NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

TEST AND EVALUATION OF NEW YORK CITY INDUSTRIES FOR THE BLIND (NYCIB) TOURNIQUETS – PHASE I

ROY E. DORY, MS, D. DUANE COX, AND BRIDGET M. ENDLER, MS

EXPEDITIONARY AND TRAUMA MEDICINE DEPARTMENT
COMBAT CASUALTY CARE AND OPERATIONAL MEDICINE DIRECTORATE

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DECLARATION OF INTEREST

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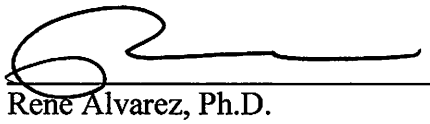
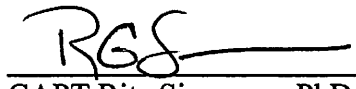
REVIEWED AND APPROVED BY:



4/3/2014
Date

Rene Alvarez, Ph.D.
Director, Combat Casualty Care & Operational Medicine
Chair, Scientific Review Board
Naval Medical Research Unit San Antonio
3650 Chambers Pass, BLDG 3610
Fort Sam Houston, TX 78234-6315



08APR14
Date

CAPT Rita Simmons, PhD, MSC, USN
Commanding Officer
Naval Medical Research Unit San Antonio
3650 Chambers Pass, BLDG 3610
Fort Sam Houston, TX 78234-6315

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EXECUTIVE SUMMARY

Background: The Joint Operational Evaluation of Field Tourniquets (JOEFT), recently performed at Naval Medical Research Unit San Antonio (NAMRU-SA), assessed the operational characteristics of ten currently fielded or FDA registered tourniquets. The tourniquets were tested according to consensus parameters established by the Department of Defense (DoD) Tourniquet Working Group Summit held in Quantico, Virginia in March 2010. The parameters defined by the working group consider tourniquet safety, efficacy, weight and size capacity in field medical bags, ease of application, tourniquet packaging, and material component standards. The current evaluation utilizes the same testing parameters as the original assessment but with three new tourniquet designs that emerged since the previous study concluded.

Objective: *Phase Ia:* To evaluate the physical characteristics of three prototype tourniquets for compliance with established consensus parameters. *Phase Ib:* To assess the efficacy and operational characteristics of the three tourniquets during application.

Methods: Three prototype tourniquets were tested: Tactical Mechanical Tourniquet (TMT), Tactical Pneumatic Tourniquet 3" (TPT3.1), and Tactical Pneumatic Tourniquet 2" (TPT2.1). *Phase Ia:* The physical characteristics of each tourniquet model (n = 5) were measured, compared to the established consensus parameters, and analyzed for standardization within each tourniquet type. *Phase Ib:* Five of each tourniquet type (n = 5) were applied to the HapMed Leg according to manufacturer instructions. Sensors in the HapMed Leg indicated when tourniquets achieved occlusion, and tourniquets were considered successful if they maintained occlusion for 1 minute after application. Application times were recorded, and a Tekscan pressure measurement system mapped the pressures exerted by each tourniquet. Tourniquets that achieved and maintained occlusion on the HapMed Leg were then applied to the HapMed Arm using the same procedure.

Results: *Phase Ia:* All tourniquets met the criteria for length, width, and weight, and physical characteristics were consistent within each tourniquet type. The TPT2.1 and TPT3.1, however, both exceeded the consensus criteria for package volume. *Phase Ib:* TMT maintained occlusion during all applications, while only three of the five TPT3.1 devices and four of the five TPT2.1 devices maintained occlusion pressure on both the arm and leg. One TPT3.1 failed during the leg application and a second failed during the arm application due to air bladder leaks. One TPT2.1 failed due to a check valve malfunction during the leg application. Application times and pressures were not significantly different among the three tourniquet models. The average

application time on the leg was 55.9 ± 11.9 sec, while the average application time on the arm was 33.3 ± 6.3 sec.

Conclusions: Each tourniquet demonstrated the ability to achieve the necessary occlusion pressure, and similar application times were observed for each type. However, individual TPT3.1 and TPT2.1 tourniquets failed to maintain air pressure, resulting in a loss of occlusion within 1 minute of application. Additional tests would be required to determine the root cause and the extent of the observed failures. Data collected from TMT, TPT3.1, and TPT2.1 will aid the sponsor in selecting tourniquet devices for further field testing.

INTRODUCTION

The recent conflicts in Iraq and Afghanistan have taken a significant human toll on our military forces across all services. Although some injuries are non-survivable, an analysis of over 4,500 casualties occurring between 2001 and 2011 revealed more than 90% of the potentially survivable injuries were associated with hemorrhage (Kragh, 2011; Eastridge, 2012). The use of extremity tourniquets has significantly increased survival rates among military personnel suffering from combat injuries (Kragh, 2008; Kragh, 2009; Blackbourne, 2008; Kragh, 2012); however, as new tourniquet designs emerge, the Department of Defense (DoD) has found it necessary to evaluate their performance and ease of application to continue to improve survival rates and patient outcomes.

The Joint Operational Evaluation of Field Tourniquets (JOEFT), recently performed at Naval Medical Research Unit San Antonio (NAMRU-SA), assessed the operational characteristics of ten currently fielded or FDA registered tourniquets (McKeague, 2012; Alvarez, 2014). The tourniquets were tested according to consensus parameters established by the DoD Tourniquet Working Group Summit held in Quantico, Virginia in March 2010. The parameters defined by the working group consider tourniquet safety, efficacy, weight and size capacity in field medical bags, ease of application, tourniquet packaging, and material component standards. The current evaluation utilizes the same testing parameters as the original assessment but with three new tourniquet designs that emerged since the previous study concluded.

MATERIALS AND METHODS

INSTRUMENTATION

*HapMed Instrumented Leg and Arm for Tourniquet Training (CHI Systems, Plymouth Meeting, Pennsylvania).*The HapMed Instrumented Tourniquet Training System (Figure 1) provides stand-alone, hands-on skills training in which trainees can experience the actual torque required to stanch bleeding from an extremity wound. Sensors within the leg and arm gauge the amount of applied pressure, and light emitting diodes (LEDs) indicate when blood flows from the extremity. When the pressure required to fully occlude blood flow is applied, the LEDs turn off completely to indicate blood flow has stopped. If the tourniquet pressure subsequently falls, the bleeding begins again and the lights indicate accordingly. Once a trial is complete, the HapMed device reports the number of seconds it took to stop the bleeding, the amount of blood loss, and provides feedback regarding position and magnitude of the applied pressure.

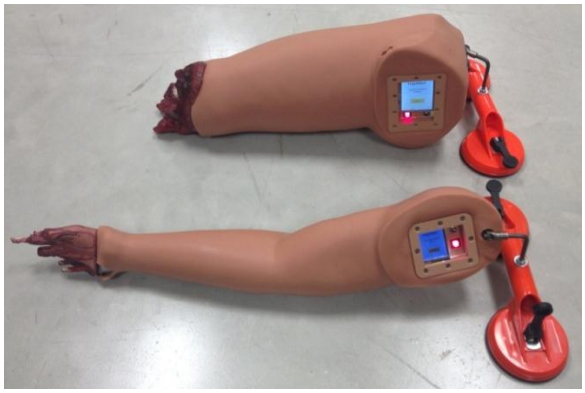

Figure 1. HapMed Instrumented Leg and Arm (CHI Systems, Plymouth Meeting, Pennsylvania). The HapMed Leg and Arm provide realistic visual and tactile feedback during tourniquet application. The devices also provide performance metrics including application time and the amount of pressure exerted by tourniquets.

Tekscan I-Scan® Pressure Measurement System (South Boston, Massachusetts). The Tekscan is a force and pressure measurement system which displays and records dynamic and static interface pressure distribution data (Figure 2). The system includes Windows-based software, scanning electronics, and pressure sensors. The scanning electronics rapidly record pressure data from an array of independent sensing elements contained within each sensor. Data from the sensors were collected at a rate of 1 Hz and used to characterize pressure distributions and analyzed to determine total contact pressures exerted on the sensing matrix.

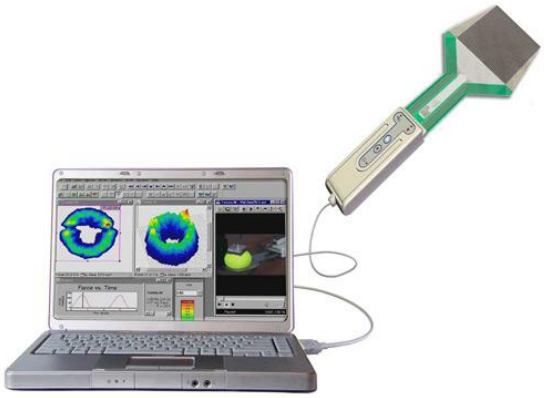

Figure 2. Tekscan I-Scan® Pressure Measurement System (South Boston, Massachusetts). The Tekscan pressure measurement system senses and maps pressure distributions across its sensing surface. The scanning electronics rapidly record data from an array of independent sensing elements contained within each sensor.

EQUIPMENT UNDER TEST

The following tourniquets were developed by the New York City Industries for the Blind (NYCIB), Brooklyn, New York). They are listed in no particular order.

Tactical Mechanical Tourniquet (TMT). The TMT (Figure 3) is a small, lightweight, mechanical tourniquet designed to occlude arterial blood flow in an extremity. The TMT uses a windlass to apply circumferential pressure to the limb, and a clip secures the windlass once tightened. A curved, semi-rigid plate positioned directly beneath the windlass allows the tourniquet to form to the limb and acts as a barrier between the limb and the strap material which bunches as the windlass is tightened. The two ends of the tourniquet clip together, and the strap material feeds through slots on the clip to pre-load the tourniquet. Self-adhering hook-and-loop fastener runs the full length of the tourniquet strap to secure it in place once tightened.

Figure 3. Tactical Medical Tourniquet (NYCIB, Brooklyn, New York).1. Windlass applied circumferential pressure to the limb. 2. A curved, semi-rigid plate forms to the limb and acts as a barrier between the limb and the strap material as the windlass tightens. 3. A clip secures the windlass once tightened. 4. The 2" wide strap material features self-adhering hook and loop along the entire length to facilitate application. 5. Slotted clips connect the two ends of the tourniquet.

Tactical Pneumatic Tourniquet 2" (TPT2.1). The TPT2.1 (Figure 4) is a pneumatic tourniquet, which contains two 2-inch wide straps that form two concentric layers when the tourniquet is applied. The inner layer contains an air bladder and is held in place with self-adhering hook-and-loop fastener (tan strap material). The second layer is applied on top of the inner layer to secure it in place (black strap material). The two ends of the outer layer clip together, and the strap material feeds through slots on the clip, which allow it to be cinched tight. Self-adhering hook-and-loop fastener runs the full length of the outer layer to fix it in place once tightened. Once both layers are applied, a rubber bulb pump inflates the air bladder.

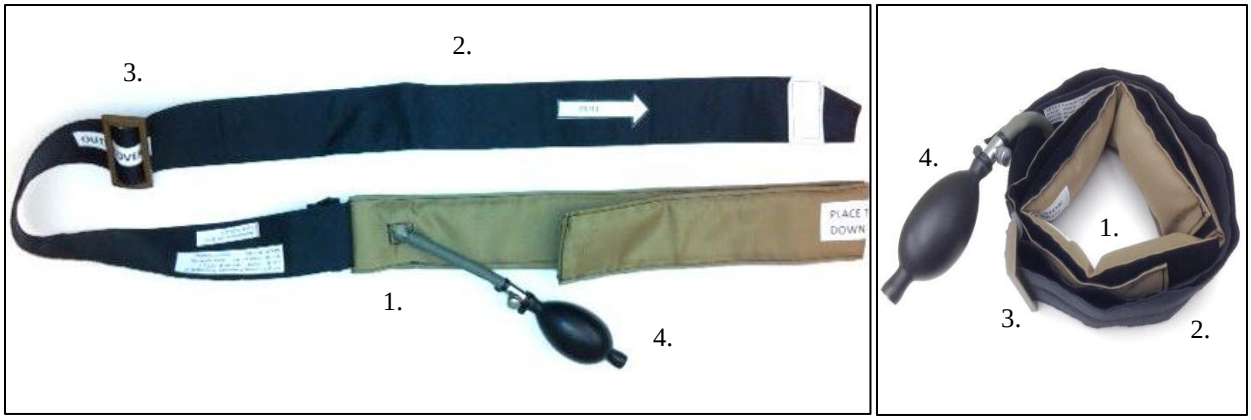

Figure 4. Tactical Pneumatic Tourniquet 2" (NYCIB, Brooklyn, New York). 1. The tan strap material contains an air bladder and forms an inner layer when the tourniquet is applied. 2. The black strap material forms an outer layer, which holds the inner loop in place. 3. Slotted clips connect the two ends of the outer layer and allow the outer layer to be tightened. 4. A rubber bulb pump inflates the air bladder in the inner layer.

Tactical Pneumatic Tourniquet 3" (TPT3.1). The TPT3.1 (Figure 5) is a pneumatic tourniquet, which utilizes the same design concept as the TPT2.1, but features 3-inch wide straps for both the inner layer that contains the air bladder (tan strap material) and outer layer that secures the inner layer in place (black strap material).

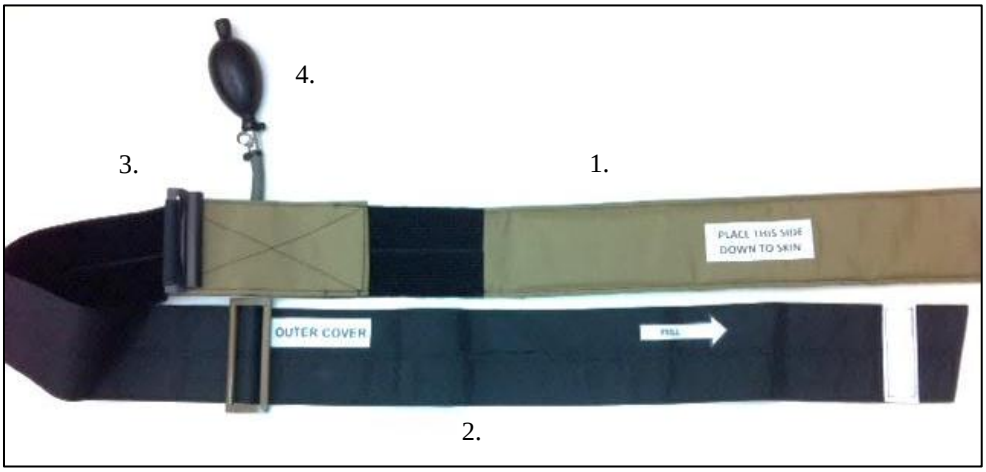

Figure 5. Tactical Pneumatic Tourniquet 3" (NYCIB, Brooklyn, New York). 1. The tan strap material contains an air bladder and forms an inner layer when the tourniquet is applied. 2. The black strap material forms an outer layer, which holds the inner layer in place. 3. Slotted clips connect the two ends of the outer layer and allow the outer layer to be tightened. 4. A rubber bulb pump inflates the air bladder in the inner layer.

TEST PROCEDURES

Phase Ia – Basic Assessment and Characterization. The physical characteristics of five of each tourniquet model (n = 5) were evaluated and recorded on a Specification Requirements Data Collection Sheet (SRDCS). The characteristics were based on consensus parameters for

safety, efficacy, and operational effectiveness defined during the 2010 DoD Tourniquet Summit. The characteristics included:

- **Food and Drug Administration (FDA) Registration** - Any information available regarding FDA registration provided by the manufacturer was verified and recorded.
- **Tourniquet Width ≥ 1.5 in -** Tourniquets were measured from the narrowest portion of the band that distributes pressure to control hemorrhage.
- **Tourniquet Length ≥ 37.5 in** - Length was acquired by laying the tourniquet flat and measuring from end to end.
- **Weight <8oz** - Weight was recorded for both packaged and unpackaged devices.
- **Cubic Size ≤ 25.6 in³** - Measurements of the height, width, and length of the packaged device were recorded.
- **Color (subdued) -** Yes/No was recorded to indicate whether the unpackaged device was subdued in color or consisted of colors that were non-subdued.
- **Protective Packaging** - Yes/No was recorded to indicate whether the device was packaged to protect it from environmental elements.
- **Tracking/Date of Manufacture Information** - Yes/No was recorded to indicate whether the presence of tracking information was included with device or located on packaging.
- **User Instructions Present** - Yes/No was recorded to indicate whether user instructions were included with device or located on its packaging.
- **Latex-free Components** - Yes/No was recorded to indicate whether the device was latex free or not.
- **Material Component Standards** - Any information included with device or on its packaging to indicate whether the device was manufactured using Military Specification Standards was recorded.
- **Single Patient Use** - Yes/No was recorded to indicate whether the manufacturer stated on the device that it is intended for single patient use or not.

Phase Ib – Tourniquet Efficacy Testing. Tekscan sensors were positioned on the upper humerus of HapMed Arm and at mid-thigh on the HapMed Leg. In total, five tourniquets of each type (TMT, TPT2.1, TPT3.1) were applied to the HapMed Leg, according to manufacturer instructions, such that the strap exerted pressure on the Tekscan sensor. The display on the HapMed Leg indicated when the necessary occlusion pressure was generated, and application

times were recorded for each tourniquet. The HapMed Leg was monitored for 1 minute after application to ensure occlusion pressure was maintained. The Tekscan system measured the spatial pressure distribution across the width of the tourniquet strap material (Figure 6) as well as the total pressure exerted by each tourniquet. After completing applications on the HapMed Leg, tourniquets that successfully achieved and maintained occlusion were applied to the HapMed Arm using the same procedure.

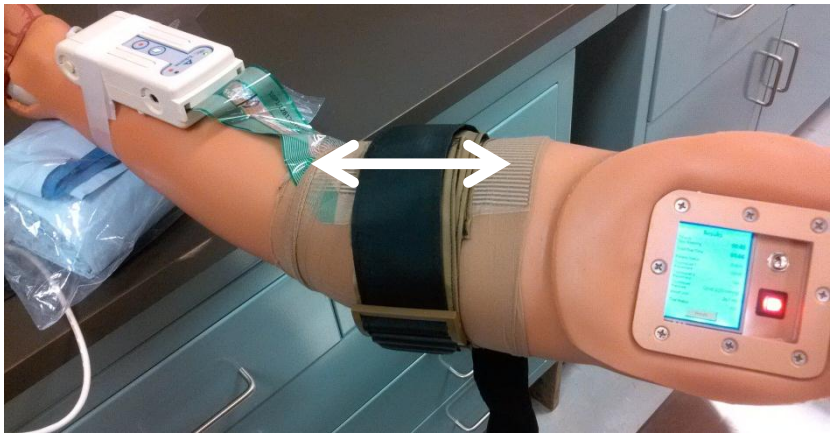

Figure 6. Orientation of pressure measurements across tourniquet strap material. The orientation of the pressure distribution measurement with respect to the HapMed Arm and Tekscan sensor.

RESULTS/DISCUSSION

Phase Ia–Basic Measurement and Assessment. Five (n=5) of each tourniquet type were measured and weighed, and the results reveal consistency in dimensions within a given tourniquet type (Table 1). Each model met the consensus requirements for minimum tourniquet width and length, as well as maximum package weight. The TPT3.1 and TPT2.1 had volumes of 45.70 ± 2.60 in^3 and 38.67 ± 1.50 in^3 respectively, which both exceeded the consensus value of 25.6 in^3, while the average TMT volume was 25.84 ± 0.80 in^3, which is within the margin of error of the target volume.

Table 1. Physical Characteristics of Tourniquet Devices and Packaging

	TMT	TPT2.1	TPT3.1
Tourniquet Width (in)	2.00± 0.00	2.00± 0.00	3.00± 0.00
Tourniquet Length (in)	38.68± 0.17	39.75± 0.00	39.13± 0.48
Weight of Device, packaged (oz)	2.98± 0.03	5.26± 0.04	6.83± 0.03
Weight of Device, unpacked (oz)	2.77± 0.02	5.02± 0.04	6.57± 0.02
Package Length (in)	4.50± 0.00	5.47± 0.16	6.21± 0.37
Package Width (in)	3.25± 0.00	3.34± 0.09	4.28± 0.02
Package Height (in)	1.75± 0.00	2.60± 0.12	2.57± 0.18
Package Volume (in^3)	25.84± 0.80	38.67± 1.50	45.70± 2.60

Note: Values reported as average ± standard deviation (n = 5).

Qualitative characteristics, including device color and information included with the tourniquets from the manufacturer, were consistent among tourniquets of a given type (Table 2). None of the tourniquets evaluated were FDA registered, and none indicated whether they were latex free or intended for single patient use. Each tourniquet was subdued in color, provided tracking information, and contained user instructions. All tourniquets had protective packaging, although TMT and TPT3.1 packages both had pinholes which would not create a barrier for moisture.

Table 2. Basic Assessment of Tourniquet Devices

	TMT	TPT2.1	TPT3.1
FDA Registered	No	No	No
Color (Subdued)	Yes	Yes	Yes
Protective Packaging	Yes*	Yes	Yes*
Tracking/Date of Manufacturing	Yes	Yes	Yes
User Instructions Present	Yes	Yes	Yes
Material Standard Components	Not Stated	Not Stated	Not Stated
Latex Free	Not Stated	Not Stated	Not Stated
Single Patient Use	Not Stated	Not Stated	Not Stated

*The protective packaging for the TMT and TPT3.1 both contained pinholes which could allow moisture to enter the packaging.

Phase Ib – Tourniquet Efficacy Testing and Operational Characteristics. Each tourniquet demonstrated the ability to generate occlusion pressure, and no significant differences were observed between tourniquet application times (Table 3). The average application time on the leg was 55.9 ± 11.9 sec, while the average application time on the arm was 33.3 ± 6.3 sec. TMT maintained occlusion during all applications, while individual TPT3.1 and TPT2.1 tourniquets had failures during the 1-minute observation period. One of the five TPT3.1 tourniquets failed to maintain occlusion pressure on the leg, and a second TPT3.1 failed to maintain occlusion pressure on the arm. Subsequent testing revealed both had air bladder leaks. One TPT2.1 failed to maintain occlusion on the leg, and testing revealed the tourniquet had a check valve malfunction, which allowed air from the bladder to bleed back into the bulb pump.

Table 3. Tourniquet Application Times and Occlusion Percentages using HapMed Instrumented Arm and Leg

	TMT	**TPT2.1**	**TPT3.1**
Leg Application Time (seconds)	53.6 ± 10.9	56.2 ± 12.5	57.8 ± 14.6
Arm Application Time (seconds)	30.0 ± 4.8	37.3 ± 5.3	33.3 ± 7.6
Occlusion Achieved on Both Arm and Leg	100%	100%	100%
Occlusion Maintained on Both Arm and Leg	100%	80%**	60%*

Note: Values reported as average ± standard deviation (n=5).
*Two TPT3.1's failed to maintain occlusion due to leaks in their air bladders.
**One TPT2.1failed to maintain occlusion due to a check valve malfunction.

Differences in pressure application curves were observed among the different tourniquet designs using the Tekscan sensor (Figure 7). The application times for each tourniquet type were similar, as was the final application pressure. The incremental changes in pressure during application, however, differed between TPT3.1 and TPT2.1, which are pneumatic, and the TMT, which features a windlass design. The pressure increase caused by a single compression of the TPT3.1 and TPT2.1 bulb pump is smaller than the pressure change caused by a rotation of the TMT windlass. As a result, the application pressure curve was smoother for the TPT3.1 and TPT2.1. In contrast, the TMT pressure application curve was much more segmented, reflecting each half-revolution of the windlass followed by a pause for grip readjustment.

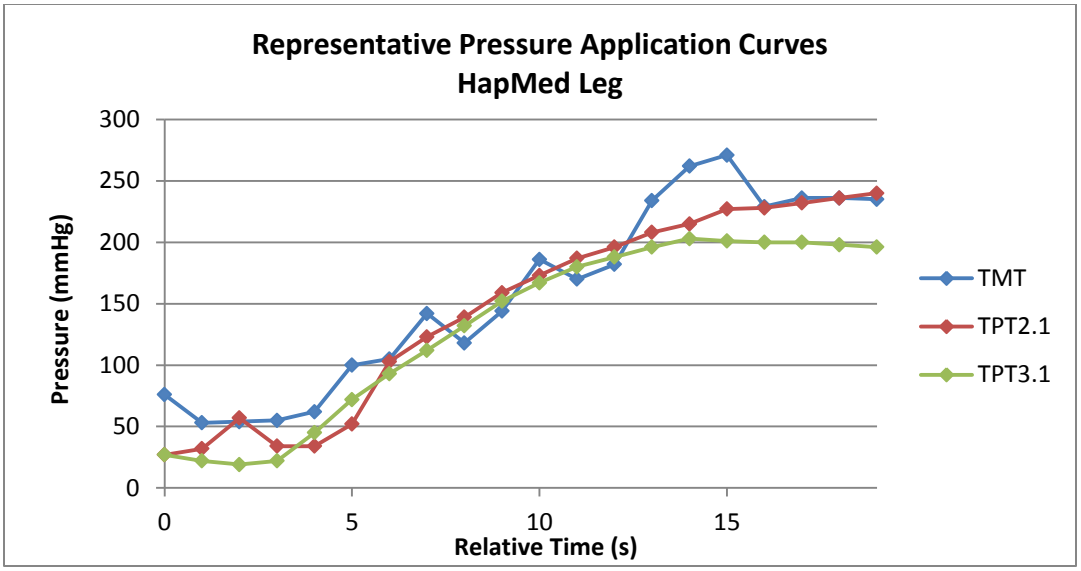

Figure 7. Individual pressure application curves. Each curve represents a single application of a tourniquet on the HapMed Instrumented Leg. The 20 second intervals shown were time-locked at onset of pressure application for the sake of comparison.

Each of the devices produced a distinguishable distribution of pressures, reflecting tourniquet mechanical properties and methods of application. The pneumatic tourniquets, TPT3.1 and TPT2.1, exhibited bell-shaped pressure curves, reflecting the convex shape of the air bladder as the tourniquet inflates (Figure 8). As one might expect, the 3-inch TPT3.1 had a wider pressure profile than the 2-inch TPT2.1. The peak pressure exerted by the TPT3.1 was also lower than the peak pressure exerted by TPT2.1 and TMT, likely due to the pressure being distributed over a greater area. The TMT produced a more even pressure distribution, which plateaued across the 2-inch width of the tourniquet, with peak pressures appearing at the edge of the strap material. The pressure variability at each position across TMT strap was greater than that of the two pneumatic tourniquets, and the greater variability was likely due to the larger incremental changes in pressure during TMT application. If occlusion was achieved, for instance, with the TMT windlass in mid-revolution, the revolution must still be completed to secure the windlass to the clip, which adds to the overall pressure exerted. In contrast, the smaller incremental changes in pressure produced by the pneumatic tourniquets resulted in more consistent application pressures with little pressure added once occlusion was achieved.

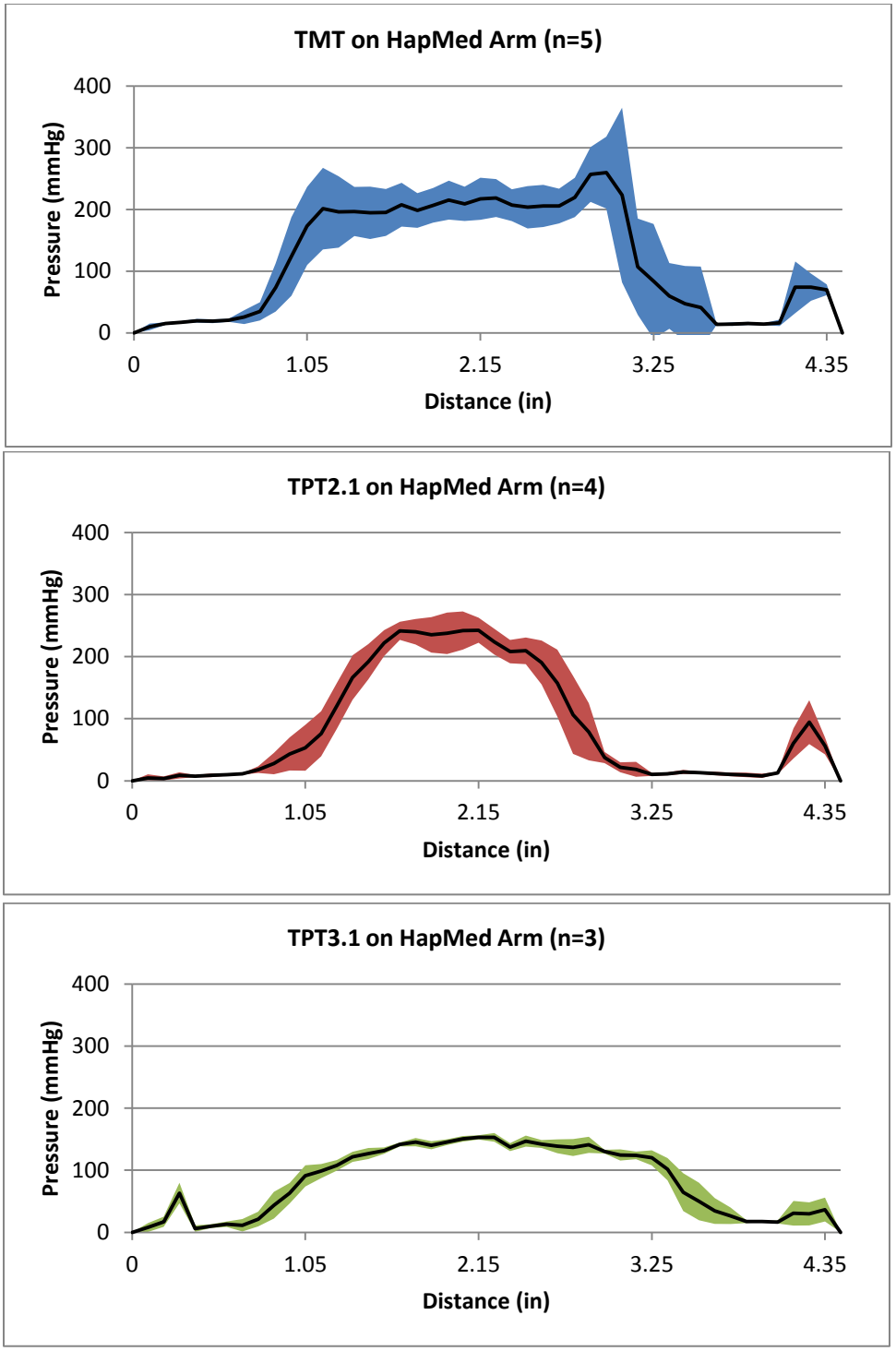

Figure 8. Tourniquet pressure distribution. Each subplot represents trials in which occlusion was maintained for each tourniquet type. The black line represents the average pressure at each position across the width of the Tekscan sensor, while the colored area represents one standard deviation.

Tekscan measurements show the total pressure exerted on the HapMed Leg during the 1-minute period after application was greater than the pressure exerted on the HapMed Arm for all three devices. The 3-inch wide TPT3.1 tended to exert slightly less pressure than the 2-inch

wide TPT 2.1 and TMT, although the result was not statistically significant. As was seen in the pressure distribution measurements, the TMT exhibited the greatest variability in applied pressure. Again, the greater variability is likely a result of the coarser adjustment inherent to the TMT device's windlass mechanism.

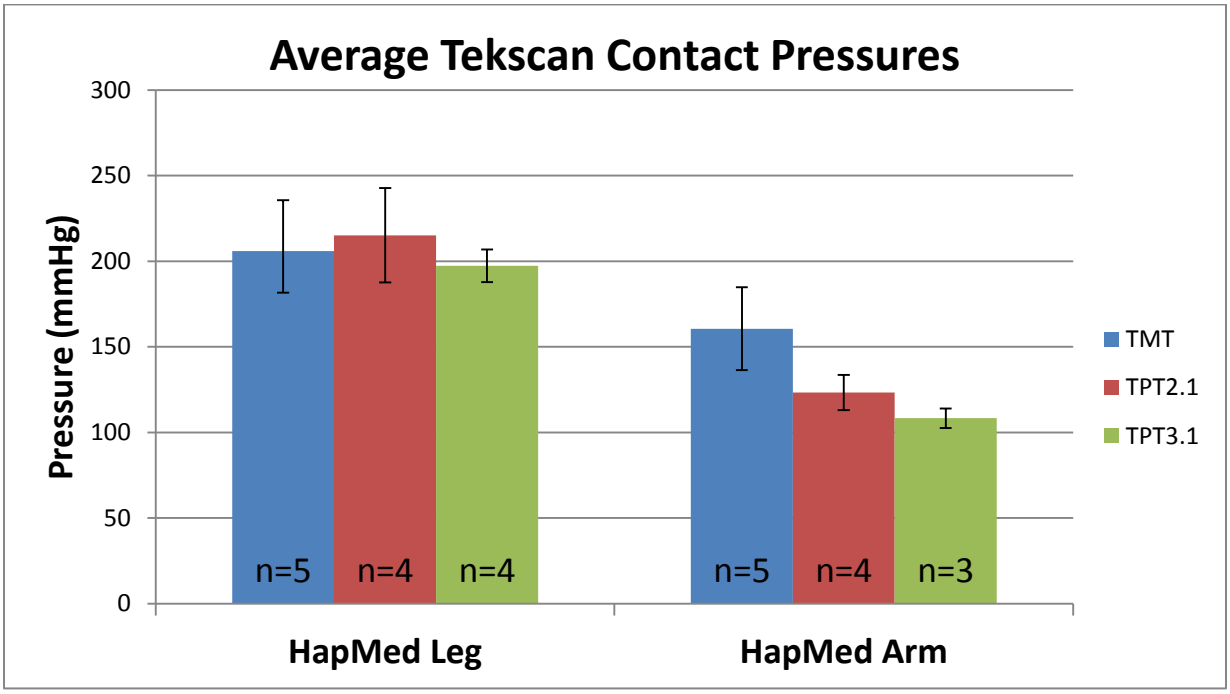

Figure 9. Comparison of pressures exerted by tourniquets. Each bar represents the total contact pressure measured by the Tekscan system. For each trial, total contact pressures were averaged during the 1-minute period after application, and values were averaged across trials. Error bars represent one standard deviation. Only trials in which the tourniquet achieved and maintained occlusion are included in the average, so the number of trials (n) varies depending on the success of the tourniquets tested. The n values are indicated on each bar.

CONCLUSIONS

Each tourniquet demonstrated the ability to achieve the necessary occlusion pressure, and similar application times were observed for each type. However, individual TPT3.1 and TPT2.1 tourniquets failed to maintain air pressure, resulting in the loss of occlusion within 1 minute of application. Due to the small sample size, additional tests would be required to ascertain the specific cause and extent of the failures, for instance whether the device failures were anomalies, whether they represent material limitations, or whether they were the result of a flaw in the manufacturing process. Data collected from TMT, TPT3.1, and TPT2.1 will aid the sponsor in selecting tourniquet devices for further field testing.

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ABBREVIATIONS

DoD	Department of Defense
HapMed	Haptic Medicine
JOEFT	Joint Operational Evaluation of Field Tourniquets
LED	Light Emitting Diode
MARCORSYSCOM	Marine Corps Systems Command
NAMRU-SA	Naval Medical Research Unit San Antonio
NYCIB	New York City Industries for the Blind
TMT	Tactical Mechanical Tourniquet, NYCIB, Brooklyn NY
TPT2.1	Tactical Pneumatic Tourniquet 2", NYCIB, Brooklyn NY
TPT3.1	Tactical Pneumatic Tourniquet 3", NYCIB, Brooklyn NY
USAMMDA	United States Army Medical Material Command

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6. AUTHORS
Roy Dory, MS, D. Duane Cox, Bridget Endler, MS

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Medical Research Unit San Antonio
3650 Chambers Pass, BHT-2, Bldg 3610
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14. ABSTRACT
The Joint Operational Evaluation of Field Tourniquets, recently performed at Naval Medical Research Unit San Antonio, assessed the operational characteristics of ten currently fielded or FDA registered tourniquets. The tourniquets were tested according to consensus parameters established by the Department of Defense Tourniquet Working Group Summit held in Quantico, Virginia in March 2010. The parameters defined by the working group consider tourniquet safety and efficacy, weight and size capacity in field medical bags, ease of application, tourniquet packaging, and material component standards. The current evaluation follows the original assessment with three new tourniquet designs, the Tactical Mechanical Tourniquet (TMT), the Tactical Pneumatic Tourniquet 3" (TPT3.1), and the Tactical Pneumatic Tourniquet 2" (TPT2.1), and compares their performance using the same metrics. All tourniquets met the dimensional consensus criteria for minimum length, width, and maximum weight. The TPT2.1 and TPT3.1, however, both exceeded the consensus criteria for package volume. The TMT demonstrated the ability to achieve and maintain occlusion during all applications, while only three of the five TPT3.1 devices and four of the five TPT2.1 devices achieved and maintained occlusion pressure on both the HapMed Arm and Leg. Two TPT3.1 devices failed to maintain occlusion due to pinhole leaks in the air bladder, and one TPT2.1 device failed to achieve occlusion pressure due to a check valve malfunction. For those devices that achieved occlusion, the final pressures across tourniquet models were comparable within testing of the leg and the arm. The TMT exhibited the greatest variability in pressure exerted on the arm and leg, likely due to coarser changes in pressure during rotation of the windlass relative to the small incremental increases in pressure during inflation of the TPT3.1 and TPT2.1 air bladders. Due to the small sample size, additional tests would be required to reveal whether the device failures are anomalies or whether they represent material defects or a flaw in the manufacturing process. Data collected from TMT, TPT3.1, and TPT2.1 will aid the sponsor in selecting tourniquet devices for further field testing.

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

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