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IN BRIEF

Short Report Comparing Generation 6 Versus Prototype Generation 7 Combat Application Tourniquet® in a Manikin Hemorrhage Model

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ABSTRACT

Background: The Combat Application Tourniquet® (C-A-T) is the standard-issue military tourniquet used in first aid in 2015, and the current model is called Generation 6. Soldiers in the field, however, have been asking for design changes in a possible Generation 7 to improve ease of use. This study compared the differential performance in use of the C-A-T in two designs: Generation 6 (C-A-T 6) versus a prototype Generation 7 (C-A-T 7). **Methods:** A laboratory experiment was designed to test the performance of two tourniquet designs in hemorrhage control, ease of use, and user preference. Ten users of the two C-A-T models placed them on a manikin thigh to stop simulated bleeding. Users included trauma researchers and instructors of US Army student medics. Ten users conducted 20 tests (10 each of both designs). **Results:** Most results were not statistically significant in their difference by C-A-T design. The mean difference in blood loss was statistically significant ($p = .03$) in that the C-A-T 7 performed better than the C-A-T 6, but only in the mixed statistical model analysis of variance, which accounted for user effects. The difference in ease-of-use score was statistically significant ($p = .002$); the C-A-T 7 was easier. All users preferred the C-A-T 7. **Conclusion:** In each measure, the C-A-T Generation 7 prototype performed similar or better than Generation 6, was easier to use, and was preferred.

KEYWORDS: first aid; damage control; hemorrhage; shock; tourniquet; resuscitation

Introduction

Tourniquet use in first aid has become a public health policy of the United States. At the White House on 6 October 2015, the Administration launched a plan to provide bystanders of emergency situations with the tools and knowledge to stop life-threatening bleeding for all Americans, in a campaign called “Stop the Bleed.”¹⁻⁷ The Combat Application Tourniquet® (C-A-T; Composite

Resources; <http://combattourniquet.com>) is the standard-issue military tourniquet used in first aid in 2015. The C-A-T is in its sixth version, called Generation 6, as there have been five sets of refinements in its design over the past decade.^{8,9} C-A-T Generation 6 (C-A-T 6) has been bought worldwide over the past several years. However, Servicemembers in the field have been asking for design changes in the current Generation 6 to improve ease of use in a possible Generation 7 version (C-A-T 7).¹⁰ The purpose of the present study was to compare the differential performance in use of the C-A-T in two designs: C-A-T 6 versus a prototype C-A-T 7 (Figures 1 and 2).

Methods

This study was conducted under a protocol for a laboratory experiment designed to compare the function of tourniquets and was reviewed and approved by the Regulatory Compliance Division of the US Army Institute of Surgical Research. The experiment was designed to test the performance of two tourniquet designs in

Figure 1 Combat Application Tourniquet Generation 6 is a US military, standard-issue tourniquet. Photograph is used with permission of North American Rescue Products.



Figure 2 *Combat Application Tourniquet Generation 7 is a prototype in redesign of the prior Generation 6. The maker entered the prototype shown into production on 3 November 2015. Photograph is used with permission of North American Rescue Products.*



hemorrhage control, their ease of use, and the design preference of users. Ten users of the two C-A-T designs placed them on a manikin thigh to stop simulated bleeding. Ten users conducted 20 tests each. The overall number of tests performed for the experiment was 200 replicates. Data were collected in October 2015.

Users included four US Army instructors of medic students, the US Army master instructor of medics, a clinician-scientist with expertise in tourniquets, a tourniquet research associate, and three laboratory personnel with little to no experience with tourniquet use. The clinician-scientist and research associate also were the trainers and assessors. The trainer-assessors were present during practice and testing to answer questions or address problems such as in manikin use.

The control group was the C-A-T 6 tests, and the experimental group was the C-A-T 7 tests. Several design traits of C-A-T 6 were refined in the C-A-T 7 version (Table 1).

Users had familiarization training in use of the manikin. Training also included instruction in C-A-T use, familiarization with both C-A-T designs, handling both devices, and one or two practice uses for each tourniquet design on the manikin before testing began.

The tourniquets were tested on a laboratory manikin that was designed to train users by providing feedback on user performance. The investigators used a HapMed™ Leg Tourniquet Trainer (CHI Systems; http://www.chisystems.com/p_medicaltrain.html); a simulated right thigh with an above-knee amputation injury was the testing apparatus. A previous report detailed use of the manikin in assessing first aid performance.¹⁰

Table 1 *Design Contrasted for Combat Application Tourniquet Generation 6 and Generation 7*

Trait	Combat Application Tourniquet	
	Generation 6	Generation 7
Buckle	Buckle has two slits	Has one slit newly contoured to ease passage of the tip of the band
Routing	May be routed singly or doubly	Can only be routed singly
Windlass	Diameter is smaller; grip rings are concave	Midshaft diameter is wider; grip rings are convex
Plate	Leading edge is squared; plate is thinner	Leading edge is rounded; plate is thicker
Strap	Windlass clip strap is white	Windlass clip strap is gray
Windlass Clip	Windlass clip is thinner without buttressed sides	Windlass clip is thicker with buttressed sides

Briefly, effectiveness was determined by the cessation of blood loss (i.e., hemorrhage control). Iterations began with a tourniquet laid out flat and undone on the benchtop. Iterations ended when the user touched the touchpad button, assessing that the hemorrhage was stopped. Both designs had the self-adhering band routed singly through the buckle. Users tightened tourniquets until they perceived that simulated bleeding stopped or until a tourniquet broke. The casualty had a medium build and the setting was Care Under Fire, a setting resembling emergency care when under gunfire.

Ease of use was assessed by each user and self-reported using a Likert scale with a range of 5 numbers: 1: very difficult, 2: difficult, 3: neutral, 4: easy, and 5: very easy. Preference was self-assessed by users in answering the following question: If you had to go to war today, and you could only bring C-A-T tourniquets of only one type of model (either Generation 6 or Generation 7), which would you prefer: 6 or 7?

Descriptive statistics were used to portray results. A mixed-model analysis of variance (ANOVA) was planned if user effects were large. Categorical data (hemorrhage control in contingency tables) were analyzed with a χ^2 test, and the likelihood ratio p values were reported. For pairwise comparison of designs, a nonparametric Wilcoxon method was used. Significance for results was established when $p < .05$. All statistical analysis was conducted using SAS software (SAS Institute; <https://www.sas.com>) and MS Excel 2003 (Microsoft Corp.; <http://www.microsoft.com>).

Results

Comparison of Results by Tourniquet Design

The difference (C-A-T 7 minus C-A-T 6) in percentage of effectiveness in bleeding control by C-A-T design was not statistically significant (96% for C-A-T 6 versus 97% for C-A-T 7; $p = .7$). Similarly, the mean differences were not statistically significant in time to bleeding control determination (23 versus 22 seconds for C-A-T 6 and C-A-T 7, respectively; $p = .1$), in total time (32 versus 31 seconds for C-A-T 6 versus C-A-T 7, respectively; $p = .2$), and in pressure (205mmHg versus 205mmHg for C-A-T 6 versus C-A-T 7, respectively; $p = .9$). Only in the un-mixed statistical model was the difference in mean blood loss not statistically significant (141mL versus 129mL for C-A-T 6 versus C-A-T 7, respectively; $p = .05$). However, ease of use results differed. The difference in ease of use was statistically significant, favoring the C-A-T 7 ($p = .002$) (Table 2); most of the results (82%) for the C-A-T 6 were either neutral or easy (29% and 53%, respectively), whereas most of the results (74%) for the C-A-T 7 were either easy or very easy (41% and 33%, respectively).

Comparison of Results by User of Tourniquets

Results by user differed significantly ($p = .04$). When analyzing all users individually for mean differences in blood loss by C-A-T design, only one user had a statistically significant difference and this result favored the C-A-T 7 ($p = .003$; eight others, $p > .058$); nine differences were negative, and one was positive. When all data of the 10 users were pooled, the mean difference in blood loss by user remained statistically significant ($p = .02$), and this result favored the C-A-T 7. All users preferred the C-A-T 7 (10 of 10; 100%).

Comparison of Results in a Mixed Statistical Model

Due to the presence of significant user effects, a mixed statistical model also was used to analyze the data. This model determined that 42% of the variability of all results was attributable to user effects. Again, the differential performance by C-A-T design was not statistically significant ($p = .3$).

Similarly, time to bleeding control determination, total time, and pressure were not statistically significant ($p > .3$

for all). For time to determination of bleeding control, total time, pressure, and blood loss, the mixed statistical model determined that 42%, 45%, 5%, and 60%, respectively, of the variability of results was attributable to user effects showing the validity of the model with user effect.

The mean difference in blood loss was statistically significant (141mL versus 129mL for the C-A-T 6 and C-A-T 7, respectively; $p = .03$) in that there was less blood loss with the C-A-T 7 than the C-A-T 6, but only in the mixed statistical model ANOVA, which accounted for user effects.

Discussion

In the present study using a manikin, the two C-A-T designs showed differential performance favoring the C-A-T 7 over the C-A-T 6. The difference is accentuated by an unpublished analysis of two previous C-A-T 7 prototypes analyzed by the present investigators in December 2014, in which the two previous prototype designs did not result in superior performance over the C-A-T 6. The feedback from the 2014 assessment led to the rejection of the previous designs and to further spiral development of the C-A-T design to what was assessed in the present report.

Some differences in performance between the C-A-T 7 and C-A-T 6 were statistically significant. These were few, however, and the sizes were small; such results are common in design refinements of satisfactory but imperfect medical devices. There was no worse performance for C-A-T 7 by any parameter.

On the other hand, interuser differences were often large and affected outcomes; 42% of the variability of overall results was attributable to user effects. In specific examples, 42%, 45%, 5%, and 60% of the variability of performance results were attributable to user effects for time to determination of bleeding control, total time, pressure, and blood loss, respectively. Although the differences in means, such as for blood loss, were small for individual subjects researched, when applied to millions of Americans, such differences would become more important. Such is the distinction between care of an individual casualty and public health policy of a nation.

Table 2 Results of Ease of Use by Combat Application Tourniquet Design

Design	Ease-of-Use Score,* No. (%)					Total
	1 (very difficult)	2 (difficult)	3 (neutral)	4 (easy)	5 (very easy)	
C-A-T 6	1 (1)	5 (5)	29 (29)	53 (53)	12 (12)	100
C-A-T 7	0 (0)	9 (9)	17 (17)	41 (41)	33 (33)	100
Total	1	14	46	94	45	200

*Data represent 10 uses of each tourniquet by 10 users. C-A-T 6, Combat Application Tourniquet Generation 6; C-A-T 7, Combat Application Tourniquet Generation 7.

Altogether, the study findings are clear, consistent, coherent, and without an unexpected result. Findings are actionable now for (1) corporate discussion that may lead to a decision on production of the newly designed C-A-T 7, (2) committees (e.g., the Committee on Tactical Combat Casualty Care, which may consider review of the present new knowledge), and (3) master instructors, who may update lesson plans and instructions for use of the C-A-T 7, since the technique of use is now refined. The manufacturer of C-A-T 7 began production on 3 November 2015. Furthermore, the growing body of knowledge in the science of bleeding control continues to show that optimization of user performance is an important aim in improving current care; such user development stands shoulder-to-shoulder with materiel development as a current research priority. Such user development includes optimization of learning curves of individual students in attainment of skill, determination of strategies for maintenance of skill level for individuals or groups of individuals, and analysis of instructor assessments of student performance.

The limitations of the present study are based in its design as a focused experiment, which is neither field testing nor healthcare delivery. There were only 10 users, only two designs, only 10 tests per design, and assessment was on a manikin and not on a real person.

Conclusion

In summary, in each measure C-A-T Generation 7 performed similar or better than C-A-T Generation 6, was easier to use, and was preferred.

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The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense or US Government. The authors are employees of the US Government. This work was prepared as part of their official duties and, as such, there is no copyright to be transferred.

Disclosures

The authors have nothing to disclose.

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