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EVALUATION OF A NOVEL CLASS 2 GRADUATED ELASTIC COMPRESSION GARMENT COMPARED TO A GOLD STANDARD COMPRESSION GARMENT

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ABSTRACT

Background: Graduated elastic compression stockings are a frequently prescribed therapy for cardiovascular conditions with established benefit. However patient compliance remains low owing to significant difficulty donning the device, discomfort and poor fit. Based on end-user feedback, a novel compression device (CompressRite CR) to facilitate one handed application with minimal use of upper extremity strength was compared to Jobst stocking (Control).

Methods: An open, prospective, single-center study was done in in volunteers and in-patients. Study subject's lower extremities were clinically classified by a blinded vascular specialist. Pressure readings were obtained using a pressure sensor in standing position every 5 minutes during two 30-minute sessions using CR and Control.

Results: Ninety study subjects (82 healthy volunteers, 8 in-patients, 34% males, 66% females, 70% White, 22% African American, %7 Asian, 1% Hispanic) completed the study. Clinical vascular classification revealed 31% C0, 18% C3, 16% C1, 7% C2, 4% C4 and 22% unclassified. CR performed similar to Control in terms of pressure delivery. Calf circumference was not impacted by pressure sessions in both groups. Application time of CR was higher but removal times were similar. Qualitative feedback collected showed that CR was superior to conventional garment.

Conclusion: CR appeared to be equally effective to Control graduated elastic stockings with a longer application time on first attempt but consistently higher scores for satisfaction. This may represent an attractive alternative with higher patient compliance rates.

Keywords: Venous insufficiency, Varicose veins, Compression therapy, Novel graduated elastic compression garment.

INTRODUCTION

It has been reported that the prevalence of Chronic Venous Insufficiency (CVI) ranges between 25–40% and 10–20% in women and men, respectively. [1] Varicose vein related health problems affect over 25 million adults in the United States alone. [2] The pathophysiologic basis of CVI is venous hypertension in the lower extremities due to ineffective calf muscle pumping or loss of vascular tone or integrity. [3] Compression garments are widely used for the treatment of such conditions since the application of external pressure to the calf muscle raises the interstitial pressure, thus resulting in improved venous return and reduction in the venous hypertension. Previous studies have suggested that healing rates with compression therapy vary from 40% to 95 % and with sub-bandage pressure values from 35 mmHg to 45 mm Hg provide the best results. [4] The therapeutic potential of compression therapy is well established, yet the noncompliance rates are 30%–65%. Several limitations contribute to non-compliance: significant upper body strength is required to stretch the garment over lower extremities; garments are uncomfortable, itchy, and warm; entire limbs are covered by garments, which preclude targeted pressure application; garments can only exert one level of pressure; under-the-clothing garments can't be applied, adjusted, or removed without removing clothing; proprietary materials make garments expensive. [5] Medical compression devices come in a variety of forms. The market for compression devices was valued at $2.9 billion in 2016, and is expected to reach $3.9 billion by 2023. [6]

In this paper we aimed to compare a novel compression garment (CompressRite, CR), which was designed to overcome the current patient centric limitations with standard class 2 graduated elastic Jobst medical compression stockings (Jobst, Control).

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METHODS

To gain insight on the use of compression stockings, physicians at UVA Health Systems were given a survey evaluating their perception of compression stockings and history of prescription. Survey responses from physicians' practice between 4 to 41 years were aggregated. Most notably, a physician practicing for 41 years no longer prescribes compression stockings citing a 100% non-compliance rate as his reasoning. Additionally, 100% of physicians listed the calf as the most important segment of leg compression.

1.1 Novel medical device design specifications

To increase user compliance, we designed a compression garment covering calf segment with a clasp that enables one-handed, low force, easy application. The current device features two main components: a clasp and an adjustable strap. The clasp was designed in a C-shape, as it corresponds to the natural curvature of the leg. The CR clasp was printed entirely in NinjaFlex 3D printing filament. The semi-flex properties of NinjaFlex filament made it an ideal choice. The slight flexibility increases comfort by allowing the clasp to yield. The clasp is backed with a medical grade felt to prevent direct contact of dense material with the skin. Compared to traditional garments, the pulley-like clasp allows users to roughly double their force (2X) while using only one hand (Fig 1C). Rare-earth magnets in the interlocking faces of the clasp further simplify the procedure, allow for clasp to auto align and prevent slippage once in position (Fig 1D). Magnets provide added security when the device is worn for longer periods of time or by patients with larger limbs. Magnetic field strengths of 8 -10 Gauss directly over implantable cardiac devices can cause interference. However, fields of less than 10 Gauss are safe as field strength varies inversely with distance from the device site. The magnets used had a field strength well below the safety threshold, so no interference was expected. The clasp design allows cuff size adjustment, which better accommodates different users. Additionally, the clasp is lightweight, making it more comfortable to wear and easy to clean between uses. Lines printed on the fabric show users how far to stretch the fabric to produce a desired pressure (Fig. 1C). The circumferential tension (T) in the stocking (radius r, width w) relates to the compression pressure (p) by the relation (1).

$$T = p \cdot r \cdot w \quad (1)$$

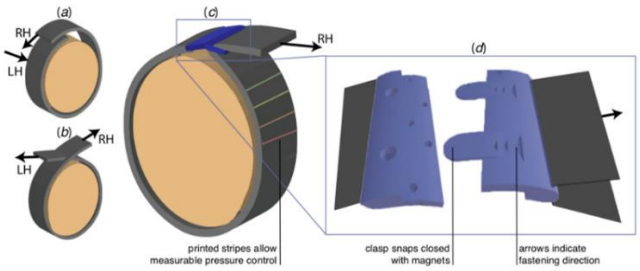

FIGURE 1: 3D MODEL OF COMPRESS RITE. A. B: PRIOR GARMENTS REQUIRE TWO HANDS (LH, RH) TO FASTEN. C: IN CONTRAST NOVEL DESIGN USES C-SHAPE CLASP TO ALLOW ONE-HANDED TENSIONING. D: AN INSERT OF THE CLASP SHOWS HOW MAGNETS ENSURE A SECURE FIT

The free ends of the straps can be adjusted to provide user-defined changes in pressure from 10 mmHg to 60 mmHg. The proportion of stretch is directly proportional to the application of pressure. Strap ends are attached to a felt band on the device itself, preventing the straps from hampering use. CR garment was made in universe size which allows to adjust to three sizes: Small (30 cm), Medium (38 cm), and Large (45 cm). Using the 2008 National Health Statistics Report, it was designed for the 10th, 50th, and 90th percentiles respectively. [7] Creating three sizes enables a better fit and enhances functionality by eliminating excess material. The small, medium, and large designations correspond to Jobst sizing, keeping in tradition with market convention. To encourage compliance, the final compression device was made from biocompatible materials, low-tech, user-friendly, and accommodated a dynamic range of sizes and pressures.

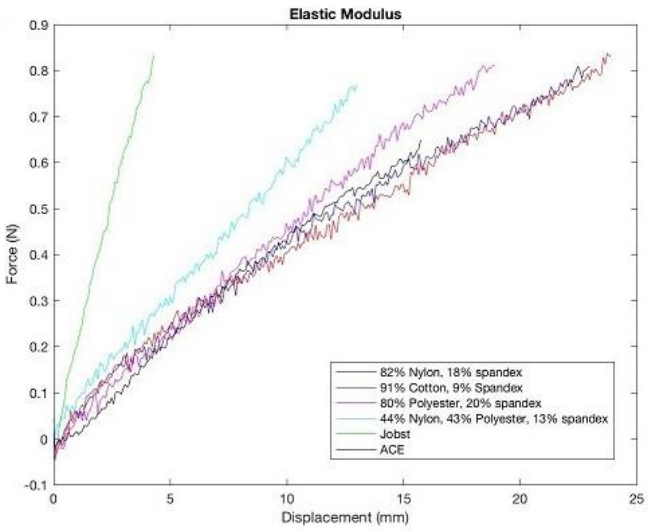

FIGURE 2: ELASTIC MODULUS: MEASUREMENT OF FABRIC RESISTANCE TO BEING DEFORMED ELASTICALLY. 44% NYLON, 43% POLYESTER, 20% SPANDEX FABRIC SHOWED CLOSEST TO JOBST MEDICAL STOCKING ELASTIC PROPERTIES

Fabric	Elastic modulus
44% Nylon, 43% Polyester, 13% Spandex	56.6
80% Polyester, 20% Spandex	44.3
82% Nylon, 18% Spandex	33.7
91% Cotton, 9% Spandex	32.6
Jobst Medical Stocking	200.0
ACE Bandage	42.5

TABLE 1: THE ELASTIC MODULUS FOR TESTED FABRICS WAS DETERMINED AND COMAPRED TO JOBST STOCKING. FABRIC MADE OF 44% NYLON, 43% POLYESTER, 20% SPANDEX WAS HAS ELASTIC MODULUS 4X LESS, WHICH MEANS LESS FORCE IS REQUIRED TO STRETCH THE FABRIC TO THE SAME LENGTH

Compression stockings are made out of elastomeric materials, which provide the necessary stretch and compressive properties. Textile properties such as fabric roughness, thermoregulation and dye, may contribute to skin irritation. [8] Lightweight, breathable elastic fabric is a key part of novel garment design. We established testing procedures for comparing fabric options against the state of the art (Jobst, Control). We tested 5 fabrics and have identified fabric 44% nylon, 43% polyester, 20% spandex performing similar to control fabric. Automated tensile tests revealed an elastic modulus which was 30% less than the control fabric (Fig.2). A greater the elastic modulus, indicates more force is required to stretch the fabric. The elastic modulus of the Jobst stocking was 200 MPa, while the modulus of the ACE bandage was 42.5 MPa (Tab. 1). Using a material with a lower elastic modulus decreases the force required to pull and secure the straps. This is especially important when designing for a device for an older population where dexterity and application of force would be a limiting issue.

1.2 Study Protocol

After receiving institutional review board approval and obtaining informed consent from study participants, a group of ninety people who met inclusion criteria were eligible for the study. Baseline demographic information and medical history pertinent to CVI was systematically collected. Photographs with no identifying characteristics of the lower extremities were taken for clinical classification by a vascular specialist blinded to subject medical history. During each session, the sub-bandage pressure was measured on the medial aspect of the lower leg at the transition of the gastrocnemius muscle into the Achilles tendon (B1 measuring point) in the standing position using a pressure transducer (Kikuhime small probe; MediTrade, Soro, Denmark). When standing the body weight was distributed between both legs. Pressure transducer was calibrated prior each measurement. Over 30-minute duration of session applied pressure was measured every 5 minutes with the total number of 7 readings. Minimal and maximal calf circumferences were measured in the standing position prior and after compression (Fig.2). Computer generated randomization scheme was used to assign study subject's extremity to wear CR or Control compression garment. Each study subject attended two sessions. By the completion of the study each study subject has experienced both garments. During the Session 1 study subject was instructed and show how to wear both devices. In Session 2 study subject applied and remove garments independently, completion time of both procedures was recorded. In Control group, subjects wore a ready-made medical compression stocking Jobst that exerts graduated pressure of 20 – 30 mmHg, thus corresponds to class 2 compression stockings. It is open toed and has no heel. Stocking size was determined for each subject according to the measured circumferences of the calf. In CR group, subjects wore a novel compression garment, that delivers pressure in the range between 10 – 60 mmHg, CR garment was sized and adjusted to pressure of 20 – 30 mmHg. Overall quantitative feedback was documented.

A practical implication of CR garment usage when worn under and over clothes was evaluated in 2 volunteers. Differences between the pressure applied by the device when worn directly on the skin and over clothes was compared.

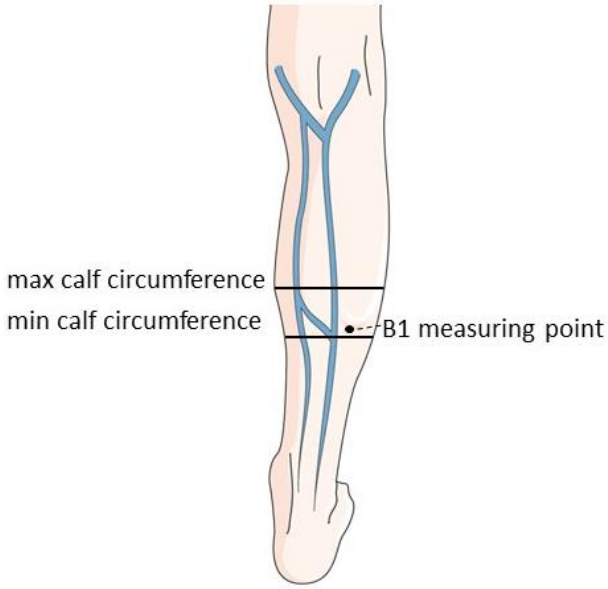

FIGURE 3: ILLUSTRATION OF MAXIMAL AND MINIMAL CALF CIRCUMFERENCES AND B1 MEASURING POINT

1.3 Outcomes

The aim of this study was to determine the efficacy of a novel CR compression garment in comparison to standard of care Jobst medical stockings. The main study outcomes were to measure mean pressure applied to the calf, minimum and maximum calf circumferences prior and post pressure application, garments application and removal timing and users' quantitative feedback.

1.4 Statistical Analyses

With a power of 80% and a confidence level of 95%, assuming the difference in applied is 20% between CR and Control groups, a total of 63 subjects were needed for this study. An independent samples t-test was used to compare means between the two groups.

RESULTS

This investigation was approved by the University of Virginia Institutional Review Board and was designed as an open, prospective, single-center study.

Healthy volunteers and patients aged at least 18 years were screened for inclusion in the trial. Overall, 90 study subjects 82 healthy volunteers, 8 patients completed the study. Study population demographics were: 34% males, 66% females, 70% White, 22% African American, %7 Asian, 1% Hispanic, mean age 43 years.

Clinical classifications based on lower extremities photographs were as follows:
C0 – 28 study subjects, corresponded to 31.11 %.
C1 – 14 study subjects, corresponded to 15.55 %.
C2 – 6 study subjects, corresponded to 6.66 %.
C3 – 13 study subjects, corresponded to 17.77%.
C4 – 4 study subjects, corresponded to 4.44%.
22 study subjects or 24.44% were not classified (Fig.3).

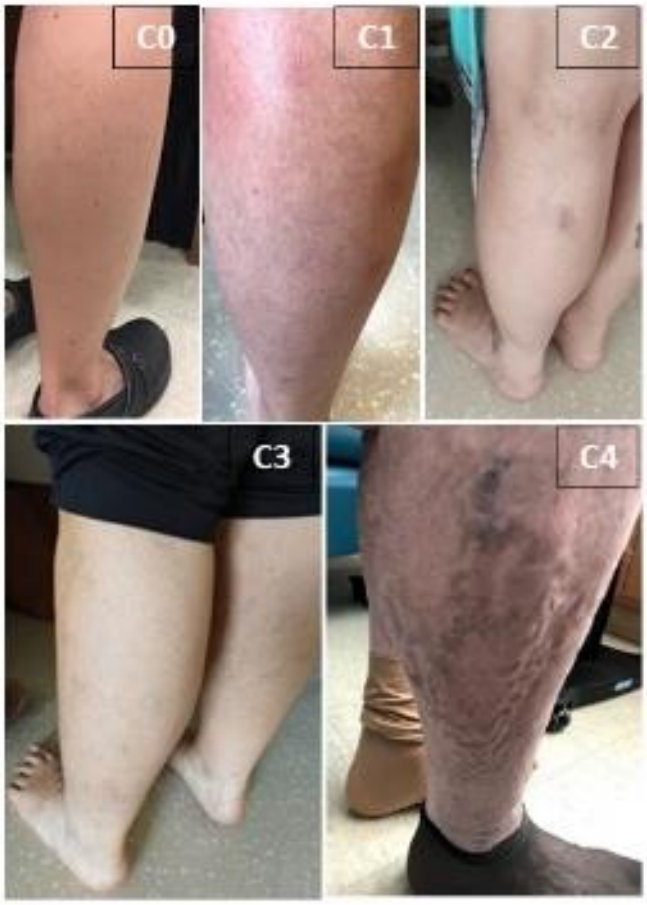

FIGURE 4: REPRESENTATIVE PHOROGRAHPS OF CLINICAL CLASSIFICATIONS IN STUDY SUBJECT POPULATION

Total population (N=90)

Parameter, Unit	CR	Control	p-value
Session 1: Mean Pressure [mmHg]	23.34 ± 7.56	22.89 ± 6.88	0.6768
Session 2: Mean Pressure [mmHg]	22.21 ± 6.30	21.76 ± 5.25	0.6063
Minimum Calf Circumference Prior Compression [cm]	22.68 ± 3.17	22.9 ± 2.28	0.6041
Maximum Calf Circumference Prior Compression [cm]	38.61 ± 3.75	38.45 ± 3.74	0.7725
Minimum Calf Circumference Post Compression [cm]	22.89 ± 2.28	22.85 ± 2.22	0.7725
Maximum Calf Circumference Post Compression [cm]	38.42 ± 3.78	38.30 ± 3.53	0.8319
Application time [s]	37.54 ± 18.9	17.51 ± 10.87	0.0001
Removal time [s]	11.92 ± 7.58	10.72 ± 7.10	0.3421

TABLE 2: TOTAL STUDY SUBJECT POPULATION RESULTS (N=90).

Patient population (N=8)

Parameter, Unit	CR	Control	p-value
Session 1: Mean Pressure [mmHg]	26.85 ± 8.93	22.42 ± 6.45	0.2748
Session 2: Mean Pressure [mmHg]	24.23 ± 5.75	18.12 ± 2.33	0.0147
Minimum Calf Circumference Prior Compression [cm]	24.11 ± 2.55	22.81 ± 2.22	0.2976
Maximum Calf Circumference Prior Compression [cm]	37.88 ± 3.75	38.66 ± 3.69	0.6827
Minimum Calf Circumference Post Compression [cm]	24.44 ± 2.62	23.55 ± 2.58	0.5066
Maximum Calf Circumference Post Compression [cm]	36.88 ± 5.04	36.33 ± 3.46	0.801
Application time[s]	44.71 ± 17.75	24.75 ± 14.48	0.0273
Removal time [s]	18.11 ± 7.14	13.0 ± 5.41	0.129

TABLE 3: PATIENT POPULATION RESULTS (N=8).

Total population (N=90)

Calf circumference, [cm]	CR	Control
Minimal Prior Compression	22.68 ± 3.17	22.9 ± 2.28
Minimal Post Compression	22.89 ± 2.28	22.85 ± 2.22
p-value	0.6107	0.8915
Maximal Prior Compression	38.61 ± 3.75	38.45 ± 3.74
Maximal Post Compression	38.42 ± 3.78	38.30 ± 3.53
p-value	0.7281	0.7803

TABLE 4: CALF CIRCUMFERENCE ANALYSIS IN TOTAL POPULATION (N=90). MINIMAL AND MAXIMAL CALF CIRCUMFERENCE DID NOT CHANGE AFTER COMPRESSION IN BOTH GROUPS

1.5 Sub-bandage pressure values

The mean resting sub-bandage pressure values at the B1 measuring point in the standing positions in the examined study groups were as follows:

CR group: minimal applied pressure was 5.42 mmHg, maximal applied pressure was 44.14 mmHg.

Control group: minimal applied pressure was 8.71 mmHg, maximal applied pressure was 44.71 mmHg.

In CR and Control groups there was no difference in mean pressure applied over 30-minute sessions (Tab.2). During the Session 1 in total population (N=90), healthy population (N=82) and patient population (N=8) p-values between CR and Control groups were 0.6768, 0.9624 and 0.2748, respectively. During the Session 2 pressure readings in total and healthy population were similar, however, in patient population (N=8) CR garment delivered higher pressure than Control stocking, 24.23 ± 5.75 and 18.12 ± 2.33, respectively, p-value 0.0147 (Tab.3).

1.6 Sub-bandage pressure under and over clothes

When the CR garment was worn over clothes, the average magnitude of the difference between the intended and target pressure was 2.78 mmHg. The average magnitude of the difference when CR garment was worn over clothes was 15.53 mmHg. Clinically, pressure differences of ± 4 mmHg do not impact treatment.

1.7 Calf circumference measurements

Minimal and maximal calf circumferences were measured prior and post compression sessions with further investigation, whether pressure application over 30-minute time interval impacts calf size. We did not note any change in minimal or maximal calf circumference after compression, neither in CR nor in Control group (Tab.4).

1.8 Application and removal timing

CR garment application time was significantly higher than application time of Control garment, in total population (N=90) 37.54 ± 18.9 s and 17.51 ± 10.87 s, respectively, p-value 0.0001; in healthy population (N=82) 36.89 ± 18.88 s and 17.51 ± 10.88 s, p-value 0.0001; in patient population (N = 8) 44.71 ± 17.75 s and 24.75 ± 14.48 s, respectively with p-value 0.0273 (Tab.2, Tab.3). However, the removal time for both garments was similar, in total population (N=90) 11.92 ± 7.58 s and 10.72 ± 7.10 s, with p-value 0.3421; in heathy population (N=82) 11.08 ± 7.21 s and 10.38 ± 7.26 s, p-value 0.6362; and in patient population (N=8) 18.11 ± 7.14 s and 13.0 ± 5.41 s, p-value 0.129 in CR and Control groups respectively.

1.9 Quantitative feedback

Study subjects, both with and without previous experience with compression stockings found Control garment difficult to put on and uncomfortable to wear. Majority of study population considered CR garment user-friendly. Collected comments showed that multiple subjects thought the CR garment was physically easier to put on compared to the Control, despite taking more time. Other qualitative feedback collected showed that the CR garment was considerably more comfortable than the Control stocking, with multiple comments about the CR device being less itchy and feeling less straining. In total, 40 study subjects stated preferences to CR over Control garment, that represents 44.44% of study population, 14 subjects (15.55%) preferred Control to CR and 36 subjects from total study population (40%) were neutral commenting advantages and disadvantages in both garments.

DISCUSSION

Medical compression devices come in a variety of forms. These include multilayer bandages, single-layer sleeves, and orthopedic supports.[9] Given the high prevalence of vascular and autonomic insufficiency, over the counter nature of these garments and the relative success if utilized, the compression garments represent a large consumer marker with Compound annual growth rate (CAGR) of 5.2% [6]. The major limiting factor remains the low patient adherence. Because they are an effective treatment for a number of chronic and transient conditions, the market for compression devices remains large. However, if patients are non-compliant, they will not receive the most effective treatment.

The novel CR garment described in this paper can effectively apply pressure to the lower region of the leg. Analysis on the pressure data showed that the CR garment was capable of applying similar pressure over time compared to the Control in total study population, and even superior level of pressure in patient population, 24.23 ± 5.75 mmHg and 18.12 ± 2.33 mmHg, respectively, p-value 0.0147. In contrast to Control, CR provides different degrees of pressure as defined by the user. By pulling on a strap, the user will dictate the level of compression applied by the CR garment.

Many users find compression stockings uncomfortable and hard to don. Due to the profile of the CR garment clasp, it can only be worn under lose fitting clothes. The pressure differences between the intended pressure and the applied pressure were greater when the CR garment was worn over clothes, however, difference was not clinically significant, suggesting the CR garment can be worn over clothes.

The long-term application of a consistent pressure has yet to be evaluated due to time and scale constraints. A larger scale multi-day study can be used to determine the compressive capabilities of the device during extended periods of wear lasting multiple hours. Coupled with this is a need to create better methods of monitoring and evaluating compliance in non-clinical settings.

Minimal and maximal calf circumferences appeared to be unimpacted by 30-minute pressure application in both groups. This finding supports previous study reported 2 class graduated compression stockings did not compress superficial or the deep veins of the calf in the standing position. [10] This evidence can be explained by short-time compression application. Some of the short-term benefits include increased blood flow, pain relief in aching legs, decreased swelling in legs, and prevention of blood clots. The major long-term benefit of compression stockings is preventing of venous insufficiency with the success of compression treatment in strongly associated with the small

ulcer surface and decrease in calf circumference. [4] Thus, we did not expect short-term pressure application result in calf circumference change.

The time for CR garment application was higher among all studied groups. It is important to note, that it was first introduction of CR garment to study population. With gaining experience learning curve will progress. CR device is still in the prototype stage of the design process. Future work will be performed to improve the device and make it easier to put on. Even with higher application time CR was more preferable than Control garment. Educational materials were developed as a part of the study. An instruction booklet outlines device application step-by-step. Multiple users felt the design was intuitive and reminded them of other devices available on the market. Some volunteers felt having one instruction on each page made them question their judgment. These users preferred a summary sheet that highlights the key application steps. Increasing user confidence increases the likelihood users will use the device. Step by step instructions may be helpful for individuals who are less familiar with these types of devices.

Improvements incorporated in the design of CR make novel compression garment universal. The ability of device to respond to user-defined changes will increase user compliance by improving user comfort. Higher compliance rates will prevent the progression of symptoms, reduce healing times, and decrease recurrence rates. Increased adherence to treatment protocol will reshape clinical practice, improve the congruence between physician and patient perception of treatment effectiveness, and reduce the incidence of preventable conditions.

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