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Assessing the Current Generation of Tourniquets

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ABSTRACT

Introduction

Tourniquet application is an urgent life-saving procedure. Previous studies demonstrated several drawbacks in tourniquet design and application methods that limit their efficacy; among them, loose application of the device before windlass twisting is a main pitfall. A new generation of modern combat tourniquets was developed to overcome these pitfalls. The objective of this study was to assess the effectiveness of three new tourniquet designs: the CAT Generation 7 (CAT7), the SAM Extremity Tourniquet (SAM-XT), and the SOF Tactical Tourniquet Wide (SOFTT-W) as well as its correlation to the degree of slack.

Materials and Methods

The three tourniquet models were applied in a randomized sequence on a HapMed leg tourniquet trainer, simulating an above-the-knee traumatic amputation by 60 military medicine track cadets. Applied pressure, hemorrhage control status, time until the bleeding stopped, estimated blood volume loss, and slack were measured.

Results

The mean (±SD) pressure applied using the SAM-XT (186 mmHg ±63) or the CAT7 (175 mmHg ±79) was significantly higher compared to the pressure applied by the SOFTT-W (104 mmHg ±101, $P < 0.017$), with no significant difference between the first two ($P > 0.05$). Hemorrhage control rate was similar ($P > 0.05$) with SAM-XT (73.3%) and CAT7 (67.7%), and both were significantly better than the SOFTT-W (35%, $P < 0.017$). Slack was similar between CAT7 and SAM-XT (5.2 mm ± 3.4 vs. 5 mm ± 3.5, $P > 0.05$), yet significantly lower compared to the SOFTT-W (9 mm ± 5, $P < 0.017$). A strong negative correlation was found between slack and hemorrhage control rate (3.2 mm ± 1.5 mm in success vs. 10.5 mm ± 3.4 mm in failure, $P < 0.001$) and applied pressure (Pearson's correlation coefficient of −0.83, $P < 0.001$).

Conclusions

Both SAM-XT and CAT7 demonstrated a better pressure profile and hemorrhage control rate compared to SOFTT-W, with no significant difference between the two. The better outcome measures were strongly correlated to less slack.

INTRODUCTION

Among the potentially survivable injuries that occur on the battlefield, hemorrhage, as a result of trauma to the extremities, trunk or junctional areas, is a leading cause of mortality.[1] While tourniquets have been used to manage extremity injuries since ancient times,[2] their efficacy and safety profile was demonstrated in thorough studies only in recent years.[3–6] Extensive data-driven research and development led to a significant improvement in tourniquet design and application methodology, giving way to the introduction of modern tourniquets in the battlefield setting.[7] The vast majority of modern tourniquets have windlass and band mechanisms, with the potential for powerful tightening sufficient to control arterial bleeding even from amputation of the thigh.

One of the most commonly used tourniquets is the combat application tourniquet (CAT, Composite Resources, Rock Hill, SC, U.S.A.) which is the tourniquet of choice in the Israeli Defense Forces[8] and is widely distributed to soldiers in the U.S. Military.[9] While a prospective survey of casualties from the campaign in Iraq demonstrates a success rate of 79% with the CAT, the highest rate among all tourniquets,[10] a different study from the campaign in Afghanistan found that pulse distal to the occlusion was present in 83% of CAT applications, indicating only partial effectiveness.[11] Further studies emphasized the reasons for failed applications, indicating that a leading cause of failure was inappropriate pulling of the band prior to windlass twisting, resulting in a loose application of the tourniquet.[7,12–14] In a previous study, we demonstrated a better pressure profile and hemorrhage control rate with a

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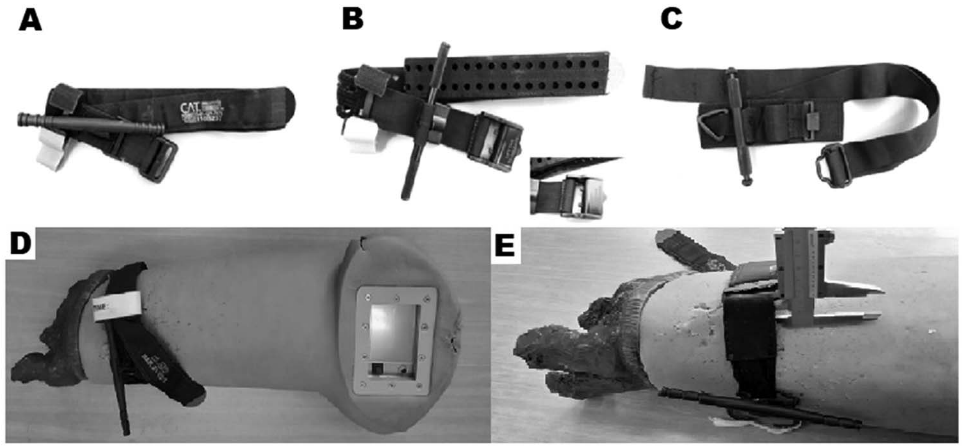

FIGURE 1. The Materials and Devices Used in This Study. A. CAT7 (CAT, C-A-T Resources LCC, Rock Hill, SC, U.S.A.) B. SAM-XT (SAM Medical Products, Wilsonville, OR, U.S.A.) C. SOFTT-W (Tactical Medical Solutions Inc, SC, U.S.A.) D. The HapMed Leg Tourniquet Trainer (CHI Systems, Fort Washington, PA) with a Correctly Placed Tourniquet E. Slack Measurement Method by Using a Caliper Measurement Device. In This Case, Demonstrating a Loosely Applied Tourniquet, With a Slack of 15 mm.

modified CAT designed to simplify slack reduction, compared to the "classical" CAT.[14] Additional factors contributing to tourniquet application failure were identified, among them are insufficient turns of the windlass, subcomponents built of feeble materials, and a too narrow strap.[4,7] Leading medical gear manufacturers designed the latest generation of tourniquets with these considerations in mind.

The present study is the first in the literature to compare the success rate of the novel tourniquet models in a validated simulation setting used in previous studies.[13–15] Furthermore, we focused on assessment of slack degree and its contribution to tourniquet application failure.

MATERIALS AND METHODS

Tested Tourniquets

The three tested tourniquets are based on a turning windlass mechanism for tightening (Fig. 1A–C). The CAT generation 7 (CAT7, C-A-T Resources LCC, Rock Hill, SC, U.S.A.) differs from its predecessors mainly by a more durable windlass rod and a single routing buckle to simplify application and allow better slack reduction. The main novelty in the SAM Extremity Tourniquet (SAM-XT, SAM Medical Products, Wilsonville, OR, U.S.A.) is a strap-featuring holes, which, along with the prongs on the buckle, create an auto-lock mechanism securing the strap in place when sufficient strap tension is achieved, allegedly reducing slack. The SOF Tactical Tourniquet Wide (SOFTT-W, Tactical Medical Solutions Inc, SC, U.S.A.) has a wider strap providing a broader compression pattern and a novel buckle with easier strap securing mechanism compared to the previous models.

The HapMed Manikin Model

The HapMed Leg Tourniquet Trainer (CHI Systems, Fort Washington, PA) is a commonly used manikin, simulating bleeding from an amputation-like injury of the right thigh, proximal to the knee (Fig. 1D). The manikin can collect performance measurements such as duration of application, applied pressure, blood loss volume, and hemorrhage control status. This model has been previously validated as the model of choice for tourniquets assessment in several trials.[13–15]

Study Protocol

The study was conducted in six nonconsecutive days. A different application order of the various tourniquet models was randomly assigned in each day, while the users assigned themselves to specific dates and times based on availability, without prior knowledge of the different application order.

Upon arrival, and following a brief explanation by an examiner, each user viewed a short standardized video demonstrating the placement of the tourniquet. Next, the user was positioned 3 meters from the HapMed Manikin and was given the same tourniquet as demonstrated in the video viewed earlier. The manikin was fixed to the floor, and the user was instructed to approach it and apply the tourniquet. Upon announcements of completion by the user, the examiner stopped the timer. Applications that took more than two and a half minutes to complete were stopped by the examiner. Performance measurements were collected at the end of every application from the electronic controller of the HapMed, including: applied pressure, time to complete application, estimated blood loss, and hemorrhage control status. Successful hemorrhage control was defined by the simulator as pressure greater than 200 mmHg. It should be noted that apart from it being the default threshold for this study, a pressure cutoff of greater than 200 mmHg is the accepted threshold commonly used in comparative studies.[14] Bleeding of more than 638 mL was set by the HapMed as the limit above which the application was considered as a failure. The extent of slack—defined as the maximal space between

TABLE I. Applied Pressure, Hemorrhage Control Rate, and Slack for Each of the Tourniquet Models. The Mean Pressure Applied Using the SAM-XT, or the CAT7 was Significantly Higher Compared to the Pressure Applied When Using the SOFTT-W ($P < 0.017$), With No Significant Difference Between the Two ($P > 0.05$). Similar Hemorrhage Control Rate was Noted ($P > 0.05$) with the SAM-XT and CAT7, Both Significantly Higher Than the Hemorrhage Control Rate Achieved With the SOFTT-W ($P < 0.017$). Slack was Similar Between CAT7 and SAM-XT ($P > 0.05$), and Significantly Lower Compared to Slack in Applications of the SOFTT-W ($P < 0.017$). . $P < 0.017$ Compared to the Other Devices

Tourniquet Model	Mean Applied Pressures ± SD (mmHg)	Hemorrhage Control (%)	Slack ± SD (mm)
CAT 7	175 ± 79	67.7	5.2 ± 3.4
SAM-XT	186 ± 63	73.3	5 ± 3.5
SOFTT-W	104 ± 101	35	9 ± 5

the band and the manikin measured by a standard caliper, after loosening the windlass—was collected manually by the examiner at the end of every application (Fig. 1E).

This same procedure was repeated two more times, using the other two tourniquets, in the order that was randomly assigned to the specific study day.

Users

Tourniquets were applied by a total of 60 users, men and women between the ages of 18 and 25 years, all cadets studying in the military medicine track of the Faculty of Medicine at the Hebrew University, Jerusalem. The users had little or no prior experience in emergency medicine in general nor in tourniquet application in particular. Those with minor experience, mostly consisting of basic first aid training as junior volunteers in Magen David Adom (Israeli National Emergency Medical Services) or a brief course during their army basic training, were included in the study. Overall, 22 users (36.67%) had minor prior experience, and 38 users (63.33%) had no first aid experience of any kind.

Statistical Analysis

The study sample size was calculated using the WINPEPI Program (Version 11.65, 2016, Brixton Health, Stone Mountain, Georgia), with the reference value of 18 mm of Hg as a clinically significant difference in pressure generated by the tourniquets and a standard deviation of 45 mm of Hg. This expected difference in pressure is based on the value observed in previous studies demonstrating a significant difference in hemorrhage control with these parameters.[14] The threshold of statistical significance was set at the standard definition of $P < 0.05$. The calculation of statistical significance was one-tailed and included three comparative analyses between each of the tourniquets, with statistical significance defined as $P < 0.017$ for any given comparative analysis according to the Bonferroni correction. Under these conditions, for the results to achieve a statistical power of over 80%, 60 tourniquet applications of each model were required.

The two-sample t-test was used for comparing quantitative variables between two independent groups. The repeated-measures ANOVA model was applied to assess the effect of the order of application of the tourniquets. This model was also applied to assess the differences between the three tourniquets while adjusting for a previous first-aid experience of some of the participants. For qualitative variables, the McNemar test of the P-value was applied for multiple pairwise comparisons. The Pearson correlation coefficient was calculated to estimate the strength of the association between two quantitative variables.

All tests applied were two-tailed, and a P-value of 5% or less was considered statistically significant, with the exception of the McNemar test wherein a P-value of 1.7% or less after the Bonferroni correction was considered significant.

RESULTS

Each of the three tourniquet models was applied one time by 60 different users. The mean (±SD) pressure applied using the SAM-XT (186 mmHg ±63) or the CAT7 (175 mmHg ±79) was significantly higher compared to the pressure applied when using the SOFTT-W (104 mmHg ±101, $P < 0.017$), with no significant difference between the two ($P > 0.05$) (Table I). A similar hemorrhage control rate was noted ($P > 0.05$) with the SAM-XT (73.3%) and the CAT7 (67.7%), and both were significantly higher than the hemorrhage control rate achieved with the SOFTT-W (35%, $P < 0.017$).

The differences in the time to stop the bleeding for CAT7 (72 s ± 29), SAM-XT (70 s ± 42) and SOFTT-W (82 s ± 33) were not significant ($P > 0.05$). The differences in the mean amount of blood loss for CAT7 (373 ml ± 152), SAM-XT (347 ml ± 111) and SOFTT-W (361 ml ± 151) were insignificant as well ($P > 0.05$). It is of importance to stress that due to simulator limitation, this analysis represents only successful applications. The order in which the various tourniquet models were applied had no significant influence on the measured performance parameters ($P > 0.05$ for all parameters).

Slack was similar between the CAT7 and SAM-XT (5.2 mm ± 3.4 vs. 5 mm ± 3.5, $P > 0.05$), with significantly lower slack in these two models compared to slack found in applications of the SOFTT-W (9 mm ± 5, $P < 0.017$). When assessing data from all tourniquet applications combined

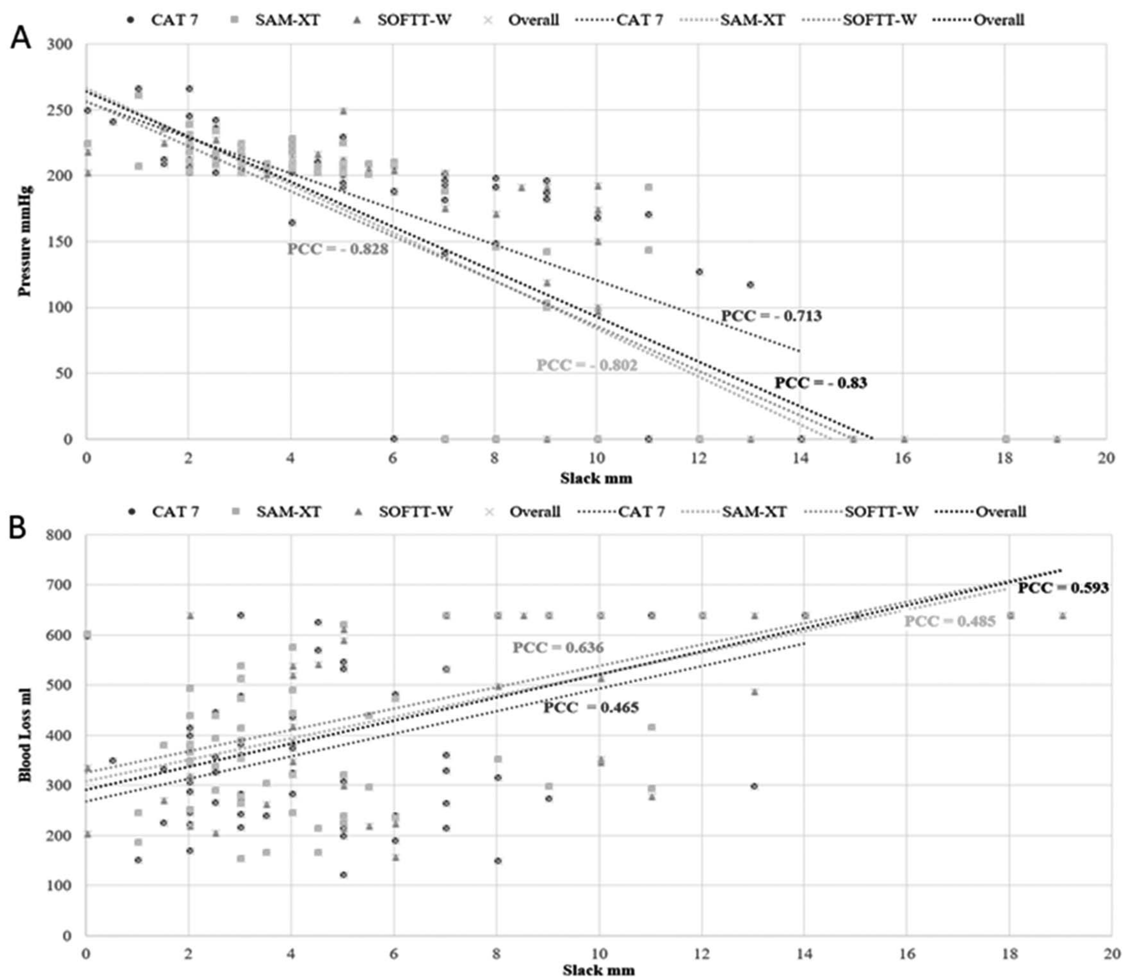

FIGURE 2. Correlation Between Slack and Pressure and Between Slack and Blood Loss. (A) Demonstration of the Correlation Between Slack (mm) and Pressure Applied (mmHg): PCC (Pearsons' Correlation Coefficient) of −0.83 Overall ($n = 180$), PCC of −0.731 for CAT7 ($n = 60$), PCC of −0.802 for SAM-XT ($n = 60$) and PCC of −0.8282 for SOFTT-W($n = 60$) ($P < 0.001$ for all results); (B) Demonstration of the Correlation Between Slack (mm) and Blood Loss (ml): PCC of 0.593 Overall ($n = 180$), PCC of 0.465 for CAT7 ($n = 60$), PCC of 0.484 for SAMXT ($n = 60$), and PCC of 0.635 for SOFTT-W ($n = 60$) ($P < 0.001$ for all results). PCC—Pearson Correlation Coefficient (r).

($n = 180$), analysis of the correlation between slack and other parameters measured in our study shows strong negative correlation between slack extent and hemorrhage control rate (3.2 mm ± 1.5 in success vs. 10.5 mm ± 3.4 in failure, $P < 0.001$) as well as between the slack and the amount of pressure applied (Pearson's correlation coefficient of −0.83, $P < 0.001$) (Fig. 2A). A positive correlation was found between the slack and the amount of blood loss (Pearson's correlation coefficient of 0.593, $P < 0.001$) (Fig. 2B). These correlation trends were analyzed separately for each tourniquet model and demonstrated the same trend for each model (Figs 2A and B).

When comparing the pressure applied and hemorrhage control rate for all tourniquets ($n = 180$), in a multivariable model adjusted for past experience and tourniquet type (Table II), we found significant difference in pressure applied (175 mmHg ±79 vs. 144 mmHg ±94, $P < 0.001$) and success rate (66.7% vs. 50.8%, $P = 0.049$), in favor of those who had a minimal past first aid experience compared to participants who had no prior experience. The difference was more pronounced with the CAT7 (206 mmHg ±25 vs. 174 mmHg ±75, $P = 0.02$) than with the other tourniquet models, which had not reached significance. The tourniquet type had no effect on the delta for neither pressure applied ($P = 0.99$) nor success rate ($P = 0.676$).

DISCUSSION

Tourniquets are essential life-saving devices to prehospital trauma care. Hemorrhage control relies heavily on application capabilities of first responders with minimal training and experience, rendering even minor tourniquet design flaws to inflict significant impact. Extensive research to improve tourniquets effectiveness has been conducted in recent years, leading to the development of a new generation of tourniquets. It was found that extensive slack is a substantial element in

TABLE II. The Effect of Experience on Mean Applied Pressure. For all Tourniquet Types, ($n = 180$), There Were Significant Differences for Pressures Applied ($P < 0.001$) and Success Rate ($P = 0.049$), in Favor of the Experienced Subgroup. In a Subgroup Analysis According to Tourniquet Device, the Differences in the Mean Applied Pressure Were Significant in Favor of the Experienced Subgroup for CAT7 ($P = 0.02$), But Not for SAM-XT ($P = 0.15$) or SOFTT-W ($P = 0.25$) There Was No Significant Difference in Hemorrhage Control Rates Between the Subgroups For Any of the Tourniquets ($P > 0.05$)

Tourniquet Model	Minimally Experienced Participants $n = 22$		Inexperienced Participants $n = 38$		Significance ($P < 0.05$ Required)	
	Mean Applied Pressure ± SD (mmHg)	Hemorrhage Control (%)	Mean Applied Pressure ± SD (mmHg)	Hemorrhage Control (%)	*P*-value for Pressure	*P*-value for Hemorrhage Control
CAT 7	206 ± 25	77.3	174 ± 74	52.6	$P = 0.02$	$P = 0.059$
SAM-XT	193 ± 66	77.3	169 ± 85	71.1	$P = 0.15$	$P = 0.6$
SOFTT-W	124 ± 101	45.6	92 ± 101	28.9	$P = 0.25$	$P = 0.2$
Overall	175 ± 79	66.7	144 ± 94	50.8	$P < 0.001$	$P = 0.049$

application failure, focusing the efforts to eliminate it. The present study is the first to compare application performance of several of the latest generation tourniquet, giving us impactful information for decision making and future research.

In this trial, we found significantly better hemorrhage control rate, a higher degree of pressure applied, and lesser extent of slack, in the SAM-XT and the CAT7 as compared with the SOFTT-W model. Differences between the resembling SAM-XT and the CAT7 were insignificant. There were no significant differences between the different models with regard to the extent of blood loss and the time needed to stop the bleed. This may be attributed to statistical limitations for this model: In order to properly apply the two-sample t-test for a triple crossover study, we had to limit ourselves to a comparison of the amount of blood loss and the time to stop the bleed strictly in cases in which participants successfully stopped the bleeding with all three tourniquet models. This was due to the fact that the maximum blood loss allowed by the manikin was 638 mL and therefore we could not compare different failed attempts for different thresholds with regard to this variable. Similarly, failed attempts at tourniquet application, including those that spanned longer than two and half minutes or that resulted in blood loss exceeding 638 mL, were halted, and therefore were not included in comparative assessment of the time variable. This was not the case for other variables such as "pressure" and "slack," which could be measured in gradation, regardless of success or failure. It should be noted that due to the relatively small number of participants with successful applications of all three models ($n = 11$, out of 60 participants in total), it was challenging to reach statistically significant results regarding these two parameters. As independent observers of the tourniquet's applications, we noticed that the SOFTT-W buckling mechanism was relatively cumbersome, which might explain its inferiority.

The link between the reduction of the slack and improved application was demonstrated in previous studies using an older generation CAT.[14] In the present study, we confirmed this finding through analysis of the current generation of tourniquets, designed, among other purposes, in a fashion aiming to reduce slack. Furthermore, our results demonstrated, as expected, a strong negative correlation between the slack and the success rate and pressure application, as well as a positive correlation to the amount of blood loss. This trend was consistent across all three tourniquet models, as can be seen in Figs 2A and B. It should be noted that excessive slack is not the only cause leading to failed application, and further studies to better define the weak spots of these tourniquets are needed.[4,7]

We conducted an analysis involving data from our previous study[14] in order to compare the older generation of the CAT model with the three new generation models. We found that the new generation CAT, the CAT7, achieved better hemorrhage control as compared to the older generation of CAT, though this finding was not statistically significant (58.6% hemorrhage control rate in the old CAT vs. 67.7% control rate in the new CAT7, $P > 0.05$). The new generation SAM-XT achieved better hemorrhage control rates than the old generation CAT, a finding which was statistically significant (73.3% hemorrhage control in the SAM-XT, $P < 0.05$). The SOFTT-W new generation model performed poorly, even compared to the older generation CAT, with a hemorrhage control rate of 35% ($P < 0.05$). While this study may indicate that some of the next-generation tourniquets are more efficient at hemorrhage control, further studies are necessary in order to compare the efficacy between older and newer generation tourniquets.

Previous studies demonstrated the significant influence of prior extensive experience on tourniquet application.[14] Our study design aimed to test the application of the current generation tourniquets by relatively novice participants, simulating an application by a common first responder. The study included participants without any experience or with minimal experience, equivalent to completing a basic first aid course. A multivariable model (Table II) that accounts both for experience and tourniquet type demonstrated that overall, for all tourniquets ($n = 180$), even a minimal past first aid experience had a positive influence on the pressure applied and the success rate. The influence of experience on tourniquet application was similar for the different tourniquet models. This finding suggests that none of the tourniquets had an advantage in simplifying the application compared to the other, allowing better results for novice users.

Several limitations of this study should be noted: The study was conducted on a simulation manikin in a sterile, nonhostile environment, and results might significantly differ in real life situations. As previous studies demonstrated that most tourniquets are applied by first responders with little experience,[16] in the present study, the tourniquets were applied only by users with no or little past first aid experience, and its conclusions cannot be implemented to more experienced users. It is of importance that in Israel, previous generations of the CAT are the most commonly used tourniquet model, probably making them more familiar to the experienced users. As discussed above, due to the HapMed model limitations, time-to-stop bleeding and blood-loss volumes were available only for successful applications, limiting their relevance.

CONCLUSION

Both the CAT7 and SAM-XT were found to be superior over the SOFTT-W, with no major difference between the CAT7 and SAM-XT. Comparison to previously reported results of older tourniquet model suggests a slight superiority of the newer devices. Slack reduction and even minimal previous experience were found to have an essential contribution to successful tourniquet application. We conclude that both advances in tourniquet engineering and adequate training play a role in tourniquet application, and that there is a room for additional research and further improvements in both areas. Additional studies with more diverse user population, participants' preferences and subjective inputs are needed to better define the advantages of the current generation of tourniquets and support further developments.

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