Optimizing the bloodless surgical field in limb surgery

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Abstract

Limb surgery under bloodless field is performed approximately 3,000,000 times a year (10,000 cases a day) in the USA. The historical method of using an Esmarch Bandage and a pneumatic tourniquet, first introduced in 1873 and 1904, respectively, dominates the practice, despite a high rate of adverse events and complications. The incidence of post-operative skin injuries and blisters is reported[8] in 20.7% of TKA cases using a state-of-the-art pneumatic tourniquet (Zimmer 4000 with LOP and curved cuff). The same study reports 39.7% of the patient having significant pain on day 4 post-operatively and one case of nerve injury among the 160 patients included in this JBJS publication. A disturbing practice is the re-use of non-sterile cuffs in many of the US hospitals and ASCs that perform limb operations which likely contribute to the relentless incidence of SSIs. An alternative safe and effective Surgical Exsanguination Tourniquet (SET) is now used in over 500 hospitals in the US with superior exsanguination, simpler OR logistics and most importantly, an impeccable patient safety track record. Multiple investigator-initiated studies published in peer-reviewed journals report no skin or nerve damage, significantly less pain, much reduced intra-operative blood loss, less SSI, less DVT and longer auto-graft harvesting for ACL reconstruction. This article is intended to provide the surgical technologist the needed knowhow on the correct application of the SET, model selection, documentation of pressure and the contraindications (same as with Esmarch). The article also reviews the biomechanics and physiology of applying a tourniquet (SET or pneumatic) to a limb. The decision which tourniquet to use is the surgeon's, but the surgical technologist should be prepared to safely assist in applying the SET when this option is requested.

Key words: Tourniquet, Esmarch Bandage, Tourniquet-pain, Tourniquet-burn, Surgical Site Infection, Post-op DVT, TKA, Pediatric orthopedics.

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Disclosure:

Gavriely is Founder, Shareholder and Executive of Oneg HaKarmel Ltd., manufacturer of HemaClear® Surgical Exsanguination Tourniquet.

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Introduction

Performing bloodless limb surgery was first described in 1873 by Johannes Friedrich August von Esmarch (1823-1908)[1] using a long bandage, now called the Esmarch Bandage. Still used to date, when wrapped tightly around the limb from distal to proximal, it expels the blood from the limb into the central circulation. This procedure is called "exsanguination". In its original application, the Esmarch Bandage was wrapped several additional times at the proximal end of the limb to also block the return of arterial blood into the limb to act as a tourniquet. While this method is still occasionally used in ORs, even in the US, it is now recognized to apply inconsistent, often excessive, pressure on the soft tissues. In 1904 Harvey Cushing, the great neurosurgeon who was concerned about tissue damage from the tight Esmarch Bandage, first described the pneumatic tourniquet using compressed gas source[2]. Despite many shortcomings and complications[3, 28, 29], the Esmarch Bandage together with the pneumatic tourniquet are the most widely used method for achieving bloodless surgical field in the United States and globally. Recently, the Surgical Technologist Journal published a review of the use of pneumatic tourniquets and military tourniquets[21], advancing the hypothesis that individualizing the cuff pressure can reduce the incidence of tourniquet-induced adverse effects including nerve damage. The article presented herewith aims to broaden the surgical technologists' knowledge and understanding on the newer methods of safely and effectively providing a bloodless limb surgical field for orthopedic, plastic and vascular surgeries, as well as the biomechanics and physiology of tourniquet-tissue interactions.

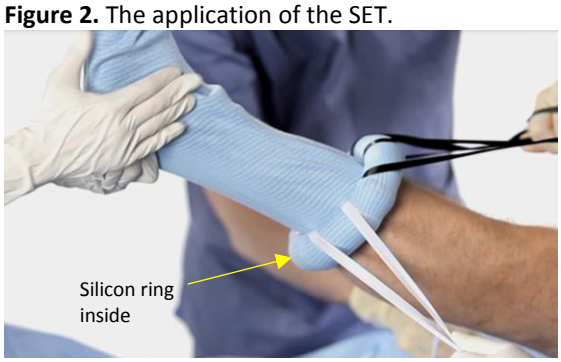
In recent years, more and more hospitals and surgical centers in the United States and around the world are using a novel device that expels the blood from the limb, blocks the blood re-entry and provides a sterile surgical field in one action. The generic name of this free-standing elastic device is the Surgical Exsanguination Tourniquet (SET)[4] Figure 1. (HemaClear®, Haifa, Israel). This article reviews practical, physiological and clinical aspects of the SET, its uses and its contraindications. It also lists the benefits of SET to the patient, the surgeon, the surgical technologist and to the OR logistics, as well and to the economy of present-day patient care.

Figure 1. SET Models are XL, Large, Medium and Small plus two specialty Models: F for the Forearm and A for the Ankle. A color-coded ruler is used to select the correct size.

The SET and its application on the operated limb

The SET is supplied sterile packed in dual peel-back pouches. The device consists of a silicone circular ring (torus) wrapped around with an elastic tubular stockinet made from woven cotton and Spandex® and with straps that end with a plastic handle (Figure 2). The SET is placed on the tips of the fingers or toes while an assistant is stabilizing the hand / foot. When the handles are pulled proximally along the axis of the limb, the torus rolls upon itself along the limb while the sterile stockinet remains on the limb.

Figure 2. The application of the SET.



Once the SET has been rolled up the limb to reach its final position (see chart in Figure 3) the straps can either be cut away or wrapped around the limb. The correct sequence of preparation for applying the SET is to first **disinfect** the skin to about 10 cm (4") above the anticipated final position of the ring and **drape** the proximal portion of the limb so that the edge of the drape is about 4-5 cm below the anticipated final ring position. After timeout is done and the patient properly draped for the procedure, the SET is applied, typically by the surgeon with the help of one or two assistants.

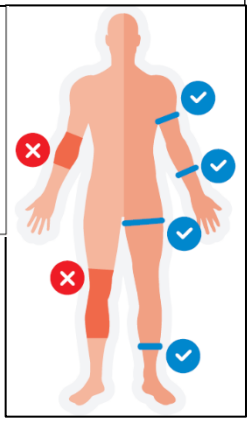
Figure 3. The recommended SET placement sites.

Placement diagram

Place where there is minimal muscle to avoid tourniquet pain:

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

Never place directly on elbow or knee.



Model Selection

There are 4 basic SET sizes: Small, Medium, Large and Extra Large (Table 1). In addition, there are two special models: Model F for the forearm and Model A for the ankle. The Medium and the Large SET models are available at 3 levels of tightness; the least tight models (Pink, Green and Blue) are suitable for patients with low blood pressure, I.e. <130 mm Hg systolic (typically children) and the tightest models (Yellow and Brown) are suitable for patients whose BP may rise up to 190 mm Hg. The medium tightness is for patients whose highest anticipated Systolic BP during the operation is not more than 160 mm Hg. Table 1 shows the models, their dimensions and the highest systolic blood pressure for which they are suitable.

Table 1: SET models, sizes, and blood pressure limits

Model		Circumference of Limb cm	Max. BP mm Hg	Common Uses/ Placement
SMALL Pink		14-28	130	Pediatric Ortho
MEDIUM Yellow		24-40	190	Adult Upper Arm
MEDIUM Red		24-40	160	Adult Upper Arm
MEDIUM Green		24-40	130	Pediatric Ortho
LARGE Brown		30-55	190	Adult upper thigh
LARGE Orange		30-55	160	Adult Ankle, Arm
LARGE Blue		30-55	130	Pediatric thigh
XLARGE B & W		50-85	160	TKA upper thigh
Model A – Ankle		22-32	160	Foot Surgery
Model F – Forearm		14-35	160	Hand Surgery

Note 1; SET and patient's Blood pressure. Once a particular model of SET is placed on the patient, the pressure remains constant for the duration of the case. There is no "upping" or "downing" of the pressure as is often done with the pneumatic tourniquet. As such, it is imperative to maintain the patient's systolic blood pressure below the designated SET maximal systolic pressure. In general, it is the anesthesia personnel who is responsible for monitoring and maintaining the blood pressure. It is, however, useful for the technical team to know the factors that cause blood pressure to rise during surgery. Pain is the most important cause of BP rise. Premature stopping of the analgesics at the (presumed) end of surgery is not helpful. Also, bringing SET up a leg very fast (i.e. in a few seconds) shifts >500 cc of blood (over 1.1 pints) from each leg to the core. This can easily cause a temporary spike of BP. "Tourniquet Pain" which is common with pneumatic tourniquet, but is not seen when SET is placed in the correct designated sites, is a well-known cause of BP rising during surgery with pneumatic tourniquet, but not with SET. Finally, taking frequent BP readings (e.g. every 5 minutes or more) is the surest way to notice early that BP is creeping upwards and do something about it. Paying attention to these details by the entire OR team helps prevent mishaps resulting in rising BP and blood seeping under the SET ring.

Selecting the correct SET model is simple; with each SET unit there is a small envelope with a color-coded measuring tape. Measuring the limb circumference at the site the surgeon decided to place it, will immediately show which size to use. SET sizes range starting from 14 cm of the SMALL (pink) SET for small babies to 85 cm of the Extra LARGE (Black & White) for oversize upper thighs. The best practice is to base model selection on the ruler and sizing. The models' sizes overlap. We recommend taking the larger model when such overlap occurs. SET is very suitable for placement on the forearm, typically 10 cm above the wrist line and on the ankle, 10-15 cm above the malleolus. This is because it does not trap the ligaments leading to the fingers/toes. If a pneumatic tourniquet is placed on the forearm or on the ankle, the ligaments cannot move and the fingers/toes are frozen. The distal placement of SET has great advantage since distal placement means less tissue is under ischemic conditions.

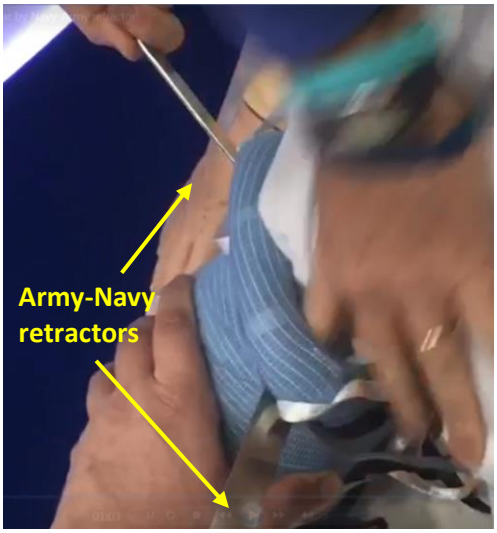
The SET is removed by cutting the ring with a scalpel. To do so safely, the pointed plastic card included with each product is inserted under the ring. It is easy to do so by holding and pulling up one of the straps. The card is designated “Protective Card”. The rest of the stockinet is best cut with a bandage scissors.

Cases in which SET can be used and its contraindications

SET can be used in all patients for whom an Esmarch Bandage and a pneumatic tourniquet can be used. To date more than 1.5 million cases were operated on with SET globally, of which about a third were in the US. The breakdown of cases in the US is approximately 48% for leg trauma, TKA and knee arthroscopy, 37% in upper extremity, 7% in pediatric orthopedics, 5% in foot and ankle surgery and 3% in miscellaneous cases such as vascular access for dialysis shunts, plastic surgery and in ER for suturing of hand lacerations. More recently, hand surgeons started using SET in procedure rooms and clinics for office-based minor procedures such as carpal tunnel release and trigger finger. The latter usually are not equipped with pneumatic tourniquet pumps, so SET is the only viable alternative for a dry field.

SET has particular benefits in cases of upper arm (elbow and humerus) surgery where the space is of an issue. Same is true for thigh cases (e.g. ORIF of femoral fractures). SET is also preferred for TKA on obese patients (e.g. BMI greater than 32) and in pediatric orthopedic cases. Both categories are known to be problematic due to the taper of the thigh that often causes migration of the pneumatic tourniquet distally when it is inflated. Other cases where SET is preferred include patients with low pre-op hemoglobin, patients with bleeding disorders (e.g. Hemophilia) and patients with weakened immunity (e.g. patients on chemotherapy, hemodialysis, steroids and patients with diabetes mellitus).

Note 2: What to do if the surgeon wants to release the SET pressure momentarily to see if there is an important bleeder? One method is to cut the SET ring, and, if needed, apply a second one. Another method is to insert two Army-Navy retractors under the SET ring (picture) at about 120 degrees angle and pull them. When the medial retractor is sufficiently pulled the pressure on the artery is released and blood flow is removed sufficiently to visualize significant bleeders. Releasing the retractors will resume the blocking of blood flow. We recommend doing so only at the end of surgery so that the limb’s blood vessels are not left full of blood for too long (see subsequent discussion of limb exsanguination below).



When SET is used in knee arthroscopy for ACL reconstruction, the length of hamstring autograft is significantly larger, particularly in short patients with conical thigh. As such, the use of a costly allograft becomes unnecessary when SET is used[6].

Note 3. Can SET be used for only the cementing of an implant (e.g. in TKA)? Some surgeons prefer to inflate the pneumatic tourniquet only during the application and setting of the cement (with or without Esmarch Bandage exsanguination). Likewise, SET can be applied only for this part of the operation. The instruments are removed, the incision is covered with a lap-pad and the SET is applied. The superb exsanguination guarantees dry field which improves the penetration of the cement into the cut-bone trabeculae. The SET can be cut away as soon as the surgeon feels it is time to do so.

Contraindications and Warnings:

The use of SET is contraindicated in the same cases where the use of Esmarch Bandage is contraindicated, namely:

1. Active deep vein thrombosis (DVT) in the operative limb; use the Wells Criteria to screen for DVT*.
2. Infection in the operated limb.
3. Cancer in the operated limb.

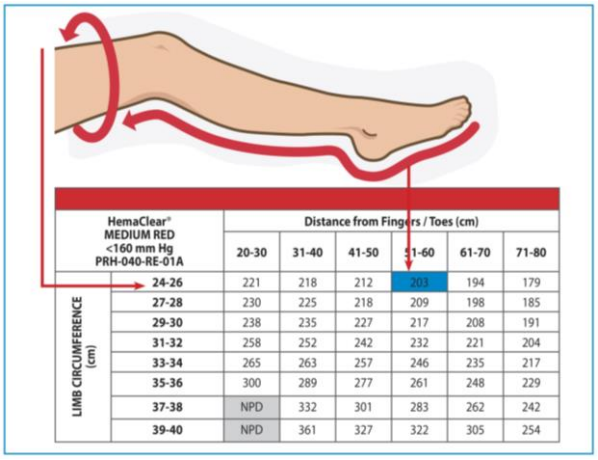
In addition, please note that the use of SET is limited to 120 minutes (same as for pneumatic tourniquet and military tourniquet). Also, it is recommended to wrap the limb with an Ace Bandage if the skin is damaged or paper-thin.

* The issue of DVT deserves a special attention. The use of Esmrach Bandage[22,23,25,26,27] as well as SET[24] has been associated with dislodging of a thrombus into the circulation causing fatal pulmonary embolus. As such, any patient with even a low level of DVT suspicion must be evaluated carefully using clinical examination, D-dimers, ultrasound (Doppler) or venography to rule out DVT before Esmarch or SET are applied. Using a pneumatic tourniquet without exsanguination is strongly discouraged (see below).

How is SET skin pressure determined?

It is customary to document tourniquet pressure in the patient's OR / anesthesia chart. With the pneumatic tourniquet the pressure is read from the pump's display, assuming that it is properly calibrated. The SET pressure is determined by measuring the limb circumference at the site the SET ring is placed and the distance from the toes/fingers to the ring. A look-up table showing the circumference vs. the distance is used to determine the pressure in mm Hg. The pressure tables such as the one shown in Figure 4 is used to determine the exact Skin Pressure. The measurement of the circumference determines exactly how much the SET is stretched (elongated), and the distance from the toes/fingers tells how much of the stockinet has been removed from the ring thereby reducing the force. Note: the next section on the biomechanics of the SET explains the difference between Skin Pressure of the SET and Distributed Pressure beneath a pneumatic cuff.

Figure 4. A pressure table for one of the SET models.



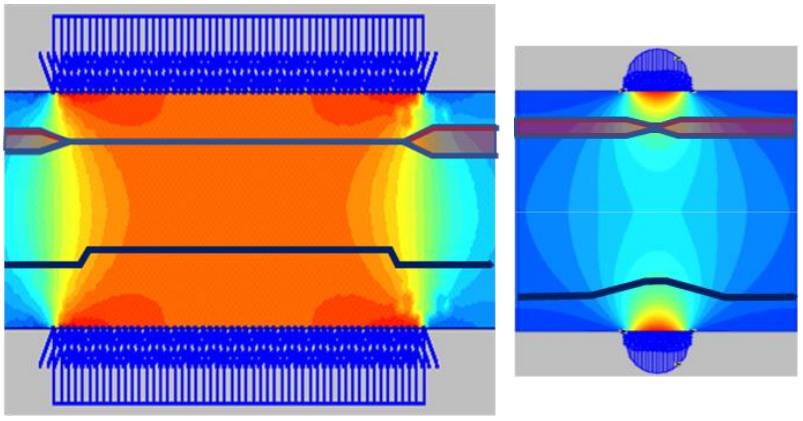
HemaClear® MEDIUM RED <160 mm Hg PRH-040-RE-01A	Distance from Fingers / Toes (cm)					
LIMB CIRCUMFERENCE (cm)	20-30	31-40	41-50	51-60	61-70	71-80
24-26	221	218	212	203	194	179
27-28	230	225	218	209	198	185
29-30	238	235	227	217	208	191
31-32	258	252	242	232	221	204
33-34	265	263	257	246	235	217
35-36	300	289	277	261	248	229
37-38	NPD	332	301	283	262	242
39-40	NPD	361	327	322	305	254

Biomechanics and physiology of applying a tourniquet to a limb

All tourniquets, including blood pressure cuffs, pneumatic tourniquet, the SET and the military tourniquets used to stop bleeding, exert pressure on the surface of the limb in order to collapse the arteries leading into it and block the inward blood flow. To do so, the pressure applied to the arteries must be greater than the systolic blood pressure over a short segment of the vessel. How much greater should the pressure outside

the vessel be? In normal arteries, just a few mm Hg are sufficient to collapse the artery, but if the arteries are calcified and stiff, the pressure should be much greater in order to overcome the stiffness. In some patients the arteries are so stiff that it is not possible to collapse them at all. Such arteries can usually be visualized on x-ray due to the density of the atheromatic calcifications. This x-ray finding is not a contraindication to using a tourniquet, including SET, but the surgeon must be aware of the possibility that the artery may not be occluded, and observe the color of the skin, ***before*** making the first incision. In our experience, if the artery was not occluded by SET, it will not be collapsed by a pneumatic tourniquet, even if the pressure is set to an excessive level (e.g. 450 mm Hg).

Figure 5. Pressure fields beneath a pneumatic tourniquet (Left) and SET ring (Right) obtained from finite element analysis of the forces and pressures in the tissues of a limb; see text for details.



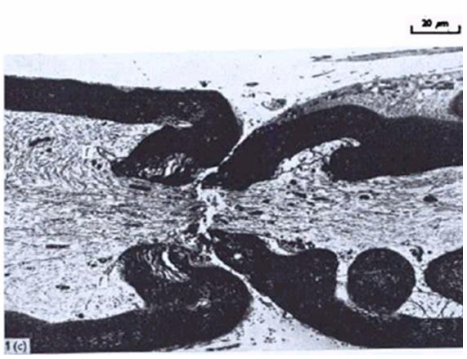
A great deal of debate has been held over the issue of tourniquet width. When measuring blood pressure, it is (correctly) recommended that the cuff should be wide enough to ensure that the pressure in the tissues beneath the cuff is exactly the same as the cuff pressure and uniform. This guaranties accurate BP measurement. Unfortunately, this notion migrated into the discussion of the use of surgical tourniquets without proper scientific evidence. In fact, biomechanical analysis of the pressures beneath wide and narrow surgical tourniquets show that it is exactly the opposite. A finite element analysis of the stresses (pressure) and strains (deformations) of tissues beneath tourniquet[5] was used to show the pressure field in the tissue beneath a wide pneumatic tourniquet and a narrow SET ring (Figure 5). The analysis shows that, as expected, the pressure beneath a wide pneumatic tourniquet (Left) is uniform and high with steep gradients at the two ends of the compressed segments. On the other hand, the pressure field beneath the SET is the same at the surface of the limb (i.e. Skin Pressure), but it dissipates gradually as we penetrate deeper into the tissue. The artery is typically about 1 cm deep in the upper arm and about 2.5 cm deep in the thigh. This means that we need higher skin pressure when SET is applied to the thigh than to the arm. Similarly, in obese or very muscular patients, the artery passes deeper inside the limb and as such, higher skin pressure is required to collapse it and block the blood flow. A look at the pressure table depicted in Figure 4 shows that for a given distance from the toes/fingers, the larger the circumference – the higher the skin pressure, exactly as needed for the collapse of the deeper situated artery in the obese patient. Figure 5 also shows an artery (top) and a nerve (bottom). The artery beneath a pneumatic tourniquet is collapsed over a larger distance. The nerve is abruptly deformed at the two ends.

Pathophysiology of skin, muscle and nerve compression by pneumatic tourniquet and SET

Compressing a limb in order to block arterial flow applies pressure and deforms the tissues. This is an inevitable result of applying any tourniquet. However, when applying a wide pneumatic tourniquet, a much larger amount of tissue is compressed than is actually needed. The compressed tissues tend to migrate towards the distal and the proximal ends of the cuff. This is particularly detrimental when the nerves are concerned, as reported by Ochoa et Al already in 1973[7].

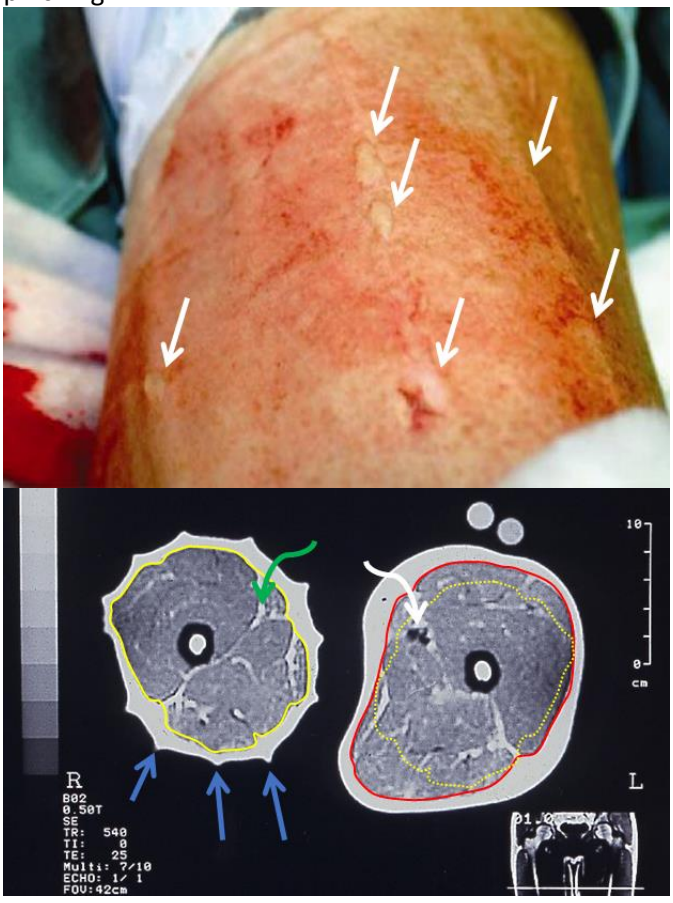
Ochoa and co-workers applied tourniquets to baboons' limbs and noted an interesting phenomenon: the nerves that were compressed beneath the tourniquet elongated and telescoped into themselves and the Nodes of Ranvier, causing axonal disruption that is clearly seen on electron microscope (Figure 6). Ochoa found these nerve telescoping events only proximally and distally to the cuff, and concluded that the wider the cuff, the higher the risk of nerve damage associated with pneumatic tourniquet. Ochoa also pointed to the steep pressure gradient at the two ends of the cuffs causing transverse shearing effect on the nerves, presenting another potential cause of nerve damage by the wide cuff. The rate of pneumatic-tourniquet-associated nerve damage is between 1:4000 to 1:1000 and is presenting an important cause of malpractice litigation in orthopedic surgery[28]. The narrow ring of the SET is not wide enough to cause nerve elongation and the gradients at its two ends are shallower. This is probably the reason why in more than 1.5 million cases done with SET to date there has not been one case of nerve damage.

Figure 6. Electron microscope image of telescoping nerve from Ochoa 1973.



Skin damage and blister formation is another bothersome adverse effect of using pneumatic tourniquet. In a study done in Karolinska hospital in Stockholm[8] it was found that despite individualization of tourniquet pressure by using LOP, 20.7% of the patients had blisters on their thigh 4 days after a state-of-the-art pneumatic tourniquet (Zimmer AST 4000 with LOP and curved cuff) was used to provide a bloodless surgical field during TKA. The mechanism of these blisters is often blamed on chemical effect on the skin beneath the tourniquet cuff. However, as seen in Figure 7 the cause is the uneven inflation of the inner (bottom) surface of the cuff, causing pinching and mechanical detachment of the epidermis, as in getting a blister when hiking with uncomfortable shoes. Using SET was never associated with pinching, blistering or skin damage. Review of FDA depository of medical devices-related problems (www.FDA.gov "Maude"[27]; search term: "tourniquet") revealed hundreds of entries related to malfunctions and injuries caused by pneumatic tourniquets. There are two Maude-listed reports from 2011 on skin-tear caused by dragging (pushing) the SET up an arm of a

Figure 7. left, photograph of skin blisters after pneumatic tourniquet was applied; right an MRI showing the uneven inflation of the cuff and the skin pinching.

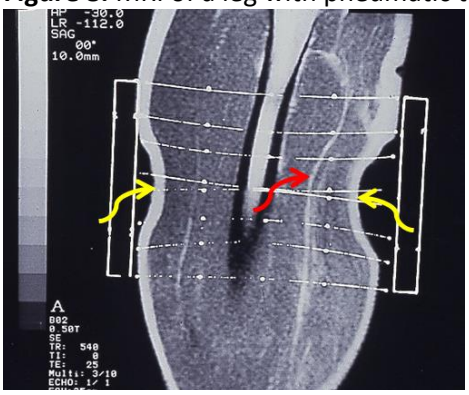


hemodialysis patient, instead of rolling it by pulling the straps. These incidences emphasize the importance of proper training on the correct application of SET.

Perhaps the most disturbing and common aspect of using pneumatic tourniquets is the post-operative tourniquet pain. For many patients this pain is actually more debilitating after surgery than the incisional pain. This is noticed in all uses of pneumatic tourniquets, and often becomes the limiting factor in early discharge of patients after TKA ("fast track"). If a patient has too much pain to ambulate to toilet and requires narcotic drugs, he or she is less likely to be discharged early, adding to the cost of surgery and to patient dissatisfaction. In the same Karolinska study[8] it was found that 39.7% of post TKA patients done with the pneumatic tourniquet with individualized tourniquet pressure and curved cuff had significant thigh pain 4 days after surgery. Other studies done with pneumatic tourniquets have shown similar results[28-31]. Studies comparing post-op pain with pneumatic tourniquet and with SET have all shown significantly reduced post-op pain when SET was used[30].

The pathophysiology of tourniquet pain can be understood from observing the MRI of a limb done while the subject (Dr. Estebe, personal communication) had an inflated pneumatic tourniquet on his thigh (Figure 8). In addition to the skin and muscle compression and displacement (yellow arrows), it is possible to see the fascia of the muscle as a dense white line (red arrow). The fascia is obviously deformed and stretched. It is well known that pain receptors are mostly present in the fascia. The pain sensation is conducted by the thin, poorly myelinated slow C fibers leading from the fascia to the spinal cord, leading the pain sensation to the brain. This image is very instructive, as it tells us NOT to place tourniquets directly on the major muscles. It also explains why the use of SET is associated with much less tourniquet pain (if any) when placed in the recommended positions (see Figure 3). These positions are chosen to be over parts of the limb where there is less (or no) muscles and as such less fascia. The specific positions are: 10 cm above the wrist, distal to the forearm muscles groups; on the upper arm above the biceps and below the deltoid muscle; on the ankle below the calf muscles and in the groin area very high up on the thigh, above the upper pole of the quadriceps muscle. When SET is placed in these locations, almost no post-operative pain is reported.

Figure 8. MRI of a leg with pneumatic tourniquet



Physiology and biochemistry of tissue ischemia and tissue compression by pneumatic tourniquet and SET

Whenever a tourniquet is placed on a limb it intentionally causes ischemia. This means that oxygen and nutrients (e.g. glucose) are not supplied to the cells and metabolic products are not cleared away. Unlike the heart and the brain that have very little reserves before loss of function (e.g. loss of consciousness, cardiac arrest) untill irreversible damage happens, the tissues of the limbs can withstand relatively long period with no oxygen supply. The muscle, in particular, has energy reserves in the form of creatine phosphate that can rapidly release its high energy phosphate stores to create ATP directly. These stores are not large and the cells continue to consume the dissolved oxygen until its level is too low to generate ATP from glucose or fat. At this point, anaerobic metabolism kicks in to generate ATP by glycolysis with the end products being Lactic acid and pyruvic acid instead of CO2. The anerobic metabolism is less efficient than the aerobic one and the lactic acid causes acidity (reduced pH). This process continues until there is no more substrate (glucose) and

at this point depletion of ATP causes cell membrane disruption and necrosis. The muscle of a fit person with normal blood supply can withstand longer periods of ischemia than in a person suffering from chronic poor blood supply such as in Peripheral Vascular Disease (PVD). Likewise, a person with chronic lung disease may start the ischemia period with less O2 in the limb. The temperature of the limb also influences the metabolic rate. Taking all factors into consideration, and the vast empiric knowledge teaches us that 120 minutes is the maximal duration of safe limb ischemia in all patients. We recommend strict adherence to this time limit. If the case is longer, the tourniquet/SET must be removed for enough time to restore oxygen and ATP stores (typically 15-20 minutes) before ischemia is induced again. If SET is used, it should be completely removed and a new one placed. If a pneumatic tourniquet is used, the pressure must be completely reduced (to zero) to avoid venous occlusion, and excessive bleeding and swelling of the limb. Before the tourniquet pressure is restored, the limb should be exsanguinated again to the greatest extent possible (see below). Excessive tissue hypoxia is thought to be associated with generation of Reactive Oxygen Species[9] and limb swelling. However, this is probably an unimportant factor if the time limit of 120 minutes is strictly observed.

The other unavoidable effect of applying pressure to soft tissue is the compression of the tissues beneath the tourniquet. This is sort of a localized "crush injury" and its effects should be taken into consideration. When a muscle is compressed for an extended period of time, biochemical substances may leak from the muscle cells, either by diffusion through cell membrane or due to disruption of the cells' walls. Muscles contain enzymes and large molecules such as Creatine Phosphokinase (CPK), Lactic Dehydrogenase (LDH) and myoglobin, but also leak small molecules and ions such as Potassium (K^+) and Lactate. Measurements of these biochemical molecules after tourniquet release in rabbits using narrow or wide tourniquets clearly showed significantly higher levels in the animals treated with the wider tourniquets[10]. Another study done in humans measured nerve conduction speed with a wide vs. narrow tourniquets in normal volunteers, showing significantly slower conduction with the wide tourniquet[11].

Why is it important to completely exsanguinate the limb before a tourniquet is used?

From early on, it was customary to empty the limb from blood as much as possible before a pneumatic tourniquet is applied. The two methods commonly used are limb elevation and tight application of Esmarch Bandage from distal to proximal. Blond et Al used radioactively tagged red blood cells and a gamma camera to obtain quantitative data on the quality of limb exsanguination with these methods[12]. They found that limb elevation, irrespective of elevation duration from 0.5 to 10 minutes, removed about 45% of the blood, while applying Esmarch Bandage removed 67% of the blood. In other words, at least half or a third of the blood remained in the limb for the duration of the tourniquet time with no flow. To understand the significance, we can calculate the amount remaining in an average leg which contains a bit more than 500 cc of blood. With limb elevation this is 275 cc and with Esmarch Bandage the volume of the remaining blood is nearly 170 cc. Some of this blood seeps into the incision and interferes with the visibility, particularly when precise soft-tissue work is needed.

However, the clinical importance of incomplete exsanguination is quite different and much more disturbing. Already in 1979 it was shown that after 15-20 minutes stagnant blood coagulates and soft fresh clots are formed. In 1993 Parmet et Al[35] used transesophageal Doppler probe to track the blood flow in the right atrium, while a pneumatic tourniquet is deflated at the end of a primary TKA. They observed showers of echogenic material starting 15 sec after the deflation and continuing for up to 15 min in ALL patients. This study was repeated by multiple researchers with the same results. The debate whether the echogenic material was blood clots/bone debris/fat/air/cement etc. was settled inserting catheters into the femoral

veins and pulmonary artery of patients undergoing TKA and aspirated blood right after the tourniquet was deflated. Microscopic examination of the aspirated blood showed only fresh clots and no other types of granular material that could give echo in ultrasonic Doppler examination. The conclusion from these studies is that upon pneumatic tourniquet deflation at the end of surgery, clots migrate from the patients' leg veins to the right atrium and from there to the pulmonary circulation causing multiple small pulmonary emboli. The physiological consequences of such interference with pulmonary blood flow is a rise in right heart blood pressure and a drop in left ventricular output, which contribute to the drop in systemic blood pressure (see further discussion below).

This pulmonary embolization, however, is not the worst part of this sequence. In about a quarter to a third of the population[14], the embryonic foramen ovale is not completely fused and is only closed with a flap that acts as a one-way valve, preventing blood to pass from the left atrium to the right. However, when the pressure in the right atrium is higher than in the left, right-to-left shunting of blood occurs. If this blood contains clots, the clots will also cross over into the left heart and from there to the systemic circulation, with preference to the carotid arteries that are first to emerge from the aortic arch. It is not surprising that in 1999 Sulek et Al[15], who used transcranial Doppler to monitor blood flow in the Circle of Willis which supplies the entire cerebral circulation, found echogenic material in over 50% of the patients undergoing TKA within 15 sec after the deflation of the tourniquet. In yet another study David et Al[18] performed MRI studies on TKA patients, once before surgery and again 2 days after surgery. In 5 of the patients (23%) they detected cerebral infarcts in the post TKA images that were NOT present before surgery. Other researchers suggested that these infarcts are the cause of the well-known post-TKA Cognitive Disfunction syndrome.

Given the fact that limb exsanguination is 95% complete when SET is used[19] (Figure 9), with the only remaining blood being in the bone marrow, it is unlikely that intravascular clots will be formed during the period of stagnation. While no studies done to date on the incidence of echogenic material after SET is removed, there are no reports of post TKA cognitive issues when SET is used.

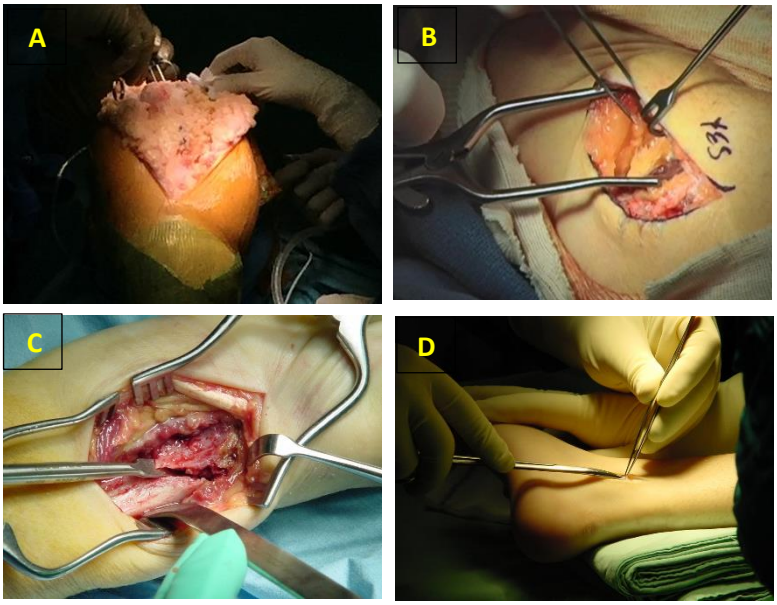


Figure 9. Images from cases done with SET showing the level of field dryness. A – TKA in an obese patient; B – Elbow surgery in a child; C – ORIF of distal radius fracture in an elderly woman; D – Ankle ligaments lengthening in an 18 years old female CP patient.

D**eflating pneumatic tourniquets and removing SET at the end of surgery**

Stopping the arterial blood flow blocking at the end of surgery is done by deflating the pneumatic tourniquet or by cutting the SET ring with a scalpel. Once this is done, blood returns to the empty blood vessels of the limb. In fact, more blood returns to the limb than was originally removed because of the physiological phenomenon called “reactive hyperemia”. This is a normal compensatory vasodilatation of the limb blood vessels after a period of ischemia. It can easily be seen as redness of the skin which lasts from a few to several dozens of minutes. If suturing and compression-dressing of the limb is delayed till after tourniquet/SET removal to facilitate meticulous hemostasis, the reactive hyperemia contributes to increased blood loss. It is imperative to deflate the tourniquet completely in order to avoid venous occlusion, which may also increase blood loss and can cause swelling of the limb, and in rare cases compartment syndrome. The removal of the pressure of SET is always complete when it is cut with a scalpel.

Systemic blood pressure falls when pneumatic tourniquet is deflated and also when SET is removed. This is primarily due to the return of blood from the central circulation to the limb. It is of interest to know if there is a difference between the BP drop in the two types of tourniquets. Likewise, it is of interest to see if there is a difference in changes in arterial oxygen saturation (SpO2) between the groups. Studies are being planned to answer these questions.

Summary and Conclusions

SET is a viable safe and effective alternative to the use of pneumatic tourniquets with Esmarch Bandage to provide bloodless surgical field during limb surgery. Tables 2-3 compare side-by-side the effects of using each of the methods on patient safety and on OR work flow. Table 4 summarizes the cases categories where using the SET is most advantageous. This article provides the Surgical Technologist with the necessary knowledge base to be able to effectively use the SET in the orthopedic OR.

Table 2. Patient safety and outcome advantages with SET vs. pneumatic tourniquet.

Category	SET	Pneumatic Tourniquet	Comments
Sterility	Always; the ring is cut at the end of surgery	Often re-used as non-sterile	Reprocessed (sterile) PT are now available
Intra-operative blood loss	Negligible	May be as much as few hundred CC	
Intra-op tourniquet pain	None	Frequent	Causes rise in BP and need for anesthetics
Post-op tourniquet pain	Seldom,	Frequent (39.7% of patients)[8]	SET needs to be placed on the designated positions
Use of pain medications	Less	Significantly more	
Skin damage	None	Frequent (blisters 20.7%)[8]	
Long-lasting nerve damage	None	1:4000 to 1:1000	AKA neuropraxia
Use for upper arm surgery	The narrow ring CAN be placed up on the arm.	Often takes too much space, even if sterile	ORIF of humerus without tourniquet may require 1-2 pints of blood
Use for femur / thigh surgery	Easy to place SET all the way up to the groin	Often takes too much space, even if sterile	ORIF of Femur fracture often requires blood transfusion
Exsanguination	95%	45% with limb elevation, 67% with Esmarch Bandage	See text for significance
Tourniquet time	8-10% shorter than with PT		Most important in pediatrics
Tourniquet failure	Occasional, when BP rises	Happens when air leaks	
Postop Deep Vein Thrombosis (DVT); Pulmonary Emboli (PE)	Significantly less than with pneumatic tourniquet	3-7% of patients	Mechanism of reduced DVT/PE with SET not known

Table 3. Effects of using SET on OR workflow and logistical considerations

Item	SET	Pneumatic tourniquet	Comments
Pump	none	Pump needs to be bought or leased	Pump pressure must be calibrated periodically
Tubes	none	Tubes need to be replaced periodically	Tubes connection to PT occasionally fails
Positioning	SET never rolls down if placed in the correct sites	Cuff often migrates distally on conical limb when inflated	
Space (“real estate”)	SET is narrow and when placed proximally on the limb, gives optimal space and exposure	Pneumatic tourniquet is wide, limiting incision space	Important when working on the upper arm/elbow and thigh and when revision knee is performed
Mobility	SET does not trap the ligaments or the muscle beneath it, permitting full ROM of fingers, toes and knee	When pneumatic tourniquet is placed on the forearm/ankle, it splints the ligaments, limiting toes/fingers motion	Trying to forcibly flex the knee with pneumatic tourniquet at mid-thigh on the quadriceps muscle may cause muscle fibers tears.
OR air quality due to use of electro-cautery	Less frequent use of cautery due to dry field;	Cautery is frequently used.	Cautery pen/forceps can be opened on demand when SET is used
Use on obese patients	XL Model readily used, never rolls distally	Often migrates distally when inflated	PT Requires tech repositioning under drapes
Need for CellSaver / autotransfusion	Not needed	Often Used in bilateral TKA, trauma	
Preparations for case	Single item	Cuff, padding, stockinet, Esmarch Bandage, pump setting and manning	
Cleanup after case	SET is discarded, no additional handling	Cuff reprocessing requires handling and cleaning by tech	
Pressure documentation	Requires measuring circumference and distance from toes/fingers	Read directly from pump display	
Timer	No built-in timer; Needs an OR clock/timer	Timer built in to pump	

Table 4. Cases where the use of SET is the sole viable alternative and/or saves money to the institution

Type of case	Clinical importance	Economic advantage
Surgery of upper arm and femur	Not enough space for PT, even if sterile, full, free ROM	No intra-operative blood loss, reduced need for transfusion
Knee arthroplasty revision	Larger operative space	Faster procedure, never need to re-do drapes
Bilateral TKA	Less bloodloss; can work simultaneously on both knees	
Knee arthroscopy ACL reconstruction	Longer harvested hamstring autograft	Obviates need for allograft
Obese patient; e.g. BMI>32	Optimal exsanguination, quicker procedure	Never need to re-do drapes
Pediatric cases; e.g. below 4 years old	No migration of tourniquet, larger real estate, no skin injury, shorter case	
Patients with low pre-op hemoglobin; e.g. Hb < 9 g%	No intra-op bloodloss reduce the need for blood transfusion	No need for CellSaver or auto-transfusion[20];
Patients with bleeding disorders; e.g. hemophilia	No intra-op bloodloss reduce the need for blood transfusion	No need for CellSaver or auto-transfusion[20]
Patients in which blood transfusion is not possible; e.g. Jehovah Witnesses, rare blood type, organ transplant candidates	No intra-op bloodloss reduce the need for blood transfusion	No need for CellSaver or auto-transfusion[20]
Patients with immune deficiency; e.g. steroids, HIV, Diabetes	Lower risk of infection due to SET sterility, less need for cautery, suctioning, pulse lavage	Lower risk for Surgical Site Infection (SSI)

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