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Preliminary Comparison of Pneumatic Models of Tourniquet for Prehospital Control of Limb Bleeding in a Manikin Model

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ABSTRACT

Background: Emergency tourniquet use has been associated with hemorrhage control and improved survival during the wars since 2001, but little is known of the differential performance of pneumatic tourniquet models. The purpose of this study was to compare the performance of three models of pneumatic tourniquets in a laboratory setting to aid a possible decision to field test suitable models for medic preference. **Methods:** A laboratory experiment was designed to test the effectiveness of tourniquets on a manikin thigh. Three models (one Emergency and Military Tourniquet [EMT] and two Tactical Pneumatic Tourniquets differing in width: 2 in. and 3 in. [TPT3]) were compared with the standard-issue Combat Application Tourniquet of a strap-and-windlass design. Two users conducted 40 tests each on a right-thigh manikin (HapMed Leg Tourniquet Trainer) with a simulated above-knee amputation injury. Measurements included effectiveness in hemorrhage control, pulse stoppage distal to the tourniquet, time to stop bleeding, blood loss, and pressure. **Results:** All four models were 100% effective in both hemorrhage control and pulse stoppage distal to the tourniquet. The TPT3 had the slowest mean time to stop bleeding and the highest mean blood loss. The EMT had the least mean pressure. An interuser difference was found only for mean pressure. **Conclusions:** All models of tourniquet performed equally well for both the critical outcome of effectiveness and the important outcome of pulse stoppage, whereas results for secondary outcomes (time, pressure, and blood loss) differed by model. The EMT had best performance for every type of measurement.

KEYWORDS: *first aid; damage control; hemorrhage, prevention and control; shock; tourniquet; resuscitation; emergency medical services*

Introduction

Uncontrolled hemorrhage from limb wounds is a common phenomenon both on civilian streets and in battlefields; however, in a minority of cases, such bleeding can cause death from hemorrhagic shock.[1–4] Such deaths are potentially preventable because limb hemorrhage is controllable with out-of-hospital tourniquet use.[5–8] During the recent wars in Afghanistan and Iraq, military services have compiled evidence associating tourniquet use with improved survival of casualties, although the level of improvement remains unclear.[9–12] Much of the field evidence gained has been with the common strap-and-stick tourniquet that is standard issue in military first aid kits for individual Soldiers.[13–16]

Despite the success of Soldiers using strap-and-stick tourniquets, military medics have different caregiving practices and access to different types of tourniquets than do regular Soldiers such as infantrymen. For example, medics often assess the bleeding control status of strap-and-stick tourniquets placed by nonmedical Soldiers for possible exchange of that tourniquet for a pneumatic tourniquet, which is safer, more comfortable, and more effective.[13,17,18] Although pneumatic tourniquets have been recommended for issue to military medics since 2004, a knowledge gap remains in a performance assessment of currently available models.[19] The purpose of the present study is to compare the performance of three models of pneumatic tourniquets in a laboratory setting to aid a possible decision to field test suitable models for medic preference.

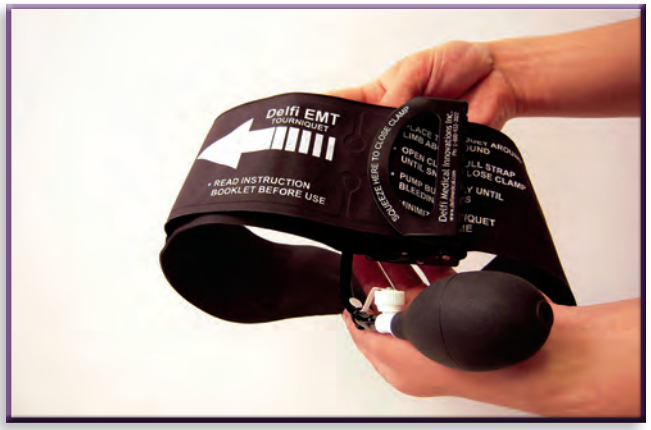
Materials and Methods

This study, involving a laboratory experiment designed to compare the function of tourniquets, was conducted under a protocol reviewed and approved by the Regulatory Compliance Division of the US Army Institute of Surgical Research. The study group included use of the three pneumatic tourniquets intended for out-of-hospital hemorrhage control during military combat or emergency medicine. The intended user in such a prehospital situation is a military medic, a civilian paramedic, or a person in an analogous position.

Data were gathered from February to August 2014. The three pneumatic tourniquet models tested were the Emergency and Military Tourniquet (EMT; Delfi Medical Innovations, http://www.delfimedical.com) and two Tactical Pneumatic Tourniquet (TPT) models differing in width: 2 in. (50.8mm; TPT2) and 3 in. (76.2mm; TPT3) (Alphapointe, https://www.alphapointe.org).

The EMT is a commercially developed field tourniquet. It consists of a heat-sealed, black nylon, inflatable bladder; a clamp; and a hand bulb inflator permanently attached via a flexible hose (Figure 1). The EMT bladder lies flat and is 88mm wide. The bladder is placed around the limb as a circumferential loop, and the running end of the strap is passed through the narrow opening between the two handles of the hinged clamp. The end of the bladder is then pulled firmly to remove slack from the loop and to make the bladder snug to the limb. To increase snugness before closing the clamp, the end of the bladder can be pulled at an angle toward the D-shaped handle of the clamp. By squeezing the handles of the clamp, the opening is closed securely down upon the bladder, which is then closed underneath. The bladder around the limb is inflated by squeezing the hand bulb repeatedly; the inflatable portion inside the bladder is 76mm wide while the overall width is 88mm, including the edges. The user deflates the bladder by twisting the air release valve to the open position; the valve is on the tube between the inflator and bladder. At the time of assessment, the EMT had been registered for years with the US Food and Drug Administration (FDA).

Figure 1 *Emergency and Military Tourniquet.*



This image used with the permission of Delfi Medical Innovations, http://www.delfimedical.com.

The TPT is a new, militarily developed field tourniquet. It consists of inner and outer covers, a pin holding the covers together, a slider that snaps into a receiving hook, and the inflation bulb. The inner cover is looped around the limb circumferentially and tightly; the inner cover includes the bladder. Then the pin is removed, allowing the outer cover to drop freely. The slider on the outer cover is snapped into the receiving hook and excess slack in the outer cover is pulled and secured down onto itself upon its surfaces of self-adhering hooks and loops. The tourniquet is then inflated by squeezing the inflation bulb repeatedly. Opening the pressure valve deflates the bladder. At the time of assessment, the TPTs were not registered with the FDA (Figure 2).

Figure 2 *Tactical Pneumatic Tourniquet.*

Photograph by J. Kragh

The investigators used two models, one 2-in. wide and the other, 3-in. wide.

For comparison with the models of the study group, the Combat Application Tourniquet (C-A-T) Generation 6 (Composite Resources, http://combattourniquet.com), of a commonly used strap-and-windlass design and which is standard issue to the military forces of multiple nations, served as the control tourniquet. The C-A-T has a buckle that permits slack removal from the strap before turning of the windlass. The C-A-T strap is 39mm wide. At the time of assessment, the C-A-T had been registered for years with the FDA (Figure 3).

Figure 3 *Combat Application Tourniquet.*

The Combat Application Tourniquet, with its strap-and-windlass design, served as the control model. It is standard issue to US military forces. This image used with the permission of Composite Resources, http://combattourniquet.com.

There were two tourniquet users—a female undergraduate student and a male clinician-scientist. Both users had familiarization training in use of the manikin. The

student was relatively inexperienced in tourniquet use, whereas the clinician-scientist was a tourniquet expert and had tourniquet experience in trauma care. The clinician-scientist trained himself on the new tourniquets and had formal military training on the standard-issue tourniquet. The clinician-scientist trained the student. Training included reading the instructions for use, handling the device, and supervised practice with each tourniquet model in one or two uses on the manikin before testing began.

The clinician-scientist tested before the student; the control group was tested by each user before the study group. Testing of models of tourniquet was done in runs of ten tests in a row per model. The order of models tested in the study group was TPT3, TPT2, and EMT.

There were 10 tests per tourniquet model per user; hence, both users had 40 tests. The overall number of tests was 80 replicates for the experiment. Devices were examined throughout testing for structural and functional integrity.

The tourniquets were tested on a laboratory manikin that was designed to train users by providing feedback on user performance. The investigators used a HapMed™ Leg Tourniquet Trainer (CHI Systems, http://www.chisystems.com); a simulated right thigh with an above-knee amputation injury was the testing apparatus.[20–24] The medial hip had an embedded computer including a smartphone-like touchpad. Software (version 1.9; CHI Systems) integral to the thigh allowed the manikin to stand alone and be operated by user input through finger touch on the pad. The thigh was placed on a laboratory benchtop and was operated in accordance with the manufacturer's instructions. The thigh did not bleed, but bleeding was represented by red lights that transilluminated the wound. The number of lights illuminated represented the bleeding rate: all 26 lights illuminated indicated uncontrolled bleeding; few lights blinking indicated intermediate control; and no lights illuminated indicated bleeding had stopped. Arterial pulses were palpable in the popliteal area. Touchpad readouts for each iteration included hemorrhage control, the time to stop bleeding, the pressure exerted under the tourniquet, and the simulated blood loss volume. The measure of time to stop bleeding extended from the start of the iteration until the manikin detected that no more blood was lost. Effectiveness was determined by the cessation of blood loss (i.e., hemorrhage control). Iterations began with a tourniquet laid out flat and undone on the benchtop. Iterations ended when the user touched the touchpad button, assessing that the hemorrhage was stopped. Users tightened tourniquets until they perceived that simulated bleeding stopped. The casualty had a medium build and the setting was "Care Under Fire," a setting resembling emergency care when under gunfire.

The manikin settings also included a constant simulated hemorrhage rate (635mL/min). With such a hemorrhage rate, the resulting bleed-out time was 4 minutes (240 seconds); thus, in the absence of any hemorrhage control, simulated death would occur at 240 seconds. If partial hemorrhage control occurred, then longer survival would result. The touchpad reported simulated blood loss volume as calculated from arterial flow and time; although the bleeding volume per pulse dropped over time, the pulse rate increased such that the bleeding rate, if mechanically unimpeded, was linear. Tourniquets, users, tests, and outcomes were uniquely identified.

Results were summarized by outcome and by tourniquet models. The critical, or primary, outcome was effectiveness (yes-no, hemorrhage control). Another important outcome was absence of palpable pulse distal to the tourniquet (yes–no). Secondary outcomes included time to cessation of bleeding (seconds); pressure (mmHg) applied to the skin (piezoelectric transducers were under the silicone skin) by the tourniquet in an attempt to achieve hemorrhage control, and the volume of simulated blood loss (mL). Effectiveness and pressure were measured by the manikin, whereas breakage and pulse stoppage were determined by the user. Categorical data such as effectiveness were summarized using percentages and compared using the chi-square test or Fisher exact test, whichever was most appropriate. Continuous data such as time to stop bleeding, pressure applied, and blood loss volume were summarized using box-and-whisker plots, with a solid line representing the median, the box containing the interquartile range (IQR), and the whickers representing the upper and lower bounds excluding outliers based on the 1.5 IQR criteria (i.e., data points more than [(quartile 1 – IQR) × 1.5] were considered outliers).[25] Analysis of variance (ANOVA) with a Tukey adjustment for pairwise comparison was used to compare the tourniquets. Tiers separating the tourniquet performance were based on the Tukey adjusted p-value being <.05. All analyses were performed using JMP version 10.0 (SAS, http://www.sas.com).

Results

Bleeding Control and Pulse Stoppage

Results of bleeding control (yes-no) by model of tourniquet showed no significant differences: all four tourniquet models tested were 100% effective. Similarly, results of pulse stoppage distal to the tourniquet (yes-no) were 100% effective for all four models.

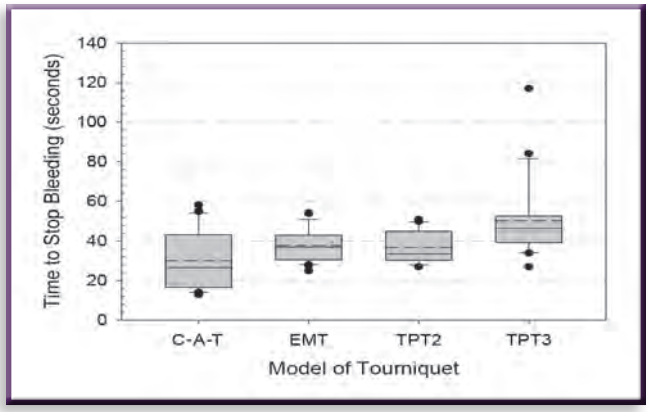
Safety-Related Events

No tourniquet broke, no injury occurred to the manikin, and no tourniquet applier sustained any injury.

Time to Stop Bleeding

Results of the pairwise comparison of mean time to stop bleeding by model of tourniquet indicated no significant difference among two pneumatic models (TPT2 and EMT) from the C-A-T, the control model ($p > .0528$ for all three), whereas all three means were significantly different than that of the TPT3, which had the slowest mean time at 50 seconds ($p < .0065$ for all three) (Figure 4). Pairwise difference in means ranged from 1 second for the TPT2 and EMT pairing ($p = .9953$) to 20 seconds for the TPT3 and C-A-T pairing ($p < .0001$). Similarly, ANOVA results were two-tiered, with the TPT3 alone in the slow tier and the three other models in the fast tier.

Figure 4 *Results of time to stop bleeding by model of tourniquet.*

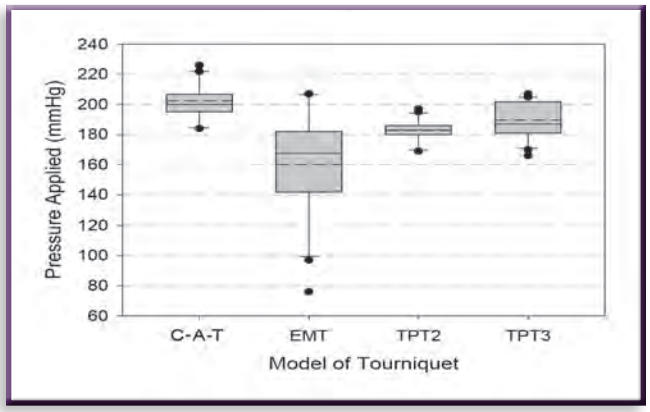


The TPT3 had the slowest mean time to stop bleeding. In pairwise comparison, there was no significant difference among mean times for the TPT2, EMT, and C-A-T, whereas all these three means were significantly different than that of the TPT3. Similarly, analysis of variance indicated that the TPT3 was alone in the slow tier and the three other models were in the fast tier. The vertical box plots depict the 25th percentile as the box bottom, 75th percentile as the box top, 5th percentile as the down bar, 95th percentile as the up bar, the dashed line as the mean, and the solid line as the median. Data points beyond bars are dots. C-A-T, Combat Application Tourniquet; EMT, Emergency and Military Tourniquet; TPT2, 2-in. Tactical Pneumatic Tourniquet; TPT3, 3-in. Tactical Pneumatic Tourniquet.

Mean Pressure Achieved

Results of the pairwise comparison of mean pressure achieved by model of tourniquet were significantly different among the pneumatic models for the TPT3 and EMT pairing and the TPT2 and EMT pairing ($p < .0044$ for both), and the C-A-T was significantly different than all three pneumatic models ($p < .0071$ for all three) (Figure 5). Pairwise difference in means ranged from 6mmHg for the TPT3 and TPT2 pairing ($p = .1153$) to 42mmHg for the EMT and C-A-T pairing ($p < .0001$). ANOVA results were three-tiered, with the C-A-T and TPT3 in the high tier (mean, 202mmHg and 190mmHg, respectively), the TPT3 and TPT2 in the middle tier (mean, 183mmHg), and EMT in the low tier (mean, 160 mmHg). Treatment groups, namely models of tourniquet, within the ANOVA model are tiered based on statistical significance between means; groups in the same tier are not statistically

Figure 5 *Results of pressure applied by model of tourniquet.*



Results of pressure applied by model of tourniquet were that the EMT had the lowest mean pressure. In pairwise comparison, there were significant differences among pneumatic models for the TPT3-EMT and TPT2-EMT pairings, and the amount of pressure applied with the C-A-T was significantly different than all three pneumatic models. Analysis of variance results were three-tiered, with the C-A-T and TPT3 in the high tier, the TPT3 and TPT2 in the middle tier, and the EMT in the low tier. C-A-T, Combat Application Tourniquet; EMT, Emergency and Military Tourniquet; TPT2, 2-in. Tactical Pneumatic Tourniquet; TPT3, 3-in. Tactical Pneumatic Tourniquet.

significant in their difference (adjusted $p \geq .05$). If groups are statistically significant in their difference they will be in different tiers, but the *same* group, which cannot be different from itself, may be in more than one tier—for example, TPT3 is in more than one tier. A model, such as TPT3, may be in two tiers if its mean is between those of two other groups, such as C-A-T and TPT2, and both differences, e.g., TPT3–CAT and TPT3–TPT2, are not statistically significant (Table 1).

Blood Loss

Pairwise comparison results for mean blood loss volume recorded by model of tourniquet differed significantly among all models except the TPT2 and EMT pairing (7mL; $p = .0658$) (Figure 6). The greatest difference in means was between the TPT3 and C-A-T pairing; the former was 176mL more ($p < .0001$). ANOVA results were two-tiered, with the TPT3 alone in the high tier (mean, 348mL) and all others in the low tier, where means ranged from 172mL for the C-A-T to 239mL for the EMT.

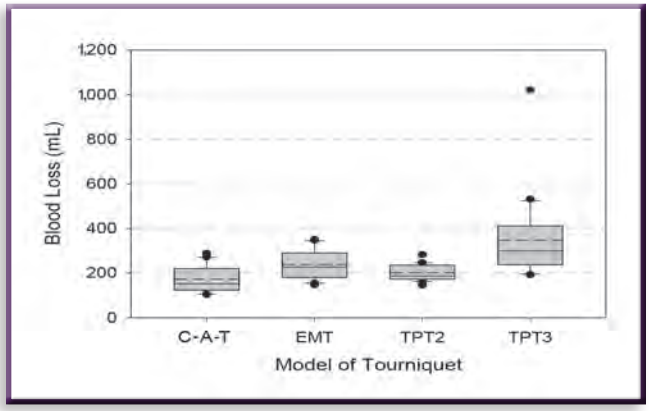
Results by User

The difference of mean time to stop bleeding by user was not statistically significant ($p = .9886$), with the less experienced user 8 seconds slower than the more experienced user. The difference of mean pressure by user was statistically significant ($p = .0210$) (Figure 7), with the more experienced user achieving a mean pressure 13mmHg greater than that of the less experienced user. The difference of mean blood loss by user was not statistically significant ($p = .8287$), with mean blood loss 6mL more when the less experienced user applied the tourniquets.

Table 1 *Mean Pressure Results as a Connecting Letters Report*

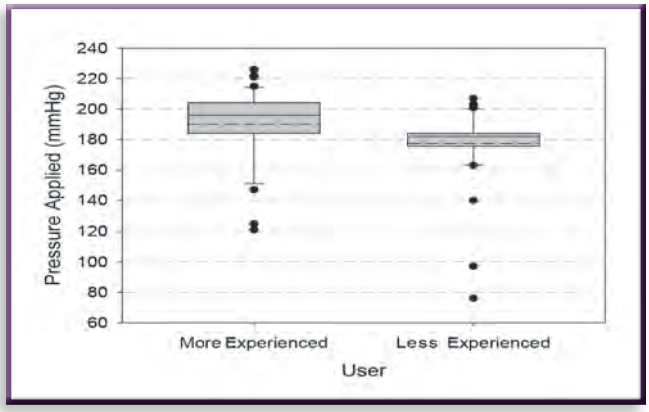
Model				Mean (mmHg)
CAT	A			202
TPT3	A	B		190
TPT2		B		183
EMT			C	160

Figure 6 *Results of blood loss by model of tourniquet.*



Results of blood loss by model of tourniquet were that the TPT3 had the highest mean blood loss. Pairwise comparison revealed significant differences among all models except the TPT2 and EMT pairing. Analysis of variance placed the TPT3 alone in the high tier and all others in the low tier. C-A-T, Combat Application Tourniquet; EMT, Emergency and Military Tourniquet; TPT2, 2-in. Tactical Pneumatic Tourniquet; TPT3, 3-in. Tactical Pneumatic Tourniquet.

Figure 7 *Results of pressure applied by user.*



The more-experienced user had the higher mean pressure by 13mmHg. No statistically significant difference between users was found among mean values for other tested parameters.

Discussion

The main finding was that all models of tourniquet performed equally well for the both the critical outcome (effectiveness) and the important outcome (pulse stoppage distal to the tourniquet), whereas results for secondary outcomes (time to stop bleeding, pressure, and blood loss) differed by model. Only the EMT had best performance for every type of measurement studied.

Two minor findings dealt with differences in biomechanics by model of tourniquet. A minor finding of mechanical advantage was due to the difference in designs of the models studied; in other words, with the methods used, pneumatic designs were able to achieve mechanical advantage more easily. The greater ease of achieving mechanical advantage, namely through compression of the skin by well-distributed pressure, with pneumatic designs compared with other designs was one reason pneumatic designs were originally developed; another reason was that pneumatic designs were safer.[26] Similarly, the second minor finding related to mechanical advantage was that pressure applied by tourniquets was inversely associated with model width: wider tourniquets such as the EMT (88mm wide), the widest model studied, applied the lowest pressure; the least-wide model (C-A-T, 39mm) exerted the highest pressure; and the two middle models by width (TPT2, 50mm; TPT3, 75mm) applied the middle pressures. This second minor finding reinforces a large and growing body of evidence that wider tourniquets achieve mechanical advantage more easily than narrow ones.[14,26] In fact, this finding is a phenomenon of collapsible tube science, wherein the length of the tube compressed is a major factor in whether the transmural pressure gradient collapses the lumen of the tube (e.g., the artery).[27]

Another minor finding dealt with differences in user performance. Despite the fact that only 10 tests were made of each model of tourniquet, a difference between users was found for a secondary outcome, pressure. The few tests limit the statistical power to detect user effects such as differences in outcomes because of differences in user that could be due to differences in user experience, skill level, strategy of use, and techniques of use. Although the clinician-scientist has been gathering such findings from multiple studies over the years that indicate user effects are common, when the studies have few tests, like the 10 per model in the present study, then user effects are difficult to detect, likely due to lack of statistical power. For example, in another similar study led by the clinician-scientist with 10 tests of improvised tourniquet use, no user effects were detected.[23] However, recently, more and more studies have reported findings on user effects, although the main focus is still on materiel difference, not on user differences. To mitigate user effects such as learning, study designs can be changed and randomization of the order of models used is included. More fundamentally, the design of the studies now can be widened, based on the scope of interest of the study, to mitigate or to include user effects such as learning curves. Because, apart from the materiel development, the user's skill development also plays an integral role in improving clinical care, study designs to understand such learning patterns are also important. Specifically, for hemorrhage care and tourniquet application, up to 2001, the weakest link in the chain of care was the

tourniquet itself. Since 2001, when tourniquet research accelerated, the tourniquet materiel has improved. Today, the weakest link is the user; skill acquisition and maintenance are examples of current research topics to be explored more to gain insights about ways to improve the overall process.

The clinical context of the present study findings is noted because in the US Army, one military medic is routinely assigned at the fundamental level to a platoon, such as in the infantry branch where there are about 36 to 41 Soldiers. In war-related hemorrhage situations, after Soldiers provide self-care to their own wounds or buddy care to the wounds of another Soldier, later casualty caregiving is typically by the assigned military medic before possible transportation of the casualty to a higher level of care, such as a hospital. In casualties, the body segment most often in need of tourniquet use is the thigh; the thigh often requires side-by-side strap-and-stick tourniquet use because the thigh's girth is often too much for a single strap-and-stick tourniquet's narrow width.[13,16] Because wide straps will not wind well within the windlass, which has an aperture for the strap, strap-and-windlass designs are limited to a narrow width. Pneumatic tourniquet designs, however, are not width limited and, therefore, may be used singly on a thigh.[13,14,26] In these ways, the medic's skill sets and clinical requirements differ substantially from those of common Soldiers; medic skills and requirements match well with pneumatic tourniquets, and further consideration of allowing doctrinal use of pneumatic tourniquets by medics is ongoing.

Limitations of the present study are rooted in its design as a laboratory experiment. The study is of a simulation, not actual care. The preliminary nature of the investigation does not allow for broad conclusions but only narrow findings of focused interest.

Future directions for further study include investigation among other people more representative of the intended user set, field assessments instead of laboratory assessments, and a detailed analysis to complement the current preliminary analysis.

In summary, all four models of tourniquet performed equally well in the present study for both the critical outcome of effectiveness and the important outcome of pulse stoppage distal to the tourniquet. Secondary outcomes (time, pressure, and blood loss) differed by tourniquet model, and the EMT had the best performance for every type of measurement.

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Disclaimer

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Disclosures

The authors declare no conflicts of interest.

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See related In Brief article, "Preliminary Measures of Instructor Learning in Teaching Junctional Tourniquet Users" by Kragh et al. on page 13.