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Stiffness of Compression Devices - International Compression Club (ICC) Meeting, 2012

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Stiffness of compression devices

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This issue of *Veins and Lymphatics* collects papers coming from the *International Compression Club (ICC) Meeting on Stiffness of Compression Devices*, which took place in Vienna on May 2012.

Several studies have demonstrated that the stiffness of compression products plays a major role for their hemodynamic efficacy. According to the European Committee for Standardization (CEN), *stiffness* is defined as the pressure increase produced by medical compression hosiery (MCH) per 1 cm of increase in leg circumference.¹ In other words stiffness could be defined as the ability of the bandage/stockings to oppose the muscle expansion during contraction.

Measurements of stiffness are performed in textile laboratories using different extensometers. However, up to now pressure ranges are declared only for compression stockings; no pressure ranges can be declared for bandages as the exerted pressure depends on the stretch applied to the bandages, number of layers and leg configuration. Information concerning stiffness is not given either for elastic stockings or for bandages.

In vivo experiments have offered useful surrogate data. The leg circumference increases when moving from the supine to the standing position and during muscle activities.²⁻⁴

To assess stiffness according to CEN definition, it would be necessary to measure the increase of compression pressure and of leg circumference simultaneously, requiring a pressure measurement device and a strain gauge plethysmograph. In order to simplify the stiffness calculation it has been proposed to assume that the increase of leg-circumference, moving from lying to standing position, is always 1 cm. In this case the so-called static stiffness index (SSI) could simply be calculated by subtracting the supine from the standing pressure.⁵ A comparison between the two measuring systems of stiffness (the first including the measurement of the leg circumference increase and the second just calculating SSI) was performed showing the same sensitivity and specificity in distinguishing between elastic and inelastic systems.² The conclusion of this comparison clarified that SSI is an effective method to calculate stiffness and that more complex measurements do not give more information.

Nevertheless the assessment of stiffness *in vivo*, as recommended in a previous consensus

meeting of the ICC,⁶ came under some criticism. Despite the fact that SSI is basically able to differentiate the elastic properties of MCH, a great variability among different patients could be a major issue. This variability depends on the fact that some other variables play a role in SSI calculation in addition to elastic properties of material: the leg position during measurements, the configuration and consistency at the measuring site of the leg, the individual muscle strength, the presence of fat and others.⁷

A new standardized method to measure the stiffness on a mannequin leg was reported⁸ which presents the advantages to be simple, highly reproducible, easily available and cheap. If this method will be widely adopted, it would also be possible to avoid that every company producing MCH measure stiffness with different systems thereby increasing the confusion. In order to differentiate between measurement *in vivo* and in laboratory (lab) the so called *in vitro* measurement, it was proposed to name the *in vitro* calculation not anymore stiffness *in vitro*, but resistance.⁹ Regarding the measuring site on the leg, the B1 point described in the ICC consensus paper⁶ was brilliantly confirmed as the most suitable site for stiffness measurement.¹⁰

Stiffness, together with pressure and hysteresis,¹¹ is an important parameter for effectiveness combined with comfort of MCH. Neumann's paper rises two important points.¹¹ One is the relevance of another indicator of stiffness the so-called dynamic stiffness index (DSI) requiring complex measuring systems. Nevertheless, an excellent correlation between SSI and DSI could be shown by using this lab equipment¹² but also *in vivo* during muscle exercise.^{2,13} This supports the idea that *in vivo* testing is a valuable tool for assessing the elastic properties especially in connection with clinical effectiveness of compression devices. The second point is the importance of the hysteresis of different compression materials. Hysteresis can be measured only in the lab and remains something *obscure* for the clinicians whereas they should receive full information by companies on this parameter.

An ideal compression device should exert a low, comfortable pressure during rest, with a strong or very strong pressure¹⁴ during standing and working in order to counteract ambulatory venous hypertension (effective). Such a device would have a very high SSI but, unfortunately, it doesn't exist yet. Inelastic material presenting high stiffness comes close to an ideal compression device,¹⁵ especially when pressure decreases after some hours from application in the supine position, the difference between standing and supine pressure is very high exerting an effective massaging effect on the leg during walking and improving significantly the hemodynamic impairment of

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chronic venous insufficiency. Elastic material, exerting a sustained pressure, not very different between supine and standing position or during muscle exercise, shows a small improvement on the impaired venous hemodynamics which is always significantly smaller than that from inelastic material.^{16,17}

Actually stiff materials exerting strong or very strong pressure showed to be clinically effective in ulcer treatment^{16,18,19} when a significant impact on venous hemodynamics is very important and also in lymphoedema.²⁰

Pressure and stiffness can be critically reduced in some areas of the leg with concave rather than convex shape as this is the case in the retro-malleolar space. Unfortunately this is a critical area where often venous ulcers occur. It has been shown that in this region the pressure as well as stiffness can be close to zero as the pressure doesn't increase in standing position or during muscle activity. Pressure and stiffness in these areas can be significantly increased by applying local compression straps²¹ which greatly improve the clinical outcome.²² An increase of pressure and stiffness can be achieved also at thigh level by means of eccentric devices, which are able to compress the thigh veins otherwise difficult to compress.²³ In this region higher pressure and stiffness leads to better outcome following surgical or endovascular procedures on the great saphenous vein.^{24,25}

In conclusion it is important to realize that stiffness can be mainly considered as a surrogate indicator of comfort and effectiveness. The higher the stiffness the greater comfort and effectiveness in improving the clinical outcomes. Stiffness is very high only with inelas-

tic material, or multilayer systems and can be enhanced by straps applied in a fan distribution or by eccentric compression devices in the leg segment that need to be treated.

In vivo measurement techniques must be better defined in order to minimize the variability; a parallel match with the lab assessments is a mandatory target for future researches. Only in this way the stiffness effective value will scientifically demonstrate to correspond to the great impact that already empirically presents in our everyday clinical practice.

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Sub-bandage dynamics: stiffness unravelled

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Abstract

The static stiffness index (SSI) is mathematical equation that results in a simple number when the sub-bandage pressure in the supine position is subtracted from the sub-bandage pressure in the standing weight-bearing position. When SSI data are reported, often a wide range of values is observed for similar materials. The aim of this study was to explore the strength and weakness of the SSI and its measurement. Pressure was recorded with bandaging materials with different resting pressures and properties. Measurements in the upright position were performed under weight and non-weight bearing conditions for up to 12 min of motionless stance. The measurements reveal that the SSI reveals more about the muscle forces of the person included in the system, rather than providing accurate information on the applied system or how well this system is applied. In addition, venous filling has a major effect on the final SSI. When performed under similar conditions, the SSI is able to differentiate between elastic and inelastic materials. The SSI gives us a rough estimate of the effectiveness of an applied system but interpretation is influenced by the muscle forces of the person being bandaged as well as the measured effects of venous filling and, because of that, the timing of the measurements. Future guidelines on measuring the SSI should include that the final standing pressure value should be taken when a stable recording over a certain period is observed.

Introduction

There is a variety of methods to describe the properties of bandaging materials. Recently a consensus document was published, in which was stated that sub-bandage pressures and material stiffness characterize the elastic properties of the used materials and are the deciding parameters determining the dosage of compression treatment.¹ Therefore, it was recommended to measure and report these characteristics in future clinical trials. Proposals were made concerning methods for measuring the interface pressure and for assessing the stiffness of a compression device in an individual patient. However, stiff-

ness is more than just a mathematical equation that results in a simple number. This article explores the strength and weakness of the static stiffness index (SSI).

The B1-position

In the European Committee for Standardization (CEN) Prestandard document,² an overview is provided on the anatomical locations to position pressure sensors on a leg. One of these locations is called cB1, the area at which the Achilles tendon changes into the calf muscles, approximately 10-15 cm proximal to the medial malleolus. Stolk *et al.*³ performed static measurements and showed that the largest differences in the circumference between the maximal dorsiflexion and maximal plantar flexion positions of the foot occur at the level of the transition from the gastrocnemius muscle into its aponeurosis (the cB1 level or simplified: B1; Figure 1). The International Compression Club (ICC) consensus document proposes that location B1 should always be included in future pressure measurements, with the exact location of the sensor situated at the segment that shows the most extensive enlargement of the leg circumference during dorsiflexion or by standing up from the supine position.¹ Although B1 should always be included as a measurement location, other sites could be included in any measurement of pressures.¹ Figure 1 shows a screenshot of measurements with the PicoPress device (Microlab Elettronica SAS, Ponte S. Nicolò, Italy) and the sensor positioned at the B1 position. The measured pressure values are marked A, B, C.

Resting pressure, standing pressure, amplitudes

The resting pressure gives an indication of how much pressure is provided by a compression system when the subject is in a relaxed supine position with a slightly flexed knee and the foot resting on a flat surface. It is important that the calf muscles are not resting on a surface, as the result may be a too high resting pressure.⁴ In Figure 1, the resting pressure (A) is around 40 mmHg.

The standing pressure gives an indication of the pressure when the subject is asked to stand up and put weight on the compressed leg.^{5,6} In Figure 1, the standing pressure (B) is around 70 mmHg.

Resting and standing pressure are both values recorded in static situations. If a measuring device (like *e.g.* PicoPress) allows dynamic recording, it is advisable to measure also the amplitudes of a specified movement.

Possible movements include the following:¹ i) dorsal and plantar flexion of the ankle joint; ii) walking, for example on a treadmill; iii) adopting a *tip-toe* stance, or flexing of the

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Contributions: JS, manuscript writing; the authors contributed equally to: conception and design; data acquisition, analysis and interpretation; final approval of the version to be published.

Conflict of interests: JS is a retired 3M employee and invented and co-developed the 3M Coban 2 Layer compression systems; JB is employed by 3M.

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knees; iv) passive ankle movement.

In Figure 1, the amplitudes are presented in the column exercise. The range of pressure values (C) is between 45 and 90 mmHg. The difference between these two pressure values results in a working pressure amplitude (WPA). The recording during the exercise in Figure 1 gives a WPA of 45.

The static stiffness index

The CEN European Prestandard document for medical compression hosiery defines stiffness as the increase in pressure per 1 cm increase of leg circumference.² For compression bandages, the extensibility of materials is often used to determine their characteristics. Partsch⁵ identified the need for a simple tool to assess both pressure and stiffness on the individual leg. He describes the method to measure the pressure at a defined position of the lower leg at rest (B1), when its circumference is minimal, and to repeat the measurement on the same spot, when the circumference has maximally increased by the muscles actively engaged to stand in the upright position. For measuring stiffness, the pressure in the supine position is subtracted from the pressure in stance. The resulting index indicates the effectiveness of the applied system.¹ This index is referred to as SSI and, although it

might be influenced by many variables, provides an indication of how well an applied compression system manages to keep forces produced by the muscle activity to stay in the upright position, inside the compressed area. In the measurement presented in Figure 1, a typical PicoPress recording is presented of the pressure under a 3M™ Coban™ 2 Layer application (3M™ HealthCare, St. Paul, MN, USA), with the sensor positioned at the B1 location. The resting pressure is presented in the column *supine* and is around 40 mmHg (A). The standing pressure can be taken from the column *stance* and is around 70 mmHg (B). This means that the SSI in this measurement is 30 (70-40).

Results and Discussion

Muscle forces

It is easy to imagine that both SSI and WPA are not only determined by the stiffness of the applied compression system but more by the muscle forces that are produced inside the bandaged area. Provided that the measurements are not performed on a leg with major disfigurements due to severe obesity or lymphoedema, the subject inside the system heavily *confounds* each measurement. As a consequence of measuring the muscle forces inside the compression system, both SSI and WPA tell more about the muscle forces of the person included in the system, rather than providing accurate information on the applied system or how well this system is applied. This can be easily demonstrated with the measurements presented in Figure 2. With the same system applied in the same way by the same experienced bandager on different subjects, the amplitudes are 23 on the left (C: 55-32) and 64 on the right pressure profile (C: 102-38).

These measurements are from a study on healthy volunteers, recorded with a Gaeltec strain gauge temperature-compensated (15-40°C) force transducer (Gaeltec Devices Ltd, Dunvegan, Isle of Skye, UK). The transducer was positioned at the B1 position and connected to a computer from which the data was recorded. The only difference in the two recordings is the volunteer. In both readings, a similar resting pressure was achieved. The SSI's (14 *versus* 46) as well as the WPA's during walking on a treadmill (23 *versus* 61) of the used system show big differences. This phenomenon can also be observed in studies in which actual SSI measurements are presented. A few studies present data on measurements on short-stretch bandages. Partsch (Derm Surg 2005) presents data of measurements on 12 volunteers. The reported SSI values vary between 10 and >40 for both Unna's

boot and multilayer short-stretch bandages. Similar differences in reported SSI's are observed in publications by Mosti *et al.*^{7,8} and Partsch *et al.*⁹ In some of these measurements, there is even an overlap of individual values from the systems with the highest and lowest mean stiffness (*e.g.* 7).

The static stiffness index and venous filling

Another factor that might influence the accuracy of the SSI is the timing of the measurements. There are no clear guidelines on when recording of the standing pressure

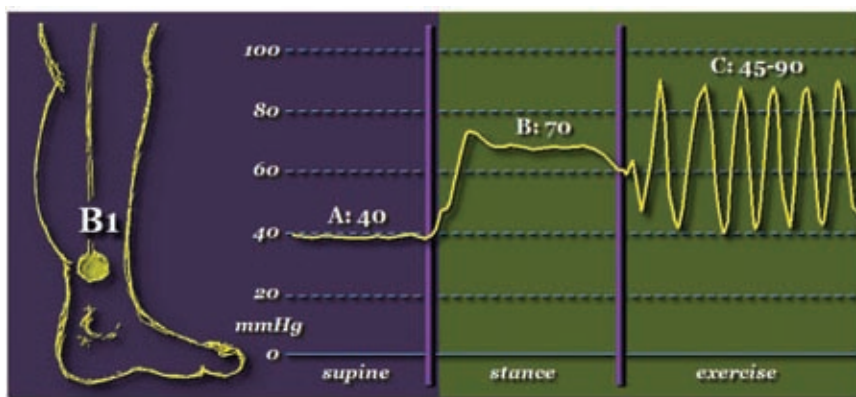


Figure 1. A typical PicoPress recording of a bandaged leg with the sensor positioned at the B1 location shown on the left. The measurements show the pressure in the supine position (A), in the standing position (B) and during functional activities (C).

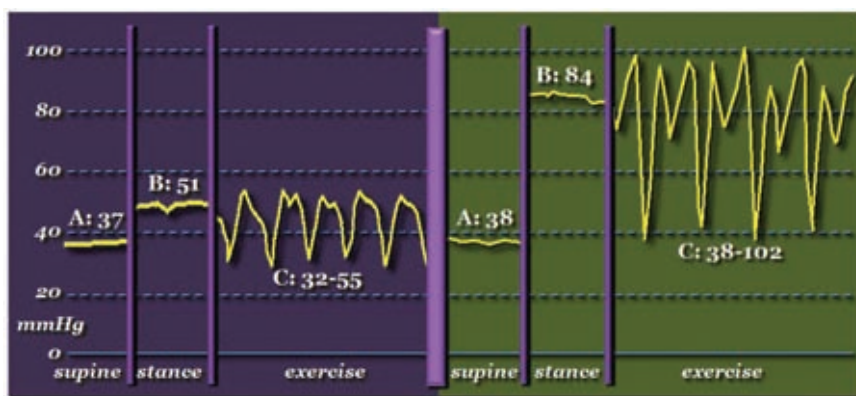


Figure 2. Sub-bandage pressure recordings from two different volunteers with the same compression system applied by the same experienced bandager.

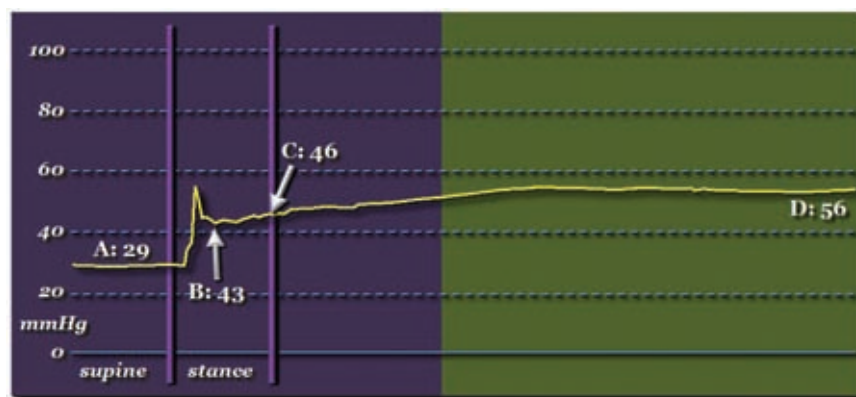


Figure 3. Recording of sub-bandage pressure of a normal limb in a Coban 2 Lite compression system, including the change from the supine to a weight bearing standing position.

should be performed. Similar to a normal unwrapped leg, the venous filling of a bandaged leg takes a certain period. Nicolaides *et al.*¹⁰ recorded intravenous pressure of a normal limb in a vein on the dorsum of the foot. After ten tip-toe movements, it takes more than 30 s before the venous pressure returns to the pressure before the exercise. A similar refilling time can be observed after the application of a compression system, when the subject changes from a supine to an upright posture. Figure 3 provides an example of a healthy subject, compressed with Coban 2 Lite (3M™ HealthCare). Recording was performed immediately after the application. During the measurements in the upright position, the volunteer holds on to a frame to avoid balancing muscle activities in the leg. If the instructions of the used device (PicoPress) are followed, the pressure is taken from some of the values in the period located between the first two pink vertical lines. At the second line, the device gives a signal that the standing period is completed. Immediately after the position change, the standing pressure is 43 mmHg (B); the pressure at the end of this period is 46 mmHg (C). Looking at the resting pressure of 29, a reported SSI could be between 14 and 17. Venous filling of the lower limb however, takes much longer than the advised period. After the position change, it takes almost a minute before a stable pressure level of 56 mmHg (D) can be observed. If that recording would be used for the calculation, the SSI would be 27. The consequence of the above observations is that, depending on the time of measurement; the SSI can vary between 14 and 27.

Figure 4 shows another recording of the same leg in the same bandage. The resting pressure is 30 mmHg (A). Now the position change takes place without weight bearing. The volunteer steps on an elevation, bearing full weight on the contralateral leg. The bandaged leg is hanging free with a relaxed Achilles tendon. The initial pressure after this position change is 23 mmHg (B) and 28 mmHg after the signal (C) of the device. As in the previous recording, it takes a minute before a final stable pressure is established. This final pressure is 48 mmHg (D). During the change from the supine to the standing position, venous filling in isolation creates a pressure increase of 18 mmHg. In patients with chronic venous insufficiency, veins refill quickly and a stable recording can be observed much faster than in the provided example with a healthy volunteer.¹¹ In addition, it might be assumed, that in patients with significant venous dilatation, pressure increase due to venous refilling is more pronounced than in healthy volunteers. This could be explained by higher volume increase of dilated veins in the upright position, until an increasing venous wall tension prevents further venous filling. This means

that in patients with chronic venous insufficiency the right time of standing pressure measurement is even more important.

Pannier *et al.*¹² measured the increase in leg volume increase after changing from a lying to a standing position and demonstrated that the position change initially leads to a rapid

increase in volume. The main change is observed in the 1st min, followed by a further slower increase in the next 9 min. The authors state that the volume increase follows a bi-exponential function fitting to a rapid filling compartment (venous pooling) and a slow filling compartment-reflecting extravasation.

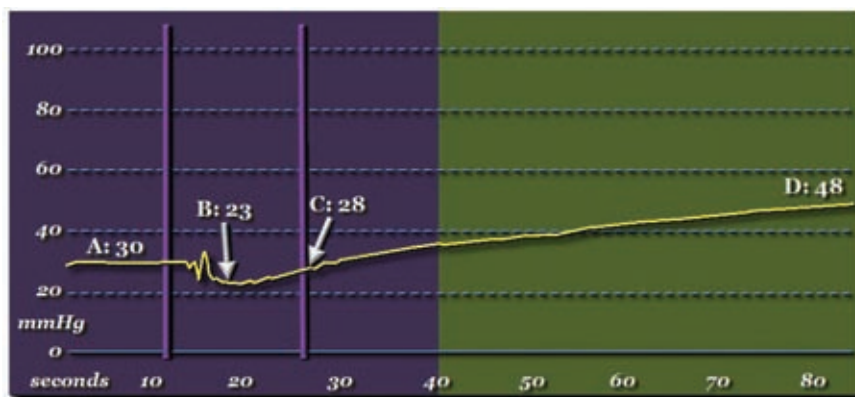


Figure 4. Recording of sub-bandage pressure of a normal limb under a Coban 2 Lite application including the change from a supine to a non-weight bearing standing position.

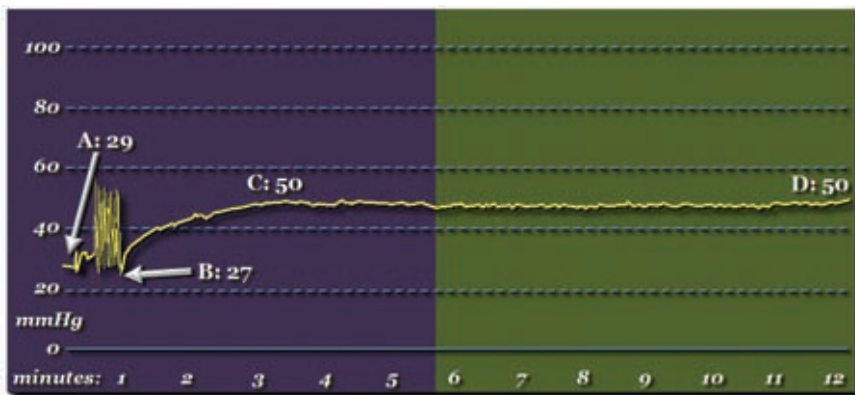


Figure 5. Recording of sub-bandage pressure of a normal limb compressed with Coban 2 Lite, including the change from the supine to non weight bearing standing position, which was maintained motionless during the entire recording time.

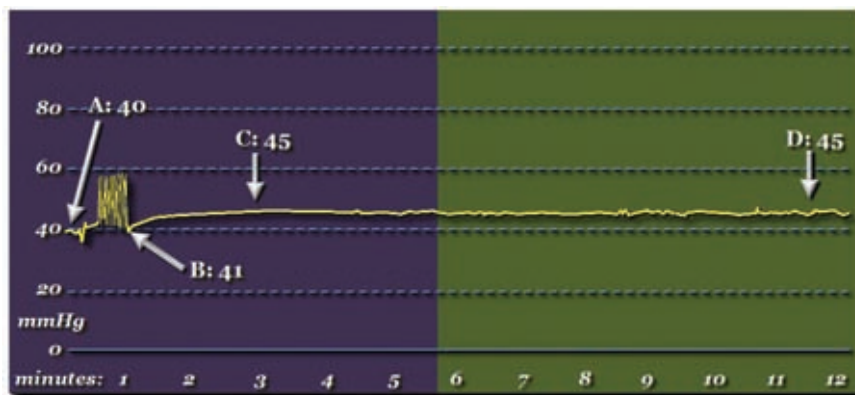


Figure 6. Recording of sub-bandage pressure of a normal limb compressed with a long-stretch bandage, including the change from the supine to non weight bearing standing position, which was maintained motionless during the entire recording time.

Stick *et al.*¹³ used strain gauge plethysmography at calf and ankle level to document the volume changes, which occurred when a subject was tilted from the supine to the upright position. In both ankle and calf, the highest volume increase was observed in the first 2 min, after which the volume further increased at a less steep slope. The authors state that after the subject has been brought into the upright posture, an increased hydrostatic pressure in the arteries makes the blood flow via the arteriolar resistance vessels and via the capillaries into the venous capacitance vessels. Next, a further volume increase is observed in the following 10 min, which is due to an increased transcapillary filtration of fluid into the interstitial space. Mosti *et al.*¹⁴ demonstrated that there is a significant correlation between the degree of improvement in venous hemodynamics of the ejection fraction (EF) examined by strain gauge plethysmography and both the SSI and the amplitudes of sub-bandage pressure during walking. The authors report that when elastic bandages are applied at high pressure and high stretch, only small pressure differences (SSI and WPA) occur by standing and walking resulting in low EF values. To evaluate the fluid shift into the interstitial space, we measured the effects of the position change on sub-bandage pressures during 12 min of standing with the leg under investigation in the non-weight bearing position. The subject is wearing the inelastic Coban 2 Lite compression system. As can be seen in Figure 5, the initial resting pressure is 29 mmHg (A). Next, the volunteer performed ten active maximal dorsal and plantar flexions. After the exercises, the pressure returned to 27 mmHg (B), a little lower than the initial resting pressure. Similar to what was observed in Figure 4; venous filling brings the pressure to 50 mmHg after 2.5 min (C). During the next 10 min of motionless stance, no change in pressure is observed (D: 50). This means that the bandage, which was applied at full stretch, manages to keep the forces that are generated by the dorsal and plantar flexions, inside the system, as well as the forces generated by the venous refilling. However, because the forces needed for the interstitial fluid shift into the lower leg (edema) are much lower than the gravitational forces responsible for venous refilling, it can be hypothesized that compression applied at full stretch also provides a sufficient counterforce for the forces responsible for the interstitial fluid shift, as they are not high enough to generate an additional increase of sub-bandage pressure (C=D).

This procedure was repeated after the application of the long-stretch compression bandage Biflex 16+ (Thuasne SA, Levallois Perret, France) with tension indicators for accuracy

of application; the tension is correct when the printed markers are square-shaped. The bandage was applied in a spica manner according to the included manufacturers instructions for use. The recording of this application is presented in Figure 6. The application provides a resting pressure of around 40 mmHg (A). After the exercises, the pressure is 41 mmHg (B). Venous filling brings the pressure to 45 mmHg after 2 min (C), a value that is still observed after 10 min of motionless stance (D). These observations, combined with the low amplitudes that are observed, demonstrate that the stretchability of the applied long stretch bandage absorbs a certain amount of the gravitational venous filling forces that are related to the position change and allows volume changes of the included leg. However, these measurements also reveal that the applied force is high enough to counteract the forces responsible for the fluid shift into the interstitial tissue. This means that also extensible materials can play a role in the prevention of edema.¹⁵

Conclusions

It can be concluded that the SSI gives us a rough estimate of the effectiveness of an applied system but interpretation is influenced by the muscle forces of the person being bandaged as well as the measured effects of venous filling and, because of that, the timing of the measurements. However, the well-established SSI in general is able to differentiate between elastic and inelastic materials¹⁶ and the suggested cut-off point of 10 by the ICC,¹⁷ represents a very simple quotient that may be taken as a rule of thumb and is measurable in patients without major disfigurements of the legs due to severe obesity or lymphoedema. Future guidelines on measuring the SSI should include that the final standing pressure value should be taken when a stable recording over a certain period is observed.

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The Mannequin-leg: a new instrument to assess stiffness of compression materials

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Abstract

Stiffness of compression material, which has major impact on the performance of the used product, has mainly been investigated by clinical *in vivo* experiments up to now. Experimental two-centre study has been performed in Japan and in Austria. Results are presented using a novel leg model, whose circumference can mechanically be extended by 1 cm. The change of the interface pressure measured under a compression device corresponds to its stiffness. Inelastic and multi-component bandages show stiffness values which are more than three times higher than those of elastic bandages and of compression stockings. There is a significant correlation between the stiffness values measured with the simple mannequin-leg and those obtained from extensometer measurements (Hohenstein-method) on one hand, and also with data on the human leg (static stiffness index) on the other hand. The average variation coefficient with repeated measurements is 5.4%. The absolute values differ with the used pressure probes. The newly developed mannequin-leg offers a simple method to measure and to compare the stiffness of compression stockings and bandages, including the combination of such devices.

Introduction

In the last years several experimental studies have clearly shown that stiffness is an important parameter determining the performance and efficiency of a compression product. In patients with chronic venous insufficiency higher stiffness is associated with a stronger effect concerning reduction of venous reflux,¹ improved venous pumping function^{2,3} and edema reduction.⁴ Measurements of the interface pressure of compression products on the leg in the lying and standing position allowed us to assess stiffness of a specific device *in vivo* and to correlate the so-called static stiffness index, which is the difference of standing minus lying pressure with the efficacy of the venous calf pump.^{5,6} Laboratory tests using dif-

ferent extensometers are used by compression hosiery manufacturers mainly to check the pressure range of the products in relation to the leg size. However, the relationship between stretch and force (the slope of the hysteresis curve), characterizing the elastic property of the product, is not declared to the consumer. The used methodologies (Hosy, Hatra, Instron, ITF, MST-Professional),⁷ are elaborate, which may be the reason why up to now the stiffness of a specific compression stocking is not declared by the producers. Also the air-filled drum device developed by R. Stolk⁸ is too sophisticated to be widely used.⁹ A report will be given on first experiences coming from Japan (M.H.) and from Europe (H.P.) achieved with a newly developed leg-model, specifically designed to assess stiffness in an easy manner.¹⁰

Materials and Methods

This report combines results obtained in the laboratory of the inventor in Japan (M.H.) with data measured in Austria (H.P.). Pressure was measured by air-filled transducers, 1 cm diameter, in Japan (air-pack type analyzer, Model AMI-3037[®], AMI Co., Tokyo, Japan), and by Picopress[®] probes, 4.5 cm diameter [Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy], in Austria. Following the definition in the European Committee for Standardization document¹¹ stiffness may be defined by the increase of the interface pressure of a compression device on the leg when the circumference increases by 1 cm. This induced Hirai and co-workers to develop an artificial model, the so-called mannequin-leg, whose circumference can be enlarged by 1 cm (Figure 1).¹⁰ Flat, air-filled pressure probes are attached to measuring points marked on the model (points B1 and C). (Point B1 on the human leg is characterized by the transition of the medial gastrocnemius muscle into the tendon; point C corresponds to a medial point at the level of the largest calf circumference). The pressure is registered immediately after application of the compression device and the model is enlarged by pushing down the lever three times. The difference between the highest-pressure increase after the third extension of the model and the following resting pressure is defined as the static stiffness index (SI) (Figure 2).

Results

Comparison compression stockings versus bandages

Compression stockings and elastic bandag-

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Contributions: MH, instrument (mannequin-leg) design, results providing; HP, personal experiences reporting, manuscript writing.

This work is dedicated to Dr. Masafumi Hirai who started the research but unfortunately passed away. Dr. Hugo Partsch concluded the project which is published in his honor and memory.

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es show significantly reduced stiffness values compared to inelastic bandages (Figure 3).¹⁰

As can be seen from Figure 4 compression stockings differ from multi-component bandages more concerning the stiffness than the exerted pressure. All stockings tested were in a pressure range between 10 and 40 mmHg at B1 (Picopress[®]), double stockings achieved pressures between 40 and 50 mmHg. Their stiffness (SI) did not exceed 10 mmHg. The tested bandages were in a comparable pressure range, but their stiffness values were all higher than 30 mmHg. Elastic tubes wrapped over by elastic bandages (T+E in Figure 4) showed SI values between 10 and 15 mmHg, which were slightly higher than the corresponding values of the stockings.

Reproducibility

Thirteen different compression stockings were applied three times to the mannequin leg and pressure and stiffness were measured. Figure 5 shows that the variation coefficients (VC) were small (3.9-5.4% in average), only applying double stockings over each other resulted in an increase of the VC to

more than 20%. This shows clearly that the main cause for the variability is the changeable pressure distribution along the leg by donning the stockings several times.

Correlation with other *in vitro* measuring devices

A comparison of stiffness values measured by the mannequin-leg and the Hohenstein method performed in Japan gave a significant correlation between the two methods¹⁰ (Figure 6).

Correlation with *in vivo* assessment of stiffness

Forty custom made, small sized compression stockings between compression classes I and III tested on the mannequin leg were applied to one and the same human leg (ankle circumference 22 cm) in which the pressure was measured in the lying and standing position at B1 by the same Picopress® probe, and the static stiffness index was calculated by subtracting lying pressure from standing pressure.⁵ The same procedure was performed by applying elastic and then an inelastic bandage over a class II stocking. Figure 7 shows an excellent correlation between the pressures measured at B1 at the mannequin leg and the corresponding measuring point on the human leg in the lying position ($r=0.91$). There was also a statistically significant correlation for the stiffness values ($r=0.75$).

Discussion

The clinical efficacy of compression devices depend mainly on the interface pressure and the stiffness of the product in use.¹⁴ For compression hosiery we rely on the pressure range in relation to the prescribed stocking-size given by the producers who, up to now, do not give us any information on the stiffness of their products. The pressure exerted by a bandage depends on the strength of application and the amount of layers. The stiffness of bandages is a rather complex parameter, relating mainly to the elasticity of the textile and to internal and external friction of the fibers. By adding several elastic layers over each other the final bandage is getting stiffer, mainly due to an increase of friction between the layers.¹² These characteristics of different types of bandages could only be elucidated by examinations performed on human legs during the last few years.^{13,14}

In vivo assessment of stiffness is based on the changes of interface pressure induced by changes of the circumference of the leg by standing up (*static stiffness index*)¹³ or by exercise (*dynamic stiffness index*).¹⁵ The preferred measuring point is B1 corresponding to the site

where the medial gastrocnemius muscle turns into the tendinous part⁶ because this leg segment shows the biggest increase of circumference by standing up and by walking.⁸ In addition at this point the gastrocnemius tendon will protrude by contraction of the muscle so that the radius at the corresponding leg segment will get smaller contributing to an increase of local pressure due to Laplace's law. It is very obvious that such changes of the leg configuration will vary between single individuals being less pronounced especially in pathological cases like lymphoedema, or lipodermatosclerosis compared to normal legs. This explains the high variability of the reported



Figure 1. It shows a picture of the model, which is commercially available (AMI Techno, Tokyo, Japan). The model, made of plastic material has an ankle circumference of 20.5 cm and a calf circumference of 34.5 cm. There is a lengthwise transversal cut, which can be extended medially and laterally by 5 mm by pushing down a lever so that the circumference of the model will increase by 1 cm at each level.



Figure 2. A ready made compression stocking, size small, achieves a pressure of 33 mmHg at the B1 point of the model. This pressure drops to 30 mmHg after stretching the model by 1 cm three times. SI=3 mmHg (Picopress® probe).

stiffness values, so that comparisons of compression devices by *in-vivo* testing only may be problematic.¹⁶ In contrast the mannequin leg offers a well-standardized procedure for comparing different compression products always under the same anatomical condition in a resting position and after stretch of the textile by an increase of the leg circumference by 1 cm. The dimension of the air-filled pressure probes and its deformation under a compression device has an important impact on the numeric outcome. This fact explains the differences between the results achieved with the AMI® transducer and the Picopress® device.

As a consequence one should be careful by

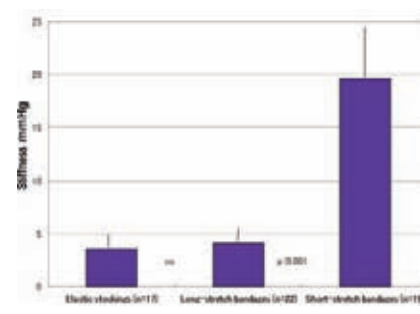


Figure 3. Comparison of stiffness values (mean+standard deviation) between elastic stockings (left), long stretch bandages (middle) and short stretch bandages (right), resting pressures 23-46 mmHg (AMI-3037®). The difference between elastic and inelastic material is significant ($P<0.001$).

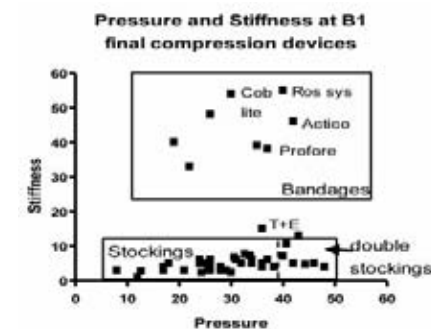


Figure 4. Characterization of several compression stockings and multi-component bandages concerning pressure (x-axis) and stiffness values (y-axis). The application of a second stocking over the first in 6 cases increases the stocking pressure to values over 40 mmHg. [T+E=tubular device (Tubulus®) + elastic bandage wrapped over]. All multi-component bandages (in the upper rectangle) showed stiffness indices over 30 mmHg (Picopress®).

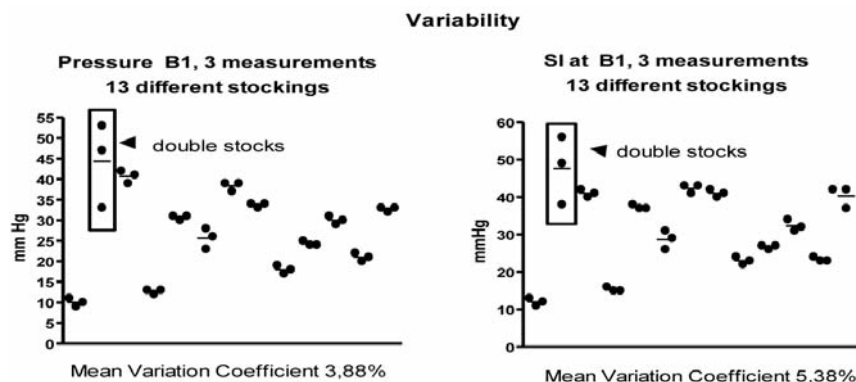


Figure 5. Measurement of pressure at B1 (left) and of stiffness (right) on the mannequin leg of 13 different compression stockings, three times repeated (Picopress® probe).

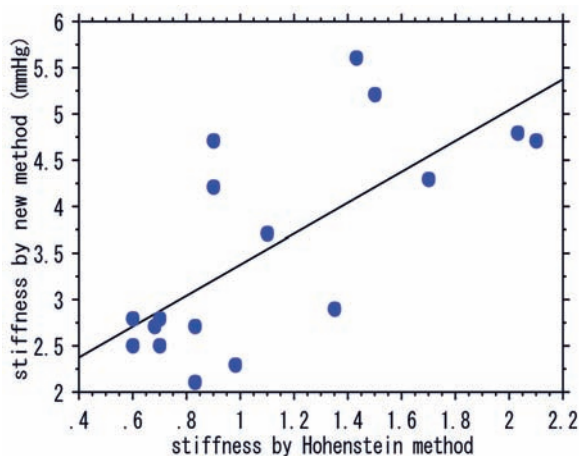


Figure 6. Correlation of stiffness measured by the Hohenstein method (x-axis) and by the mannequin-leg (y-axis) in 17 stockings (AMI-3037®).

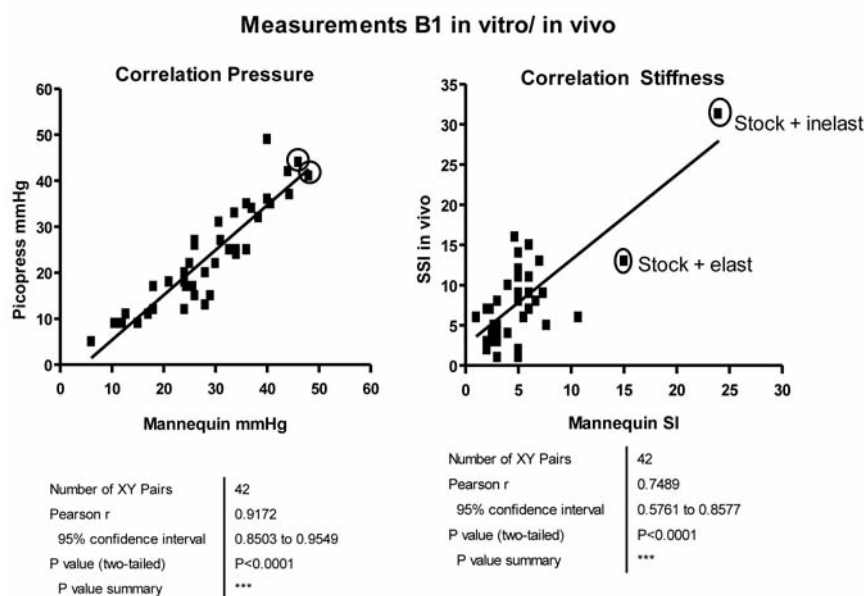


Figure 7. Correlation for pressure at B1 (left) and stiffness (right) between the Mannequin leg (x-axis) and a human leg (y-axis). Encircled are the values obtained after wrapping elastic and inelastic bandages over a class II stocking.

comparing absolute values. Based on the experiences by measuring the static stiffness index on the human leg it has been proposed to take the value of 10 as a reasonable borderline to differentiate elastic (<10) from inelastic material (>10).¹² This same cut-off could also be accepted for the mannequin-leg when a Picopress® sensor is used (Figure 4).

Using the AMI transducer® the cut-off value is lower and comes closer to the results of the tests performed with the Hohenstein-method which may be considered as the gold-standard method (Figure 6). However, in contrast to the Picopress® probe¹⁷ accuracy and variability of the AMI® probe has not yet been clearly established in clinical studies. Preliminary comparisons of custom-made stockings between mannequin- results using Picopress® and different kinds of extensometers (Hosy, Instron) showed also excellent correlations. Previous investigations had also shown a good correlation between pressure and stiffness values on human legs with extensometer data.¹⁸

Methodological flaws of the mannequin leg compared to the *in vivo* situation are the rigid consistency of the model leading to slightly higher pressure values than those measured over soft, yielding tissue and the relatively flat local radius at B1 which does not change when the model is extended. Another draw-back is the fact that up to now only one small sized model is available. Larger models or even forms containing a thigh part could be useful in order to obtain stiffness - data also from usual European sized and thigh high stockings. As shown in this report the obtained data will depend on the dimensions of the pressure probes so that comparisons of absolute data between will only be possible when the same kind of pressure monitoring system is used.

Conclusions

The presented concept of the extensible mannequin leg is a practically important step forward to assess the stiffness of different compression products and their combinations by a simple and reproducible technique.

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Terminology: resistance or stiffness for medical compression stockings?

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Abstract

Based on previous experimental work with medical compression stockings it is proposed to restrict the term *stiffness* to measurements on the human leg and rather to speak about *resistance* when it comes to characterize the elastic property of compression hosiery in the textile laboratory.

Introduction

Pressure and stiffness are the two items which characterize a medical compression stocking (MCS).¹⁻⁶ The meaning of *pressure* is easy to understand for a health care professional. The correct meaning of *stiffness* is less easy to explain, especially since this word can relate to two different concepts.

Laboratory pressure and interface pressure: definition

Pressure is defined as a force per unit of surface area, for example Newton/m² or cN/cm². For many reasons medical compression manufacturers and doctors prefer using mmHg.^{7,8}

Two different pressures should be differentiated: laboratory and in vivo pressures

The *laboratory (lab)* pressure is determined by manufacturers using a dynamometer, a special device made only for these measurements (Figures 1 and 2).⁸ Several brands of dynamometers exist and all give measurements in cN/cm² (force/cm²) easily transformed in mmHg.^{8,9}

The stocking to be measured is placed on a model leg so as to locate and mark the different points along the leg (B, C, D, etc.). The B point (ankle region of the stocking) is marked first and then the B-segment is

placed in the dynamometer jaws. Force is measured during stretch and also in the relaxed phase. Results are printed on a rolling chart.

Hysteresis curves obtained: on the x-axis the circumference of the MCS is plotted in centimeter (which simulates the leg's perimeter) and on the y-axis the corresponding pressure in mmHg (Figure 3).

Therefore it is easy to identify the MCS pressure depending on its size. This permits to declare the *lab* pressure in mmHg (or the *compression class*) on the box of the garment.

The *pressure on the human leg* is measured in clinical studies (or due to personal interest) by using special pressure probes as Kikuhime (TT MediTrade, Sore, Denmark) or Picopress® [(Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy)]. The sensor is placed on the B1 point where the medial gastrocnemius muscle turns into its tendinous part and the MCS is applied.¹⁰ The pressure measured on the leg in mmHg is called the *interface pressure*.¹⁻⁵

This method allows the pressure measurement at several levels along a leg.

Resistance and stiffness: definition

In the European Prestandard for medical compression hosiery stiffness is defined as *the increase in compression per centimeter increase in the circumference of the leg*.⁶

Two different types of Stiffness exist: the stiffness on the human leg following the above definition and the corresponding parameter derived from the hysteresis curve.

In fact the same word is used in two situations: for the *lab* measurement of stiffness used by the manufacturers and the stiffness measurements on human legs made by investigators in the course of their assessment of the quality of MCS. Such a distinction should be made by presenters and authors when discussing this topic.

Therefore in an oral presentation or publication there may be some confusion: Do the author mean *lab* or *in vivo* stiffness?

Proposition

Pressure is measured in two different situations: *in lab* and *in vivo*. The same two situations exist for the measurement of stiffness. The word used by industry to characterize the hardness or rigidity of numerous materials, for example in physics or aeronautics, is the word *resistance*. The authors and some International Compression Club (ICC) members propose that this word should be used in our Medical Compression vocabulary which

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Contributions: AC-T, manuscript writing; J-PB, J-F, ideas and experience providing.

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means *inelasticity*.¹¹ Perhaps words similar to resistance or resistance coefficient could be used such as hardness, rigidity, firmness, inelasticity and others.

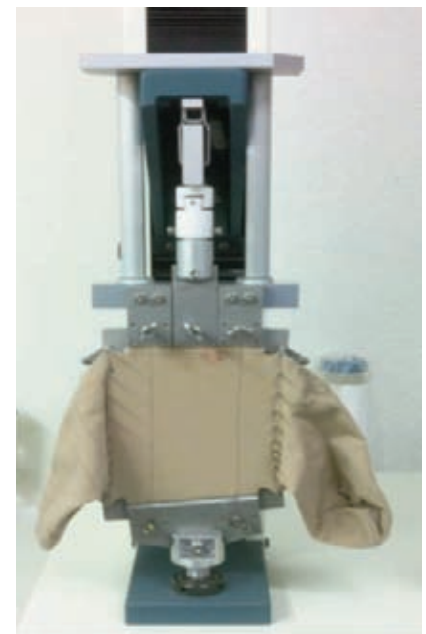


Figure 1. The IFTH dynamometer (Paris, France).

Definition and measurement

The *resistance* (laboratory measurement)

The authors suggest the definition of resistance in medical compression as the stiffness measurement performed by a dynamometer. The value should be declared on the packaging for individual compression garments. At present this value is not shown, perhaps to avoid confusion or questions from interested users. The resistance coefficient (RC) number will reflect the *hysteresis* curve at the MCS size point. In the curve shown in Figure 3 the RC is ± 1 mmHg/cm. This means that this MCS is more rigid, firm or resistant than a 0.5 mmHg/cm and less resistant than a 2 mmHg/cm.



Figure 2. The HOSY dynamometer (Germany).

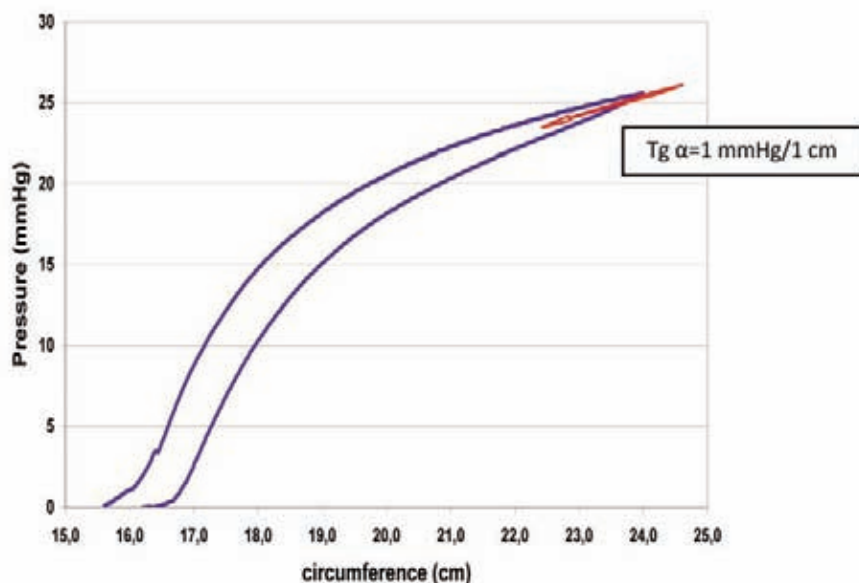


Figure 3. Hysteresis curve of a 25 mmHg medical compression stocking (MCS) with a 23-24 cm size. The resistance coefficient equals the tangent at the MCS size point. On this hysteresis curve the pressure increases in 1 mmHg between 23 and 24 cm. So the resistance coefficient equals 1 mmHg on 1 cm, equals 1.

The *stiffness* (measurement on the leg)

At the B1 point two measurements of the interface pressure are done during two successive different positions of the leg, at rest and during a significant muscle contraction (*e.g.* dorsiflexion, standing). This will create two different but similar circumferences, one maximum the other minimum. The difference between the two values characterizes the stiffness of the MCS.^{1,11} The properties of any MCS can therefore be more completely described using the following measurements: the pressure and the RC measured in the lab, and interface pressure and stiffness measured on the leg.

Arguments to differentiate resistance of a medical compression stocking and its stiffness

In summary arguments to differentiate resistance of a MCS and its stiffness are: i) the two measured points are different: B point for resistance and B1 point for stiffness; ii) the two values cannot be compared (for the moment):

- the resistance results are obtained in mmHg/cm corresponding to the steepness of hysteresis curves using a dynamometer;
- for stiffness only pressure increase is measured as a routine but not the change of leg circumference.

To consider these parameters could yield much useful information: i) MCS characteris-

tics should be completed and recorded on the box; ii) this would allow a useful comparison between different brands of MCS.

Conclusions

To avoid confusions it could be extremely useful if ICC members, companies and doctors agree with this proposed terminology: *resistance* instead of stiffness measured *in lab* and *stiffness* measured *on the leg*.

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Where should stiffness be measured *in vivo*?

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Abstract

Three points in the medial aspect of the leg are routinely used to measure the interface pressure of a compression: the C point, at the largest circumference of the calf; the B point, at the smallest circumference of the leg; the *anatomical* B1 point, at the apex of the gastrocnemius muscle and the *manufacturer's* B1 point, computed in the midline of the line joining the B point to the C point). The *anatomical* B1 point is the most reliable point from a practical point of view, and is easier to use. The underlying anatomy is the Soleus muscle. Stiffness at the *anatomical* B1 point seems adequate sufficient to assess stiffness of a medical device *in vivo*.

Introduction

In laboratory the stiffness of a medical compression device is defined as the pressure change (in mmHg) that occurs with an increase in circumference of one centimeter ($\Delta P/\Delta C$). *In vivo*, this is very difficult to measure. For this reason the static stiffness index (SSI) proposed by Partsch *et al.*¹ is used as a rough estimate of stiffness. By definition, SSI is calculated by subtracting the interface pressure (in mmHg) in the lying position from the interface pressure (in mmHg) in standing position. Compression devices are defined as *stiff* if SSI is 10 mmHg or more. Another stiffness index has also been proposed: the dynamic or dorsiflexion stiffness index (DSI) calculated by subtracting the diastolic from the systolic interface pressure (in mmHg) during dorsiflexion, while lying down.² Although slightly higher, the values of the DSI are similar to those of the SSI.

Anatomical review of the venous muscular pumps

The muscular pumps of the lower limb represent the peripheral heart of the venous system. They push blood upward against gravity, so that downward reflux can be prevented by

normally functioning valves. The main muscular pump of the lower limb is the calf pump. It is divided into two parts: i) the soleus muscle pump which works at the leg level. The soleal veins are divided into two parts, lateral and medial. The lateral veins are bigger and drain, vertically, into the fibular veins. The smaller medial veins drain horizontally into the posterior tibial veins; ii) the gastrocnemius muscle pump which works at the popliteal level. The medial part of the muscle and the medial gastrocnemius veins are very important. These veins originate by the gastrocnemius perforators, connecting end-to-end at the apex of the calf. Two or three big veins form a network inside the muscle, which join in a unique collector ending in the popliteal vein.

The main reference points of the leg

Four points in the medial aspect of the leg are routinely used to measure the interface pressure of a compression device,³ all situated at the medial aspect of the leg (Figure 1). These are: i) the C point (at the largest circumference of the calf); ii) the B point (at the smallest circumference of the leg); iii) the *anatomical* B1 point (B1a at the apex of the gastrocnemius muscle); iv) lastly, the *manufacturer's* B1 point (B1m in the midline of the line joining the B point to the C point).

Figure 2 shows a realistic 3D anatomical model, reconstructed by a multi-slice computed tomography (MSCT). This medial view demonstrates that, below the apex of the medial gastrocnemius, the Soleus muscle is the main muscle of the underlying anatomy. This muscle represents the deeper part of the triseps suralis (calf pump muscle).

Figure 3 shows that the *anatomical* B1 point which is easily found by a simple clinical exam during the muscular contraction of the calf.

Objectives

The aims of this studies were: i) to verify if these reference points are reliable; ii) to assess their variability; iii) to assess the optimal site for calculating stiffness: at the anatomical B1 point, the C point, or both; iv) to compare stiffness with two different short stretch bandages.

Materials and Methods

We performed three different studies: a clinical study on 22 healthy subjects to localize reference points, a radiological computed tomography venography (CTV) study with MSCT was performed on 19 patients to assess the anatomical landmarks of the leg, and a study assessing stiffness by two compression devices applied on ten legs.

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Clinical study to localize reference points: measurements of the legs of 22 healthy subjects (17 women and five men) were done in the *standing position*. The evaluations included the measure of the distance of the B and C points from the ground, the distances of the *anatomical* B1 and *manufacturer's* B1 points from the ground, and the height of the subject.

*Study by CT venography to assess the anatomical landmarks of the leg:*⁴ MSCT scanning was performed with a Siemens SOMATOM® Definition Flash 64 slice CT scanner, with contrast injection into a dorsal foot vein. The CT parameters were acquisition from feet to head, 120 KV, and 150 mAs. Reconstruction parameters: slice width 1 mm, slice increment 0.75, matrix 512×512, zoom factor 1.7. Post processing was performed with the volume rendering technique by OsiriX 64-bit, version 5 (Pixmeo company, www.osirix.foundation.com) Nineteen patients (thirteen women and six men) were investigated in the *lying position* before varicose vein surgery. Measurements were made using the OsiriX software on the 3D reconstructed images. Localization of the C, B, B1a, and B1m points were made and the distances between the points were computed, as well. The length of the tibia was considered to be equal to the distance from knee joint to the apex of the medial malleolus.

Clinical study to assess the stiffness of two compression devices: the stiffness of two compression devices was assessed in 23 healthy legs. Rosidal KTM (Lohmann & Rauscher), was applied to eleven legs and CobanTM2 (3MTM) to twelve. Rosidal KTM (Lohmann & Rauscher) is a short stretch bandage (5 m × 10 cm). The bandage was applied in a circular way with full

stretch. CobanTM2 is a two layer bandage consisting in a padding layer (10 cm × 2.7 m) and a short stretch bandage (10 cm × 4.7 m). The two bandages were applied according to the recommendations of the manufacturer. Each bandage being overlapped by 65%. Bandages were applied so that a target pressure of 40 mmHg at the *anatomical* B1 and C points could be achieved. The interface pressure was measured with a Kikuhime[®] device (Makoto TAKAHASHI and Sanae, Biomedical Systems Engineering, Graduate School of Engineering, Hokkaido University, Japan), using the small probe, in the lying position, at rest and during muscular contraction, and in the standing position (Figures 4 and 5).

Statistical methods

We used StatView, version 5 (Copyright 1998 SAS institute inc., USA), to compute the mean and standard deviation (σ) of the samples and to determine the median for interface pressures.

Results

Clinical measurement

The height from the ground was measured for the C point (at the largest circumference of the calf), the B1a point (at the apex of the gastrocnemius muscle), and the B1m point (in the midline of the line joining the B point to the C point), and distances between these points were all measured on 22 healthy subjects. Results are shown in Table 1. The mean distance B1a-C was 5.66 cm [standard deviation (SD) 1.76] and the mean distance B1a-m was 3.95 cm (SD 1.87). There was no correlation between the distances observed and the height of the subject.

Computed tomography venography anatomical measurement

The same parameters were measured by CTV on 19 patients before varicose vein surgery. By CTV, the average distance from B1a to

Reference points of the leg

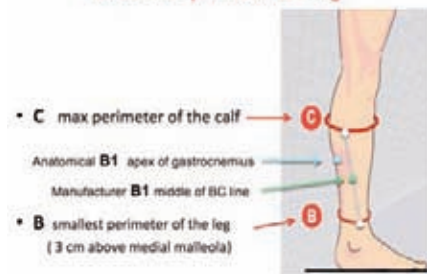


Figure 1. The main reference points of the leg commonly used to measure the interface pressure of a compression device.



Figure 2. Study of the anatomical landmarks of the reference points by 3D reconstruction with multi-slice computed tomography. Arrow shows the apex of the medial gastrocnemius muscle (B1a). MG, medial gastrocnemius muscle; Sol, soleus muscle; B1m, half distance measured between C and B.

Table 1. Values of the heights of B1a, B1m, C points above the ground. Distance between B1m, B1a and C points on 22 healthy subjects (in centimeters, single values, means±standard deviation).

B1m	Height from ground		Distance between points		
	B1a	C	B1 a-m	B1a-C	
19	23	30	4	7	
22	26	32	4	6	
18	22	27	4	5	
19	23	30	4	7	
19	24	29	5	5	
20	22	28	2	6	
22	27	32	5	5	
22	25.5	30	4	4.5	
20	26	29	6	3	
21	28	31	7	3	
16	19.5	26	4	6.5	
20	28	31	8	3	
19	22.5	27.5	4	5	
21	21	30	0	9	
21	24.5	30	4	5.5	
19	22	28	3	6	
20	23.5	30	4	6.5	
24	29	34.5	5	5.5	
23	23	33	0	10	
25	28	32	3	4	
22	27.5	32.5	6	5	
22	26	33	4	7	
Mean SD	20.64±2.06	24.59±2.65	30.25±2.16	3.95±1.87	5.66±1.76

SD, standard deviation.



Figure 3. Clinical assessment of the B1 point at the apex of the calf.

B1m was 3.6 cm (SD 1.63), average distance from B1a to C was 9.3 cm (SD 1.69). There was a significant correlation with tibial length ($r=0.4$, Table 2).

A comparison between the two measurement methods shows: i) there was a significant difference in the distance from the C point to the ground between the two measurement methods. The C point required repeated measurements and so appears to be difficult to locate clinically; ii) the *manufacturer's* B1 point is in the middle of the BC line and is not easy to locate; iii) the *anatomical* B1 point is the easiest to identify in clinical practice because it is located at the apex of the medial gastrocnemius muscle. As a result, it is easy to assess clinically and, if necessary, to verify by ultrasound. It is also the most reproducible; iv) the distance between the *anatomical* B1 and the *manufacturer's* B1 points are closer than the *anatomical* B1 and C points according to either calculation method.

Calculation of stiffness

Calculation of the median stiffness index on 11 legs with a Rosidal KTM (Lohmann & Rauscher, Table 3) shows that the SSI and the DSI were very similar at the B1a and C points; this is considered *stiff*. Median SSI was 14 mmHg at B1 vs 19 mmHg at C. Median DFSI was 29 mmHg at B1 vs 31 mmHg at C. Stiffness index measurement on 12 legs with a CobanTM2 (3MTM) (Table 4) also shows that SSI and DSI were very close at the B1a and C points; they are also considered *stiff*. Median SSI was 13.7 mmHg at B1 vs 14.3 mmHg at C. Median DSI was 26 mmHg at B1 vs 25.6 mmHg at C. Wherever the calculation of the stiffness is performed, the values at the C point and the *anatomical* B1 points were very close for both compression devices.

Table 2. Distances between the C point and B1a, B and B1m points. Distance B1a to B1m and the tibial length measured in centimeters measured on the 3D model of 19 legs prior to varicose vein surgery with OsiriX software (Pixmeo company, www.osirix.foundation.com).

Tibial length	Distance between points			
	C-B1a	C-B	C-B1m	B1a-m
33	9	22	11	2
46	13	36	18	5
46	12.8	34.4	17.2	4.4
34	8.3	22.7	11.35	3.05
36	9	23.2	11.6	2.6
39	10.7	24.8	12.4	1.7
38	7.8	21.3	10.65	2.85
37	10.4	23	11.5	1.1
39	9.4	27	13.5	4.1
37	8.5	25.4	12.7	4.2
38	8.5	26	13	4.5
35	7.1	25.7	12.85	5.75
36	10.8	24.4	12.2	1.4
34.6	7.5	20.8	10.4	2.9
43.6	8.3	26	13	4.7
32.8	7.3	19.5	9.75	2.45
39	9	31	15.5	6.5
45.6	8.2	29	14.5	6.3
40	10.2	25.2	12.6	2.4
Average	38.4	9.3	25.7	12.8
SD	4.21	1.69	4.37	2.18

SD, standard deviation.

Table 3. Interface pressure (mmHg) at B1 and C points under a Rosidal K (Lohman & Rauscher) bandage (11 legs).

	B1 point			C point		
	Rest	Contr	Stand	Rest	Contr	Stand
Average	41.4	74.5	58.3	36	61.5	51.5
SD	4.4	15	11.4	9.4	24	14.3
Median	41	70	55	35	67	54

Rest, at rest; Contr, with dorsiflexion; Stand, standing; SD, standard deviation.

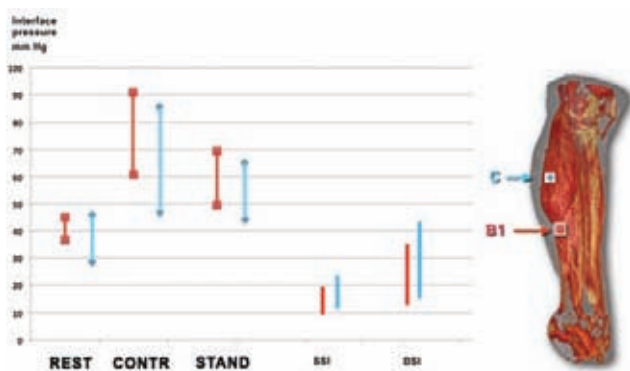


Figure 4. Pressures at rest, with dorsiflexions, during standing and stiffness indices under a Rosidal K (Lohman & Rauscher) on 11 legs. Ranges of 95% confidence interval. Rest, at rest; Contr, with dorsiflexion; Stand, standing; SSI, static stiffness index; DSI, dorsiflexion stiffness index.

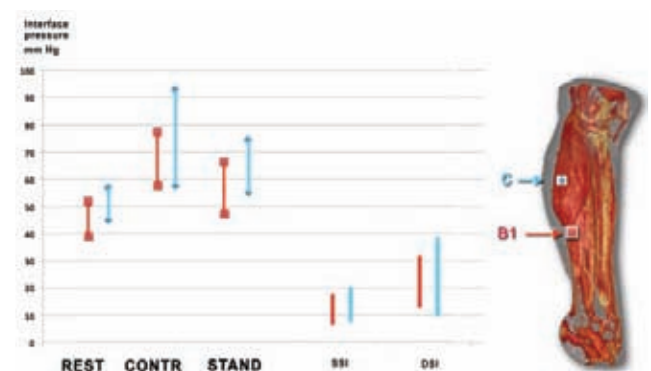


Figure 5. Pressures at rest, with dorsiflexions, during standing and stiffness indices under CobanTM2 (3MTM) on 12 legs. Ranges of 95% confidence interval. Rest, at rest; Contr, with dorsiflexion; Stand, standing; SSI, static stiffness index; DSI, dorsiflexion stiffness index.

Table 4. Interface pressure (mmHg) in B1 and C points under a Coban™2 bandage (12 legs).

	Rest	B1 point Contr	Stand	Rest	C point Contr	Stand
Average	43.3	70.9	57.6	43.9	68.8	58.4
SD	5.4	13.1	10.2	10.8	21.8	13.8
Median	42	68	55.7	45.7	71.3	60

Rest, at rest; Contr, with dorsiflexion; Stand, standing; SD, standard deviation.

Discussion

The distance between the C and *anatomical* B1 points was found to be significantly different by clinical and CT measurement (average 9.3 *vs* 5.6 cm; $P < 0.1$). The possible explanation for this result could be the different position of the subjects, supine when submitted to CT and standing during the clinical examination. In fact, the C point varies according to positioning due to isometric contraction, lying or standing.

Conclusions

The C point is difficult to locate in practice. The *anatomical* B1 point is the most reliable point from a practical point of view, and is easier to use. The underlying anatomy is the Soleus muscle.

Stiffness at the *anatomical* B1 point seems adequate sufficient to assess stiffness of a medical device *in vivo*.

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Elasticity, hysteresis and stiffness: the magic triangle

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Abstract

The use of external compression on the human leg is still a cornerstone in the treatment of venous diseases. The most important question to answer is: how will compression perform on the human leg?

Introduction

First of all the applied compression generated by a device as a medical elastic compression stocking (MECS), bandage or whatever is used, exerts its pressure on the surface of the leg, *e.g.* the skin. Normally this is expressed as interface pressure and the shape of the leg pressure differences are depending on Laplace law. Second step is the transmission of this interface pressure into the tissue as the subcutaneous fat, muscles, and veins. This process depends on Pascal law. The third item is the pressure changes during walking depending on the circumference changes of the leg (Laplace law) and, fourth, the durability of the pressure in time, which depends on the quality of the device.

Brief Report

For a long time research was focused on interface pressure, usually under static conditions and pressure course in time.¹

The quality of compression capacity of a given device is depending on the characteristics of the used materials. All used materials for medical compression therapy have three major characteristics: i) *elasticity*, which is the capacity to return to the original shape and size after the material has been stretched. The pressure/elasticity relation under static condition on the leg is influenced by Laplace law; ii) *stiffness or elasticity coefficient*; this term is defined as the increase in pressure after a certain given elongation. For MECS the Centre Européenne de Normalisation uses the increase of the normal tension at the B1 level with 1 cm expressed in hpa. Stiffness is depending on elasticity in static condition; iii) *hysteresis*, which reflects the inborn resistance of material as result of internal friction hysteresis, can be visualized in a force/elongation curve (Figure 1A). By increasing the speed to perform such a fair elongation curve the angle towards the x-axis will move. So hysteresis is influenced by the speed of movements (Figure 1B).²

These three characteristics works all together in compression therapy (Figure 2). As normally compression is only expressed as interface pressure we are not informed about the contribution of stiffness, hysteresis and changes during walking. In fact we only know the resting pressure which is far away from the reality of a walking patient with a compression device as a MECS. To overcome this problem we defined the dynamic stiffness index

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(DSI).³ Analyzing the differences between static and dynamic compression it turns out that hysteresis is the most important factor. Our triangle can be changed from static (Figure 2) into dynamic (Figure 3) where hysteresis plays the main role.

As pressure diminishes in time static compression will become ineffective during the day. However DSI remains in the same time (Figure 4).⁴ For MECS, DSI is independent from compression pressure (class) and manufacturing differences as round- and flat knitted.⁵ The clinical implication of DSI is that low

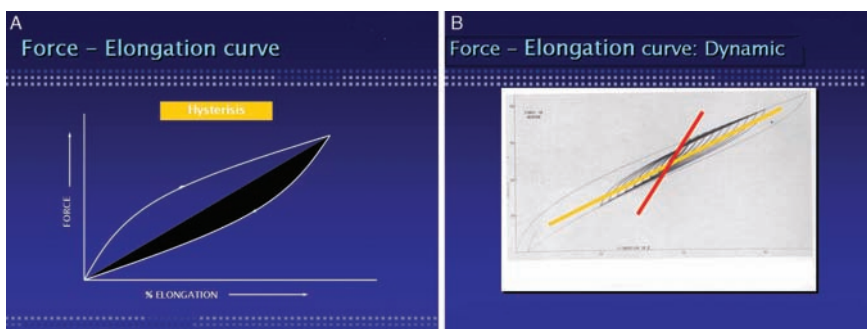


Figure 1. A) *Hysteresis curve* of an elastic fabric: X-axis represents stretch, y-axis the applied force; B) force elongation curve of elastic knitwear. The elongation increments are progressively made larger. The steepness of the initially small cycle is diminished with the increased amplitude (modified from Stolk and Salz, 1988² with permission).



Figure 2. The magic triangle, static.

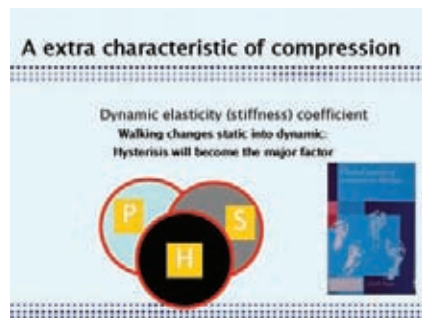


Figure 3. Dynamic relation between pressure, stiffness and hysteresis.

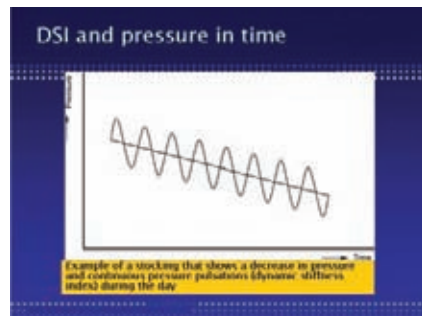


Figure 4. In spite of decreasing pressure of a stocking, stiffness is maintained (modified from Van der Wegen *et al.*, 2009⁴ with permission).

compression and high DSI can be very efficient for ambulatory patients and have the same effect as high compression with low DSI. To combine compression and DSI the physician can prescribe the optimal device, *e.g.* MECS for the patient. As logical consequence the higher changes of interface pressure during walking will be transferred to the tissue resulting in a high massage effect and by this the effects of Laplace and Pascal law comes together.

Conclusions

In order to optimize venous function with compression therapy, three key-points should be considered: i) *hysteresis*, mainly influenced by the type of knitwear determines the efficacy of compression force elongation relation; ii) the quality of compression (Laplace law) defined by DSI; iii) the final effect of compression (Pascal law) defined by the composition of the subcutaneous tissue. For daily practice: DSI is the most important characteristic of compression.

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Elastic or inelastic compression? Reported evidence from clinical trials

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Abstract

Evidence for compression therapy found in literature mainly comes from clinical studies, preferably randomized controlled trials (RCTs) and systematic reviews (SR), which are often complemented by research data, expert opinion or by data from technology assessment or regularization documents. Differences between materials/methods/intervention in clinical trials can be partly explained by variability in focus, or due to country specific issues. Results from RCTs and SRs, and the interpretation of these results may vary depending on definitions used and the adequacy of data. In the first place, the baseline comparability of study groups depends very much on the accuracy of the diagnosis. Secondly, results will very much depend on the intervention used, whether compression is used alone, or whether it is part of a more complex management like decongestive treatment including other physical methods, surgery, or pharmacological treatment. A third consideration relates to the outcome parameters, the methods used to measure them, and the length of follow-up. Properties of compression materials have been redefined and standardized, and new insights in the physiological effects of compression treatment have shaken existing myths and dogmas in this field. RCTs using *out-dated* definitions and classifications of materials have led to systematic reviews and recommendations based on the same misunderstanding; it is left to the alert reader to interpret their results with caution.

Introduction

Evidence for compression therapy found in literature mainly comes from clinical studies, preferably randomized controlled trials (RCTs) and systematic reviews (SR), which are often complemented by research data, expert opinion or by data from technology assessment or regularization documents [European Committee for Standardization (CEN), Reichs-Ausschuss für Lieferbedingungen Gütegemeinschaft (RAL-GZG), British Standards Institution (BSI)].¹⁻³

Grading and definition of the level of the selected evidence vary between publications, and this is usually described in the introduction of the manuscript. Either there will be some objective ranking of the quality/reliability of trials and evidence, or the recommendations combine objective ranking of the evidence with other considerations for practice, like the GRADE tool introduced by the American College of Chest Physicians.⁴

There aren't too many new relevant good quality RCTs each year, so there will not be too much difference between the source documents for systematic reviews, and thus most recommendation documents on compression therapy look very much alike indeed.

Variability in trials' setup

Differences between materials/methods/intervention in clinical trials can be partly explained by variability in focus, or due to country specific issues.

Focus may be differently accentuated *e.g.* depending on *authorship* and target users groups (nurses, versus medical specialties, versus true multidisciplinary groups including patients' representatives). Also, the scope may vary, depending on whether the intervention is purely conservative (compression treatment, education, etc.) versus that the consensus includes additional recommendations on medical/surgical interventions for etiological management and follow-up of the underlying disease (venous, lymphatic, thrombosis, etc.). Of course, the scope will also depend on the specific selected indication or *goal setting*: the trial or his outcomes may be aiming at getting reimbursement from health care institutions (like those from the *Haute Autorité de santé* in France, the Dutch Institute for Healthcare Improvement in the Netherlands), or aiming at setting educational endpoints, or it is meant for implementation of the uniform application of materials and techniques throughout the country (like in the Netherlands, or the 4-layer bandaging in the UK). Country specific issues may be the selection of bandages/stocking types according to availability or local preferences (stockings preferred above bandages in France? inelastic bandages preferred in the *older* guidelines in some European countries). National guidelines/recommendations on compression treatment in specific indications exist in countries like France, the Netherlands, UK, Ireland, Italy, Germany, Canada, Australia, New Zealand, Belgium, and many others.

National and International Societies have issued consensus documents or *best practice documents* regarding compression therapy, and this will most probably influence the choice of intervention by investigators.

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Variability in trial outcomes and recommendations

Results from RCTs and SRs, and the interpretation of these results may vary depending on definitions used and the adequacy of data. In the first place, the baseline comparability of study groups depends very much on the accuracy of the diagnosis. In still too many trials and reviews the *venous* ulcer etiology is based on a *normal* ankle brachial pressure index in a patient with a leg ulcer clinically compatible with a venous ulcer. Not only can the diagnosis (based only on clinical examination) be erroneous, it can underestimate the severity and extent of the problem and any relevant co-morbidity. The accuracy of a venous etiological diagnosis increases with the addition of imaging and invasive testing in chronic venous disorders. The American Venous Forum recommends duplex scanning as the first diagnostic test to all patients with suspected chronic venous obstruction or valvular incompetence.

Secondly, results will very much depend on the intervention used, be it compression alone (on top of dressing choice), or complex decongestive treatment including other physical methods [physical therapy, intermittent pneumatic compression (IPC)], or a combination of treatments including surgery, or pharmacological treatment. In the *Materials and Methods* paragraph of published trials and studies, description of the type of compression treatment should clearly state specific details, such as: what is the definition and classification

used for compression materials (bandages, stockings), is the applied pressure or stiffness measured *in vivo*, is compression strength described in (country specific) compression classes or in mmHg, are the bandages and stockings named and described so the reader can agree or not with the label used for compression materials (*e.g.* definitions like in the BSI, or definitions like inelastic, elastic, short stretch, long stretch, superposition of layers, etc.). A third consideration relates to the outcome parameters, the methods used to measure them, and the length of follow-up.

Interpretation of the results and the recommendations issued from it, are very much dependent on the above listed issues and insights, which themselves have been the topic of several recent consensus documents.⁵⁻⁷

Evidence for the effectiveness of compression therapy

A comprehensive review of evidence regarding effectiveness of compression therapy in several venous indications following the Clinical, Etiology, Anatomy, Pathophysiology (CEAP) classification and scoring system, and in lymphoedema can be found in the Consensus document published by the International Compression Club (ICC) in

2008.⁸ These indications are listed in Table 1 and include clinical stages of venous disease, treatment following phlebological interventions, venous thrombosis and lymphoedema.

The compression devices used in the trials for these indications include bandages, stockings, *ortheses* [like Circaid™ (San Diego, CA, USA), tubular elastic cotton *sleeves* like Tubigrip™ (Mölnycke Health Care, Gothenburg, Sweden), Tubulcus™ (INNOTHERA CH S.A. Service Zentrum Europa, Saint Blaise, Switzerland)], and IPC. Not all indications have been adequately studied regarding effectiveness of compression treatment, partially due to the fact that measurement outcomes are not always easily defined or assessed, and that they will be dictated by the indication at study. In this Table the references get a GRADE-label for the recommendation (*e.g.* 1B, 1A), and the insertion of weighted/graded references under a specific column head is deducted from the original classes mentioned on the respective documents. Also, the pressure values are rounded to simplified ranges. Reason for this is the known discordance between several country specific classifications of pressure range for stockings, and variations in definition of expected pressure under bandages when applied according to the manufacturers' instructions. This Table does not distinguish between elastic or inelastic materials. In most trials, measurement of the delivered pressure

was not measured *in vivo*, neither was the stiffness index. Duration of follow-up in RCTs is understandably limited, variable, and not always representative for the selected disease progression; thus in some indications the deducted recommendation of duration of treatment are decided by consensus or by expert opinion. An example to illustrate this fact is compression therapy in venous disease C4a, C4b, C5. Experimental data exist, but *Clinical Trial* data are lacking; Class III medical compression stockings said to deliver 30-40 mmHg have been shown to reduce the area of lipodermatosclerosis (LDS) in patients with healed venous ulcers.⁹ Accordingly it is also considered to improve areas of atrophie blanche and to reduce the edema and induration in the leg associated with these conditions. There are experimental data supporting effectiveness of distinct levels of compression regarding different aspects of LDS: reduction of edema, eczema, iron deposition, area of LDS, inflammation and pain, but no RCT's have been found. Clinical trials evaluating compression treatment specifically in lipodermatosclerosis are rare, presumably due to the many possible outcome parameters to choose from, of which validation is not established for the specific indication. Progression to ulceration, and prevention of this by the specific compression device is difficult to predict and so it is hard to calculate the power needed to demonstrate effectiveness.

Table 1. Indications for compression treatment. Reported efficacy of compression therapy stockings, bandages and intermittent pneumatic compression by randomized controlled trials and meta-analyses in patients with chronic venous disorders (Clinical, Etiology, Anatomy, Pathophysiology classification), venous thromboembolism and lymphedema. Only strong grades of recommendations are indicated: 1A and 1B. Adapted from Partsch *et al.*, 2008.⁸

Indications CEAP	Compression stockings			Bandages	IPC
	Compression pressure in mmHg				
	10-20 mmHg	20-30 mmHg	30-40 mmHg		
C0s, C1s	1B	-	-	-	-
C1 after sclero	-	1B	-	-	-
C2a,s	-	-	-	-	-
C2s pregnancy	1B	1B	-	-	-
C3 prevention	1B	-	-	-	-
C3 therapy	-	-	-	-	-
C4b	-	-	1B	-	-
C5	-	-	1A	-	-
C6	-	-	1B	1A	-
After procedures	-	-	1B	1B	-
VTE prevention therapy	-	-	-	-	-
	1A	-	-	-	1A
	-	1B	-	1B	-
PTS prevention therapy	-	-	-	-	-
	-	-	1A	-	-
	-	-	-	-	1B
Lymphedema therapy	-	-	-	-	-
	-	-	-	1B	1B

CEAP, Clinical, Etiology, Anatomy, Pathophysiology classification; IPC, intermittent pneumatic compression; VTE, venous thromboembolism; PTS, post-thrombotic syndrome.

Indications define the measured outcomes in clinical trials for compression treatment in venous disease, and unfortunately, there is hardly any objective standard assessment method for most outcome parameters in the clinical classes preceding an ulcer. This is one of the reasons why clinical trials are hard to find in these indications. Another explanation is that clinical progression and thus effectiveness of compression is difficult to predict during the relatively short time laps of a trial.

In the early stages of venous disease, like C1 and C2, subjective symptoms are not always present, they are not always specific nor diagnostic, and clinical progression is unlikely to be influenced by compression treatment of a trial duration. Side-effects of compression may be considered as secondary outcome, but then these would not be correlated to the clinical stage of disease. For venous edema C3, symptoms and signs may be measured although there are many different ways to do this. Several trials have demonstrated edema reduction with the use of bandages and stockings, but have not been withheld in the abovementioned publication (Table 1).⁸ As mentioned in Table 1, compression treatment has been positively evaluated in C5 for the prevention of ulcer recurrence, as compared to surgery. Most clinical trials have been performed on C6, venous ulceration, evaluating wound healing as a primary outcome parameter. This is an objectively measurable outcome, and compression materials or application methods can be compared for effectiveness. Prevention of recurrence has been studied as well, as mentioned earlier. Disease specific quality of life issues have also been evaluated, in contrast to resolution of skin changes for which no clinical trial could be found. The problem here is that dosimetry and characteristics of the compression therapy are debatable, due to outdated or confusing definitions and classification of bandages or stockings. Indeed, new insights in the physiological effects of compression treatment and updated consensus documents invite us to re-interpret older trial data. This fact relates to the intervention itself. Another consideration is that methodology of selected clinical trials fulfils *historical* quality requirements. But expectations and quality criteria become more stringent over the years (the rules of the game change while playing). Also, good trial-methods do not necessarily guarantee a correct diagnosis or scoring/grading of the clinical disease at study. This will of course apply to the systematic reviews or guidelines and consensus documents derived from these trials. That fact can be named the *inherent tragedy* of initiatives like the Cochrane database and many other *institutions gathering evidence and knowledge*: a RCT perfectly meeting today's strict requirements may be outdated and rejected in a later systematic review as soon as new insights change the rules.

New insights in compression treatment

Interpretation of the trial results and the recommendations issued from it, are very much dependent on the above listed issues and insights, which themselves have been the topic of several recent consensus documents.⁵⁻⁷

In this issue several other contributions debate the stiffness or elasticity of compression materials and the measured physiological effects on the treated limb.

Properties of compression bandages have been updated in a publication reviewing the practical aspects and definitions.⁵ In that article the acronym PLACE is proposed to summarize the essential aspects that impact on the pressure and stiffness of compression materials. These are the sub-bandage pressure range measured at the gaiter area, the number of layers (and the way they overlap), the several components of the bandage each with its own function (like padding, protection, retention, compression), and the elastic properties or behavior of the assembled bandage. This is why pressure and stiffness must (also) be measured *in vivo*, on the treated limb.

Appropriate selection and use of these four properties will define the compression treatment characteristics and effectiveness in the several indications. The term *dosimetry* of compression pressure has been proposed to describe this.

In past clinical trials on compression treatment for venous and lymphatic disease, little is known about dosimetry of the applied compression, for how long and at what level it was or should be applied to yield the described results. The different effects of elastic versus inelastic or short-stretch compression are also little understood without considering the principle of stiffness and the resulting dynamic behavior of the compression device, which is rarely discussed in most selected trials and reviews.

RCTs using *out-dated* definitions and classifications of materials have led to systematic reviews and recommendations based on the same misunderstanding; it is left to the alert reader to interpret their results with caution. The pressure-range classifications of bandages and stockings are country specific, and so are the brands and trade names. There is yet no universally accepted standard terminology or classification, application technique or methodology to apply compression treatment. The number of publications is steadily growing with research data, but there is no universal estimation of pressure-values *in vivo* (which is dependent of the material used, the care giver, and the patient), and therefore there is no consensus yet on the required pressure,

stiffness or compression technique to obtain results in specific indications.

The abovementioned considerations may provide part of the explanation for the wide variability in the materials and methods section of the several RCTs. Sound description of the dosimetry must include components, duration, pressure, layers, elasticity, stiffness, all aspects for which internationally accepted definitions are recently published, but not implemented yet, and thus not used in older trials. There is an impressive choice of compression materials and techniques like bandages, stockings, orthoses, intermittent pneumatic compression devices, and combinations of all these. As for the duration of compression therapy, this may be sustained, with or without changes during the day, or it may change over time, possibly in a *cross-over* study design. Of course, the applied pressure values or compression classes must be explicitly mentioned, referring to the methods for the *in vivo* assessment of pressure and stiffness. Blinding cannot be done for the application, but must be used for outcome assessment.

Practical problems abound when considering clinical trials on compression treatment for chronic venous leg ulcers: even if investigators do manage to agree between centers on a standardized protocol regarding materials and techniques, there is still a wide variation in the limbs under study, and there are many possible outcome parameters to test, which are not always under control or not always objectively measurable. Due to the variability of limb morphology, mobility, underlying (co-) morbidities and ulcer etiology, response to treatment will remain an individual characteristic confounding baseline comparability of studied subjects.

Nevertheless, as stated in almost all guidelines and systematic reviews, it is probably true to conclude that to heal a venous leg ulcer (C6), management that includes compression is more effective than without compression, that higher pressure (stiffness?) is more effective than low pressure values, and that compression should stay in place as long as possible. It is unclear if this means sustained pressure by elastic systems or pressure peaks under inelastic bandaging systems or stiff stockings. Some reviewers also recommend applying the highest pressure tolerated by the patient, although this may negatively influence compliance/adherence to treatment, and secondly, this statement has been refuted by recent trials in secondary lymphedema, which strongly suggest that there is a window of optimal pressure values for achieving edema reduction. The same may be true for ulcer healing, effect on skin changes, inflammation, or subjective symptoms.¹⁰

Conclusions

In order to compare the effectiveness of compression systems and materials, *modern* terminology (for which consensus exists) shall be used to describe the materials applied, and objective measurement of the *dosimetry* (pressure/stiffness/dynamic behavior/duration) is an added value in future trials and systematic reviews. Recommendations to guide clinicians and researchers hereby have been reported by consensus working groups.¹¹ The methodological validity and quality of selected previous RCTs remains, but we may have to re-interpret the results in the light of new insights which have challenged myths and dogmas¹⁰ concerning hemodynamic effects of elastic and inelastic compression treatment, and concerning pressure and stiffness, the characteristics of the *final compression system* more than those of the individual components used.

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Experimental study on efficacy of compression systems with a high static stiffness index for treatment of venous ulcer patients

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Abstract

The experimental study measured interface pressure and static stiffness index of four different compression systems in fifty-two healthy volunteers. For the study interface pressure (3 cm ø probe was placed at the anatomical B1 point) was recorded on application of the compression systems every 15 min for 4 h, in supine, standing, while sitting and during walking. For this purpose a portable Kikuhime (Harada Corp., Osaka, Japan) device was used. Further static stiffness index (SSI) was calculated. The evaluated systems were: short stretch bandage system (SSB) Rosidal sys (Lohmann & Rauscher, Rengsdorf, Germany), multi-layer bandaging (LSB) Profore (Smith & Nephew, Hull, UK), vari-stretch bandage (VSB) Proguide (Smith & Nephew) and tubular compression (CS) Rosidal mobil (Lohmann & Rauscher). The mean interface pressure of SSB, LSB and VSB was significantly higher ($P < 0.05$) in each position measured over 4 h, compared to CS. In supine VSB showed high-pressure levels, up to 60 mmHg, which remained high. The other

systems had more tolerable levels of about 30 mmHg. Interface pressure exerted on limbs is an indicator of their clinical effect. The experimental study results showed different patterns of interface pressure and SSI, which may enable clinicians to predict the frequency of bandage application, supporting an adequate and safe choice of bandage system.

Introduction

The paper was presented at the *International Compression Club Meeting* in Vienna 2012 and discussed an experimental study that was previously published.¹ The study aimed to compare interface pressure and static stiffness index (SSI) of four different compression systems that are currently in use for venous leg ulcer and lymphedema treatment of the lower limbs.

Materials and Methods

For the experimental study fifty-two ambulatory adults with healthy legs, were recruited at random in the study center, after they had given informed consent.¹ Excluded were those with an allergy against one of the used materials; arterial occlusive disease (ABPI less than 0.8); ulcers on the lower limb; lower limb edema; known history of dermatological problems such as eczema or cellulites. The evaluated systems were: short stretch bandage system (SSB) Rosidal sys (Lohmann & Rauscher, Rengsdorf, Germany), multi-layer bandaging (LSB) Profore (Smith & Nephew, Hull, UK), vari-stretch bandage (VSB) Proguide (Smith & Nephew) and tubular compression (CS) Rosidal mobil (Lohmann & Rauscher).

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Key words: interface pressure, static stiffness index, compression for venous leg ulcers.

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Contributions: the authors contributed equally.

Conflict of interests: MA is an employee of Lohmann & Rauscher (Rengsdorf, Germany), the company that provided the study products. A limited educational grant was received from Lohmann & Rauscher for conducting the study.

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Interface pressure (IP) (3 cm ø probe was placed at the anatomical B1 point) was recorded on application of the compression systems and every 15 min for 4 h, in supine, standing, while sitting and during walking. For this purpose a portable Kikuhime (Harada Corp., Osaka, Japan) device was used. Measurements during walking were recorded while subjects walked on a treadmill for at least 5 min at normal pace.

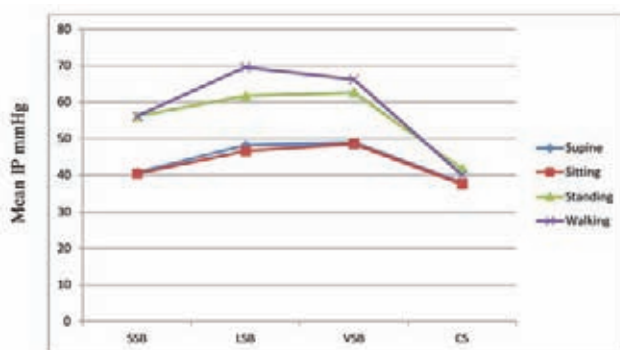


Figure 1. Mean interface pressure in supine, sitting, standing and walking (N=52). IP, interface pressure; SSB, short stretch bandage system; LSB, multi-layer bandaging; VSB, vari-stretch bandage; CS, tubular compression.

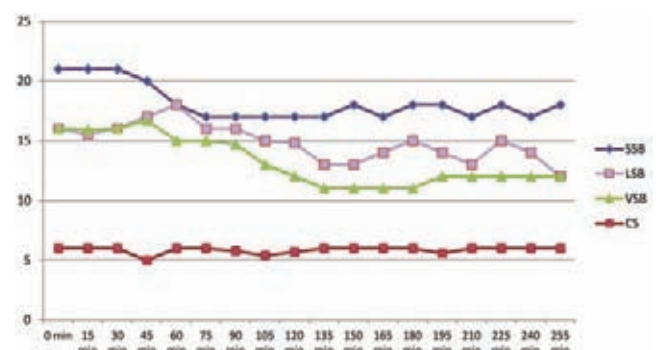


Figure 2. Static stiffness index (N=52). SSB, short stretch bandage system; LSB, multi-layer bandaging; VSB, vari-stretch bandage; CS, tubular compression.

Primary outcome measure

Interface pressure measured in supine, sitting, standing and walking and SSI. Parametric or non-parametric tests (SPSS: IBM Corp., Armonk, NY, USA) were used where appropriate. Mann-Whitney U or paired T-test were used for intragroup and per group comparisons of the IP measured in the different positions and over time.

Results

The mean interface pressure of SSB, LSB and VSB was significantly higher ($P<0.05$) in each position measured over 4 h, compared to CS (Figure 1). In supine VSB showed high-pressure levels, up to 60 mmHg, which remained high. The other systems had more tolerable levels of 30 mmHg. Measurements in sitting showed similar trends. All compression

systems maintained pressure levels in walking of at least 40 mmHg (Table 1). The SSI was the highest for SSB with 20 and remained 19 throughout the study period. LSB followed with an SSI of 18, reduced to 15, where the SSI for VSB went from 17 to 12 and CS with an SSI of 6 lagged behind (Figure 2).

Discussion

The IP for LSB and VSB in supine of ± 60 mmHg were higher than usually reported. LSB and VSB are defined systems, SSB is a variety of compression systems. LSB has an elastic layer (extensibility $>100\%$), SSB consists of short-stretch materials (extensibility $\pm 70\%$). By applying LSBs' elastic layers over each other, with a cohesive bandage as the outer layer, the final system is stiffer.² This was also shown in our study¹ and is in line with what was demonstrated by Mosti and Partsch.^{2,5}

In a clinical study⁶⁻⁸ two groups were treated with compression and one group received no compression. In selected patients IP and SSI was measured for the two compression systems LSB and SSB. The static stiffness index remained higher than 10 in both compression groups for one week, the duration of bandage application, despite of bandage pressure loss (Figure 3). The reduction in ulcer area from weeks 12 to 24 in the LSB group and usual care group (moist wound healing dressings, no compression) was not significant ($P=0.67$ and $P=0.16$), where a statistically significant reduction in ulcer area was observed in the SSB group ($P=0.047$) (Figure 4). Both compression systems treated groups showed effective ulcer healing with faster and better ulcer area and pain reduction for SSB, which may be explained by the higher SSI of the system.

Limitations

This was an experimental study on healthy

Table 1. Experimental study (N=52): interface pressure measured in supine and walking.

mmHg	SSB		LSB		VSB		CS		Paired T-test
	Supine	Walking	Supine	Walking	Supine	Walking	Supine	Walking	
Mean (\pm SD)	40.68 (± 5.01)	56.11 (± 5.01)	48.12 (± 4.57)	69.59 (± 6.24)	48.96 (± 3.99)	66.21 (± 4.02)	37.82 (± 0.58)	40.04 (± 1.77)	Supine: SSB, LSB, VSB vs CS: $P=0.05$
Median (range)	41 (39-60)	57 (52-80)	50 (44-59)	73 (64-90)	51 (46-60)	69 (64-80)	40 (39-41)	42 (40-45)	Walking: SSB, LSB, VSB vs CS: $P=0.05$

SSB, short stretch bandage system; LSB, multi-layer bandaging; VSB, vari-stretch bandage; CS, tubular compression; SD, standard deviation.

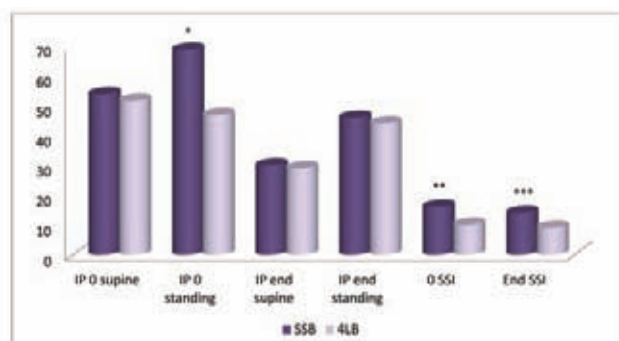


Figure 3. Clinical study (N=321): interface pressure and static stiffness index. IP, interface pressure; SSI, static stiffness index; SSB, short stretch bandage system; 4LB, four-layer bandage system; SD, standard deviation.

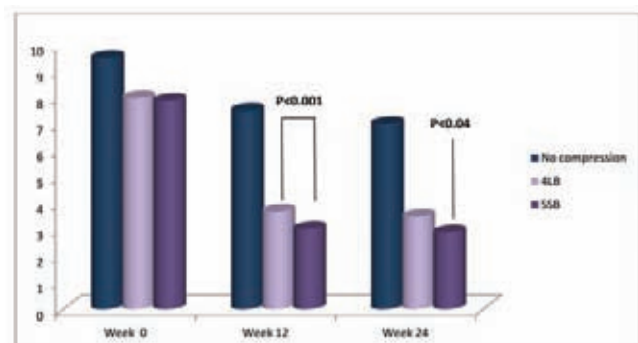


Figure 4. Clinical study (N=321): ulcer area reduction at 12 and at 24 weeks. SSB, short stretch bandage system; 4LB, four-layer bandage system; UC, usual care (a moist wound healing dressing and no compression); ANOVA, analysis of variance; SD, standard deviation.

legs over a 4-h period where typically the systems are left in place for 3-4 days up to 1 week. Moreover the device that was used to measure IP is not suitable to leave in place for over 4 h. Based on our results it is not possible to predict what the pressure levels would be over this period on for instance venous leg ulcer patients with edema.

However the reported results from a clinical study,^{6,7} suggest that when using the SSB and LSB compression systems in venous leg ulcer patients with edema, the IP levels are maintained at a therapeutic level over a week. For this study another, more suitable measurement device [Picopress®, Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy]³ was used to measure IP levels. This device can be left in place for several days up to a week, providing clinically relevant information.³

Conclusions

Interface pressure exerted on limbs is an indicator of their clinical effect. The study results showed different patterns of interface

pressure and SSI, which may enable clinicians to predict the frequency of bandage application, supporting an adequate and safe choice of bandage system. This approach may increase the patients' participation in, and compliance with, compression therapy, thereby saving on costs and nursing time.

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Relevance of stiffness of compression material on venous hemodynamics and edema

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Abstract

Elastic and inelastic stockings or bandages may provide the same degree of compression pressure in the resting supine position but inelastic material provides much greater compression pressure in the standing or working position. For elastic compression to have the same effect in the standing or exercising state would require a degree of compression in the resting position that would be intolerable. Studies have shown that this applies to reduction of reflux and improved venous pumping although both appear to have a similar effect for reducing edema.

Introduction

Stiffness and its importance on venous disease

Venous reflux, obstruction and reduced venous pumping function from the lower leg during exercise are the main pathophysiological parameters of venous disease.¹ Compression therapy can improve hemodynamic impairment. In particular compression has been proven effective in reducing venous volume, reflux, venous pumping function, edema and, consequently, ambulatory venous hypertension.²⁻⁸ Compression may be applied to the leg by different materials: elastic stockings, elastic and inelastic bandages, and/or velcro-band-devices. The main differences between these materials are the exerted pressure and the elastic properties which can influence their hemodynamic effects. The resting pressure produced by a stocking rarely exceeds 40 mmHg⁹ while the resting pressure exerted by a bandage depends mainly on the strength of application. When applied by means of inelastic bandages, which must be applied under full stretch, or of velcro band devices which are completely inelastic and inextensible, the exerted pressure is usually higher than 60 mmHg. Nevertheless, the pressure increase when moving from the resting supine to the standing position represents the main difference between elastic and inelastic material, even more important than

resting pressure. The pressure increase by standing characterizes the stiffness of the material⁹ and can be measured *in vivo*¹⁰ just by subtracting supine from standing pressure. This difference has been termed static stiffness index (SSI) and the cut off in distinguishing elastic from inelastic material is 10.^{11,12} Elastic material gives way to the muscle volume increase during muscle contraction achieving a pressure increase in the standing position only slightly higher than supine resting pressure and always lower than 10 (Figure 1).

Inelastic material doesn't give way to the muscle expansion and the exerted pressure will rise significantly; SSI will always be higher than 10. Other parameters of stiffness are the maximal working pressure, the pressure peaks and pressure amplitudes during walking (the difference between systolic and diastolic pressure).¹³ When inelastic material is correctly applied with full stretch exerting a pressure of 50-60 mmHg in supine position, the significant pressure increase to 70-90 mmHg with standing will produce a significant vein narrowing or occlusion (Figure 2). Also elastic material could exert this very strong pressure and narrow or occlude the veins but, due to its elastic characteristics, it must be applied with similar strong pressure even at rest which will make the bandage painful and intolerable (Figure 3).¹⁴ Narrowing/occlusion of veins by external compression devices is a prerequisite for their hemodynamic efficacy and can be observed with phlebography, Duplex ultrasound or magnetic resonance imaging. The amount of narrowing depends on the body position and the range of compression pressure. In the supine position a pressure of about 20 mmHg is able to narrow the veins while in the upright position, a pressure range of 70-80 mmHg will be necessary to counteract the standing intravenous pressure and to narrow up to near occlusion of the vein lumen.^{15,16} Similar vein narrowing may occur while walking with inelastic materials that produces pressure peaks which overcome the intravenous pressure with every step and leads to an intermittent narrowing of the veins¹⁵ thus restoring a kind of artificial valve mechanism.¹⁷ Elastic material or elastic stockings cannot achieve similar results because in order for the compression to be tolerable the exerted pressure range can never exceed 50 mmHg. This degree of compression can slightly influence the venous diameter but certainly cannot produce significant vein narrowing.¹⁸

Relevance of stiffness on reflux and venous pumping function in venous disease

Effect on reflux

Reflux has been shown to be abolished both in patients with post-thrombotic syndrome¹⁹

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and severe superficial venous incompetence²⁰ by using different methods that produce similar results. In the first study,¹⁹ the authors used air-plethysmography and were able to show a progressive reduction up to the abolishment of venous reflux by increasing the pressure of compression devices. At every pressure range inelastic material was able to reduce reflux more than elastic material. Only with very strong pressure of 60 mmHg does elastic and inelastic material provide similar result.

In patients with severe reflux of the great saphenous vein²⁰ similar results could be demonstrated using Duplex ultrasound: increasing leg compression led to a progressive reduction of reflux, with inelastic always more effective than elastic material.

Reflux reduction up to abolition is due to external pressure which progressively reduces the venous reservoir of the lower leg. The superiority of inelastic compared with elastic material can be explained by higher standing pressure exerted by inelastic material starting from the same supine pressure of 20 or 40 mmHg. This produces a more pronounced narrowing of leg veins, a greater reduction of their reservoir capacity leading to a greater decrease of venous reflux.

A very high pressure will occlude the leg veins irrespective of the elastic properties of materials used; therefore venous reflux is blocked by both elastic and inelastic devices.

Nevertheless it is necessary to take into account that elastic material applied with this strong pressure can be used only for the short period of time of a laboratory test but not in clinical practice because such pressure is barely tolerated by patients.^{14,20}

In conclusion reflux abolition depends only on the standing pressure necessary to narrow the veins but it is only theoretically independent from the elastic properties of the compression material: elastic material can produce a pressure strong enough to narrow the vein diameter but this pressure will be painful and impossible to use in the clinical practice.

Effect on venous pumping function

Effects of compression on venous pumping function maybe demonstrated by different plethysmographic techniques, such as foot volumetry, air plethysmography or strain gauge plethysmography.^{8,19,21-28}

With this method we could demonstrate that the ejection fraction (EF) from the lower leg is reduced in patients with chronic venous insufficiency and that it can be improved by external compression.²⁸ Inelastic compression material is able to increase EF from the lower leg and restore normal venous pumping function. The increased EF achieved by inelastic is significantly higher than by elastic material applied with the same pressure. Elastic material never restores the normal function even if applied with high stretch producing a very strong pressure higher than 60 mmHg. Therefore not only pressure but also elastic properties of the compression devices play an important role in increasing venous pumping function. In particular the difference between systolic and diastolic pressure during walking (the so called massaging effect) seems to play a deciding role squeezing blood from the leg. The significant correlation between ejection fraction and sub-bandage pressure during standing and walking and between ejection fraction, static stiffness index and walking pressure amplitudes confirm the hemodynamic superiority of inelastic material.²⁹

Furthermore inelastic material has been shown to be effective even when applied with a low pressure of 20-30 mmHg, (in a range where elastic stocking are unable to increase the ejection fraction) and demonstrated a positive correlation with an increasing application pressure.³⁰

Finally inelastic materials are claimed to lose effectiveness as they lose pressure overtime. It was proved that this material is able to maintain its effectiveness over time (one week) even despite significant pressure loss.³¹

Edema

Edema develops because of a complex interaction that involves the permeability of the capillary wall and the hydrostatic and oncotic pressure gradients that exist between the blood vessels and the tissues.³² As almost all interstitial fluid is removed by the lymphatic circulation,³³ edema will form when net capillary filtration exceeds lymphatic drainage capacity. Compression counteracts edema for-

mation by increasing the tissue pressure³⁴ and lymphatic drainage in the initial stage of lymphatic damage.³⁵

Edema is always reduced by compression and the beneficial effect of compression on edema is so clear that only relatively few studies were performed to investigate this effect. Edema is effectively treated by inelastic material applied with very strong pressure and by

elastic stockings of moderate pressure (in the range of 23-32 mmHg).³⁶ The inelastic bandage seems to be slightly more effective without statistical significance.

If elastic and inelastic materials are equally effective in treating edema we could conclude that, so far, stiffness does not seem to play a role in treating leg edema.

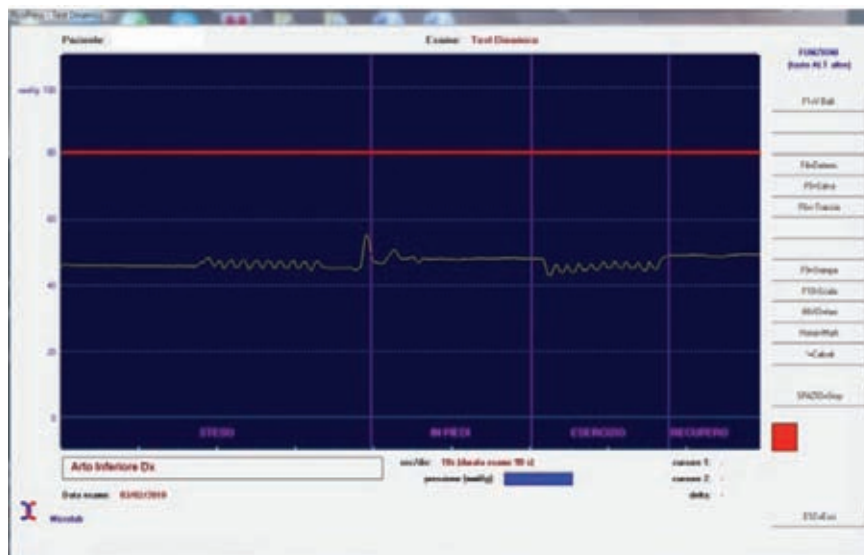


Figure 1. Interface pressure of an elastic compression device applied with 50% stretch and 50% overlapping of each layer. The exerted pressure always (during dorsiflexion in the supine position, standing, walking in place) remains well below the intravenous pressure (red line) which would be necessary to compress or occlude the veins.



Figure 2. Interface pressure of an inelastic compression device applied with full stretch and 50% overlapping of each layer. The exerted pressure always (during dorsiflexion in the supine position, standing, walking in place) overcomes the intravenous pressure (red line) narrowing/occluding the veins thus restoring a kind of valve mechanism.

Conclusions

There is clear evidence that compression exerted by inelastic materials with high stiffness are able to achieve a very strong pressure starting by low and comfortable pressure at rest. This strong pressure can narrow and even occlude the venous system. This leads to a reduction or even abolition of venous reflux and an improvement or normalization of the venous pumping function. When the supine resting position is resumed the compression pressure is lower and comfortable for the patient, but still effective when ambulation is resumed.

Elastic materials with low stiffness are unable to get strong pressure during standing and ambulation and are much less effective than inelastic with a statistically significant difference. Stiffness plays a deciding role in the hemodynamic effects of compression.

The effect of stiffness in reducing leg edema doesn't seem very relevant so far.

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Quantified hemodynamics of compression garments

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Abstract

Various forms of compression therapy have been utilized for centuries in the treatment of venous disease, with inelastic bandage systems being used in the more acute treatment of severe venous disease and elastic compression stockings used for long-term management of the disease. However, with the advancement in inelastic adjustable compression wraps, we now have the option to consider long-term management of venous disease with an inelastic system and not just elastic systems. The aim of this study was to compare the hemodynamic effect of elastic compression stockings and inelastic compression wraps on venous disease patients when both products are applied to provide the same level of compression. Utilizing the APG device (ACI Medical, San Marcos, CA, USA), venous volumes, venous filling indexes and ejection fraction measurements were captured on 10 patients with varying degrees of venous disease. Measurements were obtained for each patient at baseline (without compression), with either 30-40 or 20-30 mmHg elastic compression stockings (ECS) and an inelastic compression wrap (ICW) (Juxta-CURES[™] by CircAid Medical, San Diego, CA, USA). The compression level of the ECS was measured at the B1 point utilizing a Picopress[®] [Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy] and the ICW was adjusted to provide the exact compression level as the ECS in order to compare the effects of inelasticity versus elasticity independent of compression differences. As expected, the use of compression therapy significantly improved all measures of hemodynamics although it was found that the ICW (average static stiffness 14.3) further improved the measures over ECS (average static stiffness 2.4). Average venous volumes were reduced over baseline with ECS by 19% while ICW showed a reduction of 35%. Average venous filling indexes were reduced with ECS by 25% and 39% with ICW. The ejection fractions for both devices, ECS and ICW, improved an average of 27%. When applying the same compression level, the stiffness associated with ICW can further improve the venous hemody-

namics of venous disease patients over ECS. For certain patients, using ICW could prove to be a significant benefit in the management of their disease.

Introduction

Compression therapy continues to be the principal approach to the management of venous and lymphatic disease around the world. Even with the significant amount of research that has been conducted demonstrating the benefits of inelastic or short-stretch compression therapy over elastic compression stockings (ECS)¹⁻⁵ remain the dominant technology used in the management of chronic venous insufficiency (CVI). However, one main observation of most of these comparisons is that the compression level achieved with inelastic bandaging is significantly higher than that achieved with elastic compression stockings. This is due to the inherent characteristic of inelastic bandages to lose compression over time thus requiring an initial high compression level to provide a therapeutic effect. Additionally with bandages there is no reliable method to apply bandages to a known compression level.⁶ However, now with the advancement of inelastic compression wraps (ICW) to provide a reliable method of achieving known levels of compression that can be adjusted over time by the patient to maintain a therapeutic compression level, we can begin to practically consider the benefits of inelastic compression with improved patient compliance and concordance.

Thus, the purpose of this study is to demonstrate the differences in venous hemodynamics that are provided to venous disease patients when ECS and ICW are used eliminating any discrepancy that may arise from variances in actual compression levels applied.

Materials and Methods

In this study the venous hemodynamic and compression levels of two compression devices were measured on a total of 10 patients (M/F - 2:8; mean age 56.1 years with a standard deviation of 9.2 years). Nine of the 10 patients were clinically evaluated to have venous disease while the 10th patient demonstrated mild lymphedema in her lower leg with no evidence of venous disease (Table 1).

Utilizing air plethysmography (APG device from ACI Medical, San Marcos, CA, USA) baseline venous hemodynamic data was collected for each patient. The measures included venous volume (VV), Venous filling index (VFI) and ejection fraction (EF). These meas-

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Key words: compression, inelastic, elastic, hemodynamics, stockings, juxta-cures, CircAid, venous volume, venous filling index, ejection fraction.

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ures were taken on the leg in which the patient indicated the worse symptomatic condition (RL - 6:4).

Each patient was then measured and fit with either a knee-high 30-40 mmHg ECS or a 20-30 mmHg ECS. The actual compression level provided by the stocking was captured utilizing a pressure probe [Picopress[®], Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy] placed under the garment at the B1 position while the patient was in the supine position with their leg slightly elevated. The patient was then asked to stand firmly on both feet and a second compression level reading was captured in order to determine the static stiffness index of the ECS (Figure 1). The venous hemodynamic measures were then repeated with the APG device while the ECS remained in place.

The stocking was removed and each patient was then fit with an ICW (Juxta-Cures[™] from CircAid Medical Products, San Diego, CA, USA). The ICW was adjusted to provide the same compression level achieved with the ECS (± 1 mmHg) in the supine position and a second compression measure was captured in the standing position. The venous hemodynamic measures were again repeated while the compression wrap remained in place.

Results

With the compression levels of the ECS and the ICW essentially equivalent for each patient, we were able to determine the Static

Stiffness Index exerted by each compression device. Static Stiffness of a compression device is defined as the difference between the compression exerted at the B1 point in the standing position versus the supine. The results (Figure 2) clearly demonstrate that the ECS provided a low static stiffness index with an average of 2.4 mmHg, while the ICW produced an average static stiffness of 14.3 mmHg.

The results from the APG measurements were as expected with both the ECS and the ICW significantly improving all three measures over baseline. Furthermore, it was found that the ICW provided a significant improvement over the ECS in VV and VFI reduction.

The ECS reduced the VV (Figure 3) by an average of 19% (baseline avg - 135.5 mL and ECS avg - 109.0 mL). The ICW reduced VV by an average of 35% (ICW avg - 86.4 mL).

Similar reductions were seen in the VFI (Figure 4) with a baseline avg - 2.9 mL/s; ECS avg - 2.2 mL/s (25% reduction from baseline) and the ICW avg - 1.7 mL/s (39% reduction from baseline).

EF (Figure 5) for both compression devices significantly improved over baseline with both devices averaging an improvement of 27%.

Discussion and Conclusions

The effect of compression devices on the venous system depends on two key factors; the pressure exerted on the limb and the stiffness of the materials used in the device. ECS devices are typically elastic in nature and are designed to provide a given compression range (mmHg) in the ankle region as defined by the

manufacturer (*i.e.* 30-40 mmHg). Because of the high elasticity in ECS devices the resulting fabric is not stiff and as such stretches with the movements of the limb. ECS devices can be thought to provide *static* stiffness where the compression level provided is essentially unchanged as the user moves from supine to standing to walking positions. ICW have been available for over 20 years and deliver a compression level that is dependent upon the amount of tension applied to the closing straps. Not until the past few years has such a device been able to deliver a known level of compression similar to the of ECS devices. This has been achieved by the inclusion of a Built-in Pressure System, BPS™ (CircAid Medical Products), which correlates the tension applied to the closing straps and the circumference of the limb to a known pressure range. As the name indicates, ICWs are inelastic, stiff in nature. This inelasticity has been demonstrated to provide a *dynamic* compression under the device where the compression level increases and decreases dramatically as the patient moves from supine to standing to walking positions.

Because ECS devices are readily available, have known compression levels, are aesthetically pleasing and relatively easy to apply for a patient when compared to bandaging, they have become the dominant technology in the treatment and management of CVI around the world. However, now that ICW devices are becoming more prominent, have known compression levels and are easy for the patient to apply, we have the opportunity to consider the effect of stiffness (dynamic compression) in our treatment of CVI.

This study was designed to eliminate the variable of compression level from the assess-

ment of the effectiveness of the device by applying equal compression levels at the B1 point. This was achieved by adjusting the ICW straps until a near equivalent compression reading was obtained on the pressure monitor. By eliminating the compression variable we are able to compare the effect that stiffness of the compression device exerts on any given patient.

Our results clearly showed that the ICW was stiff and delivered a higher working pressure (14.3 mmHg) when the patients were in the standing position versus supine, while the ECS (2.4 mmHg) resulted in little to no increase in pressure on the same patients.

As expected, both compression devices significantly improved the patient's venous hemodynamics. Applying pressure to the tissue of the limb and thus preventing the expansion of the veins during refilling maintains a smaller total volume of the complete venous system. However, due to the inelastic nature of the ICW and the fact that the device has limited stretch under movement, the reduction in VV was significantly greater for the ICW (36% $P=0.008$) than that achieved with the ECS (20% $P=0.009$). Similarly, the inelasticity of the ICW resulted in a 40% ($P=0.028$) reduction in VFI *versus* 23% ($P=0.009$) for the ECS, compared to baseline measurements without a compression device.

Interestingly, both ECS and ICW improved the EF by 27% on average, although the measures did not achieve statistical significance (ICW $P=0.110$; ECS $P=0.055$). The results on average were contrary to our expectations in that Mosti and Partsch⁷ reported in 2010 higher EF percentages with inelastic bandages versus ECS when measuring with strain-gauge plethysmography, although 7 out of the 10

Table 1. Patient population.

Patient no.	CEAP	Gender	Age	Limb	Stocking label compression	Pressure B1 (mm Hg)
1	C2	M	52	RT	30-40	26
2	C3	F	65	RT	30-40	37
3	C2	F	60	RT	30-40	29
4	C4	M	52	LT	20-30	24
5	C4	F	64	RT	30-40	40
6	C3	F	65	LT	30-40	33
7	C2	F	57	LT	30-40	29
8	C3	F	56	LT	20-30	28
9	C3	F	32	RT	20-30	28
10	C0 (lymph)	F	58	RT	30-40	47
Average			56.1			32.1

CEAP, Clinical-Etiology-Anatomy-Pathophysiology classification; M, male; RT, right; F, female; LT, left.

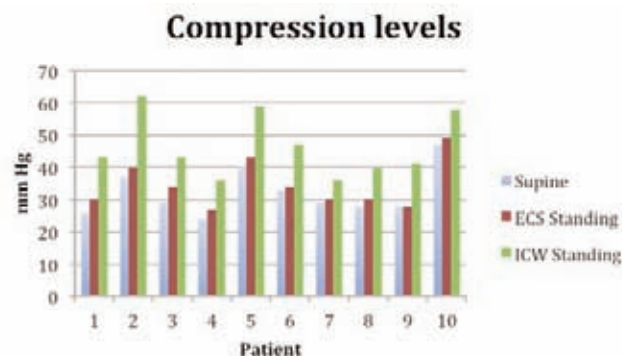


Figure 1. Compression levels measured at the B1 position. ECS, elastic compression stockings; ICW, inelastic compression wrap.

Static stiffness index

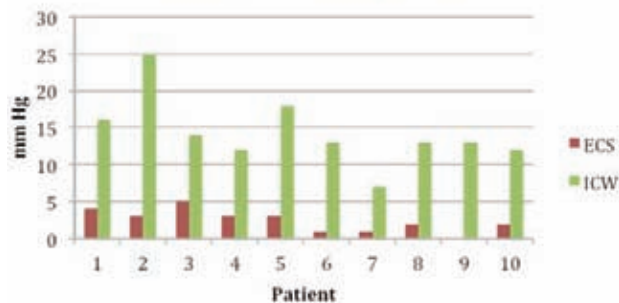


Figure 2. Static stiffness index (compression level difference between standing and supine at the B1 position measured in mmHg). ECS, elastic compression stockings; ICW, inelastic compression wrap.

Venous filling index

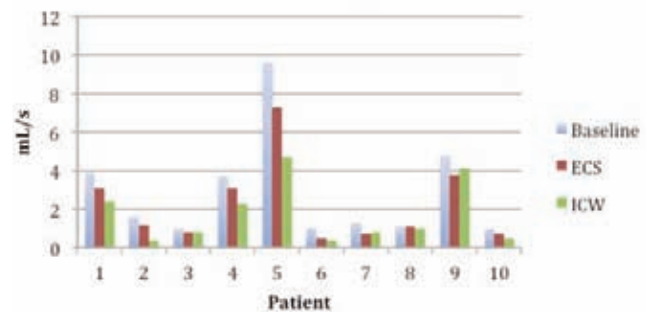


Figure 4. Venous filling index – rate of venous refilling. ECS, elastic compression stockings; ICW, inelastic compression wrap.

Venous volume

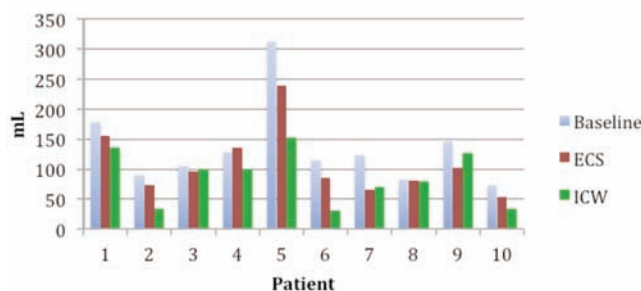


Figure 3. Total venous volume. ECS, elastic compression stockings; ICW, inelastic compression wrap.

Ejection fraction

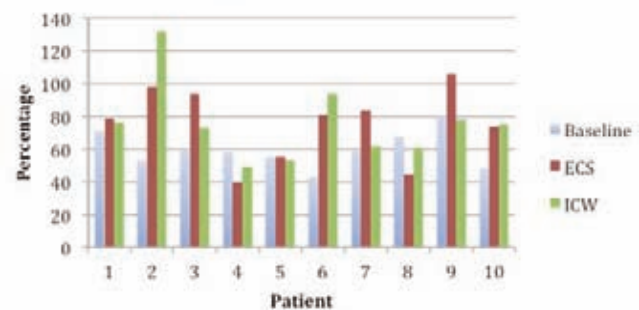


Figure 5. Ejection fraction – percentage of venous blood expelled as a result of a single calf flex. ECS, elastic compression stockings; ICW, inelastic compression wrap.

patients did see an improvement in EF with the ICW over ECS.

When considering this outcome further in view of our assumption that the EF with the ICW would be significantly improved *versus* the ECS, we observed on a patient-by-patient basis for all 3 variables measured (VV, VFI and EF) that patients number 3, 7 and 9 (Figure 5) had equivalent or superior results with the ECS versus the ICW. This suggests that there was something unique about these patients that allowed the ECS to perform better than the ICW in spite of the greater elasticity. Unfortunately, we did not observe anatomical characteristics of these patients in order to determine if a correlation exists between anatomy of the limb and the effect of compression garments. One theory is that certain tissue characteristics may be influenced more by the tension applied by an ECS once stretched, resulting in an increased force inward on the limb. In contrast, the lack of elasticity of the ICW simply prevents the limb from expanding, but does not reduce limb size based on movement. Another thought is that the tissue make-up defuses the compression differently, thus mitigating the expected effect of the inelastic device.

Regardless, this is a phenomenon that we believe justifies further investigation and recommend that additional work be conducted to determine what variables should be considered in regards to determining when an elastic device should be chosen over an inelastic device. It is our intention to repeat this study including an anatomical and ultrasound evaluation of each patient and to also monitor sub-garment compression levels throughout the various tests.

In conclusion, this study confirms that inelastic compression devices provide a superior hemodynamic effect on average and should be considered when the disease state dictates the need for the maximum impact on the circulatory system.

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Alginate hydrocolloid impregnated zinc paste bandages-an alternative in the management of lymphoedema?

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Abstract

Several studies have shown an impressive reduction in swelling as a result of compression, and inelastic bandages have become widely accepted as a part of lymphatic decongestive therapy for managing lymphoedema.

Lymphoedema bandaging is indicated to reduce swelling, improve limb shape, skin- and tissue-condition and to ameliorate symptoms such as discomfort. Compression therapy for lymphoedema is based mainly on the use of inelastic, short-stretch bandages with high compression, usually protecting the skin with polyurethane foam bandages. In this preliminary report it is shown that completely rigid material like zinc paste applied without padding provides a good level of efficacy.

Introduction

In the management of lymphoedema bandages with high stiffness are traditionally pre-

ferred. Theoretical reasons for this choice are: i) in contrast to venous diseases in which the hydrostatic problem in the upright position has to be tackled and which need compression mainly during daily activities, lymphatic pathology needs 24 h compression,¹⁻³ at least during the initial treatment phase. Therefore our compression pressure should be well tolerated in the lying position and at the same time strong in the upright position, prerequisites that are typically fulfilled by stiff materials; ii) the high massaging effect with movement will stimulate lymphatic drainage by opening initial lymphatics due to the intermittent increase of tissue pressure, by propulsion of tissue fluid into the initial lymphatics and by enhancing the spontaneous rhythmic contractions of lymph collectors.^{4,5}

This effect is certainly much stronger with stiff compression than with a yielding elastic device. Due to Pascal's law the energy created by muscle contractions will be transmitted into all directions in a closed container while it would partly be lost if the extremity is encircled by elastic material giving way to each muscle contraction (Figures 1 and 2).

Among the available compression materials zinc paste bandages are certainly the products providing minimal stretch and highest stiffness. Up to now reports concerning their use in lymphoedema patients are lacking.

In this preliminary report we would like to discuss the potential role of zinc paste bandages in the initial treatment phase of lymphoedema of the lower extremities. Based on a case series in which we concentrated on clinical aspects only, advantages and disadvantages of this alternative treatment will be considered.

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Key words: lymph bandages, stiffness, zinc paste, lymphoedema.

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Materials and Methods

In 2009 the Alegro® (Alegro Medical Hamburg, Germany) alginate zinc bandage (AZB) was introduced for treating arm lymphoedema.⁶ It is a semi-rigid zinc bandage drenched with calcium alginate and hydrocolloid that becomes stiff and inelastic by time. Twenty patients (2 males and 18 females) with primary and secondary lymphoedema (stage II-

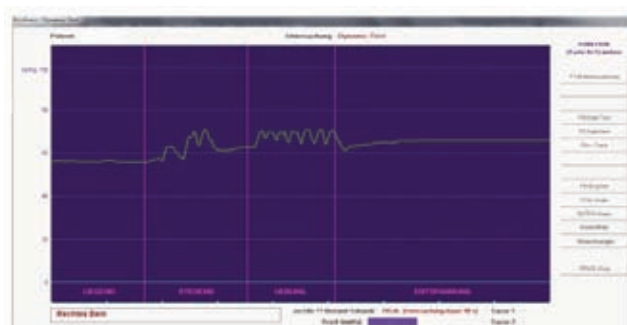


Figure 1. Typical tracing of the pressure exerted by a zinc paste bandage in the lying position and during walking on spot immediately after application in a patient with lymphoedema of the leg. Supine pressure is 55 mmHg, static stiffness index 10 mmHg.

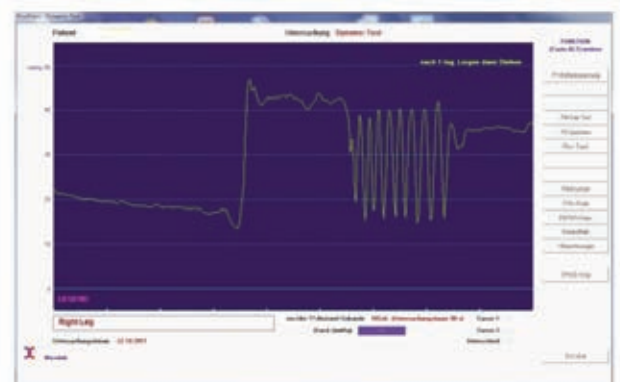


Figure 2. Pressure curve after wearing a zinc paste bandage for 24 h in a patient with lymphoedema of the leg. Lying pressure drops down to 20 mmHg but rises to more than 40 mmHg by standing up. The static stiffness index is more than 20 mmHg. The high pressure amplitudes during walking exert a strong massaging effect.

III as to International Society of Lymphology classification) of the upper (n=3) and lower limbs (n=17) received such bandages. The range of age was 28-73 years.

AZB was used on patients with hard and indurate edema, where conventional multilayer low stretch bandaging had poor results, reducing the circumference of the limb by less than 2 cm in one week. No padding was added.

The bandage was applied directly to the skin on the lower leg and forearm. An overlying short stretch bandage without additional compression was applied as the most superficial layer, in order to protect clothes.

AZB material stuck directly to the skin, without any slippage and was kept in situ for 24-48 h. When the pressure dropped to less than 30 mmHg, the bandage was changed. In 16 cases this happened after 24 h. In 4 cases the edema was so hard, that pressure reduction due to a decrease of edema occurred only after 48 h.

Sub-bandage pressure was measured on the distal medial leg (B1 point) using Picopress® [(Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy)] transducers while volume and circumference of the limb before and after treatment was evaluated by an optoelectronic device (Perometer®, Pero-System Messgeraete GmbH, Wuppertal, Germany). The zinc paste bandage was only applied on the lower leg.

Results

The reduction of volume depended on the volume of the extremity. In two patients we started the treatment from the first day with zinc bandage, because they were suffering from elephantiasis in primary lymphoedema.⁷ The residual patients received the zinc bandages 1-3 weeks after initial treatment with conventional bandaging. An example is shown in Figure 3.

Table 1 summarizes the volume reduction obtained with AZB after one week.

Two examples illustrating our experience with zinc paste bandages in patients with severe lymphoedema are presented.

he first patient was a 38-year old woman with primary lymphoedema, papillomatosis cutis lymphostatica, lymphocysts and lymphorrhoea with inflammation of the skin (Figure 4A). The patient was bandaged with Alegro®-zinc on the lower leg and long stretch Rosidal D (Alegro Germany) for the thigh. After 11 days papillomatosis was reduced, lymphocysts, lymphorrhoea and inflammation had disappeared (Figure 4B).

The reduction of circumference was 30 cm in the lower leg and 15 cm in the thigh in only 11 days (Figure 5). The volume reduction of the whole leg was 12.810 mL.

The second patient, a 23-year old man suffering from primary lymphoedema of both legs was treated with AZB on the right lower limb and a conventional lymphological bandage (inelastic, multilayer and multi component bandage)⁸ on the left lower limb.

The results showed a reduction of 3.147 mL (40.1%) in 14 days (Figure 6A) with AZB and of 1.647 mL (31.3%) by usual bandaging⁸ (Figure 6B). The volume reduction in the first 3 days was much faster on the leg treated with AZB. In the patients primarily treated with conventional multicomponent lymph bandages a clear improvement was observed when switching to AZB, as demonstrated in the following example. A 65-year old patient suffering from secondary lymphoedema, showed a volume reduction of 618 mL in 19 days (33 mL per day) with conventional bandage. After switching to AZB a volume reduction of 275 mL in 3 days (92 mL per day) was recorded (Figure 3).

This finding is in contrast to the usual volume reduction, which is mostly more pronounced in the initial phase of compression treatment (Figure 6). Only after AZB employment a more pronounced tissue softening took place and the pressure under the bandage showed a dramatic drop (57 mmHg after bandaging and 32 mmHg after 24 h) This reduction was higher than with conventional bandages corresponding to a more pronounced volume reduction (Figure 3). With AZB inflammation and dermatitis disappeared after 3-5 days, lymphorrhoea stopped after the first bandage and

cysts were not visible any more after 7 days of compression.

Discussion

Zinc paste bandages with gelatin glue, as previously used, were semi-rigid, unyielding and became totally dry after one day. We used this material for treating venous diseases, but due to the dry material skin irritations occurred sometimes. Therefore we changed to bandages with cellulose glue, but their hardening was a limitation again. As any skin injury may lead to dermato-lymphangio-adenitis (cellulites, erysipelas, lymphangitis), clinicians used pure zinc-oxide bandages very seldom in lymphoedema. As Alegro® (Alegro Germany) alginate zinc bandage has a more durable moisture level, the present authors introduced AZB also in lymphoedema patients. So far one single study reported about efficacy of AZB *vs* conventional bandaging⁶ in lymphedema. More comparative data are needed to corroborate the results of our preliminary observational study which confirmed that the stiff material results in better and faster edema and fibrosis reduction than the traditional multilayer bandaging. In venous diseases different studies demonstrated that zinc oxide bandages are well tolerated and very effective.

Table 2 summarizes some general advan-

Table 1. Volume (mL) before and 1 week after AZB (Perometer®, Pero-System Messgeraete GmbH) treatment (mean+standard deviation) in 20 patients.

Limb (patience no.)	Before	After	Difference after one week
Left leg (n=7)	12,874 mL (±4187 mL)	11,949 mL (±3617 mL)	789 mL (±1224 mL)
Right leg (n=10)	13,067 mL (±976 mL)	11,955 mL (±3578 mL)	976 mL (±1872 mL)
Right arm (n=3)	3282 mL (±944 mL)	3090 mL (±929 mL)	192 mL (±127 mL)

Table 2. Advantages and disadvantages of zinc paste.

Advantages of zinc paste

Good tolerance, no skin irritations observed

Easy to apply, the patient can move better than with conventional lymphological bandage

Better and faster results

Skin care and anti-inflammatory properties

Increased stiffness, which better supports the muscle pump, which partly explains better edema reduction

Bandage slippage is of limited relevance, which helps in the maintenance phase and for the swift to medical compression stockings/sleeves

Disadvantages of zinc paste

Necessity to re-bandage every 24-48 h in the initial treatment phase, due to fast edema reduction

Single usage of this kind of bandage makes this treatment quite expensive (the usual lymphological bandages can be washed and re-used several times)

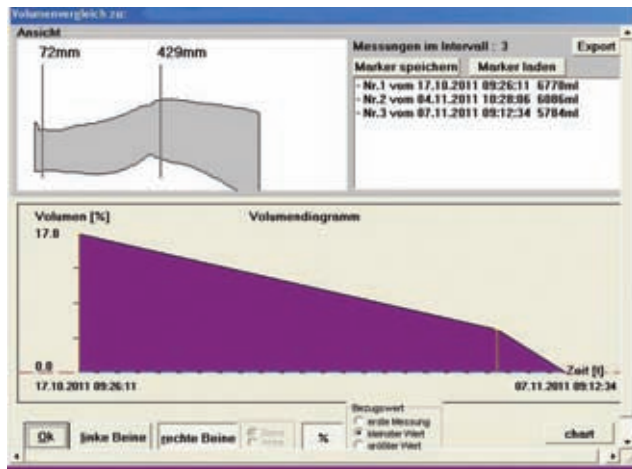


Figure 3. Slow volume reduction by conventional lymph bandages applied for 19 days, followed by a more intensive effect for the last 3 days when AZB (Perometer®, Pero-System Messgeraete GmbH) were applied.

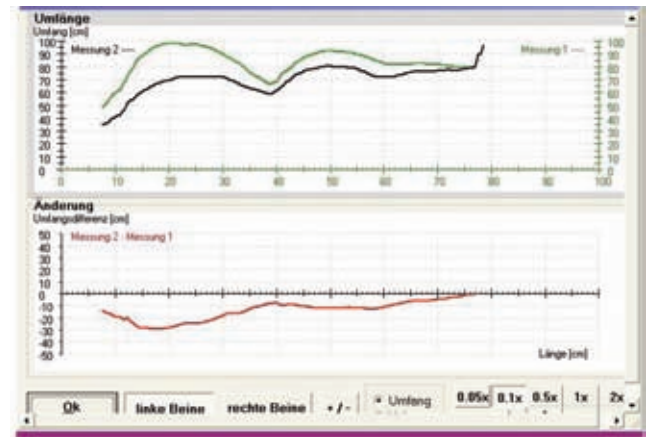


Figure 5. Top: Longitudinal profile of leg circumferences (Perometer®, Pero-System Messgeraete GmbH) before (green line) and 11 days after compression therapy. Bottom: girth-reduction (40 cm on x-axis corresponds to the height of the knee level). A more pronounced reduction of circumference on the lower leg (AZB) than on the thigh (elastic bandage) is clearly visible.

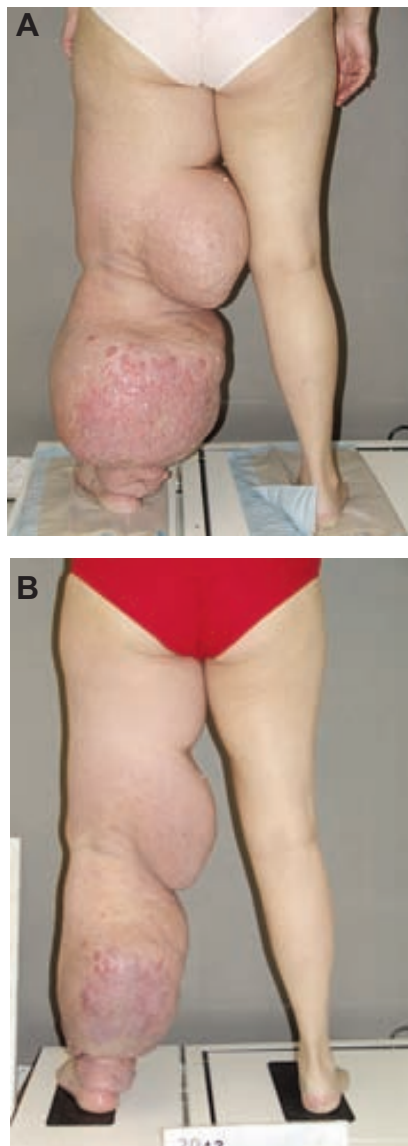


Figure 4. A) Before and B) eleven days after treatment.

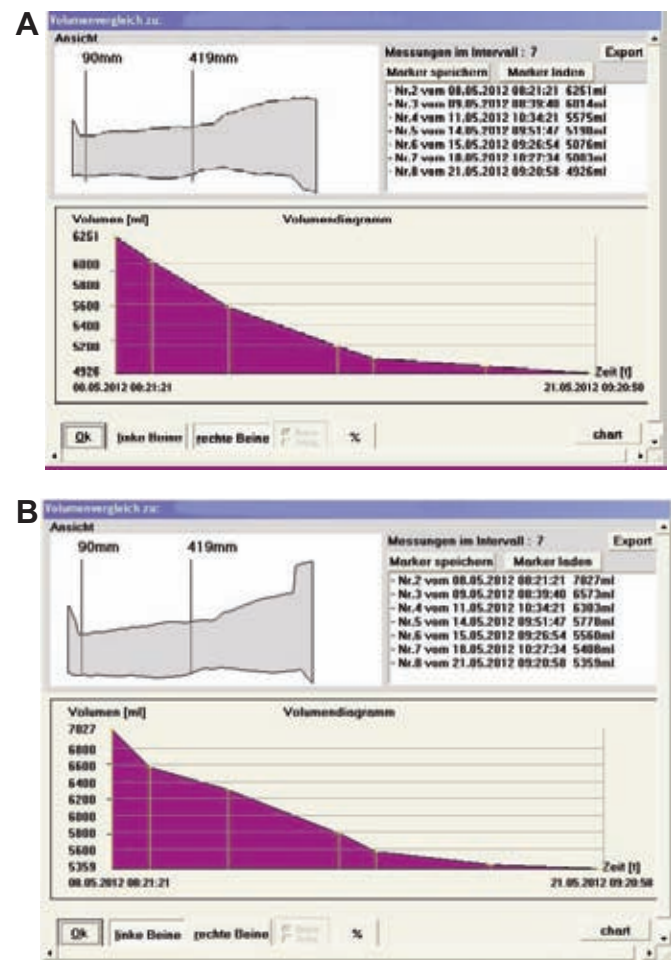


Figure 6. A) Volume reduction achieved by AZB (Perometer®, Pero-System Messgeraete GmbH) on the right lower limb; B) Volume reduction achieved by conventional lymph bandages (Perometer®, Pero-System Messgeraete GmbH) on the left lower limb.

tages and disadvantages of zinc paste, which have been highlighted in our clinical practice and in the pertinent literature.

Conclusions

Our preliminary results demonstrate that AZB (Pero-System Messgeraete GmbH) seem to be more effective than conventional multi-component lymph bandages (which include a lot of padding material) in reducing oedema in the initial treatment phase of patients with severe lymphoedema of the extremities. It is hypothesized that this is due to the very high stiffness of the alginate/zinc coated bandage, which is applied directly to the skin without padding.

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The use of strapping to increase local pressure: reporting of a sub-bandage pressure study

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Abstract

High compression is the gold standard for venous ulcer management. This brief report presents the results of a sub-bandage pressure study that investigated the pressures received from compression therapy in the region of the retromalleolar fossa. The study tested the hypothesis that therapeutic compression is not achieved behind the malleolus. The results confirm this, showing that less than 5-mmHg sub-bandage pressure is achieved despite high compression at the B1 level. This report demonstrates that the application of novel strapping below the malleolus substantially increases the compression at rest, standing and dorsiflexion. The clinical implications of this are discussed.

Introduction

The development of the strapping technique has been discussed and presented previously.¹ This technique was developed in response to the clinical complexities seen in lower limb ulceration where the ulcers are on the foot or behind the malleolus in the retro malleolar fossa. These sites typically prove difficult to heal with standard high compression therapy. This small study tested the hypothesis that standard high compression does not apply adequate pressure in this region; that therapeutic compression is only achieved at B1 or gaiter area. Standard compression therapy is ineffective in the retro-malleolar fossa region due to bandage hammocking from the heel to the malleolus. This study aimed to test this hypothesis and provide some evidence for the clinician and patient experience of this novel technique.

Materials and Methods

The sub-bandage pressures were obtained using a Picopress® [Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy] with

probes at standard B1 plus the retromalleolus fossa, both medially and laterally. Cohesive inelastic compression (Actico, Lohmann & Rauscher GmbH & Co. KG, Neuwied, Germany) was applied using a standard regime of 10 cm spiral or a non-standard 8cm in a figure of 8 from the toes. These regimes were compared with additional strapping. Strapping was applied in a fan distribution¹ (Figure 1). Sub-bandage pressures were collated at resting, standing and at dorsiflexion.

Results

The mean pressures at B1 using cohesive inelastic regime were 42 mmHg at rest and 62 mmHg on standing. Figure 2 demonstrates the range of sub-bandage pressures exhibited from the probe placed behind the malleolus. When the probe was placed in the inner/medial or outer/lateral retromalleolar fossa, the pressures were under 5 mmHg at rest, standing and on dorsiflexion. With the application of strapping, pressures in this region increased, ranging from 25 mmHg to 48 mmHg (Figures 2-4).

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Contributions: AH, FW, co-developer of the novel strapping technique, investigator and analysis; HP, advised in study design, investigation and results.

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Figure 1. Fan strapping.

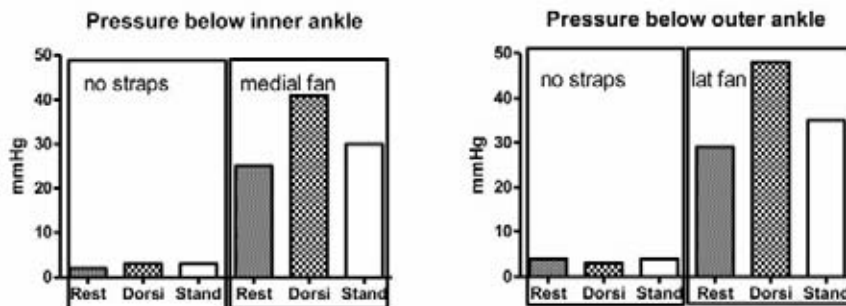


Figure 2. Range of sub-bandage pressures.



Figure 3. Lateral ankle, no straps.



Figure 4. Lateral ankle, with straps.

Discussion and Conclusions

This simple study confirmed the hypothesis that standard high compression does not provide compression to the retromalleolar area despite achieving high pressures in the B1 area. Thus this region does not receive therapeutic compression. The use of a strapping technique has been shown to significantly increase compression to this area.

The authors contend that this is of clinical significance. Where there is non-healing ulceration below the ankle and on the foot, this technique targets that area. High compression can be focused on the site without resorting to increasing compression through multiple layers of bandage from toe to knee; thus manage-

ment is tailored to the patient and limb improving tolerance of treatment. Patients report that they feel the additional pressure from the straps, that it promotes a support to the ankle and offers pain relief. This novel technique impacts on compression stiffness and also assists in reshaping the foot and anatomical shape of the malleolar fossa; the latter has often been lost through edema and reduced ankle range of motion. The pressures demonstrated at the ankle region through the use of the strapping dispute the promotion of standardized compression regimes for all patients.

The strapping technique was developed in a primary care trust. The authors claim this is a key factor in having a venous ulcer prevalence of 0.14 per 1000.²

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Comparison of knee-high Mediven ulcer kit and Mediven Plus compression stockings: measurement of leg volume, interface pressure and static stiffness index changes

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Abstract

Ulcer stockings are produced to have higher interface pressure and easier application compared to those of classic medical compression stockings. We aimed to compare volume decrease, pressure loss and stiffness index of a classical medical compression stocking and an ulcer stocking of the same interface pressure range in 10 patients with bilateral venous and 10 persons with lymphatic insufficiency. Interface pressure measurement in supine and standing positions and optoelectronic volumetry served for primary outcome variables. Both stockings were capable of inducing remarkable gradual volume reductions in different time points except classic stocking at 2 h in phleboedema care. Ulcer stocking pressures in lymph- and phleboedema were highly superior. In lymphedema a gradual interface pressure loss was attributed to both stockings regardless of body positions. Static stiffness indices did not differ statistically except classic stocking at baseline ($P=0.0312$) and 2 h ($P=0.0082$) comprising venous edema patients. Both stockings acted similarly but ulcer stocking had considerably higher interface pressures in each measurement and raised stiffness indices initially and the two-layer system facilitates donning therefore ulcer stocking could serve an alternative of classic medical compression stocking even in the treatment of leg edema.

Introduction

The intensive treatment of the two prevalent causes of chronic leg edema [chronic venous insufficiency (CVI) and lymphedema] is commonly based on various bandage systems.¹ Inelastic bandages, especially when two or more are applied in an overlapping fashion, have high stiffness, a significant pressure loss

is observed within the first hours of application due to the rapid volume reduction.² Medical compression stockings (MCSs) are elastic devices with relatively low stiffness index (<10).³ Unlike bandages, MCSs are observed to loose original interface pressure to a lesser degree.² There is an emerging body of evidence that MCSs are also capable of efficient volume reduction even in the intensive therapeutical phase.¹ Taken the previous data together, MCSs are presumed to possess some important features of efficient compression, however the achievable high interface pressures may associate low patient compliance as both donning and removal of the garment cause difficulties and require outstandingly high forces.⁴ The pressure of the two superimposed stockings was shown to roughly correspond to the direct addition of the interface pressure exerted by the single layer due to interface friction.⁵ Overlapping stockings efficiently raise interface pressure and alleviate application. Classic MCSs are recommended for daily use but depending on interface pressure in supine position, patients are sometimes asked to wear their stockings overnight. The nocturnal wear of understocking of ulcer garments is preferred.⁵ The new generation of stockings with double-layers is preferably recommended for leg ulcer healing but its potential advances over traditional MCSs give rise to a comparative study in view of stiffness.

This was the background for a clinical study in which we compared interface pressures of an ulcer stocking with that of a traditional MCS belonging to the identical pressure range.

Materials and Methods

A total of 20 legs from ten out-patients with bilateral CVI [three males, seven females; age 52-75, median 61; mean body mass index (BMI) (kg/m^2): 30.57 (21.52-45.84); mean disease duration (years): 5 (1-20); clinical Clinical-Etiology-Anatomy-Pathophysiology classification (CEAP)-classes C3-6] and another 20 legs of ten secondary lymphedema out-patients with bilateral lower limb affections (three males, seven females; age 55-81, median 70; mean BMI (kg/m^2): 36 (24-41); mean disease duration (years): 8 (4-14) were recruited. Each of the bilateral secondary lymphedema cases was stage II comprising 5 persons with gynecological cancer treatment-related moderate lymphedema and another 5 patients where repeated erysipelas affecting both legs at different time caused lymphedema. CVI was diagnosed using color-coded duplex ultrasonography. Patients did not wear any form of compression garment 48 h before the beginning of the trial (wash-out period) and lymphedematous legs did not receive sup-

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Key words: volumetry, static stiffness index, medical compression stocking, ulcer stocking.

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plementary treatment (e.g. manual lymph drainage, intermittent pneumatic compression). Inclusion criteria were in accordance with the recommendations of the International Compression Club.¹ Informed consent was obtained from each patient and the study protocol conformed to the regular ethical guidelines, as reflected in a prior approval by the University of Szeged human research committee. According to limb girths standard below-knee stockings (Mediven ulcer kit and Mediven Plus compression class 3) were provided by the Medi Company (Bayreuth, Germany). Interface pressure was measured by Kikuhime (Medi Trade, Soro, Denmark) device⁶ using small pressure probe placed to point B1 at baseline, 2, 4 and 24 h in standing and supine positions, as well. Pressure probe was not held continuously under the stocking but was placed immediately after pulling down the compression material then stocking was redone and finally the measurement was completed. According to our standards, Mediven ulcer kit was assigned to right, while Mediven Plus to the left leg. Stockings were worn for 24 h with a surprisingly sufficient tolerability. The static stiffness index (SSI) was calculated as the difference between standing and supine pressures.⁷ Leg volumes were assessed with infrared optoelectronic measurement using Perometer (Perimed, Wuppertal, Germany)⁸ at baseline and immediately after pulling down the stockings taking only 2-4 min in each case.

Feet and calves were subjected to volumetry. To compare SSI of the two products (right side *vs* left side), the non-parametric Mann-Whitney test was used. Comparisons between the pressure and volume values at different time points using the same type of stocking were made by Wilcoxon signed rank test as a nonparametric measure. P values lower than 0.05 were considered as statistically significant.

Results

Volume change

Both Mediven ulcer kit and Mediven Plus stockings were capable of inducing remarkable gradual volume reductions in different time points. Each of the measured volume decreases appeared to be significant except Mediven Plus at 2 h among patients with phleboedema.

Interface pressure

The pressure exerted by ulcer stocking in lymph- and phleboedema was highly superior to that of Mediven Plus at each measurement in lying and standing positions except a single assessment at 2 h in upright position ($P=0.0707$) of the patients with lymphedema.

Pressure alteration

In lymphedema a gradual interface pressure loss was attributed to both compression stockings regardless of body position positions (Figure 1). Mediven Plus failed to cause a pressure decrease 2 h after the beginning of application in supine ($P=0.1016$) and standing ($P=0.509$) positions, as well. Venous edema treatment with Mediven Plus associated significant pressure losses in supine positions but did not provoke any significant changes of interface pressures ($P=0.0762$ at 2 h, $P=0.1602$ at 4 h and finally $P=0.0547$ at 24 h) in standing posture (Figure 2).

Static stiffness index

The calculated static stiffness indices did not differ statistically regardless of compression material in lymphedema (Figure 3A), however this parameter of Mediven Plus (median: 2.00) was significantly inferior to that of ulcer stocking (median: 4.00) at the first two measurements (baseline: $P=0.0312$ and 2 h: $P=0.0082$) comprising venous edema patients (Figure 3B).

Discussion

According to experiments in the field of compression therapy two factors play a pivotal role in setting an efficient therapy. Interface

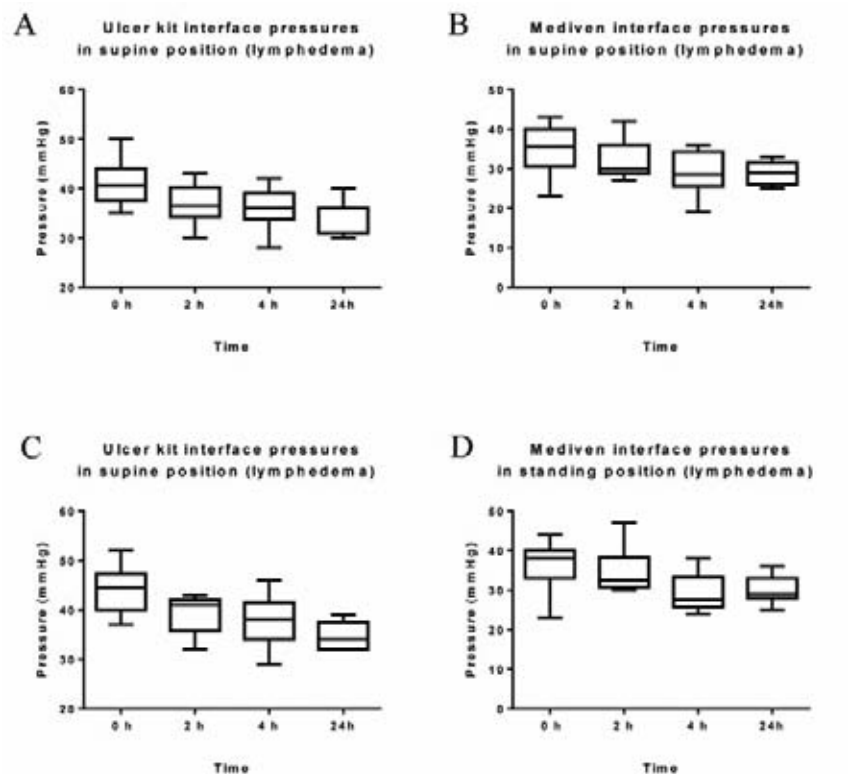


Figure 1. Interface pressures of Mediven Ulcer kit and Mediven Plus AD ccl 3 stockings in supine (A,B) and standing (C,D) positions in lymphedema.

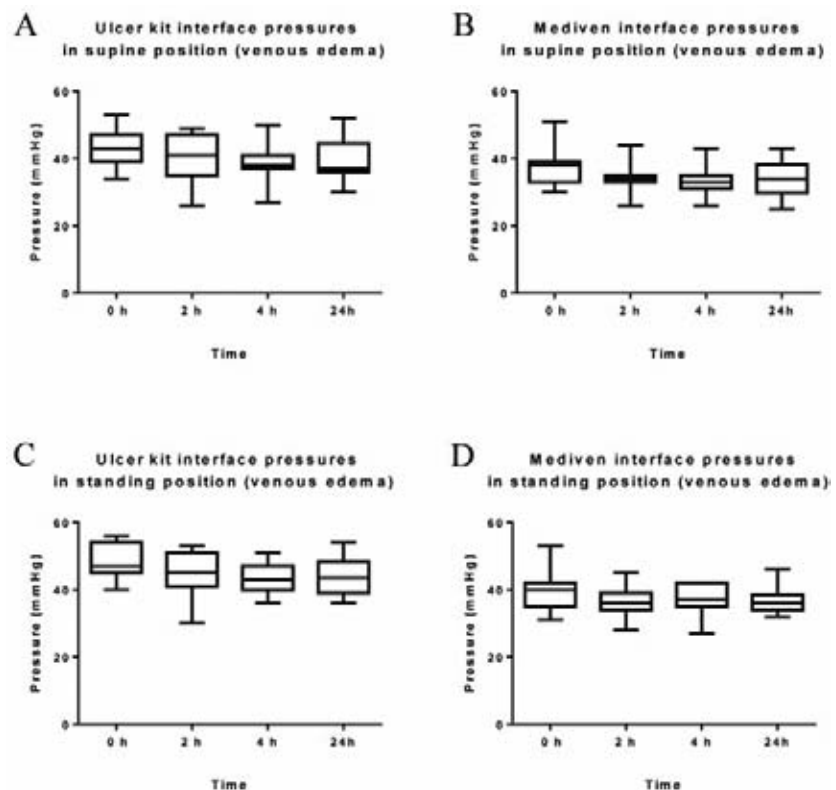


Figure 2. Interface pressures of Mediven Ulcer kit and Mediven Plus AD ccl 3 stockings in supine (A,B) and standing (C,D) positions in venous edema.

pressure measured under the compression material is able to restore venous and lymphatic insufficiency along narrowing veins and ameliorating interstitial pressure. Clinical studies demonstrated that the application of higher external pressure lead to a faster venous leg ulcer healing by efficiently counteracting the high ambulatory venous pressure thus providing an enhanced venous flow. Lower extremity edema sometimes presents in a combined form including impaired venous function, lymphatic insufficiency and increased capillary permeability,¹ thus the relatively high edema volume warrants fairly high external pressure. Evacuation of edema and the most advanced form of venous insufficiency are preferably directed to inelastic compression bandaging in a multilayer and multicomponent fashion where interface pressure is strongly correlated with the tensile forces.^{9,10} MCSs are usually used in the maintenance phase where achieved results (volume decrease, healed ulcer) should be preserved.¹ The higher success rate in leg affection is attributed to the applied pressure. If the external pressure meets the ordinary range of ambulatory venous pressure in impaired function it might minimize the risk of recurrence. Medical compression stockings are manufactured from elastic material so as to facilitate donning and positioning over bony prominences but the elastic properties possess at least two disadvantages: stockings less efficiently assist muscle pump¹¹ and keep nearly the same pressure regardless of position having low SSIs. A major burden of increasing compression pressure is the tolerability. Classic medical compression stockings of higher pressures cause difficulties in donning and keeping them on legs in lying position. A new generation of stockings tends to alleviate these problems comprising an under- and an

overstocking with relatively low pressures. These two superimposed garments set the final pressure.⁵ These overlapping stockings were designed especially to treat leg ulcers but their other advantages made them interesting for other objectives like the use in chronic leg edema (*e.g.* phleb- or lymphedema) however remained relatively poorly characterized and compared to other compression materials. Beyond their relatively easy application we were able to experience that ulcer stockings also exerted significant leg volume reduction and brought up significantly higher interface pressure compared to classical MCSs. The difference between lying and standing positions results SSI that is an accurate indicator of appropriate stocking selection for patients.¹² Low pressure at supine position and a substantial rise after standing up provides a comfortable wear and an efficient prevention against edema formation and venous dilation. We were able to show that the SSI of the given ulcer stocking was able to exceed that of compression class 3 medical stocking in venous edema during the initial phase of treatment however it remained still relatively low. Stockings with higher stiffness have a higher anti-edematous efficacy.¹³ A previous clinical trial disclosed that the superposition of two stockings did not only increase the interface pressure, but had a further additive effect to the stiffness of the final stocking combination.³

To our knowledge this is the first comparative study examining two types of stockings from the aspect of stiffness index as one of the most emphasized primary outcome variable. From the practical point of view we recommend the use of ulcer stockings instead of classic MCS with identical interface pressure when the final pressure should be adjusted along easier doffing and in case of distinct leg edema forms.

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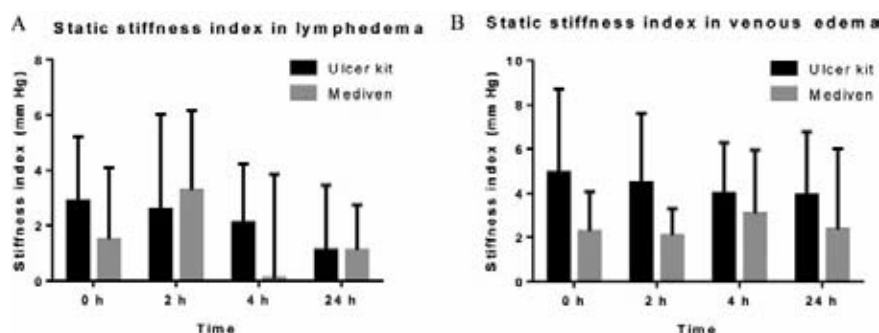


Figure 3. Comparison of static stiffness indices of Mediven Ulcer kit and Mediven Plus AD ccl 3 stockings in lymphedema (A) and venous edema (B).

