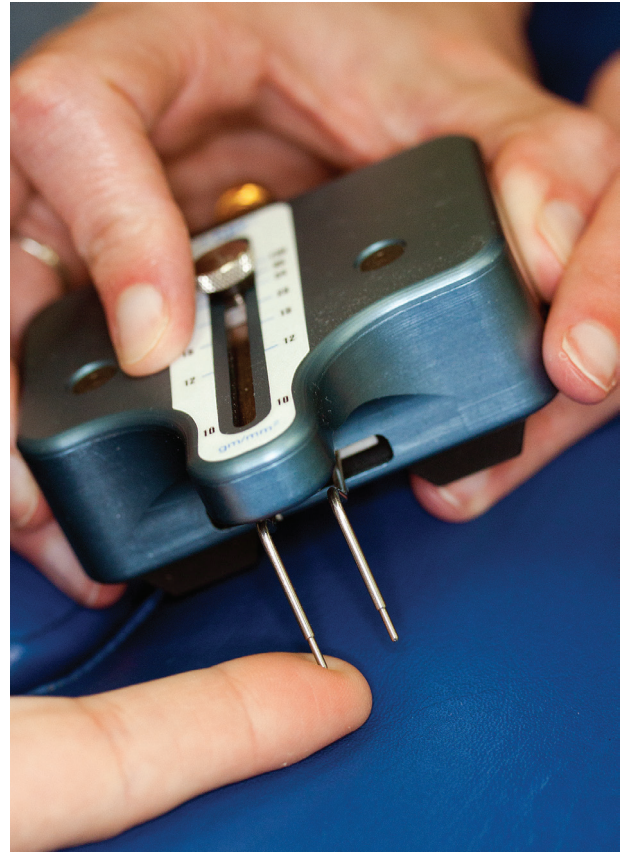


FIG. 2: The PSSD being used on the finger of a study subject to evaluate the possible influence on nerve function impairment (reprinted with permission from LifeBridge Health).

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.

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.

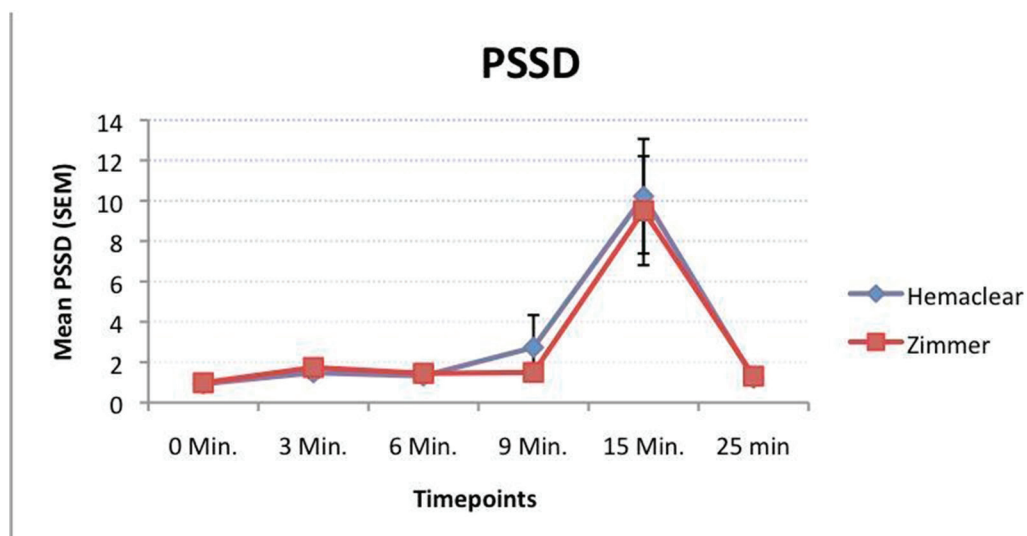


FIG. 3: Measured PSSD values (gm/mm^2) and the time course for both devices (reprinted with permission from LifeBridge Health).

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)	<i>p</i> -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 shear 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.

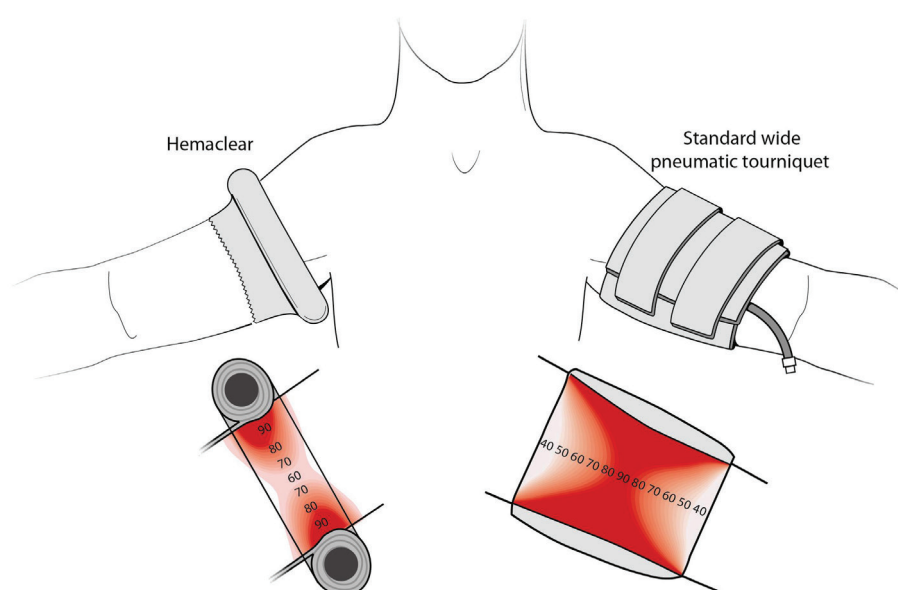


FIG. 4: Diagrammatic representation of the isobars of pressure from a wide versus a narrow tourniquet on the upper limb. Numbers represent the percentage of the pressure at the skin level just beneath the tourniquet/HemaClear™. Note that, with the wide cuff, the tissue pressure throughout the cross-section 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.

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Prospective Study

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

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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 enrollment.

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 of Zimmer Inc. in Austria failed, for providing an A.T.S.® 3000 Automatic tourniquet system, as used by McEwen. We hereby 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 variably 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 measurable 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 resonance image; Wide tourniquet; Narrow tourniquet; Human volunteers

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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 variably 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, Jandl M, Oberleitner G, Endler G, Breitensteiner 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 resonance image (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 excluded 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 ≤ 30 , a systolic arterial blood pressure ≤ 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. Then, 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., Cupertino, 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

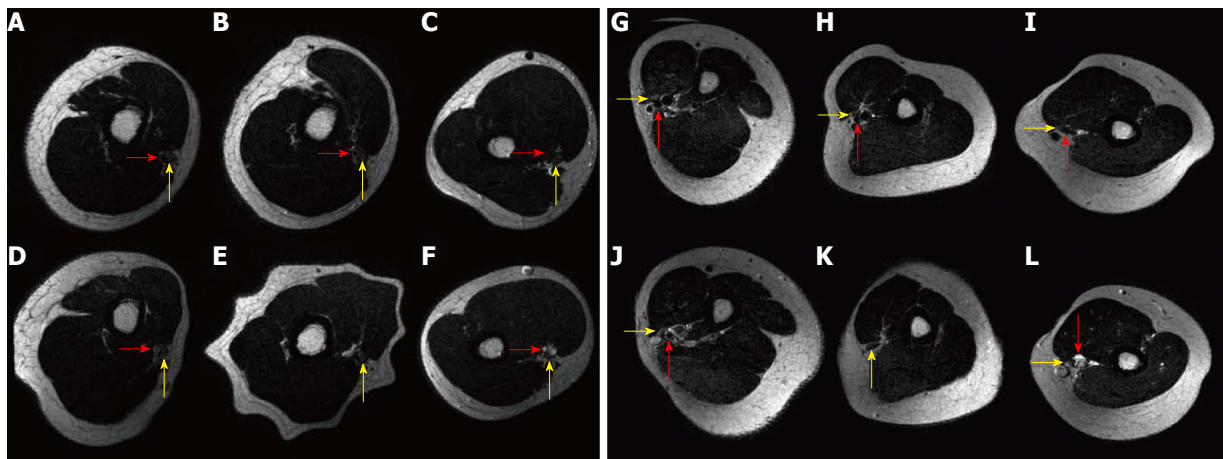


Figure 2 Red arrow indicates brachial artery, yellow arrow indicates median nerve. A-F: MRI imaging; A-C: Baseline imaging proximal, sulcus and distal humeral arm; D-F: Compression with the broad tourniquet proximal, sulcus and distal humeral arm; G-L: MRI imaging; G-I: Baseline imaging proximal, sulcus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

¹All results 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 statistician.

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 were 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.

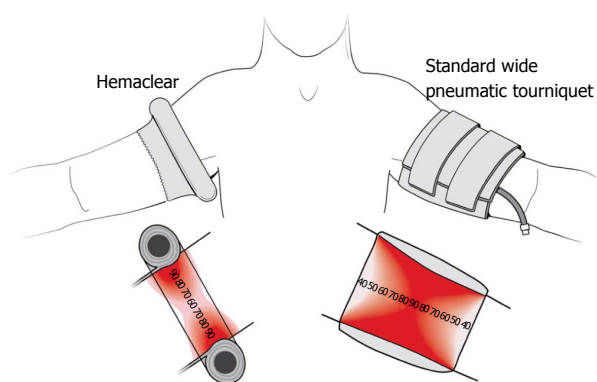


Figure 3 Detailed illustration of the different models of pressure application (reprinted with permission).

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 were observed.

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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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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 3. Rolling the silicone ring to the desired position.



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

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	<i>p</i> -value (10 mins)
<i>Pain scores at upper arm</i>				
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)	
<i>Paraesthesia at upper arm</i>				
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)	
<i>Pain scores at forearm</i>				
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)	
<i>Paraesthesia at forearm</i>				
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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Blood flow management in hand surgery using the S-MART™ device: a prospective randomized controlled study

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Abstract

Aim: Tourniquets are commonly used in ambulatory upper-limb surgery, but are still associated with complications, malfunction, and pain. We evaluated the S-MART™ device for blood-flow management compared to a conventional pneumatic tourniquet.

Methods: Sixty patients were assigned to study and control groups, where arterial occlusion was achieved by S-MART™ device and pneumatic tourniquet, respectively.

Results: S-MART™ was safe, but more difficult to apply and caused more pain.

Conclusion: The S-MART™ proved to be a fast and safe tool, but induced a compression discomfort. The costs of using this disposable product should be contemplated when considering its addition to day-care operating room armamentarium.

Keywords: Tourniquet, Esmarch, Exsanguination, Arterial occlusion, Hand, Carpal tunnel release, Evaluation, Pain, Complication.

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Introduction

Achieving a bloodless surgical field enhances the surgeon's capability to identify fine structures, shortens the duration of anaesthesia and surgery, and minimizes intraoperative blood loss. In surgical procedures performed on the upper extremity, proper visualisation is crucial, and the pneumatic tourniquet is often an inherent element of the surgical landscape. Attaining a bloodless surgical field necessitates an exsanguination followed by arterial occlusion proximal to the surgical site. The former action is often achieved by using the Esmarch technique, while the latter is achieved by using a pneumatic tourniquet.

The use of the conventional pneumatic tourniquet is associated with morbidity [1] and rare mortality [2]. Despite the paucity of information regarding the incidence of individual complications, the rate of complications associated with using the pneumatic tourniquet is estimated as 0.013% to 1.15% [3]. Potential local complications include tourniquet failure causing inadequate hemostasis, skin trauma, muscular and neuro-vascular injuries, wound infection, wound hematoma, edema, and compartment syndrome. Local discomfort or pain may increase steadily until becoming unbearable. Systemic complications include volume overload, arterial hypertension, cerebral infarction, rhabdomyolysis, pulmonary embolism, and metabolic disturbances [1, 3].

Conventional exsanguination using the Esmarch technique is performed by tightly wrapping a rubber band around the limb, and thereby propelling the blood proximally. The surgeon has no quantitative indication on the pressure applied to the patient's limb, and therefore, local complications are mostly related to the uncontrolled excessive pressures generated (pressures in excess of 100 mmHg have been reported). The twisting, compressive, and shearing forces generated jeopardize the skin and soft tissue integrity. Severe systemic complications including fatal pulmonary embolism have been reported [4]. Furthermore, pneumatic tourniquets are prone to various operational problems, and their technical reliability and consistency are limited. Regular maintenance is essential.

Still, technical failure due to malfunctioning components causing air leakage, pressure drop, and inadvertent excessive pressure are unavoidable.

The various techniques for exsanguination have limited reliability and reproducibility. Studies on changes in local blood volumes in limbs based on either plethysmographic or scintigraphic methods [5] showed that the effectiveness of the ordinary exsanguination techniques is limited. Blond et al [6] used a Gamma camera to assess the reduction in regional blood volume in upper limbs of healthy male volunteers given an autologous injection of 99mTc-labeled erythrocytes. They evaluated the effectiveness of different exsanguination techniques. The median percentage reductions of blood volume ranged between 42% when hand-over technique was used and 69% when the Esmarch technique was used. Comparable reduction rates were measured in lower limb exsanguinations [7].

Many surgical procedures on the upper limb are performed under local anaesthesia. The patient, therefore, experiences some level of discomfort or pain induced by the compressive forces applied by the pneumatic cuff. This may subjectively range from an unpleasant experience to unbearable pain, which frequently causes patient restlessness and occasionally requires discontinuation of surgery. In an attempt to decrease this discomfort, investigators have suggested various technical and ergonomic modifications, including alterations in the inflation pressure, shape, dimensions, design and location of the tourniquet [8–10].

The S-MART™ device (OHK Medical Devices – a division of Oneg HaKarmel Ltd., Haifa, Israel) was designed to achieve a combination of exsanguination, arterial flow occlusion and a sterile surgical field. The device is listed by the United States Food and Drug Administration and certified by the Israeli Ministry of Health. Boiko and Roffman [11] have published their clinical experience in using this device in upper limb surgery. They reported a quick device application and removal, and the achievement of an excellent bloodless field. Our prospective, randomized, and controlled study aimed at comparing the S-MART™ to the standard upper-arm pneumatic tourniquet,

regarding efficiency and potential adverse effects, including quantitative assessment of induced pain.

Patients and Methods

The S-MART™

The S-MART™ (OHK Medical Devices – Division of Oneg HaKarmel Ltd., Haifa, Israel) is composed of an elastic silicon ring with an inner diameter of 52mm and outer diameter of 76mm, wrapped in an elastic tubular stockinette sleeve and two straps, each ending in a pull handle (Fig. 1)



Figure 1 The S-MART™ device.

The device is provided sterile and double-packaged. It is applied to the limb after skin preparation and draping by placing the ring on the fingertips, and then pulling on both handles proximally (Fig. 2).



Figure 2 The surgeon places the ring on the fingertips and then pulls the two straps proximally.

As the ring rolls proximally it exerts a supra-systolic pressure wave

upon the limb, which both exsanguinates the limb by propelling the blood proximally and occludes the arterial flow at the level of device positioning. While rolling the ring, the stockinette unfolds onto the limb, covering it up to the occlusion location, thus placing a sterile covering (Fig. 3).

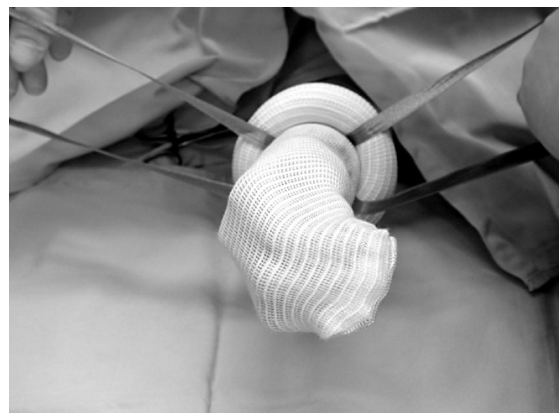


Figure 3 The silicone ring rolls up the limb and the stockinette unfolds onto the forearm during the motion.

This covering is incised to gain access to the surgical field. For carpal tunnel release we placed the device at the junction of the upper and middle thirds of forearm, where an adequate mass of soft tissue interposes between the elastic ring and bony structures. We used the S-MART™ designed for the upper limb, which is provided in three color-coded models, each designated to apply the appropriate occlusion pressure for different ranges of systolic blood pressure, covering the range of systolic blood pressure up to 180mmHg. The pressure created is supra-systolic and ranges between 250mmHg-350mmHg in limbs with a circumference between 24cm and 40cm.

Patients

Sixty patients scheduled for elective open carpal tunnel release in an outpatient setting for idiopathic primary carpal tunnel syndrome were enrolled in the study. We included patients who were 18–85 years of age and whose circumference at the occlusion site was between 24cm and 40cm. We excluded patients with a systolic blood pressure in excess of 180mmHg, and patients with congestive heart failure or chronic vascular disorders. Other exclusion criteria were clinical evidence or history of deep vein thrombosis, clinical evidence for instability of bones or joints, and infection in the limb. The S-MART device is approved and certified by the Medical Devices Department of the Israeli Ministry of Health for clinical use. All patients were provided thorough information regarding the device prior to enrolling them in the study group. The open carpal tunnel release was performed under local anaesthesia (local infiltration/injection of 5-10ml of lidocaine 2%), by three hand surgeons.

Study Protocol

The patients were randomly assigned to one of two groups: The study group (n=30) and the control group (n=30). Blood pressure (systolic and diastolic) was measured and mean blood pressure was calculated immediately before the application of the tourniquet. Patients in the study group had the exsanguination and the arterial occlusion achieved by the S-MART™ using the appropriate model as dictated by the systolic blood pressure. The device was placed at the junction of upper and middle thirds of the forearm after skin preparation and draping. An inflatable cuff was placed at the mid-arm to be inflated in cases that the S-MART™ failed or had to be abandoned. When surgery was concluded, the device was released by cutting the silicone ring and the stockinette sleeve after protecting the skin beneath with a blunt blade, and haemostasis was then undertaken and skin sutured.

In the control group a pneumatic tourniquet was used (Tourniquet 2500, VBM medizintechnik, GmbH, Sulzan, Germany). The apparatus consisted of an inflatable cuff (fabric single cuff, width – 7cm) inflated with compressed air, a pressure regulator, display and connecting tubing. The cuff was adequately padded and positioned at mid-arm. After skin preparation, draping and infiltrating the local anaesthetic agent, exsanguination was achieved by exerting external compression using an elastic bandage wrapped around the limb from fingertips up to the draped elbow, then the cuff was inflated up to a pressure of 250mmHg, the bandage unwrapped, and the surgery commenced. At the end of the surgery, the cuff was deflated, haemostasis was performed and the skin sutured. Failure of the S-MART™ or the pneumatic tourniquet was defined as poor visual quality due to an unacceptable bleeding at the surgical field, mechanical failure of the device, or patient's intolerance to pain caused by the device.

Evaluation

All patients were inquired regarding coexistent diseases and disorders including bleeding diatheses and coagulopathies, medications including analgesics (consumed within 4 hours before surgery). All relevant details were recorded in a report form for every case in both groups. The form was completed by the surgeon and included the time needed for placing the device (both exsanguination and arterial occlusion), technical difficulty in applying the device and cutting a window for the surgical site (ranked as simple, moderate, or difficult), the absence of radial and ulnar pulse and capillary filling, and the efficiency in providing a bloodless field rated from 1 (poor) to 5 (excellent). In cases where the efficiency was insufficient the blood pressure was measured and recorded. The surgeon quantified the bleeding at the surgical field either by milliliters of blood or the number of blood soaked gauzes. The surgeon also ranked the restlessness of the patient, measured the time to remove the device and ranked the difficulty in removing it, verified the resumption of arterial flow, and ranked his own overall satisfaction of the device. The duration of surgery from skin incision to wound closure was recorded as well (time needed for the application of the occlusion devices was excluded).

The patient was interrogated after the operation whether he experienced pain or inconvenience at the site of the device placement, and he had to rank this experience according to the "Visual Analogue Scale" for pain intensity – V.A.S. from 1 - "haven't experienced any pain" to 10 - "experienced intolerable pain". Failure of the device in each of the groups was declared when its use had to be discontinued, either because of ineffectiveness in securing an adequately bloodless field, inducing unbearable pain, or causing unacceptable adverse effect.

The limb was evaluated immediately after surgery and at a follow-up visit a week later, seeking local signs, and performing a complete neuro-vascular examination.

Statistical Analysis

Results were tabulated and expressed as means $\pm$ SD and ranges. Results were evaluated with unpaired two-tailed Student's t-tests, two-tailed chi-square tests, and F-test in order to check statistical differences between the two groups. P value of less than 0.05 was considered statistically significant.

We used an intention-to-treat analysis. We considered patients to be in the group to which they were assigned (even if S-MART™ failed and was substituted by the pneumatic tourniquet), and the denominator for each group was all patients assigned to that group.

Results

We enrolled 60 patients at the Rambam Medical Center (Haifa, Israel), and Ha'emek Hospital (Afula, Israel). Thirty patients were assigned to each group. The characteristics of the patients in the two groups are detailed in Table 1.

Table 1 Characteristics of the patients in the two groups^a.

Characteristic	Study group (n=30)	Control group (n=30)	P Value
Sex – M/F	7/23	8/22	0.77
Age – Yr	56 $\pm$ 11 Range [38–79]	53 $\pm$ 14 Range [26–84]	0.3
Systolic blood pressure	139 $\pm$ 22	141 $\pm$ 24	0.68
Mean arterial pressure	98 $\pm$ 14	97 $\pm$ 16	0.86
Analgesics – Yes/No	5/25	1/29	0.085

^a Plus-Minus values are mean $\pm$ SD. All values are two-tailed.

The clinical characteristics including diagnosis, surgical procedure, anaesthesia, sex ratio (male:female), age, systolic blood pressure, and mean arterial pressure were similar in the two groups. The proportion of patients who used oral analgesic drugs within 4 hours before surgery was significantly higher in the study group. The mean duration of surgery was significantly higher in the control group ($P<0.001$) (Table 2). Nevertheless, the application of the pneumatic tourniquet was reported as simple and straightforward in all control cases, while the technical difficulty in 13 applying the S-MART™ was graded as moderate in half of study cases. The SMART™ application time averaged 10.8sec, and showed a trend of getting shorter as the study progressed, while average removal time was 9.4sec (Table 2).

Table 2 Intra-operative measurements in the two groups^a.

Characteristic	Study group (n=30)	Control group (n=30)	P Value
Duration of surgery - min	15 $\pm$ 5 Range [8-30]	19 $\pm$ 3 Range [14-26]	<0.001
Time of application - sec	10.8 $\pm$ 2.6		
Difficulty in application (Simple/Moderate/Difficult)	15/15/0	30/0/0	
Time to remove device	9.4 $\pm$ 2.3		
Analgesics – Yes/No	5/25	1/29	0.085

^a Plus-Minus values are mean $\pm$ SD. All values are two-tailed.

We planned to quantify any bleeding occurring in either group by measuring the volume of blood loss (ml) and counting the gauzes saturated with blood. However, both devices were overall excellent in providing a bloodless field. In one case in the study group – a

female with a blood pressure of 163/85 mmHg – a yellow model of the S-MART™ was used; after skin incision a continuous bleeding obscured the surgical field. Blood pressure was measured and found to be within the indicated limits for the yellow model. Measures for local haemostasis were unsuccessful, and consequently the S-MART™ was released four minutes after starting surgery owing to unacceptable visual quality. Exsanguination was redone using an elastic bandage, and the pre-installed pneumatic cuff was inflated to a pressure of 250mmHg. The operation was completed in a completely bloodless field. All but one patient in the control group had a bloodless field and an excellent visual quality. In a case of a male with a blood pressure of 102/68 mmHg, minor bleeding was observed and the surgical field was ranked at 4 (in a scale of five degrees). This apparently was due to venous congestion caused by inappropriate exsanguination. The visual quality, however, was acceptable and the operation proceeded uneventfully.

All patients in both groups reported local discomfort caused by the device. However, experiencing true pain was significantly higher in the study group ($P=0.0062$) (Table 3). The average V.A.S. grading was higher in the study group ($P=0.05$), while variability of the grading was similar in both groups. Two patients in the study group ranked their pain severity as 10 on the V.A.S.. One patient reported a severity of 10 at the end of operation, which lasted 15 min. The other patient reported a severity of 10 two minutes after applying the S-MART™. The device was consequently released and substituted by a pneumatic cuff, which the patient tolerated well throughout the rest of the operation. In both cases, the surgeon reported patient's restlessness, which was graded as "unacceptable" in the latter.

The overall surgeon's satisfaction was similar in both groups. Apart from local skin redness at the site of device placement, which was uniformly observed in all patients in both groups and completely disappeared a few minutes thereafter, no skin complications, neurovascular compromise, or any other adverse effects were encountered postoperatively.

Discussion

Surgical operations on the upper limb usually involve delicate structures. Optimizing the surgical arena and ensuring adequate sighting is therefore crucial. A bloodless surgical field is an essential prerequisite for high visual quality. Hand surgeries are sometimes undertaken under local anaesthesia, and the patient may, therefore, experience some discomfort or even a distressing pain caused by the compressive force applied by the tourniquet device.

Using pneumatic tourniquets as an effective means of achieving a bloodless field has become a common practice in hand surgery. However, the effectiveness of the pneumatic device is not absolute, it is associated with potential complications, occasional technical malfunctioning and local sensation of discomfort. The SMART™ device is designed for performing three sequential functions of limb exsanguination, arterial blood flow occlusion and placement of sterile field covering. The centripetally oriented force generated by the silicon ring provide a circumferentially even and consistent supra-systolic pressure, that is independent of gas tubing, pressure regulation, and electric connections. The S-MART™ is therefore suitable for interventions undertaken at outpatient and clinic settings.

The S-MART™ can be applied to the upper arm, as well as to the forearm. By applying the device on the forearm in operations performed at distal parts of the limb, ischemia of a significant portion of the limb is spared, and the anticipated re-perfusion effect is diminished. The S-MART™ is sterile and its placement in proximity to the surgical field is possible, which further decreases the ischemic mass of tissue.

Since the S-MART™ is a sterile single-use product, the surgeon applies and removes it without the need for assistance of any non-sterile personnel. However, alternate inactivation and activation of the flow occlusion, for haemostatic purposes for example, is unfeasible. The problem of device contamination with the patient's blood and the potential for consequent cross-contamination is avoided as well. However, a comparative evaluation of the costs of using and maintaining the reusable standard tourniquets and the disposable S-MART™ is required.

Table 3 Outcome in the two groups^a.

Criterion	Study group (n=30)	Control group (n=30)	P Value
Failure of device - No. of cases	2 ^b	0	0.15
Quality of bloodless field: 1 (poor) to 5 (excellent)	4.86±0.73	4.96±0.18	0.47
Patient reported inconvenience- Yes/No	30/0	30/0	
Patient reported pain – Yes/No	15/15	25/5	0.0062
V.A.S. ^c - 1 to 10	5.7±2.5	4.53±1.99	0.05 (F-test $P=0.22$)
Surgeon reported patient's restlessness – 1 (unacceptable) to 5 (excellent)	4.77±0.77	5±0	0.10
Local signs	30 (redness)	30 (redness)	Local signs
Overall surgeon's satisfaction – 1 to 5	4.87±0.73	4.97±0.18	0.47

^a Plus-Minus values are means ± SD. All values are two-tailed.

^b Failure was declared due to bleeding and unacceptable visual quality in one patient and due to intolerable pain with patient's restlessness in another.

^c V.A.S. denotes Visual Analogue Scale. A pain severity scale: from 1 – No pain, to 10 – intolerable pain.

The average application time for the S-MART™ was found to be as short as 10.8 sec, though the application was graded as moderately difficult in half of the cases. This was explained by the difficulty in rolling the ring across the wider zone of the metacarpophalangeal joints. Application of the pneumatic tourniquet is multistage and involves padding, wrapping and fastening the cuff, connecting the tubes, exsanguination, adjusting and inflation. These actions are not done in continuity and, therefore, attempts at measuring the time needed for performing them were unsuccessful.

The S-MART™ effectively provided a bloodless field in all but one case. The bleeding in this case has probably occurred due to either inadequate exsanguination causing venous congestion, or stress-related blood pressure fluctuation before skin incision beyond the indicated range of the yellow model causing arterial leakage.

Although the proportion of patients who consumed analgesics before surgery was higher, and the mean surgical time was significantly shorter in the study group, still, significantly more patients experienced pain caused by the S-MART™ than the pneumatic cuff. The mean V.A.S. score was higher in the study group ($P=0.05$), while the two groups showed similar score variability. The S-MART™ failed in one case due to intolerable pain and the surgeon reported unacceptable patient restlessness.

One additional clinical issue was observed. Following the cutting of the stockinette, small cloth residues were scattered over the skin, and entered the surgical field thereafter. This may be avoided by soaking the stockinette with a sterile fluid. Alternatively, close-ended stockinette should be replaced by an open-ended hemmed stockinette that covers the limb distally up to the surgical site.

In summary, the S-MART™ device performed well in providing a bloodless surgical field in all but one operation of carpal tunnel release. In two cases it caused unbearable pain and had to be released in one. This well-designed ergonomic device proved to be a fast and safe tool for blood flow management. However, it induced a compression discomfort that ranged between local inconvenience and intolerable pain. The costs of using this disposable product versus the reusable pneumatic system should be contemplated when considering the addition of the S-MART™ to the operating room armamentarium.

Acknowledgement

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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 limb at occlusion site up to 40 cm) and a large size for the leg (circumference of the limb at



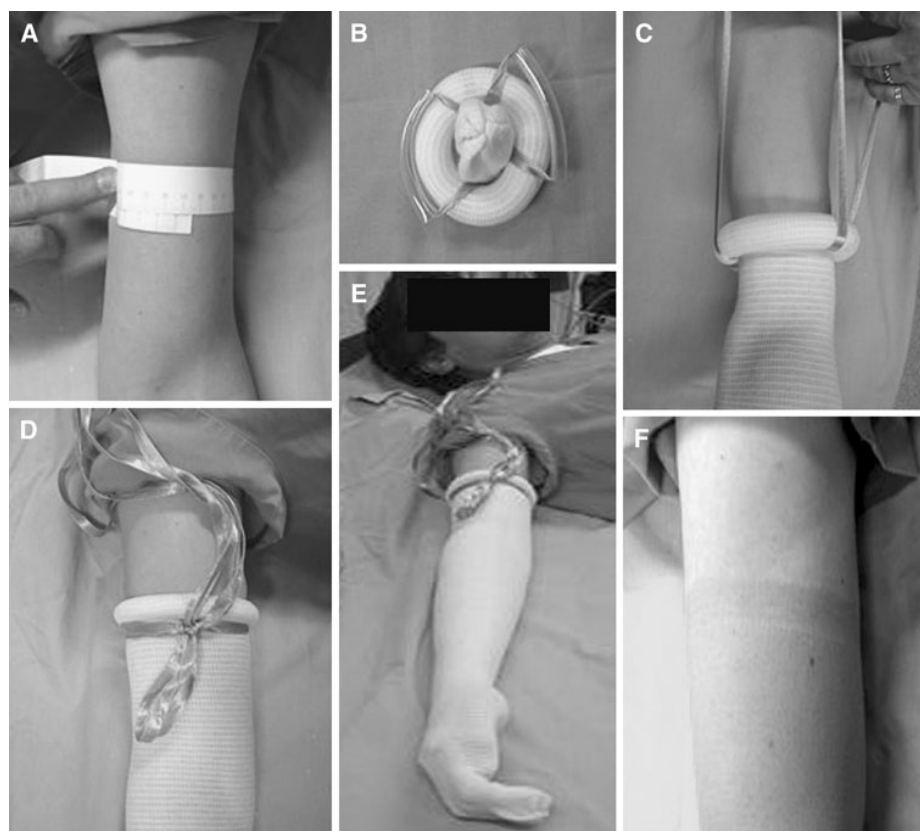
Fig. 1 Pneumatic tourniquet study with the cuff applied on the upper arm and thigh

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).

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

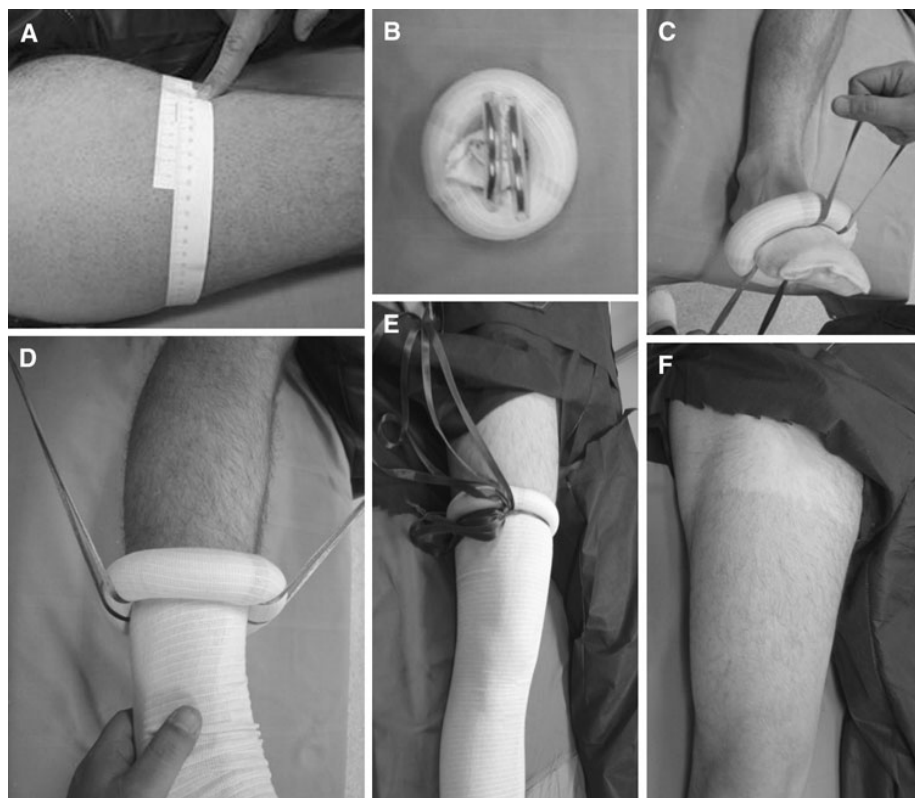
removal, and (e) at the time of complete recovery from any symptoms (recovery time).

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 $\pm$ 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		<i>p</i> 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	<i>p</i> 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

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

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

	PT	SMART	<i>p</i> 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

(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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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 ^{99m}Tc-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 autologous injection of ^{99m}Tc-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

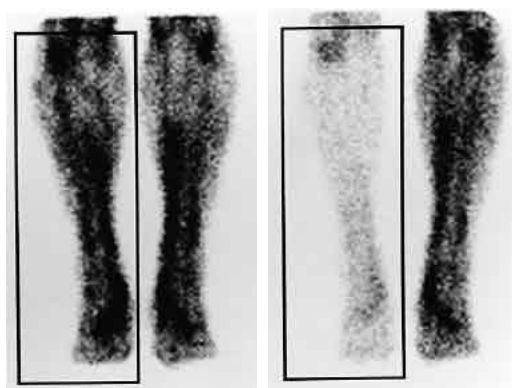


Figure 1. An example of a 1-minute scintigram of the lower limbs of a 25-year-old man obtained by ^{99m}Tc -radiolabeled erythrocytes showing the limbs from an anterior projection before and after an Esmarch exsanguination of the right limb. The frame represents the region of interest. The percentage 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 methods 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 4 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 ^{99m}Tc -radiolabeled erythrocytes evaluated changes in blood volume in limbs (coefficient of variation: within subjects 6%, between subjects 14%) more

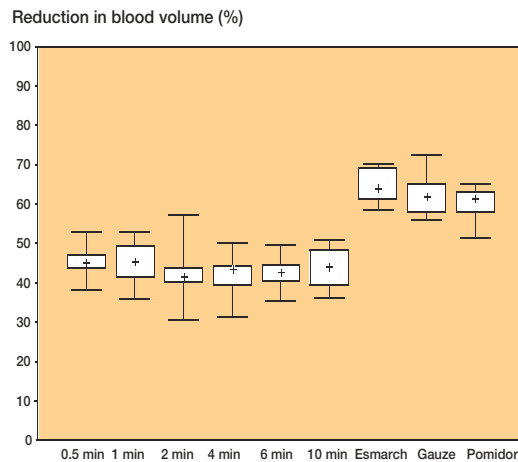


Figure 2. Results of various exsanguination methods in 12 subjects expressed as median (+), range and interquartile (box) percentage reduction in blood volume calculated from counts before and after the exsanguination.

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 and longitudinal 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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Research article

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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 $\pm$ Standard Deviation [S.D.] = 24.45 $\pm$ 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 pollicis 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 metacarpophalangeal 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.

$$CV \text{ (m/s)} = \text{distance (mm)} / (LAT_{\text{proximalcuff}} - LAT_{\text{distalcuff}})$$

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

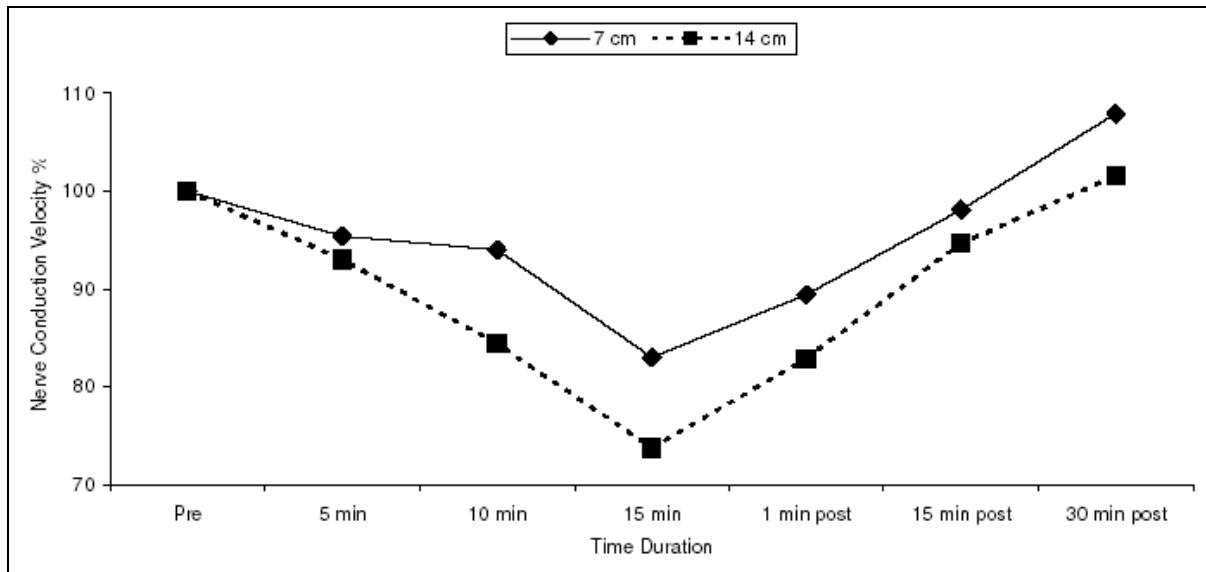
Throughout the experiment, the room temperature was maintained between 23°C and 26°C with the help of air conditioning. Paired t-test was used to compare the changes in the nerve conduction parameters with the application of 2 cuffs. All values which appear with the mean values are standard deviations [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% $\pm$ 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 $95.40\% \pm 11.94$. 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 $84.37\% \pm 10.15$ of its baseline value after 10 minutes of inflation whereas with the 7 cm cuff the MNCV was $93.97\% \pm 16.10$ 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 $73.73\% \pm 12.06$ of its baseline value for 14 cm cuff whereas it was $82.96\% \pm 16.33$ 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.

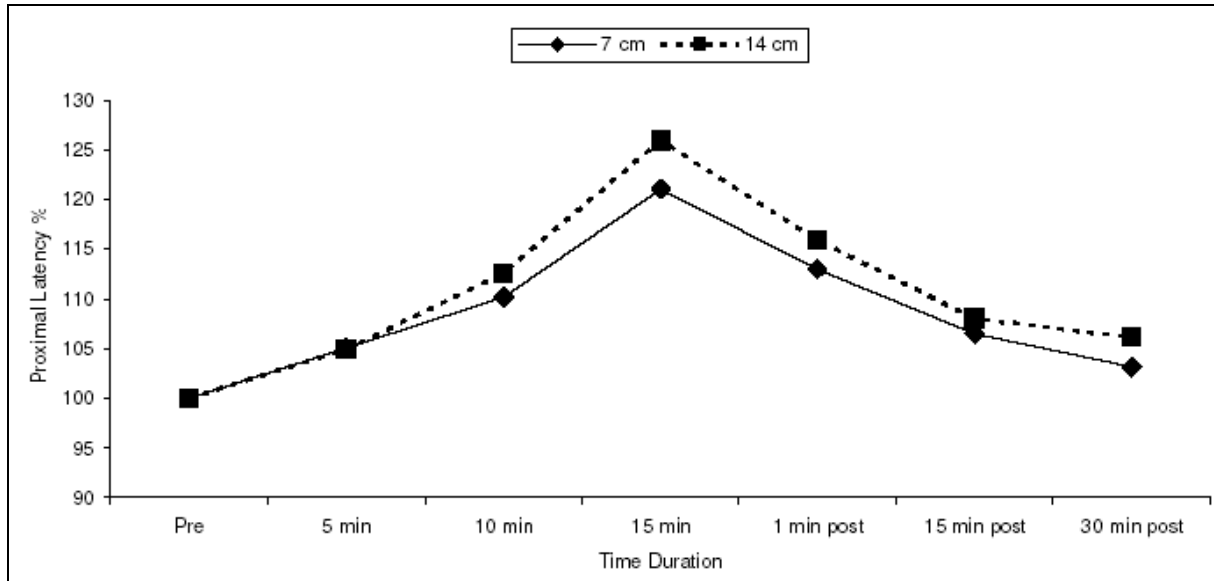
Latency

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).

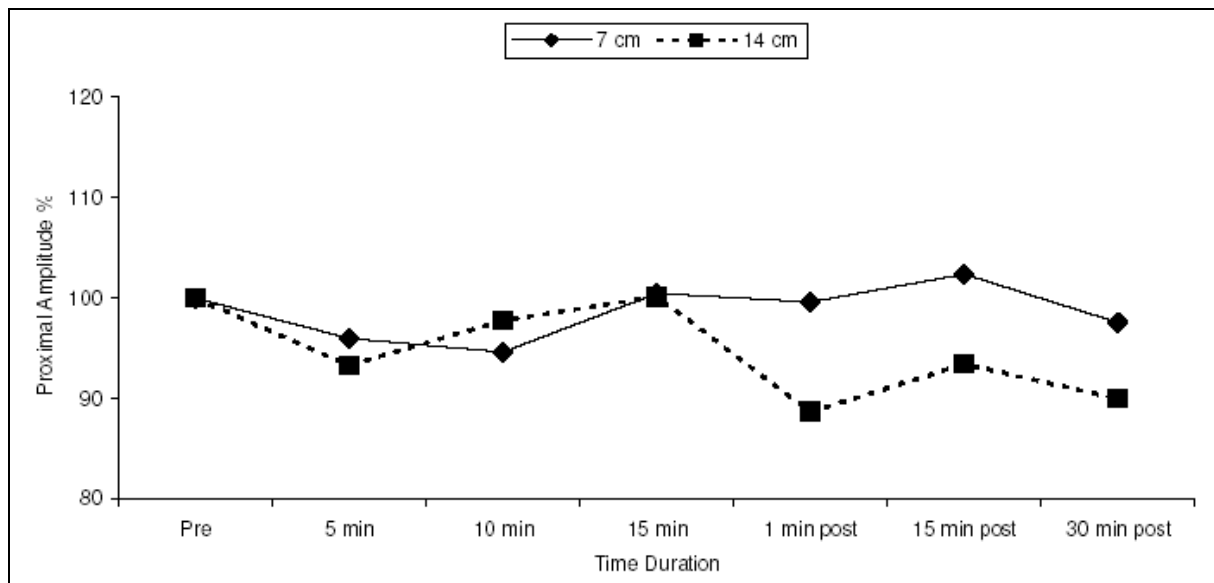
**Figure 3**

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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