

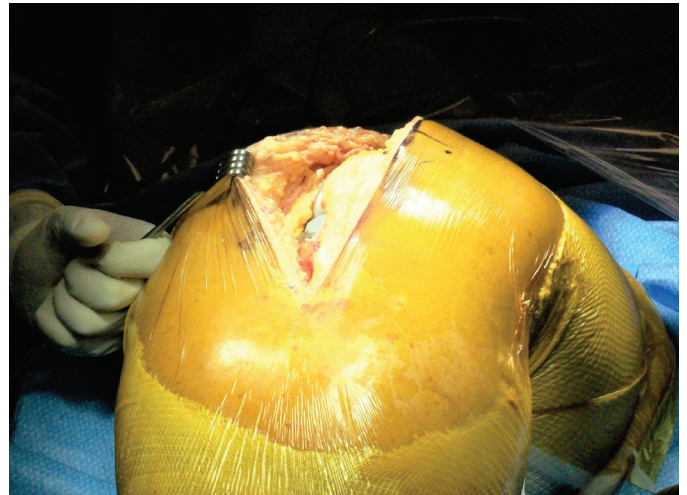
Are there published peer-reviewed studies that show HemaClear® as superior to Pneumatic Tourniquet for TKA?

Background: HemaClear® for Total Knee Arthroplasty (TKA)

HemaClear® is a Sterile Elastic Exsanguination Tourniquet for blood-less limb surgery. While being rolled up the leg, it squeezes the blood away into the central circulation and blocks it's reentry. **HemaClear®** has been used globally in more than 1.5 million cases, at least a third (0.5 million) in **TKA**. **HemaClear®** can be easily used on Obese patients (pictures) without rolling down. **Watch video at:**



The HemaClear® model most frequently used for adult TKA in Western countries is **XL -Extra Large**, which is suitable for thigh circumference from 50 to 85 cm. **HemaClear® L -Large** is often used in oriental countries (China, Thailand, etc.) where thigh circumference of 30-55 cm is more common. Model selection is based on pre-op measuring of the upper thigh (near groin) with the included HemaClear measuring tape. **HemaClear® skin pressure** is determined by measuring the thigh circumference and the distance from the toes to the ring location. A look-up chart is used to determine the exact skin-pressure.



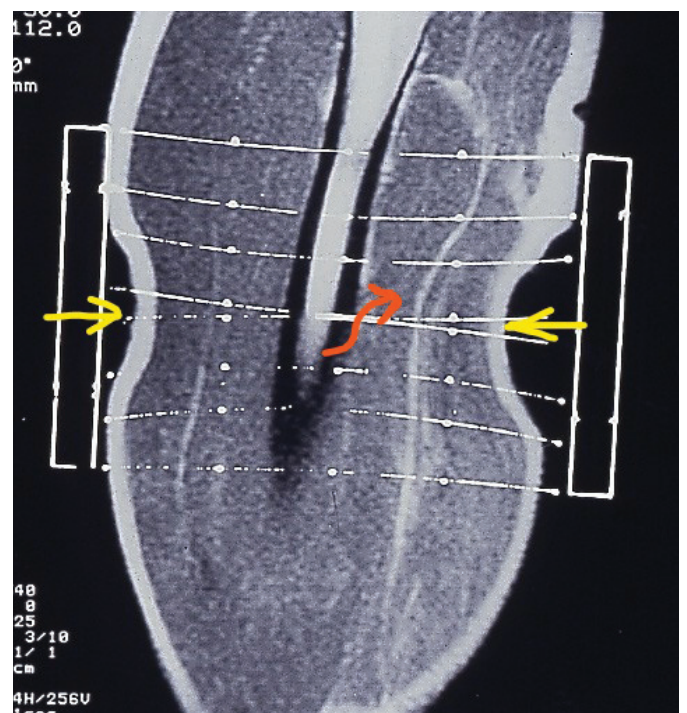
What is the pressure inside the limb? With the wide pneumatic tourniquet, the pressure inside the tissue beneath the cuff is uniform and equal to the pressure inside the tourniquet. However, with the narrow HemaClear the elastic properties of the tissue allow some of the pressure to disperse to neighboring tissues so that the pressure becomes lower, the deeper we penetrate into the limb. The pneumatic tourniquet compresses and deforms a large volume of tissue (**Figure MRI**). However, this is **absolutely not** necessary in order to collapse the artery(s) and stop the blood flow.

HemaClear® Sterile Exsanguination Tourniquet is preferred by most leading TKA surgeons for the following reasons:

Patient outcome: less blood loss, less post-op thigh pain, no skin blisters, less DVT/PE, Less Surgical Site Infection (SSI), no nerve damage, earlier mobilization and discharge from hospital. The near-complete exsanguination (>95% of the blood removed) prevents intravascular clotting and embolization.

Surgeon aspects: Drier field, no need for cauterization, faster and more accurate technique, easier and more natural knee mobility, it does not "drift" towards the surgical incision even on large conical thigh, larger "real estate", dry bone surface for cementation.

OR logistics: Faster preparations, only one item needed, no need to operate and calibrate pump, no non-sterile items to handle by nurses/techs, less shelf space and number of items to procure.



HemaClear® advantages over pneumatic tourniquets in TKA have been studied extensively; the following pages list the published studies. In addition, many **testimonials** on the use of **HemaClear®** in TKA can be viewed at www.hemaclear.com. White Paper on the basic science (biomechanics, metabolic impact) of **HemaClear®** is available upon request. To schedule a free trial of **HemaClear®** please contact Orders@hemaclear.com or your local representative.

HemaClear® for Total Knee Arthroplasty (TKA) – Literature Review (1)

Pain and Skin Complications with HemaClear vs. Pneumatic Tourniquet in 50 bilateral TKA patients.

Prospective study in 50 Bilateral TKAs; One side – Pneumatic Tourniquet; other side - **HemaClear®**. Assessed post-op tourniquet pain and tourniquet-site skin status at 24 h and 48 h. Published JCOT, 2020. Results: No skin complication with **HemaClear®** (0%). Tourniquet bruising (8) and blisters (2) on Pneumatic Tourniquet side (10/50) ($p=0.0196$). The VAS pain scores at 24 h and 48 h were lower for HC legs ($p=0.0152$; and 0.003 , respectively).

Conclusion: “Use of disposable tourniquet (**HemaClear®**) has better outcome than the conventional tourniquet with minimal or no local complications”.

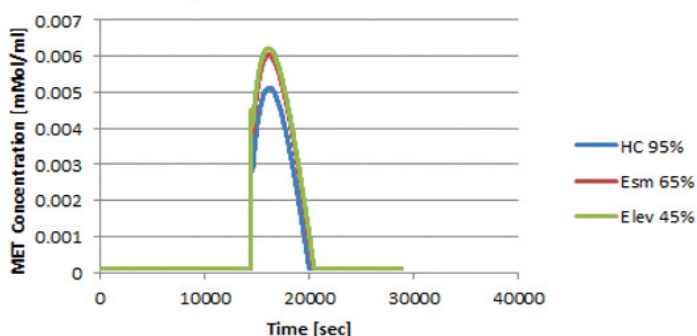
Silicone ring tourniquet (SRT) versus pneumatic cuff tourniquet (PT) in total knee arthroplasty surgery: A randomized comparative study [Metabolic]

Vicente J. León-Muñoz et Al. Spain, J. Orthopedics, 2018.

Results: “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) $p=0.07$.”

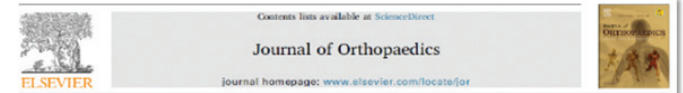
“Conclusions: The results of this evaluation have led the authors towards a systematic use of the silicone ring tourniquet in primary TKA, since this device offers the advantage of being applied in sterile conditions and being able to be located at a greater distance from the surgical field than conventional tourniquets.”

Circulating Concentration of MET vs. Time



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

Sanjay Bhalchandra Londhe^{a,*}, Ravi Vinod Shah^b, Shubhankar Sanjay Londhe^c, Pritesh Omprakash Agrawal^d, Nicholas A. Antao^e, Sushil Churhe^f



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

Vicente J. León-Muñoz^{a,*}, Alonso J. Lisón-Almagro^a, César H. Hernández-García^a, Miriam López-López^a

Discussion (NG): What happens when the tourniquet is released? Upon release, the accumulated metabolites (e.g. lactate) are washed out from the limb to the central circulation. In a recent study (above) Vicente et Al found that the postoperative serum lactate levels were 17% **higher in the Pneumatic Tourniquet group than in the HemaClear group** ($p=0.07$). This is predicted by a model based on the better exsanguination of the limb with HemaClear which slows down the washout, thereby reducing the peak level of lactate (blue line, in diagram), compared to the incomplete exsanguination with Esmarch/limb elevation, where the washout peak is higher. This phenomenon is reducing the toxicity to organs at the time of HemaClear release.

HemaClear® for Total Knee Arthroplasty (TKA) – Literature Review (2)

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

Ismail Demirkale, etAL, Ankara, J Arthroplasty, 2013.

Retrospective study of 526 patients undergoing Bilateral TKA divided into HemaClear group (Group 1) of 255 patients (510 knees), without pre-tourniquet removal and Pneumatic Tourniquet group of 227 patients (454 knees, Group 2), where post-deflation hemostasis, a Hemovac drain and Jones bandage were used.

The maximal drop in hemoglobin was significantly greater in PT Group than in HC Group (P < 0.001) and need for transfusion was 3-fold greater. Also, infection rate was significantly lower in HC Group (P = 0.017).

Conclusion: The use of sterile tourniquet removed after wound closure without Hemovac drain decreases blood transfusion need, infection rate, tourniquet related pain and postoperative complications (Table).



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

Ismail Demirkale, MD^a, Osman Tecimel, MD^b, Hakan Sesen, MD^a, Kasim Kilicarslan, MD^b, Murat Altay, MD^a, Metin Dogan, MD^c



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%)	0.002
Post op analgesics need ^d	3.1 ± 0.5	2.9 ± 0.4	<0.001

The Sterile Elastic Exsanguination Tourniquet (HC) vs. the pneumatic Tourniquet (PT) for (TKA)

Yaron S. Brin et Al; Israel, Journal of Arthroplasty, 2014.

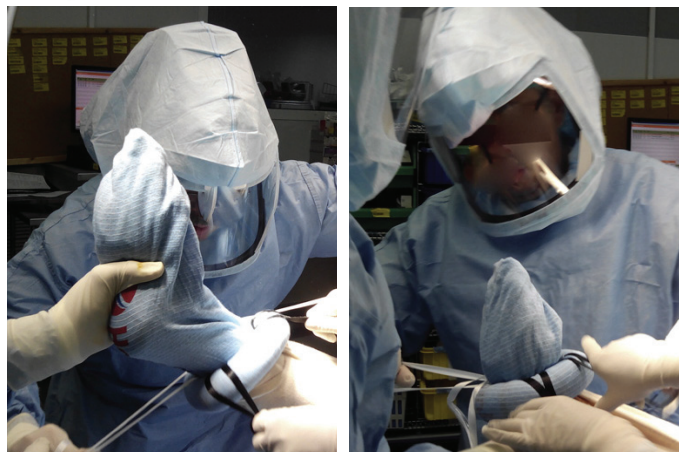
“We compared the use of HC and PT for TKA. In 145 patients PT was used and in 166 HC. Patients treated with the HC had a smaller decrease in hemoglobin on post-operative days one (P = 0.028) and three (P = 0.045). The amount of blood collected from drains at 24 h was significantly lower in the HC group. A trend towards a higher rate of wound complications within 3 months following the operation was found in the PT group.”

Conclusion: The sterile elastic exsanguination tourniquet works at least as good as the pneumatic one.



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

Yaron S. Brin, MD, Viktor Feldman, MD, Itai Ron Gal, MD, Michael Markushevitch, MD, Amit Regev, MD, Abraham Stern, MD



Discussion: Reducing blood loss during TKA is particularly important in the following groups:

- (a) patients who are anemic prior to surgery;
- (b) patients with coagulopathies (e.g. hemophilia) who are likely to lose more blood intraoperatively;
- (c) patients in which allogenic blood transfusion is detrimental (e.g. patients waiting for organ transplant);
- (d) patients with a rare blood type; and
- (e) patients who refuse transfusion for religious reasons (e.g. Jehovah Witness).

HemaClear® for Total Knee Arthroplasty (TKA) – Literature Review (3)

Silicone ring tourniquet or pneumatic cuff tourniquet for total knee arthroplasty; Jean-Yves Jenny et Al France, International Orthopaedics (SICOT), 2016.

Results: There was a significant decrease of complication rate in the 33 patients HC group (one case of skin dehiscence = 3%) in comparison to the 39 patients PT 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) (9/39; 23% p= 0.02).

Conclusions: "The rate of complication was significantly decreased in the study group. Especially, the occurrence of skin necrosis was **dramatically lower.**"

International Orthopaedics (SICOT)
DOI 10.1007/s00264-016-3160-0

ORIGINAL PAPER

Silicone ring tourniquet or pneumatic cuff tourniquet for total knee arthroplasty

Jean-Yves Jenny¹ · David Bahlau¹ · Sandra Wisniewski¹

Discussion: "We postulate that the extra-cost of the HC (50€ in France), might be compensated by a decreased operating time; – by a decreased need for allogeneic transfusion: one blood unit cost in France was about 180 € in 2015; – and by an earlier discharge with shorter length of stay.

One-stage TKA plus corrective osteotomy for osteoarthritis associated with sever extra-articular deformity. Julio de Pablos Fernandez et Al. Spain, J. Orthopedics, 2018. This is a technical note on treating complex deformities of the leg. HemaClear was used to facilitate a dry surgical field.

Julio de Pablos Fernández, M.D., Ph.D., Lucas Arbeloa-Gutierrez, M.D., and Antonio Arenas-Miquelez, M.D.

Technical Note

One-Stage Total Knee Arthroplasty Plus Corrective Osteotomy for Osteoarthritis Associated With Severe Extra-articular Deformity

Julio de Pablos Fernández, M.D., Ph.D., Lucas Arbeloa-Gutierrez, M.D., and Antonio Arenas-Miquelez, M.D.

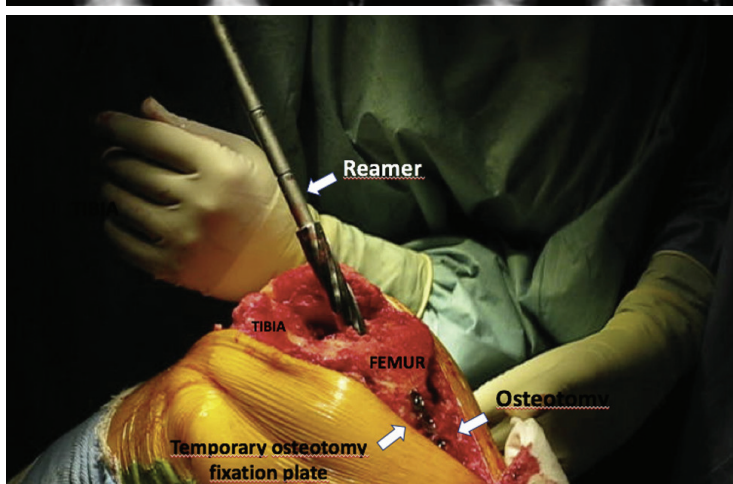
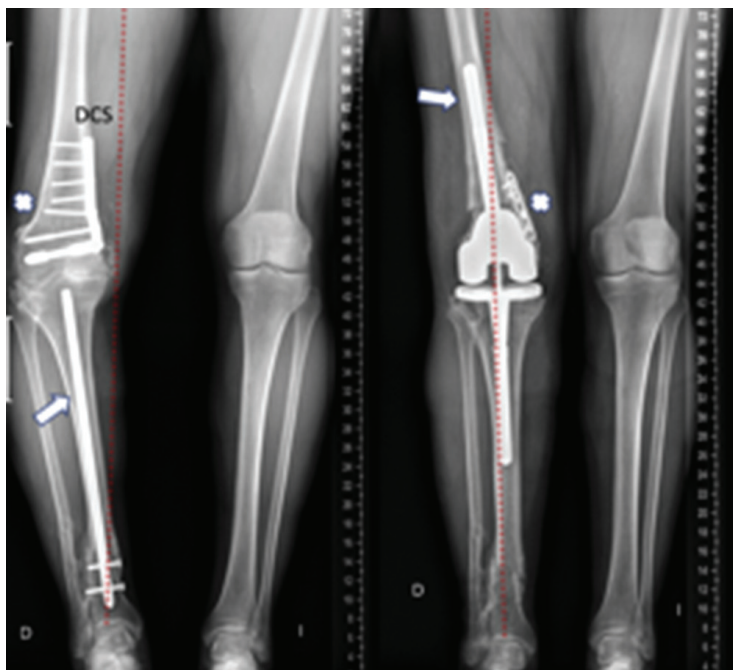


Fig 3. A right knee is shown with the patient placed in the supine position on a radio-transparent surgical table. Sterile surgical drapes are used according to standard technique for total knee arthroplasty, placing positioning boot underneath to hold the leg in the desired knee flexion at any given time. A non-pneumatic narrow disposable silicone ring tourniquet (HemaClear) was used.

Abstract

Adequate operative field space minimizes potential complications during revision knee arthroplasty. The colonization 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 (HemaClear® /S-MART™, OHK Medical Devices, Haifa, Israel) have **colonization 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.



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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 (Heamaclear® /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 useful tool for surgeons facilitating ease of revision knee surgery.

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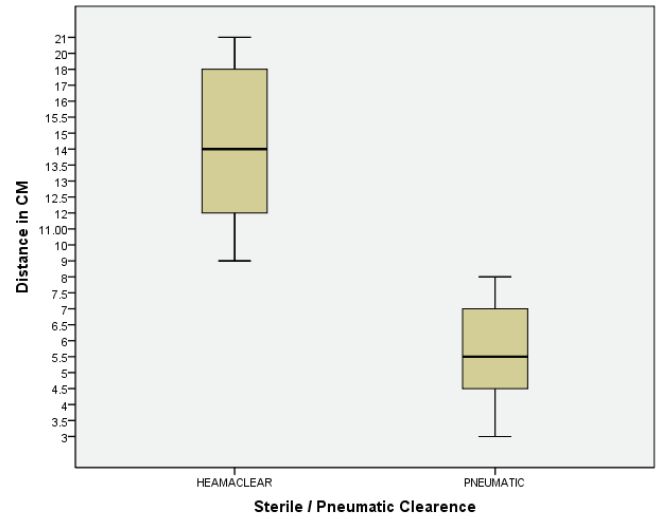


Fig 3: Box plot of the clearance of the two devices



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

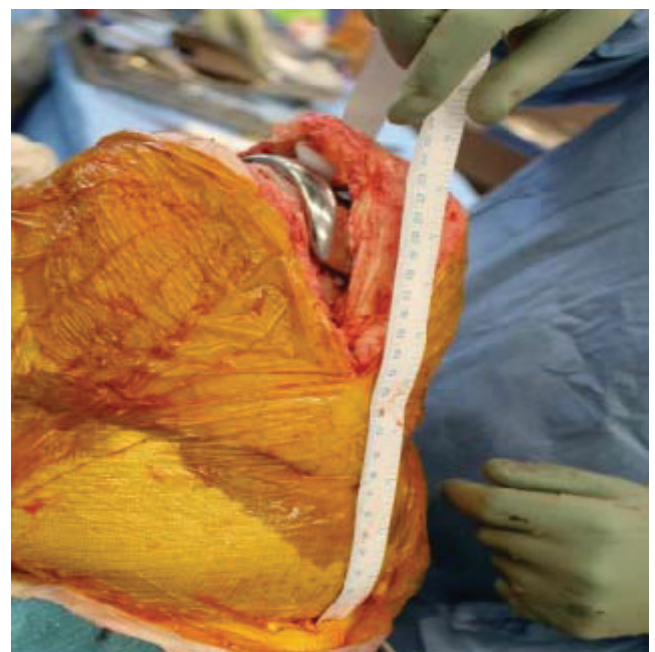


Fig 2: Measurement using sterile tape measure of the proximal extent of the wound to the distal extent of the tourniquet