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Surgical Tourniquets in Orthopaedics

Noam Gavriely

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Complications of Titanium and Stainless Steel Elastic Nail Fixation of Pediatric Femoral Fractures

To The Editor:

I read the article "Complications of Titanium and Stainless Steel Elastic Nail Fixation of Pediatric Femoral Fractures" (2008;90:1305-13), by Wall et al., with great interest. It is an interesting observation, and we are also having the same experience in our practice. I would like to know from your data, which is not mentioned in your article:

1. How many patients had a mismatch in the diameter of the nails (titanium or stainless steel elastic) as seen in Fig. 2-B (the nails are of a different diameter)?
2. Did you use more than two nails in any single patient? We have found that a child who weighs >40 kg or is over eleven years old requires more than two nails; otherwise, malunion may occur.
3. In the case of breakage, was it breakage of both nails (all nails in a single patient) or just one of the nails and was there malunion in that patient? How much did that patient weigh?
4. You mentioned that the stainless steel nails were custom made to order. Which type of steel material was used: 316L or 316LVM? What were the mechanical properties in terms of ultimate tensile strength and percentage of elongation on tensile stress? Which company made the custom-made nails? Can you tell us whether the stainless steel nails were more flexible than the titanium nails supplied by Synthes (Paoli, Pennsylvania)?

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E.J. Wall, V. Jain, V. Vora, C. Mehlman, and A.H. Crawford reply:

Thank you for your comments and the questions. Following are our answers to your questions:

1. *How many patients had a mismatch in the diameter of the nail (titanium or stainless steel elastic) as seen in Fig. 2-B (the nails are of a different diameter)?*

Except for the patient illustrated, none of the other fifteen patients with malunion had any mismatching of the nails. Overall, <5% of our patients had mismatched nail placement; the patients were evenly distributed among the stainless steel and titanium groups (three and two, respectively).

2. *Did you use more than two nails in any single patient? We have found that a child who weighs >40 kg or is over eleven years old requires more than two nails; otherwise, malunion may occur.*

We have not used more than two nails in any of our patients in the study except the two cases of implant breakage.

3. *In the case of breakage, was it breakage of both nails (all nails in a single patient) or just one of the nails and was there malunion in that patient? How much did that patient weigh?*

We had two cases of nail breakage. The nail breakage was seen in one patient with titanium nails with a resultant malunion. Only one nail was broken. This was treated by re-reduction and introduction of a third nail. The other patient had stainless steel nails, which did show breakage of one nail without malunion (according to our criteria) and was treated by insertion of a third nail.

4. *You mentioned that the stainless steel nails were custom made to order. Which type of steel material was used: 316L or 316LVM? What were the mechanical properties in terms*

of ultimate tensile strength and percentage of elongation on tensile stress? Which company made the custom-made nails? Can you tell us whether the stainless steel nails were more flexible than the titanium nails supplied by Synthes (Paoli, Pennsylvania)?

Howmedica (Rutherford, New Jersey) was the supplier of the stainless steel nails. The company was integrated into Stryker in the year 1999. All of our stainless steel nails were 316LVM. Mechanical testing of these nails was not done for the present study. According to the surgeons' clinical experience, the titanium nail feels more flexible than the stainless steel nail¹⁻³.

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These letters originally appeared, in slightly different form, on *jbjs.org*. They are still available on the web site in conjunction with the article to which they refer.

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Surgical Tourniquets in Orthopaedics

To The Editor:

In a recent article, "Surgical Tourniquets in Orthopaedics" (2009;91:2958-67), by Noordine et al., the authors expressed highly critical opinions on the use of "a non-pneumatic elastic ring designed to combine exsanguination and tourniquet functions." The only commercial device that is currently available on the market and fits this description is the S-MART/HemaClear (www.hemaclear.com; www.ohkmed.com) manufactured by OHK Medical Devices (Newark, New Jersey). The authors confidently predict that "uncritical use and acceptance of non-pneumatic tourniquets for extended periods . . . may increase the incidence of

tourniquet-related adverse events, exposing patients and surgical staff in civilian settings to unnecessary risks.” Clearly, if these presumed facts are substantiated, it is imperative that the use of the HemaClear is discontinued immediately and indefinitely. However, the excellent safety track record of the S-MART/HemaClear, as outlined below, is far from supporting the allegations by Noordin et al. As the developers, manufacturers, and distributors of HemaClear, we find it necessary to set the record clear on scientific as well as procedural levels.

Before getting into the physics and physiology of the subject matter, it is important to clarify the status of the authors and the motives that they may have had in publishing this supposedly objective scientific manuscript. It is unfortunate that the ethics rules of full disclosure have not been followed by at least one of the authors. Their disclosure statement says: “The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity.” This statement is in fact false and misleading: The intensive commercial conflicts of interest of Dr. J.A. McEwen, the founder, inventor, and officer of several commercial entities in the field of pneumatic tourniquets (e.g., www.tourniquet.org), were withheld from *The Journal* and its readers. Clearly, since the S-MART/HemaClear has been gaining rapid popularity among leading orthopaedic surgeons in the United States and elsewhere, there potentially exists a commercial and financial interest in displacing such competition from the market.

It is within this context that we now wish to address some of the scientific aspects of this paper.

First, we address the safety track records of wide pneumatic tourniquets compared with the narrow elastic exsanguination-arterial blocker ring. In a recent paper referenced by the authors, Odinson and Finsen¹ described the rate of complications using tourniquets in orthopaedic surgery in Norway. The authors found fifteen cases of neurological deficit in more than 60,000 applications of a tourniquet (a prevalence of approximately 24/100,000), the majority of which were in the lower extremity. This prevalence was no better than that reported twenty-five years earlier in Australia

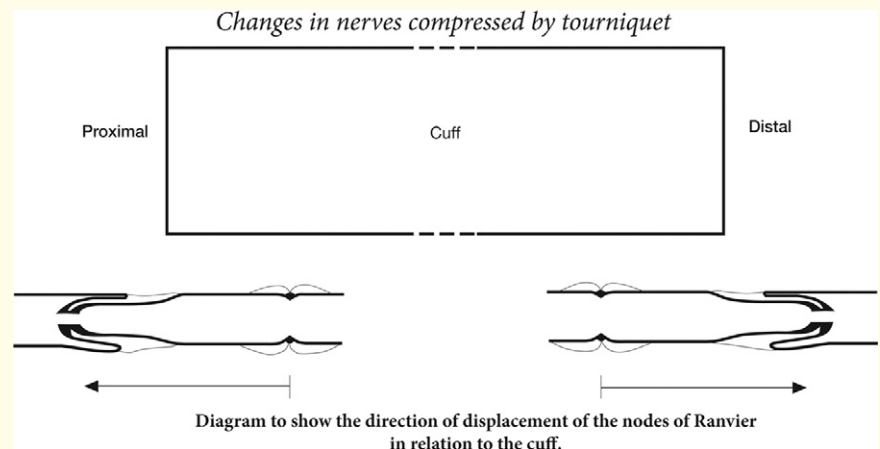


Fig. 1

Diagram from Ochoa et al.¹⁷, showing the axially displaced elongated nerve due to the compression by the wide cuff used in their study. The telescoping damage was found at the proximal and distal edges of the cuff. (Reproduced, with permission, from: Ochoa J, Fowler TJ, Gilliat RW. Anatomical changes in peripheral nerves compressed by a pneumatic tourniquet. *J Anat.* 1972;113(Pt 3):433-55.)

(Middleton and Varian²) and, in fact, was somewhat worse, despite the use of modern tourniquets (wide tourniquets with controlled pressure and monitoring) and use (i.e., with the pressure adjusted at approximately 100 mm Hg above systolic blood pressure) by the majority of the Norwegian surgeons. It is interesting to note that none of the neurological complications occurred among the 14% of the survey responders who routinely use an Esmarch bandage to control blood flow. Clearly, the one parameter that changed from Australia in 1974 to Norway in 1999 is the cuff width, which may have gotten bigger and may have been a contributing factor to the worsening of the data.

These numbers, while not high in and by themselves, are substantially higher than the data on possible nerve involvement available to OHK Medical Devices on the use of its S-MART/HemaClear in more than 150,000 cases worldwide (three cases of nerve involvement for a prevalence of 2/100,000, and all three occurred when the device was used beyond the recommended 120-minute time limit). This is despite the fact that the S-MART/HemaClear elastic ring is much narrower than the wide pneumatic tourniquet promoted by Dr. McEwen and his companies over the last twenty-five years (references related to the Noordin et al. study³⁻¹³). This obviously superior track record for safety is supported by a number of independent scientific studies that clearly provide the physical and physiological explanation to the

observed difference in incidence. Examples include the following:

1. In a recent independent study of nerve conduction during application of narrow and wide pneumatic cuffs in volunteers, Mittal et al.¹⁴ found significantly lesser subclinical, yet physiologically documentable, nerve conduction speed deficits with the narrow cuff than with the wide one.

2. In two independent studies by Drosos et al.¹⁵ and by Mohan et al.¹⁶, the tolerance of volunteers to the placement of a pneumatic tourniquet and the S-MART/HemaClear showed longer endurance with the S-MART/HemaClear, with a significant difference in the study by Mohan et al.

3. A study of the effects of a wide tourniquet on neuronal damage in experimental animals by Ochoa et al.¹⁷, in 1972, revealed the nature of tourniquet-induced nerve injury. They clearly showed that axial displacement (elongation) of compressed nerves beneath a pressurized wide tourniquet causes the transmission disruption because of telescoping (“invagination”) of the nerve into itself at the nodes of Ranvier near the edges of the tourniquet (Fig. 1). The contribution of the cuff width to the damage was clearly stated by Ochoa et al. in the Discussion section of their paper as shown in Figure 2.

4. In another independent study, published in 1993, in *Biomedical Instrumentation and Technology*, Hodgson¹⁸ concluded:

Explanation by Ochoa et al.

“Why are the lesions concentrated under the edges of the cuff? This could be explained by the pressure gradient in the tissues between the parts under the cuff and those beyond its edge. With the relatively wide cuff we have used, the gradient would be maximal under the edges of the cuff and least under its centre. Without such a gradient one would not expect axoplasmic movement or displacement of the nodes of Ranvier to occur, even if the absolute pressure in the tissues were high.”

Fig. 2

Excerpt from the discussion in the study by Ochoa et al.¹⁷, in which the direct contribution of the cuff width is emphasized.

“Use of a wider cuff in and of itself will not reduce axial strain, so if the hypothesis is correct, a wider cuff would not be intrinsically safer than a regular cuff, a result that is contrary to current opinion.”

Thus, there is a strong and well-documented body of evidence that is independent from any commercial interests to show that narrow tourniquets are actually better than wide pneumatic tourniquet cuffs. In fact, the evidence in support of using a wide cuff, outside of Dr. McEwen’s own publications, is scant or nonexistent.

Second, we address the question: What is happening inside the limb when a tourniquet is applied? Pressure. It is rather regrettable that the authors failed to comprehend the fundamental aspects of the mechanics of tissue compression beneath surgical tourniquets (pneumatic or elastic ring). The first key parameter in preventing damage to the tissues *inside* the limb (e.g., nerves and blood vessels) is the pressure inside the limb rather than at the skin surface, as described by Noordin et al. in their Figure 5. In fact, in order to stop the arterial blood flow into a limb, all that is needed is to compress the artery over a few millimeters of its length by a pressure applied just outside the artery that is a few millimeters of mercury higher than the highest fluctuation of systolic blood pressure, e.g., 150 mm Hg if the patient’s mean systolic blood pressure is 130 mm Hg.

When a wide tourniquet is used, the pressures outside the artery and the nerve are the same as those at the skin surface (i.e., approximately 100 mm Hg higher than the systolic blood pressure). This has to do with the fact that the pressure field (distribution) beneath a wide cuff is uniform, except toward the margins of the cuff. When applying the narrow cuff or the HemaClear elastic ring, the skin surface pressure dissipates when transmitted through the soft tissues (skin, fat layer,

and muscle) to the level of the artery and the nerve (i.e., radial pressure gradient), so that even if the skin-surface pressure is high, the pressure at the nerve level is quite low. Actually, in most patients, the skin pressure is around 250 mm Hg when the HemaClear 40

is used on the arm and 300 to 350 mm Hg when the HemaClear 60 and HemaClear-90-Black and White are applied to the thigh (see HemaClear pressure charts at www.hemaclear.com) and not as illustrated in Figure 5 in Noordin et al.

Third, we address the pressure gradient. The second most important parameter with respect to nerve damage is the axial pressure gradients at the edges of the tourniquet. There is an across-the-board agreement that the higher this axial gradient at the level of the nerve, the higher the risk for shear stress and telescoping injury to the axons as documented by Ochoa et al.¹⁷. However, the notion that narrower cuffs and rings exert higher axial gradients than wide cuffs (as alluded to in the hypothetical graph shown in Figure 5 of Noordin et al.) is simply not true. In fact, the experimental data to date have

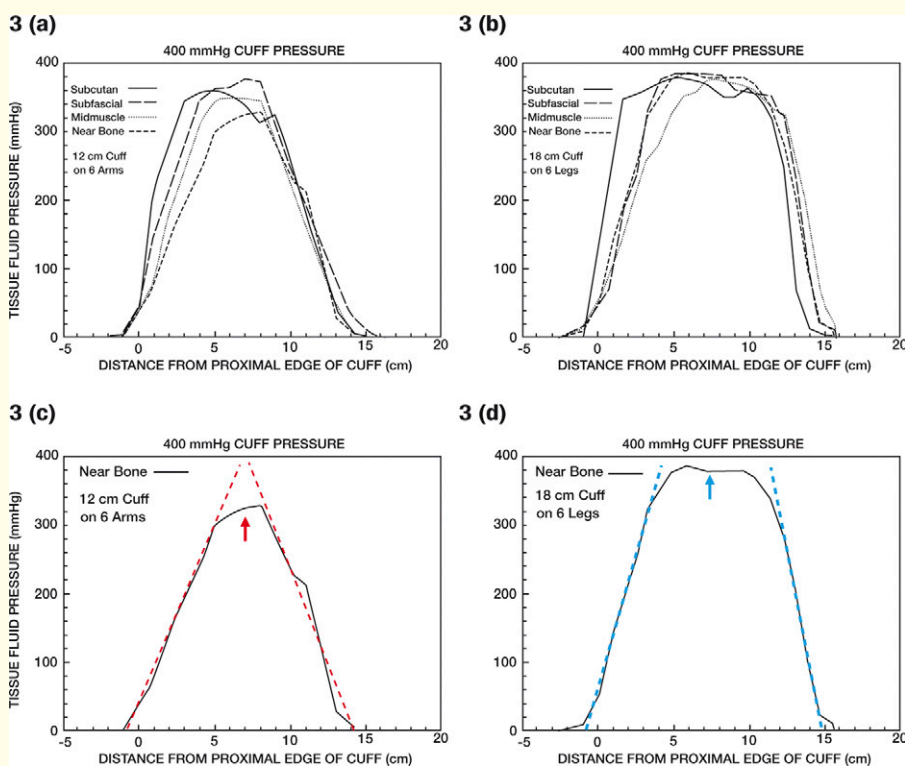


Fig. 3

Original data from Crenshaw et al.¹⁹, showing the pressures measured inside a cadaver limb beneath a narrow (a and c) and wide (b and d) pneumatic tourniquet. Panels a and b are copies of the original figures. Panels c and d show only the corresponding “Near Bone” (innermost) pressure profiles with superimposed lines to indicate the steeper axial pressure gradient with the wide cuff. Arrows indicate that the peak pressure inside the limb is lower with the narrow cuff. The data in this classic paper clearly show that the shear strain and pressure stress at the inner part of the limb are higher with the wide cuff. (Reproduced, with modification, from: Crenshaw AG, Hargens AR, Gershuni DH, Rydevik B. Wide tourniquet cuffs more effective at lower inflation pressures. *Acta Orthop Scand*. 1988;59:447-51. Reproduced with permission.)



Fig. 4-A

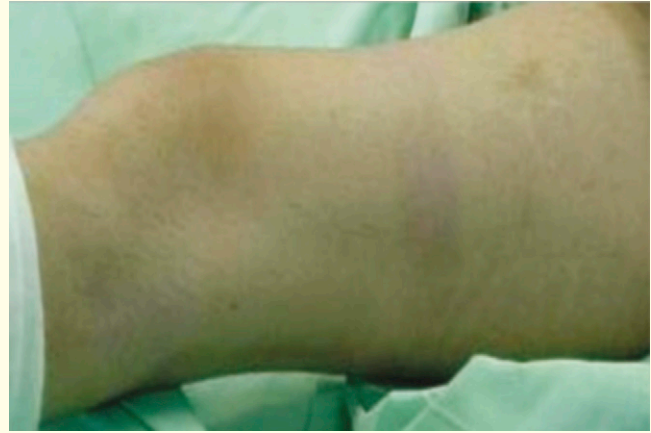


Fig. 4-B

Figs. 4-A and 4-B Skin condition following use of a wide pneumatic tourniquet (Fig. 4-A) and HemaClear (Fig. 4-B). Note the blisters at skin folds and hemorrhagic abrasions caused by the pneumatic tourniquet. The transient skin erythema at the HemaClear ring position faded over the subsequent forty-five minutes.

shown exactly the opposite. The figure shown here from the landmark 1988 study by Crenshaw et al.¹⁹ clearly demonstrates it (Fig. 3). The graphs show the intralimb axial pressures at four radial locations with narrow (Fig. 3, *a* and *c*) and wide (Fig. 3, *b* and *d*) tourniquet cuffs inflated to 400 mm Hg. It is readily seen that the gradients with the narrow cuff (red lines in Fig. 3, *c*) are much less steep than with the wide cuff (blue lines in Fig. 3, *d*). Similar experimental data as well as computational models confirm this observation. The graphs also show that the actual pressure internally is lower with the narrow cuff.

Thus, with pressures at the nerve level that are lower with the narrow cuff and with gradients that are much less steep, it is not surprising that the incidence of nerve injury is higher with the wide cuff.

Fourth, we address the question: Is the higher pressure at the skin level with narrow cuffs or an elastic ring a cause for concern? The pressure exerted on the skin by the S-MART/HemaClear depends only on the limb circumference and the distance of the placed ring from the toes or fingers. This pressure is factory calibrated and cannot be exceeded. With pneumatic tourniquets, while the pressure used in the majority of patients is not more than 300 to 350 mm Hg, it is possible that if bleeding starts into the surgical field because of a sudden surge in arterial blood pressure, the surgeon will instruct to increase the pressure on the controller. Pneumatic tourniquet controllers can be dialed up to 475 mm Hg in the cuff, with a 700 mm Hg

reservoir (e.g., ATS 2000; Zimmer, Warsaw, Indiana²⁰). It is, however, more important to note the overall skin safety record of wide pneumatic tourniquets compared with the S-MART/HemaClear. The recent study by Din and Geddes²¹ on skin complications following the use of a wide pneumatic tourniquet indicated a prevalence of 6%, even when adequate padding was used. This is far beyond the very few cases known to us from among the >150,000 patients managed with the HemaClear. This is attributed to the round contour of the ring-skin interface and the many layers of stockinette left around the elastic ring. Figures 4-A and 4-B show examples of skin conditions with a wide pneumatic tourniquet and the S-MART/HemaClear.

In summary, the data described above clearly document the superior safety track record of the elastic exsanguination tourniquet (S-MART/HemaClear) over the wide tourniquet promoted by Dr. McEwen and materially refute his unsubstantiated allegations. The smaller pressure inside the limb at the nerve level and the less steep internal axial pressure gradients are the underlying mechanisms of this improved patient outcome. The fact that the patient's skin tolerates the S-MART/HemaClear better than the wide tourniquet cuff has to do with specific design details. These features are accompanied by other advantages: the overall lower volume of tissue that is under compression conditions, the time needed for preparation and application, the fact that the S-MART/HemaClear exsanguination is superior, with an excellent

surgical field and larger room for wider exposure because of the smaller footprint of the occluding ring, its usefulness both on the upper part of the limbs (arm and thigh) as well as on the tapered parts of the limb (calf and forearm), and its sterility all contribute to the popularity that this product is gaining.

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S. Noordin, J.A. McEwen, J.F. Kragh Jr., A. Eisen, and B.A. Masri reply:

We thank Dr. Gavriely for raising important questions that will serve to stimulate further

thinking about current concepts relating to tourniquets in orthopaedics. His question about conflict of interest has been addressed directly with the Editor, and an erratum has been published.

We trust that this will not detract from consideration of some important questions raised by Dr. Gavriely's letter, which include the following:

1. What are the basic mechanisms of tourniquet-related injuries, as reported in the literature?
2. What is the relationship between tourniquet-related injuries and the levels and gradients of pressures applied to limbs by tourniquet cuffs?
3. Do narrower tourniquet cuffs, whether pneumatic or non-pneumatic, necessarily require higher pressures and higher pressure gradients to stop arterial blood flow?
4. What ranges of pressures may be produced by narrow, non-pneumatic tourniquet devices that are applied manually and in which applied pressures cannot be accurately monitored or regulated after application?
5. What is the reported incidence of tourniquet-related injuries, and what factors may affect their recognition and reporting?

In our manuscript, we attempted to analyze the pertinent literature relating to each of these questions, among others.

The literature on the mechanism of tourniquet injuries is clear and consistent and well established by many investigators over many years. There is a relationship between higher tourniquet pressures, higher pressure gradients, and a higher probability of injury.

Dr. Gavriely's main assertion is that narrow elastic tourniquet rings are superior to wider cuffs¹⁻⁶. It appears to us that Dr. Gavriely has misunderstood or misinterpreted aspects of earlier peer-reviewed papers by Ochoa et al.⁴, Hodgson⁵, and Crenshaw et al.⁶. The important findings by Ochoa et al. about the mechanism of tourniquet-related injuries are accurately described in our manuscript (see Figure 3 and page 2959) and do not support Dr. Gavriely's assertion. Hodgson⁵, in 1993, described an interesting biomechanical model and hypothesized, on the basis of that model, that wider tourniquet cuff designs having a gradual roll-off of pressure near the edges would be optimal in avoiding tourniquet-induced neuropathy; cuffs having such designs subsequently became available. Also, Dr. Gavriely may have misunderstood the importance of the results

of Crenshaw et al.⁶: "The cuff pressure required to eliminate blood flow decreased as cuff width increased. . . . Thus, wide cuffs transmit a greater percentage of the applied tourniquet pressure to deeper tissues than conventional cuffs; accordingly, lower cuff pressures are required, which may minimize soft-tissue damage during extremity surgery." Dr. Gavriely may not have appreciated that if a lower tourniquet pressure can eliminate blood flow past a specific cuff, then the pressure gradients produced by that cuff will be correspondingly lower. Figure 4 in our study summarizes the relationship between tourniquet cuff width and limb occlusion pressure reported in the literature over many years. Nevertheless, we recognize there are circumstances, particularly certain military applications, when narrow, non-pneumatic tourniquets are appropriate and life-saving.

We find it necessary to correct Dr. Gavriely in his assertion regarding the data presented in Figure 5 in our study: these data were not hypothetical but were based on measurements. Dr. Gavriely suggested that different sizes of an elastic ring tourniquet could be matched to a limb location according to a look-up table able to produce a desired applied pressure. We were not able to find data or evidence of pressure measurements supporting the recommendations of a look-up table and the resultant pressures produced. Further, that suggestion raises safety concerns arising from an inadvertent mismatch between ring and limb size by a user if actual tourniquet pressure is not measured. In the study, we pointed out that the use of non-pneumatic tourniquet devices of current designs precludes accurate pressure measurement, pressure monitoring, and pressure control during use. A direct understanding of some of the relevant safety concerns can be gained by a reader by self-application of any of the tourniquet devices in Figure 5, by operating each as recommended to eliminate blood flow, and by comparing the relative levels of pain experienced. The variation in focal pressure concentration and pain perception is substantial.

We remind Dr. Gavriely of aspects of our brief historical review: narrow rubber bandages were used as tourniquets at the end of the nineteenth century, but their use in surgical, nonmilitary applications was quickly supplanted after Cushing introduced the pneumatic tourniquet in 1904, thereby reducing tourniquet-related injuries by permitting tourniquet pressure to be measured,