ORIGINAL RESEARCH

Experimental Simulation Study to Assess Pressure Distribution of Different Compression Applications Applied Over an Innovative Primary Wound Dressing

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ABSTRACT

Introduction. Compression is integral to the management of edema and the prevention of venous leg ulcers (VLUs). **Objective.** The aim of this study is to assess the sub-bandage pressure distribution under 3 compression applications as well as to assess the impact of an innovative primary wound dressing, applied under the compression products, on pressure distribution. **Materials and Methods.** A series of controlled tests were performed using a simulated leg model (SLM). A pressure mapping sensor and system software was used to measure the interface pressure (IP) and pressure distribution created by the application of 3 different compression systems with and without the addition of an elastic longitudinal stockinette (fuzzy wale compression; FWC). These included: (1) 2-layer cohesive wrap; (2) 3-layer compression application; and (3) 4-layer compression application. The IP was pressure between the SLM and the innovative dressing over which the compression applications were applied. Seven different configurations were tested, including the compression applications alone and in combination with the FWC. In addition to the IP measurements, pressure mapping visualizations were captured with the pressure mapping sensor and system software. A custom MATLAB program was written for data analysis, differentiations in discrete high- and low-pressure locations across the compressed area, and graphing of the pressure readings. **Results.** The overall average pressure for each testing setup without FWC ranged from 34.65 ± 4.84 mm Hg for the 2L configuration to 63.92 ± 7.08 mm Hg for the 4L configuration. The addition of the FWC resulted in a 19% increase for the 2L, 9% increase for the 3L, and 7% increase for the 4L compression systems. Additionally, it was noted that the inclusion of FWC resulted in a significant change in pressures vertically oriented under the 2-, 3-, and 4-layer compression applications of 34.52 ± 9.06 mm Hg, 99.21 ± 29.81 mm Hg, and 128.96 ± 22.97 mm Hg, respectively. The pressure distribution under the compression alone was observed to be largely uniform except for areas of overlap that produce horizontal bands of elevated pressures. The presence of the primary wound dressing did not have a significant impact on the IP measurements. The addition of FWC to all compression applications demonstrated a vertical distribution of compression along the sensor with alternating areas of little or no compression. **Conclusions.** The unique alternating pressure distribution observed in the in vitro pressure testing with the use of FWC in a clinical setting has been observed to produce better edema management and wound edge migration that mirrors the vertical pressure distribution observed in the study. Additional in vitro and in vivo research to evaluate the biophysical impact of IP created by the use of a combination of primary wound dressings and compression applications with focus on the total pressure and the distribution across the surface of intact tissue and open wound bed is warranted.

KEY WORDS

compression, venous leg ulcer, interface pressure distribution, wound dressing, fuzzy wale compression

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Wounds 2020;32(12):353–363. Epub 2020 August 17

Compression therapy is a cornerstone in the management of venous disease and chronic edema presentations, including lymphedema, chronic venous insufficiency, and venous leg ulcers (VLUs). Compression also has been shown to improve circulation (ie, arterial, venous, and lymphatic), enhance trophic changes/outcomes (eg, lipodermatosclerosis, venous stasis, eczema), and improve clinical symptoms (eg, heaviness, itching, pain, quality of life).[1-12] The known pathophysiological impacts of compression can be categorized into 5 groups: lymphatic, venous, arterial, inflammatory/trophic changes, and clinical symptoms[2-11,13-16] (**Table 1**). Despite evidence affirming the benefits of compression, few studies have quantified therapeutic

Table 1. Pathophysiological impact of compression

Lymphatic	Reduced formation of excess interstitial fluid by opposing fluid filtration from blood capillaries into the tissue, thereby decreasing the lymphatic load[2,3] Shifting of fluid into uncompressed areas with functional lymphatics[3] Increased lymphatic reabsorption and stimulation of lymphatic contractions and increased lymphangion function[2] Enhanced muscle pump resulting in increased frequency and amplitude of lymph collector contractions[2,4]
Venous	Reduced venous reflux and improved venous return[5,6] Reduced venous hypertension[3,6] Maximized calf muscle pump[3,7] Elevated matrix metalloproteinase levels are reduced, promoting healing of venous leg ulcers[8]
Arterial	Increased arterial flow demonstrated with intermittent or moderate sustained pressure[13,14] Increase in leg pulsatile blood flow because of increases in both peak flow and pulse width[15] Skin blood perfusion substantially reduced when compression (40mmHg) is applied to dorsum of the foot and tibia[16]
Inflammatory and trophic changes observed with compression use	Reduced inflammatory response by the release of anti-inflammatory mediators[3,9] Downregulated proinflammatory cytokines[2,3,9] Increased fibrinolytic activity softens the skin[10] Removal of excess fluid has been shown to suppress proliferation of keratinocytes, fibroblasts, and vascular endothelial cells[10]
Clinical symptoms	Reduced pro-inflammatory cytokines have an anti-inflammatory effect, reducing pain[3] Reduced edema allows for normal shoewear and participation in normal activities of daily living, improving quality of life[7,11]

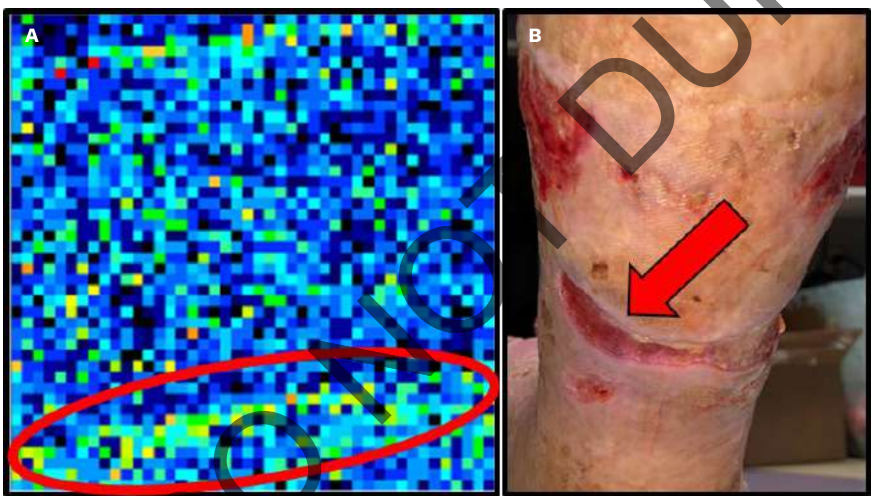


Figure 1. (A) Horizontal band of elevated pressure depicted in the image of pressure mapping from overlapping layers of a 2-layer cohesive in this study; and (B) the region of elevated pressure mirrored the presentation of a device-related injury that occurred following the application of a 2-layer cohesive wrap. Used with permission of the author.

pressures, and there is no consensus with regard to optimal compression materials, techniques, and dosage (ie, interface pressure [IP]).[5,7,12,17]

Much of the compression literature focuses on the impact of compression on the deep venous system with reported primary outcome measures that include venous reflux, venous hypertension (HTN), or venous filtration.[1,3-6] Secondary outcomes address edema reduction and wound healing as related to the impact of compression on venous hemodynamics, with a more recent focus on the lymphatic function.[1-3,5-7,11-15] As such, the measurement of compression dosage has focused on IP measurement using pneumatic pressure transducers (PicoPress, Microlab Elettronica; or Kikuhime, TT Meditrade).[18-20] Interface pressure and the static stiffness index of the compression application are used as indicators of the hemodynamic impact of compression applications.[3,17-20] Although measurement devices have been found to be reliable instruments for ascertaining the pressure under a compression device, they lack the ability to assess the distribution of compression across the surface of the tissue and/or across a wound bed when compression is applied with or without a primary dressing.

The purpose of a primary dressing is to optimize the wound healing environment.[21,22] Moisture management is essential to protecting the periwound area as well as promoting wound healing. The importance of exudate management for timely wound healing is evident in the plethora of wound dressings currently available and documented in a 2019 consensus document.[22,23] An unexplored area of research in the wound care and compression science is the impact of a primary dressing on the IP measured at the skin/wound interface. A review[24] of the literature found only 1 study that investigated the impact of a primary dressing on IP. In 2011, Cook[24] observed an increase in sub-bandage pressure readings with the expansion of a superabsorbent dressing applied under compression. However, readings were not obtained under the dressing, but rather from the contralateral side of the limb.

The distribution of pressure applied by a compression textile and/or a primary wound dressing across the surface of the tissue has clinical implications. Clinicians often are directed to pad certain bony areas when applying compression in order to distribute the force of the compression evenly around the surface of the limb. In addition, bolster dressings applied over VLUs that occur in concave or bi-planar locations have been found to improve healing rates.[25] Alteration of IP directly under a bolster dressing applied in combination with compression bandage varied depending on location. No published research has examined IP or the pressure distribution produced when a geometrically non-uniform woven compression product is applied alone or in combination with a primary dressing or secondary compression.

Localized areas of pressure or circumferential pressures have been shown to contribute to tissue damage, particularly in patients with fragile skin or in persons with a compromised circulatory status (ie, peripheral arterial disease [PAD]), diabetes mellitus, or compromised sensation.[26] Thicker primary dressings with bulky edges can result in raised pressure points, which mirror the primary dressing dimensions when applied under compression applications. Furthermore, superficial skin trauma has been documented (as seen in **Figure 1**); horizontal ligature skin trauma on fragile skin was noted following layered compression application. The observed skin trauma mirrors the elevated pressure profile observed with a boxed compression application in this study. The similarities of these observations herald the need for further investigation of IP distribution across the skin/wound created by the application of commercially available compression textiles when applied with or without a primary dressing.

The goal of this experimental simulation study was to quantify and compare the interface pressure and compression profiles of 3 clinically relevant compression applications applied over an innovative primary dressing, with and without the addition of an elastic longitudinal stockinette (fuzzy wale compression; FWC) that has been clinically observed by the primary author to alter the wound healing appearance. In this study, the phrase *pressure profile* refers to the arrangement of discrete pressures across a specific area. This includes both its magnitude and pattern (ie, the pressures that are seen between the compression wrap and the simulated leg). The authors hypothesized there would be measurable differences among IP measurements between the different compression wrappings tested, as well as unique differences in local distribution of IP across the sensor with the addition of the FWC under the compression wrap materials tested. The authors hypothesized that the addition of the FWC would create a sinusoidal-like pressure profile under the pressure dressing that mirrored the non-uniform geometrical weave of the dressing.

MATERIALS AND METHODS

To evaluate the pressures generated by compression wrapping systems, including the IP measurements and distribution of pressure across the sensor, a simulated leg model (SLM; **Figure 2**) was created using clear acrylic tubing (McMaster-Carr): (outer diameter: 4.5 in, wall thickness: 1/8 in, length: and 5 ft). This model was sized

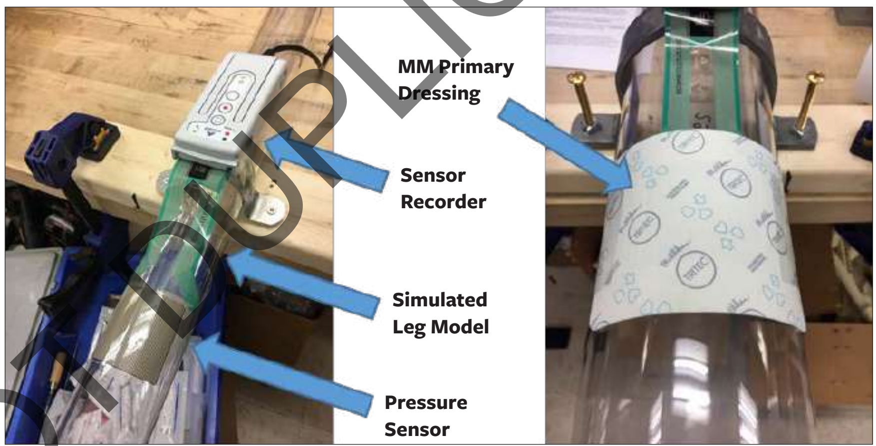


Figure 2. Schematic of the simulated leg model with the pressure sensor and the moisture-management (MM) primary dressing positioned in the center. The MM primary dressing was placed on top of the pressure sensor.

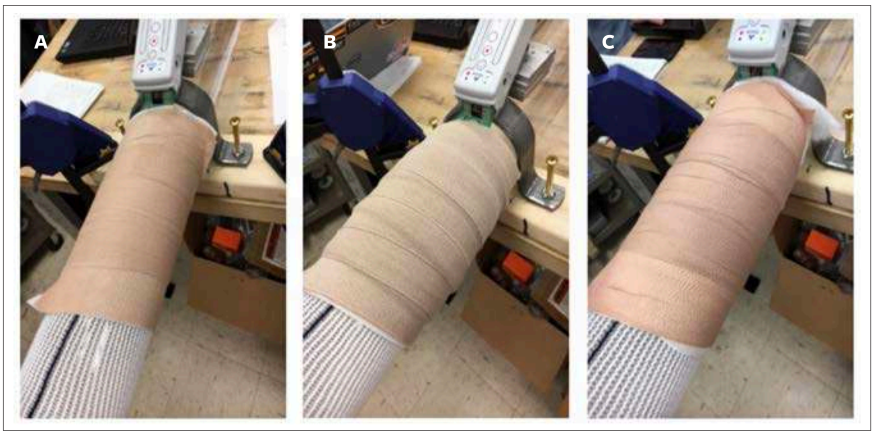


Figure 3. Representative examples of the testing setup with fuzzy wale compression (FWC), where the moisture-management primary dressing and FWC were applied beneath the (A) 2-layer, (B) 3-layer, and (C) 4-layer compression systems.

to mimic lower limbs as described both in the literature and clinically (**Figure 3**). This stiff material was chosen as a baseline for assessment of simulated differences in compression wrap materials and configurations. Softer substrates that simulate more clinically relevant tissues should be added/ considered in future work.

A pressure mapping sensor and system software (I-Scan; TekScan) was used to measure the IP and pressure distribution created by the application of compression wrap system combinations. The mapping/ sensor system combines a flexible, thin-film, matrix-based sensor that contains vertical and horizontal intersecting sensels interfaced with corresponding computer software for data collection. Previous literature that has examined this pressure mapping system found it to be more accurate than competing systems, with measured errors ranging from -2% to 3%.[27,28] Before testing, the sensors were calibrated using known pressures to establish a calibration curve. Using the calibrated sensors, the system was used to capture static pressure mapping visualizations for each experimental setup (**Figure 3**).

To prepare the SLM, a thin moisture-management (MM) primary dressing (1.5 mm thick, TRITEC; Milliken Healthcare Products, LLC) was lightly applied

Table 2. Application order of the individual components in the SLM, showing the 7 compression configurations tested

APPLICATION ORDER FOR THE INDIVIDUAL COMPONENTS OVER THE SLM							
Away from leg ↓	**SLM**						
	Pressure sensor						
	Moisture-management primary dressing (MM)						
	FWC	2L	FWC 2L	3L	FWC 3L	4L	FWC 4L

SLM: simulated leg model; FWC: fuzzy wale compression; 2L: 2-layer; 3L: 3-layer; 4L: 4-layer

Table 3. Description of the textile characteristics, manufacturer details, and application notes for the materials used

STUDY DRESSINGS	COMPRESSION APPLICATION	TEXTILE CHARACTERISTICS
Moisture management	TRITEC (Milliken Healthcare Products, LLC)	A 1.5mm thick moisture management primary dressing consisting of micro-knit fabric that pulls away and traps excess exudate
Fuzzy wale compression	Fuzzy wale compression (EdemaWear; Compression Dynamics, LLC)	Elastic, tubular stockinette made of medical-grade Lycra spandex and nylon. Utilizes textile technology to create a fuzzy nexus with the skin with compression arranged in vertical channels rather than horizontal as seen with other elastic stockinette products
2-layer	CoFlex TLC (Milliken Healthcare Products, LLC)	• Layer 1: open-cell polyurethane foam containing cyclodextrin (odor control) and aloe (comfort/itch control) • Layer 2: non-latex short stretch cohesive compression bandage. Standard compression offering of 35–40mmHg applied per manufacturer's instructions
3-layer	CompriFoam and Comprilan (BSN Medical)	• Layer 1: CompriFoam—open-cell polyurethane rolled foam of 0.4cm thickness • Layer 2: Comprilan—short-stretch compression bandage applied in a spiral pattern with a 50% overlap • Layer 3: Comprilan—short-stretch compression bandage applied in a spiral pattern with 50% overlap
4-layer	PROFORE (Smith+Nephew)	• Layer 1: PROFORE #1 Absorbent Padding Bandage—subwadding bandage made of 100% rayon fleece • Layer 2: PROFORE #2 Light Conformable Bandage—light, conformable short-stretch bandage • Layer 3: PROFORE #3 Light Compression Bandage—light compression long-stretch elastic bandage • Layer 4: PROFORE #4 Flexible Cohesive Bandage—latex-containing long-stretch cohesive compression bandage. All compression bandages applied per manufacturer's instructions

over the pressure sensor to model in the same manner compression wraps might interact with the leg (**Figure 3**).

Three compression wrapping configurations were examined, with and without the inclusion of a FWC (EdemaWear; Compression Dynamics, LLC) layer. The FWC layer also was tested by itself, and it has a non-uniform geometrical weave that is hypothesized to create a sinusoidal-like pressure profile under the compression dressings. This resulted in 7 distinct compression wrapping configurations, as follows (**Table 2**).

- FWC: Fuzzy wale compression alone
- 2L: 2-layer compression with and without FWC
- 3L: 3-layer compression with and without FWC
- 4L: 4-layer compression with and without FWC

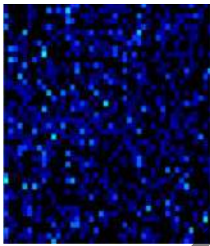
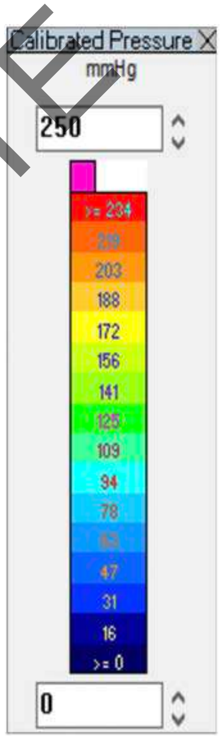
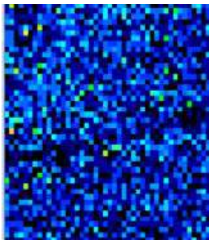
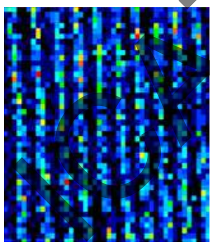
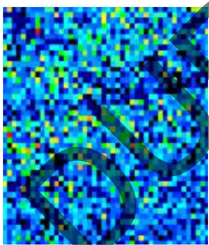
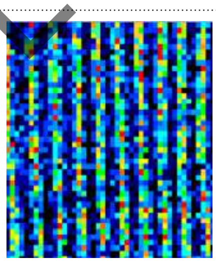
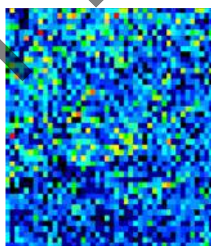
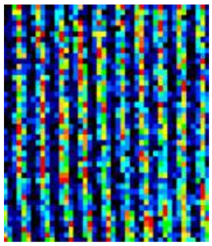
Specific manufacturer details, textile characteristics, and application notes for all of the materials and compression wrapping configurations used in this study are summarized in **Table 3**. A full description of the application procedure for these configurations is described below.

The calibrated pressure sensor was positioned within the center of the SLM, ensuring no wrinkles or folds (**Figure 3**). The primary wound dressing and compression systems were applied by a single technician (bachelor of science in biomedical engineering), who had been previously instructed by a clinical specialist in the standard application procedure of each bandage system. A single operator was chosen to reduce pressure application variations, which could be caused by inaccurate application (overlap ratio, stretch) or application inconsistencies between multiple operators. Each configuration was evaluated 5 times for each compression application within 30 seconds of initial application. New compression wrap materials were used for each iteration.

Pressure mapping images were captured using the pressure mapping sensor and system software to visually display the pressure profiles seen at the pressure sensor interface (**Table 4**). Areas of dark blue indicate lower pressures, whereas areas of red/pink indicate higher pressures.

In addition to the pressure mapping visualizations, a custom MATLAB data processing computer program (The MathWorks Inc) was written for data analysis, differentiations in discrete high- and low-pressure profiles across the compressed area, and graphing of the pressure measurements. Overall pressure was calculated by averaging pressure values from each individual sensel. The average pressure in each column of sensels also was linearized and calculated within the custom program. These points were graphed, and a spline was used as the trend-line. Based on this spline, local minimums, if positive and

Table 4. Examples of pressure mapping allowing for the visualization of the IPs experienced in the trials

	WITHOUT FWC	WITH FWC	
FWC			
2L			
3L			
4L			

The combination the layered compression with the FWC enhanced the presentation of the alternating pressure profile.
Note: The legend on the far right corresponds to the color gradient for each of the pressure maps; dark blue indicating low/no pressure and red/pink indicating high pressure.
IP: interface pressure; FWC: fuzzy wale compression; 2L: 2-layer; 3L: 3-layer; 4L: 4-layer

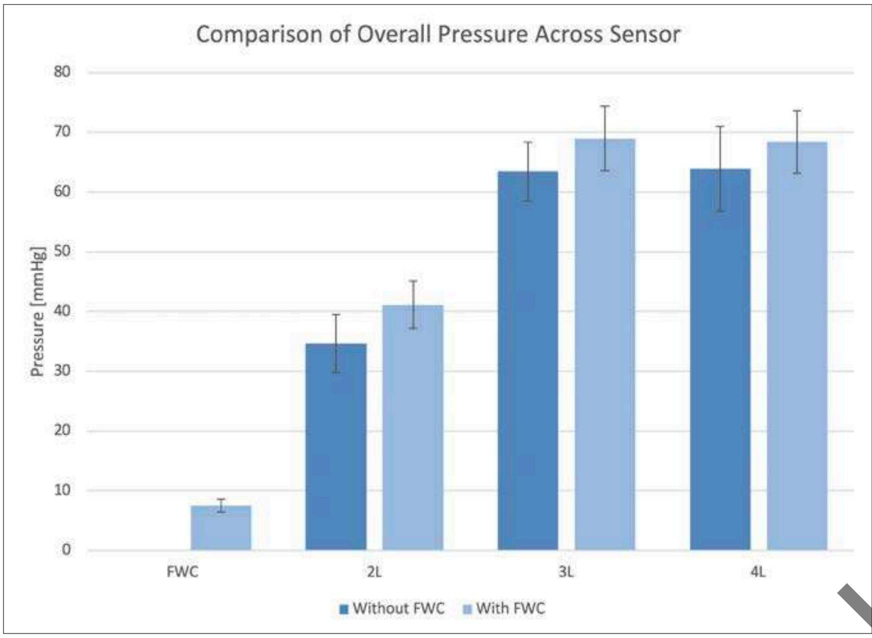


Figure 4. Overall average pressure measured across all sensels within the pressure sensor for all testing configurations.
Note: Fuzzy wale compression (FWC) was only tested individually in the set of trials with FWC. Therefore, it has no value within the trials without FWC.

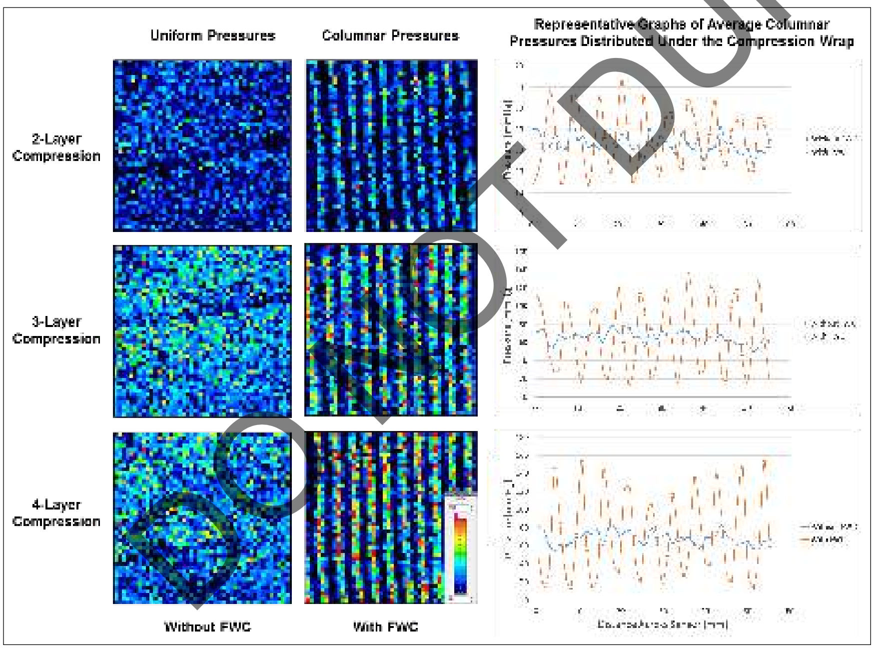


Figure 5. Representative pressure maps and graphs of the columnar pressure averages for testing configurations with and without fuzzy wale compression (FWC) beneath compressive wrapping systems. The spline fit to each phase's data was used to isolate local maximums and minimums along the curves.

below the average overall pressure, and local maximums, if above the average overall pressure, were isolated for analysis. The average of the local minimums was compared to the average of the local maximums for each individual compression wrap system. This comparison resulted in values of the average range of alternating pressure. The overall pressure, average range of alternating pressure, and standard deviations were calculated for each testing setup. Statistical differences between compression wrap systems were determined in Microsoft Excel (Microsoft Corp) using a one-way ANOVA with a significance level of 0.05 ($\alpha = 0.05$).

RESULTS

The overall average pressures for each testing setup without FWC were 34.65 ± 4.84 mm Hg for the 2L configuration, 63.48 ± 4.89 mm Hg for the 3L configuration, and 63.92 ± 7.08 mm Hg for the 4L configuration (**Figure 4**). The FWC layer alone produced very little pressure (average, 7.56 ± 1.05 mm Hg). With the additional application of the compression wraps over the FWC, the overall average pressures increased 19% (to 41.14 ± 3.98 mm Hg) with the 2L, increased 9% (to 68.98 ± 5.41 mm Hg) with the 3L, and increased 7% (to 68.41 ± 5.21 mm Hg) with the 4L compression systems in the overall pressure across the sensor.

Figure 5 graphs the range of alternating pressures calculated across the sensor. Without an FWC layer, pressures were uniform and produced little change in pressures across the sensor. However, with the inclusion of the FWC material, significant bands of sinusoidal high-to-low pressure lines were observed under the compression wraps. **Figure 6** illustrates these increased ranges of variations in pressure observed, with the 2L, 3L and 4L configurations producing ranges of sinusoidal pressures of 34.52 ± 9.06 mm Hg, 99.21 ± 29.81 mm Hg, and 128.96 ± 22.97 mm Hg, respectively. These data represented a 243% increase with the 2L, a 573% increase with the 3L, and a 698% increase with the 4L in the average range of sinusoidal pressure ranges compared with having no FWC layer under these compression wrapping systems.

The addition of the FWC between the sensor and the compression applications produced a statistically significant increase ($P < .05$) in the average range of alternating pressures recorded with the 2L, 3L, and 4L. A comparison of the overall pressure experienced across the sensor for trials with and without FWC was not statistically significant ($P > .05$).

Visual images from the trials without FWC show the pressures experienced

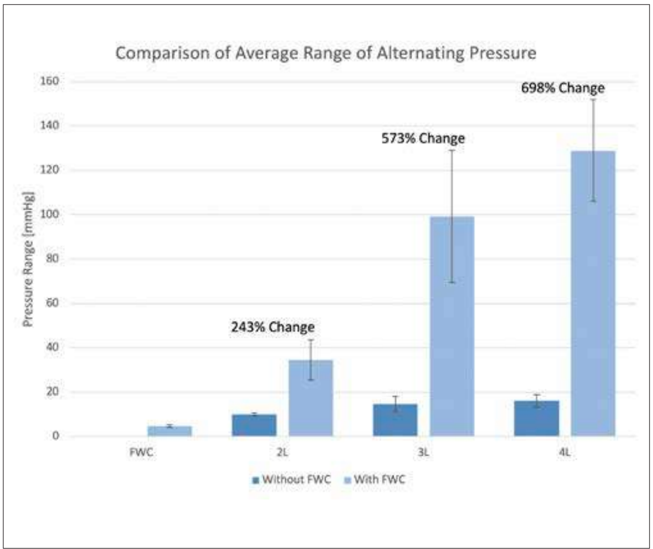


Figure 6. Average range of alternating columnar pressure for all testing configurations. The fuzzy wale compression (FWC) was only tested individually in the set of trials with FWC. Therefore, it has no value within the trials without FWC.

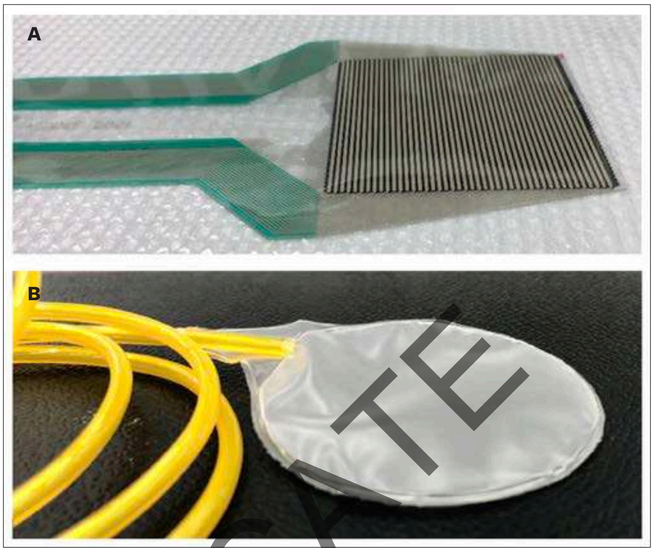


Figure 7. Shown is (A) the I-Scan (Tek Scan), a thin, low-profile pressure sensor, compared with the (B) pneumatic pressure transducer (PicoPress, MicroLab Elettronica) bladder that inflates during readings.

when the multilayered compression systems are applied over the top of the MM primary dressing were uniform except for a slight diagonal candy cane-like line seen from left to right, observed as an elevated pressure line where the bandages overlapped the previous circumferential wrap at about 50% of its width. Images from trials with FWC clearly show the impact FWC has when added between the MM primary dressing and the additional compression system. Linear patterns were created by the longitudinal compression of the FWC. The addition of FWC created linear areas with little to no pressure in-between areas of higher pressure when compared with pressure mapping images from the trials without FWC.

DISCUSSION

Multicomponent compression in vivo is applied as part of the standard of care for patients in the management of chronic venous disease and edema. The amount of pressure applied is dependent on the compression textile composition and application pattern, skill of the operator, patient morphology, type of pressure measurement device (if one is present), and the location in which the pressure is measured (in vitro vs. in vivo).[1,29-32] The pressure on the external surface of the limb that is generated by a textile compression application is transmitted to the internal tissues.[1] Although numerous lab and clinical studies have compared different compression applications, the present study is the first to assess the distribution of the pressures across the tissue/pressure sensor surface; in addition, to the authors' knowledge, it is the first to look at the impact of a primary dressings on the IP or the distribution of the pressure profile directly under a compression application.

The measurement of compression at different points under a compression application is influenced by multiple variables, including anatomy, posture, activity, physical characteristics of the compression system, and the physical properties of the measurement device.[19-20,27,32,33] In order to minimize the number of variables capable of influencing the accuracy of the measurements, the compression applications were applied to a cylinder of uniform consistency and shape. Additionally, the sensor was chosen due to its low-profile nature in order to reduce the impact of the pressure measuring probe on the pressure measurements (**Figure 7**).

At the outset of the study, 2 questions were posed that specifically related to the impact of compression textile composition (both the number of layers and texture) selection on the IP applied to the SLM, distribution of the pressure across the sensor utilized in the study, and impact of the presence of a primary wound dressing on the IP measurements. A visible and statistically significant difference was noted between both the distribution of the pressure across the sensor and the pressure peaks respectively. In trials without FWC, the 2L, 3L, and 4L compression systems produced similar compression distribution across the sensor and exhibited a slight diagonal candy cane-like line seen from left to right, observed as an elevated pressure line where the edge of the bandages overlapped the previous circumferential wrap at about 50% of its width. The FWC application produced a uniquely different compression profile with vertical orientation of pressure channels.

In trials with FWC, the addition of FWC under the compression bandage application produced significantly increased averages of each IP ($P < .05$); in addition, the angled horizontal linear pressure zones were not visualized in the compression profile images. The addition of the FWC under the compression application resulted in vertical channels of higher but more equally distributed IP measurements. In addition to elevated readings, areas of relief were noted where there was little to no

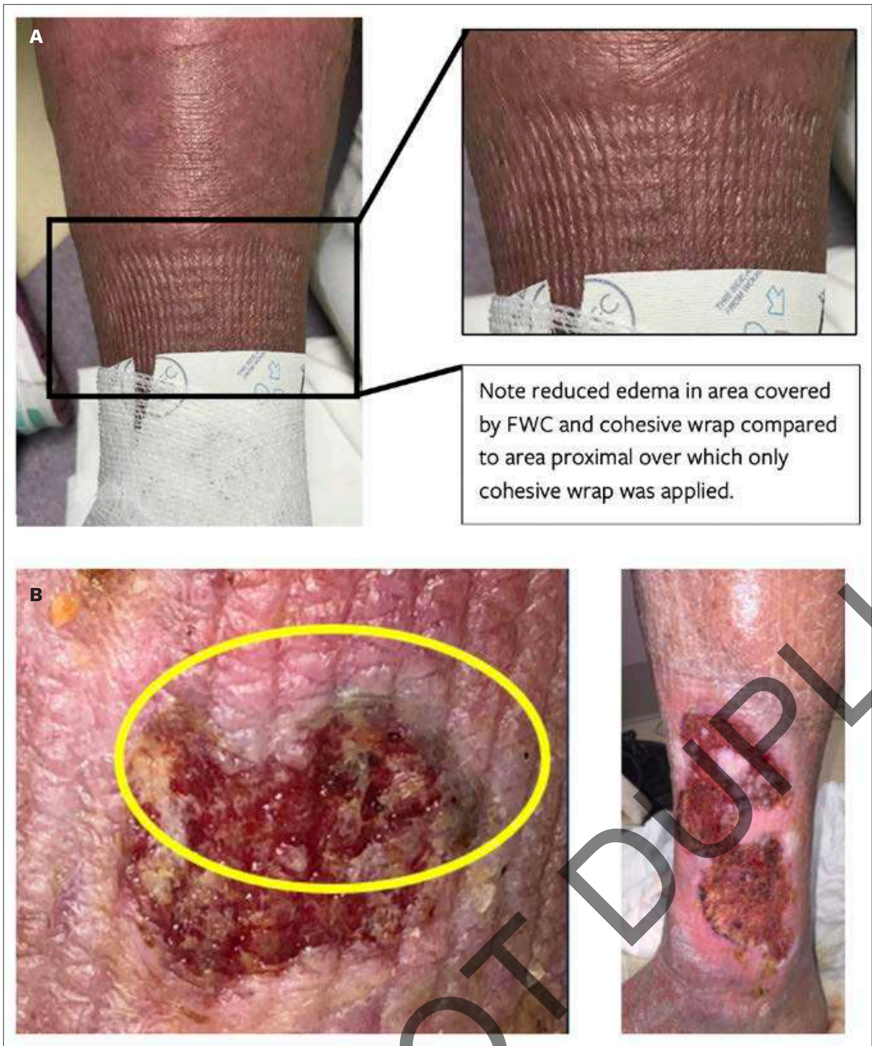


Figure 8. (A) clinical example of the linear pattern observed with incorporation of fuzzy wale compression (FWC) under a boxed compression application; and B) healing edge of wound forming scalloped pattern that mirrored the visualized alternating pressure profile observed in this study. Additionally, observed linear epithelization in the center of wound bed that mirrors unique pressure profile observed in this study when a moisture-management primary wound dressing was in combination with FWC and a pre-packaged compression application. Images used with permission of the author.

pressure. The alternating pressure profile, coined *lymphedema alternating pressure profile* (LAPP) by Bjork and Ehmann has been hypothesized to apply microstrain on initial lymphatics, in turn stimulating function.[34-36] A study by Chohan et al[37] showed increased oxygenation in healthy volunteers when a compression application with a similar LAPP was applied.

A statistically significant difference was found between the average IP measured under the different compression applications except for 2 of the multicomponent systems (3L, which is commonly used by lymphedema therapists for the intensive phase of therapy, and 4L) that produced almost identical IP measurements (63.48 mm Hg and 63.92 mm Hg, respectively). The elastic stockinette, FWC, produced very low IP measurements (average, 7.56 mm Hg), which is typical of other elastic stockinette dressings that advertise compression of 8 mm Hg to 12 mm Hg. According to published research,[17] this IP would not be enough to have a significant therapeutic effect on deep venous hemodynamics.

All of the tested compression bandage applications created IP measurements that have been documented in the literature to provide therapeutic effect on vascular hemodynamics (34.65–63.48 mm Hg)[3,5,7,17,38]; 2L IP ranges from 35 mm Hg to 40 mm Hg and 4L IP ranges from 17 mm Hg (at the knee) to 40 mm Hg (at the ankle).[38,39] The higher pressure ranges observed during this study could be due to the overlap of the compression layers onto the pressure sensor, creating areas of higher pressure from the nature of the pressure mapping sensor measuring across the sensor versus point pressure due to the firm SLM over which the compression therapy is applied.

No studies have been published evaluating the IP created with the 3L utilized in this study. However, as observed in other compression literature, higher IP readings were observed with compression applications that incorporated multiple layers.[1,34,39-41] The increased number of layers of compression textile application was not found to be directly proportional to the increase in average IPs observed (2L: 34.65 mm Hg vs. 3L: 63.48 mm Hg vs. 4L: 63.92 mm Hg); rather, it was dependent on the textile's characteristics and application pattern with which the compression was applied.[1,32,33,40,42] Because pressure measurements for each subsequent layer were not assessed as part of this evaluation, it is outside the scope of this study to comment on the impact of the textile characteristics of each layer as it relates to the total pressure observed for the compression applications reviewed. Nonetheless, it is an important observation that additional layers of compression created increased IP. Of interest, the addition of FWC to the compression applications produced a statistically significant increase in both overall IP and the pressure peaks that is beyond what has been reported in previously published studies. Ruckley et al[33] and Dale et al[42] observed that successive bandage layers, when applied as part of a multilayered system, added a bit more than 50% of the pressure achieved by the same bandage when applied alone. However, in the current study, it was observed that the addition of the FWC with the compression bandage sets produced dramatically greater increases. Through the addition of the FWC under the compression wraps, higher pressure values were observed beneath the thin linear components of the FWC.

In addition to a localized elevated IP reading, the addition of FWC produced a unique linear distribution of pressure that matched the textile construction. A pattern of alternating pressure and no pressure were observed. This pressure distribution was observed with the FWC alone and in combination with the compression system applications studied. The presence of the MM primary dressing did not significantly occlude the pressure patterning of the FWC compression. As the compression applications were not measured without the MM primary dressing in this initial work, the authors cannot directly state that the MM primary wound dressing had an impact on the total IP. However, the pressure profile of the FWC was apparent despite the presence of the MM primary dressing due to the low-profile nature of the dressing itself.

Furthermore, it was observed that the addition of the FWC not only applied greater localized IP, but it also created a significant difference between maximum and minimum pressure values. The pressure distribution of the compression systems was oriented in vertical channels when the FWC was included between the MM primary dressing and the compression systems.

Clinical implications

The observed linear epithelialization mirrored the linear areas of low pressure produced by the FWC, as well as the reduced epibole/improved edge effect seen with the addition of the FWC to the wound care regimen (**Figure 8A**). One possible explanation is that elevated IP observed with the addition of FWC to the compression application lowered the tissue pressure in areas of the wound bed and along the margins, allowing for an enhanced microcirculation in those channels of lower pressure. This microcirculation provided a favorable environment for epithelial advancement. Epithelial advancement used as a sign of wound healing may suggest this unique type of compression benefits wound healing.[17,22,43,44]

Findings of this study, particularly the alternating pressure profile created by the FWC as well as the objective data (total elevated compression dosage and alternating areas of reduced or no compressive forces), supports previous observations of the primary author (S.E.). She anecdotally has observed enhanced edema reduction, improvements in tissue texture, and progressive wound healing when FWC was incorporated into her compression applications. Clinically, she has observed that applying FWC directly to the wound bed and/or over a single layer of the MM primary dressing produced healing in a pattern that mirrored the pressure distribution observed in this study. Linear epithelization as well as scalloped edges corresponding to areas of reduced pressure produced by the FWC are visualized in **Figure 8B**. As such, this author hypothesized that the biophysical action of the FWC could include directional flow of dermal congestion away from the wound bed, resulting in decongestion of the periwound tissue. Reduced tissue congestion could have optimized wound healing in the area of lowered pressure. A second hypothesis may be that the mechanical deformation of the tissue created by the textured nature of FWC may have further stimulated the lymphatics system and/or created a release of chemical mediators to promote enhanced wound healing. Further research is necessary to fully investigate the biophysical impact of textured compression applications to both the tissue and wound beneath different compression and primary wound dressings.

In addition to the lack of data in the literature about the impact of a primary dressing on the sub-bandage IP measurement at the site of the wound and periwound area, there is no documentation of the impact of a primary dressing on the distribution of pressure across the tissue or across the wound surface. These missing data from the literature impair the cumulative assessment of the impact on IP in the area of the wound that is produced when these dressings are layered under compression applications.

The impact of a primary dressing on the IP and pressure profiles experienced when using different types of advanced wound care dressings on tissue and wounds warrants further research. Future research to look at the impact of different pressure profiles on underlying circulation as well as investigation of the impact of textured compression on tissue density are necessary to define the ideal compression product and to match compression products to individual patient presentations. Therapeutic compression is more than a static number. Compression science looking at the pressure change (resting pressure and interface pressure) as well as how the pressure is distributed across the tissue/wound can provide insight into the overall function of a compression product.

LIMITATIONS

This study was not designed to test the performance of different types of bandages under simulated conditions of use. As such, there are several limitations. First, the uniform shape and hardness of the acrylic tube of the SLM could have affected the measured pressures, which would limit the clinical ramifications of the specific pressure values. The SLM utilized was based on previously reviewed studies published in the literature, including studies by Hirai et al,[32] Melhuish et al,[45] and Thomas.[46] Future studies could potentially apply these methodologies to SLMs with an anatomical slope and a skin simulant material to more accurately predict in vivo pressure. Ideally, the same research design should be carried out on healthy human volunteers with varying size/shape limbs.

Second, variations between individual applications are difficult to avoid given the subjective nature of the application of compression bandages. Testing was performed on different days, sometimes separated by weeks between different experiments, and this could have affected the consistency of the application of the compression wrap systems. Future work should utilize larger sample sizes to better average out these discrepancies. Finally, this was a static test that did not capture dynamic compression textile characteristics and how the pressure might have changed with movement, increased or decreased volume of limb, or change in tissue texture. Additional study is warranted to evaluate the effects of these variables. Overall, future research could build upon the aforementioned methods presented to provide clinically relevant and translatable data that will clarify the role of various compression textiles and FWC in IP development.

CONCLUSIONS

The aim of this study was to assess the sub-bandage pressure distribution under 3 compression applications as well to assess the impact of an innovative primary wound dressing, applied under the compression products, on pressure distribution. A series of controlled tests were performed using a SLM and pressure mapping sensor and system software to measure the IP and pressure distribution created by the application of 3 different compression systems with and without the addition of an FWC: (1) a 2-layer cohesive wrap; (2) a 3-layer compression application; and (3) a 4-layer compression application. The overall average pressure for each testing setup without FWC ranged from 34.65 ± 4.84 mm Hg for the 2L configuration to 63.92 ± 7.08 mm Hg for the 4L configuration. The addition of the FWC resulted in a 19% increase with the 2L, 9% increase with the 3L, and 7% increase with the 4L compression system. Additionally, it was noted that the inclusion of FWC resulted in a significant change in pressures vertically oriented under the 2-, 3-, and 4-layer compression applications of 34.52 ± 9.06 mm Hg, 99.21 ± 29.81 mm Hg, and 128.96 ± 22.97 mm Hg, respectively. The pressure distribution under the compression alone was observed to be largely uniform except for areas of overlap, which produced horizontal bands of elevated pressures.

The presence of the primary wound dressing did not have a significant impact on the IP measurements. The addition of FWC to all compression applications demonstrated a vertical distribution of compression along the sensor with alternating areas of little or no compression. The unique alternating pressure distribution observed in the in vitro pressure testing with the use of FWC has been clinically observed to produce better edema management and wound edge migration that mirrors the vertical pressure distribution observed in this study. Additional in vitro and in vivo research to evaluate the biophysical impact of IP created by the use of a combination of primary wound dressings and compression applications with focus on the total pressure and the distribution across the surface of intact tissue and open wound bed is warranted.

ACKNOWLEDGMENTS

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Disclosure: This research study was sponsored by Milliken Healthcare Products, LLC.

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