Performance Evaluation of the Solo-T and the Combat Application Tourniquet in a Perfused Cadaver Model

George J. Holinga, PhD1*; John S. Foor, MD, FACS, RPVI2; Steven L. Van Horn3; James E. McGuire, BS4

ABSTRACT

Purpose: We evaluated a 10.2-cm-wide, minimally elastic, adhesive wrap-based tourniquet (Solo-T or ST) alongside a 3.8-cm-wide windlass-based tourniquet (Combat Application Tourniquet Generation 7, or CAT) to determine if the tension wrap-tightened ST could deliver hemorrhage control equivalent to the windlass-tightened CAT. Methods: A cadaver model was used to simulate lower-thigh femoral arterial hemorrhage at “normal” (146 ± 5 mmHg) and “elevated” (471 ± 3 mmHg) perfusion pressures (mean ± standard error). Three study participants used the ST and CAT to control hemorrhage during 48 timed trials. Arterial occlusion was established by Doppler ultrasound and tourniquet performance was quantified by under-tourniquet pressure cuffs. Results: Participants achieved 100% (24/24) occlusion success rates and reported similar ease of use for both tourniquets. Occlusion and application times (mean ± standard error) were similar (p > .05) for the ST and CAT under “normal” (occlusion, ST: 25 ± 2 seconds, CAT: 22 ± 2 seconds; application, ST: 27 ± 2 seconds, CAT: 26 ± 2 seconds) and “elevated” (occlusion, ST: 24 ± 7 seconds, CAT: 24 ± 7 seconds; application, ST: 25 ± 7 seconds, CAT: 25 ± 7 seconds) perfusion alike. The ST mean completion pressures (mean ± standard error) were >40% lower than the CAT under both “normal” perfusion (ST: 110 ± 20 mmHg; CAT: 210 ± 30 mmHg; p = 0.009) and “elevated” perfusion (ST: 190 ± 50 mmHg; CAT: 340 ± 30 mmHg; p = 0.03). Conclusion: The adhesive wrap-based ST tourniquet delivered equivalent hemorrhage control performance at significantly lower completion pressures than the CAT.

Keywords: first aid; hemorrhage control; perfused cadaver; tourniquet; tourniquet pressure; trauma care

Introduction

Over the past few decades, a significant body of research has emerged demonstrating that the tourniquet is one of the most fundamental and important tools available for delivering life-saving prehospital treatment following traumatic injury.1-4 These findings have led to substantial progress in awareness, first-aid protocols, and emergency preparedness surrounding trauma-associated hemorrhage control in both military and civilian populations.5-12 Consequently, the military community has reported significant benefit from its sustained efforts to educate and train servicemembers to apply tourniquets to battlefield casualties when medically appropriate.13,14 Evidence of an analogous patient benefit from tourniquet education and use amongst the civilian community has also begun to emerge.5,6 Nonetheless, some ambivalence about tourniquets has remained in the civilian medical community. This ambivalence is often attributed to concerns about risk of permanent damage to nerves and soft tissue in treated limbs.

There is a broad range of emergency tourniquet designs which have been commercialized for use in the pre-clinical treatment of life-threatening limb hemorrhage.7 One of the most common emergency tourniquet designs utilizes an inelastic, flexible strap which is looped around the limb and then tightened with a mechanical advantage system such as a windlass or rachet that permits shortening of the strap’s looped circumference.14-17 Another common design is the Esmarch-style tourniquet which typically utilizes a highly elastic strap, tube, or band which is stretched and tightly wrapped around a limb multiple times under tension before being secured by tucking or tying off the free end.18-20 The adhesive wrap-based tourniquet design shares some similarities with Esmarch-type devices, yet it differs most notably in being constructed of a tape-like, polymer material with minimal elasticity, an adhesive coating on its inner surface, and a limited-stick, release coating on its outer surface. When applied, the adhesive wrap tourniquet is repeatedly wound around a limb under tension in a process resembling that of the Esmarch tourniquet. However, the bonding interaction between the adhesive- and release coated-surfaces of the adhesive wrap tourniquet functions to circumferentially self-secure it around the limb during application, while permitting subsequent unwinding, adjustment, and re-securement. As a result, the end of the adhesive wrap tourniquet is not required to be tied or tucked at the conclusion of the application process. Several additional emergency tourniquet designs beyond those briefly mentioned above have been developed and commercialized, but summary descriptions of these have been excluded from this report for brevity.13,21-24

The purpose of this study was to evaluate the performance of the Solo-T (ST; Entrotech Life Sciences Inc., San Francisco, CA, USA, www.entrotechlifesciences.com), an adhesive wrap-based tourniquet and the Combat Application Tourniquet Generation 7 (CAT; C•A•T Resources, LLC, Rock Hill, SC, USA, www.combattourniquet.com) a hook-and-loop strap, windlass-based tourniquet. A perfused human cadaver model was used to simulate a patient with serious limb hemorrhage.

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for comparison of hemorrhage control performance between the two tourniquet designs.

Methods

Study Setting

Study protocol approval was granted under a previously approved proposal submitted to the Wake Forest School of Medicine Institutional Review Board. This human tissue study was conducted at the Bowman Gray Center for Medical Education under the ethical oversight of the Wake Forest School of Medicine.

Perfused Cadaver Model

A standard, perfused human cadaver model was used in this study to simulate life-threatening, arterial limb hemorrhage in the research laboratory.\textsuperscript{25–27} The cadavers were never frozen, not embalmed, and were preserved in refrigerated storage. Four hours prior to study initiation, the cadavers were transferred into the laboratory theater to gradually warm to ambient temperature.\textsuperscript{21} The cadavers were each placed on a dissection table in a supine position, perfusion tubing was inserted and sewn into the abdominal aorta, and the lower extremities were subsequently prepared for independent, regional arterial perfusion of each leg using the Minneti method.\textsuperscript{25} A deep, 5–8-cm-long incision was made on the lower, posterior side of each thigh severing the femoral artery. Vascular clamps were used to restrict simulated hemorrhage to a single limb for each trial. The mid-thigh anatomical site was selected for tourniquet placement due to the expectation that it would generally require higher arterial occlusion pressures than a calf, bicep, or forearm site based on the combined findings of Graham et al. and Gordon et al.\textsuperscript{28,29} Each tourniquet was applied at the same, prespecified mid-thigh location for a given limb to allow for consistent data collection, and the mid-thigh application sites ranged between 33.0 and 35.5 cm in circumference. A summary of cadaver demographics is provided in Table 1.

A centrifugal pump and solenoid valve were serially connected and digitally controlled to produce a pulsing flow of blood analog solution which simulated circulatory function in a hemorrhaging patient.\textsuperscript{21,23,26} During the course of this study, the perfusion pump system was operated at two different settings to simulate both “normal” (146 ± 29mmHg; 40% pump power) and “elevated” (471 ± 8mmHg; 100% pump power) systolic pressures (mean ± standard deviation). A summary of the perfusion system details used in this study is provided in Table 2.

Study Design

Each tourniquet type was applied mid-thigh to a perfused cadaver limb and evaluated in single, alternating order until 20 trials had been conducted for each under “normal” perfusion parameters. The process was then repeated under “elevated” perfusion parameters for an additional four alternating trials of each tourniquet type resulting in a combined total of 48 trials. Trials were conducted on right side and left side anatomical sites at similar frequencies. Arterial occlusion was defined as the cessation of arterial fluid flow as determined by Doppler ultrasound auscultation.\textsuperscript{13,21} Occlusion time was defined as the time elapsed from the start of tourniquet application until arterial occlusion was achieved.\textsuperscript{27,30} Application time was defined as the occlusion time plus the subsequent time elapsed during the final tourniquet securement steps until hands-free, completed application was achieved.\textsuperscript{13,27,30} Success for a given trial was defined as the achievement of both cessation of arterial flow and the completion of tourniquet application in < 4 minutes.\textsuperscript{27} Ease of use and applied tourniquet pressure were recorded at the time of application completion for each trial.\textsuperscript{30,31}

Tourniquet Users

A total of three persons applied the tourniquets individually. The study participants were, in order, a civilian-vascular surgeon, a retired Navy SEAL, and a civilian-scientist. The tourniquet users were males between the ages of 35 and 60. None of the users had any previous training or experience applying the ST. The retired Navy SEAL had previous training and field experience applying the CAT, while the other participants had no previous training or experience applying the CAT. One day prior to the laboratory portion of the study, participants were issued two units of each tourniquet along with a copy of the application instructions from the manufacturer of each. Application instructions for the CAT are available at the manufacturer’s website, and the application instructions provided on the ST product packaging are presented in Figure 1. Participants were instructed to self-train on the application of each tourniquet prior to arrival at the laboratory the next day. Throughout the laboratory portion of the study, all tourniquets

### TABLE 1 Cadaver Demographics

<table>
<thead>
<tr>
<th>Cadaver 1</th>
<th>Sex (M/F)</th>
<th>Ethnicity</th>
<th>Age, y*</th>
<th>Height, cm*</th>
<th>Weight, kg*</th>
<th>BMI*</th>
<th>Mid-Thigh Circumference, cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadaver 1</td>
<td>M</td>
<td>W</td>
<td>70</td>
<td>176</td>
<td>64</td>
<td>20.7</td>
<td>33.9 (R), 33.0 (L)</td>
</tr>
<tr>
<td>Cadaver 2</td>
<td>M</td>
<td>W</td>
<td>65</td>
<td>183</td>
<td>70</td>
<td>20.9</td>
<td>35.5 (R), 35.3 (L)</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
<td>67.5</td>
<td>179.5</td>
<td>67</td>
<td>20.8</td>
<td>34.4</td>
</tr>
</tbody>
</table>

BMI = body mass index, F = female, L = left thigh, M = male; R = right thigh, W = white.
*Values are approximate.

### TABLE 2 Perfusion System Details

<table>
<thead>
<tr>
<th>Perfusion Pressure</th>
<th>Peak Pulsate Pressure, mmHg (Med, Min, Max)</th>
<th>Perfusion Pump Power</th>
<th>Pulsed Flow Interval, bpm</th>
<th>Flow Rate, mL/min</th>
<th>Blood Analog Density, g/mL</th>
<th>Blood Analog Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Normal”</td>
<td>146 ± 5 (143, 115, 279)</td>
<td>40%</td>
<td>80</td>
<td>63</td>
<td>1.33</td>
<td>Water, Red Food Dye, Confectioners’ Sugar</td>
</tr>
<tr>
<td>“Elevated”</td>
<td>471 ± 3 (469, 463, 484)</td>
<td>100%</td>
<td>80</td>
<td>195</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

bpm = beats per minute, max = maximum, med = median, min = minimum, SE = standard error.
were applied in accordance with the manufacturers’ published instructions, and each user applied both tourniquet types in equal numbers and for a total of fourteen or more consecutive trials. Additionally, each user applied tourniquets on a minimum of two different cadaver limbs.

**Data Collection**

Independent laboratory support staff were responsible for determining when arterial occlusion was successfully achieved during all trials to eliminate risk of investigator bias. Specifically, perfusate flow through the femoral artery was monitored by a licensed ultrasound technician using arterial Doppler pulse signal (color Doppler ultrasound model Venue Go R2 with 9L probe, GE Healthcare, www.gehealthcare.com).

A given trial was begun when the tourniquet user announced “start,” at which time application was initiated while a laboratory assistant concurrently activated a stopwatch to allow for determination of occlusion and application times.17,32 Once the ultrasound technician made their determination that arterial occlusion was achieved, they declared “occlusion” to simultaneously notify the laboratory assistant to record the occlusion time and to notify the tourniquet user that it was acceptable to begin the securement/completion stage of the application process. As soon as the user finished the application process and was hands-free, they announced “complete” or “stop” to notify the laboratory assistant to record the application completion time. Lastly, the user assessed and self-reported tourniquet ease of use at the completion of each trial by recording their response to the statement “The tourniquet was easy to use,” using a 5-point Likert scale ranging from “0 – strongly disagree” to “4 – strongly agree” in a manner similar to other tourniquet studies.20,27,30

Applied pressure was measured under each tourniquet immediately following completed application using a pair of #1 neonatal blood pressure cuffs (A-XT-04W(1), APK Technology Co., www.apk-technology.com) in an experimental configuration similar to that reported by Wall et al. in 2015.31 The neonatal blood pressure cuffs were inflated to 20mmHg above atmospheric pressure to establish a baseline, and then each was independently connected to a 5-V DC pressure transducer prior to being taped to medial and lateral locations on the mid-thigh at the site of subsequent tourniquet placement. Pressure readings from the cuffs were automatically measured and recorded every 0.067 seconds for the duration of each tourniquet trial. Both the investigators and laboratory support staff were effectively “blinded” from the ability to perceive differences in applied pressure between tourniquet trials in the laboratory. This was due to the non-linear transducer signal of the multi-sensor measurement system. After data collection, the measured pressure from the two cuffs was averaged for each trial to correct for potential data variation due to alignment of the tourniquet relative to the cuffs. Upon completion of the trials, the facility support staff used a calibrated, adult pressure cuff to secure one neonatal cuff around the outer surface of a rigid cylinder. The adult cuff was then repeatedly inflated from 0–280mmHg in 0.8mmHg increments while neonatal cuff pressure readings were recorded. The resulting data was used to construct a fifth-order, polynomial calibration curve for the neonatal cuffs and pressure transducer readings collected during the tourniquet trials.

**Tourniquets Evaluated**

The two commercial emergency tourniquets evaluated in this study were the CAT, Ref. No. C-A-TGEN7, Lots: 200A190 and 200E570 and the ST, Ref. No. 2021KB, Lot: 20K1030 as shown in Figure 2. The CAT was selected for this study as it is one of the non-pneumatic tourniquets classified as “recommended” by the Committee on Tactical Combat Casualty Care (CoTCCC) for use by the United States Armed Forces, thus making it well suited as the control tourniquet in a comparative performance study alongside the ST.13

**FIGURE 2** Emergency tourniquets tested.

The CAT includes a 3.8-cm-wide by 95.3-cm-long hook and loop strap looped around a limb and threaded through a routing buckle to adjust initial fit at the beginning of the application process. Next, the tourniquet strap is tightened to the desired level of limb compression by twisting a windlass rod. This rod serves to shorten the strap circumference with each additional degree of rotation. The windlass rod of the tightened CAT is then secured using an integrated locking windlass clip which allows for hands-free hemorrhage control. Post-application, the CAT is adjusted by first unfastening the tightening rod from the integrated windlass clip and subsequently rotating the windlass rod. Once the desired compression is achieved, the rod is then refastened within the rod clip at the nearest reengagement opportunity.

The ST consists of a 10.2-cm-wide by 396-cm-long, self-wound, polymer adhesive wrap with minimal elasticity and limited stretch. The wrap includes a pressure sensitive, acrylic adhesive coating on its inner surface and a limited-stick, release coating on its outer surface. The release coating on ST’s...
outer surface and the adhesive coating on its inner surface physically interact in a way that allows the wrap to be repeatedly adhered to and de-bonded from itself. During application, the ST is tightly wound around a limb two or more times in an application process similar to the placement of an Esmarch tourniquet. Next, the ST is tightened to the desired level of limb compression by application of additional wraps while under user-applied, pull tension. Once hands-free hemorrhage control is achieved, any remaining unused length of the adhesive self-secured ST can be left intact or removed if desired. Post-application, the ST is adjusted by peeling back the free end from the limb and unwinding a portion of the wrap before rewinding it around the limb under modified tension until the desired compression is achieved.

**Statistical Analysis**

The mean, standard deviation, and standard error for each performance metric as well as the calibration curve for pressure transducer readings were calculated using Microsoft Excel for Microsoft 365 (Microsoft Corporation, Redmond, WA, USA). Additional statistical computations were performed using the permute R package (version 0.1.0, https://github.com/statlab/permute) and the R language and environment for statistical computing and graphics (version 4.0.5, www.r-project.org). For each tourniquet performance metric, evidence for the null hypothesis of no difference in means between the two devices was assessed against an alternative hypothesis of (non-directional) inequality. A difference-in-means test statistic (two-sample t-statistic with pooled variance) was used to examine performance metrics between the two tourniquets, with a permutation test used to generate a null distribution by shuffling the tourniquet identities 10,000 times while stratifying over tourniquet types and are reported in Table 4.

**Results**

**Time to Achieve Arterial Occlusion**

Success rates for achieving arterial occlusion were identical for the CAT and ST tourniquets at both the “normal” and “elevated” arterial perfusion pressure regimens used. As summarized in Table 3, the mean time to achieve arterial occlusion was similar between the two tourniquet types for both sets of perfusion parameters.

**Time to Complete Tourniquet Application**

The mean time required to complete tourniquet application was nearly identical between the CAT and ST under “normal” and “elevated” perfusion pressures as presented in Table 3. Ease-of-use scores across all trials were similar for both tourniquet types and are reported in Table 4.

**TABLE 4 Tourniquet Ease-of-Use Scores**

<table>
<thead>
<tr>
<th>Scoring Response to Statement, “Tourniquet was easy to apply.”</th>
<th>ST</th>
<th>CAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 - Strongly agree</td>
<td>17 (71%)</td>
<td>19 (79%)</td>
</tr>
<tr>
<td>3 - Somewhat agree</td>
<td>6 (25%)</td>
<td>3 (13%)</td>
</tr>
<tr>
<td>2 - Neutral</td>
<td>1 (4%)</td>
<td>2 (8%)</td>
</tr>
<tr>
<td>1 - Somewhat disagree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0 - Strongly disagree</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Pooled self-reported user scores from each tourniquet trial.

**Tourniquet Completion Pressure**

As shown in Table 3, the mean tourniquet pressure immediately following completed application was found to be > 40% lower for the ST than for the CAT under both “normal” and “elevated” arterial perfusion pressures with statistical significance (p < .05). It should be noted that a positioning error which compromised the collection of pressure readings from both cuffs was discovered and corrected by an independent member of the laboratory support staff prior to the eighth tourniquet trial conducted at “normal” perfusion pump pressures. As a result, tourniquet pressure measurements obtained during the first four CAT trials and the first three ST trials under “normal” perfusion parameters were excluded from the data analysis described herein and presented in Table 3. The pressure sensor issue did not impact or result in the exclusion of any other experimental data points collected during the first seven tourniquet trials.

**Discussion**

**Tourniquet Completion Pressures**

The most significant finding of this laboratory study was that the 10.2 cm wide, minimally elastic, adhesive wrap–based ST can provide rapid and effective hemorrhage control performance at tourniquet application completion pressures substantially lower than the 3.8-cm-wide, windlass-based CAT. While other studies of the ST have not been published to-date, previous studies of the CAT conducted on healthy, adult human volunteers and which used similar pressure monitoring systems reported mid-thigh, tourniquet completion pressures that corroborate the CAT completion pressures measured in this cadaver study. As a result, our research finding has significant patient safety implications since a leading concern surrounding the use of tourniquets is the risk of permanent nerve and soft tissue damage resulting from high, sustained

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**TABLE 3 Tourniquet Performance**

<table>
<thead>
<tr>
<th>Tourniquet</th>
<th>ST</th>
<th>CAT</th>
<th>ST</th>
<th>CAT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>146 ± 29mmHg Perfusion</td>
<td>471 ± 3mmHg Perfusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success (n %)</td>
<td>20 (100)</td>
<td>20 (100)</td>
<td>4 (100)</td>
<td>4 (100)</td>
</tr>
<tr>
<td>Time to achieve occlusion, s</td>
<td>25 ± 2</td>
<td>22 ± 2</td>
<td>p = .23</td>
<td>24 ± 7</td>
</tr>
<tr>
<td>Mean ± SE</td>
<td>22, 15, 51</td>
<td>20, 13, 37</td>
<td></td>
<td>23, 10, 40</td>
</tr>
<tr>
<td>Time to complete application, s</td>
<td>27 ± 2</td>
<td>26 ± 2</td>
<td>p = .56</td>
<td>25 ± 7</td>
</tr>
<tr>
<td>Mean ± SE</td>
<td>23, 16, 52</td>
<td>22, 16, 42</td>
<td></td>
<td>24, 11, 41</td>
</tr>
<tr>
<td>Pressure at completion, mmHg</td>
<td>110 ± 20</td>
<td>210 ± 30</td>
<td>p = .009</td>
<td>190 ± 50</td>
</tr>
<tr>
<td>Mean ± SE</td>
<td>77, 31, 315</td>
<td>188, 44, 420</td>
<td></td>
<td>207, 51, 309</td>
</tr>
</tbody>
</table>

SE = standard error
compressive forces on the treated limb.\textsuperscript{34} The general consensus amongst a majority of leading trauma researchers is that the benefits of prehospital tourniquet use far outweigh the risks of tourniquet-associated sequelae.\textsuperscript{2,5,6,31} Nonetheless, decreasing the risk of those sequelae is desirable for improving patient outcomes. The finding that the 10.2-cm-wide, minimally elastic, adhesive wrap–based ST can deliver quick, effective arterial occlusion with completion pressures lower than the windlass-based CAT addresses an important concern associated with emergency–use tourniquets.

While the 10.2-cm-wide ST was found to deliver mid-thigh tourniquet completion pressures lower than the 3.8-cm-wide CAT, the data from this study do not provide direct evidence about the origin(s) of this phenomenon. The characterization of the relationship between tourniquet width and delivered limb compression, occlusion pressure, tissue pressure profile, and other parameters has been an active area of research for many years.\textsuperscript{15,28,33,36,37} Some progress has been made in this area through the use of pneumatic tourniquet pressure data, but a mathematical relationship which accurately predicts occlusion pressures for nonpneumatic designs remains elusive.\textsuperscript{28,37} For example, a study by Wall et al. reported a 3.8-cm-width, nonelastic strap, rachet-based tourniquet achieving completion pressures similar to a 10.2-cm-width, elastic, wrap-based tourniquet in certain cases, while the 3.8-cm-wide, nonelastic strap CAT generally achieved occlusion at higher pressures.\textsuperscript{35} Therefore, attributing the observed differences between ST and CAT completion pressures specifically to their differing widths without additional supporting data is inadvisable. This is because these two tourniquets also differ meaningfully in their structure and composition as well as how each is tightened and secured.

**Tourniquet Application and Human Use Factors**

Despite substantial differences between the design, composition, and application process for the ST and CAT, it is important to note that no statistically significant differences were observed in their times to occlusion and completion or in their ease–of–use ratings. This finding suggests that the adhesive wrap–based design of the ST does not negatively impact its ability to efficiently deliver hands–free hemorrhage control relative to the CAT.

While the physical design of a tourniquet can provide a lower limit for the time and number of steps required for it to be effectively deployed, human factors such as intuitiveness of design, ease of handling, and the complexity of each application and adjustment step can critically influence how efficiently a tourniquet delivers hemostasis for a real–world user. This aspect of tourniquet use was highlighted by Baruch et al., who reported that a user’s ability to effectively apply a tourniquet to a mannequin limb model can be impacted by the user’s level of understanding of a specific tourniquet’s mechanism of action.\textsuperscript{38} While the CAT and several similar, windlass-based tourniquets have been widely used for many years, the same cannot be said of the minimally elastic, adhesive wrap–based ST tourniquet. Therefore, while the ST somewhat resembles an Esmarch tourniquet, experienced tourniquet users who are unfamiliar with the ST would be expected to require practice to achieve occlusion times, application speeds, and success rates at parity with more familiar tourniquets.

**Implications of ST Findings in Context of Wrap–Based Tourniquets**

The findings of this study demonstrate the functional feasibility of the minimally elastic, wrap–based ST tourniquet design. While both ST and Esmarch tourniquets are tightened around a limb by successive circumferential wraps while stretched under pull–tension, there are important differences between these devices. Beyond the presence of an adhesive and release coating on its opposing surfaces, the ST most notably differs from the Esmarch tourniquet in that it is minimally elastic. This structural difference is important as a study on canines of a 8.5-cm-wide, shape–stabilized pneumatic cuff and an 8-cm-wide Esmarch tourniquet reported that the tissue pressure profile decreases from the midpoint outward to the edges of a tourniquet, but to a substantially greater extent in the Esmarch device.\textsuperscript{39} Furthermore, the Esmarch tourniquet was observed to show pressure concentration at the center of the limb, and such a pressure concentration is expected to increase risk of tourniquet–associated tissue damage. Thus, while a wider, elastic wrap might be presumed to present a lower risk of tissue injury than a narrower non–elastic tourniquet, this may not be the case. The laboratory validation of the ST suggests the feasibility of future studies investigating the local tissue pressure profiles of similarly sized, minimally elastic and elastic wrap–based tourniquets. Such studies may provide a better understanding of the complex interplay between the width and elasticity of tourniquets and their resulting capacity to safely distribute pressure while delivering arterial occlusion.

**Limitations**

The mid–thigh tourniquet application site was selected based on the expectation that it would require greater pressures to achieve arterial occlusion than an alternate site of smaller limb circumference, and thus the mid–thigh was also expected to allow for greater experimental resolution of any differences in occlusion pressures, and by extension, completion pressures. However, the pressure required for a given tourniquet to achieve occlusion is known to be impacted not only by tourniquet configuration and limb circumference, but also by hemorrhage location, muscle tension, arterial depth, and other anatomical characteristics which were not explored in this study.\textsuperscript{15,28,33,40} Thus, it is unknown if an analogous difference would be observed between the completion pressures of the CAT and ST if the study were repeated at another limb site.

This study was conducted in a controlled laboratory setting on perfused cadavers with similar demographics and not on living patients. While the CAT and ST were applied at an appropriate, limb extremity site in a process similar to how each might be used on live patients, differences remain between the cardiovascular output and tissue response of a living patient compared with that of a perfused cadaver. As a result, a future study of the pressure required for the CAT and ST to deliver arterial occlusion in the limbs of healthy human volunteers would provide valuable context for the findings reported herein.

While the experimental protocol for this study was designed to simulate the emergency treatment of serious arterial hemorrhage, it nonetheless did not fully replicate the real–world conditions in which a tourniquet is typically used. As previously noted, the efficacy of a tourniquet is a function of both its inherent operational capabilities as well as user–related factors such as intuitiveness of design, complexity of application, and ease of adjustment. Therefore, a focused investigation of
how human use aspects of the CAT and ST impact the field performance of both tourniquets when used by a larger and more diverse cohort of users may yield critical insights about the generalizability this study’s findings.

Conclusion
In this study, the adhesive wrap–based ST delivered hemorrhage control at high success rates, rapid application and occlusion times, and with ease-of-use scores similar to the windlass-based CAT, yet at 40% lower completion pressures thus significantly reducing a leading risk factor for tourniquet-associated limb injury. This finding warrants further investigation as it suggests that minimally elastic, wrap-tightened designs may be a safer alternative to windlass-tightened tourniquets.

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Financial Disclosures
GJH, SVH, and JEM are employees of Entrotech Life Sciences Inc. JSF is a financially compensated consultant of Entrotech Life Sciences Inc.

Author Contributions
All authors conceived of the study concept. JEM obtained funding. JSF oversaw the study. GJH, SVH, and JEM participated in the study and collected data. GJH designed, coordinated, and managed the study, analyzed results, and wrote the manuscript. All authors approved the final manuscript.

References


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