# NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

## JOINT OPERATIONAL EVALUATION OF FIELD TOURNIQUETS (JOEFT) – PHASE IIIA

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**ABBREVIATIONS**

| | |
|---|---|
| CAT | Combat Application Tourniquet® (Composite Resources; Rock Hill, SC) |
| DCS | Data Collection Sheet |
| DOD | Department of Defense |
| EMT | Emergency and Military Tourniquet (Delfi Medical; Vancouver, BC) |
| FDA | Food and Drug Administration |
| JOEFT | Joint Operational Evaluation of Field Tourniquets |
| NAMRU-SA | Naval Medical Research Unit San Antonio |
| RMT | Ratcheting Medical Tourniquet™ (m2®, Inc.; Winooski, VT) |
| SSH | SynDaver™ Synthetic Human Cadaver (SynDaver™ Labs) |
| SOFFT-W | Special Operations Forces Tactical Tourniquet - Wide (Tactical Medical Solutions®; Anderson, SC) |
| TMT | Tactical Mechanical Tourniquet (Alphapointe™; Kansas City, MO) |
| TPT | Tactical Pneumatic Tourniquet (Alphapointe™; Kansas City, MO) |

## EXECUTIVE SUMMARY

**Background:** Tourniquets provide vital limb stabilization during extremity hemorrhage, which remains a leading mechanism of injury in deaths on the battlefield considered potentially survivable. Several tourniquet designs are commercially available, and rigorous testing is necessary to ensure the warfighter is equipped with the most effective and operationally sound tourniquet. Conventional test platforms, which include animal, mannequin, and human models are each limited in their ability provide repeatable, clinically, and operationally relevant tourniquet performance data; however, the recent development of the SynDaver™ Synthetic Human (SSH) Cadaver has opened the door for tourniquet testing with a level of complexity and fidelity not previously attainable with other trauma mannequin systems.

**Objective:** To evaluate seven extremity tourniquets (CAT, EMT, RMT-PAR, RMT-TAC, SOFTT-W, TMT, and TPT) during extended application periods and during simulated patient transfers, using the SSH with a simulated lower-extremity arterial hemorrhage.

**Methods:** Ten of each tourniquet design were applied to the mid-thigh of the SSH. Each tourniquet was tightened until arterial pressure distal to the application site fell below 1 mmHg. Volume of blood loss and interface pressures between the tourniquet and SSH were measured for five minutes. After the first monitoring period, the SSH was lifted, held for 20 seconds, and lowered, to simulate a patient transfer. Blood loss and contact pressure were then measured for a second five-minute monitoring interval.

**Results:** All seven tourniquet designs achieved initial occlusion in each of the tests. Mean application times ranged from a low of $59.1 \pm 8.9$ s for the EMT and a high of $87.6 \pm 19.6$ s for the TPT. During the RMT-PAR applications, a significant drop in contact pressure ($p < 0.05$) was measured between the end of tourniquet application and end of the second monitoring period. During RMT-TAC and the SOFTT-W applications, there was a significant increase in the volume of blood accumulated ($p < 0.05$). The CAT, RMT-TAC, and SOFTT-W each had trials in which there was greater than 100 mL of blood loss after initial occlusion.

**Conclusions:** In this evaluation of extremity tourniquets on a state-of-the-art human replica cadaver model, quantitative data, including application times, blood loss, and pressure distributions were measured and compared across 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 system.

## INTRODUCTION

Extremity hemorrhage remains one of the most prevalent causes of death on the battlefield. While some injuries are non-survivable, an analysis of over 4,500 casualties occurring between 2001 and 2011 showed that over 90% of the potentially survivable injuries were associated with hemorrhage (Eastridge et al., 2012). Extremity tourniquets temporarily stabilize a bleeding limb until they can be converted to a hemostatic or pressure dressings or until the casualty can receive more comprehensive treatment at a higher echelon of care. Tourniquets are currently found in the military issued Individual First Aid Kit (IFAK), Medical Care Bag, Ground and Air Medical Equipment Sets (MES), and other MES kits.

Several extremity tourniquet models are on the market, and to ensure the effectiveness of candidate tourniquet designs in the hands of the warfighter, a joint-services Department of Defense (DOD) Tourniquet Working Group was established in 2010 to recommend standardized tourniquet safety, efficacy, and operational requirements. These recommendations were implemented in two initial phases of testing, the Joint Operational Evaluation of Field Tourniquets (JOEFT) Phase I, which assessed basic device characteristics and functionality in a controlled test environment, and Phase II, which assessed device performance in the hands of non-medical personnel under various environmental conditions (McKeague et al., 2012; Alvarez et al., 2014; Dory et al., 2014; Dory et al., 2015). Of the thirteen device types that were evaluated, seven designs successfully met all of the requirements for tourniquet safety and efficacy in JOEFT Phases I and II.

The seven remaining tourniquet designs underwent a third phase of operational testing, presented here, in which performance was evaluated over extended application periods and during simulated patient tranfers. Until recently, a practical and reliable human model capable of testing the efficacy of hemorrhage control devices did not exist. Animal models of hemorrhage have been used to evaluate hemostatic dressings; however, evaluating devices that control blood flow via external pressure requires human equivalent tissue characteristics, morphology, and vasculature. Testing with human volunteers is also limited, as repeated testing with multiple devices is uncomfortable, device applications are only tolerable for short durations, and hemodynamic variables are not controllable. The emergence of the SynDaver™ Synthetic Human (SSH) Cadaver, a human tissue equivalent cadaver model, which features anatomically accurate vasculature, has opened the door for repeatable tourniquet testing with a level of

complexity and fidelity not previously seen in trauma training mannequin systems. Data from device testing with this sophisticated model will aid the DOD in the down-selection of candidate extremity tourniquets to increase standardization, effectiveness, and safety.

## MATERIALS AND METHODS

### INSTRUMENTATION

*SynDaver™ Synthetic Human (SSH) Cadaver (SynDaver™ Labs, Tampa, FL).* The SSH is a sophisticated human anatomical and physiological replica (Figure 1). Individual tissues are constructed to mimic the geometry as well as the physical properties of the live tissues they are designed to match, including the fiber content, modulus in tension, compression, shear, and coefficients of friction (Sakezles, 2009). The SSH also features a circulatory system with the heart, coronary arteries, aorta, vena cava, and the primary arterial and venous trunks leading to the extremities. A pump circulates water through the vasculature with pulsed flow away from the heart and drainage through the venous system. This unique synthetic cadaver system allows for a thorough evaluation of extremity tourniquets not possible with previous mannequin systems. The SSH also provides a platform for repeatability that would not be safely feasible for extended durations with human subjects.

**Figure 1. SynDaver™ Synthetic Human (SSH) Cadaver.** SSH musculature is shown without the skin and adipose tissue. The SSH is comprised of individual tissues designed to mimic the mechanical properties of living tissues.

*Tekscan I-Scan® Pressure Measurement System (South Boston, Massachusetts).* The Tekscan I-Scan® 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 grid. A Model 5101 sensor was used to measure and map the pressure exerted by the extremity tourniquets. The Model 5101 has a 4.40" x 4.40" sensing matrix, which contains 1936 individual sensing elements, providing a spatial resolution of 100 elements per square inch. Data from the sensor were collected at a rate of 1 Hz and analyzed to determine the average contact pressures exerted on the sensing matrix over time.

**Figure 2. Tekscan I-Scan® Pressure Measurement System.** 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 tested. They are listed in alphabetical order:

*Combat Application Tourniquet® (CAT, Composite Resources; Rock Hill, SC).* The CAT (Figure 3) is a mechanical tourniquet, which uses a windlass to generate circumferential pressure. The CAT features a self-adhering hook-and-loop fastener integrated into the strap, which is threaded through a slip lock buckle to generate initial pressure around the limb. Once the initial tension is applied and the strap secured with the hook-and-loop fastener, secondary pressure is applied using a windlass. Once tightened, the windlass is held in place with a C-

shaped windlass locking clip and further secured with a hook-and-loop windlass securing strap, which closes the opening in the clip.

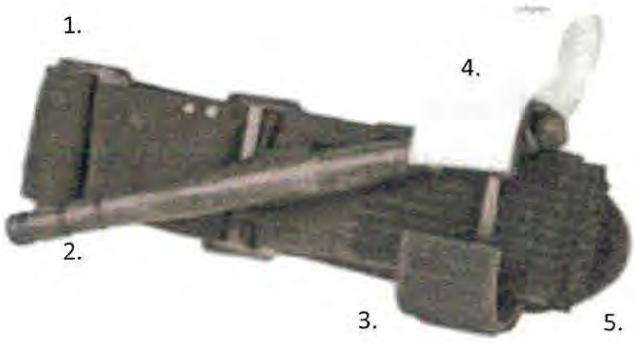


**Figure 3. Combat Application Tourniquet.** 1. Slip lock buckle. 2. Windlass. 3. C-shaped windlass locking clip. 4. Windlass securing strap. 5. Strap material with integrated hook-and-loop fastener.

*Emergency & Military Tourniquet (EMT, Delfi Medical; Vancouver, BC).* The EMT (Figure 4) is a pneumatic tourniquet, which features a bladder integrated directly into the full length of the 3.5" wide strap material. Initial tension is exerted by pulling one end of the bladder/strap through a clamping mechanism. The clamp holds the bladder/strap in place, creating an airtight seal across the width of the bladder, and ensuring only the effective portion of the bladder requires inflation. Once secured, a hand bulb pump, which is permanently fixed to the bladder with a flexible hose, is used to inflate the tourniquet.


**Figure 4. Emergency and Military Tourniquet.** 1. Strap with integrated bladder. 2. Hand bulb pump. 3. Clamping mechanism.

*M2 Ratcheting Medical Tourniquet™ (Paramedic version: RMT-PAR, Tactical version: RMT-TAC, m2®, Inc.; Winooski, VT).* The RMT (Figure 5) is mechanical tourniquet which uses a ladder strap and ratcheting buckle to generate circumferential pressure. Pre-tension is applied by threading the strap material through slip lock rings, and pulling the strap tight. Secondary pressure is generated using the ratcheting mechanism, which incrementally increases tourniquet pressure while locking the ladder strap in position. Two RMT models were tested: RMT-PAR and RMT-TAC. Both feature 1.5" straps and function in the same manner. The RMT-TAC is lighter and more compact with a 0.75" wide ratcheting mechanism and a tan color scheme, while the RMT-PAR is slightly larger and heavier with a 1" wide ratcheting mechanism and a black color scheme

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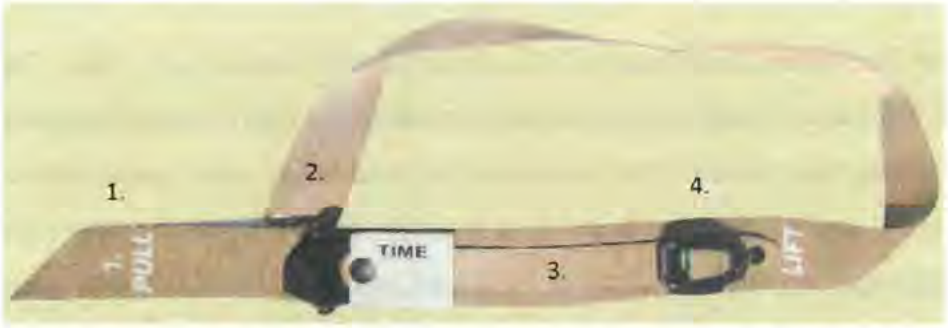


**Figure 5. Ratcheting Medical Tourniquet ™ (tactical model).** 1. Strap material. 2. Slip lock rings. 3. Ladder strap. 4. Ratcheting mechanism.

*Special Operations Forces Tactical Tourniquet – Wide (SOFTT-W, Tactical Medical Solutions®; Anderson, SC).* The SOFTT-W (Figure 6) is mechanical tourniquet, which uses a windlass to generate circumferential pressure. The tourniquet has a 1.5" wide strap material and a hooking clasp, which eliminates the need to thread the strap. The strap is pre-threaded through a slip lock mechanism integrated into the clasp, which is pulled tight to generate initial tension. Secondary pressure is generated with the windlass. Once tightened, the windlass is held in place with a triangular ring, which fits into a groove at the end of the windlass.


**Figure 6. Special Operations Forces Tactical Tourniquet – Wide.** 1. Strap material. 2. Hooking clasp (connected) with strap threaded through integrated slip lock mechanism. 3. Windlass. 4. Locking ring to secure windlass.

*Tactical Mechanical Tourniquet (TMT, Alphapointe™; Kansas City, MO).* The TMT (Figure 7) 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. A 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. The slip lock mechanism alone holds the strap secure, and the self-adhering hook-and-loop provides additional locking. The windlass applies secondary pressure and is secured with a locking clip once tightened.


**Figure 7. Tactical Mechanical Tourniquet.** 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 2" (TPT, Alphapointe™; Kansas City, MO).* The TPT (Figure 8) 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. The slip lock mechanism alone holds the strap secure, and the self-adhering hook-and-loop provides additional locking. Once the inner and outer layers are applied, a hand bulb pump inflates the air bladder.


**Figure 8. Tactical Pneumatic Tourniquet.** 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. Hand bulb pump. 4. Hook portion of clasp for outer strap. 5. Clasp with outer strap threaded through slip lock mechanism.

## TEST PROCEDURES

*Overview of Tourniquet Applications.* Ten extremity tourniquets of each design were evaluated during applications to the SSH leg. The tourniquet test order was randomized such that each block consisted of one of each tourniquet model, and tourniquet model order was randomized within block. This randomization minimized order dependence and reduced the effect of user learning, ensuring user experience accrued evenly across tourniquet models. Tourniquets were applied to the SSH leg by a NAMRU-SA test engineer who had previous experience with each of the models tested. Tourniquets were applied using the proximal thigh placement recommended by the guidelines for Tactical Combat Casualty Care for Care Under Fire. The SSH was outfitted in battle dress uniform (BDU) pants, and the tourniquets were

applied over the pants. As depicted in the timeline in Figure 9, the tourniquets were first tightened until blood flow was occluded distal to the application site. No adjustments were made to the tourniquet after the initial application. After five minutes had elapsed, volume of blood loss and interface pressures between the tourniquet and SSH were recorded to measure any material stress relaxation. After the monitoring period, the SSH underwent a simulated patient transfer. The SSH was lifted, held for 20 seconds, and returned to the supine position. Blood loss and pressure gradients were recorded again after a second five minute monitoring period.

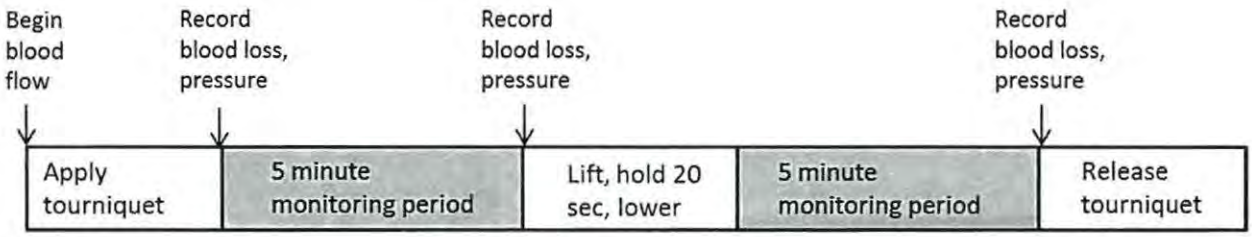


**Figure 9. Tourniquet evaluation timeline**. The timeline shows tourniquet application, SSH transfer, and tourniquet removal. Blood loss was recorded after application and at the end of both monitoring periods. Interface pressures between the tourniquet and the SSH skin were recorded continuously during the application and monitoring periods.

*Pressure Measurements.* Interface pressures between the tourniquet and SSH were measured using the Tekscan pressure measurement system. The 4.40" x 4.40" pressure sensing matrix was positioned on the anterior surface of the upper SSH thigh, centered over the target tourniquet application site, and held in place with thin, elastic material wrapped around the limb. Average contact pressure measurements from the sensing matrix were collected at 1 Hz during the five minute monitoring intervals following tourniquet application and SSH transfers. The contact pressure measurement was calculated as the average pressure exerted on loaded cells within the sensor matrix. A lower threshold of 50 mmHg was used to minimize noise generated by matrix cells that sensed a small amount of pressure, but were not directly beneath the tourniquet.

A verification step was used prior the tourniquet applications to determine the consistency of the pressure sensor between trials. The procedure resembled a test application with the Tekscan grid placed at the same location on the SSH anterior thigh. A pneumatic blood pressure cuff with a pressure gauge was applied to the limb, covering the entire sensor matrix. The cuff was inflated to 280 mmHg, as indicated on the cuff gauge, and the corresponding Tekscan pressure was recorded.

Across the repeated tourniquet applications, a degradation was observed in the Tekscan pressure sensor, likely caused by wear on the sensing surface. The degradation was observed during the verification step as a reduction in the Tekscan pressure values during the 280 mmHg cuff inflation, which was gauged independently. To compensate for the reduction, a correction factor was determined by fitting a regression to the Tekscan data collected during the 280 mmHg blood pressure cuff applications against number of times the sensor had been loaded. Post hoc testing confirmed consistency in the calculated scaling curve between multiple Tekscan sensors loaded in the same manner. The correction factor effectively scaled or calibrated the Tekscan pressures using pressures measured during the 280 mmHg cuff inflation. While the sensor degradation introduced noise into the pressure measurement, the scaled values provide a means to approximate relative differences in interface pressures between the tourniquet designs.

*SSH Configuration and Blood Loss Measurements.* The SSH ankle was dissected to expose Luer lock fittings, integrated into the vasculature by the SSH manufacturer to provide access to the arterial and venous system. The SSH anterior tibial artery was disconnected from the venous vasculature, and three-port valves were inserted to measure blood pressure and to simulate hemorrhage during the evaluation periods. As shown in Figure 10, the arterial blood flow was split into two lines: one attached to a pressure transducer (Omegadyne, Sunburry, OH), and the other passed through an outlet valve and emptied into a collection container, positioned on a digital scale (Ohaus, Parsippany, NJ). The venous line was connected prior to the outlet valve to allow normal circulation when the valve was closed. When the valve was open, fluid was collected and weighed to determine the volume lost.

With no pressure exerted on the SSH leg, the rate of fluid loss through the anterior tibial artery was on average 124 ml/min. The threshold of occlusion was defined as the point at which arterial pressure fell below 1 mmHg. With the arterial pressure below 1 mmHg, blood loss often ceased completely or consisted of a slow drip. The SSH limb occlusion pressure on the proximal thigh, which is defined as the bladder pressure in a standard 4-inch wide pneumatic surgical tourniquet at the point occlusion is achieved, is approximately 300 mmHg. This limb occlusion pressure is at the upper end of the range typical in a clinical setting and represents a challenging scenario for the extremity tourniquets (Younger et al., 2004).

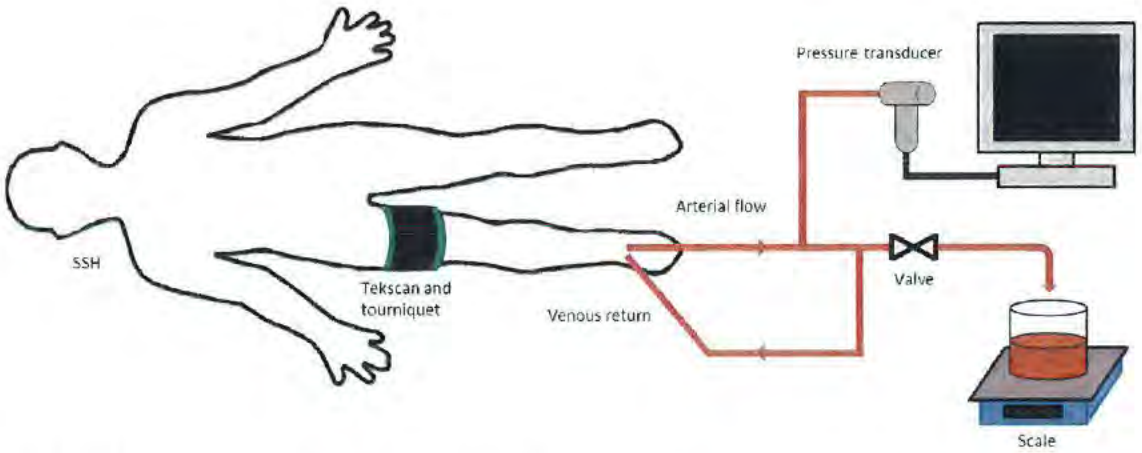


**Figure 10. SSH setup and blood loss measurement.** The schematic illustrates the position of the Tekscan pressure sensor and the tourniquet application site on the SSH thigh. The line carrying arterial flow branched with one end going to a pressure transducer and the other to an outlet emptying into a container to be collected and weighed. The venous flow from the SSH was attached to the arterial line between the branch for the transducer and the outlet.

An example of an arterial pressure profile during a tourniquet application is shown in Figure 11. Prior to the start of the hemorrhage, the mean arterial pressure (MAP) was approximately 67 mmHg. Once hemorrhage began, the MAP dropped to approximately 32 mmHg, with minor fluctuations as the tourniquet was wrapped around the limb. With the tourniquet in place, the secondary pressure mechanism was applied quickly, causing a steady decrease in arterial pressure. The application was considered complete when the arterial pressure fell below 1 mmHg, marking the start of the first monitoring interval.

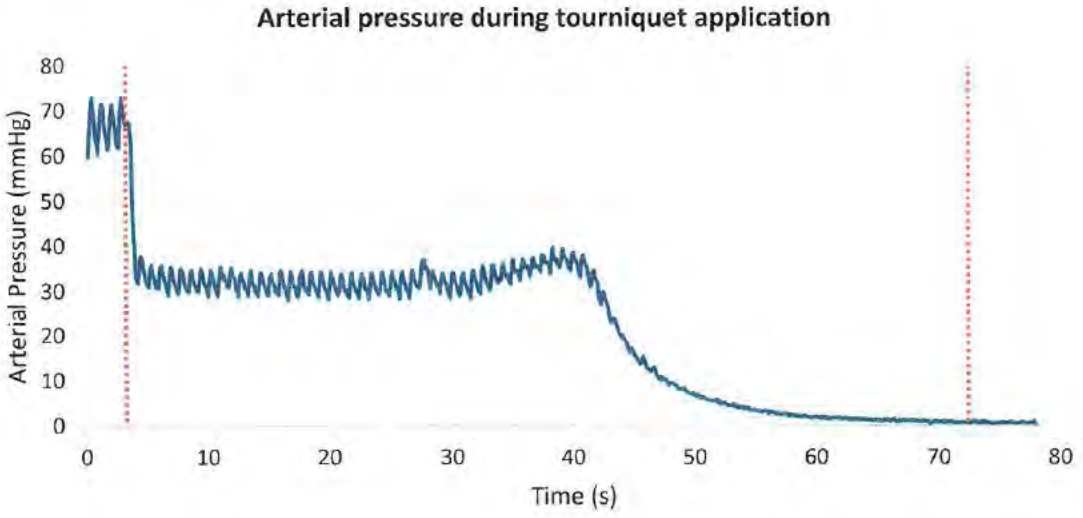


**Figure 11. Example arterial pressure profile during a tourniquet application.** The first red line indicates initiation of hemorrhage and the start of the tourniquet application. The second indicates the end of the application when the arterial pressure fell below 1 mmHg.

## RESULTS/DISCUSSION

*Tourniquet Occlusion and Application Times.* Each tourniquet design successfully achieved initial occlusion during each of the applications. An example tourniquet application is shown in Figure 12. Mean application times ranged from a low of 59.1 ± 8.9 s for the EMT and a high of 87.6 ± 19.6 s for the TPT (Figure 13). The times for the SOFFT-W and the TPT were both significantly longer than those for other models at $p = 0.05$ (EMT, RMT-PAR, TMT and CAT, EMT, RMT-PAR, RMT-TAC, TMT, respectively). There were no significant differences between application times across the different pressure mechanisms employed, which included: windlasses (CAT, SOFTT-W, TMT), pneumatic bladders (EMT, TPT), and ratcheting straps (RMT-PAR, RMT-TAC). Instead, differences in application times were primarily driven by the number of application steps and individual design features.

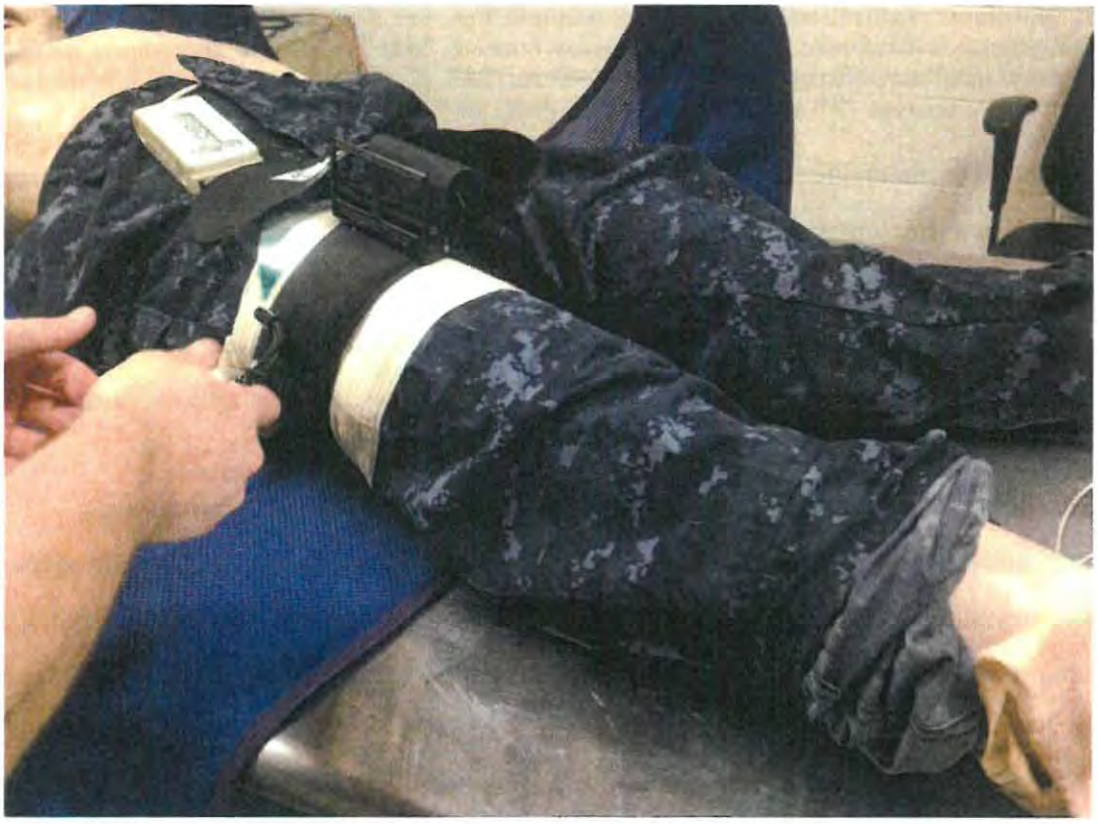

**Figure 12. Example tourniquet application to the SSH**. The Tekscan pressure sensor was secured to the thigh of the SSH with an elastic bandage and the EMT is applied over it. The patient sling was beneath the SSH during the application, ready for the simulated transfer after five minutes of occlusion.

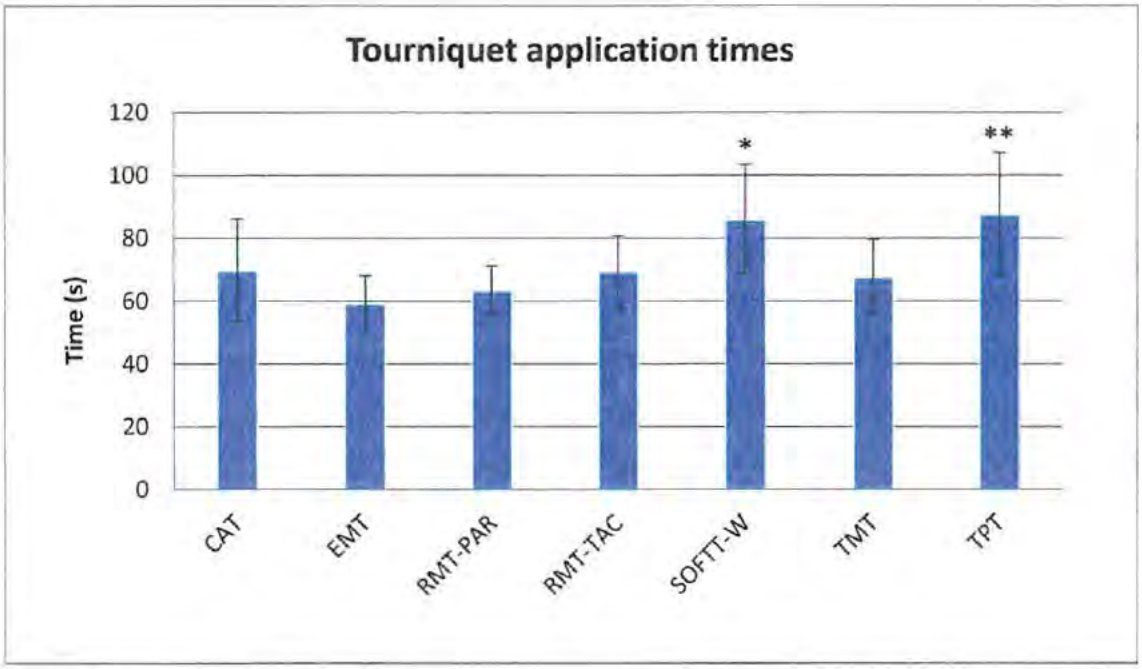


**Figure 13. Tourniquet application times.** Time was measured from start of application to the point of occlusion, when arterial pressure in the anterior tibial artery fell below 1 mmHg. Error bars indicate one standard deviation ($n = 10$). * indicates significant difference between SOFTT-W and EMT, RMT-PAR, TMT ($p < 0.05$). ** indicates significant difference between TPT and CAT, EMT, RMT-PAR, RMT-TAC, TMT ($p < 0.05$).

Among the pneumatic tourniquets, the EMT had the shortest overall application time, while the TPT had the longest application time. The disparity was driven by differences in the number of application steps required by the two models. The EMT required only a single wrap of the air bladder, before the air bladder was secured with a clamp and inflated. In contrast, the TPT required the air bladder to be applied first, then a second securing strap to be wrapped, connected, and tightened, prior to inflation.

Similarly, there were differences in application times among the windlass-type tourniquets, driven by specific tourniquet features. The initial tension produced by all of the windlass tourniquets was generated by pulling the tourniquet strap material tight through a slip-lock mechanism; however, the SOFTT-W slip lock features a floating locking bar, while the CAT and TMT both use static locking bars (Figure 14). The SOFTT-W floating locking bar clamps the strap material to prevent the strap from loosening, but the locking bar also clamps down on the strap as it tightens, limiting the amount of initial tension that can be generated. As a result, the SOFTT-W remained looser than the CAT and TMT after applying initial tension, and required more pressure to be maintained by the windlass. The CAT and TMT windlasses attach to narrow, thin straps that are distinct from the rest of the tourniquet material, whereas the SOFTT-W windlass interfaces directly with the thicker and wider strap material that comprises

the majority of the tourniquet. The thicker strap material often made tightening and securing the SOFTT-W windlass challenging and added to the overall application time. A combination of the thick material and extra tension limited the windlass's range of motion and made maneuvering and securing the windlass into the triangular locking ring a challenge.

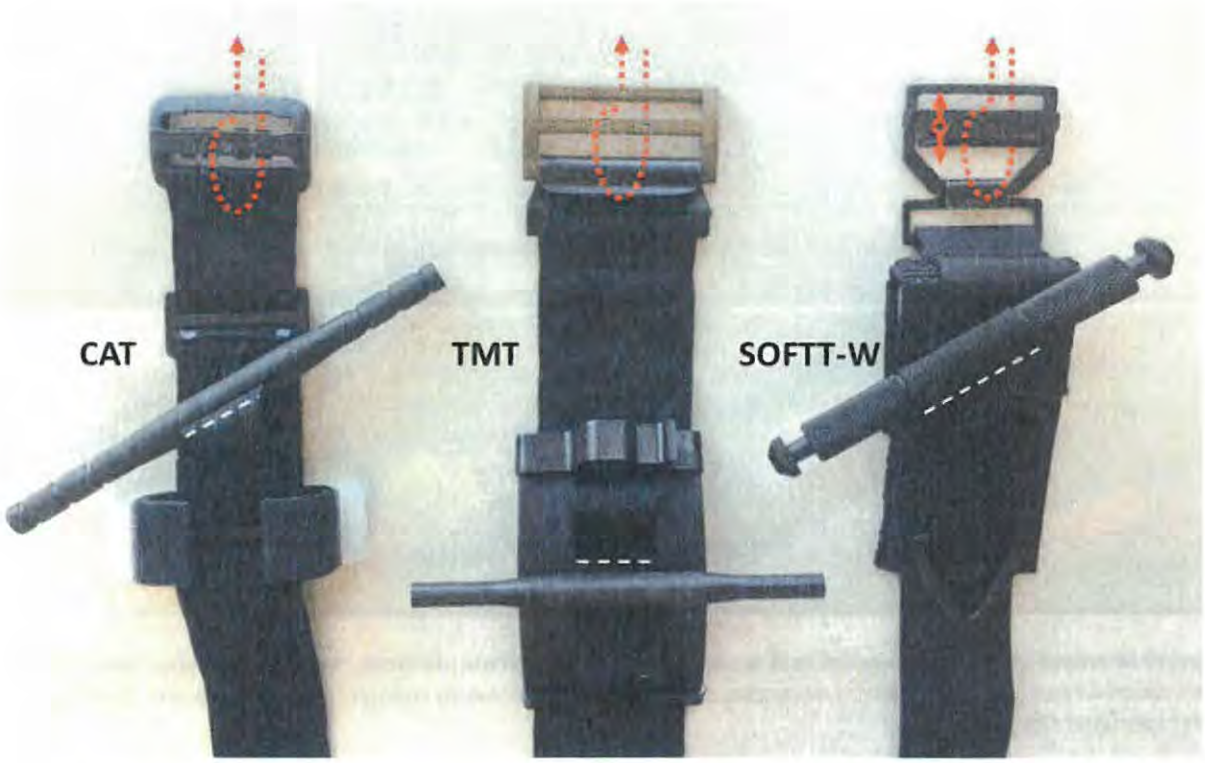


**Figure 14. Comparison of slip-lock mechanisms and strap materials for windlass-type tourniquets.** All three windlass-type tourniquets employ slip-lock mechanisms, although the CAT and TMT use static locking bars, while the SOFTT-W uses a floating locking bar. The routing of the strap material through the slip lock is indicated with a red dotted line and arrows, and the movement of the SOFTT-W floating locking bar is shown with the red solid arrows. Differences between the windlass interface materials are also highlighted, and the strap widths are indicated with a white dotted line. The CAT and TMT use small, thin straps to attach the windlass, while the SOFTT-W uses a thicker and wider strap material.

*Pressure measurements*. Example pressure distributions, generated by the seven tourniquet models immediately following application, are shown below in Figure 15. Each tourniquet pressure map has characteristic shapes, peak values, and distributions. Creases and folds, which formed in the BDU pants and SSH skin during tourniquet applications, also caused regions of unevenness in the pressure maps. The windlass-type tourniquets generated narrow regions of concentrated pressure directly beneath the windlass and rigid locking mechanisms, with wider and more even pressure distributions seen underneath the strap. The ratcheting-type tourniquets, RMT-PAR and RMT-TAC, exerted a regular pressure distribution along the strap

width with concentrated pressures underneath the ratcheting clip, shown on the left side of the measurement area. The pneumatic devices, EMT and TPT, exerted the most uniform pressure distributions along the functional width of the strap, due to the air bladder compliance and the lack of rigid mechanical features.

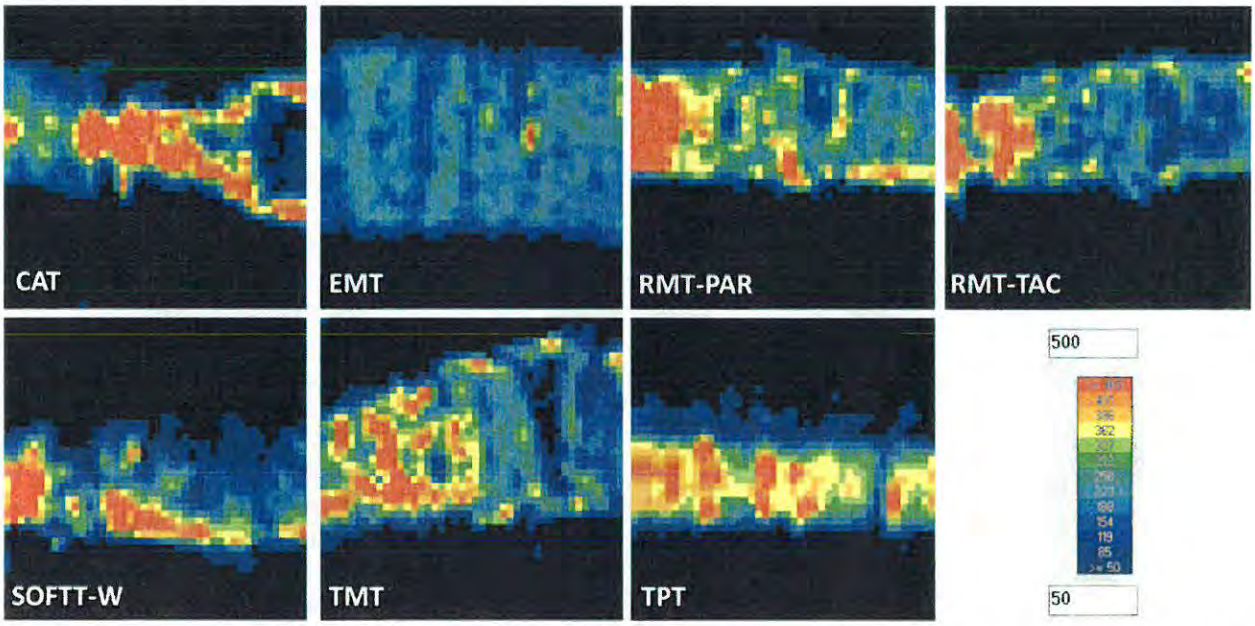


**Figure 15. Pressure maps at the end of example trials for each tourniquet type**. Pressure data have been filtered within a desired range and smoothed by averaging adjacent sensing elements to highlight the shape and distribution of each tourniquet design.

The contact pressure measurements depict changes in pressure at the interface between the tourniquets and SSH leg over time. Example pressure profiles for each tourniquet model are shown in Figure 16. The contact pressures are plotted from the start of the tourniquet application period, and the first red line indicates the point at which occlusion was achieved. The second red line indicates the end of the first monitoring period and the start of the simulated transfer, and the plots continue through the end of the second monitoring period. Transient spikes in the contact pressure can be seen prior to occlusion as the tourniquets were manipulated and the locking mechanisms secured. The contact pressure between SSH and the tourniquets fell, to some extent, during each of the applications. The pressure change is most pronounced in the example RMT-PAR application, while the change was less evident during EMT and TPT applications. Small deviations in pressure can be seen during the simulated patient transfer, but the values return to the original levels once SSH is lowered.

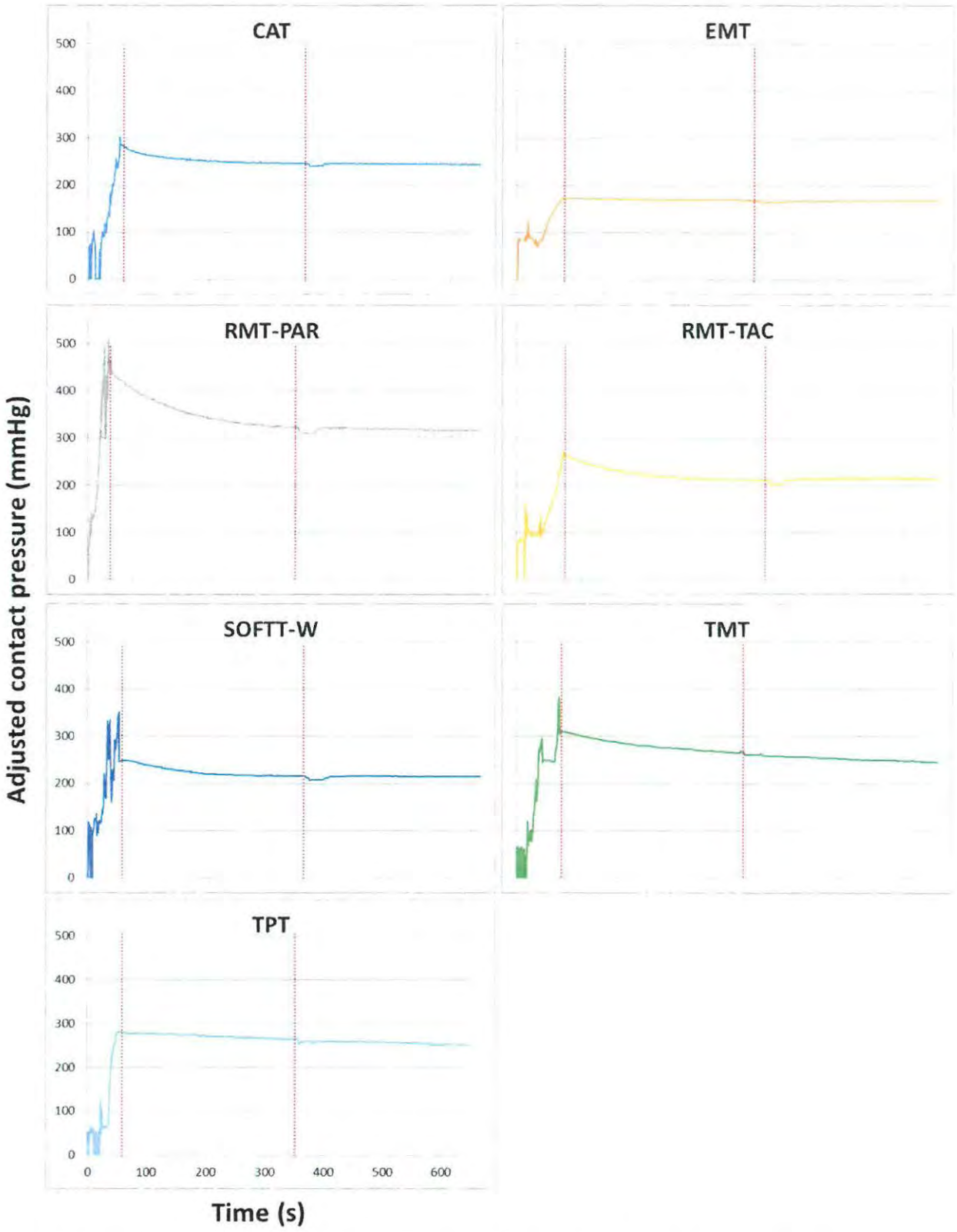


**Figure 16. Characteristic contact pressure profiles for each tourniquet type**. The first red line denotes the recorded pressure for the first time point at which occlusion was reached. The second red line denotes the time point at the end of the first five-minute monitoring period, immediately before the patient transfer.

Average contact pressures are shown in Figure 17 after the initial tourniquet application and following the two monitoring intervals. Over the approximately 10-minute interval between the tourniquet application and end of second monitoring period, the decline in contact pressure was only statistically significant for RMT-PAR ($p < 0.05$). The fall in the interface pressure could have been caused by either a relaxation in the tourniquet strap material or a displacement of tissue and moisture in the SSH leg beneath the application site. Significant changes in interface pressure between time points did not correspond to significant changes in blood loss. During windlass and ratcheting tourniquets applications, the interface pressures tended to fall during the first monitoring period, and remain even during the second monitoring interval, while the pneumatic designs maintained a more consistent pressure across the test period.

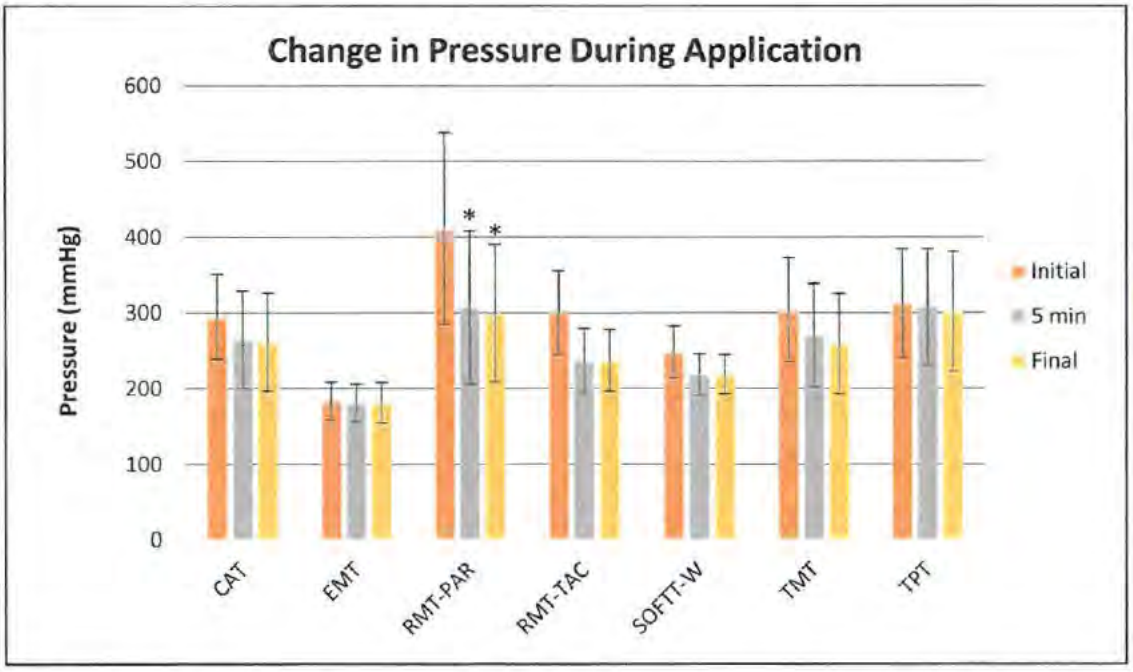


**Figure 17. Changes in estimated contact pressure during tourniquet applications**. Initial: the tourniquet was applied and blood flow is occluded. 5 min: after first monitoring period. Final: after simulated transfer and second monitoring period. Error bars indicate one standard deviation ($n = 10$). * indicates a significant difference in interface pressures relative to the initial time point ($p < 0.05$).

*Blood loss measurements*. The primary metric used to quantify the simulated hemorrhage was the amount of fluid lost, recorded immediately after initial tourniquet application and after the two monitoring intervals. The initial fluid loss was a function of exerted pressure and elapsed time during the tourniquet application. The fluid loss after the first monitoring interval was driven by deformation or shifts in the tourniquet and SSH materials, while additional stresses

exerted on the tourniquet and SSH during the patient transfer contributed to the fluid loss measured after the second monitoring interval. Across the three time points, there was a significant increase in the volume of blood accumulated during the RMT-TAC and the SOFTT-W applications ($p < 0.05$), indicating continued bleeding after initial application (Figure 18). The relatively high RMT-TAC average volume was driven primarily by a single application in which there was 478 mL of blood loss after initial occlusion. In comparison to the other models, there was greater than 100 mL of fluid loss after initial occlusion and across the two monitoring intervals, during 2 of 10 CAT applications, 1 of 10 RMT-TAC applications, and 4 of 10 SOFTT-W. During each EMT, RMT-PAR, TMT, and TPT application, fluid loss remained less than 100 mL across the two monitoring intervals after initial occlusion was achieved.

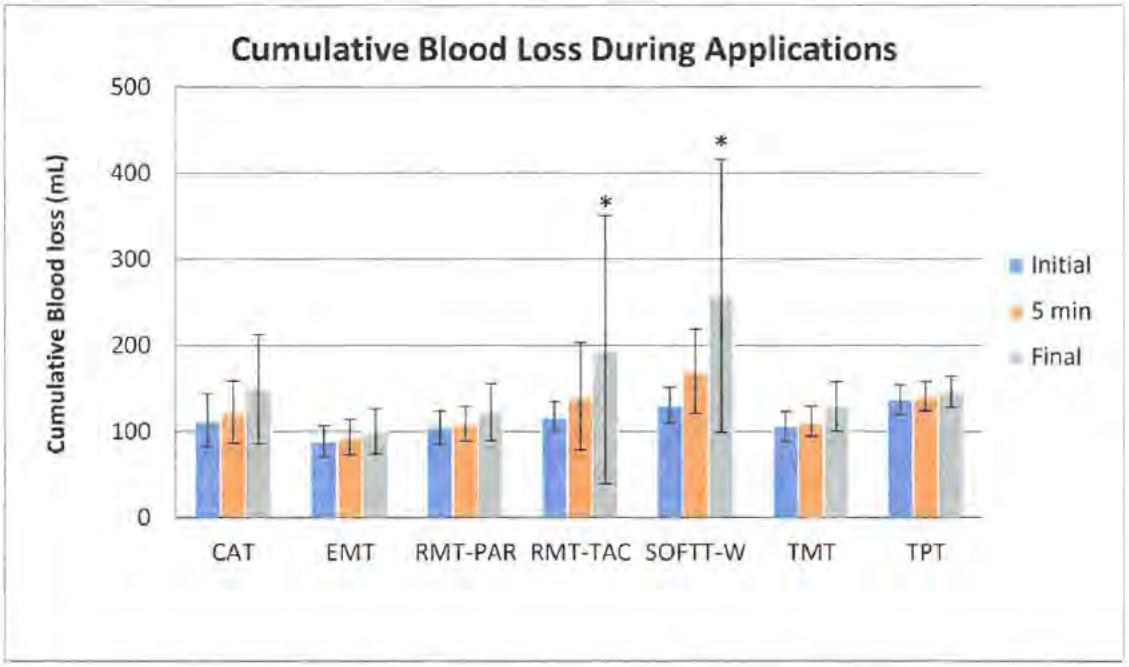


**Figure 18. Average cumulative blood loss during tourniquet applications**. Initial shows average blood loss immediately after occlusion pressure was reached. 5 min shows the cumulative blood loss after first monitoring period. Final shows the cumulative blood loss after the simulated transfer and second monitoring period. Error bars indicate one standard deviation ($n = 10$). * indicates a significant increase in accumulated blood relative to the initial time point ($p < 0.05$).

The blood loss after initial occlusion stresses the importance of monitoring after an extremity tourniquet is applied. The guidelines for Tactical Combat Casualty Care recommend reassessing prior tourniquet application during basic management in Tactical Field Care. The guidelines also recommend providing additional tightening if bleeding persists or applying a

second tourniquet next to the first. During the current protocol, there were no adjustments made to the tourniquet after the initial application.

## CONCLUSIONS

In this evaluation of extremity tourniquets on a state-of-the-art human replica cadaver model, quantitative data, including application times, blood loss, and pressure distributions were measured and compared across tourniquet designs. Each of the seven tourniquet designs successfully achieved occlusion during each of the tourniquet applications; however differences were observed during the extended monitoring period and simulated patient transfer. There was a significant decrease in average pressures at the interface between the RMT-PAR and SSH during the test period, and the CAT, RMT-TAC, and SOFTT-W each had applications in which greater than 100 mL of fluid were lost after occlusion was initially achieved. 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.

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Test Equipment item descriptions are derived from publicly available manufacturer or distributor sources.

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**14. ABSTRACT**

Background: Tourniquets provide vital limb stabilization during extremity hemorrhage, which remains a leading mechanism of injury in deaths on the battlefield. Several tourniquet designs are available, and rigorous testing is needed to ensure the warfighter is equipped with the most effective and operationally sound tourniquet. Conventional test platforms, are limited in their ability provide repeatable, clinically, and operationally relevant tourniquet performance data; however, the recent development of the SynDaver™ Synthetic Human (SSH) has opened the door for tourniquet testing with a level of complexity and fidelity not previously attainable with other trauma mannequin systems. Objective: Evaluate seven extremity tourniquets during extended application periods and during patient transfers, using the SSH with a simulated lower-extremity arterial hemorrhage. Methods: Ten of each tourniquet design were applied to the mid-thigh of the SSH. Each tourniquet was tightened until arterial pressure distal to the application site fell below 1 mmHg. Blood loss and interface pressures between the tourniquet and SSH were measured for five minutes. After the first monitoring period, the SSH was lifted, held for 20 seconds, and lowered, to simulate a patient transfer. Blood loss and contact pressure were then measured for a second five-minute interval. Results: All seven tourniquet designs achieved occlusion in each of the tests. Mean application times ranged from 59.1 ± 8.9 s for the EMT to 87.6 ± 19.6 s for the TPT. During the RMT-PAR applications, a significant drop in contact pressure ($p < 0.05$) was measured between the application and the second monitoring period. During RMT-TAC and the SOFTT-W applications, there was a significant increase in the volume of blood accumulated ($p < 0.05$). The CAT, RMT-TAC, and SOFTT-W each had trials in which there was greater than 100 mL of blood loss after initial occlusion. Conclusions: In this evaluation of extremity tourniquets on a state-of-the-art human replica cadaver model, quantitative data, including application times, blood loss, and pressure distributions were measured and compared across 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 system.

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