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 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. View video at:

https://www.youtube.com/watch?v=yts1mDIzn6A

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 pressure.



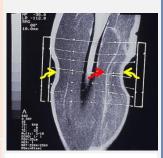


HemaClear[®] Sterile Exsanguination Tourniquet is preferred by most leading TKA surgeons for the following reasons:

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 nearcomplete exsanguination (>95% of the blood removed) prevents intra-vascular 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 thight, larger "real estate", dry bone surface for cementation. OR logistics: Faster preparations, only one item needed, no need to

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



MRI of the thigh beneath a pressurized pneumatic tourniquet (Estebe, personal communication, Rennes, France). Red arrow points to deformed fascia. Yellow arrows show soft tissue compression by the cuff.

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

The following are essentials of 6 clinical studies publications in peer-reviewed journals on the use of HemaClear® in TKA. 5 of them are comparative to Pneumatic Tourniquet, one is a surgical technique paper.

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-Muñoza 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." Annual of Orthoppadless

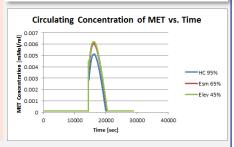
Journal of Clinical Orthopaedics and Trauma

sable silicone ring tourniquet during Total Knee Arthroplasty

on of local pain and tissue reaction between conventional pr

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

Vicente J. León-Muñoz^{1, o}, Alonso J. Lisón-Almagro¹, César H. Hernández-García⁴ Mirian López-López^b



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.

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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 b 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 Ismai Deminkle, ND⁺, Oman Tecimel, MD⁺, Halan Sesen, ND⁺, Kasim Kilicarsian, MD⁺, Murat Altay, MD⁺, Mein Dogan, MD⁺



Table 5 Postoperative Complications.

	Group 2	Group 1	Р
Uninary teact infection	10 (4 49)	11 (4 99)	0.061
Deep venous thrombosis	12 (5.3%)	4 (1.6%)	0.023
Homarthrosis	0 (0%)	2 (0.76%)	0.005
Tourniquet related pain	18 (7.9%)	5 (2%)	0.0022
rost op analgestes need	J.1 ± 0.5	2.0 ± 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. Vator Fedman, MD, Ital Ron Gal, MD, Michael Markushevitch, MD, Amit Resey, 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).
- Use of HemaClear significantly reduces Intra-operative blood loss and need for transfusion

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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."

silicone ring tourniquet or pneumatic cuff tourniquet for total knee arthroplasty Jean-Nyes Jenny¹, David Bahlau¹, Sandra Wixniewski

Coast.

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

Technical Note

One-Stage Total Knee Arthroplasty Plus Corrective Contact of the second 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.

Abstract: The mainstay for treatment of articular deformity caused by advanced tricomp knee is total knee anthroplasty. When this is also associated with an extra-anticular compensated or corrected. In this semaño, it is essential to achieve an optimal mechanical anatomical and mechanical limb axes and an adequate soft-issue balance. These premision ad achieve satisfactory functionality and implant survival over time. A reconstructive singu-for patients with knee osteoanthritis amenable to anthroplasty and a severe extra-articular both problems ismultaneously. partmental osteoa r deformity, this nical situation by es are ne



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 a 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.

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a dry surgical field.



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