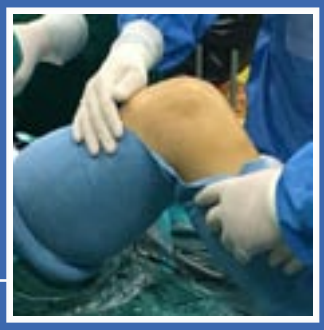
HemaClear®

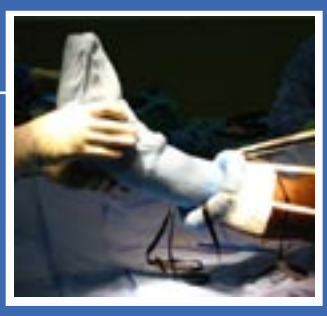
Sterile & Bloodless Surgical Field.

The All-In-One, Sterile, Exsanguination Tourniquet. Improving Patient Safety. Saving Time and Clutter in the Operating Theater.

"The HemaClear technique is unparalleled."

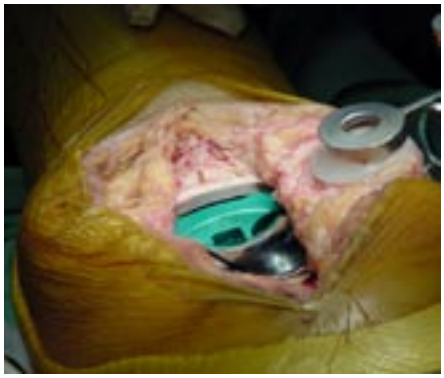
Dr. David Helfet, Chief of Orthopedic Trauma
Hospital for Special Surgery, New York





Sterile Bloodless Surgical Field in Limb Surgery

Dry Surgical Field



HemaClear® Exsanguinates 95% of the blood to provide a dry field and optimal visibility. Image on Right shows TKA. Image below was taken during PIP joint replacement. Bottom Right shows simultaneous bilateral TKA. Left leg with HemaClear. Right leg with pneumatic cuff; Note the use of cautery, suction and pulse lavage on right leg.

Sterile; Less Surgical Site Infection (SSI)

HemaClear® is always sterile. Its ring is cut at the end of surgery and can never be re-used. HemaClear does not require handling, cleaning or soaking at the end of surgery and does not expose the nurses or technicians to contamination risk.

Image on left shows placement of non-sterile pneumatic cuff on a limb. **ALL** non-sterile cuffs are contaminated. **Evidence:**

Microbial Colonization of Tourniquets Used in Orthopedic Surgery
By Eric F. Walsh, MD; Debby Ben-David, MD; Mark Ritter, MD; Anthony P. Mechrefe, MD; Leonard A. Mermel, DO, ScM; Christopher W. DiGiovanni, MD
ORTHOPEDICS 2006; 29:709.

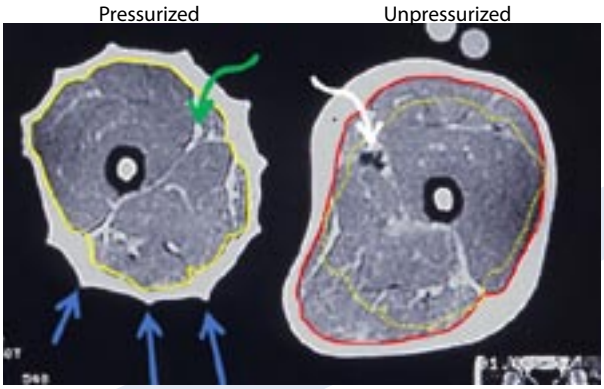
A Study of Microbial Colonization of Orthopaedic Tourniquets
SMY Ahmed, R Ahmad, R Case, and RF Spencer **Ann R Coll Surg Engl. 2009 Mar; 91(2): 131-134.**

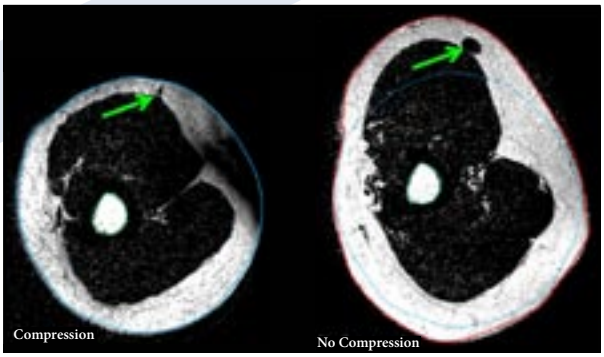
Microbial Colonization of Pneumatic Tourniquets in the Orthopedic Operating Room Syed H. Mufarrih , Nada Q. Qureshi, Rizwan H. Rashid, Bilal Ahmed, Seema Irfan, Akbar J. Zubairi, Shahryar Noordin **8/2019 Cureus 11(8): e5308**

The effect of sterile versus non-sterile tourniquets on microbiological colonization in lower limb surgery SM Thompson, M Middleton, M Farook, A Cameron-Smith, S Bone, A Hassan **THEATRE TECHNIQUES Ann R Coll Surg Engl 2011; 93: 589-590.**

No Skin Injury

Skin injury with blisters is common with pneumatic tourniquet (top photograph, white arrows point to blisters). The linear cascades are caused by pinching the skin by inflated tourniquet (Blue arrows, middle MRI of thighs with tourniquet on Left side)





Bottom picture: MRI with HemaClear® on Left thigh. Green arrows point to blood vessels, the smooth perimeter.

Additional Patient Advantages

- Virtually **no intra-operative blood loss**, reduced need for transfusion
- Less post-op Deep Vein Thrombosis (**DVT**) and Pulmonary Embolism (**PE**)
- Shorter **Tourniquet Time**
- Significantly less **SSI**
- Less tissue under **compression** (narrower band)
- Less tissue under **ischemia** (can be placed distally)

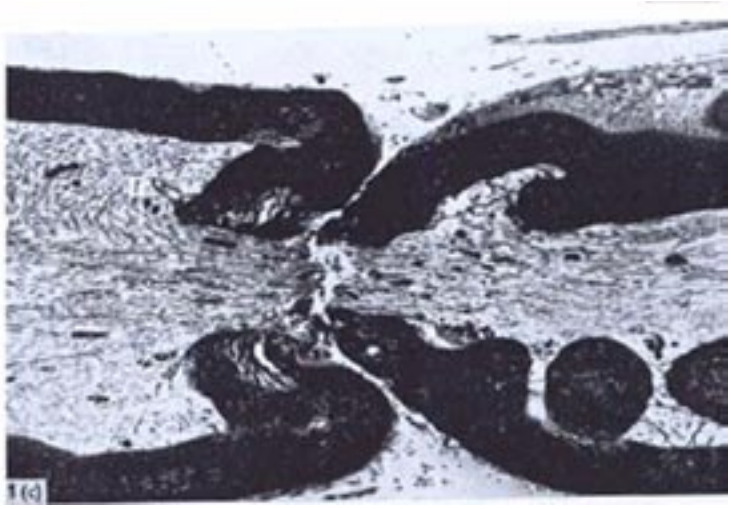
No Nerve Injury

In over 1,500,000 cases done with HemaClear®, no nerve injury was reported.

The incidence of Pneumatic Tourniquet nerve injury is varying from 1:4000 in general to 7.7% in procedures lasting more than 2 hours, Mayo Clinic. Tourniquet-Related Iatrogenic Femoral Nerve Palsy after Knee Surgery: Case Report and Review of the Literature (hindawi.com);

Anesthetic, Patient, and Surgical Risk Factors for Neurologi... : Anesthesia & Analgesia (lww.com)

The mechanism of pneumatic-tourniquet-induced nerve damage was revealed by Ochoa et Al (Ochoa J, Fowler TJ, and Gilliatt RW. Anatomical changes in peripheral nerves compressed by a pneumatic tourniquet. J Anat (1972), 113, 3, 433-455.) who found that the nerves compressed under the tourniquet elongated and telescoped into themselves (picture) at the Nodes of Ranvier where the nerve is weaker. Axonal disruption is clearly seen in the electron microscopy image.



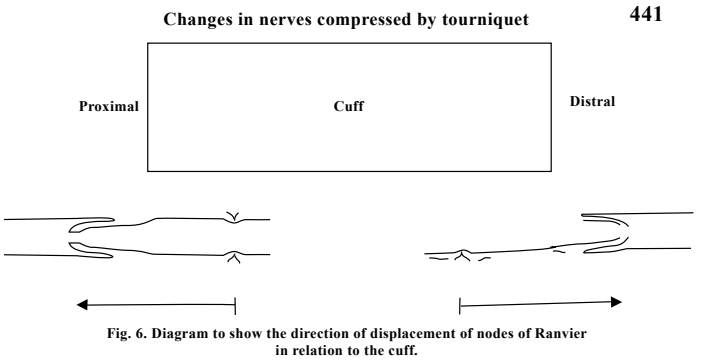


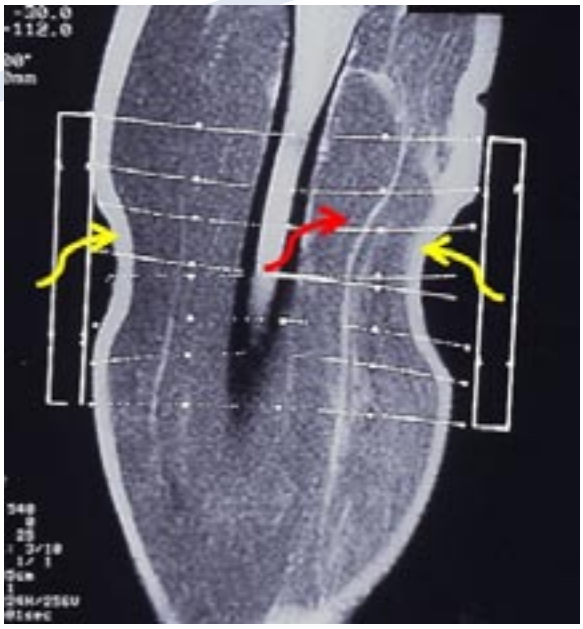
Fig. 6. Diagram to show the direction of displacement of nodes of Ranvier in relation to the cuff.

The telescoping was found only at the two edges of the cuff and were directly attributed to its width. Another mechanism described by Ochoa et Al is related to the steep pressure gradient at the ends of the cuff, causing shearing force on the nerves. **Both mechanisms do not exist with the HemaClear.**

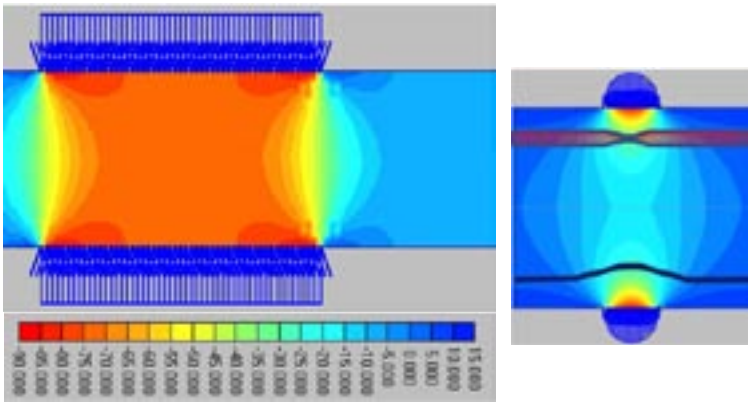
Less Pain

Intra-operative and post-operative tourniquet pain is common (40%) with pneumatic tourniquet.

Multiple independent peer-reviewed clinical studies have shown that Tourniquet pain is significantly reduced when HemaClear® is used. What is the mechanism of wide-tourniquet tourniquet pain and how is it mitigated by the narrow HemaClear®?



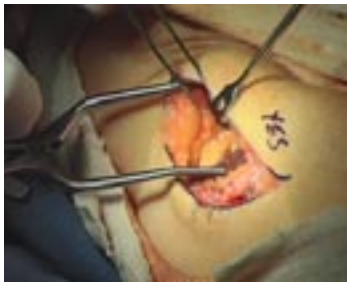
This MRI of a thigh with pneumatic tourniquet clearly shows the source of the pain: the deformation and stretching of the fascia (red arrow), where the C-fibers that conduct pain to the spinal cord reside. It is like a "Charlie Horse" all around.



The diagrams shown above from E. Levenberg's finite element analysis of stresses and strains in a limb beneath a wide (left) and a narrow (right) tourniquet help understand the biomechanics and the safety of HemaClear.

The pressure distribution beneath a pneumatic tourniquet is uniform and as high as the tourniquet pressure all around. The surface (skin) pressure beneath a HemaClear is essentially the same as under a pneumatic tourniquet, but it dissipates into the limb due to the elastic properties of the tissues. **The result is that the pressures acting on the artery (upper insert) and the nerve (lower insert) are lower, extend over a much shorter distance and the gradients are much less abrupt.**

"With over 3000 procedures and not a single complication, HemaClear may be superior to traditional torniquets in terms of the pressure." -Peter F Sharky, MD
https://www.youtube.com/watch?v=MGX1UoqNubY



"HemaClear lasts a long time during surgery and gives me a better predictability and more exposure when I work around the elbow."
- Jessie B Jupiter, MD
https://www.youtube.com/watch?v=-fmFSU7bjFk

"The more you use it, the more you get used to it. It's so quick just to put on and it's always sterile. We use HemaClear for all cases."
- John Herzenberg, MD
https://www.youtube.com/watch?v=Xftq9Hrv3C4

"It is very easy to use. You just put it on and it's done. I think it's a very good option to use for operations."
- Doron Norman, MD
https://www.youtube.com/watch?v=39oJhqwpRVc

Value

HemaClear overcomes the adverse effects and risks of pneumatic tourniquet: no skin damage or blisters, no nerve damage, less intra-operative and post-op pain, less DVT/PE, less Surgical Site Infection (SSI).

Excellent exposure and very dry field. Broad space to work. Longer hamstring autograft for ACL reconstruction.

Predictable: never slides down towards the incision; easy and quick to apply, never pressure loss and re-do drapes.

Logistics: no clutter and shorter preparation time, less shelf space for models, replaces cuff, Esmarch, stockinet, padding material, pump, tubing extensions. Competitive cost.

Application

Select: HemaClear Model is selected by using the color-coded ruler supplied with each unit.

Place: position on fingers/toes and pull handles to roll up the limb. https://www.youtube.com/watch?v=yts1mDIzn6A

Remove: HemaClear® ring is cut by scalpel after inserting the Protective Card to protect the skin. Stockinet is cut by scissors.

Determine pressure: use the ruler to measure circumference and distance from fingers/toes. Use look-up table for pressure.

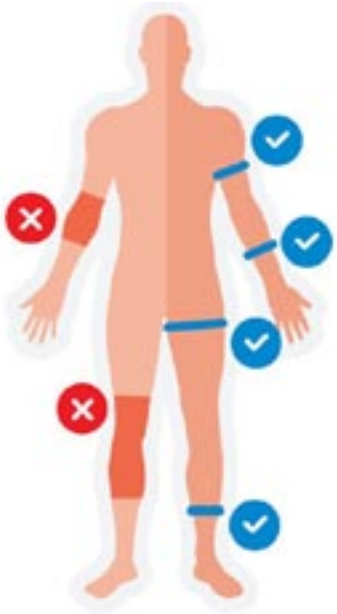
Release temporarily: insert and pull two Army-Navy retractors.

HemaClear® Models, Uses and Ordering Information

Model	Catalog #	Units /Case	Circumference of Limb cm	Max. BP mm Hg	Common Uses/ Placement
SMALL Pink	PRH-028-PI-01A	10	14-28	130	Pediatric Ortho
MEDIUM Yellow	PRH-040-YE-01A	10	24-40	190	Adult Upper Arm
MEDIUM Red	PRH-040-RE-01A	10	24-40	160	Adult Upper Arm
MEDIUM Green	PRH-040-GR-01A	10	24-40	130	Pediatric Ortho
LARGE Brown	PRH-060-BR-01A	10	30-55	190	Adult upper thigh
LARGE Orange	PRH-060-OR-01A	10	30-55	160	Adult Ankle, Arm
LARGE Blue	PRH-060-BL-01A	10	30-55	130	Pediatric thigh
XLARGE B & W	PRH-090-BW-01A	10	50-85	160	TKA upper thigh
Model A - Ankle	PRH-032-MA-01A	12	22-32	160	Foot Surgery
Model F - Forearm	PRH-035-FA-01A	25	14-35	160	Hand Surgery

Max BP - Maximal Blood Pressure (Systolic); B & W - Black and White; Ankle - for Ankle placement; Forearm - for Forearm placement. HemaClear is supplied in cases.

Size selection is by color-coded ruler supplied with each HemaClear® Unit.



Placement diagram

Place where there is minimal muscle to avoid tourniquet pain:

- 10 cm above wrist
- Between deltoid and biceps
- 10 cm above ankle
- As high as possible on groin

Never place directly on elbow or knee.

Representative information

HemaClear® is a product of Oneg HaKarmel Ltd. Haifa, Israel

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