NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

EVALUATION OF EXTREMITY TOURNIQUETS IN THE HANDS OF NON-MEDICAL PERSONNEL IN SIMULATED FIELD CONDITIONS

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DECLARATION OF INTEREST

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government. This work was funded by work unit number G1211. The study protocol was approved by the Naval Medical Research Unit San Antonio Institutional Review Board in compliance with all applicable Federal regulations governing the protection of human subjects.

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TABLE OF CONTENTS

ABBREVIATIONS

CUF	Care Under Fire
FDA	Food and Drug Administration
HapMed	Haptic Medicine
JOEFT	Joint Operational Evaluation of Field Tourniquets
NAMRU-SA	Naval Medical Research Unit San Antonio
NVG	Night Vision Goggles
USAMMDA	United States Army Medical Material Command
TCCC	Tactical Combat Casualty Care
TPT	Tactical Pneumatic Tourniquet
TMT	Tactical Mechanical Tourniquet

EXECUTIVE SUMMARY

Background: Policy decisions implemented in 2005 to broaden tourniquet use by US military personnel in tactical combat casualty care have led to a dramatic reduction in the number of deaths attributed to extremity hemorrhage in the last decade. Currently, several extremity tourniquets are on the market, and rigorous, independent testing is imperative to ensure the US warfighter is equipped with the most effective, reliable, and operationally sound tourniquet designs.

Objective: To assess the performance and effectiveness of two recently developed tourniquets, the Tactical Mechanical Tourniquet (TMT) and the Tactical Pneumatic Tourniquet (TPT), in the hands of non-medical participants in simulated field conditions.

Methods: Participants applied each tourniquet design to a HapMed instrumented leg (Phase IIa) and arm (Phase IIb) in four simulated field conditions, which included combinations of dry or simulated blood-soaked tourniquets in daylight or simulated nighttime conditions: 1) Dry/Light, 2) Dry/Dark, 3) Wet/Light, and 4) Wet/Dark. Ten non-medical volunteers, recruited from Fort Sam Houston, TX, participated in each phase (n=10). A tourniquet was deemed effective if it achieved occlusion within five minutes and maintained occlusion during a one-minute monitoring period, without critical malfunction or deformation.

Results: *Phase IIa.* All participants successfully applied both the TMT and TPT to the mannequin leg within five minutes, and occlusion was maintained during the one-minute monitoring period in each of the test conditions. Both the TMT and TPT were applied to the leg in the shortest amount of time during the Dry/Light condition (55.8 ± 17.9 s and 55.3 ± 15.4 s, respectively), and in the longest amount of time during the Wet/Dark condition (89.1 ± 35.0 s and 91.8 ± 58.1 s, respectively). *Phase IIb.* All participants also successfully applied both tourniquet models to the mannequin arm within five minutes, and occlusion was maintained during the monitoring interval in each of the test conditions.

Conclusions: In the hands of non-medical volunteer participants, both TMT and TPT tourniquets effectively halted blood flow on the HapMed mannequin leg and arm, in each of the simulated field conditions. These data serve to inform the tourniquet selection process and ensure the US warfighter is equipped with the most effective and operationally sound tourniquet designs.

INTRODUCTION

Analyses of casualties early in the wars in Iraq and Afghanistan revealed hemorrhage at the extremity to be a leading mechanism of injury in deaths considered to be potentially survivable. Prior to 2005, tourniquet use was primarily limited to special operation forces; however, in response to compelling statistics and research initiatives that demonstrated the effectiveness of prehospital tourniquets, US Central Command issued a directive that all deployed military persons must carry an extremity tourniquet (Walters, 2005; Beekley, 2008). Since implementing the directive, the number of deaths attributed to hemorrhage at the extremities has fallen sharply from an average of 23.3 deaths per year to 3.5 deaths per year (Eastridge, 2012).

Relatively simple in design, several extremity tourniquets are currently on the market, and rigorous, independent testing is imperative to ensure the US warfighter is equipped with the most effective, reliable, and operationally sound tourniquet designs. A joint-services Tourniquet Working Group was established in 2010 to standardize safety, efficacy, and operational requirements for extremity tourniquets. Those consensus requirements were implemented in two initial phases of testing, the Joint Operational Evaluation of Field Tourniquets (JOEFT) Phases I and II (McKeague, 2012; Alvarez, 2014), which evaluated eleven tourniquet designs that were Food and Drug Administration (FDA) registered.

Since completion of the original evaluations, two new tourniquet designs were released and registered with the FDA. The new tourniquets were recently evaluated for safety, efficacy, and physical parameters using the methods established in JOEFT Phase I, and both designs met all required performance criteria (Dory, 2014). The evaluation described here tests the two tourniquet designs, using the methods developed in JOEFT Phase II, to assess the performance and effectiveness of the devices, in the hands of non-medical volunteer subjects in simulated field conditions.

MATERIALS AND METHODS

Participants

The study was conducted under an approved Naval Medical Research Unit San Antonio IRB Protocol (NAMRU-SA.2014.0003) in compliance with all applicable federal regulations governing the protection of human subjects. Fourteen healthy active duty military and civil

service volunteers between the ages of 18 and 45 years old were recruited from Fort Sam Houston, TX, without regard to gender or ethnicity. Exclusion criteria included being outside the target age range, having a physical injury or impairment that would impact manipulation and adjustment of testing instruments, or having a glycerol allergy (primary ingredient in the blood simulant). The participant pool consisted of 11 males and 3 females, ranging in age from 18 to 42, with a height range between 63 and 76 inches, and weight range between of 125 and 256 pounds. Informed consent was obtained from each volunteer prior to participating in the study.

Experimental Design

Tourniquet evaluation was divided into two sub-phases, leg applications (Phase IIa) and arm applications (Phase IIb). Tourniquet designs that met the success criteria for Phase IIa advanced to Phase IIb. Each phase was a split-plot randomized block design. The tourniquets were applied to instrumented mannequin limbs in four test conditions, which included combinations of dry or simulated blood-soaked tourniquets applied in daylight or simulated nighttime conditions: 1) Dry/Light, 2) Dry/Dark, 3) Wet/Light, and 4) Wet/Dark. Participants applied each tourniquet design to the extremity in each of the four test conditions, with both condition and tourniquet order randomized.

Tourniquets were considered successful if they obtained occlusion within a five-minute test period and maintained occlusion for a one-minute monitoring period. Failures were recorded if: 1) a tourniquet had critical malfunctions, deformations, or broke during application; 2) volunteers were unable to apply the tourniquet and reach occlusion within five minutes; and/or 3) the device did not maintain occlusion for one minute post-application. If occlusion pressure was lost after initially being achieved, participants had one opportunity to regain occlusion, as long as the five-minute time limit had not expired.

Results were projected upon a binary space; hence, the tourniquet either met all success criteria for the test condition or did not. A power analysis indicated a minimum of ten participants would be required for the study, yielding a statistical power of 80% and a 0.66 coefficient of variation at a 95% confidence level. As a result, differences between any two tourniquets were considered significant when the number of successful trails differed by 5 or more (Hines & Montgomery, 1980).

Instrumentation

HapMed Instrumented Leg and Arm for Tourniquet Training (CHI Systems, Plymouth Meeting, Pennsylvania). The HapMed instrumented leg and arm (Figure 1) provide stand-alone, hands-on skills training in which trainees can experience the actual torque required to stanch bleeding from an extremity wound. Sensors within each device gauge the amount of pressure applied, and LED lights indicate when bleeding slows and occlusion pressure is reached. The HapMed devices support a number of different testing scenarios. For both Phase IIa and Phase IIb tests, the "hasty" application setting was selected on the HapMed devices, which requires the proximal tourniquet placement recommended by the tactical combat casualty care (TCCC) guidelines for care under fire (CUF). The "average" leg and arm size were selected, which requires a 180 mmHg occlusion pressure for the leg and a 200 mmHg occlusion pressure for the arm. At the completion of a scenario the HapMed interface displays: 1) tourniquet application time, 2) pressure generated by the tourniquet, 3) total blood loss, calculated as a function of applied pressure and elapsed time, and 4) an indication of whether the tourniquet is placed correctly.

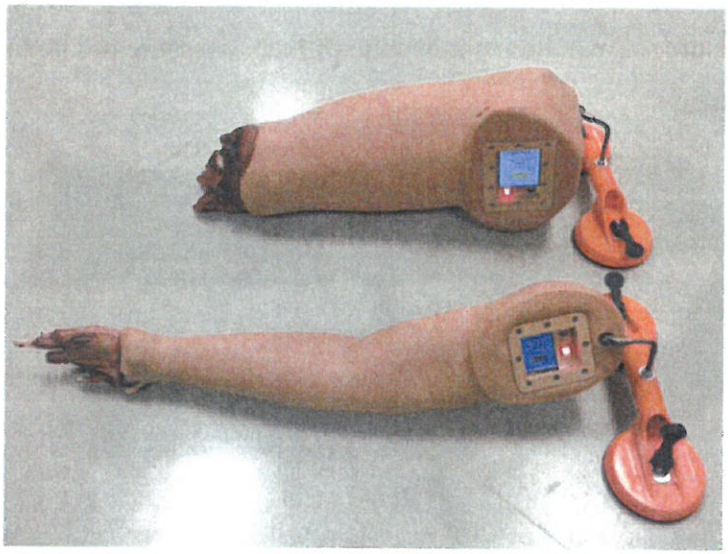

Figure 1. HapMed Instrumented Leg and Arm. The HapMed Leg and Arm provide realistic visual and tactile feedback during tourniquet application. The devices also provide performance metrics including application time and the amount of pressure exerted by tourniquets.

Simulated Blood (Vata, Inc., Canby, OR, #2494). Tourniquets were submerged in a blood simulant prior to the blood-soaked conditions. The simulant is glycerol-based, and once reconstituted in water, has the same viscosity as real blood.

Night Vision Goggles (NVGs; Night Optics USA, Huntington Beach, CAD-221G-MS Gen 2+ Dual Tube Stereo Vision Goggle). Head-mounted, binocular NVGs were used to limit visibility and depth perception during simulated nighttime conditions. During NVG tests, the room lights were dimmed and pin-hole covers were worn over the optics to prevent washout.

Equipment under Test

The tourniquets evaluated are classified as Class I devices by the FDA, which are 510(k) exempt from premarket notification and approval. The tourniquets are listed in alphabetical order.

Tactical Mechanical Tourniquet (TMT; Alphapointe™; Kansas City, MO). The TMT (Figure 2) is a mechanical tourniquet, which uses a windlass to apply circumferential pressure to the limb. A hooking clasp connects the two ends of the tourniquet and eliminates the need to thread the strap. Self-adhering hook-and-loop fastener runs the length the strap material, and is pre-threaded through a slip lock mechanism integrated into the clasp. Initial tension is generated by pulling the strap tight through the slip lock mechanism, and the self-adhering hook-and-loop ensures the strap is secure. A windlass applies the primary pressure and is secured with a locking clip once tightened.

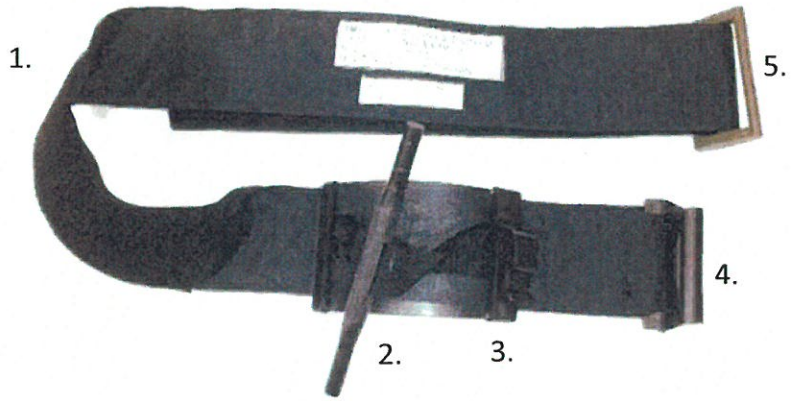

Figure 2. Tactical Medical Tourniquet (TMT). 1. Strap material with integrated hook-and-loop fastener. 2. Windlass. 3. Windlass locking clip. 4. Hook portion of clasp. 5. Clasp with strap material threaded through slip lock mechanism.

Tactical Pneumatic Tourniquet (TPT; Alphapointe™; Kansas City, MO). The TPT (Figure 3) is a pneumatic tourniquet, which forms two concentric strap layers around the limb when applied. The inner layer (tan) contains an air bladder and is held with self-adhering hook-and-loop fastener. The second layer (black) is applied on top of the inner layer to secure it in

place. The outer layer has a hooking clasp with self-adhering hook-and-loop strap material pre-threaded through a slip lock mechanism. The hooking clasp secures the outer layer around the inner layer, and the strap material is pulled tight through the slip lock mechanism and secured with the self-adhering hook-and-loop fastener. Once the inner and outer layers are applied, a half-bulb hand pump inflates the air bladder to generate the primary pressure.

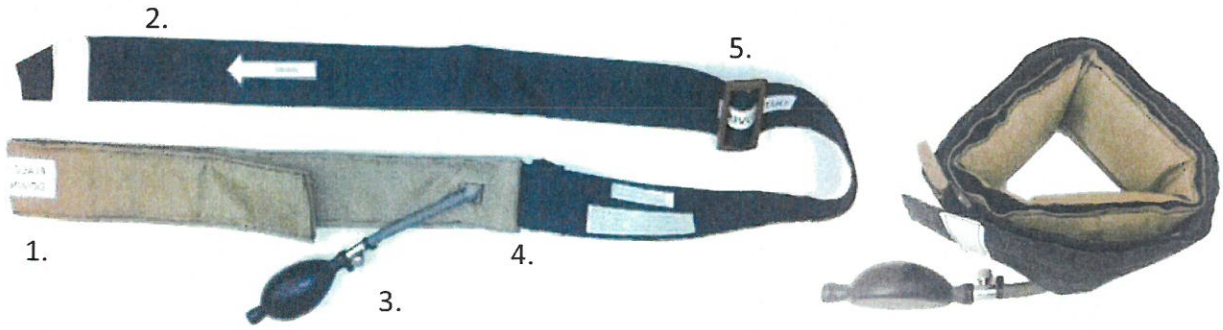

Figure 3. Tactical Pneumatic Tourniquet (TPT). 1. Inner layer of strap material (tan) with integrated air bladder and hook-and-loop fastener. 2. Outer layer of strap material (black) with integrated hook-and-loop fastener. 3. Air bulb. 4. Hook portion of clasp for outer strap. 5. Clasp with outer strap threaded through slip lock mechanism.

Test Procedures

Participant Training. Prior to testing, participants were trained on correct placement and application of each tourniquet, according to the manufacturer's instructions, using the proximal placement recommended by the TCCC guidelines for CUF. During the training, a research team member demonstrated how to apply each tourniquet to the HapMed limbs and allowed participants to practice applying the two designs (Figure 4). Research personnel verified successful placement and application of each tourniquet and addressed any questions prior to testing. Six of the Phase IIa participants returned on a separate day to participate in Phase IIb. Those six participants received refresher training and again demonstrated proper application of each tourniquet before beginning Phase IIb.

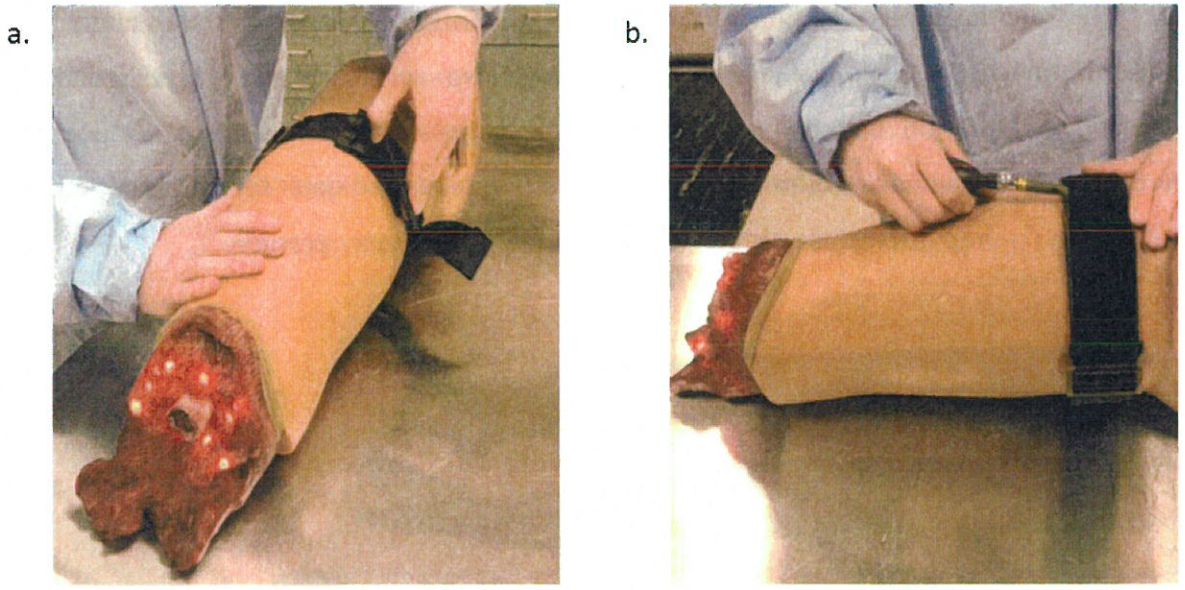

Figure 4. Application demonstrations of the tourniquet designs. a) TMT: A research team member rotates the windlass to tighten the device around the HapMed leg. b) TPT: With the tourniquet straps secured, a research team member uses the air bulb to inflate the pneumatic bladder.

Phase IIa: Leg Application. Ten volunteers participated in Phase IIa, applying the TMT and TPT each to the HapMed leg in the four test conditions. Prior to dark conditions, participants donned NVGs and the room lights were dimmed; otherwise, the room remained illuminated and the NVGs were not worn. Next, participants removed the tourniquet from the packaging and handed the tourniquet to a researcher to annotate the test number. For the blood-soaked conditions, the tourniquet was then submerged in blood simulant; otherwise, the tourniquet remained dry. Once the participant was ready, a research team member handed the tourniquet to the participant and initiated the HapMed scenario. The participant applied the tourniquet to the proximal thigh of the HapMed leg. Participants were monitored during applications, and test administrators recorded application times, pressures generated by the tourniquets, blood loss, and any adverse events.

Phase IIb: Arm Application. Ten volunteers participated in Phase IIb, which tested the same tourniquets under the same four conditions as Phase IIa, but this time applied to the proximal brachium on the HapMed arm. Again, volunteers were monitored during applications, and test administrators recorded application times, pressures generated by the tourniquets, blood loss, and any adverse events.

RESULTS & DISCUSSION

Phase IIa – Leg Applications

All ten participants applied both the TPT and TMT successfully to the HapMed leg, generating occlusion within five minutes, and maintaining occlusion during the one-minute monitoring period, in each of the four test conditions. During 8 of the 40 total TMT applications, and 2 of the 40 total TPT applications, a participant achieved initial occlusion; however, once the tourniquet was secured, the HapMed limb indicated bleeding had begun again. In each case, the participant was able to modify the application either with additional turns to the TMT windlass or with additional pumps to the TPT air bulb, and occlusion was regained and maintained for the required one-minute monitoring period.

The high occurrence of retightening required for the TMT is likely a result of the windlass clip. When the windlass is turned clock-wise, the windlass must be rotated beyond the clip before it can be secured (Figure 5). In cases where the HapMed leg registered an applied pressure near the threshold of occlusion, with the windlass rotated beyond the locking clip, the relaxation that occurred when the windlass settled into the clip was enough to lose the occlusive pressure. In each case, occlusion was regained by adding a turn to the windlass.

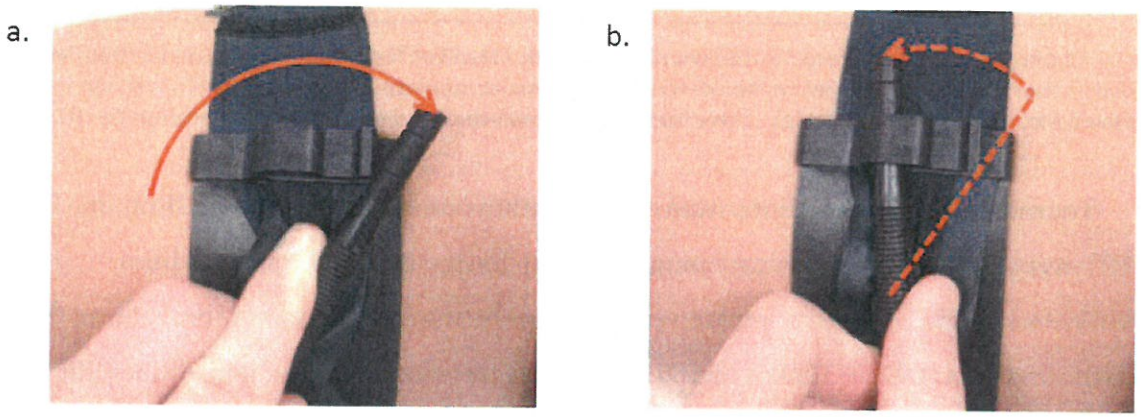

Figure 5. TMT windlass locking mechanism. a) When the TMT windlass is tightened in a clockwise direction, the windlass must rotate past the locking mechanism before it can be secured. b) The windlass slightly reduces applied tension when it settles into the locking clip. In multiple instances, the reduction in pressure was enough to lose occlusion.

The pressures exerted on the HapMed limb at the end of the test scenarios were consistent between tourniquet designs and across test conditions (Figure 6). This finding is to be expected, as the HapMed uses the pressure measurement to determine when occlusion is achieved. The pressure data does, however, demonstrate the consistency of the mannequin system across limb applications. Although not statistically significant, the TMT tended to exert

slightly more pressure on the HapMed leg than the TPT. The difference is likely explained by the primary pressure mechanisms employed by each tourniquet. The TPT air bulb generates pressure in smaller increments than the TMT windlass (Dory, 2014), which allows the applier to stop adding pressure very close to the point of occlusion. During TMT applications, if occlusion pressure is achieved in the middle of the windlass turn, then the turn still must be completed to secure the windlass, adding pressure beyond the target pressure threshold.

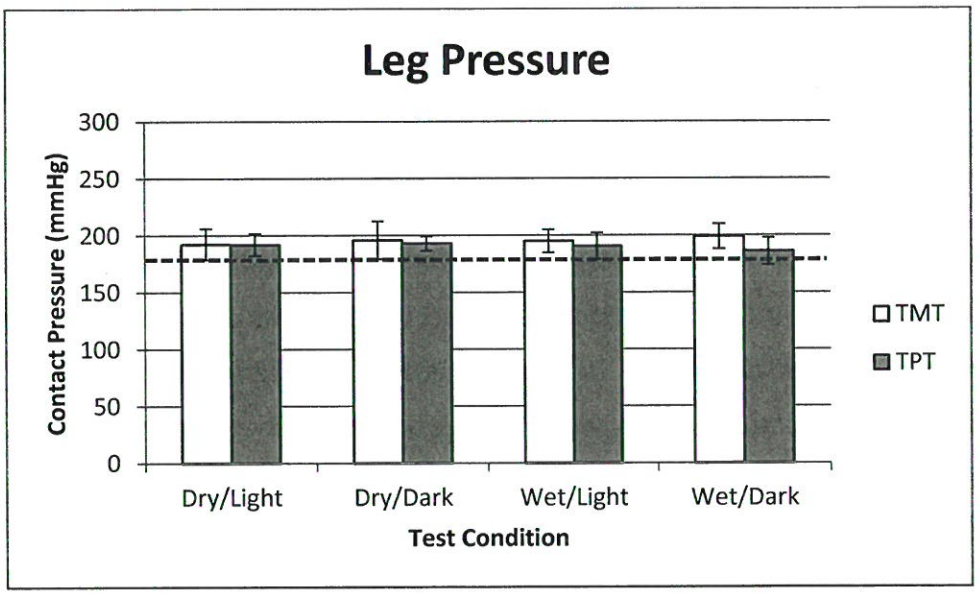

Figure 6. Contact pressure exerted by the tourniquet on the HapMed leg. These values derive from sensors embedded in the HapMed and appear on the device display once an application is complete. The red line indicates the threshold for occlusion (180 mmHg). Error bars indicate one standard deviation from the mean (n=10).

Tourniquet application times were similar within condition (Figure 7). Both the TMT and TPT were applied in the shortest amount of time during the Dry/Light condition (55.8 ± 17.9 s and 55.3 ± 15.4 s, respectively), and in the longest amount of time during the Wet/Dark condition (89.1 ± 35.05 s and 91.8 ± 58.1 s, respectively). In none of the four conditions was there a significant difference between the TMT and TPT mean application times ($p > 0.05$). The longer application times in the Wet/Dark condition were caused by participants experiencing a wider variety of setbacks such as problems with grip, placement, and general manipulation of the tourniquets. During applications in the wet conditions, several participants found it more difficult to grip and manipulate the TMT windlass. Also during the wet conditions, there were multiple instances in which moisture caused the check valve in the TPT air bulb to stick, making it more challenging to fill the air bladder. Those cases often required participants to use both hands to squeeze the bulb in order to add air to the TPT bladder.

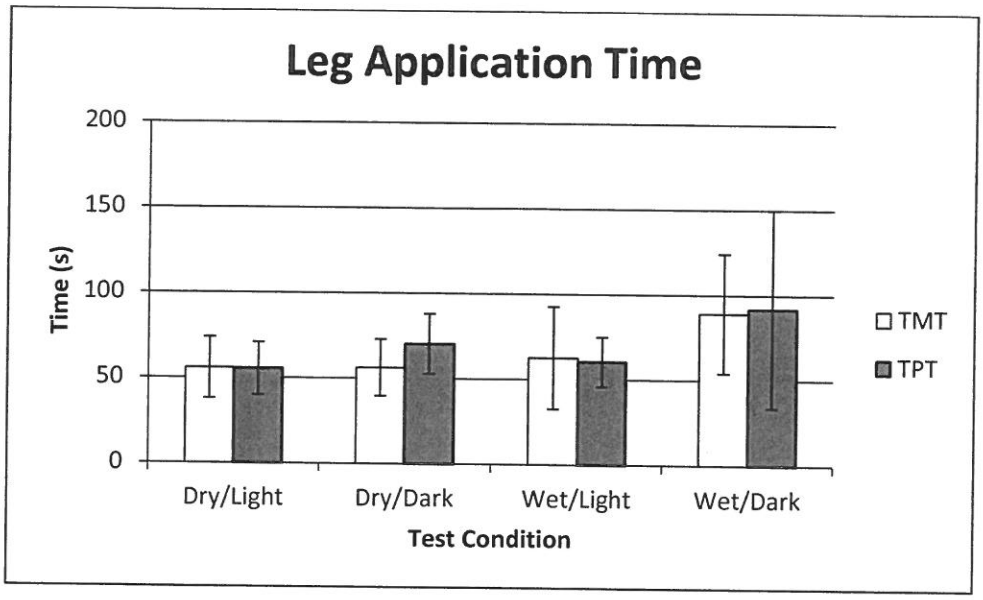

Figure 7. Tourniquet application times for the leg. Recorded time starts with the unpackaged tourniquet, and ends with the device correctly applied to the HapMed and the display indicating occlusion. Error bars indicate one standard deviation from the mean (n=10).

In all four conditions, the calculated blood loss was less during TMT applications than during TPT applications, although only in the Dry/Dark condition was the difference in means between the tourniquets significant ($p < 0.01$; Figure 8). The differences in amount of blood loss likely result from inherent differences between how the devices are applied. The TPT requires the inner air bladder layer and the outer securing strap to be applied before primary pressure is generated by the air bulb. A large portion of the TPT application time was consumed applying the two strap layers, during which little pressure was applied to the limb; however, once secured, primary pressure generated by the air bulb was applied rapidly. On the other hand, the TMT requires only a single strap, which was secured more quickly than the TPT, allowing primary windlass pressure to be exerted sooner. While the applications times were similar, a greater portion of the TMT application time was spent tightening and securing the windlass, during which a modest amount of pressure was exerted on the limb, slowing the loss of blood.

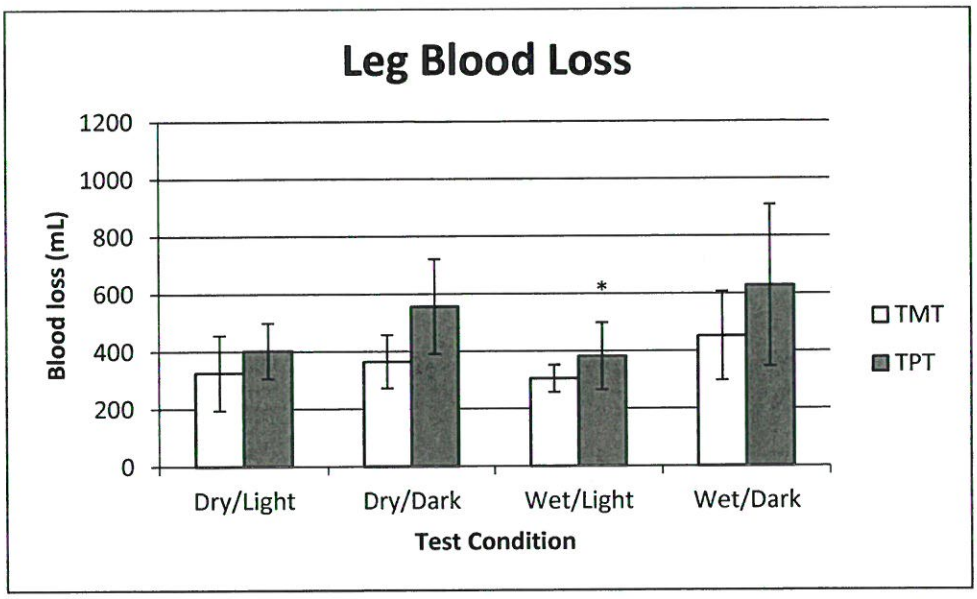

Figure 8. Estimated blood loss from the HapMed leg. The HapMed leg calculates estimated volume of blood lost based as a function of elapsed time and pressure exerted. Values shown are out of a maximum 2500 mL of blood loss. Error bars indicate one standard deviation from the mean (n=10), except for the bar marked * (n=9), which had a missing data point due to HapMed reset error.

Phase IIb – Arm Applications

All ten subjects were also able to successfully apply the TMT and TPT tourniquets to the HapMed arm, within five minutes, and maintain occlusion for one minute, in each of the four test conditions. In 5 of the 40 TMT applications and 2 of the 40 TPT applications, the HapMed indicated bleeding had resumed during the monitoring period, and the participant needed to reposition or tighten the tourniquet for proper occlusion. Again, by adding turns to the TMT windlass or pumps to the TPT air bulb, occlusion was regained in each instance, and maintained for the required one-minute period.

As with the Phase IIa applications, the mean contact pressures for the arm were consistent across applications (Figure 9). The higher average pressures for all tourniquets and conditions in this phase reflect the higher threshold of occlusion employed by the HapMed arm, relative to the leg. Although well within the target range, pressures applied to the HapMed arm tended to overshoot the threshold of occlusion by a greater magnitude than pressures applied to the leg. Incremental changes in tourniquet strap tension generated by the TMT windlass and TPT air bulb produce relatively larger changes in applied pressure on the arm versus the leg, because the tension is exerted over a smaller circumference. The larger incremental changes afford less precision when applying pressure to the smaller circumference arm, making it easier to exceed the threshold of occlusion.

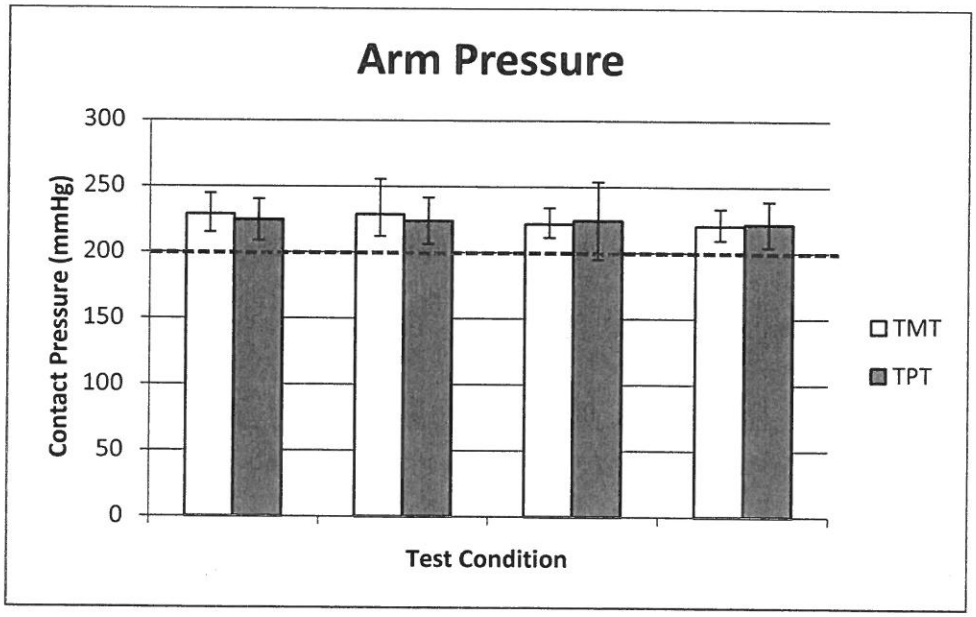

Figure 9. Contact pressure exerted by the tourniquet on the HapMed arm. These values derive from sensors embedded in the HapMed and appear on the device display once an application is complete. The red line indicates the threshold for occlusion (200 mmHg). Error bars indicate one standard deviation from the mean (n=10).

As was seen in Phase IIa, tourniquet application times were similar within condition, and no significant differences were found between the two tourniquet designs (Figure 10). In all cases but the TMT Wet/Dark condition, mean application times were longer on the arm than on the leg. The slip lock mechanism and clasp on the TMT is pre-threaded when the tourniquet comes out of the packaging, and its position is well-suited for the circumference of the proximal thigh of the HapMed leg; however, due to the smaller arm circumference, the TMT slip lock mechanism requires greater adjustment when applied to the HapMed arm, which added to the application times. Additionally, participants were often challenged by the excess self-adhering strap material, which adhered to itself and made adjustment difficult. Similarly, during TPT applications, the smaller arm circumference required more layers when wrapping the air bladder layer, also resulting in excess strap material. It was more difficult for participants to control the orientation of the TPT air bulb and the clasp for the outer strap layer when applying the inner bladder layer to the smaller limb; often the air bulb or clasp would end up positioned underneath the arm, which made inflating the air bladder and securing the outer strap layer more challenging.

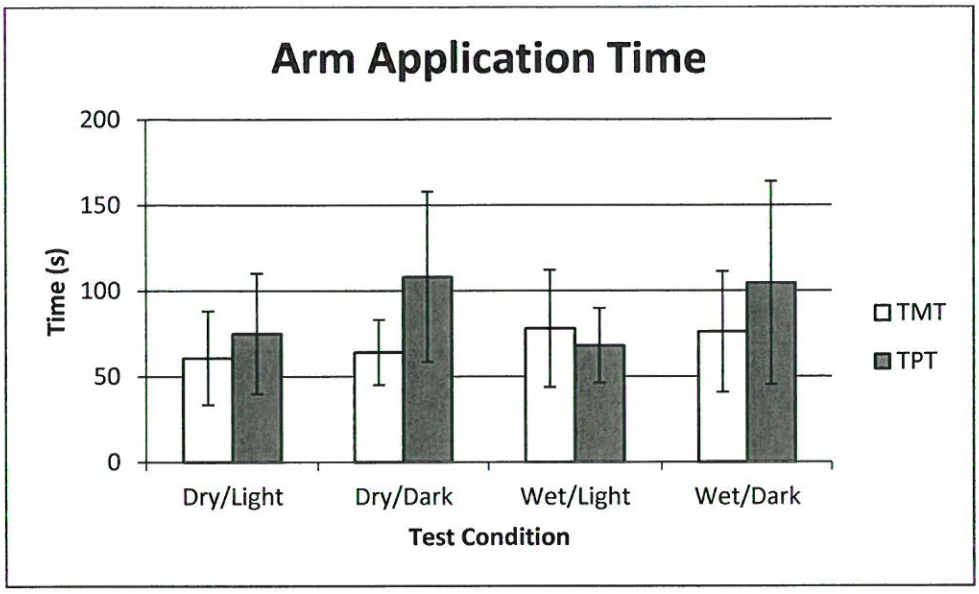

Figure 10. Tourniquet application times for the arm. Recorded time starts with the unpackaged tourniquet, and ends with the device correctly applied to the HapMed and the display indicating occlusion. Error bars indicate one standard deviation from the mean (n=10).

Similar to the Phase IIa applications, there was a greater amount of blood lost during the TPT applications than during TMT applications in each of the test conditions; however, this difference was statistically significant only for the Dry/Light and Dry/Dark conditions ($p = 0.02$ and $p = 0.01$, respectively).

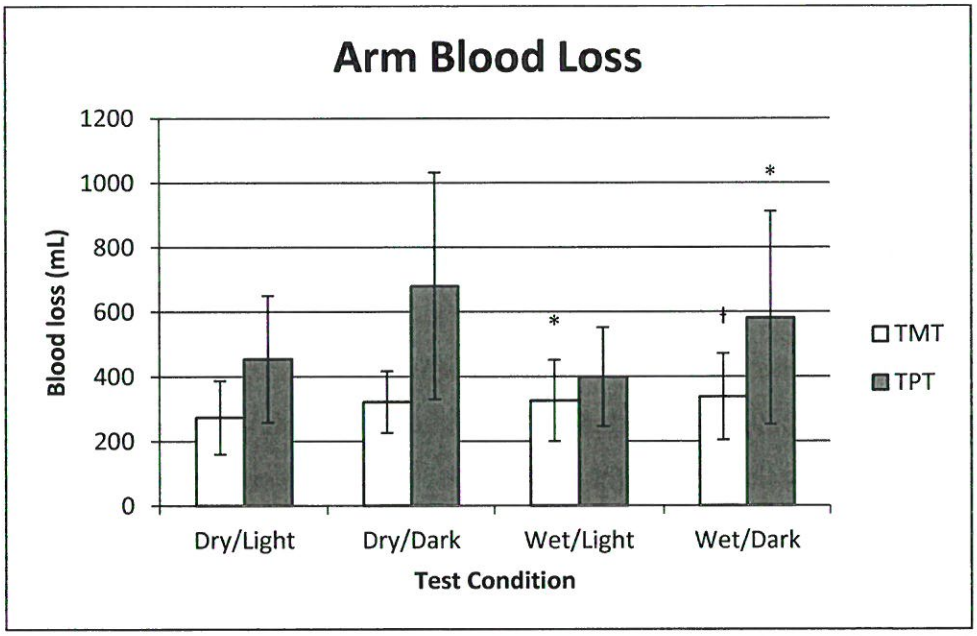

Figure 11. Estimated blood loss from the HapMed arm. The HapMed arm calculates estimated volume of blood lost based as a function of elapsed time and pressure exerted. Values shown are out of a maximum 2500 mL of blood loss. Error bars indicate one standard deviation from the mean (n=10), except for the bars marked * (n=9) and † (n=8), which had missing data points due to HapMed reset error.

CONCLUSIONS

In this evaluation of extremity tourniquets, conducted in the hands of non-medical volunteer participants, both TMT and TPT tourniquets effectively halted blood flow on the HapMed mannequin leg and arm, in each of the simulated field conditions. By using standardized methods and test instruments established in earlier tourniquet evaluations (Alvarez, 2014), the overall success and performance of the TMT and TPT tourniquets, can be compared not only against each other, but relative to previously tested tourniquets. The performance metrics obtained here also function as benchmarks for emerging tourniquet designs. These data serve to inform the tourniquet selection process and ensure the US warfighter is equipped with the most effective and operationally sound tourniquet systems.

REFERENCES

Alvarez, R., Cox, D., Dory, R. (2014). Joint Operational Evaluation of Field Tourniquets (JOEFT) – Phase II (Report No. 2014-09). Naval Medical Research Unit San Antonio, TX.

Beekley, A., Sebesta, J., Blackbourne, L., Herbert, G., Kauvar, D., Baer, D., et al. (2008). Prehospital Tourniquet Use in Operation Iraqi Freedom: Effect on Hemorrhage Control and Outcomes. *The Journal of Trauma*, 28-37.

Dory, R., Cox, D., Endler, B. (2014). Test and Evaluation of New York Industries for the Blind (NYCIB) – Phase I (Report No. 2014-23). Naval Medical Research Unit San Antonio, TX.

Eastridge B., Mabry R.., Sequin P., Cantrell J., Tops T., Uribe P., Blackbourne L. (2012). Death on the battlefield (2001-2011): Implications for the future of combat casualty care. *Journal of Trauma and Acute Care Surgery*, 73, S431-437.

Hines, W., Montgomery, D. (1980). Probability and statistics in engineering and management science. New York: Wiley.

McKeague, A., Cox, D. (2012). *Phase 1 of Joint Operational Evaluation of Field Tourniquets.* (Report No. 2012-013). Naval Medical Research Unit San Antonio, TX.

Walters, T., Wenke, J., Baer, D. (2003). Research on Tourniquet Related Injury for Combat Casualty Care. *R T Organization*, 1-8.

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13. SUPPLEMENTARY NOTES
N/A

14. ABSTRACT

Policy decisions implemented in 2005 to broaden tourniquet use by US military personnel in tactical combat casualty care have led to a dramatic reduction in the number of deaths attributed to extremity hemorrhage in the last decade. Currently, several extremity tourniquets are on the market, and rigorous, independent testing is imperative to ensure the US warfighter is equipped with the most effective, reliable, and operationally sound tourniquet designs. The objective of this study was to assess the performance and effectiveness of two recently developed tourniquets, the Tactical Mechanical Tourniquet (TMT) and the Tactical Pneumatic Tourniquet (TPT), in the hands of non-medical participants in simulated field conditions. Participants applied each tourniquet design to a HapMed instrumented leg (Phase IIa) and arm (Phase IIb) in four simulated field conditions, which included combinations of dry or simulated blood-soaked tourniquets in daylight or simulated nighttime conditions: 1) Dry/Light, 2) Dry/Dark, 3) Wet/Light, and 4) Wet/Dark. Ten non-medical volunteers, recruited from Fort Sam Houston, TX, participated in each phase (n=10). A tourniquet was deemed effective if it achieved occlusion within five minutes and maintained occlusion during a one-minute monitoring period, without critical malfunction or deformation. *Phase IIa.* All participants successfully applied both the TMT and TPT to the mannequin leg within five minutes, and occlusion was maintained during the one-minute monitoring period in each of the test conditions. Both the TMT and TPT were applied to the leg in the shortest amount of time during the Dry/Light condition (55.8 ± 17.9 s and 55.3 ± 15.4 s, respectively), and in the longest amount of time during the Wet/Dark condition (89.1 ± 35.0 s and 91.8 ± 58.1 s, respectively). *Phase IIb.* All participants also successfully applied both tourniquet models to the mannequin arm within five minutes, and occlusion was maintained during the monitoring interval in each of the test conditions. In the hands of non-medical volunteer participants, both TMT and TPT tourniquets effectively halted blood flow on the HapMed mannequin leg and arm, in each of the simulated field conditions. These data serve to inform the tourniquet selection process and ensure the US warfighter is equipped with the most effective and operationally sound tourniquet designs.

15. SUBJECT TERMS
extremity hemorrhage control, tourniquet, Tactical Pneumatic Tourniquet, Tactical Mechanical Tourniquet

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