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Design, Manufacture, Mechanical Testing and Clinical/Mri Assessment of the Medical Elastic Compression Stockings, Base on Taiwanese’s Leg Size

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Abstract

Chronic Venous Insufficiency (CVI) in the lower limb is commonly associated with varicose veins. In Asian countries, demand has increased for Medical Elastic Compression Stockings (MECS) as conservative treatment for varicose veins and CVI; however, their efficacy requires further investigation. The legs of 726 Taiwanese participants were measured, and MECS were designed and manufactured accordingly. Manufacturing processes included “fixation of the elastic fiber,” “design of the fabric,” “application of techniques for high-pressure stockings,” and “application of techniques for configuration.” Further techniques used for the production of functional MECS included “elastic yarn composite techniques,” “incremental pressure fabric weaving,” and “pressure shaping of fabrics.” Parameters for the mechanical testing of MECS included size measurement, extensibility, practical elongation, compression, and residual pressure on corresponding points of the leg. Clinical assessments and Magnetic Resonance Imaging (MRI) analyses using noncontract-enhanced Magnetic Resonance Venous (MRV) techniques were also performed on 100 participants with varicose veins pre-and post-MECS use. The average circumferences and lengths of specific points of the lower legs of the 726 participants were smaller than U.S. measurements by approximately 12% to 19%. This suggested that Taiwanese - and possibly Asian - MECS should not be manufactured according to Western sizes. Subjective clinical questionnaire results included relief of symptoms of heaviness of the legs, spasticity in the evenings, and convulsion during sleep. According to MRV analyses, deep venous blood flow increased significantly (relief of high pressure), and available hemoglobin in the deep vein increased (reduced tissue hypoxia) post-MECS use. Our findings provide important reference material for the establishment of Taiwanese and Asian standards for MECS. Results from clinical and MRV analyses confirmed the efficacy of prolonged use of MECS, with results indicating that 4 h/d and 112 h of use is sufficient to improve deep venous insufficiency.

Keywords: Medical elastic compression stockings; Non-contrast enhanced MRV techniques; Venous insufficiency; Varicose veins

Introduction

Varicose veins are a common manifestation of venous incompetence in the lower limbs, appearing as dilated, elongated, or tortuous superficial veins. Visible tortuous varicose veins occur in 25% of adult women and 10% of adult men [1]. Minor degrees of varicosis (eg, superficial spider veins) affect 50% of adult women [1]. Risk factors for varicose veins include age, female sex, pregnancy, geographical location, and race [2].

In developed Asian countries, the prevalence of varicose veins has increased. In Japan, the total prevalence rate is more than 45%, which is lower than in the United States and Europe but higher than in Africa [3]. Severe venous disease of the legs causes considerable morbidity, and its treatment incurs health care costs [4]. This causes a significant economic burden and can potentially influence a country’s gross domestic product [5]. In Taiwan, similar to Japan, superficial and deep venous disorders of the legs occur commonly, and range in severity from minor asymptomatic venous valve incompetence to chronic leg ulceration [1].

In the lower extremities, deep and superficial veins occupy distinct compartments, separated by the fascia and muscles of the leg. The deep veins within the calf muscle converge to form the popliteal vein, which consequently becomes the femoral vein and a conduit for venous blood to return to the heart. The superficial compartment of the lower leg is a low-pressure chamber, whereas the deep compartment is a high-pressure chamber, primarily because of calf muscle contractions returning venous blood to the heart.

Chronic Venous Insufficiency (CVI) occurs when venous valve

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incompetence and reflux disturbs normal venous blood transport. This causes progressively increased pressure on the calf muscle to ensure blood flow into the superficial venous system. These valve incompetent veins can then deteriorate to become varicose veins. In the deep venous system, reduced flow is associated with deep venous flow insufficiency [6-10]. CVI leads to increased venous pressure in the lower leg, which can lead to skin changes such as hyperpigmentation, induration, and eventual ulceration. Gastrocnemius muscle cell changes because of prolonged hypoxia and ischemia are further complications of CVI that can cause soreness, pain, and cramping [11-13].

In 1994, an international ad hoc committee of the American Venous Forum developed the Clinical Etiology Anatomy Pathophysiology (CEAP) classification for Chronic Venous Disorders (CVD), which countries have adopted worldwide. Physicians typically recommend compression therapy according to the CEAP's indications for compression therapy in phlebology and lymphology, predominantly CVD, acute venous diseases, and lymphedema [14,15]. Bandages with compressing effects can be manufactured from various extensible materials that display varying elastic properties and exert differing influences on different leg locations. The European Committee for Standardization (CEN), therefore, recommended classes for compression stockings, with compression at the ankle ranging from 10 mmHg to 14 mmHg (mild) to 49 mmHg (very strong) (Figure 1) [16].

Manufacturers of medical compression stockings provide different pressure values for stockings, evaluated using different methods. A range of instruments can be used for the measurement of a person's leg [17]. Typically, higher compression values occur distally, with gradual decreases in pressure toward proximal parts of a limb. Pressure at the ankle is highest; therefore, compression is needed to facilitate venous return and decrease leg edema.

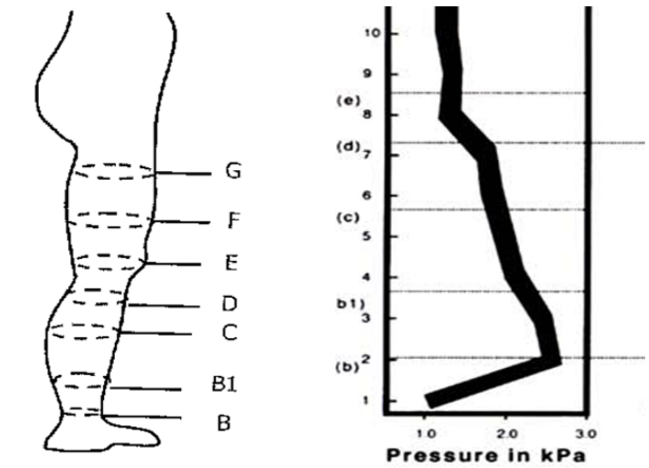
When investigating compression stockings, the daily duration of compression, total wearing time, and patient compliance with the prescribed MECS are all factors that should be evaluated. Tables 1 and 2 display international standards for compression stockings; however, a widely implemented Asian standard is lacking. Considering the increasing demand for compression stockings in Asian countries such as Taiwan, the establishment of regional criteria and standards remains a priority because the average lengths and circumferences of the legs of Taiwanese people might differ from average European and North American measurements. Investigation of the leg measurements

Compression Class	Compression at the ankle (mmHg)
Ccl A light	Oct-14
Ccl I mild	15-21
Ccl II moderate	23-32
Ccl III strong	34-46
Ccl IV very strong	49 and higher

Table 1: It shows the recommendations of the European CEN commission regarding compression classes of stockings.

National Standards	United Kingdom	Germany	United States (US)	Taiwan (provided by current studies)
Unit:% ---Point B (ankle tension) as the baseline as 100%				
E	50	20~50	20~50	20~50
D	-	50~80	50~80	50~80
C	70	-	-	-
B1	-	70~100	70~100	70~100
B	100	100	100	100

Table 2: International standards for compression stockings.



(a) (b)

Figure 1: (a) Points of pressure measurement corresponding to gradually declining stocking compression levels, from point B (below) to G (upper) levels. (b) Gradual pressure drops in MECS compression, provided by an extension of the elastic formation of the fabric. This characteristic reduces large jumps in pressure at different levels of the leg by taking into account the curvature of the leg.

of people from Asian countries to ascertain possible differences from Western sizes is, therefore, needed. In this study, we measured the legs of Taiwanese participants and compared them with Western sizes. According to the results, we then designed and manufactured medical elastic compression stockings (MECS). We conducted clinical and medical imaging assessments of participants with varicose veins and CVI pre- and post-MECS use.

Materials and Methods

Evaluation of the leg sizes of Taiwanese people

The lower legs of 726 participants (168 men and 558 women) were measured, and clinical assessments were conducted. The participants' heights ranged from 149.2 to 185 cm, their body weights from 44.1 to 90 kg, and their ages from 29 to 83 years. To establish the possible differences between participants' leg measurements and those of Western people, we collected point of pressure measurements corresponding to gradually decreasing stocking compression levels, from points B, C, and G (Figure 1).

Design of MECS

Short-stretch bandage and wadding design MECS (I-Ming Sanitary Materials, Changhua, Taiwan), which provided graduated static external compression were applied to participants' lower legs (Figure 1). In Taiwan, commercial compression stockings have several technical issues, including ineffectiveness at reducing pressure. Medical-grade compression stockings should gradually reduce pressure from the ankle to the knee by providing pressure in 2 distinct areas. Tables 1 and 2 displays the international standards for compression stockings in various countries.

However, most commercially available elastic stockings provide only segmental reductions in pressure, that is, small reductions in pressure between segments. At low-pressure requirements, this might not result in major differences in compression between different segments, even if the reduction in pressure is not gradual. However, at high or very high pressure requirements, marked reductions in pressure between segments can cause discomfort and suboptimal leg venous pressure, which is incongruous with natural leg patterns. This can potentially lead to additional burden on the leg veins.

This study evaluated a locally manufactured MECS, designed to provide low-level reductions in leg pressure. The elastic component of the fabric was extended to achieve a gradual reduction in compression. This characteristic protected against large increases in pressure at different levels of the leg. Considering leg curvature, the stockings ensured gradual changes in pressure without increasing pressure significantly or increasing the burden on the supportive inner leg tissues.

MECS manufacturing processes

After measurement of the legs of the Taiwanese participants and the design of the MECS, the manufacturing processes included "fixation of the elastic fiber," "design of the fabric," 'techniques for high pressure stockings," and "techniques for configuration." Tests of pressure and medical-grade evaluations of the clinical effects of the MECS (general analyses and MRV imaging) (Figure 2) were also performed.

To produce functional MECS that is superior to current commercial compression stockings, further innovative manufacturing procedures included "elastic yarn composite techniques," "incremental pressure fabric weaving," and "pressure shaping of fabrics." To maintain the stretch and elasticity of the MECS, elastic yarn was selected as the composite. However, because of the unstable features of elastic yarn, it was mixed with hard yarn to form elastic yarn coating. Techniques for elastic yarn coating included "core spinning," "core twisting," "air jet converting," and "hollow spindle wrapping" (Figures 3 and 4).

Usually, the stitch density is at the ankle portion of compressing stockings, so as to create highest compressing force.

To ensure that MECS provide compressed pressure, progressively attenuated pressure, and pressure stability, the elastic yarn should have the characteristics of stable tensile strength and stable tensile stress, and avoid curling filaments, wool-like filaments, and folds in the yarn. This study, therefore, adopted the hollow spindle-wrapping technique, using a double coating of elastic yarn (centerline) and a hard yarn sheath for MECS manufacture. The sheath was coated in 2 mutually reverse directions: Z-twist (clockwise) and S-twist (counterclockwise) directions.

A pretraction extension system was employed to control the drawing of the elastic yarn, improve yarn extension, prevent defects in the empty sheath, and prevent core leakage (Figures 3 and 4). Multidimensional weaving molding and yarn tension regulation were then performed as components of incremental pressure fabric weaving (Figures 4 and 5).

The final stage in the production of the MECS was the pressure shaping of fabrics, including procedures of "molding," "setting," "steam pretreatment and closing of the mold," "hot pressing and shaping," and "provision of tension and unloading" (Figure 6).

Several manufacturing devices were implemented during production, including a circular knitting machine (Merz), a Jacquard broadband machine (Muller), industrial sewing machines (Shing Ray), an ironing machine (Cortese), a pressure-testing machine (Salzmann), a silk warper (Texma), a spindle machine (Menegatto), and a covering machine (Menegatto).

Quality control and mechanical testing of MECS

The testing items for the MECS included size measurement, extensibility, practical elongation, compression, and residual pressure on points B to G (Figure 1). Pressure at the ankle is highest and should

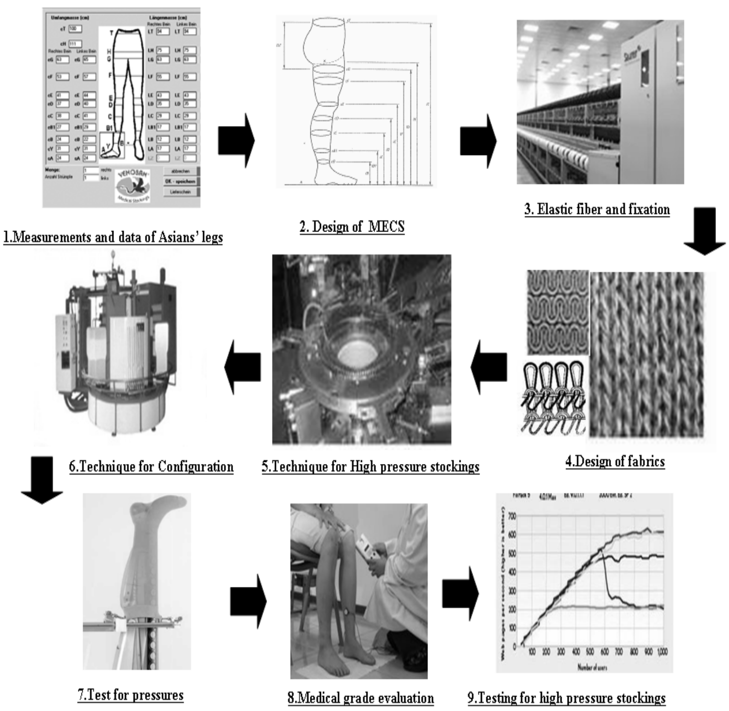


Figure 2: It shows different processes of design, manufacture and testing on MECS.

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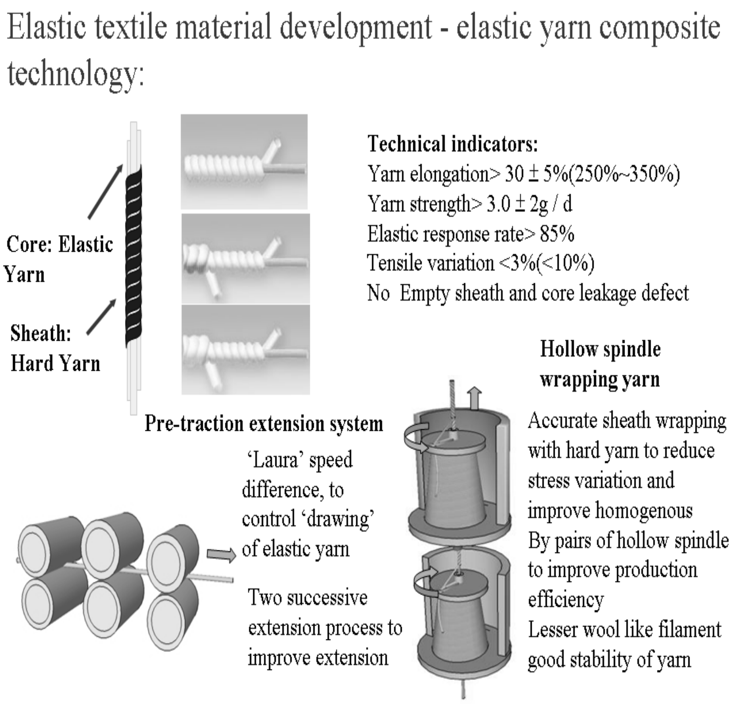

Figure 3: Elastic textile material development-elastic yarn composite technology.

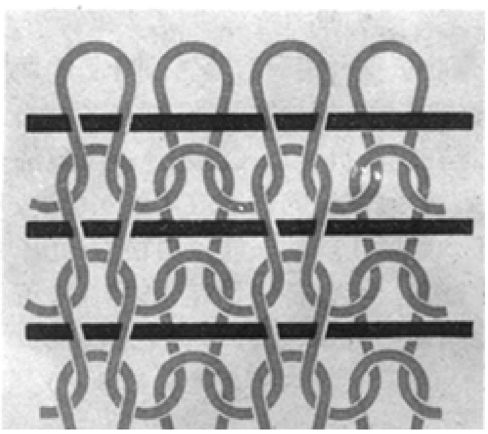

Figure 4: Shows a sandwich coil penetrates a yarn stitch, the stitch density determines the compressing force. The higher stitch density sandwiching the yarn per unit area, produce higher rendered pressure of the stockings, and verse versa.

gradually decrease with compression (Table 3).

Selection of participants for clinical and MRV assessments

From January 2011 to April 2012, the research project was advertised in the reception of the radiological department at Taipei Medical University Hospital. Participants were required to fulfill one clinically observable criterion: superficial varicose veins of the lower leg surface, with a venous caliber greater than 0.5 cm in diameter or palpable. Exclusion criteria were previous major surgery for Deep Vein Thrombosis (DVT), pulmonary embolism, short life expectancy (<2 years), paralysis of the leg, preexisting leg ulcers, or evidence of venous insufficiency [4,8,9]. Patients were also excluded because of malignant disease, pregnancy, peripartum, or severe medical illness. The final sample consisted of 100 patients (91 women, 9 men; 52.9 ± 10.4 y). This study was approved by the ethics committee (TMU-JIRB 201011011) and all patients provided informed consent.

Leg measurement and provision of MECS according to size

Leg circumferences at the standard compression pressure levels (E, D, C, B1, and B) of 132 participants were measured by medical technicians. The lengths of their legs at the respective points (ie, from E, D, C, B1, and B to the ground) were recorded.

Participants' health conditions and any necessary precautions were recorded prior to evaluations. Participants with severe skin allergy to MECS and claustrophobia (likely to be triggered during MRI) were excluded from the study.

Clinical assessment of participants using questionnaire

Participants were asked to wear the MECS once prior to the first non contrast MRI scanning procedure. We visited each participant and requested feedback following the first 3 days of MECS use, to remain informed on possible cases of inappropriate MECS application and potential reasons for failure. This enabled us to assess if participants required a different sized MECS or if their involvement in the research should be terminated.

Symptoms, such as heaviness of the legs, spasticity in the evenings, convulsion during sleep, erythema of the skin, itching and papules, and telangiectasia (spider veins) were also recorded. The initial questionnaire recorded the participants' medical history, and was administered prior to delivery of the MECS. The MECS was provided according to the participants' leg sizes. After the participants had worn the MECS for 112 h, at a rate of 4 h/d, 7 d/wk, for 4 weeks, the final MRI scanning procedure was conducted and a second questionnaire

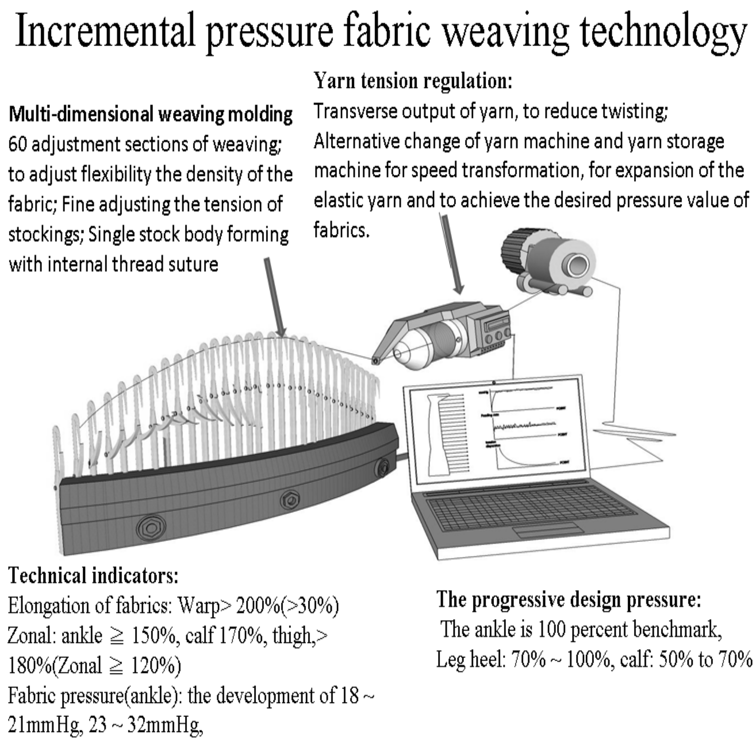

Figure 5: Incremental pressure fabric weaving technology.

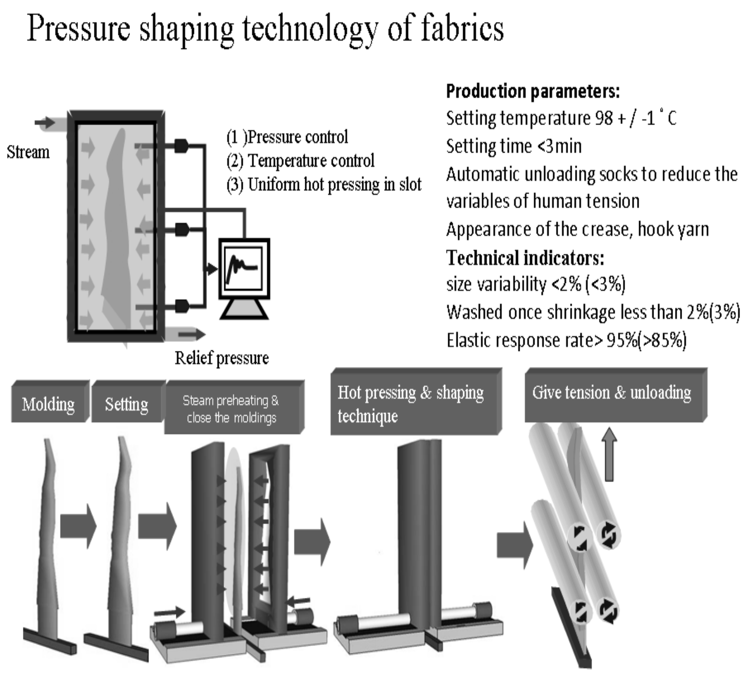

Figure 6: Pressure shaping technology of fabrics.

was administered. This questionnaire recorded information on daily MECS usage, major complaints following the use of the MECS, and levels of comfort and stretch or flexibility when using the MECS. Possible methods for providing relief of symptoms, or events that exacerbated symptoms following MECS application were recorded. The questionnaire also established participants' general degree of satisfaction with the MECS.

Gradings of Compression of MECS	Compression (mmHg) (kPa)
I Low	18-21 (2.4-2.8)
II Moderate	23-32 (3.1-4.3)
III High	34-46 (4.5-6.1)
IV Very high	Over 49 (>6.5)

Table 3: Gradings of Compression of MECS (according to the standard of RAL-GZ 387/1).

	G (cm)		C (cm)		B (cm)	
	US	Our study	US	Our study	US	Our study
S	44 ~ 55	41 ~ 47	30 ~ 36	26 ~ 31	20 ~ 23	16 ~ 19
M	50 ~ 61	45 ~ 53	34 ~ 40	29 ~ 35	23 ~ 26	18 ~ 22
L	56 ~ 68	51 ~ 58	38 ~ 44	33 ~ 39	26 ~ 29	21 ~ 25
XL	62 ~ 70	56 ~ 64	42 ~ 48	37 ~ 43	29 ~ 32	24 ~ 28
XXL	68 ~ 82	62 ~ 70	46 ~ 52	41 ~ 47	32 ~ 35	27 ~ 31

Table 4: The comparison of the circumferences on G, C & B points in different size of compressing stockings between US and our study.

Figure 7: MRV was performed for patients with MECS (arrow).

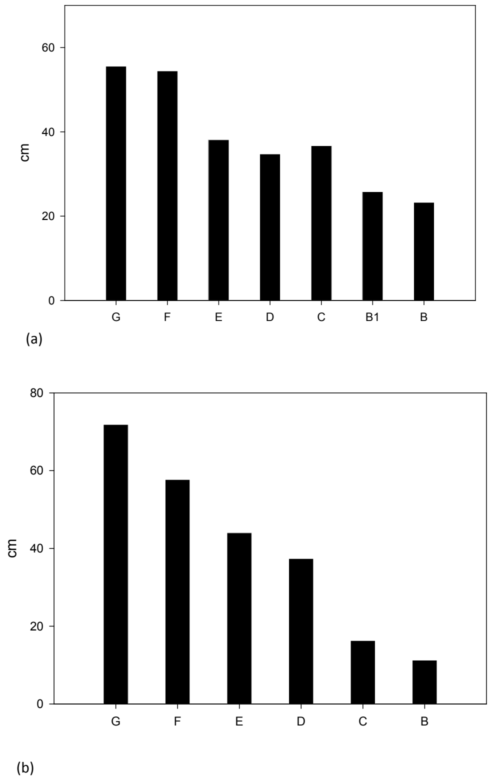

Figure 8: Leg measurements of 726 candidates on points of pressure measurement corresponding to gradually declining stocking compression levels. (a) The average leg circumference at respective points of candidates (G, F, E, D, C, B1, B). (b) The average leg length at respective points of candidates (G, F, E, D, C, B1, B).

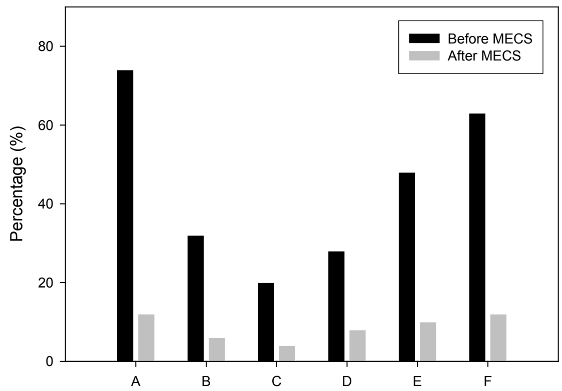

Figure 9: Candidates' major symptoms and complaints related to varicose veins before and after using MECS. A: heaviness of the legs; B: spasticity in the evenings; C: erythema of the skin; D: itching and papules; E: convulsion during sleep; and F: telangiectasia (spider veins) (N=100).

Noncontrast enhanced MRV imaging

One-hundred participants were required to undergo 2 MRI scans: the first on Day 1 and the second after 112 hours of MECS use. All examinations were performed using a 1.5-T superconducting magnet (Signa, GE Medical Systems, Milwaukee, WI) using an 8-channel knee array coil. Axial, coronal, and sagittal T2 gradient echo images were initially obtained as routine localization images.

Cine phase-contrast MRI is used for the quantitative measurement of axial anatomical area. Cine phase-contrast combines cine MRI and phase-contrast MRI techniques, providing a motion cycle that enables imaging of moving signals such as blood flow. Cine MRI collects image data over several cycles of periodic motion, and then retrospectively sorts the data into the desired number of timeframes to produce a series of anatomic images. Phase-contrast MRI allows quantitative measurement of 3-D velocity over an entire imaging plane by encoding the velocity of the blood flow in the phase of the magnetic resonance signal. The combination of cine and phase-contrast MRI provides a technique that can quantitatively measure the velocity of deep veins in vivo, and produce sets of images according to the direction of measured vessels.

In our previous study, we observed that compression stockings rapidly yielded effects in patients with varicose veins, decreasing the superficial vein flow volume significantly, and increasing superficial and deep venous blood flow rates in the short-term [18]. In this study, each patient was arranged in the supine position for deep vein recordings [19]. The cross-section of the level of the popliteal vein (located between the superior and inferior margins of the patella) was selected for analyses. Quantitative 2-D fast cine phase-contrast MR images were acquired on axial planes that were perpendicular to the popliteal artery [18]. Velocity Encoding (VENC) determines the highest and lowest detectable velocity of blood flow (in cm/s). In this study, velocity-encoded cine imaging was performed with VENC arranged at 20 cm/s in the axial plane. Peripheral pulse gating was used for cine images, with a flip angle of 20˚, a 16-cm field of view, a TR/TE ratio of 40/8, a slice thickness of 4 mm, an acquisition matrix of 256/160, and a temporal resolution sufficient to obtain 16 phases/cardiac cycle. Magnitude and phase images were acquired during each velocity encoding series. Following the scanning of these sequences, patients were asked to wear the MECS, and then all series acquisitions were repeated (Figure 7). The same MRV method was performed at the same position on participants' legs to enable comparison of the superficial and deep venous blood flow diameters and intensities.

Calculation of changes in area, flow velocity, and available hemoglobin in the deep veins

Two technologists, each with 10 years of experience, calculated blood flow (ml/beat) using commercially available software (GE Software Report Card 4.0; GE Medical Systems). The technologists selected the deep veins and the Regions of Interest (ROI) in these areas. Calculations were performed on images acquired pre- and post-MECS application. Three main parameters were measured using non contrast MRI/MRV techniques:

- Changes in the area of deep veins
- Flow velocity changes in the deep veins and
- Available hemoglobin in the deep veins

Each parameter was measured (A) prior to the initial use of the MECS, (B) following the initial use of the MECS, (C) between 2 MRI examinations without use of MECS, and (D) between 2 MRI examinations with MECS use. Changes in available hemoglobin in the deep vein were calculated according to the concept of geogèng (*Geometria indivisibilibus*), based on the results from (1) and (2) [20-22].

Statistical analysis

Analyses were conducted using post processing MRI software. The statistical relationship between groups was determined using Student's *t* test, with *P* values <0.05 considered significant.

Results

Leg measurements of 726 Taiwanese people

We collected point of pressure measurements corresponding to gradually decreasing stocking compression levels from B to G. Our results provide reference material for the establishment of a database in the Taiwan Textile Institute of the Ministry of Economic Affairs, to develop parameters and criteria for product sizes of medical compression stockings. Table 4 shows the circumferences of different sizes of compression stockings used in our study and those from the United States.

Figure 8 shows the average leg circumferences and lengths at points G, C, and B of our study participants and those of people in the United States. Results indicated that the average leg circumferences (G, C, and B points) of our participants were smaller than US measurements by approximately 12% to 19% (Figure 8).

Clinical outcomes and assessments of participants using MECS

In this study, we classified the majority of patients as having level I and II MECS requirements, with fewer participants classified as requiring level III and IV MECS. The majority of participants were women, with 91 women and 9 men included in the evaluations. The major comorbidities were skin reactions in 22 participants (2 men and 20 women), diabetes in 3 participants (3 women), hypertension in 9 participants (2 men and 7 women), and claustrophobia in 1 participant (1 woman).

Our records indicated that participants predominantly required small- and medium-sized stockings, with a smaller proportion requiring large sizes. We evaluated size distribution according to frequency and percentage (S: 34%; M: 39%; L: 22%; XL: 5%).

Participants' major symptoms and complaints related to varicose veins prior to MECS use

Participants' self-reported complaints prior to using MECS were, in decreasing order of frequency, heaviness of legs>telangiectasia (spider veins)>convulsion during sleep>spasticity in the evening>itching and papules>erythema of skin (Figure 9).

Participants' comfort and stretch/flexibility post-MECS use

The majority of participants reported feeling comfortable or very comfortable wearing the MECS (72%), with 5% experiencing discomfort (Figure 10). The majority of participants were satisfied or very satisfied with the stretch and flexibility of the MECS (69%), with 8% reporting dissatisfaction.

Changes in area/flow velocity/available hemoglobin in the deep veins

Figure 11 shows the changes in area/flow velocity/available hemoglobin in the deep veins. The differences in the available hemoglobin in the deep veins between MRI examinations performed pre- and post-MECS use were significant (*P*<0.05).

Discussion

This is the first study to aim to establish Taiwanese or Asian standards for MECS. Our study participants' average leg circumferences and lengths from points G, C, and B were smaller than US measurements by approximately 12% to 19%. This indicated that Taiwanese - or possibly all Asian-MECS should not be sized according to Western standards. Our results support the development of new standards and criteria for MECS sizing.

During MECS manufacture, the application of the hollow spindle-wrapping technique for the coating of hard yarn on a central core of elastic yarn, with changes in internal and external twist, created

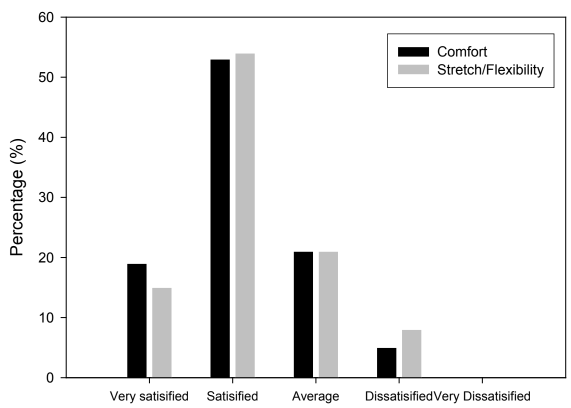

Figure 10: The majority of candidates felt comfortable and satisfied with the stretch and flexibility of MECS (N=100).

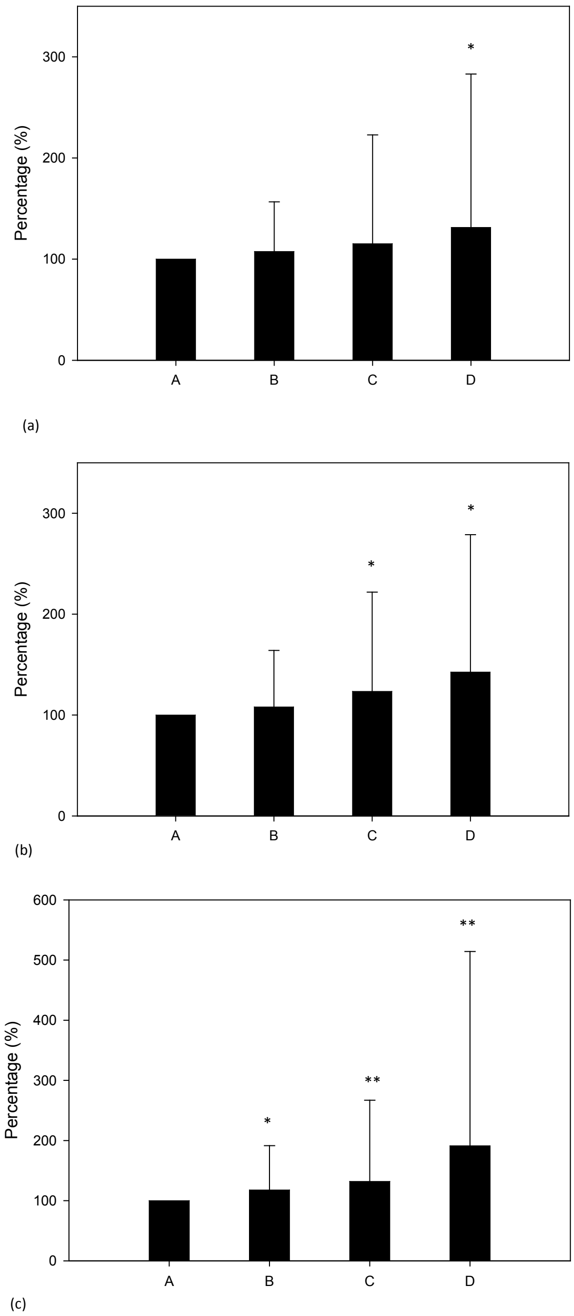

Figure 11: (a) Area changes in deep veins (b) Flow velocity changes in deep veins (c) Changes in available hemoglobin passing through the deep vein. A: before the first use of MECS; B: after the first use of MECS C: between the 2 intervals of MRI examinations without the use of MECS; and D: between the 2 intervals of MRI examinations with the use of MECS (N=100).

different tactile sensations. An appropriate internal and external twist ratio can protect the flexible wire from external damage and the yarn from internal torque. This reduces curling of the yarn and increases the durability, stability, and flexibility of the fabric.

In this study, we observed that middle-aged women with venous disease of the lower legs constituted the majority of patients requiring MECS. Taipei City's hot and humid climate was one major reason for discomfort and caused 32 participants to withdraw from the study at an early stage. Other reasons for withdrawal included itching of the skin (allergy), tightness, slipping, and size mismatch. The 100 participants who successfully completed the program wore the MECS for 4 h/d, totaling 112 hours prior to undergoing the second MRV examination. We observed that specifying a daily wearing time of 4 h increased patient compliance and reduced study withdrawal, with 61.5% of the participants reporting feeling comfortable or very comfortable wearing the stockings and less than 4% describing discomfort.

For pre-MECS use, the participants' most significant symptoms for relief included heaviness of the legs, spasticity in the evenings, erythema of the skin, itching and papule, convulsion during sleep, and telangiectasia (spider veins). Initially, we suggested that participants should not wear the MECS for longer than 4 h/d because of several conditions that limit the prolonged use of MECS [23-29]. During the evaluation period, 69% of the participants reported feeling satisfied or very satisfied with the stretch and flexibility of the stockings. Less than 10% of patients were unsatisfied with these aspects.

Non contrast MRI/MRV analyses indicated that all measured parameters (area, flow velocity, and available hemoglobin in the deep veins) had improved to some extent following the use of compression stockings. MRV analysis findings of significantly increased deep venous blood flow (relief of high pressure) and increased available hemoglobin in the deep veins (reduced tissue hypoxia) can explain the questionnaire-reported clinical outcomes of relief of heaviness of the legs, spasticity in the evenings, and convulsion during sleep following the use of the MECS.

Conclusion

Our study results provide important reference material for the future establishment of Taiwanese standards for MECS. We designed, manufactured, and mechanically tested MECS that provide graduated compression from the ankle to the proximal parts of the leg. Using clinical and MRV assessments, we confirmed the efficacy of prolonged use of MECS for improving deep venous insufficiency, and identified that wearing the MECS for 4 h/d and for a total of 112 hours provided optimal effects.

Acknowledgments

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