New and Established Models of Limb Tourniquet Compared in Simulated First Aid

John F. Kragh Jr, MD1*; Nicola J. Newton2; Andy R. Tan2; James K. Aden 3d, PhD2; Michael A. Dubick, PhD4

ABSTRACT

Background: The performance of a new tourniquet model was compared with that of an established model in simulated first aid. Methods: Four users applied the Combat Application Tourniquet (C-A-T), an established model that served as the control tourniquet, and the new SAM Extremity Tourniquet (SXT) model, which was the study tourniquet. Results: The performance of the C-A-T was better than that of the SXT for seven measured parameters versus two, respectively; metrics were statistically tied 12 times. The degree of difference, when present, was often small. For pretime, a period of uncontrolled bleeding from the start to a time point when the tourniquet first contacts the manikin, the bleeding rate was uncontrolled at approximately 10.4 mL/s, and for an overall average of 39 seconds of pretime, 406 mL of blood loss was calculated. The mean time to determination of bleeding control (± standard deviation [SD]) was 66 seconds (SXT, 70 ± 30 seconds; C-A-T, 62 ± 18 seconds; p = .0075). The mean ease-of-use score was 4 (indicating easy) on a scale of 1 to 5, with 5 indicating very easy (mean ± SD: SXT, 4 ± 1; C-A-T, 5 ± 0; p < .0001). C-A-T also performed better for total trial time, manikin damage, blood loss rate, pressure, and composite score. SXT was better for pretime and unwrap time. All users intuitively self-selected the speed at which they applied the tourniquets and that speed was similar in all of the required steps. However, by time segments, one user went slowest in each segment while the other three generally went faster. Conclusions: In simulated first aid with tourniquets, better results generally were seen with the C-A-T than with the SXT in terms of performance metrics. However, the degree of difference, when present, was often small.

Keywords: tourniquet; manual skill; psychomotor performance; first aid device comparison/education/standards; hemorrhage/prevention and control

Introduction

First aid in emergencies may include limb tourniquet use to stop bleeding.1–3 In 2005, the emphasis was mainly on training deployed Servicemembers.4 However, subsequent to the publication of military reports, civilian use of tourniquets became more common overall albeit unevenly from place to place.5–7 In 2015, first-aid authorities upheld, in part, the following notions: (1) “the evidence supports the use of tourniquets in the civilian setting when standard first aid hemorrhage control (e.g., direct wound pressure) fails to control severe external limb bleeding”2 and (2) “[t]he task force strongly believes that education in first aid should be universal: everyone can and should learn first aid.”2,3 In line with these notions, the US Government, in 2015, integrated tourniquet use into public health policy4 so inventors and educators pivoted to focus on users such as law enforcement officers and civilian laypersons who had little training with tourniquets. Consequently, technology continued to evolve, and tourniquet studies since 2004 have shown that some models were both safe and effective.9,10 With later refinements in various tourniquets, some design features, such as rods and bands, have become popular, and such favored features have tended to become more similar over time among different models. For example, a wide band became a favored feature.10–12 In fact, developed commonality of favored features can occur as technologies converge. Since 2015, designed refinements have shifted to address practical traits like ease of use, whereas before 2003, safety and effectiveness were questioned and subsequently addressed.9,13,14 The purpose of the present study was to compare the performance of a new tourniquet model with that of an established model in simulated first aid.

Methods

This experiment was conducted within the protocol guidelines set forth at the Institute of Surgical Research in 2017. The design was a performance comparison between tourniquet models: An established model served as the control tourniquet and a new model was the study tourniquet (Figure 1).

Data grouping was by model. The established model was the Combat Application Tourniquet (C-A-T; generation 7; C-A-T Resources, www.combatourniquet.com). The new model was the SAM Extremity Tourniquet (SXT; SAM Medical Products, www.sammedical.com). Both were designed principally for easy use (Figure 2). For example, the C-A-T refinements from its prior version were not about safety or effectiveness but about making use easier.15 Similarly, the SXT design aimed to make steps such as slack removal easier.

Four persons used the tourniquets individually. All users were familiar with the C-A-T but not with the SXT. The four users were, in order, a clinician-scientist, an associate researcher,
and two military cadets. The scientist oriented users to the study procedures. First, the user unrouted the band, laid the tourniquet flat on the table, and went over the names and functions of the component with the scientist. Then the user reconfigured the tourniquet for one-handed use. The user followed written and video instructions for tourniquet use and for one or two uses on the manikin. After each use, the user unclipped the rod, peeled back the band, removed the tourniquet from manikin, pulled the tourniquet out to length, reset the SXT prongs, and reconfigured the tourniquet.

An assessor aided the users. The scientist was the assessor except when he was the user, and this was when the associate took the assessor role. The assessor started and ended tests, ran a stopwatch, and assessed performance. Users were to think out loud and the assessor was to be silent during tests.

Test order was randomized by model. Each of the four users performed 20 tests of each of the two models, for a total of 160 tests. Tourniquets were stowed in a first aid kit laid on a table (Figure 3). The kit had the model to be tested, a pair of gloves (acrylonitrile; Halyard Health, http://www.halyardhealth.com/solutions/infection-prevention/medical-exam-gloves.aspx), a marker pen, and a roll of 1-in cloth tape (Durapore; 3M, https://www.3m.com). To simulate caregiving, the user wore safety glasses, and stood two steps and faced away from the table until the assessor said, “Start.” The user turned, stepped to the table, decided to use a tourniquet, unzipped the kit, grasped and donned examination gloves, unwrapped the tourniquet, unrouted the band by removing it from its course through the buckle, and applied the tourniquet to the manikin. The user could troubleshoot problems. After the user judged the test as completed satisfactorily, including securing the rod and recording the time of day, the user said, “Done.” The assessor pressed the button to stop the manikin and test.

The manikin was previously described. Briefly, a HapMed Leg Tourniquet Trainer (CHI Systems, http://www.chisystems.com) simulated a limb amputation. The scenario included a single patient (large adult), standard first aid, placement 2–3 in above the wound, feedback off, and bleed-to-death time of 240 seconds.

The manikin measured total trial time and time to determination of bleeding control. The manikin determined patient status (bleeding, stable, or dead), trial status (go [satisfactory] or no go), tourniquet placement, pressure, and blood loss. The user judged ease of use, turn number, bleeding control (by visual inspection), and whether the distal pulse was stopped (yes or no by digital palpation). The assessor determined don time (start through donning gloves), unwrap time (grasp tourniquet to tourniquet placement), and checked whether the user assessed for bleeding control and pulse stoppage.

After each test, the assessor and user recorded data, noted findings, and then discussed problems, such as damage to a tourniquet or to the manikin, and user symptoms, such as tiredness.

Data were entered into a spreadsheet. From these data, the following were calculated: pretime (sum of don time and unwrap time), posttime (total trial time minus time to determination of bleeding control), and bleeding rate (blood loss volume divided by time to determination of bleeding control). Logic functions were made for effectiveness (patient status was marked as yes if stable or no if patient status was either bleeding or dead) and for composite score (sum of counts of satisfactory results among seven parameters: time to determination of bleeding control 120 seconds or less, go trial status, ease of use neutral or better [i.e., score 3, 4, or 5], no manikin damage, no user symptoms, and turn number fewer than four). Additional...
analysis was done for combinations of data by model to assess how robust the difference in performance was.

Descriptive statistics were used to portray results. Categorical data were analyzed by contingency tables, and likelihood ratios were calculated. Continuous data were summarized by mean, which was analyzed using analysis of variance (ANOVA) to see differences. Fixed-effect tests were made by tourniquet model. For pairwise comparisons of means, a nonparametric Wilcoxon method was used. Pairwise comparisons were then put into levels on the basis of statistical significance. A mixed-model ANOVA was used for analysis of the user as a random effect in that model. User effects were presented as a percentage of the overall variance component based on the restricted maximal likelihood variance method. $R^2$ is reported as the percentage of the response variable's variance that is explained by a linear model. Significance for results was established when values were $p < .05$. Statistical analyses were conducted with SAS software (JMP, version 12.0; SAS Institute; http://www.sas.com) and MS Excel 2003 (Microsoft; www.microsoft.com).

Results

Patient status ended in bleeding for three tests and as stable for 157 (effectiveness: SXT, $n = 78$; C-A-T, $n = 79$). The inter-model and inter-user differences were not statistically significant ($p = .6$, both).

Most tests ($n = 154$; 96%) had satisfactory results in a “go” status (SXT, $n = 78$; C-A-T, $n = 76$). Only user 3 had each trial receive “go” status, but differences among models and users were not significant ($p = .4$ and .9, respectively).

Tourniquet placement was always correct, with neither model nor user differences ($p = 1$, both). Bleeding control was assessed in 159 tests (SXT, $n = 79$; C-A-T, $n = 80$). Model and user differences were not significant ($p = .2$ and .4, respectively). Pulse stoppage was assessed in 157 tests (SXT, $n = 79$; C-A-T, $n = 78$). The two cadets forgot that assessment three times; however, model and user differences were not significant ($p = .6$ and .2, respectively).

Tourniquets were damaged in two tests of the SXT by user 4. Model and user differences were not significant ($p = .1$, both). Manikin damage occurred in 18 tests (SXT, $n = 15$; C-A-T, $n = 3$; $p = .002$). The scientist, user 1, detected 12 damages; user 3 detected 4 damages; user 2 detected 1 damage; user 4 did not detect any. Users noted glove damage in 14 tests (SXT: $n = 10$, tears were attributed to its rod; C-A-T: $n = 4$, tears were attributed to user errors). User 4 noted gloves catching on the SXT rod in seven other tests; no such instances were reported when using the C-A-T. The assessor even abraded the table with the SXT rod in another test. Users noted that the SXT rod, which was metal, rigid, and textured coarsely like a wood file, often abraded the wound, a hard plastic portion of the manikin. However, users noted the C-A-T rod (a composite of fiberglass and plastic, semi-rigid, and not coarsely textured) contacted and moved over the wound surface without causing damage. Furthermore, its rod could be lifted slightly to avoid contact altogether, and lifting was most needed at higher turn numbers. However, the SXT rod could not lift at higher turn numbers, because it sawed rigidly through the central fulcrum to drive the opposite tip of the rod down into the manikin skin, which blocked both tipping and lifting.

The mean glove-donning time (± standard deviation [SD]) was 23 seconds (SXT, 22 ± 3 seconds; C-A-T, 23 ± 6 seconds; $p = .733$). The analysis showed that 43% of the variance of results in time could be attributed to the users. Users were in two levels of significance by ANOVA, with users 1 and 3 being slow and users 2 and 4 being fast ($p < .0001$, four pairs).

The mean time to unwrap was 16 seconds (mean ± SD: SXT, 16 ± 4 seconds; C-A-T, $n = 17$ ± 4 seconds; $p = .0115$). Two reasons for a difference were recorded: (1) Approximately 20% of SXTs had no paper instructions for use (IFU), because the shipment was delivered so early in production, and C-A-T IFU was wedged between the clips to keep the IFU and tourniquet together. (2) If present, the SXT IFU often fell away when unwrapped, whereas the always-present C-A-T IFU, on occasion, were manually extracted from the clips. Users noted both reasons caused an intermodel difference in time. The analysis showed that 3% of the variance of results in unwrap time could be attributed to the users who were in one level of significance. Interestingly, one user recalled an SXT IFU falling away right after a test in which the assessor specifically observed and noted that it had been manually extracted from its wrapper.

The mean pretime was 39 seconds (mean ± SD: SXT, 38 ± 6 seconds; C-A-T, 40 ± 8 seconds; $p = .0166$). The analysis showed that 31% of the variance of results in pretime could be attributed to the users. Users were in two levels of significance, with users 1 and 3 being slow and users 2 and 4 being fast ($p < .0001$, four pairs). On average, 41% of pretime (16 of 39) was due to unwrapping and 59% (23 of 39) was due to glove donning.

The mean time to determination of bleeding control was 66 seconds (mean ± SD: SXT, 70 ± 30 seconds; C-A-T, 62 ± 18 seconds; $p = .0075$). The analysis showed that 44% of the variance of results in time could be attributed to the users. Users were in two levels, with users 1 and 2 being slow and users 3 and 4 being fast ($p < .0049$, six pairs).

The mean total trial time was 116 seconds (mean ± SD: SXT, 121 ± 43 seconds; C-A-T, 111 ± 26 seconds; $p = .0038$). The analysis showed that 67% of the variance of results in time could be attributed to the users. Users were in three levels, with users 1 and 2 being slowest and next to slowest, respectively, and users 3 and 4 being fast ($p < .0012$, six pairs).

The mean post-time was 51 seconds (mean ± SD: SXT, 51 ± 25 seconds; C-A-T, 50 ± 15 seconds; $p = .4883$). The analysis showed that 40% of the variance of results in time could be attributed to the users. Users 1 and 2 were slowest and next to slowest, respectively, and users 3 and 4 were fast ($p < .0028$, five pairs). SXT would have had a higher mean and lower variance and user 4 would have been slower if he had not forgotten to check bleeding control; as a result, that one test had no post-time.

The mean blood loss volume was 508mL (mean ± SD: SXT, 505mL ± 135mL; C-A-T 511mL ± 120mL; $p = .6219$). The analysis showed that 62% of the variance of results in blood
loss could be attributed to the users. Blood loss was highest in the tests performed by users 1 and 2 (most and next to most, respectively), and least in those performed by users 3 and 4 ($p < .0006$, five pairs).

The mean bleeding rate was 8.0mL/s (mean ± SD: SXT, 7.6mL/s ± 1.2mL/s; C-A-T, 8.5mL/s ± 1.0mL/s; $p = .0001$). The analysis showed that 5% of the variance of results in rate could be attributed to the users who were in one level of significance. Users noted that partial control of bleeding was achieved more quickly with the SXT than with the C-A-T, whereas with the C-A-T, full control was achieved more abruptly and quickly than with the SXT, and both facts cause the rates to diverge.

The mean tourniquet pressure was 331mmHg (mean ± SD: SXT, 320mmHg ± 102mmHg; C-A-T, 343mmHg ± 116mmHg; $p = .0024$). The analysis showed that 85% of the variance of results in pressure could be attributed to the users. Users were in two ANOVA levels, with users 1 and 2 being low and users 3 and 4 being high ($p < .0001$, four pairs). Users 1 and 2 had use of one manikin, and users 3 and 4 had use of another because the first broke between users 2 and 3, and it was replaced. The software for pressure determination had been redesigned in the second manikin. The mean pressure with the first manikin was 233mmHg, and with the second, 429mmHg. The difference could have been greater had not user 4 raced through his first test and forgot to check both bleeding control and pulse stoppage; that pressure was 101mmHg, the minimum by 112mmHg.

The mean number of rod turns was three (mean ± SD: SXT, 2.9 ± 1 turns; C-A-T, 3.1 ± 1; $p = .0663$). The analysis showed that 47% of the variance of results in number could be attributed to the users, who were in two levels by ANOVA: Users 1 and 2 had higher means in number of turns while users 3 and 4 had lower means ($p < .0001$, four pairs). For the first and second manikin, the mean number of turns was 3.5 and 2.5, respectively. However, the difference was zero between manikins for the mean difference between users (i.e., user 2 minus user 1 for manikin 1, and user 4 minus user 3 for manikin 2). Such results indicate a manikin effect.

The mean ease-of-use score was 4 on a scale of 1 to 5, with a higher score corresponding to easier use (mean ± SD: SXT, 4 ± 1; C-A-T 5 ± 0; $p < .0001$; Figure 4). The analysis showed that 27% of the variance of results in ease of use could be attributed to the users, who were in two levels. In ANOVA, one level contained user 1, with “very easy” mean scores, and the other three users’ with “easy” mean scores ($p < .0018$, three pairs).

The mean composite score was 7, with higher being better performance (mean ± standard error: SXT, 6 ± 0; C-A-T, 7 ± 0; $p < .0001$). The analysis showed that 30% of the variance of results in composite score could be attributed to the users, who by ANOVA were in two levels with users 1 and 2 in the low level and users 3 and 4 in the high level ($p < .0003$, four pairs). The mean difference between paired users (i.e., user 2 minus user 1 and user 4 minus user 3) between manikins was nearly zero and indicated, again, a manikin effect.

For composite analyses, the six performance metrics which were results of categorical data showed the C-A-T performing better (Tables 1–3). The five metrics which were composite results of continuous data generally showed the C-A-T performing better by a small degree. Metrics which were composites combining categorical and continuous data generally showed the C-A-T performing better. The intermodel difference in performance was robust, with the C-A-T generally performing better.

Discussion

The key finding of this study was that the performance in simulated first aid of an established model of limb tourniquet was better than that of a new model. The better results were general in that they applied to more performance metrics (i.e., the C-A-T outperformed the SXT on seven parameters vs two, respectively, and performances were tied for 12 metrics) and the degree of difference, when present, often was small. At summit of stakeholders, this type of unsurprising result was predicted by one of the authors as a trait of the tourniquet marketplace (Kragh J, oral communication, Tourniquet Working Group, Stafford, VA, March 23, 2010). The predictions then were that new models would likely be better than those manufactured before 2005 and would tend to perform similarly in laboratory assessments (as three had done at that point), and, in the long run, well-performing models may tend to share similar features, such as bands of adequate width. The marketplace changed, with the C-A-T becoming dominant in 2005.

Many people have learned how to use a tourniquet by training on the C-A-T, and many of them like and trust it. Meanwhile, many people have not learned how to use another model and, thus, have not come to prefer another model. Thus, changing preference today may tend to be unlikely or take time and effort. One user wrote regarding C-A-T: “I enjoy using the C-A-T so much more,” “C-A-T feels so natural to put on [and] take off,” and about SXT: “[it] is more difficult to remove,” and “[it] is more difficult to turn [the rod].”

All users made multiple notes describing SXT difficulties, like its propensity to tear gloves, the roughness of its rod, its particulate debris falling from its hook-and-loop material, and greater forces required to turn its rod. The quantitative results and user comments favored C-A-T in general. A study of a different design may test whether the degree of familiarity users have with different models affects their performance. Given the marketplace as changed today, the benchmark to decide among tourniquets is no longer limited to testing but includes actual caregiving.
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The first minor finding was a surprisingly large difference in blood loss due to donning gloves and unwrapping a tourniquet. For pretime, a period of uncontrolled bleeding, the bleeding rate was approximately 10.4 mL/second. Over an average of 39 seconds, loss was calculated to be 406 mL. Some educators consider such a volume as double the minimally important amount indicating tourniquet use in the first place, specifically, half of a 12-oz can of soda (6 oz [177 mL]).

The second minor finding was also surprising: All users made the same mistake in their implicit strategy applied both to the task of tourniquet use and each of its steps. Users spontaneously self-selected their own strategy. For example, three users raced through whether the aim was to minimize bleeding or to assess if the intervention controlled bleeding. Their strategy was “the race is to be to the swift.” To race through the step in assessment of whether the tourniquet worked felt too obvious to question. On the flipside, one user went slower to reduce errors, whether in carefully checking or in stopping the bleed. His strategy was “to be flawless.” In fact, both strategies were flawed, because the steps are evaluated differently than the task. This insight did not appear to us until we saw all the data analyzed, especially by segmenting times and blood losses. Although the task is an aggregate of its steps, for the first time, we knew that the steps can be evaluated independently.

### Table 1: Six Performance Metrics, Which Are Composite Results of Categorical Data

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<tr>
<th>Metric</th>
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<th>C</th>
<th>D</th>
<th>E</th>
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### Table 2: Five Performance Metrics, Which Are Composite Results of Continuous Data

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<tr>
<td>Metric component 3: Blood loss volume, mL</td>
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### Table 3: Five Metrics, Which Are Composite Combinations of Categorical and Continuous Data

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</table>

C-A-T, Combat Application Tourniquet; SXT, SAM Extremity Tourniquet.
but they vary in value for different steps. In a yin-yang balance, a tradeoff between thinking and speed occurred in this study, and user 3, a cadet, balanced it best. This surprising finding of user judgment reinforces a principle: Caregiving engines are human, and caregiving analyses have to account for that fact.

Preference as an aspect of performance is a tricky, evolving science, and there is little awareness of its subtleties in the operational health community. We have come a long way in improved understanding of first aid performance with tourniquet use since 2004. In 2004, safety and effectiveness of limb tourniquets were capability gaps, but these were achieved in 2005 among all tests of three models in a study that soon aided in widespread fielding of C-A-T to deploying Servicemembers. Later, tourniquet technology converged as models became even more alike and performed more similarly, which made it even harder to stratify performance. Performance and its assessment, such as by use of a metric, are linked, and if understanding of differential performance is important, then metric usefulness should be clear to judge assessments. For example, the bleeding rate we used is a mean and not as care-driven tourniquet systems for the far-forward setting. From before training to afterward with four junctional tourniquet models: 53% of users changed their preference.

The limitations of this study emerge from its design being based in simulation and not caregiving. The study informs a conversation about optimal models of tourniquets within the context of the marketplace to include human factors of users. The development of more complex methods of testing led to longer periods collecting data, more difficulties with equipment, and more errors, but the simulation rendered was more realistic. Future directions for scholarly work include refinements of model designs, glove damage as a metric, stepwise assessment of tasks, assessment of cognitive burdens among users, assessment of laypersons for public health relevance, and user preference studies.

Conclusion
Better results were obtained, in general, in simulated first aid with tourniquets when the established tourniquet model (C-A-T) was used, compared with the new model (SXT), as evident from better performance metrics. However, degree of difference, when present, often was small.

Funding
This project was funded by the US Army Medical Research and Materiel Command.

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Disclosure
The authors have indicated they have no financial relationships relevant to this article to disclose.

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