HemaClear® Bloodless Surgical Field - the Anesthesiologist Perspective

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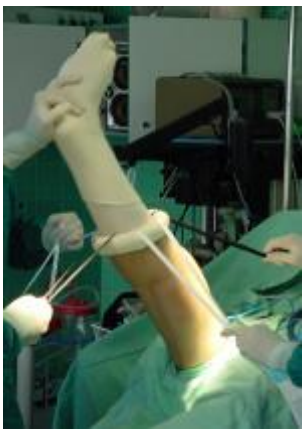
Synopsis

HemaClear® (HC) is a new device used to prepare a bloodless surgical field in limb surgery. It replaces the Esmach bandage, the pneumatic tourniquet with its accessories and the stockinet. It is an elastic, sterile single-patient use product that has sizes that cover from pediatrics to obese for both lower and upper extremities. Its superiority over the old pneumatic tourniquet method, from the procedure and surgeon's standpoint is accompanied by important advantages from the overall patient's safety and wellbeing as seen from the anesthesiologist's perspective. These include tissue mechanics, circulatory, hematology, infection-prevention, DVT prevention and logistical aspects which are reviewed below. In particular, the narrow footprint of the HC ring minimizes the amount of tissue under compression, reduces the stress and strain on the nerves and facilitates proximal placement for extended view bleeding-free procedures in mid-shaft femur and humerus/elbow cases. The sterile HC can also be placed close to the surgical incision thereby minimizing the amount of tissue under ischemic conditions (e.g. on the forearm for hand/finger procedures). The near-perfect exsanguination prevents blood from being left behind to clot and reduce the accumulation of cardio-depressive ischemic by-products (CO_2, lactic acid, K^+) as is manifested by post-tourniquet release shower of emboli and the drop in blood pressure seen with the traditional method. The use of the HC has been shown to reduce the need for post-op blood transfusion in bilateral TKA. Its use can reduce tourniquet time and OR time and simplify the procurement while pre-op preparations are markedly streamlined.

The usual contraindications of the bloodless field preparation apply to the HemaClear® including the presence of DVT, infection or malignancy in the operated limb. Skin lesions are relative contraindications and peripheral vascular diseases should be viewed with caution and certainly with attempt to cut ischemia time to a minimum. The anesthesiologist should be aware of the fact that the device is designed and factory-calibrated to withstand an upper limit of systolic blood pressure (130, 160, 190 mmHg, depending on model). If the patient's BP rises above the rated level (e.g. due to pain), blood will penetrate the limb causing bleeding and disrupting the surgical procedure. The tourniquet time (in patients with normal circulation) is limited to 120 minutes. A second device can be applied in long procedures after a period of re-perfusion. Correct size and site selection is a shared responsibility with the surgeon. The overall rate of side effects is very small with no reported cases of long-standing tourniquet neuropraxia. Two cases of possible fat necrosis were reported in obese elderly patients with no consequences.



The HemaClear® is a cardiovascular product that is serving in orthopedic surgery. As such, full understanding of its mechanics, physiology and clinical implications by the anesthesia team is essential. The material below is a brief review of these aspects.

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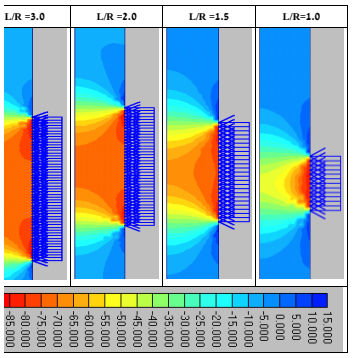
Introduction

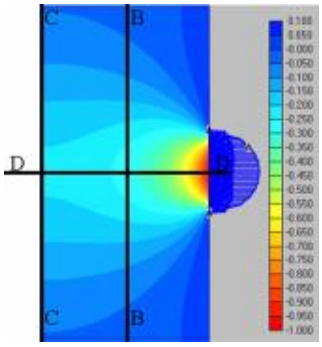
Establishing a bloodless surgical field for limb procedures is routinely achieved by squeezing the blood out of the limb ("exsanguination") and arterial blood flow blocking ("tourniquet"). HemaClear® (HC) is an elastic exsanguination tourniquet (EET). It is now used extensively (more than 600,000 cases) instead of the traditional Esmarch bandage + pneumatic tourniquet combination. The aim of this note is to review the use of the HC device from the anesthesiologist's point of view, with emphasis on its advantages, pitfalls, contra-indications and side-effects. It is also intended to review the mechanics of the device-tissue interactions with respect to its much narrower footprint.

Mechanics of Narrow Footprint EET.

The HC occludes the arterial inflow into the limb with a tight elastic ring that remains in-place for the duration of the procedure (up to 120 minutes). Its width is about $1/7^{th}$ of that of the typical pneumatic tourniquet. When circumferential pressure is applied to the surface of the thigh or an arm, the pressure propagates inward towards the center of the limb. To block arterial flow, it is necessary (and sufficient) to exert just enough pressure outside the artery to overcome the peak systolic blood pressure of the patient. When using the traditional wide pneumatic cuff, the same pressure generated in the cuff is uniformly distributed throughout the diameter of the limb and over nearly the entire width of the cuff (Figure 1a). As such, a cylinder of tissue with a volume **V** that is equal the cross section area **A** of the limb multiplied by the cuff's width **H** (e.g. for a thigh with a radius **r** of 20 cm , **A** = π X r^2 = 3.14 X 10^2 = 314 cm^2 using a tourniquet with width **H**=15 the compressed volume **V** = **A** X **H** = 314 X 15 = 4710 ml or 4.7 liters of tissue) is under significant compression for the duration of the procedure. This is roughly 5-6% of the body volume of an adult patient.



This color diagram shows the distribution of tissue pressure (stress) when circumferential constricting force is applied to a limb. The pressure fields are demonstrated by color coding in the axial (along the limb) and radial (across the limb) directions with red indicating higher pressure, equivalent to the pressure applied by the constricting device (tourniquet or HC) on the skin and colder colors indicate the gradients of pressure in the tissue as we move further into the limb and axially away from the center of the cuff. The diagrams are shown as half cross sections, but are symmetric around the limb circumference. Note that with the wide tourniquets (Length/Radius ratio: L/R=3.0 and 2.0) the pressure is uniformly high across the entire limb, but as the L/R gets smaller (right most panel in the top diagram and lower diagram depicting the pressure distribution beneath the HC, the tissue pressure dissipates quickly and is smaller than just under the contact point of the device.



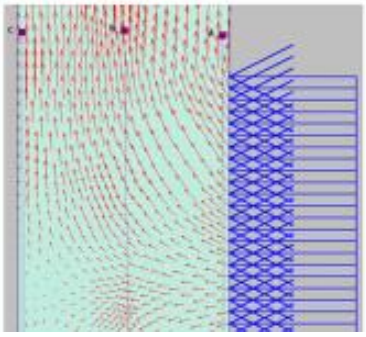


Figure 2 shows using arrows the axial migration (strain or deformation) of tissue elements caused by the compression pressure (stress) of a wide tourniquet (see below).

The HC elastic tension was carefully designed to apply sufficient blocking pressure at the arterial level (typically about 15 mmHg above the rated highest systolic blood pressure for the specific device chosen (130, 160, or 190 mmHg)). However, the main difference is that because of its narrow footprint, the

applied skin pressure dissipates quickly into the limb (Figure 1b) so that not much less tissue is exposed to pressure, and the bulk of the internal tissues (including the nerves) are exposed to pressure that is lower than that typically used by pneumatic tourniquets. As such, the overall tissue volume under compression with the HC is much less than with the pneumatic tourniquet.

When nerve damage is concerned, it has been shown nearly 40 years ago[2] (Ochoa 1972) that the main causes are the elongation of the compressed nerve along its axis by the wide tourniquet which causes telescoping or intussusception of the nerve into itself as shown in the figure.

Figure 2. Electron-micrograph from Ochoa et al (2) showing the telescoping of a nerve at the Node of Ranvier following application of a wide tourniquet in an experimental animal.

Ochoa et al further suggested that sheer stress at the two ends of the tourniquet where there is a sharp pressure step and deformation at the transition from the high pressure beneath the tourniquet to the low pressures proximal and distal to the tourniquet contribute to the nerve disruption. Neither phenomenon occurs with the ultra-narrow HC.

In a recent study Mital et al[5] showed less nerve conduction interference with a narrow tourniquet than with a wide cuff (both pneumatic) as shown in the line drawings on the next column. This explains the lack of sensory or motor deficits with the use of the HC as opposed to an incidence of approximately 1 in 4000 cases with the pneumatic tourniquet (Odinsson 2006[3]).

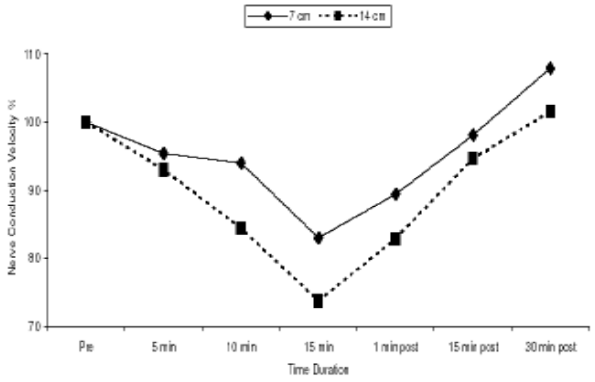


Figure 3. Nerve conduction velocity with wide (14 cm) and narrow (7 cm) cuffs in normal volunteers. Note the significantly larger drop in conduction velocity with the wide tourniquet (squares).

Clinical effects of improved exsanguination

In a brilliant series of studies, Blond et al (refs) documented the level of limb exsanguination by limb elevation (45%) and by Esmarch bandage (67%).

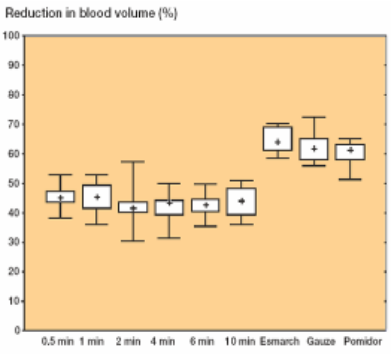


Figure 2. Results of various exsanguination methods in 12 subjects expressed as median (+), range and interquartil (box) percentage reduction in blood volume calculated from counts before and after the exsanguination.

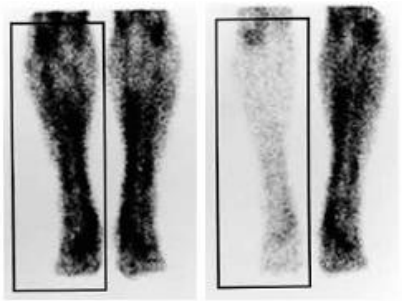
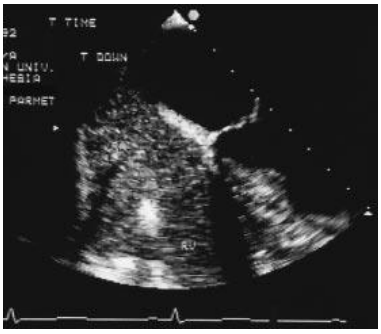


Figure 1. An example of a 1-minute scintigram of the lower limbs of a 25-year-old man obtained by 99mTc-radiolabeled erythrocytes showing the limbs from an anterior projection before and after an Esmarch exsanguination of the right limb. The frame represents the region of interest. The percentage reduction in blood volume, calculated from counts obtained before and after the exsanguination, was 61% here.

Figures 4a-c. (a) images of blood scan with red cells tagged with 99mTc isotope before (left) and after Escmach exsanguination. (b) The % reduction of blood volume with limb elevation for 0.5-10 min (45%) and with Esmarch bandage applied (65%).

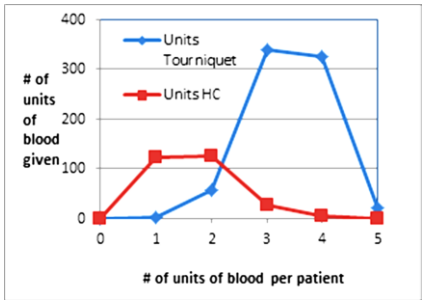
The HC exsanguination is nearly complete (95%) leaving only the blood in the bone marrow. Beyond the obvious reduction of blood loss (Demirkale et Al 2013[17]), the improved emptying of the blood from the vessels has two important advantages that have effect at the time of tourniquet release: (a) if blood is left behind in the blood vessels, much of it clots by the end of the procedure. As such, when the pneumatic tourniquet pressure is released, a shower of emboli has been observed (using trans-esophageal echo – Doppler) traversing the right atrium immediately post release in 100% of patients (Parmet et Al 1993[13]). Subsequent studies published in the anesthesia literature confirmed this finding. These emboli occlude some branches of the pulmonary arterial circulation and contribute to the post-tourniquet release drop in blood pressure (see below). Moreover, in a study using trans-cranial Doppler, 57% of the patients had small particles passing through their circus of Willis immediately post release (ref). In a second study the rate was 63% (Sulek et Al 1999[16]). These micro-emboli have been implicated as contributing to post-operative cognitive changes in TKA cases (Rodriguez et Al 2005[19]). It is conceivable that the much reduced residual blood with the HC will reduce this phenomenon. This is yet to be shown experimentally in a prospective study.



The second important effect of fully emptying the vessels is the fact that less ischemic by-products (e.g. K^+, H^+, CO_2, etc.) accumulate inside the vessels. This means that the washout of these cardiodepressive elements is gradual when the exsanguination is optimal whereby minimizing the BP drop seen in these patients post HC removal (personal communication).

Less blood transfusion with HemaClear®

A large study was conducted to compare the transfusion rates in patients undergoing cemented **bilateral TKA** using two methods of blood-loss management: (a) Pneumatic tourniquet → Tourniquet release → Haemostasis → Haemovac® drain. (n=227); and (b) Disposable sterile exsanguination tourniquet (SET/HC) → Haemostasis → Jones Bandage → HC release without drain (n=255). The difference in total and per-patient transfusion units used was highly significant ($p<0.0001$) as shown in the Figure (Demirkale et Al 2013[17]).



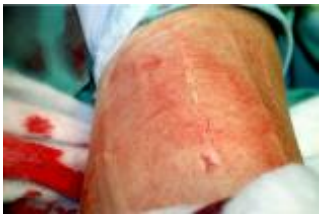
Additional Benefits

Being a sterile, single patient device, the HC can be placed nearer to the surgical field (i.e. mid forearm; lower leg, 15 cm above lateral malleolus). As such, the volume of tissue under ischemic conditions is reduced with its systemic as well as local benefits. The HemaClear can also be placed high up on the thigh or upper arm, so that with its small footprint facilitating performing procedures that otherwise would not have been possible under bloodless conditions (e.g. mid-shaft femur and humerus). The fact that it is sterile also allows application over an open incision to minimize tourniquet time or apply a second HC when a long procedure (i.e. over 120 minutes) is performed. The HC can be anchored in place using its straps even in a highly tapered limb such as common in infants and morbidly obese persons.

The prep time and complexity is markedly reduced with only a single device to prepare and only 4 sizes to choose from. The use of the HC often reduces tourniquet time and OR time with better overall OR throughput. The need to calibrate the controller

pump, check and attach tubings and secure the cuffs with their not too rare mishaps is eliminated, and the less than desired presence of un-cleanable reused tourniquets (photograph) is removed (Thompson 2011[16]).

The benign yet unsightly skin lesions often called "tourniquet burn" (photo) are not present due to the fully concentric roll up of the HC. There have been few cases reported of minor ecchymosis with improper use of the HC (trying to push it up the limb rather than use the straps) and 2 cases of long standing fat necrosis, which have also been described in the use of pneumatic tourniquets (18).



Contra-indications and items for the anesthesiologist to pay attention to

As with the pneumatic tourniquet/Esmach, the use of the HC is dangerous and contra-indicated in patients with deep vein thrombosis (DVT). It is also contraindicated in cases of infection or malignancy in the operated limb to prevent spread. Patients with significant skin lesions should not be treated with the HC applied directly over the lesions. Wrapping with a sterile Ace bandage prior to applying the HC is recommended. Caution should be used in peripheral vascular disease (Birger, Diabetes vasculitis etc.) and if used, the tourniquet time should be minimized. In patients with unstable limb, the surgeon will use axial traction during HC donning.

The anesthesiologist should be aware of the fact that once HC is on the limb, its tension cannot be changed (increased/reduced). The pediatric size HC is rated only to 130 mmHg, the HC40 and HC55 come in 3 levels of tension - 130, 160, and 190 mmHg and the obese size – HC/XL is rated to 160 mmHg of systolic blood pressure. The devices are designed to withstand systolic BP values that are slightly higher (e.g. 10-15 mmHg) than the rated values, but not more. As such, it is essential to maintain close watch over the blood pressure monitor during the procedure (e.g. pain control). Even a brief rise in systolic BP can cause secondary failure of the occlusion and bleed.

The placement of the HC over areas where nerves are near the skin surface is discouraged. In particular, the immediately proximal and distal to the knee and the elbow and the axilla should be avoided. The Anesthesiologist also has the overall responsibility to keep the tourniquet time under 120 minutes and to record the pressure per the pressure tables provided with the Product.

Unlike with the Pneumatic Tourniquet, the use of HC has not been associated with long-standing tourniquet paralysis, paresis or sensory deficit. The 3 cases reported to the Company (out of >600,000 uses) of post-op neural deficit resolved quickly (by the first follow-up visit) and were non-consequential. There were also 2 cases of fat necrosis and occasional ecchymosis as outlined above. There was one case of skin-tear in a patient with paper-thin skin due to end-stage renal failure where the HC was used for adjusting dialysis vascular access port (Ladenheim 2013[20]).

Primary tourniquet failure (i.e. the device never occluded) is rare and associated with incorrect selection of model (e.g. low pressure device for a hypertensive patient), size relative to the limb circumference, or site selection, or due to overlooked severe calcification of the arteries. Secondary

tourniquet failure mostly results from a sudden (often transient) rise in blood pressure.

Summary and Conclusions

While the surgeon is the one who determines the type of tourniquet that will be used on each patient, the fact that tourniquet use has far-reaching implications on the overall well being of the patient, places a non-insignificant responsibility on the side of the anesthesiologist. This is particularly important in the very young and very old and in those who have cardiopulmonary co-morbidities. Reducing the volume of tissue under compression and ischemic conditions, reducing the risk for pulmonary and cerebral micro emboli, reducing the drop in BP at tourniquet release, and the shortening of tourniquet time and infection risk may all contribute to a better overall patient outcome. The anesthesiologist who delivers anesthesia to orthopedic limb cases should familiarize him/herself with this new device and method including their advantages, contra-indications, pitfalls and side-effects.

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