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ORIGINAL ARTICLE

Inelastic Compression Legging Produces Gradient Compression and Significantly Higher Skin Surface Pressures Compared with an Elastic Compression Stocking

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The purposes of this study were to (1) investigate compression levels beneath an inelastic legging equipped with a new pressure-adjustment system, (2) compare the inelastic compression levels with those provided by a well-known elastic stocking, and (3) evaluate each support's gradient compression production. Eighteen subjects without venous reflux and 12 patients with previously documented venous reflux received elastic and inelastic compression supports sized for the individual. Skin surface pressures under the elastic (Sigvaris 500, 30–40 mm Hg range, Sigvaris, Inc., Peachtree City, GA) and inelastic (CircAid C3 with Built-In-Pressure System [BPS], CircAid Medical Products, San Diego, CA) supports were measured using a calibrated Tekscan I-Scan device (Tekscan, Inc., Boston, MA). The elastic stocking produced significantly lower skin surface pressures than the inelastic legging. Mean pressures (± standard error) beneath the elastic stocking were 26 ± 2 and 23 ± 1 mm Hg at the ankle and below-knee regions, respectively. Mean pressures (± standard error) beneath the inelastic legging with the BPS were 50 ± 3 and 38 ± 2 mm Hg at the ankle and below-knee regions, respectively. Importantly, our study indicates that only the inelastic legging with the BPS produces significant ankle to knee gradient compression ($p = .001$).

Key words: *chronic venous insufficiency, deep venous thrombosis, dependent edema, lymphedema*

Chronic venous insufficiency (CVI) is a significant health concern and is said to affect 2 to 6 million patients in the United States.[1] CVI is due to the inability of the venous system to efficiently return blood to the heart from the lower extremities and involves disturbed venous hemodynamics.[2,3] This condition occurs when the venous valves or the calf muscle pump in the lower extremities fail to prevent retrograde blood flow.[3] The calf muscle pump consists of the calf muscles compressing the deep veins to aid venous return of blood. CVI can cause varicose veins, lower extremity pain, edema, blood pooling, and venous ulcers.[3,4] CVI is a significant health concern owing to the number of people it affects and the large costs incurred from treatment, which are estimated to total more than $1 billion per year.[5]

Compression therapy is the "gold standard" treatment for CVI.[6,7] Elastic stockings are currently the most well-known option for compression therapy. However, inelastic leggings, the Unna boot, and intermittent pneumatic compression are other compression therapy options for CVI treatment. As opposed to daily CVI treatment, the Unna boot and intermittent pneumatic compression are typically used for short-term treatments, such as for venous ulcers. The elastic stocking and inelastic legging are the preferred option for everyday CVI symptom management. These compression supports consist of an elastic or inelastic material that provides gradient compression from the ankle to the knee region (higher pressures at the ankle and lower pressures below the knee). Compression supports force blood toward the heart against gravity

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and prevent blood pooling.[6] Previous studies have shown that gradient compression increases venous return more than uniform compression.[8]

Compression supports are classified as I, II, III, or IV according to the pressures they produce at the ankle. According to the US designations, class I provides mild pressure (15–20 mm Hg), class II provides moderate pressure (20–30 mm Hg), class III provides strong pressure (30–40 mm Hg), and class IV provides very strong pressure (> 40 mm Hg). Previous studies document that supports within the same classification can still vary in their material stiffness, thus indicating possible differences in the surface pressures they generate.[9] Although elastic and inelastic supports come in a variety of pressures, compression support pressures greater than 30 mm Hg are particularly beneficial to patients with CVI.[10]

A variety of pressure transducers have been used in studies to measure surface pressures at the interface between compression supports and the skin. Some of these include the medical stocking tester, the Kikuhime device (TT Medi Trade, Denmark), and the Tekscan Industrial Sensing (I-Scan) system (Model 4300, Tekscan, Inc., Boston, MA).[10–12] In this study, we implement use of the Tekscan device owing to its ease in application, its flat nature, and its range of pressure sensors. Furthermore, initial application pressures with the subject in a seated position are the target of this study as pressures in various ambulation sequences and postures have been previously investigated.[6,7,13]

In our study, we investigated supports that aimed to generate pressures that are consistent with class III and IV levels and provide gradient compression from the ankle to the knee. The purposes of this study were to (1) investigate compression levels beneath an inelastic legging equipped with a new pressure adjustment system, (2) compare the inelastic compression levels with those provided by a well-known elastic stocking, and (3) evaluate each support's gradient compression production. We hypothesized that both elastic and inelastic supports effectively produce class III and IV pressures at the ankle and that both sets of supports produce gradient compression.

Methods

Thirty subjects (14 females, 16 males; ages 55–77 years) received elastic (Sigvaris 500, 30–40 mm Hg range, Sigvaris, Inc., Peachtree City, GA) and inelastic (CircAid C3 with Built-in-Pressure System [BPS], CircAid Medical Products, San Diego, CA) compression supports sized for each individual. Twelve of these subjects had previously documented venous reflux. Exclusion criteria were as follows: misshapen legs, the presence of existing ulcers, poor underlying health, under the age of 55 years, allergies to study materials, pregnant women, recent development of deep venous thrombosis (DVT) (within 6 months), the presence of congenital arteriovenous malformations, paraplegia, and those likely to be noncompliant. Approval by the University of California-San Diego Human Research Protections Program was obtained for this study, and all subjects provided informed, written consent.

The elastic stocking was made from nonadjustable, elastodien yarn (derived from natural rubber) materials that slide over the foot, up to the knee. The stocking was applied by each subject according to the manufacturer's instructions. The stocking was pulled over the foot and up the calf to the knee region (Figure 1). This stocking type was chosen as a standard because it is a popular and commonly prescribed elastic stocking option.

The inelastic legging consisted of material with a single, stretchable neoprene strip that provided tension when stretched. The inelastic legging was applied by each subject using the BPS according to the manufacturer's instructions. The BPS method consists of three Velcro straps that intertwined with each other, were then pulled together to adjust the legging, and generated the compression (Figure 2). Indices on the neoprene strip were aligned with indices on the BPS measuring card to calibrate the legging and provide the appropriate pressures.

Skin surface pressures were taken along the medial aspect of the right leg with the subject in a seated position and the knee at a 110° angle to ensure experiment repeatability. Pressures were measured under the elastic and inelastic supports at the narrowest part of the calf, just above the ankle (approximately 5–8 cm above the

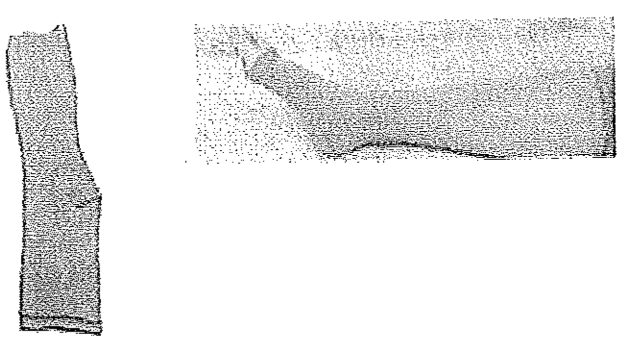

Figure 1. Elastic stockings. The elastic stocking consists of a nonadjustable, elastodien yarn that is pulled over the foot and calf in a fashion similar to sock application.

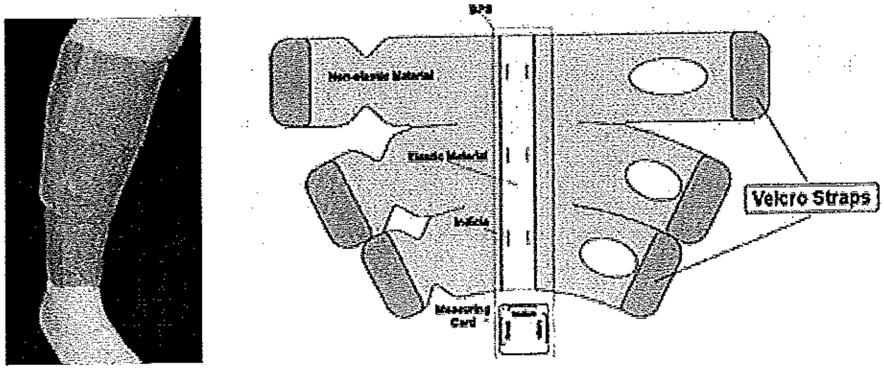

Figure 2. Inelastic legging. The inelastic legging consists of a neoprene strip down the center of the legging that is flanked by Velcro straps. The Velcro straps are drawn together, one through the other, and stretched to a distance determined by a BPS calibration card. The straps are then attached to close the legging.

malleolus) and at the top of the calf muscle, just below the knee (approximately 8 cm below the patella), using the calibrated Tekscan Industrial Sensing (I-Scan) system (Figure 3). In this study, we used the Tekscan device and validated its pressure readings against a Kikuhime air bladder. The flat nature of the Tekscan device allowed quick, easy adhesion to the leg and did not fold or bunch as air bladders can when the compression supports were applied. Additionally, the Tekscan device covered the entire stretch of the compression support and provided small ranges of pressures over target areas from which average pressures were recorded. The Kikuhime device has been previously validated as an effective pressure transducer for use under pressure garments; however, this device measures pressures only within one area.[11] The Tekscan sensor strip contained a row of pressure sensor cells along the length of the strip. The pressure readings from five continuous sensor cells were recorded at both the ankle and below-knee regions for 15 seconds, during which pressure had stabilized (see Figure 3). The average pressure reported by the five cells over the 15 seconds was recorded for the ankle and below-knee regions. The order of support application was randomized to reduce the effects of test order.

The Tekscan sensor readings were corroborated against an independent Kikuhime pressure sensor device (see Figure 3). The Kikuhime sensor was placed under the elastic stocking just above the malleolus, and pressure readings were compared with the Tekscan pressure readings at the ankle under the elastic stocking. The Tekscan sensor was present under the legging throughout the Kikuhime pressure readings. Pressure readings from the Tekscan and Kikuhime sensors reported the same means at the ankle under the elastic stocking.

To evaluate reproducibility using the inelastic legging with the BPS, subjects donned and redonned the inelastic legging 10 times. One minute elapsed between each donning and redonning. Mean skin surface pressures at

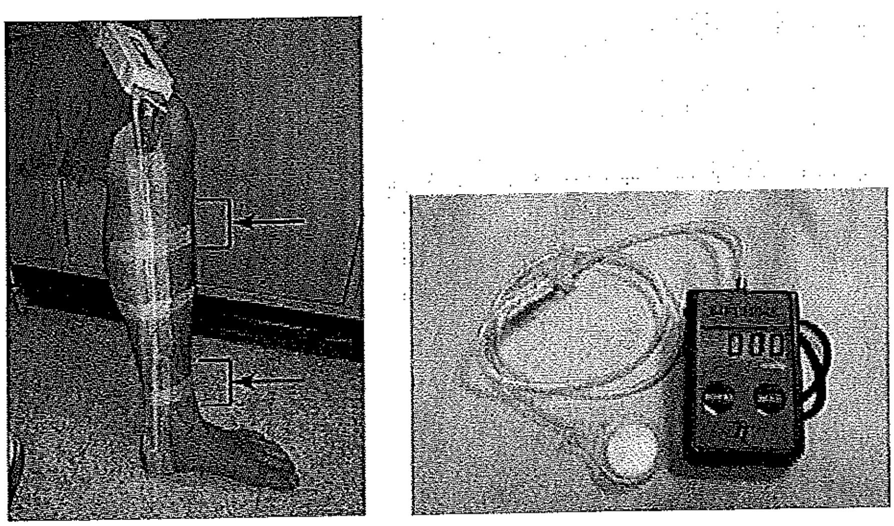

Figure 3. Application of the Tekscan sensor along the medial side of the leg and the Kikuhime pressure sensor device. The *brackets* and *arrows* indicate the ankle and knee regions from which the five Tekscan sensor cells reported the pressures (*left*). The Tekscan data acquision device can be seen connected to the top of the sensor. The Kikuhime air bladder transmits surface pressures to the data reporting device (*right*).

the ankle and below the knee were calculated for the 10 trials for each subject. The coefficient of variance (standard deviation/mean × 100) was determined.

Elastic and inelastic support surface pressures were compared using paired *t*-tests to identify differences between the mean surface pressures generated by the two types of leg supports. The ankle and below-knee regions within each support group (elastic or inelastic) were also compared using paired *t*-tests to investigate gradient compression between the ankle and below-knee regions. A p value of less than .05 was considered statistically significant for all comparisons.

Results

The elastic stocking produced significantly lower skin surface pressures than the inelastic legging in both the ankle and below-knee regions ($p < .001$) (Figure 4). Mean (± standard error) surface pressures produced at the ankle by the elastic and inelastic supports were 26 (± 2) and 50 (± 3) mm Hg, respectively. Mean surface pressures produced below the knee by the elastic and inelastic supports were 23 (± 1) and 38 (± 2) mm Hg, respectively. The tested elastic stocking produced pressures at the ankle in their designated class III, 30 to 40 mm Hg range in 23% of the subjects. The inelastic legging as tested produced pressures at the ankle in the class IV range in 67% of the subjects.

The tested elastic stocking did not produce gradient compression with pressures of 26 (± 2) and 23 (± 1) mm Hg at the ankle and below the knee, respectively (p = .141). The tested inelastic legging produced significant

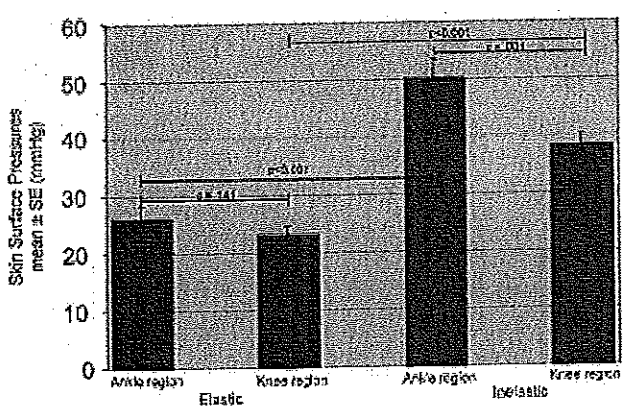

Figure 4. Elastic versus inelastic support pressures. The elastic stocking tested produces significantly lower surface pressures than the inelastic legging with the BPS ($p < .001$) and does not produce significant gradient compression ($p = .001$). The inelastic legging with the BPS produces significant gradient compression.

gradient compression between the ankle and the knee with pressures of 50 (± 3) and 38 (± 2) mm Hg, respectively ($p = .001$).

The inelastic legging with the BPS produced a mean (± standard deviation) of 47 (± 16) mm Hg at the ankle and 35 (± 11) mm Hg below the knee with 10 times of donning and redonning. The coefficients of variation for reproducibility were 17% and 19% for the ankle and below-knee regions, respectively. There were no observational differences between the venous reflux and normal subjects. Skin surface pressures produced in the reflux and normal groups were within the same range.

Discussion

In this study, we hypothesized that both tested brands of elastic and inelastic supports effectively generate class III to class IV skin surface pressures as well as gradient compression. Our results document that the tested elastic stocking generates pressures that are below their designated class III, 30 to 40 mm Hg range. Meanwhile, the tested inelastic legging produces pressures that are consistent with a class IV designation. Also, only the inelastic legging tested produces gradient compression.

Compression supports are fundamental as a common, nonsurgical treatment for CVI and are known to treat an array of CVI symptoms, including edema, varicose veins, and ulcers.[14,15] Moreover, Andreozzi and colleagues have documented that compression supports significantly improve the overall quality of life for those suffering from CVI.[16] Additionally, compression supports are used to prevent and treat DVT.[17,18] Despite the known benefits of compression supports, the surface pressures that are produced in vivo by different types of compression supports are largely unknown and possibly significantly different from the claims of their manufacturers. Stemmer argued that support prescription methods should be as precise as medication prescription processes.[19] Such accuracy in prescription requires that the correct designated pressures be produced by a given compression support.

The elastic stocking in this study is designed to produce skin surface pressures between 30 and 40 mm Hg, but our study indicates that this stocking produces pressures of only 26 ± 2 and 23 ± 1 mm Hg for the ankle and below-knee regions, respectively. This range of pressures does not meet the class III, 30 to 40 mm Hg designated range. Liu and colleagues agreed with this assertion and also found that measured ankle pressures produced by elastic stockings were consistently lower than their manufacturers' claims.[20] Unfortunately, the pressure transducers in their study were not calibrated before use, adding some uncertainty about the accuracy of their results.[13] The benefits of the elastic stocking may be compromised if the stocking does not produce the 30 to 40 mm Hg compression as claimed.

The BPS-ensured inelastic legging produces pressures with means of 50 ± 3 and 38 ± 2 mm Hg at the ankle and below the knee, respectively. These pressures are consistent with class IV designations of greater than 40 mm Hg. Owing to the adjustability of the inelastic legging in this study, the legging can provide lower surface pressures if needed. Furthermore, our study indicates that redonning the inelastic legging slightly decreases the high pressures produced in the first application from a mean of 50 mm Hg to 47 mm Hg at the ankle. The lower average pressure could be a result of repeated legging donning or could be due to the BPS allowing each subject to adjust the legging to a slightly different tension each time. The average pressures provide evidence that the inelastic legging with BPS can generate pressures that are considered most beneficial to patients with CVI.[10]

Importantly, our study indicates that of the two supports tested, only the inelastic legging produces ankle to below-knee gradient compression. Gradient compression increases venous flow more in comparison with a uniform pressure application.[8] Without gradient compression, the elastic stocking may not optimize the benefits of compression.

One limitation of our study is that only one type of both elastic stocking and inelastic legging was tested. Furthermore, skin surface pressures were recorded only while subjects were in a static, sitting posture. Future studies may investigate other elastic stocking and inelastic legging brands as well as different postures and during ambulation. However, most compression support manufacturers do not measure skin surface pressures produced by their compression supports on ambulating subjects; instead, manufacturers commonly test their supports on wooden leg models. Partsch and colleagues commented that wooden leg models do not reflect the common irregularities that are present in human legs.[21] These anatomic differences between wooden and human leg models could affect the skin surface pressures that are measured in vitro versus those that are measured in vivo. This might provide an explanation for the disagreement between the claimed and actual pressures as recorded in our study. Additionally, the sitting posture used in this study could also account for discrepancies as the standing position is more readily used when measuring skin surface pressures. The sitting position was implemented in this study to ensure repeatability and investigate only the initial skin surface pressures produced on support application.

In this study, we found that the elastic stocking does not produce the designated class III range of pressures or the recommended gradient compression. The inelastic legging that we tested produces gradient compression and pressures that are consistent with the class IV range of pressures. The inelastic legging in this study may have a therapeutic advantage over the elastic stocking because the inelastic legging is adjustable and thus can provide higher or lower levels of pressure accordingly. Importantly, the inelastic legging with the BPS also provides gradient compression, which is thought to be important for improved venous return[8] and DVT prevention.[22]

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