Preliminary Comparison of New and Established Tactical Tourniquets in a Manikin Hemorrhage Model

Ruby Gibson; Greggory J. Housler, MS, MBA; Stephen Rush, MD; James K. Aden 3rd, PhD; John F. Kragh Jr, MD; Michael A. Dubick, PhD

ABSTRACT

Background: Emergency tourniquet use has been associated with hemorrhage control and improved survival during the wars since 2001. The purpose of the present study is to compare the differential performance of two new tactical tourniquets with the standard-issue tourniquet to provide preliminary evidence to guide decisions on device development. **Methods:** A laboratory experiment was designed to test the effectiveness of tourniquets on a manikin thigh. Three models of tourniquets were assessed. The Rapid Application Tourniquet System (RATS) and the Tactical Mechanical Tourniquet (TMT) were compared with the standard-issue Combat Application Tourniquet® (C-A-T). Two users conducted 30 tests each. **Results:** Percentages for effectiveness (hemorrhage control, yes/no) and distal pulse cessation did not differ significantly by model. When compared with the RATS, the C-A-T performed better ($p < .001$) for time to hemorrhage control and fluid loss. The C-A-T and TMT had comparable responses for most measures, but the C-A-T applied more pressure ($p = .04$) than did the TMT for hemorrhage control. **Conclusion:** All three tactical tourniquets showed substantial capacity for hemorrhage control. However, the two new tourniquet models (RATS and TMT) did not offer any improvement over the C-A-T, which is currently issued to military services. Indeed, one of the new models, the RATS, was inferior to the C-A-T in terms of speed of application and simulated loss of blood. Opportunities were detected for refinements in design of the two new tourniquets that may offer future improvements in their performance.

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

Introduction

Tourniquet use in the current war has changed from a procedure of last resort to one of first aid.[1–3] Emergency tourniquet use for limb wounds has been associated with effective hemorrhage control, prevention of shock onset, and improved survival rates.[4–6] These three findings support a recommended strategy of early hemorrhage control in out-of-hospital care, especially at or near the point of injury.[7–9] A particularly warranted point-of-injury setting for early hemorrhage control is that of tactical care under fire (CUF). Under such circumstances, tourniquet use not only improves survival of the casualty, but also lessens risk to rescuers attempting to control the hemorrhage.[10–13] Such desired improvements in survival have led to tourniquets being specifically designed for tactical settings.[14–16]

Periodically, new designs of interest enter the tactical tourniquet marketplace. Two recent models are the Rapid Application Tourniquet System (RATS; RATS Tourniquet; http://ratstourniquet.com) and the Tactical Mechanical Tourniquet (TMT; Alphapointe). As these two tactical tourniquets are new, there is no public evidence that distinguishes their relative merits or any knowledge concerning their appropriate methods of use. Currently, the standard-issue tactical tourniquet is the Combat Application Tourniquet® (C-A-T; Composite Resources; http://combattourniquet.com), for which there is a large body of evidence regarding its merits.[6,17,18] The purpose of the present study is to compare the performance of these two new tactical tourniquets with the standard-issue tourniquet to provide preliminary evidence to guide decisions on their development.

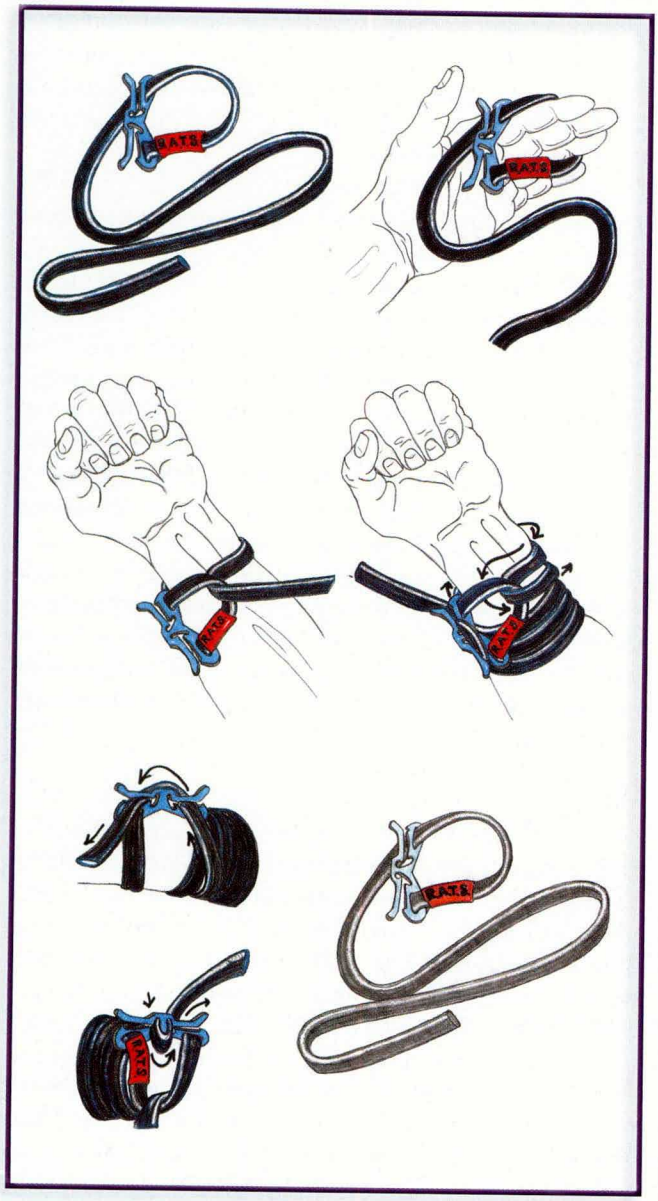
Methods

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 study group included two new tactical tourniquets intended for out-of-hospital hemorrhage control during CUF. The intended user in such a tactical situation is a nonmedical Soldier, a law enforcement officer, or a person in a similar position. The two new tourniquet models were the RATS and the TMT. One device per tourniquet model was tested unless wear and tear occurred, upon which another device of the

same model replaced the damaged device; the present testing intended that each device tested was structurally and functionally normal. Devices were examined throughout testing for structural and functional integrity Data were collected February to August, 2014.

The RATS is a commercially developed tactical tourniquet. It has a wrap design with a long, flexible, cloth-covered, rubber-like band; it is oval in cross-section (4mm x 12.5mm) (Figure 1). The running end is routed through the other end's loop, and the running end is tensioned to compress the underlying tissue. Further spiral wrapping distally, down the limb, with the running end allowed 1.5–3 inches of tissue width to be compressed. After compression was complete, a cleat allowed tension of the running end to be held by the tourniquet itself so the user's hands were freed. At the time of assessment, the RATS was not in the US Food and Drug Administration (FDA) registry of medical devices, but subsequently it was registered after our suggestion to the maker.

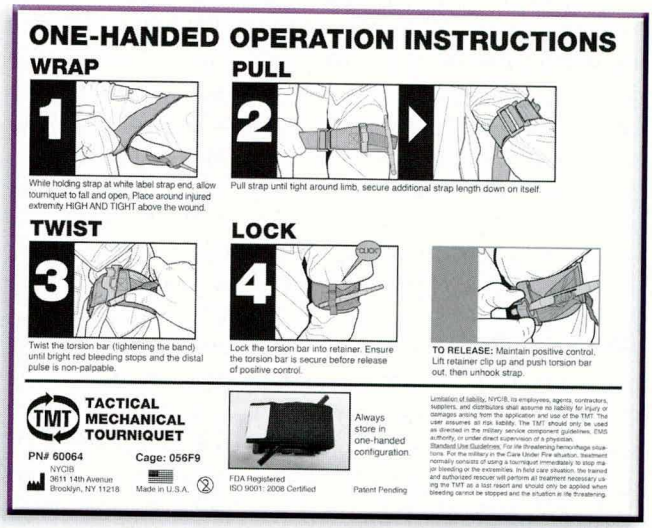
Figure 1 *The Rapid Application Tourniquet System images from its Instructions for Use (IFU). The IFU are the stepwise techniques the user is to follow in placing the RATS on the limb. An IFU is also known as a product insert, which the US Food and Drug Administration reviews upon registration of the medical device. This image is used with permission of RATS Tourniquet.*



The TMT is a tactical tourniquet initially developed by the US Army. It has a strap-and-windlass design, with a buckle that permits slack removal from the strap (Figure 2). The TMT strap is 50mm wide. The strap is looped around the limb circumferentially, and the running end of the strap is pulled to remove slack from the loop. Any excess length of the running end strap beyond the buckle can be secured down onto the looped strap with its self-adhering hook-and-loop fabric (Omnitape®; Velcro Industries BV; http://www.velcro.com). After the strap was secured, the windlass was turned to twist the strap tighter. To maintain tension, the windlass was placed into a retainer so it did not unwind. The intent behind the medic-designed TMT was to increase the circumferential surface area that would be compressed to occlude underlying arteries at a lower pressure. The TMT has a secondary locking mechanism if the Velcro fails. These latter two are design differences not seen in the control tourniquet. At the time of assessment, the TMT was not in the FDA registry of medical devices, but if the development by the military moves further along, such registration may be made.

The control group used the C-A-T in its 6th generation. The C-A-T has a strap-and-windlass design with a

Figure 2 *The Tactical Mechanical Tourniquet Instructions for Use are the stepwise techniques the tourniquet user is to follow in placing the TMT on the limb. This excerpted image is used with permission of Alphapointe.*



buckle that permits slack removal from the strap before turning of the windlass. The C-A-T strap is 39mm wide. At the time of assessment, the C-A-T had been registered for years with the FDA (Figure 3).

Figure 3 *The Combat Application Tourniquet is a US military, standard-issue tourniquet.*

There were two tourniquet users: a female undergraduate student and a male clinician-scientist. Both had familiarization training in use of the manikin. The student was relatively inexperienced in tourniquet use, whereas the clinician-scientist was a tourniquet expert and had tourniquet experience in trauma care. The clinician-scientist trained himself on the new tourniquets and had formal military training on the standard-issue tourniquet (i.e., the C-A-T). The clinician-scientist trained the student. Training included reading the instructions for use, handling of the device, and one or two practice uses for each tourniquet model on the manikin before testing began. The clinician-scientist tested before the student; the control tourniquet was tested by each user before the study tourniquets. There were 10 tests per tourniquet model per user; hence, both users performed 30 tests. The overall number of tests performed for the experiment was 60 replicates.

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.[19,20] The medial hip had an embedded computer and a smartphone-like touchpad. Software (version 1.9; CHI Systems) integral to the thigh allowed the manikin to stand alone and be operated by user input by finger touch on the pad. The thigh was placed on a laboratory benchtop and was operated in accordance with the manufacturer's instructions. The thigh did not bleed, but bleeding was represented by red lights that transilluminated the wound. The number of lights illuminated represented the bleeding rate: all 26 lights illuminated indicated uncontrolled bleeding; few lights blinking indicated intermediate control; and no lights illuminated indicated bleeding had stopped. Arterial pulses were palpable in the popliteal area. Touchpad readouts for each iteration included hemorrhage control, the time of use, the pressure exerted under the tourniquet, and the simulated blood loss volume.

The measure of time to determination of hemorrhage control extended from the start of the iteration until the manikin detected that no more blood was lost; if the tourniquet broke, then the manikin could determine that hemorrhage control had not occurred and the user could stop the test iteration by touching the pad. 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. 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 CUF, a setting resembling emergency care when under gunfire.

The manikin settings also included a constant simulated hemorrhage rate (635mL/min). With such a rate, the resulting bleed-out time was 4 minutes (240 seconds), and in the absence of any hemorrhage control, simulated death would occur at 240 seconds. If partial hemorrhage control occurred, then longer survival could occur. The touchpad reported simulated blood loss volume as calculated from arterial flow and time. Tourniquets, users, tests, and outcomes were uniquely identified.

Results were summarized by outcome and by tourniquet models. The critical, or primary, outcome was effectiveness (hemorrhage control, yes/no). Another important outcome was absence of palpable pulse distal to the tourniquet (yes/no). Secondary outcomes included time to cessation of bleeding (seconds); pressure (mmHg) applied to the skin by the tourniquet to achieve hemorrhage control, and the calculated volume of simulated blood loss (mL). Turn numbers were the number of windlass turns (180° was a turn for C-A-T and TMT) or wraps around the circumference of a limb (RATS). Effectiveness and pressure were measured by the manikin, while breakage, turn numbers, and pulse stoppage were determined by the user.

Descriptive statistics were used to portray results. Categorical data (hemorrhage control and pulse stoppage in 2-by-2 contingency tables) were analyzed with a chi-square test and the likelihood ratio p values were

reported. For pairwise comparison of models, a nonparametric Wilcoxon method was used. For pairwise comparison of model means, the Tukey 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

Tourniquet Model Comparisons

Neither tourniquet effectiveness ($p = .10$) (Table 1) nor pulse cessation ($p = .33$) (Table 2) differed among tourniquet models. Time to hemorrhage control did not differ between C-A-T and TMT, but both achieved effectiveness sooner than the RATS model ($p < .001$) (Figure 4). The mean pressure was 18% less for the TMT than for the C-A-T ($p = .04$) (Figure 5). Neither of those mean pressures differed from that needed by the RATS tourniquet ($p \geq .26$) (Figure 4). Paralleling results associated with the time to hemorrhage control, simulated blood loss did not differ between C-A-T and TMT, and both were associated with lower simulated blood loss than occurred with the RATS ($p < .0001$) (Figure 6). For correct tourniquet application, the C-A-T required more turns (mean 2.35; range 2–4; $p < .01$) than did the RATS and the TMT, which each required two turns in all tests, and which did not differ from each other ($p = 1.0$).

The statistically different results, such as for time, where also clinically significant. For example, in CUF, the difference between the mean for time to hemorrhage control for the C-A-T and RATS was 68 seconds, which delimits added risk of danger, such as being shot, for the user and the patient. The mean pressure difference between the C-A-T and the TMT was 37mmHg, because there were two TMT pressures that were less than 26mmHg and so were ineffective.

Table 1 *Hemorrhage Control Results by Tourniquet Model**

Tourniquet Model	Hemorrhage Control,** Occurrence, No. (%)†	
	No	Yes
C-A-T ($n = 20$)	0 (0)	20 (100)
RATS ($n = 20$)	0 (0)	20 (100)
TMT ($n = 20$)	2 (10)	18 (90)
Total ($N = 60$)	2 (3)	58 (97)

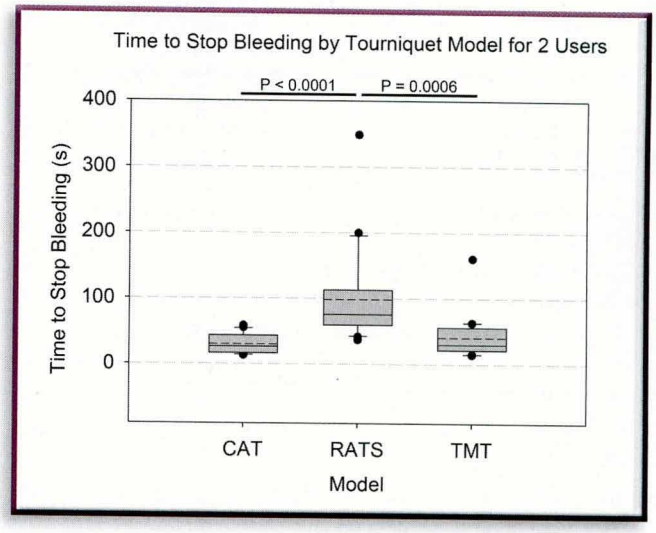
*Chi-square analysis found no differences among tourniquets ($p > .05$). **Hemorrhage control was defined by cessation of bleeding (no/yes). †Percentage was calculated by dividing the number of occurrences for each column (no/yes) by total number of occurrences and multiplying by 100. C-A-T, Combat Application Tourniquet; RATS, Rapid Application Tourniquet System; TMT, Tactical Mechanical Tourniquet.

Table 2 *Distal Pulse Cessation Results by Tourniquet Model**

Tourniquet Model	Pulse Cessation,** Occurrence,† No. (%)	
	No	Yes
C-A-T ($n = 20$)	0 (0)	20 (100)
RATS ($n = 20$)	0 (0)	20 (100)
TMT ($n = 20$)	1 (5)	19 (95)
Total ($N = 60$)	1 (2)	59 (98)

*Chi-square analysis found no differences among tourniquets ($p > .05$). **Pulse cessation was defined by absence of measurable pulse (no/yes). †Percentage was calculated by dividing occurrences for each column (no/yes) by total occurrences and multiplying by 100.

Figure 4 *Box-and-whisker plots depicting the time (seconds) needed to stop simulated bleeding using three different tourniquets and a manikin with a simulated above-knee amputation injury.*



The box top is the 75th percentile, the bottom is the 25th percentile, the tip of the upper vertical line is the 95th percentile, the tip of the lower vertical line is the 5th percentile, and dots beyond the vertical lines are individual data points. The solid line across the box is the median; the dashed line is the mean. The RATS took more time than the C-A-T ($p < .0001$) and TMT ($p = .0006$). C-A-T, Combat Application Tourniquet; RATS, Rapid Application Tourniquet System; TMT, Tactical Mechanical Tourniquet.

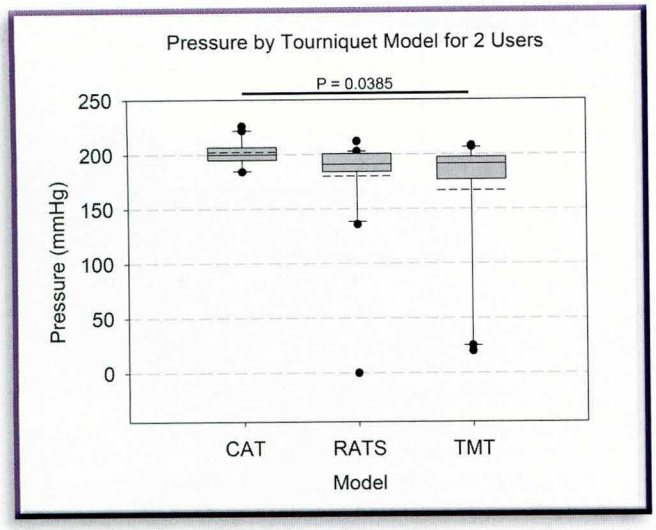
User Comparisons

Users did not differ in either effectiveness ($p = .48$) or in simulated blood loss ($p = .59$), but pressures applied did differ ($p < .01$). All pressures were in a safe range; however, the experienced user remained in an effective range while the inexperienced user had four values that were outside that range (<100mmHg).

Opportunities Identified for Potential Refinements in Tourniquet Design

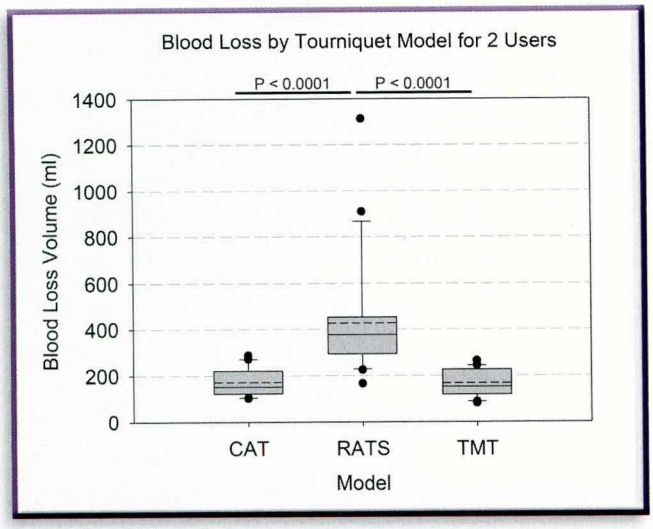
Opportunities for refinements in design were noted during the collection of data from tourniquet use. Identified opportunities included lengthening of the RATS and redesigning the TMT where the windlass contacts the

Figure 5 *Box-and-whisker plots depicting the pressure (mmHg) needed to stop simulated bleeding using three different tourniquets and a manikin with a simulated above-knee amputation injury.*



All graphic representations and abbreviations are as identified for Figure 3. Pressures applied for the C-A-T and TMT tourniquets are different (p = .04).

Figure 6 *Box plots depict simulated blood loss occurring with use of different tourniquets and a manikin with an above-knee amputation injury.*



All representations and abbreviations are as identified for Figure 3. More fluid loss occurred with RATS use (p < .0001).

inner strap. The TMT inner strap had wear and tear on two devices; two devices were replaced, such that three TMTs were tested altogether. All three devices had wear and tear, but the first device was replaced after 10 uses, the second device was replaced after eight uses, and the third device was used twice, and this number completed the data collection. All three had inner-strap wear or tear near the windlass aperture, which had a sharp edge. The first TMT had an incomplete tear, the second used had a complete tear, and the third had only wear.

Discussion

In this study using a manikin, the two new tourniquet models (RATS and TMT) did not offer any improvement over the currently issued military tourniquet, the C-A-T. Indeed, one of the new models, the RATS, was inferior to the C-A-T tourniquet in terms of speed of application and simulated loss of blood. It is evident, however, that a second tourniquet, the TMT, did perform as well as the C-A-T, and required a lower mean pressure to stop hemorrhage. Hence, subject to the relative cost of each, the TMT might prove to be a successful competitor on the open market.

Regarding an opportunity to improve the TMT design, reinforcing the inner strap or smoothing the edge of the windlass' aperture may improve function. To round off the sharp edge of the windlass aperture may allow the inner strap to lie over a smoother edge while distributing strap forces with less stress during strap twisting as the windlass is turned. Early C-A-T versions had a similar problem that was addressed well in a similar way.

It was also evident that the poorest performing tourniquet for secondary measures, the RATS, could be improved with increased length and improved technical training. Lengthening the RATS would permit higher effectiveness, as the running end may be spiraled more around the limb. These additional wraps would ensure an increase in the length of the artery compressed and associated tourniquet effectiveness.[14,16,18] However, if lengthened too much, then the added length would make handling of the running end more difficult.

Differences among the tourniquet models were clinically small, although, occasionally, differences were statistically significant. The C-A-T is in its sixth version, as there have been five sets of design refinements over a decade. In contradistinction to the C-A-T's present reliability after such sequential refinements, the two new models presently have their first opportunity for refinement.

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 two users, only three models, only 10 tests per model, and assessment was on a manikin and not on a real person. The preliminary evidence of new tourniquets has limited meaning and limited generalization, but it introduces new tourniquets to the medical literature and instructs on their use. The time to hemorrhage control was complex; time was measured from the start of the iteration until the manikin detected that no more blood was lost or the user stopped the iteration; the latter event occurred twice with the TMT. If the user had alternatively determined that the broken TMT could be made to work, then the iteration would have continued and

blood loss would have include two high values, which would have increased the mean value and, perhaps, the statistical results. Although this complexity is an experimental limitation, such a determination is made when a medic switches to a different hemorrhage control intervention, such as wound packing. Two models, C-A-T and RATS, were commercially developed, while TMT was developed primarily by the US Army. However, the C-A-T is most familiar to many users, since it has had widespread sales, including to the military.

Given the present study, which introduced RATS and TMT to preliminary assessment, future directions for further research include assessment with more users, and in a field setting or with tactical situations.

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Disclaimers

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.

Disclosure

The authors declare no conflicts of interest.

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Ms Gibson is an undergraduate student at both the University of Texas at San Antonio and University of Texas Health Science Center at San Antonio, Texas. She also works at the US Army Institute of Surgical Research (USAISR).

Mr Housler is a biomedical engineer working as a program manager for the US Army Medical Materiel Agency, Fort Detrick, Maryland.

Lt Col Rush, USAF, MC is a US Army Air Force radiation oncologist and flight surgeon who serves as medical director of the 103rd Rescue Squadron, Westhampton Beach, New York. He has been involved in operational medicine and the Special Operations Medical Association for over a decade. He is affiliated with the Departments of Radiation Oncology and Neurosurgery, NYU Langone Medical Center, New York, New York.

Dr Aden is a statistician at the USAISR, Joint Base San Antonio Fort Sam Houston, Texas. He has published many papers in operational medicine.

Dr Kragh is a tourniquet researcher at the USAISR, Joint Base San Antonio Fort Sam Houston, Texas. He is an orthopedic surgeon who was the 3rd Ranger Battalion Surgeon from 1990 to 1993. He is an associate professor in the Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, Maryland. E-mail: john.f.kragh.civ@mail.mil.

Dr Dubick is a resuscitation researcher at the USAISR, Joint Base San Antonio Fort Sam Houston, Texas. He is the task area manager of the department of Damage Control Resuscitation. He has published many papers in operational medicine.