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Interface pressures and stiffnesses of different bandages studied on a Hiraï leg

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Abstract

Hirai *et al.* have developed a tool to assess the *in vitro* pressures of different compression devices. This tool has the advantage of being easy to use and finally inexpensive.

The study of 7 bandages (Biflex 16, Urgo K2, Urgo K1, Coban 2, Biflex kit, Rosidal K and Rosidal Sys) on a Hirai leg allowed a precise analysis of the evolution of pressures and stiffnesses.

Interface pressures were measured using the Picopress system and a 5 cm diameter probe. The difference between pre-stretch and stretch pressures in mmHg characterized stiffness. If the difference is greater than 10 mmHg, the bandage is considered stiff. These bandages were applied with a pressure of 45±2 mmHg at point B1. One hundred extension maneuvers were then performed.

A decrease in mean pre-stretch pressures was noted more frequently for Rosidal K, Urgo K1 and Coban 2 than for the other bandages.

Biflex 16 has a stiffness of less than 10 mmHg ($p<0.001$). Urgo K1, Urgo K2, Coban 2, Kit Biflex have very similar stiffnesses (p=ns). Rosidal K and Rosidal Sys have higher stiffness ($p<0.001$).

Introduction

A few definitions

In clinical practice, the stiffness of a bandage is assessed using the Static Stiffness Index (SSI). This corresponds to the difference in mmHg between the interface pressure measured at point B1 in the standing position minus the interface pressure measured in the supine position.[1]

This point is characterized by the transition of the medial gastrocnemius muscle into the Achilles tendon. The stiffness is measured in mmHg. If the difference is greater than 10 mmHg, the device is considered stiff (Figure 1).

Several studies have shown that stiffness is a critical parameter in evaluating the efficacy of a medical compression device. In patients with chronic venous insufficiency, devices with stiffness greater than 10 mmHg have been shown to improve venous function[2] and microcirculation[3] during exercise compared to devices with stiffness less than 10 mmHg. In clinical practice, stiffness is responsible for a massage effect.[1,4]

Clinical assessment of bandage stiffness is an approximation. In fact, the static stiffness index of bandages should not be influenced by the mechanical properties of the calf, but only by local geometric variations.[5] These geometric variations could explain the instability and variation of interface pressures from one subject to another in the upright position, while the interface pressures remain close in the supine position.

On the other hand, according to the European Committee for Standardization (CEN), *in vitro* stiffness is defined as the increase in pressure produced per 1 cm increase in leg circumference.[6] Stiffness measurements are carried out in textile laboratories using various extensometers to check the relationship between stretch and force, which characterizes the elastic property of a device. The methods Hosy, Hatra, and IFTF are complex and not easily comparable. This may explain why the specific compression device characteristics are not utilized in clinical practice.

In 2008, the ICC proposed a classification of bandages[7] according to their stretch and characteristics (Figure 2).

To address this issue, Hirai *et al.*[8] developed an artificial leg model that eliminates variability and allows for the comparison of bandages. The model can increase the leg's circumference by 1 cm (Figure 3) and interface pressures are measured using the Picopress system with a 5 cm diameter probe. Pressures are recorded following the application of the compression device, and the leg circumference increases as the lever is pushed down. The Hirai leg can only be used to study the behavior of a bandage with a circumference of 20.5 cm (lever raised). During the maneuvers, when the lever is raised, the volume of the leg increases but the shape remains constant, unlike that of a human subject's leg. Indeed, during a muscular contraction, the leg changes very little in volume, but above all in shape. The muscles are in fact trapped in its aponeurosis. There are slight variations in the local radii facing the probe. According to Laplace's law (Pressure = tension/local radius), the pressures will change. This effect is particularly noticeable at point B1.

The recorded pressure variations are solely due to the friction between the layers of the bandage. During successive maneuvers, the smaller the variations in pressure recorded when the lever is raised compared with the initial pressure, the higher the coefficient of friction between the layers of the different bandages. The coefficient of friction is the ratio between the sliding force and the holding force produced when two surfaces come into contact.

To our knowledge, the coefficient of friction for bandages would be very complex. In 2012 a study[9] presented a simple formula for calculating a friction index between 2 Compression Stockings (CS).

Friction Index = Pressure under 2 CS / Pressure first CS + Pressure second CS.

In this case, the index is easy to calculate because there are only 2 layers. In the case of a bandage, there are many factors involved (number of layers, stretch, *etc*.).

Stiffnesses are most likely different for different circumferences. But unfortunately, there is only one circumference available with a Hiraï leg.

Objective

The objective of this *in vitro* test was to investigate the evolution of pressures and stiffnesses of 7 bandages or bandage kits applied to a Hirai leg with a starting interface pressure of 45±2 mmHg at point B1 (a word of clarification, the application was repeated when the right pressure was not obtained).

Materials and Methods

Materials

Urgo K1 (Urgo; Dijon, France): a single short-stretch (>10% and <100%.) bandage with single layer multi-component system (single use);

Urgo K2 (Urgo): a kit composed of a soft padded short-stretch (>10% and <100%.) bandage and a cohesive long-stretch (>100% stretch) bandage (single use);

Rosidal K (Lohmann Rauscher; Rengsdorf, Germany): a single short-stretch (>10% and <100%) textile bandage (reusable);

Rosidal Sys (Lohmann Rauscher): a kit with 2 identical short-stretch (>10% and <100%) textile bandages (reusable);

Coban 2 (3M; Saint Paul, USA): a kit with 2 bandages: a bandage with a polyurethane foam inner layer for comfort (very low pressure <6 mmHg); and a cohesive short stretch (>10% and <100%) bandage (single use);

Biflex kit (Thuasne; Levallois-Perret, France): a with 2 different short-stretch (>10% and <100%) bandages (reusable);

Biflex 16 (Thuasne): a long-stretch textile bandage (stretch >100%) (reusable).

Methods

We used the Hiraï leg with an ankle circumference at point B1 of 20,5 cm when the lever is raised and 21,5 cm when the lever is lowered (Figures 3-5).

The bandages were applied according to the recommendations of each manufacturer (instructions for use recommendations on the manufacturer's website).

Biflex 16 was applied in a circular way with a 75% overlap. With a stretching: From rectangle to square on bandage markings.

The different bandages were applied by the same nurse the same day.

The order of application of the seven bandages was chosen through randomization provided by http://www. random.org/lists/

Interface pressure measurements were performed using the PicoPress® transducer (Microlab®; Padova, Italy) and a 5 cm diameter probe placed on point B1 of the Hirai leg. In healthy subjects, this point would correspond to the medial aspect of the calf, at the junction of the medial gastrocnemius muscle and the Achilles tendon facing the soleus muscle.

We measured the pressures when the lever was raised (before stretching) and when it was lowered after 1, 2, 3, 4, 5, 6, 9, 10, 11, 24, 25, 26, 49, 50, 51, 98, 99, 100 bandage stretching maneuvers.

Statistical analysis

Statview version 5 (Mac) was used for the statistical analysis.

We calculated the mean of the pressures of the seven bandages before and after stretching measured after 1, 2, 3, 4, 5, 6, 9, 10, 11, 24, 25, 26, 49, 50, 51, 98, 99, 100 lever maneuvers.

This allowed us to calculate the stiffness (measured pressure with stretching -lowered lever- minus measured pressure without stretching -raised lever-) of each bandage and to compare the performance of each bandage with each other (Student's t test).

Results

The bandages were applied according to the objective of the study and the method described above.

At measure N°1 without stretching, the pressures were similar around 45±2 mmHg (p=ns). After 100 maneuvers of stretching (raised lever), we found that Rosidal K, Urgo K1, and Coban 2 bandages showed a more significant reduction in pressure compared to the other bandages (p<.001) (Table 1, Figure 6).

Coban 2, Urgo K1 and Rosidal K are single short-stretch bandages, while Biflex 16 is a long-stretch bandage. The pressure stability under Biflex 16 during maneuvers is attributed to the characteristics of the bandage (long stretch) (Figure 6).

Under the bandage kits, the number of layers at one point is greater than under single short-stretch bandages. This can be explained by a higher coefficient of friction due to the number of layers, with the result that pressure on the leg decreases less rapidly during maneuvers.

Regarding stiffness (Table 2, Figure 57), it remains significantly lower (p<0.001) for Biflex 16. On the other hand, the differences in stiffness are not significant for Urgo K2, Urgo K1, Coban 2 and Kit Biflex. The difference remains small (p=ns).

In contrast, for Rosidal K (a short stretch bandage) and Rosidal Sys (2 identical short stretch bandage kits), their stiffness is significantly higher ($p<0.001$)

These results are coherent with the components of the different bandages, their elastic properties (stretch),[7] and other studies already published.[10,11]

A long stretch bandage (Biflex 16) provides low stiffness (<10 mmHg). The following bandages Urgo K2, Urgo K1, Coban 2, Biflex Kit have lower stiffness than Rosidal K and Rosidal sys.

Discussion

This study confirms the advantage of using a Hiraï leg to compare the pressures and stiffnesses of different bandages. To do this, the bandages must be applied strictly according to the manufacturers' recommendations. This device then provides measures with low standard deviations.

It should be noted, however, that the material used on the Hirai leg is a hard plastic that does not replicate the skin and hypodermis of a patient. Resting pressures in patients would likely be lower in clinical practice.

Methodological flaws of the mannequin leg compared to the *in vivo* situation are the rigid consistency of the model leading to higher pressure values than those measured over human tissue and the local radius at B1 which does not change when the Hiraï leg is extended. Another flaw is the fact that only one model is available.

One question remains about stiffness. With the exception of Biflex 16, which is a long stretch bandage, pressures decrease but stiffnesses are maintained. No studies have been published to clarify this phenomenon.

A clinical study following a half-hour walking test[10] in healthy volunteers found the same phenomenon. In another study in healthy volunteers,[11,12] using Rosidal Sys, Profore and Proguide (Smith & Nephew; London, UK), stiffness did not vary during the first 30 minutes and then gradually decreased.

These data highlight the need to carry out real-life measurements on pathological subjects. It is likely that after 48-72 hours, the effectiveness of a bandage will be questionable, with the exception of long-stretch bandages, which maintain their pressure and stiffness over time. It should be noted that long stretch bandages should be removed at night because of the risk of ischemia in elderly patients.

However, stiffness is an important consideration because the higher the stiffness, the more venous hemodynamics are increased[2,4] especially in patients with chronic venous insufficiency. Other factors to consider when treating a leg ulcer include comfort, whether the bandage is single-use or reusable, ease of application, and night-time pressure, especially in patients with mixed ulcers. It is also important to consider the overall cost of the bandages. Finally, slippage of a high-rigidity bandage is a phenomenon well known to caregivers, but is essentially a function of the application technique. There is no absolute truth in this area.

The use of hosiery in the treatment of venous leg ulcers is limited to ulcers of small size without leg dysmorphia, stage of the wound (epithelialization) and because of the difficulty of donning.

While randomized studies are subject to biases that can undermine current certainties, protocols of clinical research should be improved.[13]

Conclusions

The study of these 7 bandages on the Hirai leg allows a precise analysis of these bandages according to pressure and stiffness. A comparison between these different bandages applied at 45±2 mmHg is then possible.

Urgo K1, Urgo K2, Coban 2, Kit Biflex have very similar stiffnesses. Rosidal K and Rosidal Sys have higher stiffnesses. These results raise a question. Is the clinical potential of these high stiffness bandages superior to other lower stiffness bandages? Other criteria should also be considered (comfort, ease of use, overall cost of treatment).

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Mean in mmHg	**Biflex 16**	**Kit Biflex**	**Urgo K2**	**Rosidal Sys**	**Coban2**	**Urgo K1**	**Rosidal K**
Measure n°1	46	43	46	47	46	44	44
All 100 maneuvers	47.9	46.5	44.8	42.1	38.4	35.6	34
Standard deviation	*0.9*	*1.3*	*1*	*3.2*	*2.5*	*3.6*	*4.3*
Drop	+1.9	+3.5	-1.2	-4.9	-7.6	-8.4	-10

Table 1. Evolution of the mean pressure without stretching (raised lever).

Mean in mmHg	**Biflex 16**	**Urgo K2**	**Urgo K1**	**Coban 2**	**Kit Biflex**	**Rosidal K**	**Rosidal Sys**
Stiffnesses on all measures	8.4**	24.1*	25.8*	25.6*	26.5*	34.4#	36.7#
Standard deviation	0.6	0.8	1.4	1.2	1	1.4	1

Table 2. Mean stiffnesses of the different bandages (100 maneuvers).

*similar stiffness p=ns

**lower stiffness p<0.001

#higher stiffness p<0.001

Stiffness of a bandage	Difference of pressure in mmHg for one cm increase	ΔP in mmHg/1 cm
Static stiffness index	Interface pressure in standing position (mmHg) minus interface pressure in lying position (mmHg)	SSI = Standing pressure – lying pressure
Stretch	Extension of a bandage to its maximum	See table II
Elasticity	Capacity of a material, after being stretched, to return to its initial shape	

Figure 1. A few definitions.

	Inelastic : Stretch 0% to 10%	Short stretch Stretch 10% to 100%	Long stretch Stretch > 100%
Textile	□	□	□
Adhesive		□	
Cohesive		□	
Zinc oxide	□	□	

Figure 2. Characteristics of bandages.

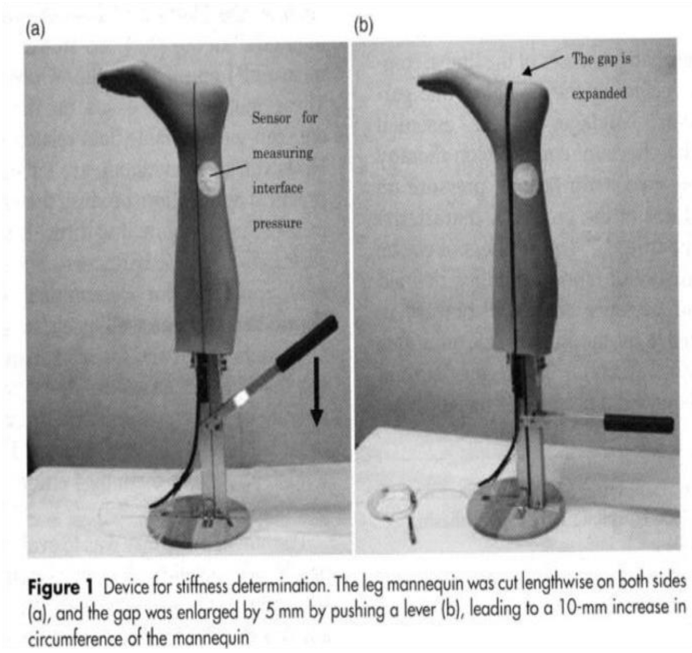

Figure 3. Hiraï plastic leg.

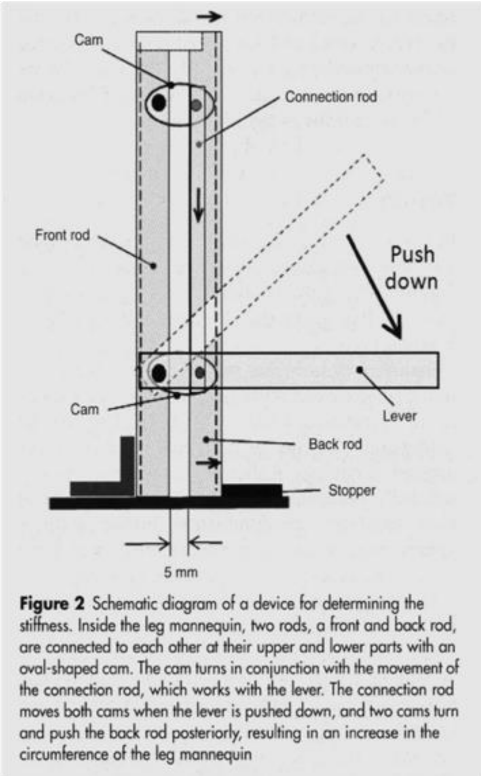

Figure 4. Schematic diagram of Hiraï leg.

Figure 5. Examples of interface pressure (lever raised and lever lowered) under Kit Biflex.

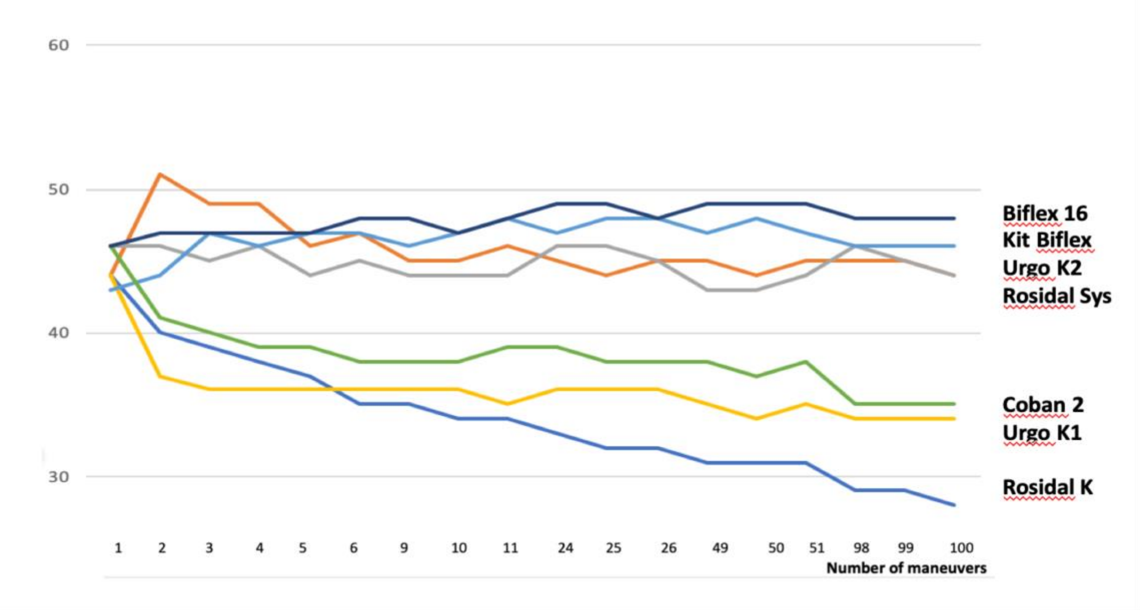

Figure 6. Evolution of pressures before stretching maneuvers.

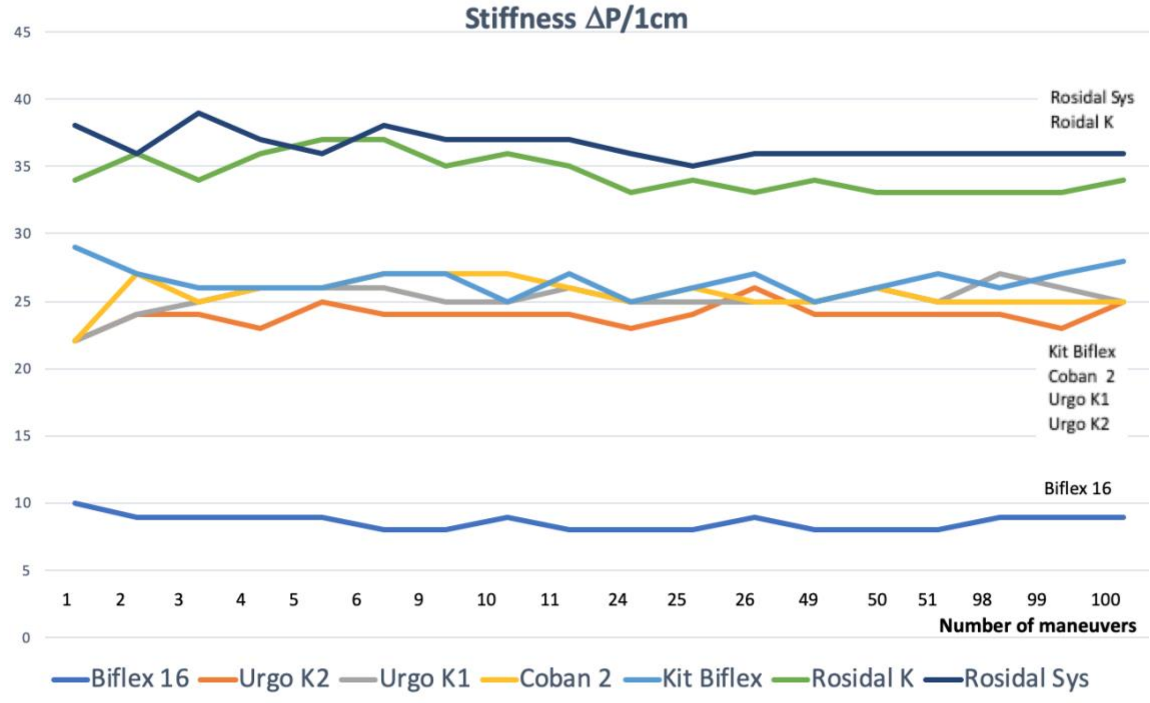

Figure 7. Comparison of evolution of stiffness for all bandages.