



## NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

### TEST AND EVALUATION OF COMPRESSION BANDAGES

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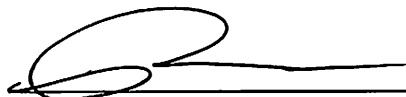
***DECLARATION OF INTEREST***

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## EXECUTIVE SUMMARY

**Background:** Though simple in form, compression bandages are vital for hemorrhage control in battlefield trauma care. Compression bandages stop or slow bleeding, optimally allowing normal blood clotting to occur without compromising distal blood flow. Many types of compression bandages are available and in development, and quantitative data is required to test the performance of these devices and ensure fielding of effective bandage systems.

**Objective:** *Phase Ia:* To evaluate the physical properties and features of six compression bandages. *Phase Ib:* To evaluate the operational characteristics of each compression bandage during application to instrumented mannequins.

**Methods:** Six compression bandages were tested: AirWrap™, Battle Wrap™, Emergency Bandage, H-Bandage, Honeycomb, and Olaes®. *Phase Ia:* Five of each compression bandage model (n = 5) were measured and weighed, and physical characteristics were recorded. Compression bandage elasticity was assessed by measuring the force-elongation curve as bandages were incrementally loaded, and bandages containing primary dressings were evaluated for fluid absorption. *Phase Ib:* Five of each bandage type were applied to the HapMed instrumented mannequin leg and five to the HapMed instrumented mannequin arm to a target contact pressure of 90 mmHg. Pressure distributions were measured using a pressure sensing grid. Bandages were then applied to the SynDaver™ Synthetic Human (SSH) using the same target contact pressure, and blood flow distal to the compression bandage location was measured and compared to baseline values. Application times were recorded for both HapMed and SSH trials.

**Results:** *Phase Ia:* Physical measurements demonstrated consistency within bandage type, although differences were observed across bandage types. Bandage elasticity differed considerably across types, with the Honeycomb and Olaes® stretching the most under load (211% and 212%, respectively), and the Battle Wrap stretching the least (36%). *Phase Ib:* All bandage types, except the Battle Wrap™, were able to achieve the target contact pressure during HapMed leg and arm applications. Average HapMed application times were all less than 100 seconds, with the Battle Wrap™ having the shortest application times (Arm: 49.6 ± 10.2 sec, Leg: 37.8 ± 8.2 sec; p < 0.05). The Emergency Bandage, H-Bandage, and Olaes®, all of which possess mechanisms to focus pressure, produced the highest peak pressures over the simulated wound site. Consistent with HapMed applications, the Battle Wrap™ did not achieve the target

contact pressure when applied to the SSH, although the Battle Wrap™ application times were again significantly shorter than those of the other bandages ( $47.2 \pm 10.3$  sec;  $p < 0.05$ ). The Honeycomb bandage was the only device to significantly reduce distal blood flow when applied to the SSH ( $-20.0 \pm 16.7$  %;  $p < 0.05$ ).

**Conclusions:** The compression bandages tested in this study included a variety of sizes, materials, and features. Some consisted solely of bandage material while others utilized mechanical features to focus applied pressure. Bandage designs which incorporated a mechanical pressure focus were consistently able to achieve high peak pressures over a target area without inadvertently occluding blood flow to the distal limb. Evaluating the physical and operational characteristics of compression bandages is a critical step in highlighting strengths and areas of improvement for currently available devices. The results from this testing and evaluation provide metrics for comparison and can help to define performance criteria for emerging designs.

## INTRODUCTION

The Iraq and Afghanistan conflicts have taken a significant human toll on our military forces across services. While some injuries are non-survivable, an analysis of over 4,500 casualties occurring between 2001 and 2011 revealed that greater than 90% of the potentially survivable injuries were associated with hemorrhage (Eastridge, 2012). Though simple in form, medical compression bandages are a vital instrument for hemorrhage control in battlefield trauma care, and direct pressure on the bleeding site is critical for treatment (Cloonan, 2004).

The function of a compression bandage is to stop or slow bleeding, optimally allowing normal blood clotting to occur without compromising distal blood flow. The bandage also protects the wound site from contaminants, which may cause infection or renew bleeding. With many compression bandage variations available, each with individual features and strengths, data is needed to evaluate and compare the performance of these types of devices.

A recent summit of medical experts and medical industry representatives established four consensus parameters on which to characterize and evaluate both simple and complex compression bandage systems (Partsch, 2008). The consensus parameters include: pressure, layers, components, and elastic properties, which provide a general guide for assessment. This study addresses each of these key factors and serves to provide critical data regarding compression bandage use and efficacy. The results will aid the DoD selection process and improve quality of care in combat environments.

## METHODS

### INSTRUMENTATION

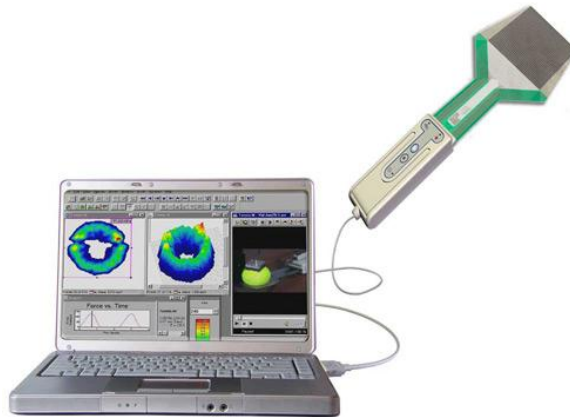
*SynDaver™ Synthetic Human (SSH) Mannequin (SynDaver™ Labs, Tampa, Florida).* The SSH mannequin (Figure 1) is a head-to-toe synthetic physical representation of human anatomy, including skin with fat and fascia planes. The mannequin also features every bone, muscle, tendon, and ligament in the human body, fully articulating joints, a functioning respiratory system including trachea, lungs, and diaphragm, a complete digestive tract from the esophagus to rectum, and a circulatory system with heart and coronary arteries, aorta, vena cava, and the primary arterial and venous trunks leading to the extremities. The SSH has a heart pump, which produces pulsed flow away from the heart and drainage to the heart. Individual tissues of construction have been validated to mimic mechanical and physio-chemical properties of the corresponding living tissues.



**Figure 1. SynDaver™ Synthetic Human Mannequin**

*Tekscan I-Scan® Pressure Measurement System (Tekscan®, South Boston Massachusetts).*

The Tekscan® is a force and pressure measurement system that 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. A Tekscan® Model 5101 sensor was used to measure and map the pressure exerted by the compression bandage systems. The Model 5101 has a 4.40" x 4.40" sensing matrix, which contains 1936 individual sensing elements, to provide 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 both the peak and average contact pressures exerted on the sensing matrix.

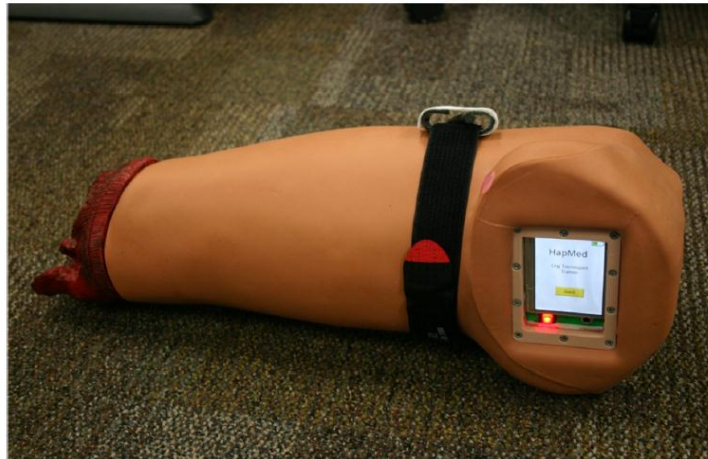


**Figure 2. Tekscan I-Scan® Pressure Measurement System.** The Tekscan® pressure measurement system senses and maps pressure distributions across its sensing surface. The scanning electronics rapidly record data from an array of independent sensing elements contained within each sensor.

*HapMed Instrumented Tourniquet Training Leg and Arm (CHI Systems, Plymouth Meeting, Pennsylvania).* The HapMed Instrumented Tourniquet Training System (Figure 3)



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 gauge the amount of pressure being applied, and as pressure increases, LED lights indicate when the bleeding slows. When sufficient pressure is applied to fully occlude blood flow, the lights indicate accordingly. If pressure is subsequently reduced, the “bleeding” will begin again. Once a trial is complete, the HapMed reports the time it took to stop the bleeding and provides feedback regarding position of the applied pressure.

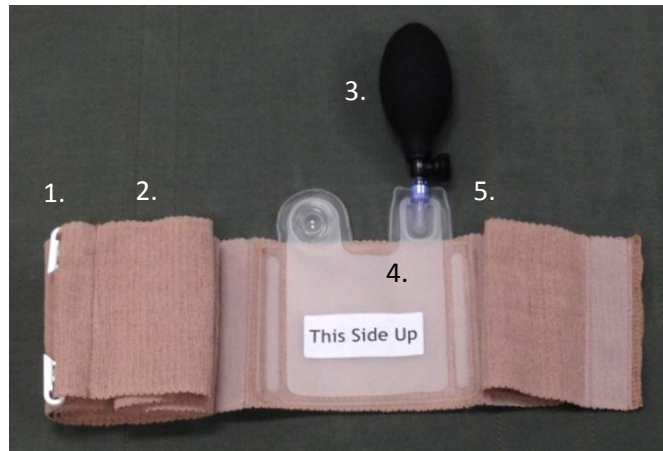


**Figure 3. HapMed Instrumented Tourniquet Training Leg.** The HapMed leg contains embedded sensors to provide feedback on whether the applied pressure is sufficient to achieve occlusion.

## EQUIPMENT UNDER TEST

*AirWrap™ Compression Bandage (RevMedx Inc., Wilsonville, Oregon).* The AirWrap™ is a secondary bandage intended for application over a primary wound dressing to provide pressure on the wound site. The AirWrap™ consists of a manual pump air bladder paired with an elastic bandage. The bladder has a manual pressure release and both visual and tactile indicators of proper inflation pressure.

During application, the elastic bandage is wrapped around the limb with the air bladder placed directly over the wound site. Strips of hook-and-loop fastener on either side of the air bladder keep the bandage layers above firmly fixed, and a closure bar secures the applied bandage in place. Once the bandage is secured, the manual pump is attached to the air bladder with standard luer connectors. An indicator pops up to show when proper inflation pressure is achieved.



**Figure 4. AirWrap™ Compression Bandage, RevMedx, Inc.** 1. Closure bar to secure end of applied bandage. 2. Elastic bandage. 3. Manual air pump. 4. Air bladder. 5. Luer lock connectors.

*Battle Wrap™ (Entrotech, Columbus, Ohio).* The Battle Wrap™ is a clear, self-adhering compression wrap designed to apply pressure to a wound site while allowing visualization of bleeding. According to the manufacturer, the product is nonslip, extremely strong, and uses a unique adhesive that sticks to the skin but does not leave a residue.



**Figure 5. Battle Wrap™, Entrotech.** This product comes rolled on a plastic tube with a cardboard tab to start unrolling for easy application.

*Emergency Bandage (First Care Products, Amsterdam, Netherlands).* The Emergency Bandage is designed for hemorrhage control and wound treatment in pre-hospital environments. The Emergency Bandage includes a built-in, patented pressure applicator that exerts pressure directly over the wound site. During application, the elastic bandage is inserted through the pressure applicator clip, which is fixed orthogonal to the orientation of the bandage, after the first wrap of the limb. The elastic bandage is then tightened by pulling back on the pressure

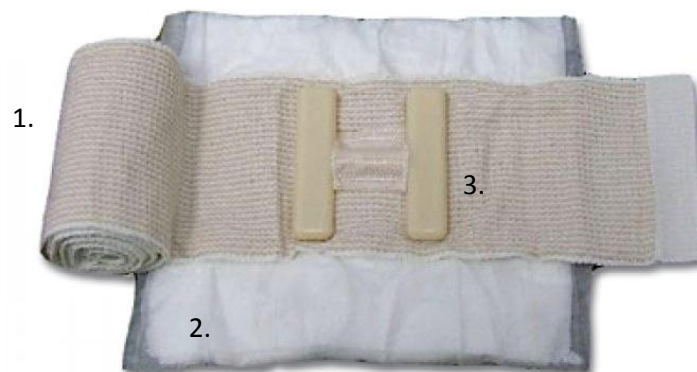
applicator, forcing the pressure bar down onto the pad. The remaining portion of the elastic bandage is then wrapped tightly over the limb, and the hook ends of the closure bar secure the end of the bandage.



**Figure 6. Emergency Bandage, First Care Products.** 1. Closure bar to secure end of applied bandage. 2. Elastic bandage. 3. Pressure applicator clip.

*H-Bandage (H&H Medical Corporation, Ordinary, Virginia).* The H-Bandage has an 8” x 10” army battle dressing (ABD) pad and 5 feet of elastic wrap. The bandage features an H-shaped cinch, sewn into the bandage, designed to facilitate application and exert pressure over the wound site.

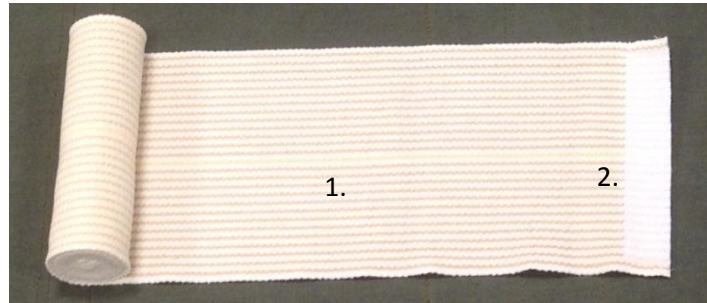
To apply the H-bandage, the cinch is placed directly over the wound site. The elastic bandage is wrapped once around the limb, and then looped around the near H-bar and pulled taut. The bandage is then wrapped under the limb in the opposite direction, and then looped around the other H-bar. The rest of the bandage is then be wrapped over the existing layers and secured with the strip of hook-and-loop fastener at the end.



**Figure 7. H-Bandage, H&H Medical Corp.** 1. Elastic bandage. 2. Army battle dressing. 3. H-shaped cinch.

*Honeycomb Lite (Avcor Health Care Products Inc., Arlington, Texas).* The Honeycomb

Lite is an elastic bandage with a Double Velcro® Self Closure. The bandage is constructed of a highly absorbent and durable cotton-synthetic blend. According to the manufacturer, the knit is breathable, and the scalloped edges do not dig into the skin. The bandage is secured in place with hook-and-loop fastener.



**Figure 8. Honeycomb Lite, Avcor Health Care Products Inc.** 1. Elastic bandage. 2. Hook-and-loop fastener.

*Olaes® Modular Bandage (Tactical Medical Solutions, Anderson, South Carolina).* The Olaes® Modular Bandage consists of an elastic bandage, 3 meters of gauze, a removable occlusive plastic sheet behind the dressing pad, and a pressure bar that can also act as an eye cup.

To apply the bandage, sterile gauze is removed from behind the dressing pad and used to pack or cover the wound. The elastic bandage is then applied with the plastic pressure bar placed over the wound. Velcro® strips secure the bandage as it is applied and prevent the elastic roll from accidentally unraveling.



**Figure 9. Olaes® Modular Bandage, Tactical Medical Solutions.** 1. Elastic bandage. 2. Wound pad. 3. Pressure bar to focus pressure over wound site. 4. Sterile 4-ply gauze.

## TEST PROCEDURES

*Phase Ia – Basic of Physical and Functional Characteristics.* The physical characteristics of five of each compression bandage model were evaluated and recorded on a Data Collection Sheet (DCS). The characteristics included:

- **Weight** - Weight was measured for both packaged and unpackaged devices.
- **Dimensions** - Measurements of the height, width, and length of both packaged and unpackaged devices were recorded.
- **Volume** - Packaged device volume was measured by displacement using a graduated cylinder.
- **Food and Drug Administration (FDA) Registration** - Any information available regarding FDA registration provided by the manufacturer was verified and recorded.
- **Color (subdued)** - Yes/No was recorded to indicate whether the unpackaged device is subdued in color or consists of colors that are 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.
- **Single Patient Use** - Yes/No was recorded to indicate whether the manufacturer stated on the device that it is intended for single patient use.

The bandages were also evaluated for functional characteristics that would provide added benefits during field use. Characteristics included:

- **Presence of Primary Dressing** - Yes/No was recorded to indicate whether the compression bandage included a primary wound dressing.
- **Presence of Device to Focus Pressure** - Yes/No was recorded to indicate whether the compression bandage contained a mechanical feature to focus applied pressure over the wound site.

- **Mechanical Advantage** - Yes/No was recorded to indicate whether the device provides a mechanical advantage during application.
- **Use as a Tourniquet** - Yes/No was recorded to indicate whether or not the compression bandage could feasibly function as a tourniquet. One of each compression bandage type was applied to the HapMed arm and one to the HapMed leg with maximum exertion. Once applied, sensors within the HapMed arm and leg indicated whether sufficient pressure was applied to occlude blood flow.
- **Elasticity** - Compression bandage elasticity was measured by characterizing the relationship between force and the resulting bandage elongation. Twenty-five centimeter long sections from five bandages of each type were tested for elasticity. The test apparatus consisted of two clamps, which were attached to either end of the 25 cm samples. The bandage was hung from one clamp, and weights were incrementally added and removed from the second clamp. To standardize the measure for bandages of varying size, the magnitude of the incremental weights scaled with the bandage width using methods described by Partsch et al. (2008). Weights were added in 1 N/cm-bandage-width increments until 10 N/cm-bandage-width was reached (10.16 N increments for 4" wide bandages, 15.24 N increments for 6" wide bandages). The bandage lengths were measured at each increment, and the loaded bandages were subsequently unloaded, using the same increments, to determine the elastic hysteresis. During the test, increments were applied or removed every 20 seconds.
- **Absorption** - Three bandages, the Emergency Bandage, H-Bandage, and Olaes<sup>®</sup>, featured absorbent primary wound dressings and were evaluated for fluid absorption. The absorbent dressings from five of each bandage model were first removed from the elastic bandage material and any mechanical features. The dressings were then weighed, fully submerged in a blood simulant (2491 Simulated Blood, VATA, Inc.), allowed to drip of excess fluid for one minute, and weighed again to determine the amount of fluid retained. Fluid absorption was defined as the ratio of the weight of fluid absorbed to the weight of the dry dressing, and absorption measurements were compared to all-purpose, 4-ply gauze sponges (Versalon<sup>™</sup>).

*Phase Ib – Assessment of Operational Characteristics.* The operational characteristics of the compression bandages were evaluated in Phase Ib during application to instrumented mannequins.

- **HapMed Application** - Contact pressure was measured using the Tekscan<sup>®</sup> pressure measurement system on the HapMed arm and leg, which provided smooth contact surfaces for recording the pressure distributions during bandage applications. The amount of pressure needed to effectively slow or curb blood loss depends on both local and systemic factors including size, depth, and location of the wound, as well as hemodynamics variables. However, prior research has shown that when applied by medical personnel, compression bandages exert an average of 90 mmHg at the wound site, a pressure sufficient to overcome peak blood pressures in the smaller arteries, arterioles, capillary beds, and venous vasculature (Naimer et al., 2004). Thus, 90 mmHg was used as the target pressure during application. Five of each bandage model were applied to 2” x 2” simulated wound sites at mid-thigh on the HapMed leg, and above the elbow on the HapMed arm. The Tekscan<sup>®</sup> pressure sensing grid was used to verify an approximate pressure of 90 mmHg was achieved across the wound site, and the pressure distribution was characterized for uniformity or for the presence of distinct regions of high or low pressures. The number of layers of bandage material produced over the wound site, and the bandage application times were recorded for each device.
- **SSH Application** - The SSH was used to measure relative changes in distal blood flow during bandage application. The SSH circulatory system was primed with water and enabled, and the heart rate was set to 70 beats per minute. Although hemodynamic variables may be altered following a traumatic injury, the lower heart rate was selected to provide greater sensitivity to relative changes in distal blood flow. Five of each bandage type were applied to a 2” x 2” simulated wound site at mid-thigh on the SSH leg, and the Tekscan<sup>®</sup> pressure measurement system verified an approximate pressure of 90 mmHg exerted across the wound site. Application times were again recorded for each compression bandage. Once the bandage was secured, blood flow to the limb was measured by disconnecting arterial supply from venous return, distal to the bandage material. Fluid was collected for a one-minute period, and the total volume was compared to baseline measurements with no bandage applied.

*Statistical Analysis.* Statistical differences were tested across compression bandage types using the independent samples t-test for measured compression bandage pressures, application times, and changes in distal blood flow. The significance level was set at  $\alpha = 0.05$ . Any suspected outliers were tested using the Grubbs' test, a statistical method used to detect outliers, based on the sample mean, standard deviation, and sample size.

## RESULTS/DISCUSSION

*Phase Ia – Basis Assessment and Measurements.* Results show consistency in package size and weight measurements within compression bandage types (Table 1). The Emergency Bandage weighed the most ( $4.53 \pm 0.12$  oz), while the Battle Wrap™ weighed the least ( $1.92 \pm 0.14$  oz). The Battle Wrap™ was also the smallest device tested, with a packaged volume of  $9.98 \pm 0.80$  in<sup>3</sup>, and the AirWrap™ the largest, with a package volume of  $23.41 \pm 1.28$  in<sup>3</sup>, which included the manual pneumatic pump.

**Table 1. Physical Characteristics of Compression Devices and Packaging**

	AirWrap™	Battle Wrap™	Emergency Bandage	H-Bandage	Honeycomb	Olaes®
<b>Weight, packed (oz)</b>	$3.81 \pm 0.03$	$1.92 \pm 0.14$	$4.53 \pm 0.12$	$3.74 \pm 0.04$	$2.53 \pm 0.01$	$3.95 \pm 0.24$
<b>Weight, unpacked (oz)</b>	$3.45 \pm 0.02$	$1.85 \pm 0.15$	$4.05 \pm 0.12$	$3.28 \pm 0.04$	$2.52 \pm 0.04$	$3.41 \pm 0.25$
<b>Package Length (in)</b>	$7.22 \pm 0.49$	$5.34 \pm 0.21$	$9.43 \pm 0.22$	$7.19 \pm 0.33$	$6.22 \pm 0.04$	$9.03 \pm 0.44$
<b>Package Width (in)</b>	$6.89 \pm 0.06$	$2.40 \pm 0.13$	$5.10 \pm 0.11$	$5.82 \pm 0.09$	$2.00 \pm 0.03$	$6.37 \pm 1.01$
<b>Package Height (in)</b>	$2.03 \pm 0.06$	$1.51 \pm 0.04$	$1.35 \pm 0.04$	$1.66 \pm 0.12$	$1.89 \pm 0.01$	$1.86 \pm 0.59$
<b>Package Volume(in<sup>3</sup>)</b>	$23.41 \pm 1.28$	$9.98 \pm 0.80$	$16.48 \pm 0.48$	$17.00 \pm 0.78$	$21.64 \pm 0.77$	$18.73 \pm 1.15$
<b>Unpackaged Length (in)</b>	$58.66 \pm 0.28$	$56.38 \pm 8.19$	$62.20 \pm 0.39$	$61.02 \pm 0.74$	$63.0 \pm 0.58$	$38.03 \pm 2.34$
<b>Unpackaged Width (in)</b>	$4.25 \pm 0.05$	$4.06 \pm 0.00$	$6.17 \pm 0.03$	$3.94 \pm 0.05$	$5.78 \pm 0.02$	$5.97 \pm 0.12$

*Note:* Values reported as average  $\pm$  standard deviation (n = 5).

Some deviations were observed between the nominal device width dimensions provided by the manufacturer (4" or 6") and those measured. The Emergency Bandage width measured



6.17 ± 0.03 in, the Honeycomb 5.78 ± 0.02 in, and the AirWrap™ 4.25 ± 0.05 in. Unloaded bandage lengths were consistent within type, except the Battle Wrap™, which measured 56.38 ± 8.19 in, with a range of 45.9 – 57.3 in. The longest bandage was the Honeycomb (63.0 ± 0.58 in), while the shortest bandage was the Olaes® bandage (38.03 ± 2.34 in).

Qualitative characteristics, including device color and information included with the compression bandages from the manufacturer, were consistent among bandages of a given type (Table 2). Each of the bandages was FDA registered, subdued in color, and intended for single patient use. Each manufacturer provided protective packaging, although the Honeycomb bandage packaging was not waterproof. Each manufacturer also provided tracking information and user instructions. The AirWrap™ was clearly marked to indicate latex-free, while the others were unmarked or contained latex.

**Table 2. Basic Compression Bandage Characteristics**

	AirWrap™	Battle Wrap™	Emergency Bandage	H-Bandage	Honeycomb	Olaes®
<b>FDA Registered</b>	Yes	Yes	Yes	Yes	Yes	Yes
<b>Color</b>	Tan	Clear	Green	Tan	White/Tan	Tan
<b>Protective Packaging</b>	Yes	Yes	Yes	Yes	Yes*	Yes
<b>Tracking Date</b>	Yes	Yes	Yes	Yes	No	Yes
<b>User Instructions Present</b>	Yes	No	Yes	Yes	No	Yes
<b>Latex Free</b>	Yes	Unmarked	Unmarked	No	Unmarked	No
<b>Single Patient Use</b>	Yes	Yes	Yes	Yes	Yes	Yes

*Note:* Values presented were consistent for all tourniquets of a given type (n = 5).

\*Honeycomb packaging was not waterproof.

*Phase Ia – Assessment of Functional Characteristics.* The Honeycomb and the AirWrap™ bandages did not have a primary wound dressings, while each of the other bandages had dressings intended for application directly over the wound site (Table 3). The Battle Wrap™

and the Honeycomb bandages did not have mechanical features to focus applied pressure over the wound site, while the other bandages had mechanisms to focus pressure. The H-Bandage, Emergency Bandage, and AirWrap™ each provided mechanical advantages to facilitate application. The H-Bandage and Emergency Bandage featured cinches, while the AirWrap™ featured a manual pneumatic pump to apply pressure.

When tested for feasibility of use as a tourniquet, each of the compression bandages was able to generate adequate circumferential pressure to act as a tourniquet when applied to the HapMed arm, while none of the bandages were able to generate sufficient pressure to act as a tourniquet on the HapMed leg. Although tourniquet pressures could be produced by the compression bandages when applied to the HapMed arm, the applications required significant physical exertion, and it would likely not be feasible to achieve necessary tourniquet pressures during self-application.

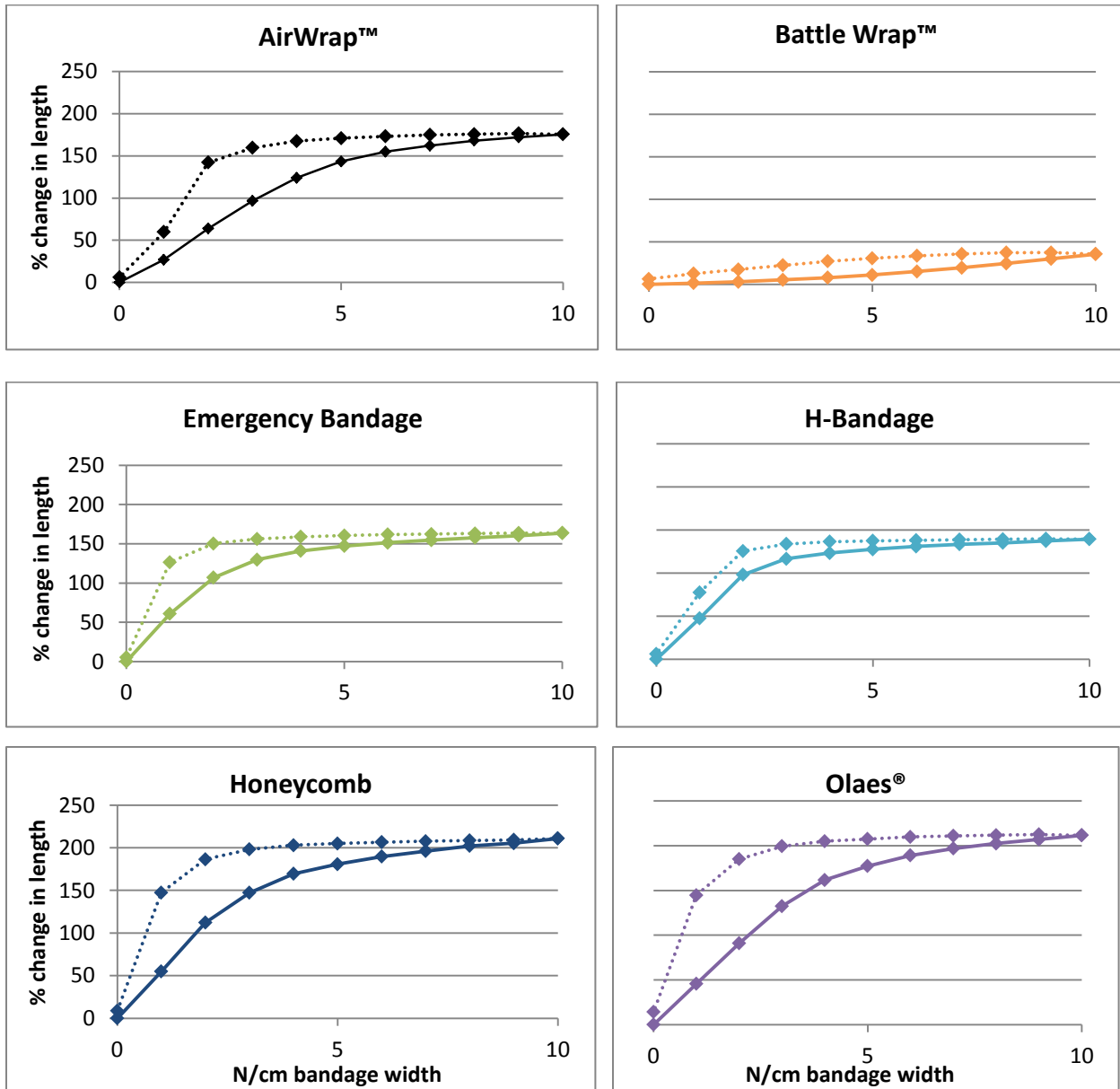
**Table 3. Compression Bandage Functional Characteristics**

	<b>AirWrap™</b>	<b>Battle Wrap™</b>	<b>Emergency Bandage</b>	<b>H-Bandage</b>	<b>Honeycomb</b>	<b>Olaes®</b>
Primary dressing?	No	Yes	Yes	Yes	No	Yes
Pressure focus?	Air bladder	No	Pressure Clip	H-cinch	No	Domed pressure bar
Mechanical Advantage	Yes	No	Yes	Yes	No	No
Achieves occlusion in arm?	Yes	Yes	Yes	Yes	Yes	Yes
Achieves occlusion in leg?	No	No	No	No	No	No

*Note:* Values presented were consistent for all tourniquets of a given type (n = 5).

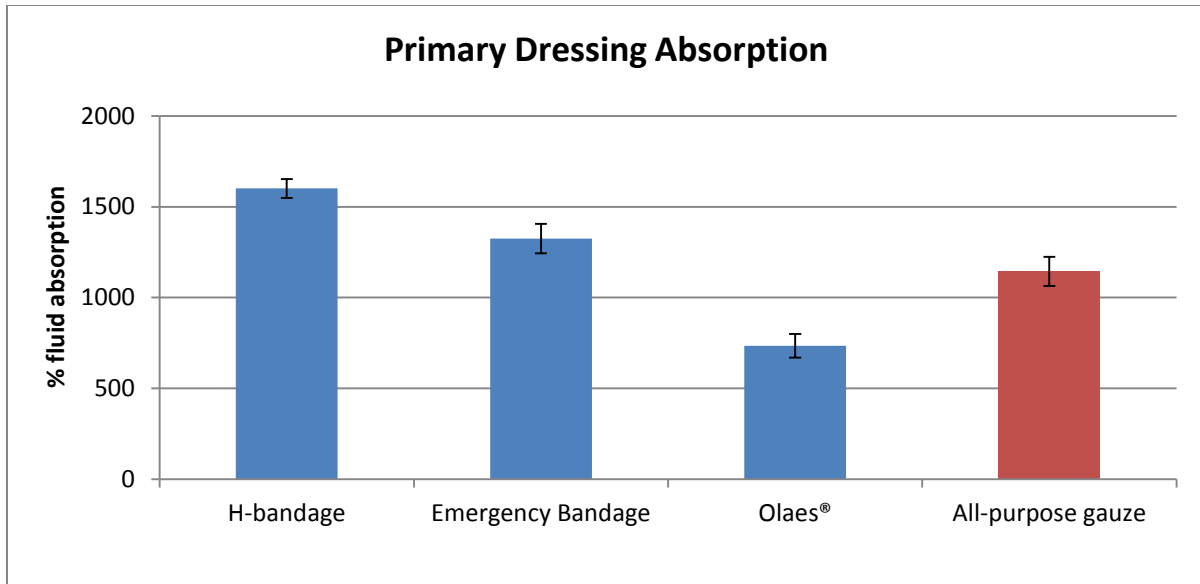
*Phase Ia – Compression Bandage Elasticity.* Each bandage was incrementally loaded and unloaded to determine the elastic properties of the bandage materials (Figure 10). The Honeycomb and the Olaes® bandages were the most elastic, stretching 211% and 212%, respectively. The Battle Wrap™ stretched the least under load (36%), due to its plastic sheet composition. Hysteresis was observed in all compression bandage materials and can be seen in Figure 10 as the difference in the degree of stretch during loading (solid line) relative to unloading (dotted line). During incremental unloading, each bandage maintained some degree of

deformation beyond that measured during loading. This difference was most pronounced in the Olaes® bandage, which maintained the most stretch as it was unloaded.



**Figure 10. Elastic bandage deformation during loading and unloading.** Average percent change in bandage lengths shown during incremental load changes (n = 5). Solid lines indicate loading cycle; dashed lines indicate unloading cycle.

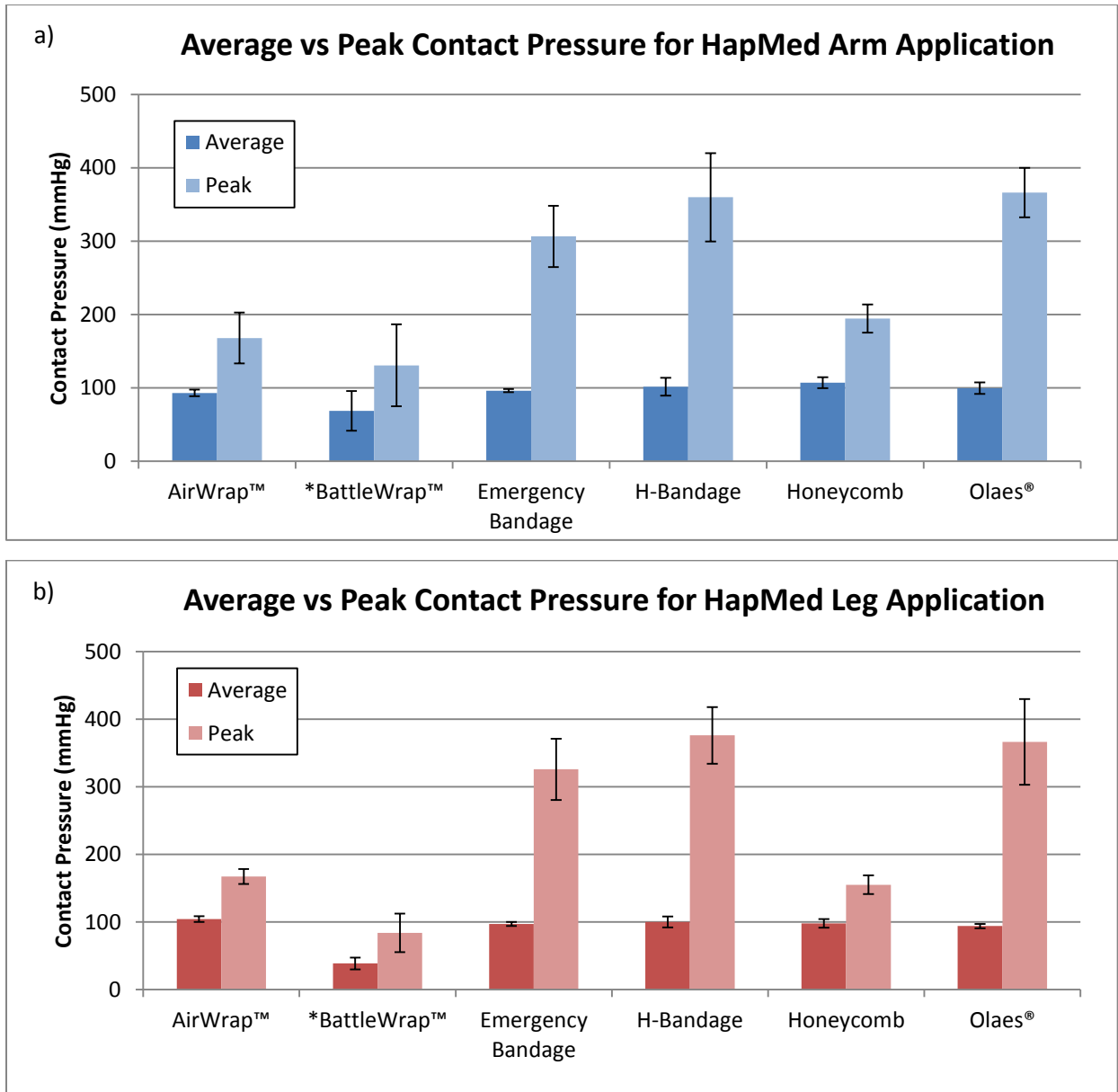
*Phase Ia – Compression Bandage Absorption.* Compression bandage absorption was comparable to the all-purpose gauze (Figure 11). The Olaes® bandage had the thickest layer of gauze material of those bandages with absorbent dressings, but retained the least amount of fluid relative to the initial dressing weight. The H-Bandage had the largest surface area of the bandages with absorbent dressings and retained the most fluid relative to the initial weight.



**Figure 11. Pressure Dressing Absorption of Primary Bandages.** Primary dressing absorption is shown as the ratio of fluid weight absorbed to the weight of the dry dressing. Error bars indicate one standard deviation (n = 5).

*Phase Ib – Compression Bandage HapMed Application.* The compression bandages were applied to the HapMed leg and arm with a target application pressure of 90 mmHg across the 2” x 2” wound site, depicted by the darker bars in Figure 12 below. Each of the bandages tested produced the target application pressure on both the arm and the leg, except for the Battle Wrap™, which did not achieve the target pressure on either arm or leg. The Battle Wrap™ exerted  $63.4 \pm 24.0$  mmHg on the arm and  $38.0 \pm 9.7$  mmHg on the leg. The relatively short length of the Battle Wrap™ bandage and the low elasticity of the plastic bandage composition contributed to the Battle Wrap™ being unable to achieve the target application pressure. The adhesive quality of the Battle Wrap™ material, however, may provide some added benefit for sealing the wound site that was not evaluated in this study.

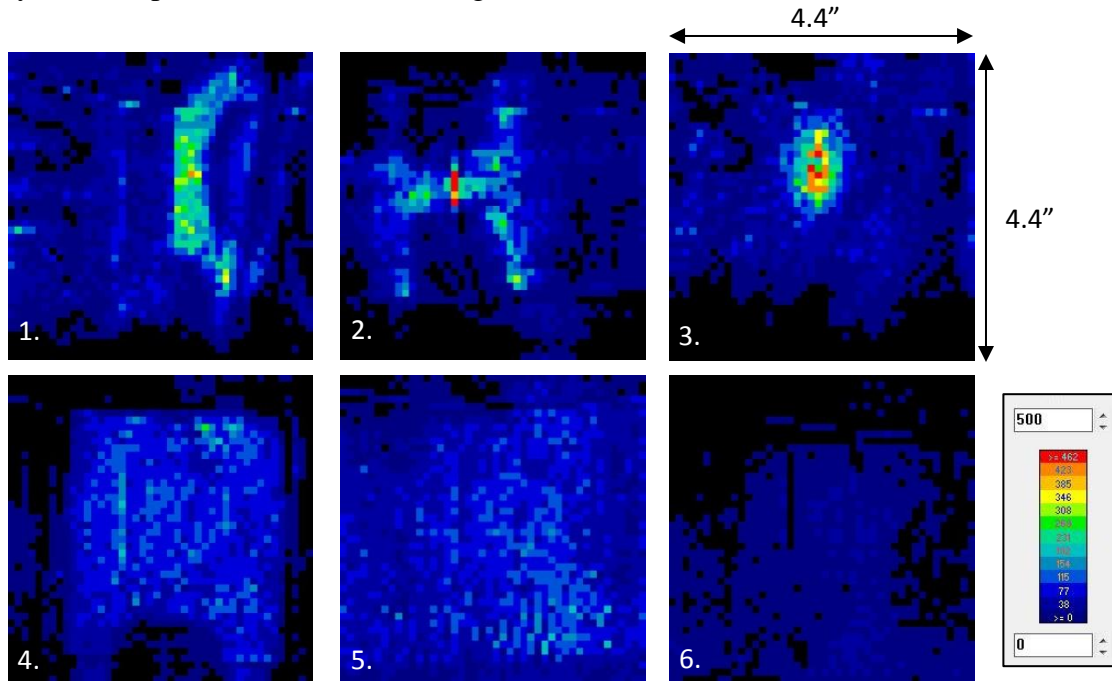
Peak pressures exerted on the 2” x 2” wound site were also measured and are depicted by the lighter bars in Figure 12. The Emergency Bandage, H-Bandage, and Olaes® bandages, all of which possess a rigid mechanical pressure focus, produced significantly higher peak pressures than the Battle Wrap™, AirWrap™, and Honeycomb bandages ( $p < 0.05$ ).



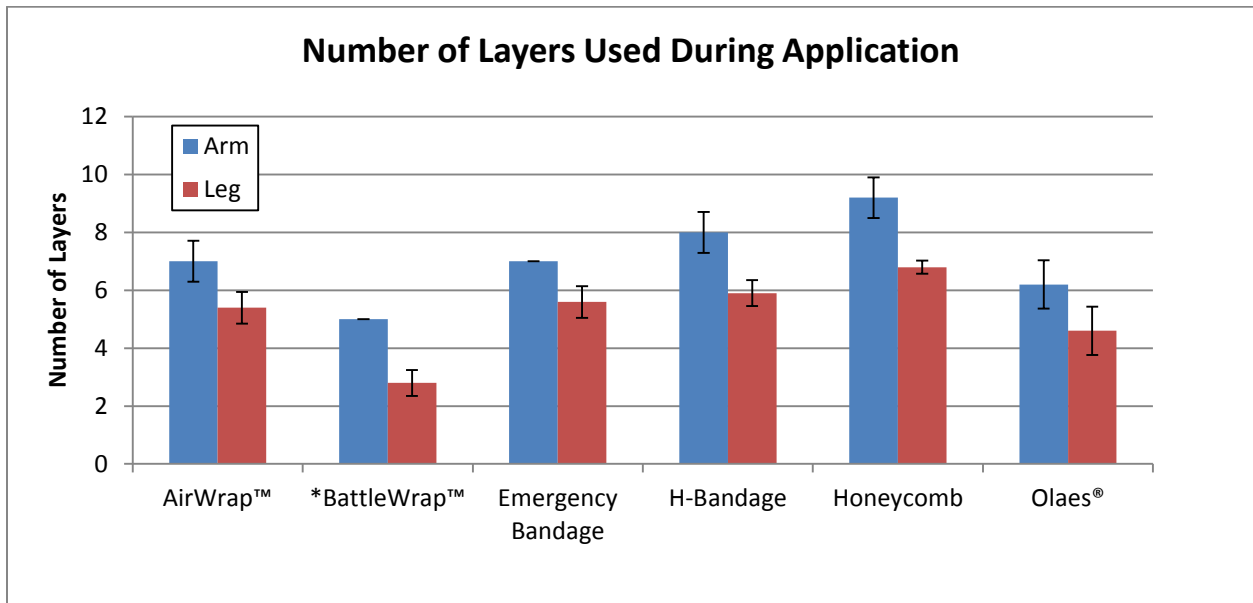
**Figure 12. Average and Peak Contact Pressures for a) HapMed Arm and b) HapMed Leg Applications.** Average pressures exerted by compression bandages across wound sites on the HapMed arm and leg are depicted by dark bars, and peak pressures are depicted by light bars. Error bars indicate one standard deviation (n = 5). \*Battle Wrap™ did not achieve the target contact pressure.

The pressures exerted on the HapMed arm and leg reflect the shape of each device’s pressure pad (Figure 13). The Emergency Bandage, H-Bandage, and Olaes® each have rigid mechanical features that focus bandage pressure over the wound site, and produce concentrated regions of higher pressure. The AirWrap™ has a pneumatic bladder that also focuses the applied pressure, although the peak pressures exerted by the AirWrap™ were not as high or concentrated as those produced by rigid pressure applicators (i.e., Emergency Bandage, H-Bandage, and

Olaes<sup>®</sup>). The Honeycomb and Battle Wrap<sup>™</sup> do not have pressure applicators, resulting in relatively uniform pressure distributions (Figure 13).



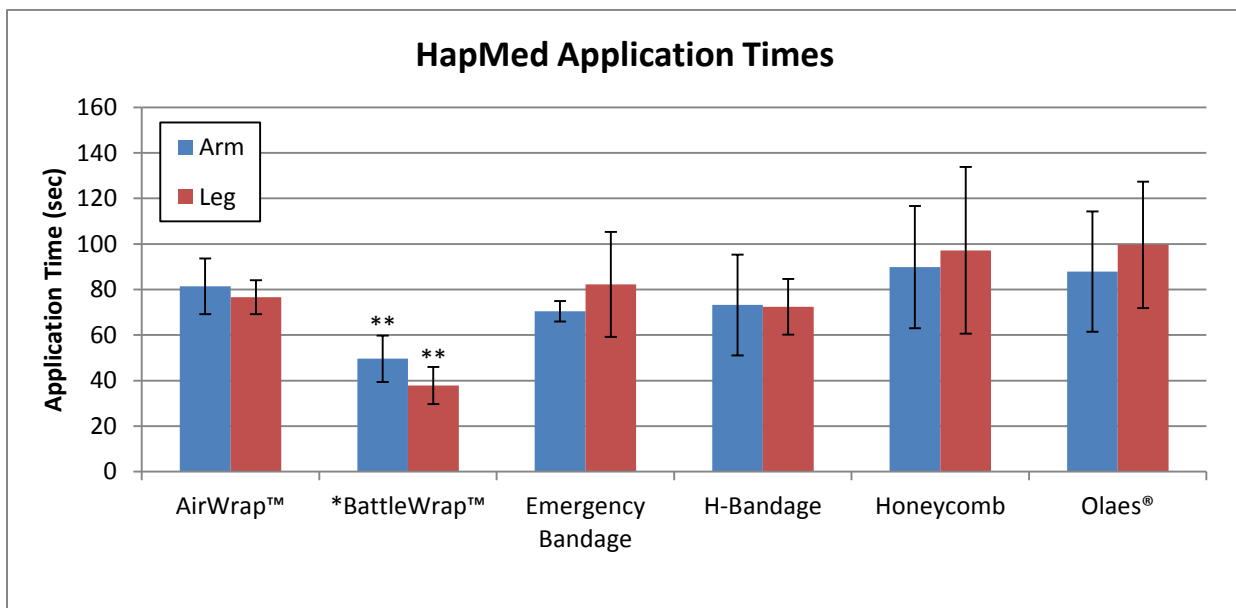
**Figure 13. Representative pressure distributions exerted on the HapMed leg.** 1. Emergency Bandage: pressure concentrated under applicator. 2. H-bandage: increased pressure under H-shaped cinch. 3. Olaes<sup>®</sup>: pressure focus beneath domed pressure bar. 4. AirWrap<sup>™</sup>: increased pressure beneath pneumatic bladder. 5. Honeycomb: uniform pressure. 6. Battle Wrap<sup>™</sup>: relatively uniform pressure.



**Figure 14. Number of layers for HapMed arm and leg applications.** The number of layers produced by each bandage is shown during applications to the HapMed arm and leg. Error bars indicate one standard deviation (n=5). \*Battle Wrap<sup>™</sup> did not achieve the target contact pressure.

The number of layers generated during bandage applications to the HapMed arm and leg were consistent within bandage type, and deviations were limited to within one layer of the mean (Figure 14). Across all bandage types, more layers were applied over the wound site on the arm than leg due to the difference in limb circumference. The number of layers applied reflects bandage length and elasticity. The Honeycomb bandage was the longest, with the greatest elasticity, and it produced the most layers (Leg:  $6.8 \pm 0.8$  layers; Arm:  $9.2 \pm 0.8$  layers). While the results demonstrate relative differences between the length and elasticity of the compression bandages, the number of layers applied over a wound site will depend on the location of the wound and the physical characteristics of the individual on which the bandage is applied.

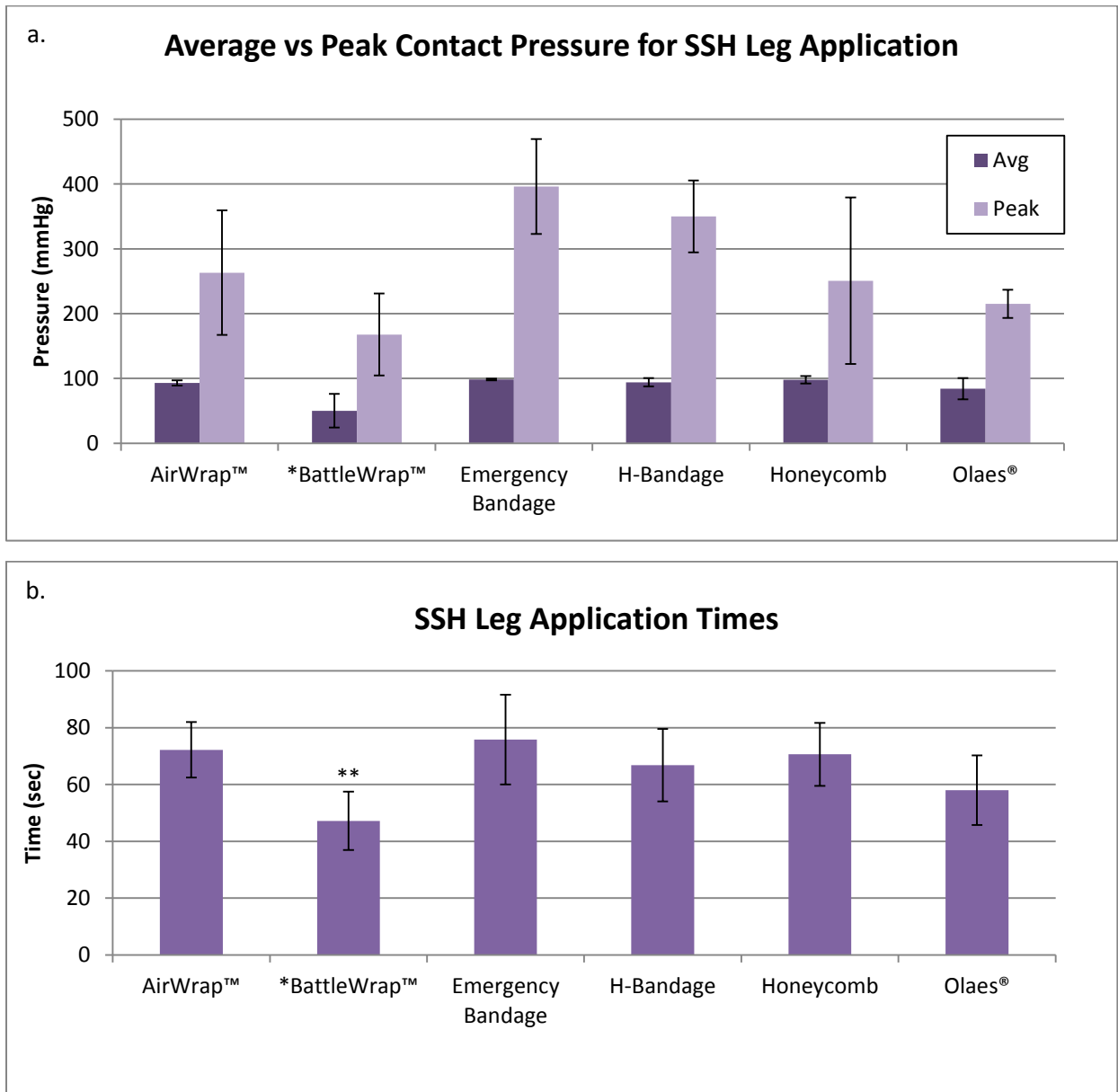
HapMed application times were similar among compression bandage types, and no significant differences were observed between arm and leg applications (Figure 15). However, the Battle Wrap™ application times (Arm:  $49.6 \pm 10.2$  sec; Leg:  $37.8 \pm 8.2$  sec) were significantly shorter than the other compression bandages ( $p < 0.05$ ). The shorter application times were a result of the fewer number of wraps, and the adhesive bandage material, which secured the bandage in place during application.



**Figure 15. HapMed Arm and Leg Application Times.** Application times are shown during compression bandage applications to the HapMed arm and leg. Error bars indicate one standard deviation ( $n = 5$ ). \*Battle Wrap™ did not achieve the target contact pressure. \*\*Significant difference ( $p < 0.05$ ).

*Phase Ib – Compression Bandage SSH Application.* Consistent with the HapMed tests, all bandages were able to achieve the 90 mmHg target contact pressure with the exception of the Battle Wrap™ ( $50.2 \pm 25.8$  mmHg). The peak pressures exerted were comparable between SSH

leg and HapMed leg applications, with the exception of the Olaes<sup>®</sup> bandage, which exerted a lower peak pressure on the SSH. The lower peak pressures are likely due the greater compliance of the SSH tissue, relative to the more rigid HapMed leg and arm, and the convex shape of the Olaes<sup>®</sup> pressure focus (Figure 16a). Also consistent with the HapMed results, the Battle Wrap<sup>™</sup> application time ( $47.2 \pm 10.3$  sec) was significantly shorter than the other bandages ( $p < 0.05$ ). No significant differences were observed between HapMed and SSH application times (Figure 16b). (See the Appendix for photos of bandages applied to the mid-thigh of the SSH.)

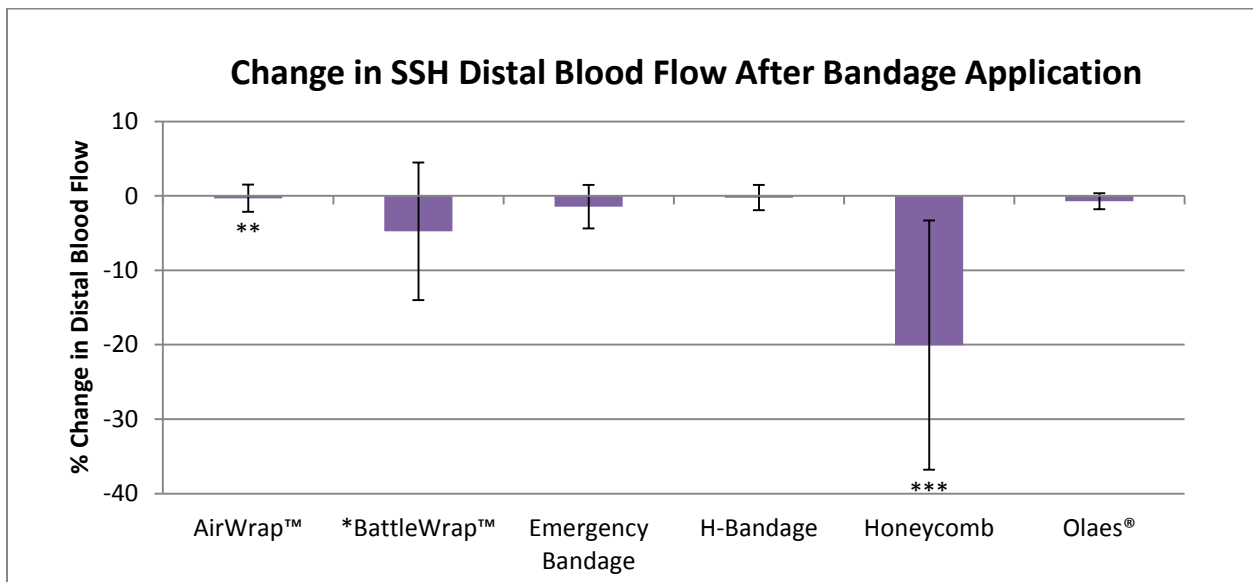


**Figure 16. a) Average and Peak Contact Pressures for SSH Leg Bandage Application. b) SSH Leg Application Times.** Error bars indicate one standard deviation ( $n = 5$ ). \*Battle Wrap<sup>™</sup> did not achieve the target contact pressure. \*\*Significant difference ( $p < 0.05$ ).



The effects of bandage pressure on distal limb blood flow during application to the SSH leg are shown in Figure 17. Only the Honeycomb bandage significantly reduced distal blood flow ( $-20.0 \pm 16.7\%$ ;  $p < 0.05$ ). Because the Honeycomb bandage lacks a mechanism to focus applied pressure, the force is circumferentially applied to the limb causing a reduction in distal flow. To achieve the target pressure at the wound site, an equivalent pressure is transferred (or exerted) across the entire limb, which can cause inadvertent occlusion. The other compression bandages did not significantly affect distal blood flow, with minimal variation between trials. One AirWrap™ bandage distal flow measurement deviated significantly from the other measured values. The bandage was re-tested; however, the result could not be replicated. The anomalous value met the Grubbs' test criteria for being an outlier ( $p < 0.01$ ) and was not included in the reported results.

While relative changes in distal blood flow were observed on the SSH, other factors, including limb circumference and tissue composition in the vicinity of the wound site play a role in the distribution of pressures internally. The effect of compression bandage pressure on distal blood flow may differ depending on the location of the wound site and the physical characteristic of the individual on which the bandage is applied. Hemodynamic variables, including systemic pressure and cardiac output, may also affect the external resistance required to disrupt blood flow.



**Figure 17. The effect of compression bandages on distal blood flow.** SSH distal blood flow measurements are shown normalized to blood flow with no bandage applied. Error bars indicate one standard deviation ( $n = 5$ ). \*Battle Wrap™ did not achieve the target contact pressure. \*\*AirWrap™ had an outlier that was excluded ( $n = 4$ ). \*\*\*Significant difference ( $p < 0.01$ ).

## CONCLUSION

The compression bandages tested in this study included a variety of sizes and materials. Some consisted solely of bandage material, while others employed mechanical features to facilitate application or focus applied pressure. All bandages types except the Battle Wrap™ were able to achieve the target application pressure of 90 mmHg within a simulated wound site. Since the Battle Wrap™ is functionally different than the other bandages, with a strong adhesive to provide a seal over the wound, the lower contact pressures measured do not provide conclusive evidence regarding device efficacy. Bandage designs that incorporated a mechanical pressure focus were able to consistently achieve high peak pressures over an area of interest without inadvertently occluding blood flow to the distal limb. Evaluating the physical and operational characteristics of compression bandages is a critical step in highlighting strengths and areas of improvement for currently available devices. The results from this testing and evaluation provide metrics for comparison and can help to define performance criteria for emerging designs.

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## ABBREVIATIONS

DoD	Department of Defense
FDA	Food and Drug Administration
NAMRU-SA	Naval Medical Research Unit San Antonio
DCS	Data Collection Sheet
SSH	SynDaver™ Synthetic Human

## APPENDIX



**Compression Bandages Applied to SSH.** Compression bandages are shown applied to the mid-thigh of the SSH: 1. AirWrap™ 2. Battle Wrap™ 3. Emergency Bandage 4. H-Bandage 5. Honeycomb 6. Olaes®

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**14. ABSTRACT**  
Though simple in form, compression bandages are vital for hemorrhage control in battlefield trauma care. Many types of compression bandages are available and in development, and quantitative data is required to test the performance of these devices and ensure fielding of effective bandage systems. Study objectives were divided into two phases: Phase 1a - To evaluate the physical properties and features of six compression bandages (AirWrap™, Battle Wrap™, Emergency Bandage, H-Bandage, Honeycomb, and Olaes®), and Phase 1b - To evaluate the operational characteristics of each bandage during application to instrumented mannequins. Phase 1a: Five of each compression bandage model were measured and weighed, physical characteristics were recorded, and bandage elasticity was assessed. Phase 1b: Five of each bandage type were applied to both the HapMed instrumented mannequin leg and instrumented mannequin arm to a target contact pressure of 90 mmHg. Pressure distributions were measured using a pressure sensing grid. Bandages were then applied to the SynDaver™ Synthetic Human (SSH) using the same target contact pressure, and blood flow distal to the compression bandage location was measured and compared to baseline values. Application times were recorded for both HapMed and SSH trials. Phase 1a: Physical measurements demonstrated consistency within bandage type, although differences were observed across bandage types. Bandage elasticity differed considerably across types. Phase 1b: All bandage types, except the Battle Wrap™, were able to achieve the target contact pressure during HapMed leg and arm applications. Average HapMed application times were all less than 100 seconds, with the Battle Wrap™ having the shortest application times. The Emergency Bandage, H-Bandage, and Olaes®, all of which possess mechanisms to focus pressure, produced the highest peak pressures over the simulated wound site. Consistent with HapMed applications, the Battle Wrap™ did not achieve the target contact pressure when applied to the SSH, although the Battle Wrap™ application times were again significantly shorter than those of the other bandages. The Honeycomb bandage was the only device to significantly reduce distal blood flow when applied to the SSH. The results from this testing and evaluation provide metrics for comparison and can help to define performance criteria for emerging designs.

<b>15. SUBJECT TERMS</b> hemorrhage control, compression bandage, HapMed instrumented mannequin, SynDaver,
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