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Comparison of 4-Layer Bandages and an Adaptive Compression Therapy Device on Intended Pressure Delivery

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■ ABSTRACT

PURPOSE: To characterize and compare interface pressure profiles of an adaptive compression therapy (ACT) device and a traditional 4-layer bandage (4LB) system.

DESIGN: A prospective, randomized, open-label, 1-arm, active controlled study.

SUBJECTS: The sample comprised 12 healthy volunteers.

METHODS: Subjects wore both devices for 8 hours on 3 consecutive days. Treatments were randomized to left and right legs. One clinician performed all applications and was experienced in the clinical use of both devices. Pressures were measured in seated and standing positions at the lower, mid, and upper calf immediately post application and after 1, 4, and 8 hours.

RESULTS: Pressures achieved with the ACT were closer to targeted 40/30/20 mmHg graduated pressure values and were significantly less than the 4LB for corresponding sites/postures ($P < .001$). In the seated position, initial interface pressures (mean ± SD) for the ACT were 36.9 ± 4.9, 30.5 ± 4.5, and 21.0 ± 3.6 mmHg. Corresponding interface pressures for the 4LB were 52.5 ± 8.4, 57.5 ± 10.3, and 53.5 ± 12.9 mmHg. In the standing position, initial interface pressures for the ACT were 40.7 ± 4.8, 35.6 ± 4.5, and 21.1 ± 4.6 compared to 54.6 ± 12.5, 64.4 ± 10.9, and 53.7 ± 14.3 for the 4LB. At 1, 4, and 8 hours after application, the 4LB showed a significant progressive decline in interface pressure in both seated and standing positions ($P < .001$). Conversely, the ACT did not decrease over time and there was a slight but significant increase for lower and mid-calf sites in the seated position ($P < .001$).

CONCLUSIONS: The ACT device provided more consistent interface pressures than the 4LB and the pressures achieved were consistent with contemporary venous ulcer therapy standards.

KEY WORDS: Adaptive compression therapy, Chronic venous insufficiency, 4-layer bandage, Pneumatic compression, Venous leg ulcers

■ Introduction

Compression bandaging to enhance venous return is a mainstay treatment for severe stages of chronic venous insufficiency (CVI) and venous leg ulcers (VLUs).[1-5] However, pressure loss starts immediately after bandage application that limits the efficacy of conventional compression techniques. This pressure loss is more pronounced with stiff, nonelastic material than with more elastic compression hosiery.[6,7] The friction that occurs between the elastic components of "4-layer bandages" (4LBs) is adequately high that this form of compression is categorized as a "stiff bandage"[8] and pressure is lost over time. The main reason for this loss of pressure is reduction of the leg volume which occurs in individuals with edema and healthy persons.[6]

A new adaptive pneumatic compression device was designed to deliver both sustained compression and on-demand intermittent compression.[9] The dual-mode functions are controlled by a microprocessor that inflates 4 pneumatic pressure chambers to achieve target pressures within each sequential chamber in the foot, ankle, and calf. Integrated sensors provide feedback to the control unit that automatically measures and adjusts the interface pressures to maintain the preset target pressures within each chamber. This device is relatively easy to use and can

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be applied and removed by the patient for normal bathing and sleep encourages adherence to therapy.[9]

A 12-week, prospective, randomized controlled study was completed that compared the adaptive pneumatic device to a 4LB compression system in 90 patients with venous leg ulcers. No significant differences in venous ulcer healing were found, but patients treated with the adaptive pneumatic device experienced statistically greater improvements in health-related quality of life compared to patients treated with the 4LB system.[9] The pneumatic device also provided better exudate management, skin protection, removal ease, and improved ability allowing patients to bathe.[6] The purpose of this study was to compare interface pressure profiles of the adaptive device and a traditional 4LB system and compare the ability of each compressive system to sustain graduated compression after application and over time.

■ Methods

A prospective, randomized, open-label, 1-arm, active controlled study was completed in healthy volunteers. We compared the amount, variability, and consistency of interface pressure over time delivered by 2 methods of lower limb compression: an adaptive compression therapy (ACT) device (ACTitouch, Tactile Medical, Minneapolis, Minnesota) and a 4LB system (Profore Multi-Layer Bandaging System, Smith & Nephew Medical Wound Management, Hull, the United Kingdom).

The target population was healthy volunteers older than 18 years who were willing and able to wear both compression devices under study and follow the clinical study plan. Study inclusion required an ankle brachial pressure index of 0.9 or more and a chronic venous disorders CEAP (clinical-etiology-anatomy-pathophysiology) classification of C_0-C_2.[10] Subjects were excluded if they had a history of skin sensitivity to any of the components of either device, participated in any clinical study within the previous 3 months, had a deep vein thrombosis within the past 3 months, or had leg circumferences that exceeded the fit range for either device.

A sample size of 12 subjects (24 legs) was chosen; no formal power calculation was performed. Subjects wore both test devices simultaneously, and treatments were randomized for application between the left and right legs according to a predetermined, computer-generated, randomization schedule. No attempt was made to blind either the participants or study investigators as to the applied treatment, as each compressive modality had a distinct appearance and method of application.

Study procedures conformed to the ethical guidelines of the Declaration of Helsinki as amended, October 2008,[11] and all procedures were conducted in compliance with the Good Clinical Practice guidelines and ISO 14155:2003 Clinical Investigation of Medical Devices for Human Subjects, parts 1 and 2.[12,13] An ethics review was conducted by the Freiburg Ethics Committee International, Freiburg, Germany. All participants provided written informed consent before study enrolment.

Interventions

The ACT device has been previously described in the literature.[9] Briefly, it combines sustained and intermittent pneumatic compression (IPC) into 1 device that can be worn discretely beneath clothing and with regular shoes. The device allows for normal mobility during the sustained compression mode and can be applied and removed by the user for normal bathing and sleep. The device consists of a lightweight, wraparound sleeve with 4 chambers and an electronic control unit. Each chamber has a separate bladder that allows independent control of interface pressures to the upper, mid, and lower calf as well as the foot and ankle. For this study, the ACT device was worn in the sustained pneumatic compression mode only (no IPC) and programmed to deliver 40 mmHg at the foot and ankle, 30 mmHg at the mid-calf, and 20 mmHg below the knee.

The 4LB was applied according to manufacturer's instructions as described in the package insert. The 4LB was applied by the same health care professional who was trained and experienced in bandaging. The 4LB is designed to provide a profile of 40 mmHg at the ankle graduating to 17 mmHg at the upper calf when correctly applied.[14] A new 4LB was applied on each day of the study. Both the ACT and the 4LB were applied with the subjects in the seated position.

A PicoPress Compression Measurement System (CMP, Microlab Electronica, Ponte S. Nicolò, Italy) was used to continuously measure interface pressures exerted by compression in both static and IPC mode; the CMP was used to assess interface pressures for both compression devices.[15] A 0.22-mm probe (5 cm in diameter) that was inflated with 2 cc of air by means of an electronically controlled syringe integrated in the system was used for measurements. Calibration tests have shown a high degree of reliability of the system in comparison with other devices.[16] Sensors were positioned at the same 3 locations under both compression devices, which included site 1: 6 to 10 cm proximal to the inner malleolus (lower calf); site 2: 14 to 20 cm proximal to the inner malleolus (middle calf); and site 3: 21 to 31 cm proximal to the inner malleolus (upper calf) (Figure 1). The sensors were centrally located under each of the upper 3 chambers of the ACT device, with corresponding positions on the 4LB treated leg. The locations of sensor placement were marked on each subject to enable reproducibility for the duration of the 3-day study. Interface pressure measurements were taken immediately following device application and after 1, 4, and 8 hours with the probes attached to their positions.

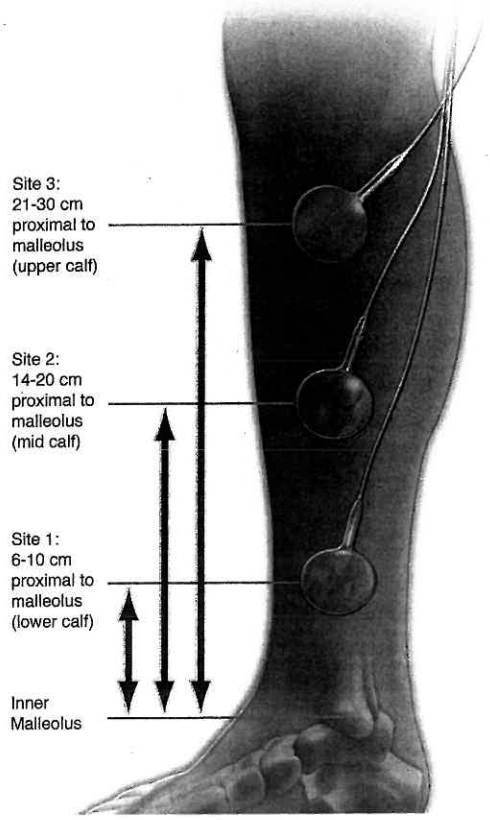

FIGURE 1. Approximate sensor placement for each of the 3 measurement sites on the medial aspect of the leg.

Device application was randomized to the left and right legs of subjects during the first day of treatment. Subjects wore both devices on opposite legs for sequential periods of 8 hours each for 3 consecutive days. Both devices and the measuring probes were applied by the same experienced clinician on each day of the study.

Outcome Measures

Demographic and pertinent clinical data were collected at the start of the study; they included gender, age, ankle brachial pressure index, and CEAP classification. The primary study outcome was skin-compression device interface pressures taken at 3 anatomical locations on 3 consecutive days of study in the sitting and standing positions.

Data Analysis

Pressure values obtained for each of the 3 days (n = 36) were included in the computation of the average pressure and its standard deviation for each site (lower calf = site 1, mid-calf = site 2, and upper calf = site 3) and for each posture (sitting and standing). To test for differences in pressures among the 4 measurement times (0 hour/immediate, 1 hour, 4 hours, and 8 hours), a general linear model for repeated measures was used. In these evaluations, separate analyses were used for each site and each postural position. A similar general linear model analysis was used to test for day-to-day variations in measurements for each site and measurement time. Because a single person wrapped the 4LB for all subjects, the consistency of that application was assessed by determining the coefficient of variation of the immediately measured subbandage achieved by that application in the seated position for each of the 3 days of its application. The coefficient of variation for the ACT device was similarly determined.

■ Results

Mean pressures achieved with the ACT device were less than those achieved with the 4LB for corresponding sites and postures at all measurement times ($P < .001$; Table 1). Nevertheless, initial pressures for the ACT device, measured immediately after application, were closer to targeted values than those measured for the 4LB system (Table 1). Targeted values for sites 1, 2, and 3 (lower, mid, and upper calf) were 40, 30, and 20 mmHg, respectively, with subjects seated. For the ACT device, measured interface pressures were (mean ± SD) 36.9 ± 4.9, 30.5 ± 4.5, and 21.0 ± 3.6 mmHg, respectively. Corresponding interface pressures measured for the 4LB were significantly higher (52.5 ± 8.4, 57.5 ± 10.3, and 53.5 ± 12.9 mmHg for sites 1, 2, and 3, respectively).

Figure 2 shows the pressure under the ACT device continuously registered for 1 hour in the sitting position of 1 healthy individual as an example. Sequential changes in pressures for the ACT and the 4LB for the resting seated position are shown in Figure 3. The 4LB system showed a significant decline in pressure with time ($P < .001$) for all sites (upper 3 curves), but the ACT device was associated with no decline, and there was a slight immediate pressure increase at sites 2 and 3 ($P < .001$). At site 2 (lower calf), the average pressure under the 4LB system decreased by 9.1 mmHg (−16%), while it increased under ACT from the initial application and 8 hours later by 4.9 mmHg (+16%).

Sequential changes in pressures for the ACT and the 4LB for the standing position are shown in Figure 4. As for the resting position, 4LB showed a significant pressure drop ($P < .001$) over all positions (upper 3 curves) while pressure values stayed fairly constant under ACT. The maximum decrease under 4LB occurred at site 2 with an average decrease of 12.5 mmHg (−19%). At the corresponding site, interface pressures measured under the ACT changed by a mean of 0.9 mmHg (−2.5%).

■ Discussion

Combined static and dynamic compression are important components in the treatment of venous leg ulcers. The static component is most often achieved by compression bandaging; this intervention is associated with beneficial effects on venous,[17] arterial,[1-3,20] and microvascular[21,22] hemodynamics and periwound edema.[23] It is a widely

TABLE 1.

Mean Interface Pressure (mmHg) Measured in the Seated and Standing Positions for the ACT Device and the 4LB at 0, 4, and 8 Hours After Application[a]

	Site 1 (Lower Calf), N = 36	Site 2 (Mid Calf), N = 36	Site 3 (Upper Calf), N = 36	*P*
Sit0 ACT	36.9 ± 4.9	30.5 ± 4.5	21.0 ± 3.6	.0001
Sit0 4LB	52.5 ± 8.4	57.2 ± 10.3	53.5 ± 12.9	
Stand0 ACT	40.7 ± 4.8	35.6 ± 4.5	21.1 ± 4.6	.0001
Stand0 4LB	54.6 ± 12.5	64.4 ± 10.9	53.7 ± 14.3	
Sit1 ACT	40.0 ± 5.2	32.7 ± 4.5	21.7 ± 6.6	.0001
Sit1 4LB	50.4 ± 9.0	52.6 ± 8.8	47.1 ± 10.3	
Stand1 ACT	40.5 ± 6.2	33.0 ± 5.6	19.7 ± 6.8	.0001
Stand1 4LB	52.4 ± 8.5	56.1 ± 9.3	48.1 ± 12.3	
Sit4 ACT	40.5 ± 7.4	34.9 ± 6.1	19.9 ± 6.8	.0001
Sit4 4LB	48.9 ± 8.9	49.8 ± 8.1	45.7 ± 10.8	
Stand4 ACT	41.4 ± 7.1	35.2 ± 6.0	18.7 ± 7.4	.0001
Stand4 4LB	49.9 ± 8.1	53.6 ± 9.1	45.6 ± 13.0	
Sit8 ACT	41.7 ± 7.8	35.4 ± 5.9	19.5 ± 6.7	.0001
Sit8 4LB	47.3 ± 7.5	47.9 ± 7.4	45.1 ± 10.6	
Stand8 ACT	41.6 ± 7.7	34.7 ± 6.0	17.1 ± 6.6	.0001
Stand8 4LB	48.4 ± 7.8	51.9 ± 9.2	44.3 ± 13.5	

Abbreviations: 8, measured 8 hours after application; 4, measured 4 hours after application; 1, measured at 1 hour after application; Sit, seated position; Stand, standing position; 0, measured immediately after application.

[a]Data are shown as mean values ± standard deviation.

accepted concept that in addition to the static pressure requirement, patients with chronic venous insufficiency benefit when treatment includes a dynamic component, often referred to as working pressure. Research has shown that there is a strong correlation between working and standing pressures measured at B1, and that pressure peaks during walking were only slightly higher than the standing pressure.[23] If a compression bandage or stocking is applied, this dynamic pressure is achieved by contraction of the underlying leg muscles working against the encircled compression bandage or stocking. This action produces a dynamic or time varying pressure pattern that reduces ambulatory venous hypertension[24] and is postulated to enhance the healing process by producing more effective

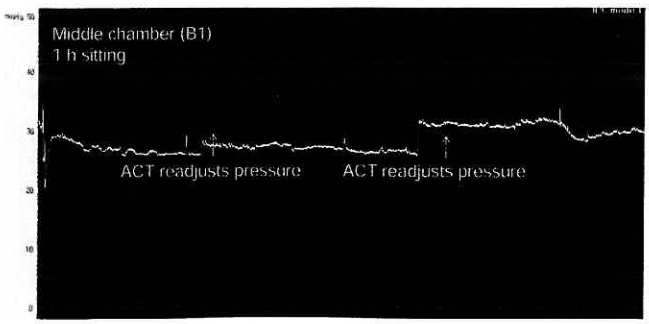

FIGURE 2. Pressure under the ACT device for 1 hour in the seated position.

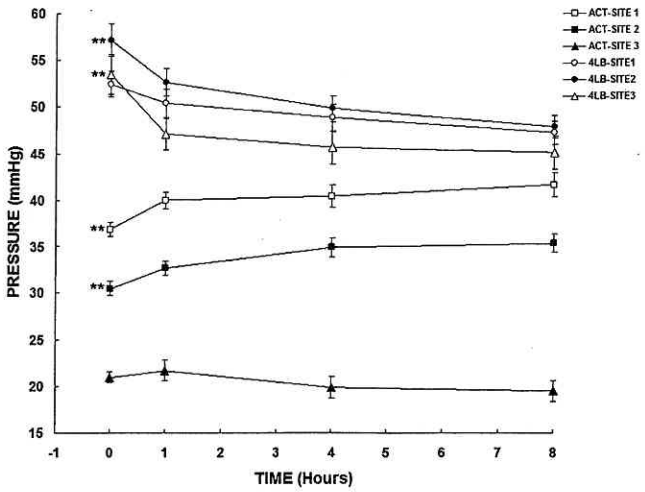

FIGURE 3. Temporal changes in interface pressure while seated. Data points are the average values for interface pressure determined at each site with subjects sitting. The double asterisk (**) indicates that the immediate pressure was significantly different from that achieved at 1 hour later.

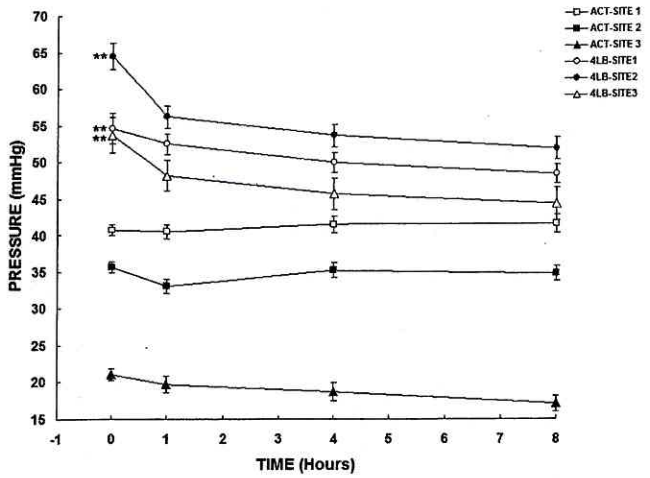

FIGURE 4. Temporal changes in interface pressure while standing. Data points are the average values for interface pressure determined at each site with subjects standing. The double asterisk (**) indicates that the immediate pressure after 4LB application was significantly different from that achieved 1 hour later. For the 4LB, pressures significantly declined over time from the immediate value to the value measured after 8 hours of bandage wearing ($P < .001$). For ACT, interface pressure declined only at site 3 ($P < .001$).

venous return while lowering interstitial, lymphatic, and periwound fluid pressures. If a patient's activity levels are insufficient or muscle strength too weak to facilitate an adequate calf muscle pump, then the dynamic pressures typically produced by walking are unlikely to be achieved with the use of compression bandaging alone. The active and dynamic treatment provided by IPC simulates calf muscle pump action, enhancing blood return, whether the individual is ambulating or not. However, despite the reported utility of IPC for venous-related conditions,[25-28] most currently available compressive devices are not designed to provide both stable measured static and dynamic pressures. Data from this study suggest that the ACT device is able to provide these pressures. Thus, it was important to determine if this device could produce and sustain static pressure levels and gradients known to be vital for effective treatment of CVI and VLU.

Study findings show that the ACT device achieved leg interface pressures immediately after its application that matched the intended target values of 40, 30, and 20 mmHg from the lower calf to upper calf, respectively. Moreover, these pressures were sustained in both the seated and standing positions without a significant decline over 8 hours of wear per day and did not significantly vary from day to day upon repeated applications. In contrast, the immediate pressures achieved with the application of the 4LB were higher than the targeted values and did not produce a pressure gradient that decreased from ankle to calf. This occurred despite the fact that the 4LB was applied by a person with an extensive amount of bandage application experience. The immediate pressures achieved with the 4LB declined considerably with 8 hours of wear, in contrast to the ACT device, which sustained a more constant applied pressure. Continuous pressure measurements under 4LB for 1 week has been shown to result in an average pressure loss of 30%.[29] These findings suggest that the efficiency of the 4LB may decrease over time. We renewed the bandage daily to assure that data were collected under experimental conditions that were ideally comparable to those associated with ACT use. However, 4LBs are not typically applied daily in clinical practice, and the discordance in applied pressures with 4LB is likely to be greater. Repeated daily application of a 4LB (in contrast to weekly application) would also be extremely expensive, due to both the cost of the disposable material and working time of specialized staff. Findings from this study also suggest that the ACT, which can be applied by the patients themselves,[9] maintains a pressure constant at targeted levels, even were it left on for an extended period of time, since any leg volume change will automatically be compensated by the calibrated mechanism.

Limitations

We evaluated the applied and measured pressures in subjects with healthy, nonedematous legs. It is not known whether differences may occur when applied in patients with chronic venous insufficiency and venous leg ulcers. Second, the efficacy of delivery of only the sustained pressure component of the ACT device was evaluated. This variable was deliberately selected as the main outcome measure in our study. Future studies are needed to consider evaluation of the IPC mode's ability to attain the dynamic target pressures and to measure their impact on healing of venous leg ulcers.

■ Conclusion

An ACT device delivered a more consistent and predictable sustained interface pressure compared to a 4LB control. The compressive pressure values were consistent with contemporary venous ulcer therapy standards. In contrast, the 4LB system demonstrated significant pressure loss despite being applied daily by specialized staff. The self-applied ACT maintained the applied interface pressure over the whole day. The capability to attain and maintain specific targeted sustained pressures over time is an essential adjunct to the well-understood physiological benefits of IPC for treatment of venous leg ulcers.

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