

Why being selective with the initial introduction of HemaClear[®] is sometimes needed?

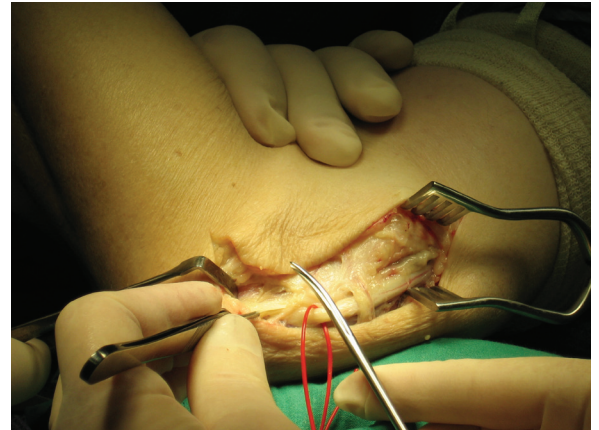
Economic Reality

The use of HemaClear Sterile Exsanguination Tourniquet clearly reduces adverse events and is logistically superior to pneumatic tourniquets. However, many hospitals and OR administrators perceive HemaClear as being more expensive than nonsterile reused pneumatic tourniquets. They are often concerned that using HemaClear for all patients will cause a noticeable step-change in the OR direct budget. We developed this program of prioritizing HemaClear use for those patients who need it the most and with whom cost-saving will be most noticeable. This document lists these patient groups and how to characterize them in objective, quantitative and verifiable terms.

1: Surgery of the elbow and humerus and above the knee

Even sterile Pneumatic tourniquets (PT) can not be used during surgery of the thigh (e.g. ORIF of femoral fracture) and the upper arm, including elbow due to space limitations. Intra-operative blood loss during ORIF of femur fracture was found to be >1000 ml in 65% of patients (1. EAOJ; Vol. 4: Sept. 2010) and 15% of patients undergoing ORIF for humerus fracture require blood transfusion (2. Am J Orthop (Belle Mead NJ). 2002 Sep; 31(9): 513-6). Bloodloss can be reduced to minimum in these cases if HemaClear is used (Surg Technol Int 2013; 23:251-7).

Eligibility: All patients in category

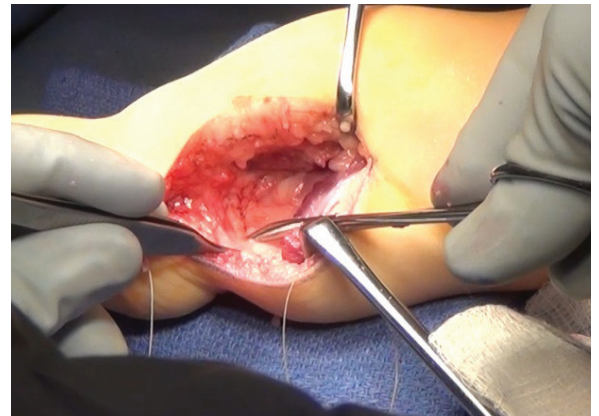


Elbow surgery with HemaClear.
Note the available space and the dry field.

2: Children

Using pneumatic tourniquet in young children is challenging. There is not enough space on the small child limbs, the limbs are conical and the skin is tender. In addition, minimizing anesthesia time is essential. Use of HemaClear mitigates all of these issues (4. Journal of Pediatric Orthopaedics B. 15(5):379-384,)

Eligibility: Children younger than 5 years; smaller than 16 kg.



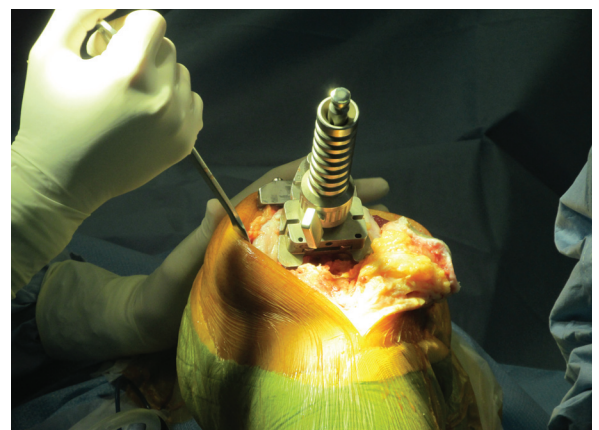
Ankle surgery of a young child. Note the dry field.

3: Obese patients

Applying pneumatic tourniquet on the conical thigh of an obese patient is challenging. It often slides distally towards the surgical field and can cause postoperative thigh pain and skin injury. Using HemaClear solves these problems while providing a dry field, mobility and large working space. For more information visit our site:



Eligibility: Patients undergoing knee surgery with BMI greater than 34

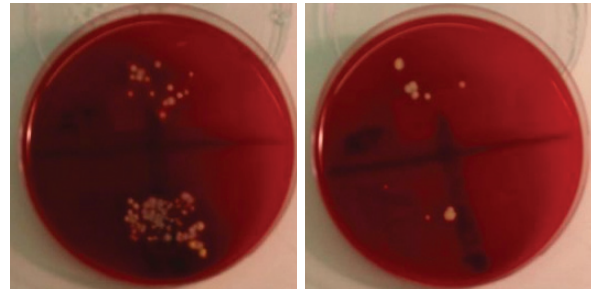


TKA of an obese patient

4: Immune deficient patients

The risk of Surgical Site Infection (SSI) is greater in patients with immunological weakness such as HIV, Diabetes (5. Infect Control Hosp Epidemiol. 2016 Jan; 37(1): 88–99.), patients on steroids and patients on chemotherapy. The use of sterile HemaClear® has been shown to reduce SSI in TKA by 2/3rd (6. J. Arthroplasty 2014 Volume 29, Issue 5, Pages 993–997).

Eligibility: Patients with immune deficiency.



Petri dishes with cultures from Thompson's study on tourniquet contamination. Ann R Coll Surg Engl 2011; 93: 589–590

5: Anemic patients and patients with contraindications for transfusion

This heterogenic group consists of:

- (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 rare blood type; and
- (e) patients who refuse transfusion for religious reasons (e.g. Jehovah Witness).

Eligibility: Anemia with preop Hemoglobin less than 10 g/100cc or patients with confirmed categories b-e.



Blood transfusion is almost never needed for intraoperative blood loss when HemaClear is used.

6: Other – Specific indications

- a. Short patients undergoing ACL reconstruction with hamstring ligament autograft often end up with need for an allograft because of harvested graft length. This is resolved by using HemaClear® (Journal of Orthopaedic Surgery 2018 26(3) 1–6.).
- b. In Patients undergoing Bilateral TKA or other bilateral corrections (e.g. pediatric club foot) blood loss can be minimized by using HemaClear and therefore reduce the risk for allogenic transfusion (J. Arthroplasty 2014 Volume 29, Issue 5, Pages 993–997).

**Eligibility: Patients undergoing same-day bilateral surgery.
Patients undergoing ACL reconstruction surgery**

Relevant bibliography:

1. EAOJ; Vol. 4: September 2010 Factors Affecting Blood Loss during ORIF of Isolated Closed Femoral Fractures at Mulago Hospital C.K. Kinyanjui
2. Am J Orthop (Belle Mead NJ). 2002 Sep; 31(9): 513-6. Blood transfusion in proximal humerus fractures. Rojer DE1, Yu RS, Barron OA.
3. Surg Technol Int 2013;23:251–7. Drosos GI, Ververidis A, Mavropoulos R, et al. The silicone ring tourniquet in orthopaedic operations of the extremities.
4. Journal of Pediatric Orthopaedics B. 15(5):379-384, SEPTEMBER 2006 A novel elastic exsanguination tourniquet as an alternative to the pneumatic cuff in pediatric orthopedic limb surgery Mark Eidelman; Alexander Katzman; Viktor Bialik;
5. Infect Control Hosp Epidemiol. 2016 Jan; 37(1): 88–99. Diabetes and Risk of Surgical Site Infection: A systematic review and meta-analysis. Emily T. Martin, MPH, PhD, Keith S. Kaye, MD, MPH, Caitlin Knott, Huong Nguyen, Maressa Santarossa, Richard Evans, Elizabeth Bertran, and Linda Jaber
6. J. Arthroplasty 2014 Volume 29, Issue 5, Pages 993–997 Nondrainage Decreases Blood Transfusion Need and Infection Rate in Bilateral Total Knee Arthroplasty. Ismail Demirkale, Osman Tecimel, Hakan Sesen, Kasim Kilcarslan, Murat Altay, and Metin Dogan.
7. Journal of Orthopaedic Surgery 2018 26(3) 1–6. The effect of tourniquet type and thigh concity on the length of hamstring Autograft. Mehmet Faruk Catma and Alper Oztu`rk