

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 ($r=0.75$).

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.

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

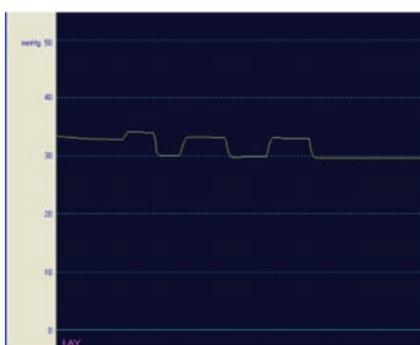


Figure 2. A ready made compression stocking, size small, achieves a pressure of 33 mmHg at the B1 point of the model. This pressure drops to 30 mmHg after stretching the model by 1 cm three times. SI=3 mmHg (Picopress[®] probe).

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

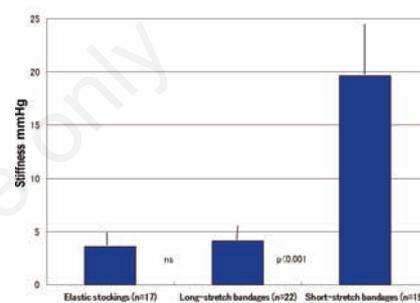


Figure 3. Comparison of stiffness values (mean+standard deviation) between elastic stockings (left), long stretch bandages (middle) and short stretch bandages (right), resting pressures 23-46 mmHg (AMI-3037[®]). The difference between elastic and inelastic material is significant ($P<0.001$).

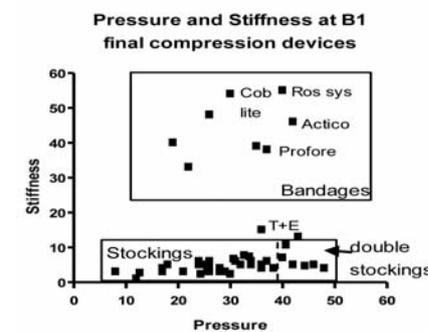


Figure 4. Characterization of several compression stockings and multi-component bandages concerning pressure (x-axis) and stiffness values (y-axis). The application of a second stocking over the first in 6 cases increases the stocking pressure to values over 40 mmHg. [T+E=tubular device (Tubulcus[®])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

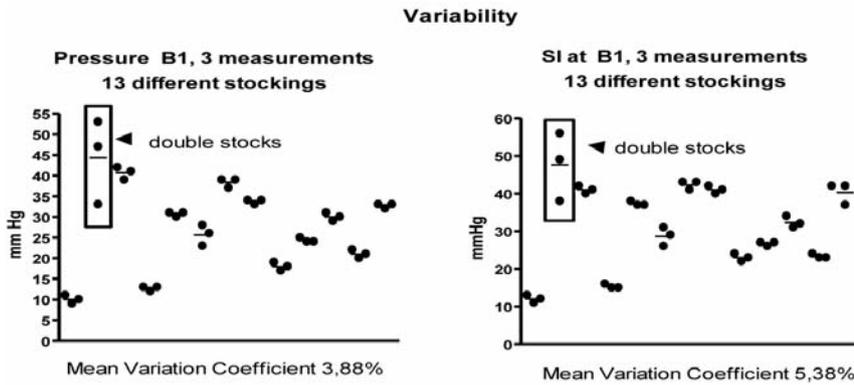


Figure 5. Measurement of pressure at B1 (left) and of stiffness (right) on the mannequin leg of 13 different compression stockings, three times repeated (Picopress® probe).

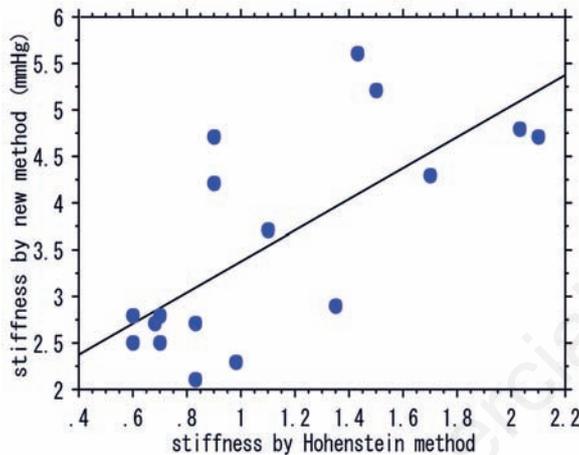


Figure 6. Correlation of stiffness measured by the Hohenstein method (x-axis) and by the mannequin-leg (y-axis) in 17 stockings (AMI-3037®).

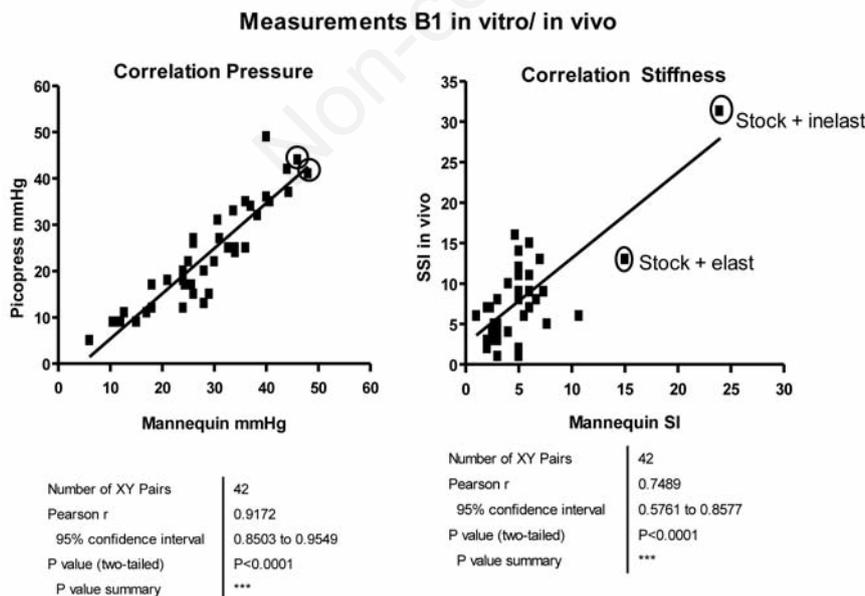


Figure 7. Correlation for pressure at B1 (left) and stiffness (right) between the Mannequin leg (x-axis) and a human leg (y-axis). Encircled are the values obtained after wrapping elastic and inelastic bandages over a class II stocking.

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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