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

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ABSTRACT

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

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

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

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

Methods

Patients

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

Outcome Measures

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

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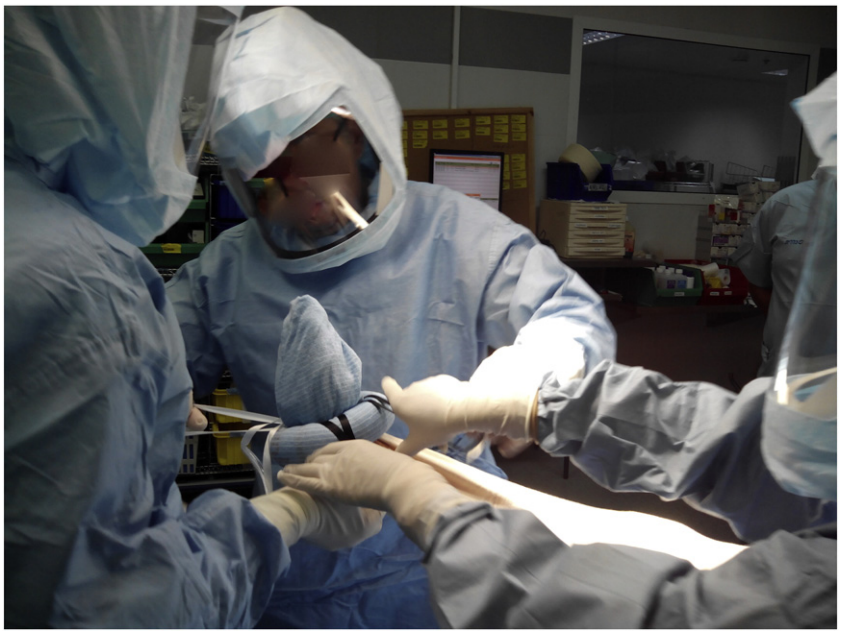

Fig. 1. The physician places the ring on the toes.

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

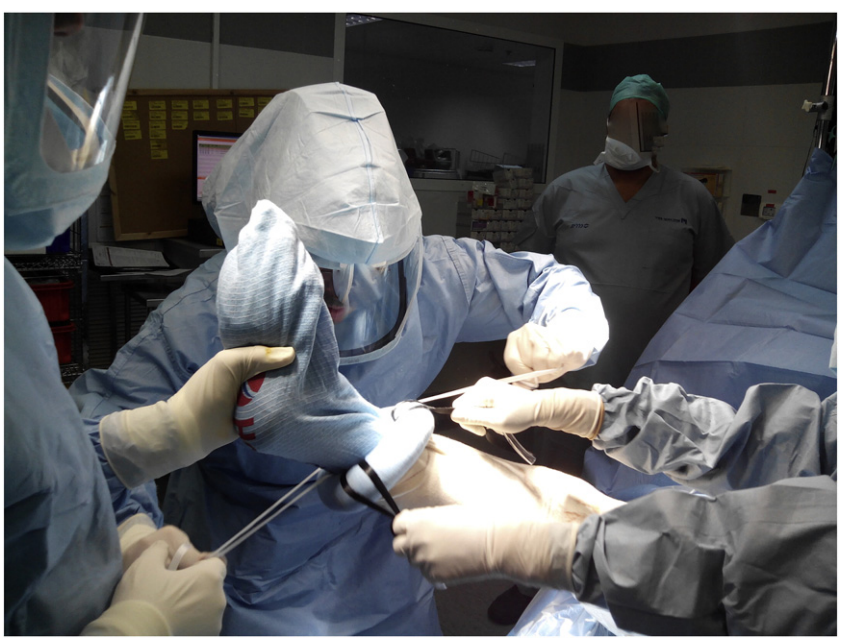

Fig. 2. The physician pulls the silicon ring proximally.

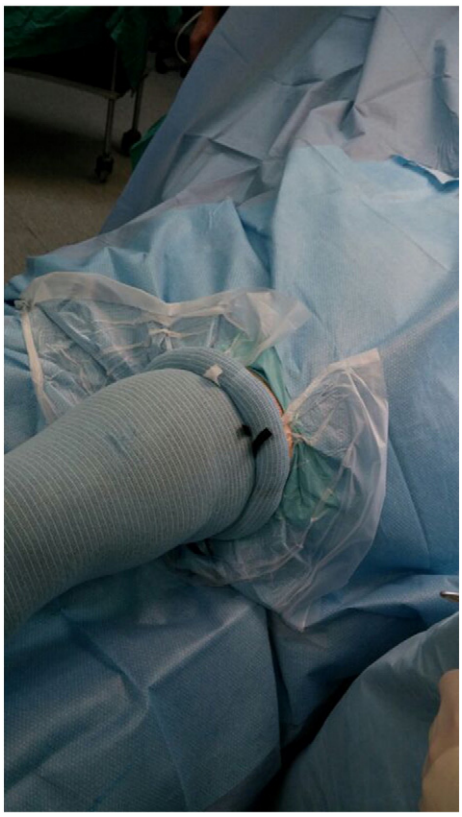

Fig. 3. The stockinet sleeve unrolls onto the limb, covering it entirely up to the occlusion level and thus drapes a sterile cover over the surgical field.

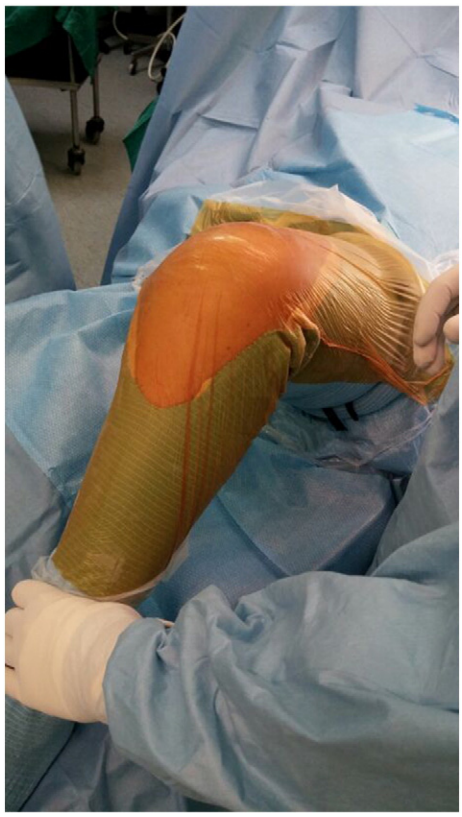

Fig. 4. The stockinet sleeve is cut and provides a sterile surgical field.

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 Biovac™ closed wound system drain, including a 450 ml bulb and a 14Fr PVC drain (Biometrix, Gronsveld, The Netherlands), was inserted in all knees prior to fascia closure. Fascial layers were closed in the usual fashion and staples were used superficially. A compression bandage was applied to the limb following closure. In all the knees, hemovac drains were used for 24 h and the amount of blood drainage from the knee was recorded in the patients' files. All patients were treated with subcutaneous enoxaparin 40 mg per day for 35 days following the operation. The treatment started in the hospital, and continued in the patients' home by the patients or by a nurse in cases when the patients had difficulties in injecting the drug. Physiotherapy with full weight bearing ambulation with the assistance of a walker began in the department on the 1st post-operative day, and continued at the patients' home.

Statistical Analysis

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

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

All analyses were performed using SPSS-21 software.

Results

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

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

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

Table 1
Demographics.

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

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

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

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

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

Discussion

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

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

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

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

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

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

Table 2
Main Results.

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

Hb = hemoglobin.

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

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

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

Summary

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

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

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