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In vivo stiffness of wraps: a tool to estimate the number of patients who will respond to treatment

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Abstract

Adjustable Compression Devices (ACDs), also known as wraps, offer a promising alternative treatment to bandages in complicated stages of chronic venous disorders. Nevertheless their characterisation and clinical place depending on their stiffness, are still pending questions. We propose a new approach to measuring stiffness *in vivo* in a small group of individuals

Measurement of the Static Stiffness Index (SSI) of two adjustable compression devices commercially available in 10 healthy volunteers.

Ten healthy volunteers of 37.6±8.6 years old (25-50), mean, Standard Deviation (SD), and range, respectively, participated in the study. SSI was measured at the resting pressure of 30 mmHg for both ACDs at point B1. SSI was 21.9±10.3 mmHg (0-33) for Coolflex and 12.5±6.2 (0.6-24.6) for Compreflex.

At a cut-off level of 10 mmHg of SSI, 10 % of volunteers for Coolflex and 30 % for Compreflex were under the cut-off level.

The SSI measured *in vivo* made it possible to discriminate between wraps and estimate the percentage of patients who would better respond to this treatment.

Introduction

Adjustable Compression Devices (ACDs), also known as wraps, are an easy-to-use therapy for complicated stages of chronic venous insufficiency such as edema, lipodermatosclerosis, ulcers,[1-6] or lymphedema.[7] It is simple to put on and take off and easy to readjust if the pressure is too high or too low by caregivers or even by the patients themselves.[8-9] Nevertheless, there is a lack of clinical studies to establish this device as a treatment accepted by consensus in the course of severe stages of CVI or other disorders.[10] Moreover, there are even several commercially available devices, the characteristics and physical behaviour of which are unknown.[11] Yet, this prerequisite should be mandatory, for any medical compression device prior to future clinical studies.[12]

Differentiating wraps in terms of composition does not clear up their physical ability to address clinical questions conversely to pressure and stiffness, which are key characteristics for bandages and ACDs and have a strong link with physiological effects.[13-17] For instance, medical compression stockings have much less stiffness than bandages, and both do not treat the same stages of chronic venous insufficiency.[16,18-19]

Stiffness is not the only characteristic that gives the physiological effect, but it contributes to a great proportion of the results and is thought to play a part in the effectiveness of bandages in oedema, lipodermatosclerosis, and ulcers.[12]

The physiological effect of compression devices and the clinical indications for which they are designed can be deduced from stiffness values, which can be measured in various ways: static or dynamic indices with dorsiflexion, tip-toeing, or measured in laboratories using extensometers, mannequin legs.[13,18,19-24] Modelisation had been even recently used.[25]

In studies, stiffness is consensually measured at a pressure point located at the transition of the muscular part of the medial gastrocnemius into the tendinous, called the B1 point.[24] This seemed to be a reductor for authors[27], nevertheless, if it is technically possible to get the pressures at any point of a leg under a specific compression device using modelisation, practically, it would be impossible, due to the huge set of data to interpret the results in order to adapt the compression to patients.

Benigni *et al*. have studied the stretchability and stiffness of various ACDs.[11] In their work, the Static Stiffness Index (SSI) was measured *in vivo* on five volunteers. They concluded, as many other authors did mainly for bandages, that SSI can discriminate against ACDs. They propose, as is the case for stockings, a laboratory test on mannequin legs to correctly address the future question of the standardization of wraps and let the *in vivo* measurements for clinical cases approach.[11,26]

The objective of this present work is to demonstrate that the variability of SSI measured *in vivo* could not be a problem to discriminate between wraps without the need for textile laboratory testings, in terms of stiffness in a reproducible way. Moreover, the results of *in vivo* testing could even be applied to estimate how many patients would respond more adequately to this treatment.

Materials and Methods

It is a pilot, monocentric, open-label study on healthy people that aims to compare the stiffness of two ACDs using the Static Stiffness Index (SSI).

This study was registered under the SI number 24.01972.000353, national number 2024-A00996-41, acronym RIIDA, accepted by the « Comité de Protection des Personnes Est III » on June 18th, 2024.

Ten healthy non-obese volunteers were enrolled in the study, and their informed consents were collected. Each volunteer wore the two ACDs on the same leg successively, the right leg being arbitrarily selected, and the order of ACDs was randomly selected. Among the commercially available ACDs, two ACDs were chosen because they are at the extreme range of stretch according to the results of a previous study by Benigni *et al*.[11] These are Coolflex with a 0-10 % stretch – its stretch is limited by the seams - and Compreflex with a 127% stretch, the two devices are sold by SIGVARIS SAS (St Gallen, Switzerland). Each volunteer was equipped with the ACDs, respectful of the sizing system of Sigvaris. During the experiment, the ACDs were applied by the same investigator.

In order to calculate SSI, interface pressure measurements in lying and standing positions are required.[13] Interface pressures used a Picopress device (Microlab®, Padua, Italy).[12] Interface pressure measurements were made at the B1 point, which is, according to international consensuses, localized at the "transition of the gastrocnemius muscle into the Achilles' tendon".[24] The interface pressure was measured first with the volunteer lying at rest, the ankle resting over a pad to avoid any compression of the sensor, then waiting for 2 minutes before measurement following the standing position.

Static Stiffness Indexes were then calculated according to already published recommendations by dividing standing-to-rest interface pressures.[13]

Interface pressures, volunteers lying at rest and then in the standing position, were also measured at the highest circumference of the calf level. The difference was also noted. In addition, B1 point and calf curvature radiuses were measured when the patient was standing using a set of curvature templates since the interface pressure value depends on the geometry of the leg according to the Laplace law.[28,29]

The ACDs were stretched to obtain 20, 30, 40, and 50 mmHg at rest at the B1 point for each volunteer when possible. The SSI was calculated at the calf, considering only the variation of interface pressure at the B1 point.

Therefore, the measurement template provided by the manufacturer for caregivers or patients included in the ACDs' package was not used.

Statistics

Measurements were all repeated three times and the mean of the three measurements was used for SSI calculation. Descriptive parameters used were: means, Standard Deviations (SD), and ranges. The percentage of volunteers above or below SSI cut-off levels was used in our hypothesis to discriminate *in vivo* stiff to not stiff ACDs, and independence was tested using Khi-deux tests with a risk alpha of 5%. An SSI at 10 mmHg was the first cut-off level chosen to discriminate between stiff and not stiff devices following the international consensus. Then, other cut-off levels were tested by incrementation of one mmHg by one up to 15 mmHg.[30] The comparison used the overall SSI, globalizing the results whatever the interface pressures were. The only condition was that SSI was calculated at the same interface pressures for both ACDs.

Results

Ten healthy volunteers of 37.6±8.6 years old (25-50), mean, SD, and range, respectively, participated in the study; none of them left the study. Ankle perimetry was 21.7±1.1 cm (20.2-23.7), and at the calf, perimetry at the greatest girth, also named point C, was 35.1±1.8 cm (32.8-37.8). The curvature radiuses in the standing position were 29.2±5.8 mm (24-44) at the B1 point and 56.8±15.8 mm (36-80) at the calf.

Stretching the ACDs at their maximum, the highest resting pressure achieved at B1 point for Coolflex was 30 mmHg for all volunteers except one in whom a pressure of 40 mmHg was achieved. The highest resting pressure achieved at the B1 point for Compreflex was 50 mmHg for all volunteers.

When the individual SSI values were presented as a function of the radii under different pressures at rest at point B1, the SSI values were dispersed for both Compreflex and Coolflex (Figure 1).

The SSI for Coolflex was 19±10.3 mmHg (0-35.5), increasing from 15±9.4 mmHg (0-33) at 20 mmHg to 21.9±10.3 mmHg (1.3-35.5) at 30 mmHg. The SSI for Compreflex was 12.5±6.2 (0.6-24.6), linearly increasing from 10.1±4.6 mmHg (3-17.3) at 20 mmHg to 13.7±7.0 mmHg (1.3-20.3) at 50 mmHg (Figure 2).

The SSI, when it was calculated at point C, was 9.4±7.4 mmHg (0-34.6) for Coolflex increasing from 8.3±4.7 mmHg (0-16.3) at 20 mmHg to 10.6±9.6 mmHg (0-34.6) at 30 mmHg. The SSI, when calculated at the calf, was 3.2±3.1 mmHg (0-13) for Compreflex increasing from 3.2±2.8 mmHg (0-8.6) at 20 mmHg to 3.8±4.1 mmHg (0-13) at 30 mmHg (Figure 3).

Considering point B1, which is the consensual measurement point for stiffness, a cut-off level of 10 mmHg for SSI for a resting pressure of 30 mmHg did not discriminate between the two ACDs in terms of stiffness (p=0.490). Considering the 10 volunteers included, the minimum cut-off level at which ACDs were discriminated was 14 mmHg (p=0.027) (Table 1).

At a cut-off level of 10 mmHg of SSI for a pressure of 30 mmHg at point B1, 90 % of volunteers for Coolflex and 70 % for Compreflex, if they needed to be treated by these ACDs, would be compressed with enough stiffness.

Individual variations of SSI as a function of the interface resting pressure at point B1 for each ACD showed that the SSI was increased for Coolflex and did not change linearly for Compreflex (Figure 4).

Discussion

Measurement stiffness *in vivo* on a healthy population of 10 volunteers of two commercially available ACDs, Coolflex and Compreflex, demonstrated that both ACDs were stiff since the means for SSI were superior to 10 mmHg. Nevertheless, the study was able to distinguish between the two devices at a cut-off level of 14 mmHg using the Static Stiffness Index without the need for textile laboratory tests.

The two ACDs were chosen, on the basis of previous work, at the two extremes of the stretching characteristics of commercially available ACDs,[11] on the assumption that their stiffness would also be different. The results confirmed that the two ACDs have different behaviour in terms of stiffness. Consequently, their clinical place in the treatment of venous or lymphatic disorders would not be the same since, for example, high stiffness seems to be a necessary characteristic for the healing of venous ulcers.[4]

Stiffness was measured using the SSI, which was, following international requirements, the simplest *in vivo* test to characterise the behaviours of compression devices, which includes ACDs. Dynamic Stiffness Index (DSI), which is another stiffness test, might have been closer to real life but was not measured in this pilot study since it is more difficult to use, and knowing that DSI is correlated to SSI.[13] At the present time, as highlighted by Benigni *et al*., very few physical property data are available on wraps.[11]

Discriminating between commercially available wraps is an important issue before splitting them into clinical indications. Benigni *et al*. demonstrated that the stretching property of ACDs is linked to the ability of the device to be applied at high resting pressure. We confirmed that using the low stretch Coolflex, we were unable to reach a resting pressure superior to 40 mmHg for all volunteers, conversely to Compreflex.

Consequently, the only interest of stretching characteristics was the capability to reach high pressures at rest, which was less easy to get with less stretchable material. Moreover, so-called stretchable materials, more often confused with elastic material, is, not a prerequisite to getting stiff material, as it has already been shown.

This study was able to show that SSI is increasing with the increase of the resting pressure for the less stretchable ACD, Coolflex, this trend was less evident with Compreflex. The increase of SSI did not depend on the curvature radius of point B1 at rest. Due to technical reasons, measuring curvature radiuses the volunteer standing, which would have been more informative since SSI strongly depends on the variation of leg geometry from rest to standing position, was not possible.[29]

The comparison of the two ACDs is made at a resting pressure of 30 mmHg, the highest pressure at which both ACDs can be compared. This pressure is, generally speaking, the resting pressure recommended in most of the indications of CVI. The cut-off level of 14 mmHg that differentiates the two ACDs is probably depending on the number of volunteers included. Conversely to already published data, the increase of resting pressure at point B1 in this study did not mean a systematic increase of SSI, as shown in the individual results for more stretchable material (Figure 4). This could be explained by changes in skin properties under different pressures.[27]

This study not only confirmed most of the results of the pilot study of Benigni *et al.* but addresses new questions.

Firstly, not only was this study able to discriminate *in vivo* between two ACDs, but it was also able to show that 90% of subjects with Coolflex and 70% with Compreflex were above the stiffness cut-off levels. Clearly, it indicated that the volunteers above the cut-off, likely due to their leg geometry and skin characteristics, if they had to be treated by ACDs, for example, for venous ulcers, would get the expected stiffness while wearing the wrap. It is a possible explanation to non-responders in clinical trials.

Secondly, laboratory testing was proposed as a method to characterise the behaviour of ACDs.[11] These tests could use dynamometers that stretch the ACD fabric as it is used for compression stockings in many countries,[20] or leg-shaped (Hirai's leg) whose circumference can be increased and pressure measured using the interface pressure measurement procedure. If calibrated model legs (Hohenstein's legs) are successfully used for stockings, regarding the high rate of dispersions of results of pressure measurement for ACDs, this method doesn't seem to be adapted to ACDs.

There is no need for the model device to resemble that of a leg. A simple tube may suffice, provided that the circumference of the tube is not oversized compared with the average circumference of a human leg. The use of the Hirai's leg would have the advantage, as noticed by Benigni *et al*., that the same leg would be used by all the manufacturers developing a wrap. Nevertheless, in such a leg, the curvature radius on the point where interface pressure is measured is unchangeable, and when the leg opens, it does not vary conversely to what is observed in real legs. If a model leg had to be used, then a new device needs to be developed capable of changing from a circular to an elliptical tube, which would change the radius of curvature where the measurement is envisaged from large to small. Since such a device does not exist, we suggest that instead of laboratory methods *in vivo* methods be used.

Nevertheless, questions are pending: which reference population? How many participants should be included in a testing trial to characterize wraps? Maybe these questions should be addressed through a consensus document directed by the International Compression Club. For instance, it could be suggested, before commercialisation, a three-center study, 60 volunteers each, with a mean age of around 40.

Consequently, on a general level, the lack of clinical data on the application of stiffness in pathology limits the scope of this study. Experimental limitations include the small number of volunteers, the absence of dynamic pressure recordings and measurements of radii of curvature between the resting and standing positions, and the choice of two pressure points at the interface. Nevertheless, on this last point, it is currently possible to use modeling to obtain thousands of pressure values on a single patient's leg. The question is: what should we do from a clinical point of view with these thousands of values, and how should we use them? There is no answer to this question.

Conclusions

This work confirms for wraps the expected variability of the Static Stiffness Index due to the variability of leg curvature geometry at the B1 point. It shows that SSI measured *in vivo* could be able to discriminate between Stiffness of wraps. Nevertheless, the precise cut-off level of stiff and not stiff wraps should be established on a larger population. SSI *in vivo* could be a tool for estimating the percentage of patients who, above the cut-off level, will clinically better respond to this treatment.

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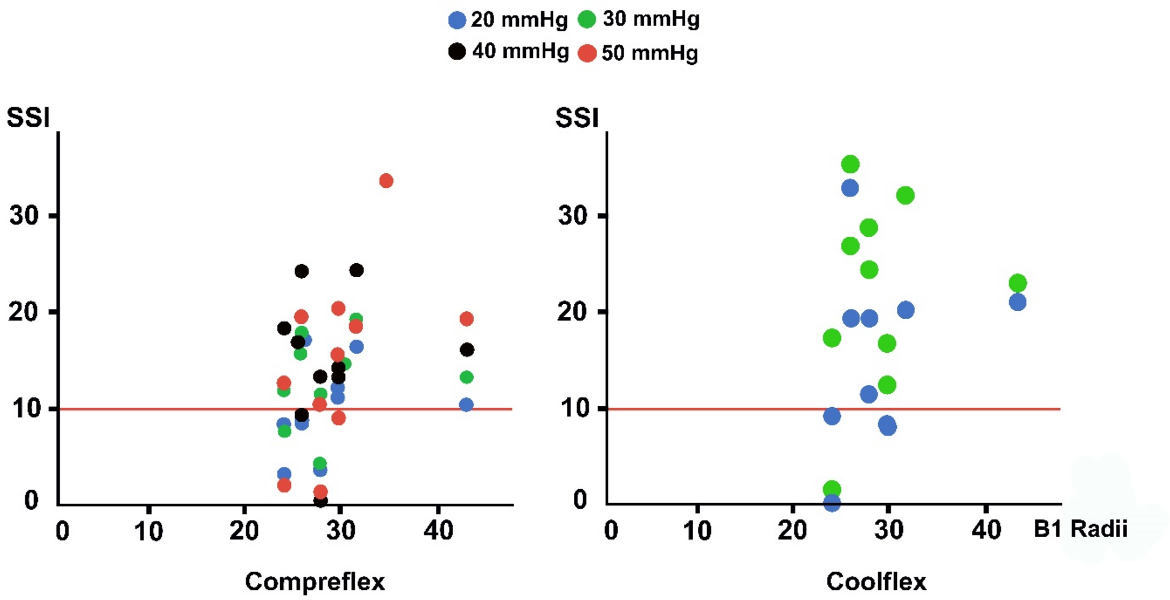

Figure 1. Static Stiffness Index (SSI) (in mmHg) as a function of the radii (in mm) under different pressures (colored dots) at point B1 for Compreflex (left) and Coolflex (right). The red line materialises the established level of SSI that discriminates stiff devices (>10 mmHg) from not stiff devices.

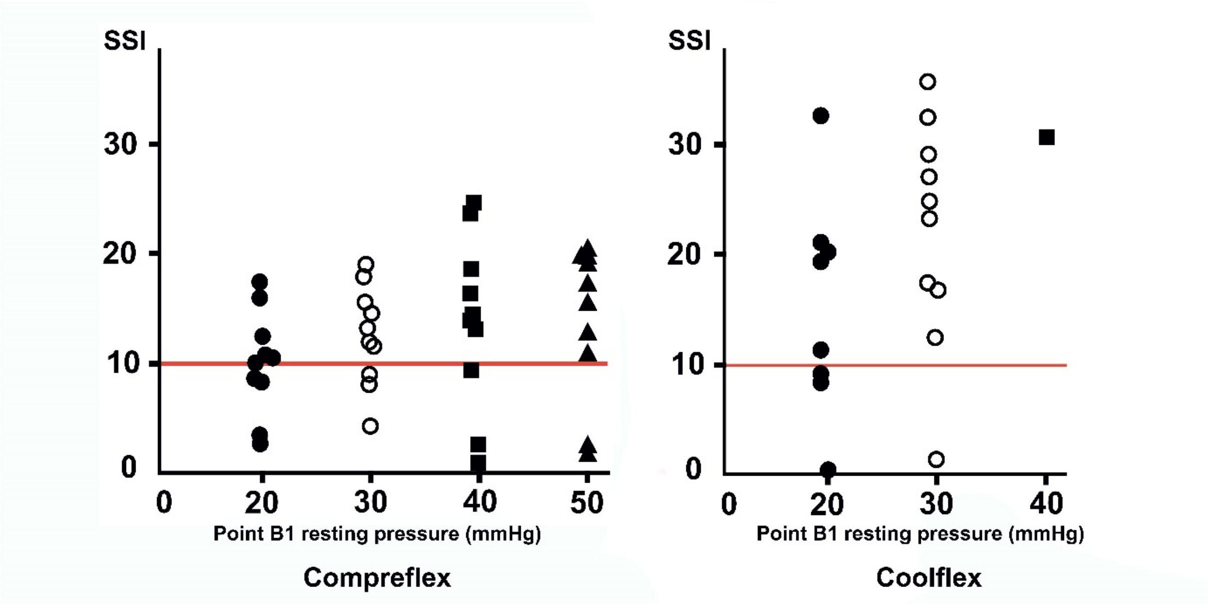

Figure 2. Static Stiffness Index (SSI) (in mmHg) as a function of the pressures at point B1 for Compreflex (left) and Coolflex (right). The red line materialises the established level of SSI that discriminates stiff devices (>10 mmHg) from not stiff devices.

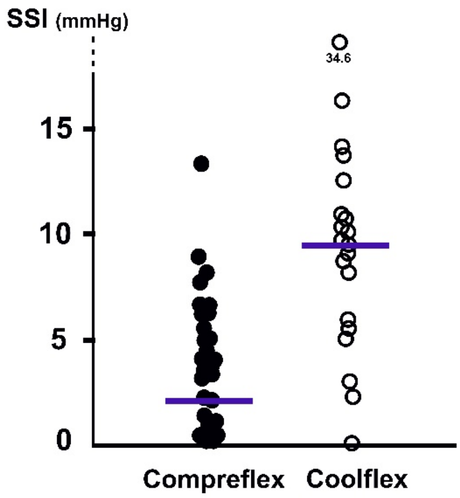

Figure 3. Static Stiffness Index (SSI) in function of resting pressures at 20 mmHg and 30 mmHg, mixed, at the calf for Compreflex and Coolflex Adjustable Compression Devices (ACDs). The blue horizontal bars represent the means.

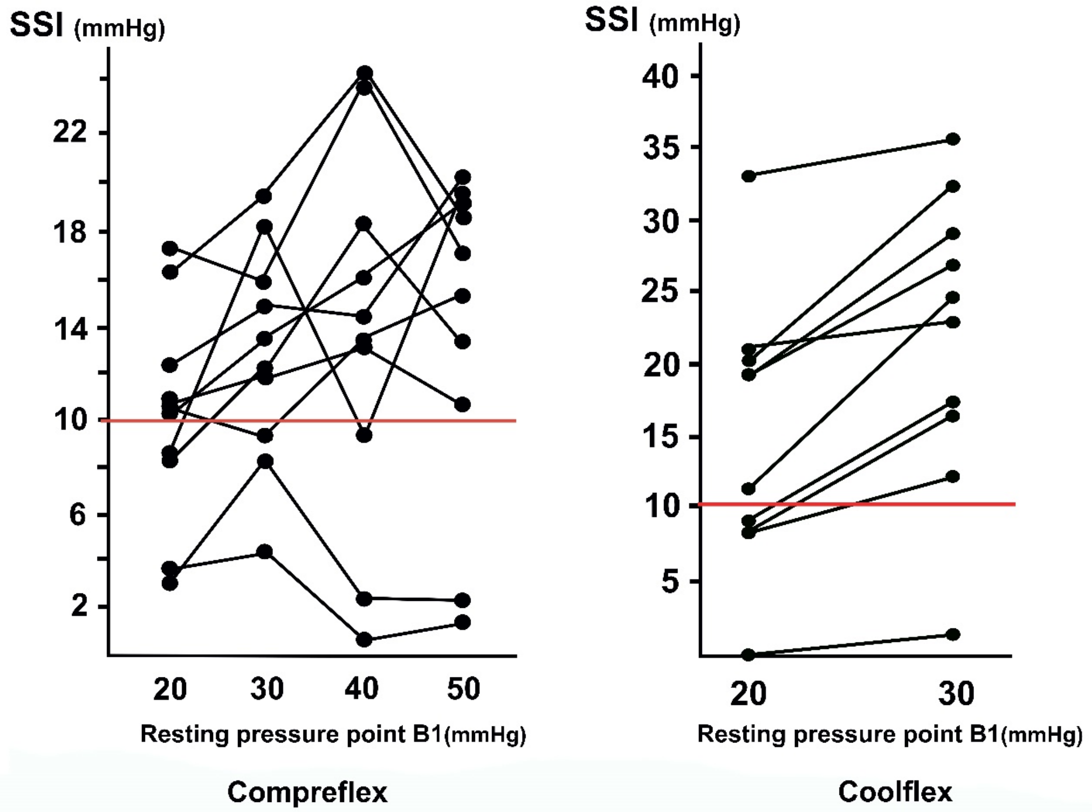

Figure 4. Individual variations of Static Stiffness Index (SSI) in function of the interface resting pressure at point B1 for Compreflex and Coolflex Adjustable Compression Devices (ACDs). The red line materialises the established level of SSI that discriminates stiff devices (>10 mmHg) from not stiff devices.

Table 1. Comparison of Static Stiffness Index (SSI) for Coolflex and Compreflex Adjustable Compression Devices (ACDs) using Chi-square tests at different cut-off levels and at 20 and 30 mmHg of resting pressures at point B1.

SSI (mmHg)	**Compreflex**	**Cooflex**	**Chi-square test**
Cut-off	**n=20**		**p-value**
>10	13	15	0.490
>11	11	15	0.185
>12	9	14	0.109
>13	7	13	0.058
>14	**6**	**13**	**0.027**
>15	**5**	**13**	**0.011**