HemaClear®
Sterile & Bloodless Surgical Field

Why are there less Surgical Site Infections (SSI) when HemaClear® is used?

This document presents published data that shows:

- ALL non-sterile tourniquets are contaminated with a variety of pathogens, including MRSA;
- Disinfecting tourniquets by detergents in the OR is insufficient to eradicate bacteria;
- Draping over contaminated tourniquets becomes ineffective as a barrier over time;
- The longer the tourniquet time, the higher the incidence of Surgical Site Infection (SSI) in orthopedics;
- Use of cautery, suction and pulse-lavage may bring bacteria into the incision
- Blood transfusion is an independent risk factor for SSI.

We further present published data that show that HemaClear® is sterile and that the use of HemaClear significantly reduces SSI incidence.

Studies that show that ALL non-sterile tourniquets are contaminated

	Title	Authors, Institution and Journal	1⁰ finding	Conclusion
1	"Microbial Colonization of Tourniquets Used in Orthopedic Surgery"	**Walsh et Al,** Rhode Island Hospital, USA ORTHOPEDICS 2006; 29:709	"100% of Tourniquets used in the operating room were contaminated"	"Tourniquet contamination may be a risk factor for the development of surgical site infection in orthopedic surgery."
2	"A study of microbial colonization of orthopedic Tourniquets"	**Ahmed et Al** Weston General Hospital, UK ORTHOPAEDICS Ann R Coll Surg Engl 2009; 91: 131–134	"All sampled tourniquets were contaminated with colony counts varying from 9 to > 385"	"In addition to the manufacturer's guidelines, **we recommend the cleaning of tourniquets with a disinfectant wipe before every case"**
3	"Tourniquets and exsanguinators: a potential source of infection in the orthopedic operating theater?"	**Brennan et Al** Cappagh National Orthopaedic Hospital, Dublin, Ireland Acta Orthopaedica 2009; 80 (2): 251–255	Bacteria commonly implicated in surgical site infections were prevalent.	**Infectious organisms reside on the tourniquets and exsanguinators presently used in the orthopedic theater and may possibly be a source of surgical site infection.**

Published data that show that the use of Sterile HemaClear significantly reduce SSI incidence.

Table 4
Comparison of Infection Rates.

Infection Rate	Group 1 (n = 255)	Group 2 (n = 227)	*P*
Total	7 (2.7%)	17 (7.5%)	0.0168
Deep	2 (0.78%)	6 (2.6%)	0.111
Superficial	5 (1.96%)	11 (4.85%)	0.0776

RCS ADVANCING SURGICAL STANDARDS

THEATRE TECHNIQUES

Ann R Coll Surg Engl 2011; **93:** 589–590
doi 10.1308/147870811X13137608455334

The effect of sterile versus non-sterile tourniquets on microbiological colonisation in lower limb surgery

SM Thompson, M Middleton, M Farook, A Cameron-Smith, S Bone, A Hassan

St Peter's Hospital, Chertsey, UK

HemaClear®
Sterile & Bloodless Surgical Field

Additional Studies that show that ALL non-sterile tourniquets are contaminated

	Title	Authors	1⁰ finding	Conclusion
4	"The effect of sterile versus non-sterile tourniquets on microbiological colonization in lower limb surgery"	**Thompson et Al** St Peter's Hospital, UK Ann R Coll Surg Engl 2011; 93: 589–590	"23/34 of sampled non-sterile tourniquets were contaminated. 36 **HemaClear** were used, with no contamination."	**"There was significant contamination of 68% of orthopedic surgical tourniquets** used regularly in procedures involving the placement of prosthesis and metalwork, and **can act as a potential source of infection."**
5	"Microbial colonization of Orthopaedic tourniquets: A potential risk for surgical site infection"	**Sahu et Al** VSS Medical College, Burla, Sambalpur, Odisha, India Indian J Med Microbiol 2015;33, Supp S1:115-8	"All the tourniquets were colonized with bacteria. After antiseptic treatment, the colony count was significantly reduced."	**"We recommend the routine treatment of orthopedic tourniquets with a disinfectant, preferably an alcohol-based solution, to reduce the risk of contamination of surgical fields."**
6	"Microbial Colonization of Pneumatic Tourniquets in the Orthopedic Operating Room."	**Mufarrih et Al,** Aga Khan University, Karachi, Pakistan Cureus. 2019 Aug 2;11(8): e5308.	"Four out of 12 (33%) samples obtained after simply wiping the pneumatic tourniquet with a cloth soaked in sodium hypochlorite cultured coagulase-negative Staphylococci."	**"Tourniquets, wiped with a cloth soaked in sodium hypochlorite and ready to be used on the next patient, were found to be contaminated with species notorious for causing surgical site infections following implant-related surgeries."** .

Organisms cultured in each of the published studies

	Organisms (Numbers correspond to publications listed above)
1	coagulase-negative staphylococci, Bacillus, Staphylococcus aureus, Streptococcus sanguis, Aerococcus viridans, and Cornyebacterium species
2	mostly coagulase-negative; Staphylococcus spp. Some tourniquets had growths of important pathogens including **methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas spp., and S. aureus.**
3	coagulase-negative staphylococci, Staphylococcus aureus and Proteus spp. **We also found a resistant strain of Acinetobacter and Candida**.
4	different organisms including coagulase-negative Staphylococcus spp, Staphylococcus aureus, Sphingomonas paucimobilis, Bacillus spp, and **coliforms.**
5	coagulase-negative staphylococci, Staphylococcus aureus, Bacillus, **diphtheroids, Pseudomonas, Acinetobacter, enterococci, enterobacteria, and Candida.**
6	coagulase-negative Staphylococci.

HemaClear®
Sterile & Bloodless Surgical Field

Myths and Facts on Tourniquet and Surgical Site Sterility

Myth 1: Draping prevents bacterial migration to the sterile field.
Fact 1: Published data shows that **draping over contaminated tourniquets become ineffective** as a barrier over time.

- AW Blom, et Al., Bristol, UK Journal of Orthopaedic Surgery 2007;15(3):267-9

Fact 2: Field dryness and reduced intraoperative blood loss help reduce **Surgical Site Infection (SSI)** in orthopedics. When surgical field is not dry **cautery (i.e. burning) and suction are used** throughout surgery for hemostasis. Both are risk factors for incisional contamination. As such, **Blood transfusion is a risk factors for SSI:**

- Kim JL, Park JH, Han SB, Cho IY, Jang KM. Allogeneic blood transfusion is a significant risk factor for surgical-site infection following total hip and knee arthroplasty: a meta-analysis. J Arthroplasty. 2017;32(1):320-
  5. https://doi.org/10.1016/j.arth.2016.08.026.
- Everhart JS, Sojka JH, Mayerson JL, Glassman AH, Scharschmidt TJ. Perioperative allogeneic red blood-cell transfusion associated with surgical site infection after total hip and knee arthroplasty. J Bone Joint Surg Am. 2018;100(4):288
  94. https://doi.org/10.2106/JBJS.17.00237.

- SSI is a significant complication of all orthopedic operations.
- The cost and suffering are enormous with >$60,000 per case with post TKA infection.
- Often needing IV antibiotics, prolonged hospitalization, removal of implant and re-do after prolonged delay.
- The prevalence of SSI is 0.5-4.5%. US averages are 1.35% for TKA, 0.5% for hand surgery, 4.5% in foot surgery (11% in diabetic patients).
- The cause of SSI is multifactorial. However, quite **often the kind of bacteria that grow in cultures from SSI are the same as those found on re-used pneumatic tourniquets.** **Using sterile tourniquets, shortening surgery time, reducing blood loss and blood transfusion, and preventing tourniquet skin injury are all facilitated by using HemaClear. This explains why SSI with HemaClear is much less than with pneumatic tourniquet as shown in multiple peer-reviewed articles.**

Contents lists available at ScienceDirect
Journal of Clinical Orthopaedics and Trauma
journal homepage: www.elsevier.com/locate/jcot
ELSEVIER

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]

Table 1
Demographics and Preoperative Haemoglobin Levels of the two Patient Groups.

Demographic/hb	Group 1 (n = 255)	Group 2 (n = 227)	P
Average age (years)	64.4 (47–84)	63.9 (43–88)	0.41
Male:female	39:216	26:201	0.32
Prhb	12.8 ± 1.8	13.1 ± 2.5	0.62

Hb = Haemoglobin; Prhb = Preoperative haemoglobin.

Table 3
Variables used in the study.

Variables	Conventional tourniquet	Disposable tourniquet	P value
Local bruising	8	0	0.0196
Blister formation	2	0	
VAS score 24 h	5.6 ± 2.1	4.3 ± 1.5	0.0152
VAS score 48 h	3.3 ± 1.2	2.1 ± 1.5	0.003
Post operative blood loss (ml)	185.6 ± 26.5	180.4 ± 28.2	0.3444

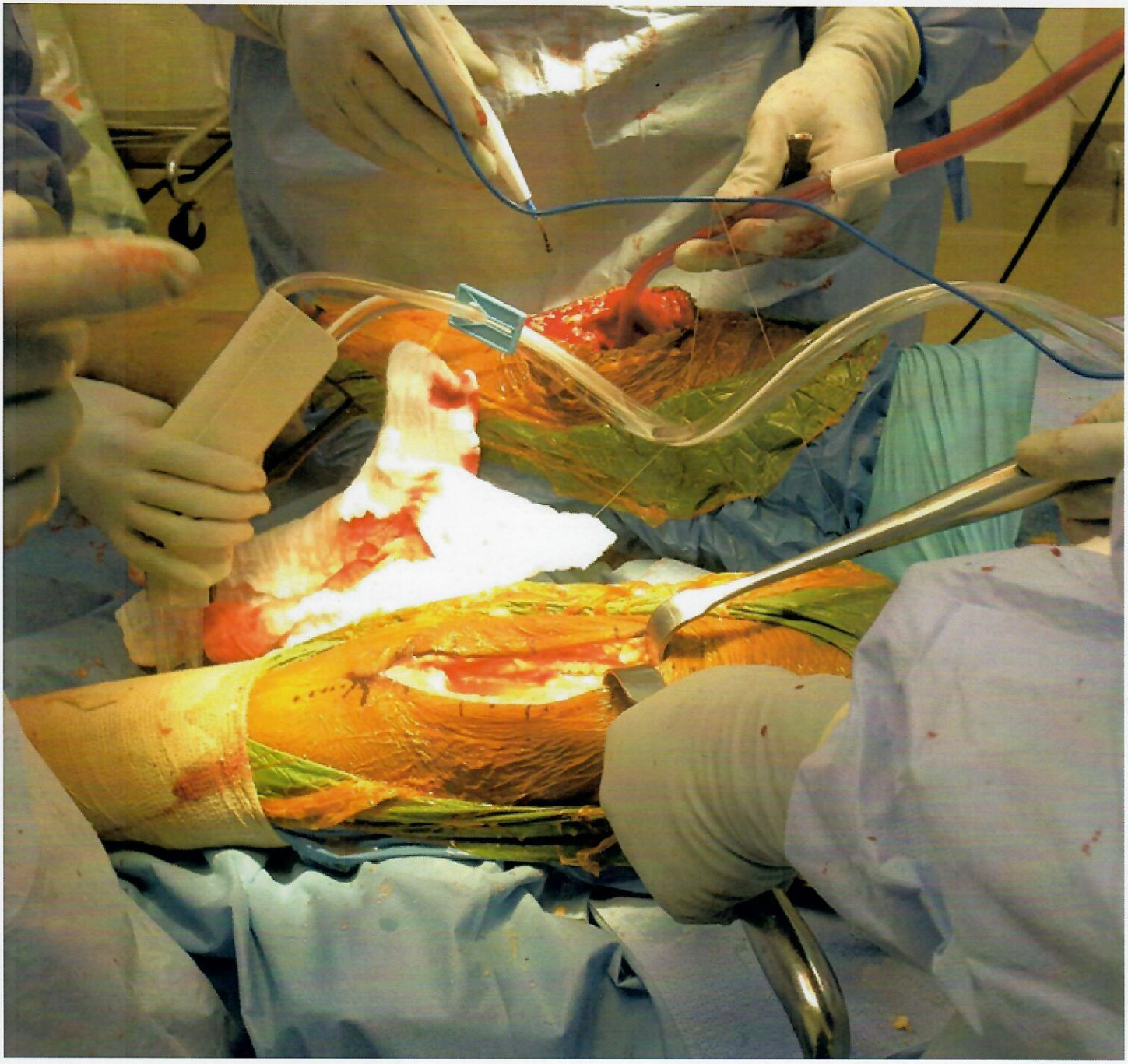
Contents lists available at ScienceDirect
Journal of Clinical Orthopaedics and Trauma
journal homepage: www.elsevier.com/locate/jcot
ELSEVIER

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]

HemaClear®
Sterile & Bloodless Surgical Field

Bleeding and hemostasis contribute to incisional contamination



Bilateral TKA with pneumatic tourniquet on right leg and HemaClear on left leg. Note the dryness of the HemaClear side.

BR2021-4.V1.0