

Interface pressure and stiffness of ready made compression stockings: Comparison of in vivo and in vitro measurements

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Objective: It is unknown if the pressure values of compression stockings indicated by the producers correspond to the actual compression pressure exerted in vivo. This study compared pressure and stiffness of ready-made compression stockings (Venosan) of different classes, measured on the leg and by laboratory testing.

Methods: This was an experimental study conducted in a textile laboratory of a company that manufactures compression stockings. Twelve legs from healthy volunteers were fitted with ready-made calf-length compression stockings of the European classes I, II and III. In addition, two class I stockings were applied over each other. The in vivo interface pressure was measured using the medical stocking tester (MST) in position B1, eight cm proximal to the inner ankle. Stiffness was defined by an increase of pressure due to an increase of stretch that reflects the elastic property of the textile and was assessed by measuring the difference of interface pressure between standing and supine position at B1. In the laboratory, the MST was used to check the pressure of these stockings on wooden leg models. Then circular slices were cut out from the stockings at the B1 level and stretched by a Zwick dynamometer in the transverse direction. Force/extension-curves were plotted, from which the pressure and stiffness of each individual stocking was calculated.

Results: The pressure profile measured on four positions along the leg by MST showed a degressive gradient on the wooden model but not on the human leg due to the measuring geometry in the ankle region. Pressure values on the leg correspond to the in vitro measurements calculated from the force/extension-curve with a bias (difference of the means) of -2.1 and 4.1 mm Hg. In 95% of the subjects, the difference was between -10.1 and 5.8 mm Hg (Bland Altman plot). The correlation between in vivo and in vitro measurement was highly significant ($P < .0001$, Spearman correlation coefficient; $r = .8161$). In vivo and in vitro measurement shows an increase of stiffness with increasing compression classes. The highest values are found for two class I stockings applied over each other.

Conclusion: Pressure and stiffness can be measured in vivo, correlate well with laboratory findings, and should be used in future studies, especially when different compression devices are to be compared. (J Vasc Surg 2006;44:809-14.)

Clinical studies have clearly shown that the effect of compression therapy in chronic venous insufficiency depends mainly on two factors¹⁻⁴: (1) the interface pressure of the fabric on the diseased leg, and (2) on the elastic property (stiffness) of the material that determines the performance of the product during standing and walking. With each muscle systole, the leg circumference increases so that the counter pressure of the bandage will increase, more with an inelastic than with an elastic fabric.

These parameters defining the "dosage" of compression therapy should be of major interest for the clinician and should be declared in future studies. The prescriber of compression stockings only rarely realizes that the pressure ranges indicated on the box are based entirely on measurements made in the

lab and not on human legs. Basically, the pressure of a stocking is calculated from the force/extension-diagram of the elastic fabric on a leg model with defined circular cross sections using Laplace's formula. The range of the compression pressure indicated by the manufacturers is determined by the measurement of the force which is necessary to stretch the stocking at certain levels in transverse direction. The proportion of stretch and force for each circumference level, which corresponds to the steepness of the so-called slope in the force/extension-curve, reflects the elasticity of the material of the stocking.⁵

Recently, measuring tools have been proposed to assess interface pressure and stiffness of compression materials in vivo.⁶ The aim of the present study was to compare pressure and stiffness of several medical compression stockings measured on the individual leg with pressure and stiffness of the same samples evaluated by in vitro methods as used by the stocking-producer.

MATERIALS AND METHODS

Test subjects. The interface pressure of several medical compression stockings was measured on 12 legs from six employees (5 women, 1 man) of Salzmänn Medico, who gave their written informed consent to participate in this study. They were a mean age of 43.2 years (range, 20 to 61). The clinical classes (C) of the 12 legs assessed by CEAP

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Competition of interest: Hugo Partsch and Bernhard Partsch have been paid travel expenses by Salzmänn Medico, St. Gallen, Switzerland. Walter Braun is an employee of Salzmänn Medico. The study was performed in a textile laboratory of Salzmänn Medico, St Gallen, Switzerland.

Presented as a poster at the Eighteenth Annual Meeting of the American Venous Forum, Miami, Fla, Feb 22-26, 2006.

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0741-5214/\$32.00

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doi:10.1016/j.jvs.2006.06.024

Table I. Main characteristics of the test subjects

Age (y)	Sex	CEAP C-class	BMI	Circumference		Stocking size prescribed
				Ankle (cm)	Below knee (cm)	
46	F	C1, C0	20.2	20	30	Small
20	F	C0, C0	22.5	19.5	30	Small
29	F	C2, C0	30.1	26.5	42	Large
42	F	C1, C1	25.6	23.5	29	Medium
61	M	C0, C0	22.1	23	36	Medium
61	F	C1, C2	24.6	20	26.5	Small

BMI, Body mass index.

corresponded to C0 (6 legs), C1 (4 legs), and C2 (2 legs). **Table I** summarizes some basic characteristics of the test subjects. No individual was routinely using compression stockings. The study was done in a laboratory of Salzmann Medico in Switzerland.

In vivo measurements. A medical stocking tester (MST, Salzmann Medico, St. Gallen, Switzerland) was used. It consists of a flat, air-filled sleeve with a large surface area and a minimal volume, with four electrical contact points at which the pressure can be registered at four different levels.⁷

The measuring points^{8,9} on the medial aspect of the leg were B, ankle behind the inner malleolus; B1, 8 cm above, where the tendinous part changes into the calf muscle; C, 19 cm above the ankle at mid-calf; and D, 30 cm above the ankle. **Fig 1** shows the MST instrument attached to a wooden leg model and the corresponding measuring points.

Calf-length, custom made-stockings (Salzmann Medico) fitted to the individual legs by measuring the smallest girth at ankle level and at the leg circumference corresponding to the upper end of the stocking (**Table I**) were donned over the MST tester as follows: one Venosan class I; two Venosan class I; one Venosan class II; and one Venosan class III.

The pressure ranges at B-level declared by the producer are 15 to 21 mm Hg for class I, 23 to 32 mm Hg for class II, and 34 to 46 mm Hg for class III, following the European standards.^{8,9} According to these regulations, the pressure profile along the leg has to be 70% to 100% at B1 and 50% to 80% at point C and D compared with the pressure exerted at ankle level B.

In vivo measurements of the interface pressure were done in the supine and in the standing positions. The exact B1 measuring site of the MST taken as the reference was marked on the stocking and on the leg. As a useful parameter characterizing the elastic property of the tested products, the static stiffness index (SSI) was calculated by subtracting the resting pressure at B1 in the supine position from the pressure at the same site in the standing position.¹⁰

In vitro measurements. The same stockings that were used on the human legs were donned on wooden leg models, and an MST tester was used to measure the interface pressure in the different levels (**Fig 1**). Three different models were used representing the sizes “small,” “medium” and “large” in accordance with the dimensions of the individ-



Fig 1. Measurement of interface pressure by medical stocking tester (MST). The measuring points are B, ankle; B1, gaiter area; C, largest calf circumference; and D, below knee.

ual legs (**Table I**). Then 5-cm-wide transversal slices from the marked B1 region were cut from each stocking. The annular specimens were mounted into a Zwick dynamometer (Zwick-Roell, Ulm, Germany) and stretch-tension curves were obtained after five repeated cycles of light overstretch.⁹

The sixth stretching cycle was registered, in which the fabric was stretched to the half-length of the circumference at B1, which was 13.25 cm for the “small” size, 15 cm for “medium,” and 17 cm for “large.” The resulting stretch/extension-curve represents the relationship between the stretching force in Newton (N) and the elongation (stretch) of the fabric in centimeters.

Pressure is defined by the amount of the stretching force per surface area. The unit of pressure is Pascal (Pa), defined by 1 N/m². Medical pressure units are usually given in mm Hg, 1 N/cm² being 75 mm Hg. The local pressure (P1) for the B1 segment is calculated by dividing the force by the surface area of a cylinder of 1 cm height and a circumference corresponding to the leg segment at B1.

From the curve, one can also calculate the force that is necessary to elongate the fabric by 1 additional centimeter. This can be transposed into the local pressure (P2) to the B1 segment with a virtual increase of circumference by 1 cm. By definition, the difference P2 – P1 corresponds to stiffness, which is the increase of pressure due to an increase of the circumference by 1 cm.⁸

Table II. Interface pressure (mm Hg) measured by the medical stocking tester (MST) tester with different stockings in the supine and standing position in 12 legs and on wooden leg models*

Stocking classes	B (ankle)	B1 (gaiter)	C (calf)	D (below knee)
Cl I supine	19.1 ± 3.9	18.3 ± 3.2	14.0 ± 3.8	12.1 ± 5.0
Standing	16.8 ± 7.0	21.1 ± 3.1	16.4 ± 3.7	13.6 ± 6.5
Wooden leg	21.3 ± 0.9	18.7 ± 0.9	14.0 ± 0.9	12.7 ± 1.8
Cl I+I supine	35.5 ± 5.6	31.6 ± 5.1	26.1 ± 5.2	23.4 ± 10.1
Standing	34.3 ± 8.0	37.6 ± 7.3	29.8 ± 7.3	24.9 ± 13.9
Wooden leg	42.5 ± 4.1	39.4 ± 5.6	27.3 ± 4.3	25.2 ± 3.2
Cl II supine	21.3 ± 3.7	21.3 ± 3.7	17.2 ± 3.7	15.8 ± 4.5
Standing	16.5 ± 8.9	23.6 ± 3.9	19.8 ± 6.5	17.7 ± 8.5
Wooden leg	28.1 ± 2.2	24.3 ± 3.1	17.2 ± 3.9	17.3 ± 1.9
Cl III supine	29.8 ± 5.6	28.7 ± 5.2	22.6 ± 4.9	20.2 ± 5.2
Standing	26.3 ± 9.5	33.0 ± 6.9	26.0 ± 5.4	23.1 ± 9.6
Wooden leg	39.7 ± 2.8	32.8 ± 4.9	23.8 ± 3.7	21.0 ± 4.0

Statistical differences at B1: ** $P < .01$, *** $P < .001$.
Supine: Cl I vs I+I***; Cl I vs III**, Cl I+I vs II***.
Standing: Cl I vs I+I***; Cl I vs II***; Cl I vs III***.
Wooden leg: Cl I vs I+I***; Cl I vs III**, Cl I+I vs II***.
*Data are shown as mean values ± standard deviation.

Statistics. Mean values and standard deviations are given. Comparisons among the stockings were performed using the nonparametric Friedman test with Dunns' post-test for multiple comparisons. Nonparametric (Spearman) correlation and Bland-Altman plots were used to compare the different measuring methods.¹¹

RESULTS

Interface pressure measured by MST tester. Table II shows the interface pressures of the tested stockings for all measuring points in the supine and standing positions and on the wooden leg models. The statistical differences between the stocking classes are given for the B1 region, which was the target zone for our dynamometric comparisons. The pressures from the leg model at position B are in the range of the values indicated by the producer for each class. The mean pressure measured at the ankle (point B) in the human leg is often lower than at B1, whereas the wooden leg model always shows the highest values at the ankle. A direct comparison of our in vivo data obtained from point B1 with the in vitro pressure values declared by the producer is therefore not possible, because the international standards refer to the ankle level B, which is a very unsuitable region for in vivo measurements.⁶

It is interesting to note that the highest pressure levels are obtained with two class I stockings donned over each other, which are even higher than the values for a class III stocking.

Comparison between MST (in vivo) and dynamometer (in vitro) data pressure. The interface pressure values of the different stocking classes measured by the MST tester at B1 are comparable with the values calculated from the force/extension-curves that are obtained from the dynamometric measurement of the B1 segment cut out from the stockings when single layer stockings are compared (Fig 2).

The Bland Altman plot in Fig 3 takes into account all single-layer stockings and shows that the values of interface pressure measured in vivo and in vitro are in fact quite close,

with a bias (difference of the means) of -2.13 and 4.1. In 95% of the subjects, the difference was between -10.1 and 5.8 mm Hg. The correlation was highly significant (Fig 4; $P < .0001$, Spearman; $r = 0.8161$).

Stiffness. Stiffness is defined by the increase in compression per centimeter increase in the circumference of the leg.⁸ The static stiffness index in vivo has been defined by the difference of the interface pressure values between active standing and relaxed supine position.^{6,10} The differences measured by MST for all stockings at the four measuring points B, B1, C, and D on the 12 legs were -2.96 ± 8.19 , 3.78 ± 3.84 , 3.06 ± 4.44 , and 1.96 ± 7.82 , respectively. The highest values are observed at position B1, which is the region on the leg that shows the most pronounced change of local radius and increase of circumference on the leg by dorsiflexion.¹²

In vitro stiffness was calculated from the slope of the stretch/extension-curve. As shown in Fig 5, both the in vitro and the in vivo measurements revealed the highest stiffness values when two class I stockings were applied over each other, with significant differences compared with class II stockings in vivo ($P < .05$) and with class I stockings in vitro ($P < .01$).

Pressure gradient. All stockings showed decreasing pressure values between point B1 and point D, both at the wooden model and on the human leg in the supine and standing positions (Table II). Fig 6 gives a graphic example showing the median values exerted by class III stockings in the supine and standing positions and on the wooden leg model. In the ankle region (position B), the in vivo values are lower than those from the model because of the different measuring geometry.

DISCUSSION

It is a remarkable fact that the indicated pressure ranges and compression classes of medical compression stockings are entirely based on the manufacturers' in vitro measure-

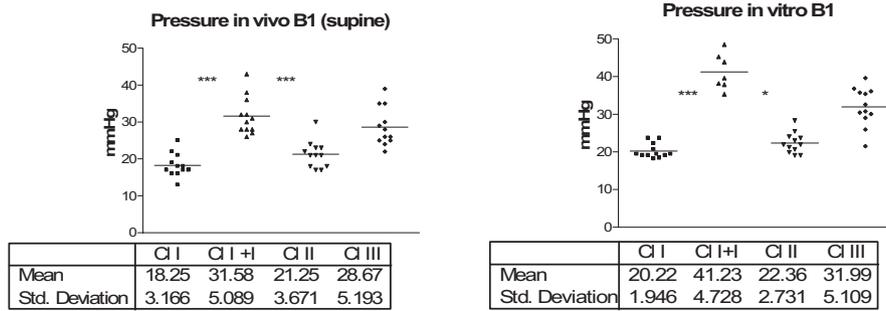


Fig 2. Comparison of in vivo and in vitro measurement of interface pressure. **Left,** Pressure of several stockings measured by medical stocking tester (*MST*) tester at position B1 (gaiter area). **Right,** Pressure calculated from the force/extension-curves of the dynamometer from the same stockings. **P* < .05. ****P* < .001.

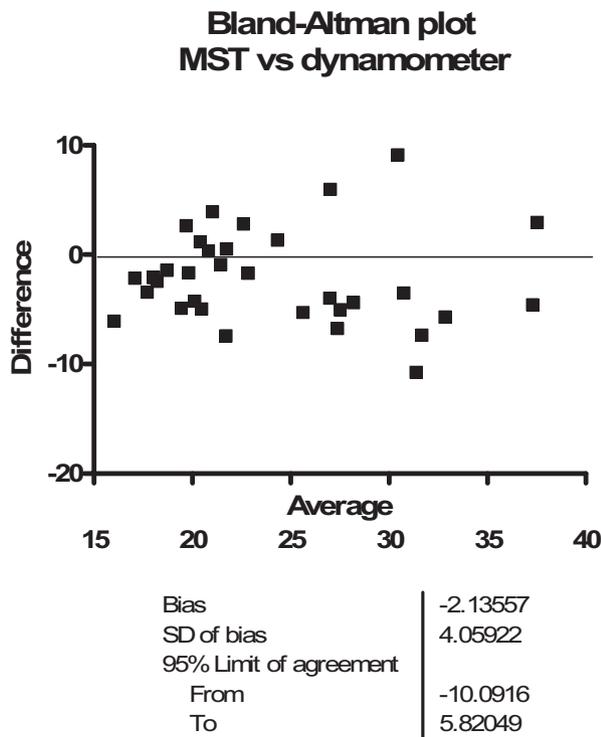


Fig 3. Comparison of in vivo pressures measured at B1 (gaiter area) by the medical stocking tester (*MST*) with in vitro pressure calculated from the force/extension-curve (dynamometer). The *x* axis shows the average of both measurements, and the *y* axis shows the difference of the two measurements.

ments. Only a few attempts have been made to compare several measuring procedures.¹³ The present study shows that at least for the tested products, these pressure ranges are in satisfactory agreement with the interface pressure measured in vivo.

Test subjects. Healthy volunteers with different leg configuration have been selected for this study. The parameters of compression pressure and of stiffness measured immediately after stocking application are not different between healthy subjects and patients with venous or lym-

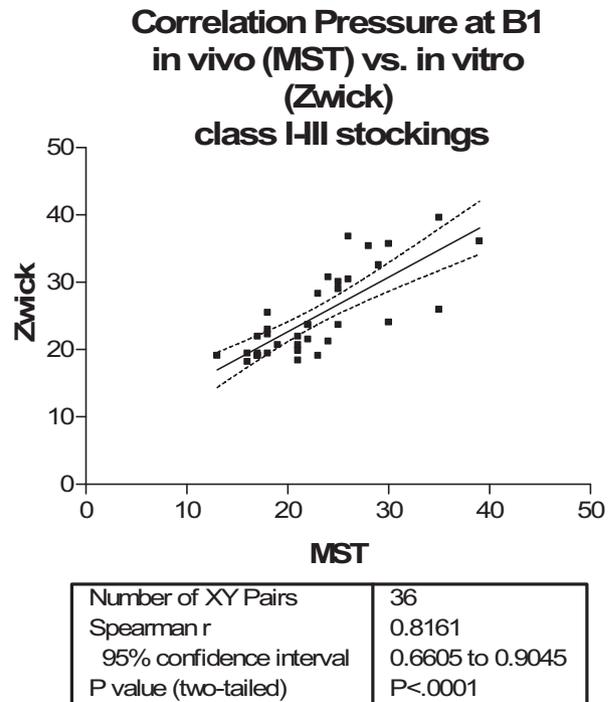


Fig 4. Correlation of interface pressure values measured by the medical stocking tester (*MST*) in vivo and by the Zwick dynamometer in vitro.

phatic disease. As this is demonstrated by the good correlation between the pressure values on the human and on the wooden legs, not even severe lipodermatosclerosis would have had a major influence on the measured data in the acute experiment. However, when the target of similar studies is directed towards an improvement of edema, repeated measurements of interface pressure and of limb volume after some time are advisable.

Measuring probe and measuring site. From a comparative investigation with three devices measuring subbandage pressure, the group of Dale et al¹⁴ recommended the *MST* as the preferred machine for future experiments. The instrument is able to measure the interface pressure

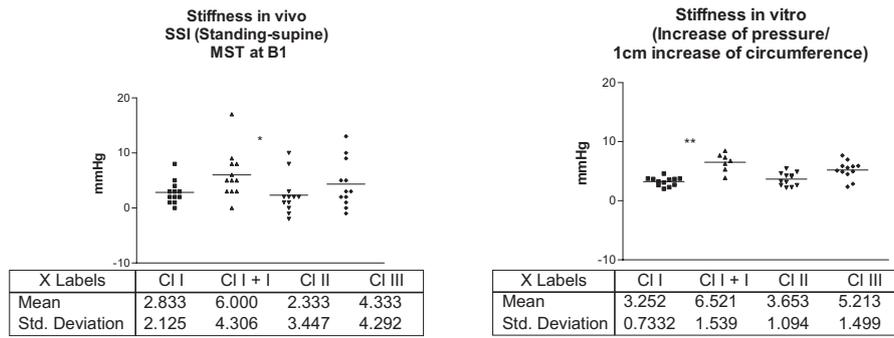


Fig 5. Left, Static stiffness index (SSI) of the different stockings measured by the medical stocking tester (MST) in vivo ($*P < .05$ between two class I (CI) and one class II (CII) stocking). Right, Calculated stiffness values of these stockings derived from the dynamometer curves in vitro ($**P < .01$ between two class I and one class II stocking). There is also a significant difference ($P < .05$) between class I and class III in vitro (not shown in the graph).

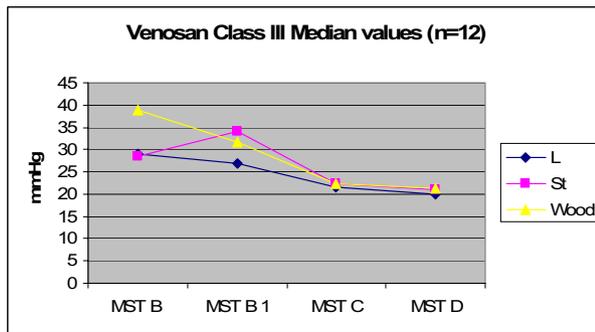


Fig 6. Medical stocking tester (MST) pressure values obtained by class III stockings on the human leg in the lying (L) and standing (St) position compared with the data obtained with the same stockings on a wooden leg model.

simultaneously at several points of the leg and has been shown to be a reliable device for routine measurements.^{7,14} Disadvantages are its restricted availability and its usage only for resting conditions and not for a continuous on-line registration during walking.

For the stocking producers, the reference point for indicating the compression class or pressure range is the ankle region, point B. The stretch of the fabric measured by a dynamometer is referred to the surface of a cylinder with a circular cross section so that, theoretically, the pressure would be the same at each point of the B-segment. In reality the B-region on the human leg corresponding to a cross section at ankle level is the one with the most extensive differences of curvatures of the lower limb. In fact, the pressure values measured in the retromalleolar region are frequently lower than the values from the measuring point 8 cm above (B1) (Table II), underlining the deciding importance of the local radius of the leg segment. (Due to Laplace's law the local pressure is indirect proportional to the radius.)

Pressure gradient. As summarized in Table II and presented in Fig 6, the wooden leg model with its circular cross sections shows a steady depression of pressure from

distal to proximal. There is a good agreement with the in vivo values at the largest calf circumference (position C) and below the knee (position D), where the cross section of the human leg comes also close to a circle and does not change much with standing. The in vivo values for B are lower because of the retromalleolar position of the probes, where curvature is flat or even concave. The highest pressure difference between standing and supine is found at B1 (Table II, Fig 6), indicating that this point is the best position to assess stiffness.

Assessment of stiffness in vivo. Stiffness can be defined as the increase in compression pressure per centimeter increase in the circumference of the leg mainly caused by muscle action.⁸ This parameter characterizes the distensibility of a textile, which is important in performance of a compression device during standing and walking.^{8,10} Several experiments have shown that even with the same resting pressure compression, devices with a higher stiffness are more effective to reduce edema,³ reflux,² and ambulatory venous hypertension¹ in patients with chronic venous insufficiency. Positioning the pressure transducer to the medial leg at the area of B1, the pressure increase occurring with standing up from the supine position is a simple parameter for stiffness, the static stiffness index.¹⁰

This increase of pressure is due to the diminution of the local radius by protrusion of the muscle tendon according to Laplace's law and to the increase of the leg circumference occurring with every dorsiflexion during every single step.¹² Plethysmographic measurements in the standing position with plantar flexion and with dorsiflexion revealed changes of the leg circumference depending on the measuring site. In the B1 region, an average increase of the circumference of 8 mm was found, whereas a decrease of 2 to 4 mm was measured at the proximal parts of the lower leg.¹² The changes of the local radius that occur by a protrusion of the tendon with ankle movement are highly variable between different individuals. The high variance of the static stiffness index values reflects mainly the considerable intraindividual differences of the leg configuration between standing and walking.

There is a higher pressure increase with inelastic compression material and a lower increase with a yielding, elastic textile.^{6,10} Compression stockings have a lower stiffness index than short stretch bandages. A comparison of stiffness values is only possible when the same transducer is used, always exactly at the same site.⁶

A surprising finding is that the superposition of two class I stockings not only produces higher resting pressures at B1 compared with a class III stocking (Table II) but also results in higher stiffness values, both with in vivo and in vitro testing (Fig 5). This fact can be explained by the friction between the two stocking layers.¹² When the leg circumference increases with standing or walking, a tangential stress is exerted on the fibers of the compression fabric. Friction between the rough surfaces of different layers opposes the expansion of the leg in addition to the elastic strain of the fibers.

Validity of interface pressure measurements in vivo. The pressure values measured by the MST tester on the human leg are not only in good agreement with those on the wooden model (Table II) but also correlate very well with the calculated data derived from the force/extension-curves (Fig 4). This is in contrast to recently published data obtained by in vivo measurements with a resistive transducer showing interface pressure values for class III stockings of a maximal 15 mm Hg.¹⁵ In this latter study, unfortunately, no attempt was made to calibrate the transducers or to compare the values with a reference method.

Our values obtained by in vivo measurements are also in good agreement with the pressure ranges recommended by several international regulations as long as the more reliable data from B1 are taken and not the B values. To obtain a pressure gradient, the European prestandard recommends a pressure for B1 that should be 70% to 100% from the values at B.⁸ This has to be taken into account when comparing the in vivo and in vitro data at B1 (Fig 2).

Practical consequences for future international standards of compression hosiery. The following points should be discussed with the producers of compression hosiery:

- For characterizing different strengths of stockings, ranges of mm Hg should be used instead of compression classes.
- The pressure ranges, which at present time are measured by varying methods in the laboratory only, should also be checked by in vivo measurements on human legs.
- B1 should be taken as the reference point for such measurements.
- In vivo measurements should be performed in the supine and in the standing positions. The difference for point B1 could be taken as a parameter for stiffness.
- Measurements of this sort should be done in future hemodynamic and clinical studies testing new developments or comparing different devices.
- Multilayer stockings offer interesting new ways not only in respect of easier application for the patient but

also concerning higher pressure and higher stiffness. By adding or removing layers the desired compression pressure can be adjusted to the daily activities and to periods at rest.

AUTHOR CONTRIBUTIONS

Conception and design: HP
 Analysis and interpretation: HP, BP
 Data collection: HP, BP, WB
 Writing the article: HP, BP
 Critical revision of the article: HP, BP
 Final approval of the article: HP, BP
 Statistical analysis: HP
 Obtained funding: HP, BP
 Overall responsibility: HP

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Submitted Dec 27, 2005; accepted Jun 25, 2006.