

# A comparison of efficacy, efficiency, and durability in novel tourniquet designs

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<b>BACKGROUND:</b>	Exsanguination due to extremity hemorrhage is a major cause of preventable traumatic deaths. Extremity tourniquet use has been shown to be safe and improve survival. The purpose of this study was to compare the efficacy, efficiency, and durability of the Generation 7 Combat Application Tourniquet (CAT; North American Rescue, Greer, SC), the Tactical Mechanical Tourniquet (TMT; Combat Medical Systems, Harrisburg, NC), and the SOF Tactical Tourniquet—Wide (SOFTT-W; Tactical Medical Solutions, Anderson, SC).
<b>METHODS:</b>	This study was a three-phase randomized, cross-over trial. In successive trials, subjects were timed during the application of each tourniquet to the upper and lower extremity. Following successful lower extremity application, subjects low crawled 25 ft and then were dragged 25 ft, after which effectiveness was reassessed, as defined by the cessation of distal pulses by Doppler ultrasound.
<b>RESULTS:</b>	In arm application, both the CAT and TMT had significantly less failure rates than the SOFTT-W (5.56%, 19.44%, 58.33%), with the CAT being the fastest tourniquet when compared with TMT and SOFTT-W (37.8 seconds, 65.01 seconds, 63.07 seconds). In leg application, the CAT had significantly less rates of failure when compared with the SOFTT-W, but there was no other significant difference between the tourniquets (27.78%, 44.44%, 61.11%). In addition, the CAT was significantly faster than both the TMT and SOFTT-W when applied to the leg (8.33 seconds, 40.96 seconds, 34.5 seconds). There was no significant difference in tourniquet failure rates between the three tourniquets after subject maneuvers in phase 3 (34.29%, 42.86%, 45.45%).
<b>DISCUSSION:</b>	The CAT is as effective as the TMT and significantly more effective than the SOFTT-W. In addition, the CAT demonstrated shorter application times than either the TMT or SOFTT-W. However, there was no significant difference between the three tourniquets in their ability to maintain pulselessness after subject maneuvers. ( <i>J Trauma Acute Care Surg.</i> 2021;91: S139–S145. Copyright © 2021 Wolters Kluwer Health, Inc. All rights reserved.)
<b>LEVEL OF EVIDENCE:</b>	Care management, level II.
<b>KEY WORDS:</b>	Tourniquet; extremity hemorrhage; durability.

One of the leading causes of battlefield deaths is exsanguination due to extremity hemorrhage.<sup>1</sup> Since the 1600s, tourniquets have been applied quickly at the point of injury to decrease this risk, with mixed results.<sup>2</sup> However, in the last two decades of conflict during Operation Enduring Freedom and Operation Iraqi Freedom, multiple generations of tourniquets have been approved by the Committee of Trauma Combat Casualty Care (CoTCCC).<sup>3</sup> There is a preponderance of evidence validating both their safety and efficacy in reducing mortality in extremity trauma.<sup>4–8</sup> Thus, tourniquet use has become increasingly more widespread both on the battlefield and in the civilian sector.

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Among the current CoTCCC-approved tourniquets are the Generation 7 Combat Application Tourniquet (CAT) (North American Rescue, Greer, SC), the Tactical Mechanical Tourniquet (TMT) (Combat Medical Systems, Harrisburg, NC), and the SOF Tactical Tourniquet—Wide (SOFTT-W) (Tactical Medical Solutions, Anderson, SC) (Fig. 1).<sup>3</sup> Both the CAT and SOFTT-W underwent major recent design changes from prior generations that were approved by CoTCCC. The CAT was modified to incorporate a single routing buckle and thicker windlass.<sup>9</sup> Meanwhile, the SOFTT-W underwent changes to include an increased strap width, the removal of a windlass D-ring and locking screw, and the addition of a tourniquet retention assistance clip (TRAC). Finally, the TMT is a newer tourniquet and differs from the previous two tourniquets by the addition of a dual locking mechanism if the velcro fails. While there are studies that have compared the CAT and SOFTT-W<sup>10,11</sup> and the CAT and TMT,<sup>12,13</sup> there is no study to date that directly compares the efficacy and efficiency of these three popular tourniquets. In addition, there are limited data evaluating the tourniquet durability and the ability to maintain vascular occlusion during patient movement.

The primary outcome of this study is to compare the CAT, SOFTT-W, and TMT tourniquets in three key areas: efficacy in achieving pulselessness, speed of application, and maintenance of pulselessness during patient maneuvers. The secondary



**Figure 1.** (A) Generation 7 CAT (North American Rescue); (B) TMT (Combat Medical Systems); and (C) SOFTT-W (Tactical Medical Solutions).

outcome of this study evaluates subject preference for the individual tourniquets.

## PATIENTS AND METHODS

This study was conducted under the provisions of DOD Instruction 3216.2 (Protection of 136 Human Subjects in DOD

Supported Research), SECNAVINST 3900.39D (Protection of Human Subjects), 32 CFR Part 219 (Protection of Human Subjects), NAVMEDCENPTSVAINST 6710.10E (Use of Investigational Agents in Human Beings), and the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" at the Naval Medical Center Portsmouth. All activities were approved by the Naval Medical Center Portsmouth Institutional Review Board (protocol number, NMCP.2018.0081) before commencement of subject recruiting and data collection. All subjects were uncompensated volunteers who freely gave informed consent. No research-related procedures were performed before informed written consent was obtained.

All 36 subjects were active-duty Navy Corpsmen capable of low crawling and dragging other subjects. Exclusion criteria included a history of diabetes, hypertension, venous thromboembolism, coronary or peripheral arterial disease, active extremity infection, or extremity surgery in the past 6 weeks.

The study design is a randomized, self-controlled, cross-over trial performed in three phases. Subjects were given a pre-event survey to assess their baseline clinical experience, in addition to their prior use, training, and degree of confidence in each tourniquet. The subjects were then shown instructional videos on all three tourniquets and allowed to physically interact and manipulate each type of tourniquet. Pulses were identified and marked using a Doppler device on each subject's dominant radial artery and right dorsalis pedis or posterior tibial artery.

Each subject was given a new tourniquet before the start of data collection. In phase 1, subjects were timed while single-handedly applying prelooped tourniquets to their dominant arm using their nondominant hand. Successful application was defined by the elimination of Doppler signal of the radial pulse. In phase 2, subjects were timed while placing self-routed tourniquets to the right proximal thigh with two hands. The presence or absence of pulse by Doppler was again recorded. In phase 3, subjects wore a plate carrier and were given three untimed attempts with each tourniquet to establish pulselessness on the right proximal thigh. If achieved, subjects then low crawled 25 ft and were then dragged in a supine position by their plate carrier 25 ft back to the starting point. Their pulse was then again checked by Doppler. For each tourniquet, if the subjects were unable to achieve pulselessness after three tries during phase 3, they did not proceed to the low crawl, and it was considered a failure. Each participant used their individually assigned tourniquets (CAT, SOFTT-W, and TMT) in all three phases. After data collection, the subjects completed a postevent survey evaluating tourniquet preference for each phase using a Likert scale, as well as overall tourniquet preference.

For the primary outcomes, tourniquet efficacy was graded in a binary fashion based on the elimination of the premarked Doppler pulse. Tourniquet efficiency was measured by total elapsed time from start of tourniquet application until the subject believed that pulselessness had been achieved or they could no longer tolerate the tourniquet secondary to pain. Tourniquet durability was also graded in a binary fashion, based on the ability to maintain elimination of the lower extremity pulse after subject maneuvers. The order of tourniquet use for each phase of the study was randomized using a Latin table for each respective subject number.

Sample size was determined by tests based on power using G\*Power software.<sup>14</sup> Assuming an effect size of 0.50 SDs ( $d = .50$ ) to detect a clinically relevant difference between tourniquet application times, statistically significant results would be realized on 80% of opportunities (power, 0.80) with as few as 33 participants in this counterbalanced design. Therefore, to endure adequate power, 36 participants were included. All statistics and graphs were performed using GraphPad Prism 8 for Windows (GraphPad Software, San Diego, CA). One-way analysis of variance was used to compare continuous measures, followed by Tukey's multiple comparisons test. Kruskal-Wallis test was used for ranks, followed by Dunn's multiple comparison test.  $\chi^2$  Test was used for binary outcomes, followed by Fisher's exact test for pairwise comparisons with Bonferroni adjusted  $p$  values. Differences were assessed at the  $p < 0.05$  threshold for statistical significance.

## RESULTS

The mean clinical experience as an active-duty corpsman was 3.6 years (SD, +2.9 years), ranging from 0 to 14 years of experience. All subjects were Trauma Combat Casualty Care certified. Six (16.67%) of 36 had undergone live tissue training, 1 (2.78%)

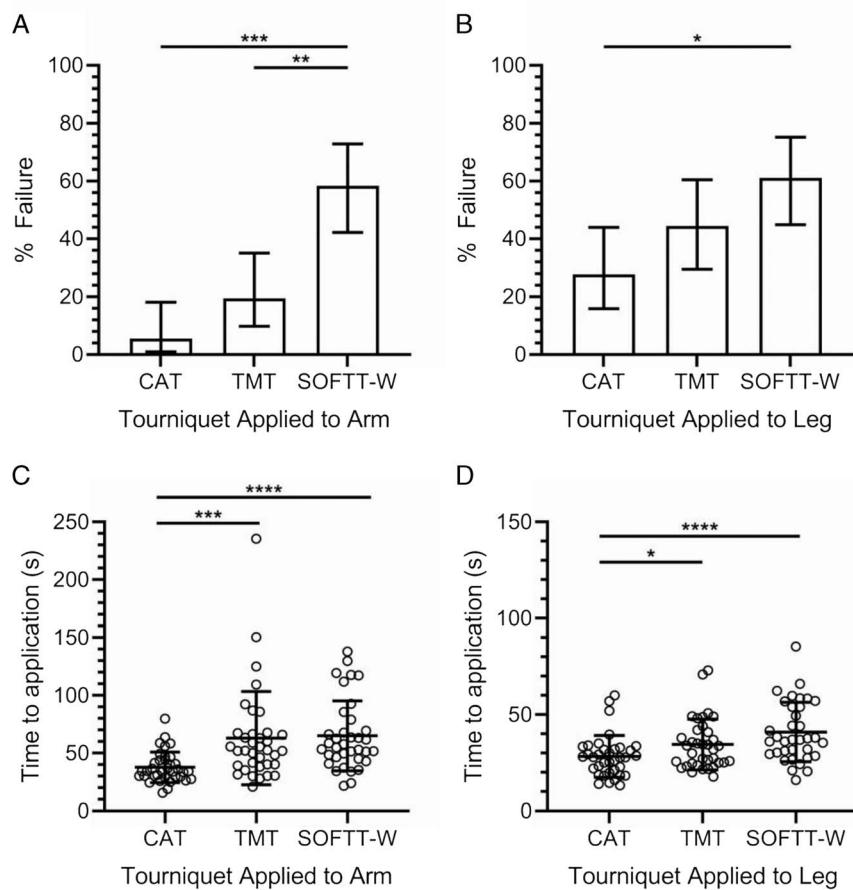
of 36 had deployed to a combat zone, and no subject had used a tourniquet to treat a casualty while on deployment.

### Efficacy

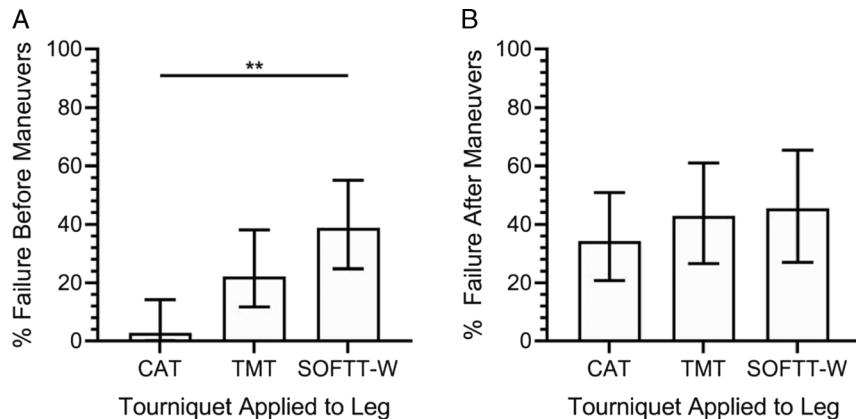
In application to the upper extremity, the CAT failed to achieve pulselessness at an average rate of 5.56% (95% confidence interval [CI], 0.99–18.41%), the TMT failed at an average rate of 19.44% (95% CI, 9.75–35.03%), and the SOFTT-W failed at an average rate of 58.33% (95% CI, 42.20–72.86%). There was a significant difference in rate of pulselessness between the CAT and SOFTT-W ( $p = 0.0003$ ) and between the TMT and SOFTT-W ( $p = 0.0045$ ) but not between the CAT and TMT ( $p = 0.1514$ ) (Fig. 2A).

In application to the lower extremity, the CAT failed to achieve pulselessness at an average rate of 27.78% (95% CI, 15.85–43.990%), the TMT failed at an average rate of 44.44% (95% CI, 29.54–60.42%), and the SOFTT-W failed at an average rate of 61.11% (95% CI, 44.86–75.22%). There was a significant difference in rate of pulselessness between the CAT and SOFTT-W ( $p = 0.0258$ ) but not between the CAT and TMT or the SOFTT-W and TMT (Fig. 2B).

When assessing durability, the CAT was unable to achieve pulselessness before maneuvers at an average rate of 2.78%



**Figure 2.** Efficacy and efficiency data for arm and leg application. (A) Time of application of tourniquet to upper extremity. (B) Time of application of tourniquet to lower extremity. (C) Percent failure rate of tourniquet application to upper extremity. (D) Percent failure rate of tourniquet application to lower extremity. Error bars for A and B represent 95% CIs; error bars for C and D represent SD. \* $p < 0.05$ ; \*\* $p < 0.01$ ; \*\*\* $p < 0.001$ ; \*\*\*\* $p < 0.0001$ .



**Figure 3.** Durability and tourniquet failure rates. (A) Percent failure rate of tourniquet application to the leg before maneuvers. (B) Percent failure rate of tourniquet application to leg after maneuvers. Error bars represent 95% CIs. \*\* $p < 0.01$ .

(95% CI, 0.14–14.170%), the TMT was unable to achieve pulselessness before maneuvers at an average rate of 22.22% (95% CI, 11.72–38.080%), and the SOFTT-W was unable to achieve pulselessness before maneuvers at an average rate of 38.89% (95% CI, 24.78–55.14%). There was a significant difference between the CAT and SOFTT-W in efficacy before application ( $p = 0.0039$ ) (Fig. 3A).

### Efficiency

In phase 1, the mean application time of the CAT was 37.8 seconds; the SOFTT-W, 65.01 seconds; and the TMT, 63.07 seconds. There was a significant difference in application time between the CAT and TMT ( $-25.28$  seconds [ $p = 0.0004$ ; 95% CI, -39.73 to -10.82 seconds]) and the CAT and SOFTT-W ( $-27.22$  seconds [ $p < 0.0001$ ; 95% CI, -40.49 to -13.94]) but not between the TMT and SOFTT-W ( $-1.94$  seconds [ $p = 0.9679$ ; 95% CI, -21.43 to 17.55]) (Fig. 2C).

In phase 2, mean application time of the CAT was 28.33 seconds, the SOFTT-W was 40.96 seconds, and the TMT was 34.5 seconds. There was a significant difference in application time between the CAT and TMT ( $-6.17$  seconds [ $p = 0.0175$ ; 95% CI, -11.39 to -0.95]) and the CAT and SOFTT-W ( $-12.64$  [ $p < 0.0001$ ; 95% CI, -18.93 to -6.34]) but not between the TMT and SOFTT-W ( $-6.46$  [ $p = 0.0594$ ; 95% CI, -13.14 to 0.2137]) (Fig. 2D).

### Durability

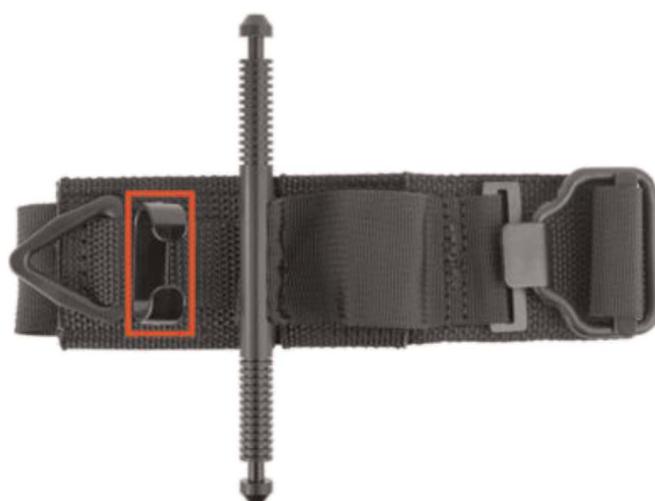
For those subjects who achieved initial pulselessness and underwent maneuvers, the CAT regained pulse at an average rate of 34.29% (95% CI, 20.83–50.85%), the TMT regained pulse at an average rate of 42.86% (95% CI, 26.5–60.92%), and the SOFTT-W regained pulse at an average rate of 45.45% (95% CI, 26.92–65.34%). There was no significant difference between the three tourniquets in failure rates after subject maneuvers ( $p = 0.6201$ ) (Fig. 3B).

During the course of data collection with the SOFTT-W, the TRAC (Fig. 4) experienced multiple episodes of breaking. Each time the TRAC broke, subjects were given a new SOFTT-W tourniquet with the start of a new phase. If the tourniquet broke in the middle of a phase, the phase was completed with the broken tourniquet, results were recorded, and the phase was not repeated. Of

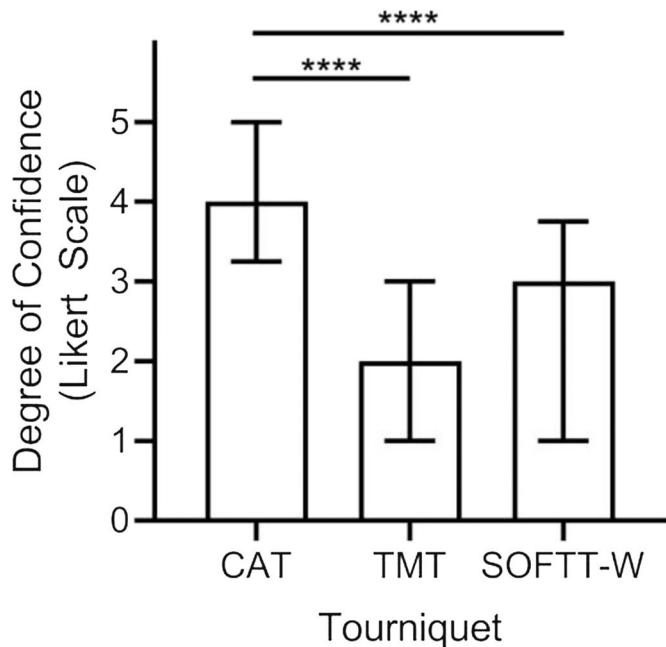
the total 45 SOFTT-W tourniquets used in the course of the study, the TRAC broke 16 times (35.56%). Six (37.5%) broke on the first use of the tourniquet, six (37.5%) broke on the second use, and four (25%) broke on the third use. In the times the TRAC broke, pulselessness was not achieved 63% of the time (10 of 16 subjects). No other tourniquets experienced mechanical failures or breakage, and no other component of the SOFTT-W experienced failure or breakage.

### Preevent and Postevent Surveys

In preevent surveys, each subject was asked about their degree of confidence in each tourniquet on a Likert scale ranging from 1 to 5 as least to most confidence in the ability of the tourniquet to achieve pulselessness. The median rank of the CAT, TMT, and SOFTT-W was 4 (interquartile range [IQR], 3.5–5), 2 (IQR, 1–3), and 3 (IQR, 1–3.75), respectively, showing a significant preference of the CAT tourniquet over the TMT or SOFTT-W ( $p < 0.0001$ ) but no significant difference in prestudy confidence between the TMT and SOFTT-W (Fig. 5).



**Figure 4.** Tourniquet retention assistance clip (red box) on the SOFTT-W.



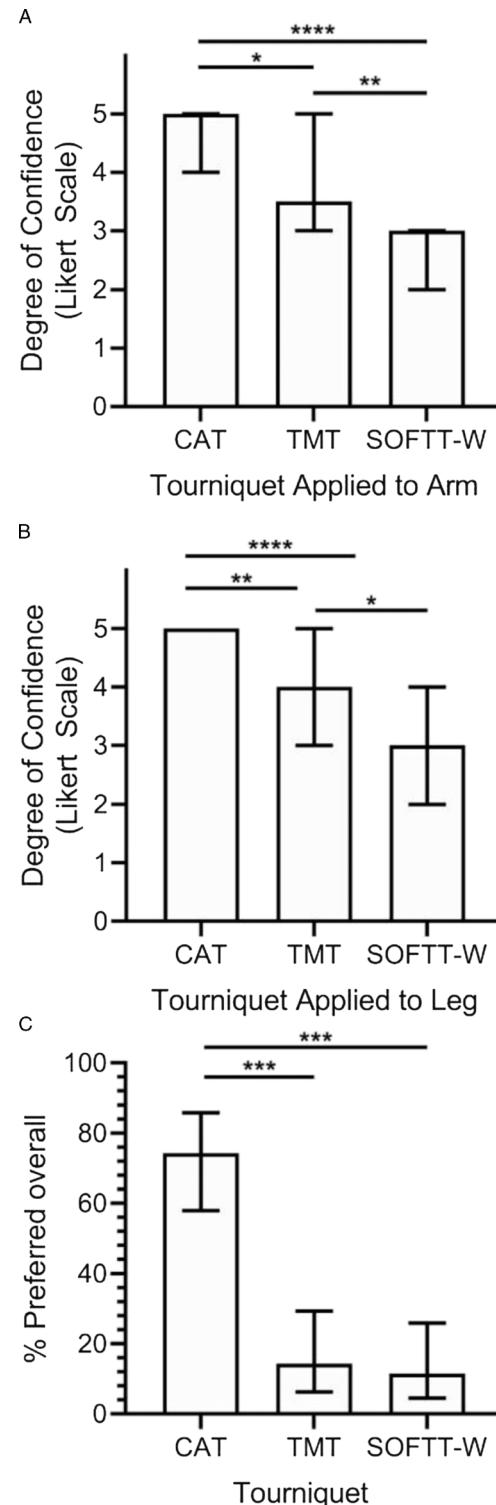
**Figure 5.** Preevent survey confidence. Error bars represent IQR.  
\*\*\*\* $p < 0.0001$ .

In postevent surveys, each subject was asked using a Likert scale from 1 to 5 about their degree of confidence in application of each tourniquet to the arm and leg, as well as their perception of tourniquet stability during the transport phase. In addition, each subject was asked which tourniquet they would most prefer to use. For arm application, the median confidence rankings of the CAT, TMT, and SOFTT-W were 5 (IQR, 4–5), 3.5 (IQR, 3–5), and 3 (IQR, 2–3), respectively. There was a significant difference between the CAT versus TMT ( $p = 0.0019$ ), the CAT versus SOFTT-W ( $p < 0.0001$ ), and the TMT versus SOFTT-W ( $p = 0.0054$ ) (Fig. 6A). For leg application, the median confidence rankings of the CAT, TMT, and SOFTT-W were 5 (IQR, 5–5), 3 (IQR, 2–4), and 4 (IQR, 3–5), respectively. There was a significant difference between the CAT compared with either the TMT ( $p = 0.0024$ ) or the SOFTT-W ( $p < 0.0001$ ) and between the TMT and SOFTT-W ( $p = 0.026$ ) (Fig. 6B).

The tourniquet that was the most preferred overall by subjects was the CAT tourniquet (74.30%), followed by the TMT (14.30%) and the SOFTT-W (11.42%). One subject failed to complete this section of the postevent survey. There was a significant difference in terms of overall preference when the CAT is compared with the TMT and SOFTT-W ( $p = 0.0003$ ) but not between the TMT and SOFTT-W (Fig. 6C).

## DISCUSSION

The use of tourniquets to control extremity hemorrhage has an interesting history, from what was once thought to be an extreme last-resort measure to what is now the first-line intervention to reduce mortality.<sup>1</sup> Operation Iraqi Freedom and Enduring Freedom have shown that prehospital tourniquet use reduced mortality in what remains a leading cause of battlefield deaths.<sup>4,6,7</sup> These findings led to increased use of tourniquets in the civilian



**Figure 6.** Postevent survey data. (A) Subject degree of confidence in tourniquet ability to successfully cause pulse cessation in arm application. (B) Subject degree of confidence in tourniquet ability to successfully cause pulse cessation in leg application. (C) Overall subject tourniquet preference. Error bars from graph A and B represent IQRs. Error bars in graph C represent 95% CIs. \* $p < 0.05$ ; \*\* $p < 0.01$ ; \*\*\* $p < 0.001$ ; \*\*\*\* $p < 0.0001$ .

sector, with similar results: decreased mortality, reduced need for transfusions, and low rates of tourniquet-related complications.<sup>2,5,8,15</sup> As tourniquet use has grown, so has the total number and different designs for tourniquet options. With the wide variety of tourniquets available for use today, it is important to provide head-to-head comparison in functionality between the tourniquets. For a tourniquet to be functional, it must be effective in establishing pulselessness, be efficient and quick to apply, and durable enough to maintain pulselessness during patient movements.

For effectiveness, in application to both the arm and leg, the CAT Generation 7 was equally as effective as the TMT but was significantly more effective in obtaining vascular occlusion than the SOFTT-W. For efficiency, the CAT was significantly faster in both the upper and lower extremity than the TMT or SOFTT-W, with no significant difference between the TMT or SOFTT-W. There was no statistically significant difference between the three tourniquets in regard to their durability defined by the ability to maintain pulselessness after subject maneuvers. However, the CAT failed 8% and 11.5% less often than the TMT and SOFTT-W in the durability phase, respectively. While this trends toward clinical significance, post hoc power analysis for durability failure rate shows a very small effect size of 0.072. Interestingly, the SOFTT-W experienced an unexpected outcome in that the TRAC experienced multiple episodes of breaking. The TRAC is one of the design additions to the SOFTT-W and is designed to aid in holding the windlass temporarily while the operator works to secure the windlass in the D-ring. There was no association between TRAC fracture and the number of times the tourniquet was used. In addition, it may have caused inability to achieve pulselessness in 63% of subjects. Neither the CAT nor TMT experienced mechanical failures during the study. The failure of the TRAC device has not been previously reported, but the high rates of breakage seen in this study are concerning. This finding warrants further evaluation of the tourniquet to ensure product safety and effectiveness for the patient.

The CAT was preferred by corpsmen before the study compared with either the TMT or SOFTT-W, but there was no difference in preference between the TMT and SOFTT-W. In the postevent survey, the preferred order of tourniquet for use on both the arm and leg was the CAT, TMT, and then SOFTT-W, by a significant factor. In addition, the CAT was the most preferred tourniquet overall by a significant margin. While there was a wide range of years of experience as a corpsman in our subject group, when compared as a subgroup to those corpsmen with <2 years of experience ( $n = 18$ ) with those with >2 years of experience, there was no difference in efficacy in either the arm or leg tourniquet application.

There were some limitations with the study. The involved tourniquets in this study are marketed and sold as single use but were used multiple times by the subjects. This may have reduced their durability by the time the subjects reached phase 3. In addition, per the preevent survey, subjects were most familiar and had the highest level of confidence in the CAT. As seen by Kragh et al.,<sup>16</sup> the subject's increased prior familiarity with the CAT may have impacted the positive results seen with the CAT. Future studies evaluating tourniquets may focus on evaluating subjects who have not had prior tourniquet training to remove any confounding variables. Also, the subjects were not blinded to their own results of achieving pulselessness, which may have

added a psychological factor in their repeated attempts as they progressed through the study. Finally, subjects did not have any visual feedback if they had achieved pulselessness (e.g., bleeding cessation), and it is thought that the incentive to fully achieve pulselessness in the battlefield on a hemorrhaging extremity is greater than in laboratory conditions.

In conclusion, this study found that in a comparison of the CAT, TMT, and SOFTT-W, the CAT was as efficacious as the TMT but outperformed the SOFTT-W. In addition, the CAT tourniquet was the most efficient and most preferred tourniquet. Finally, there was no statistically significant difference in durability between the three tourniquets in their ability to maintain pulselessness during subject maneuvers.

#### AUTHORSHIP

C.T. is primary investigator and contributed in the study design, data collection, statistical analysis, and article development. T.L. is associate investigator and contributed in the data collection, and article development. S.M. is associate investigator and contributed in the data collection, statistical analysis, and article development. B.K. contributed in the study design, protocol development, and article development. M. Boboc is an associate investigator and contributed in the data collection and article development. M. Bohan is an associate investigator and contributed in the data collection, and article development. C.G. is an associate investigator and contributed in the protocol development, data collection, and article development. E.F. contributed in the statistical analysis and article development. S.S. contributed in the data collection, statistical analysis, and article development.

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#### DISCLOSURE

The authors declare no conflicts of interest.

The views expressed in this article reflect the results of research conducted by the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

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