

Interface pressures and stiffness indexes before and after a treadmill test of an adjustable compression wrap. Comparison with two compression bandages.

JP Benigni¹, JF Uhl², W Taha³, P Filori⁴, F Balet⁵

¹ Bureau d'appui à la Pédagogie, Faculté de Médecine Pitié-Salpêtrière, Médecine Sorbonne Université, 91 bd de l'hôpital, 75013, Paris, France. benigni.jp@orange.fr

² Paris City University, France

³ General Secretary of EAVLA, Cairo, Egypt

⁴ Physiotherapist, Marseille, France

⁵ Nurse, Adapei Var-Méditerranée, Pélissanne, France

submitted: Nov 2, 2024, accepted: Dec 23, 2024, Epub Ahead of Print: Dec 27, 2024, published: Dec 31, 2024

Conflict of interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article

DOI: [10.24019/jtavr.217](https://doi.org/10.24019/jtavr.217) - Corresponding author: Dr. Jean-Patrick Benigni, benigni.jp@orange.fr

© 2024 Fondazione Vasculab impresa sociale ONLUS. All rights reserved.

Abstract Background: ReadyWrap[®] Calf, Rosidal[®] Sys and Urgo K2[®] respond to the same physical laws. But they were studied with different methods. This makes it difficult to compare them. ReadyWrap[®] Calf has an estimated stretch of 60 %. After 5 hours of wear in healthy volunteers, its static stiffness index (SSI) is around 15 mmHg when applied with a resting pressure of 40 mmHg. The SSI of Rosidal[®] Sys and Urgo K2[®] remains constant before and after a 30-minute treadmill test (25 mmHg for Rosidal[®] Sys and 15 mmHg for Urgo K2[®]). The aim of this trial is to study these compression devices using the same method, with a view to carrying out comparative clinical trials at a later date. Aim of the study: The purpose of this pilot study was to compare the interface pressures and stiffness indices of three compression devices (ReadyWrap[®] Calf, Urgo K2[®] and Rosidal[®] Sys) on volunteer subjects before and after a 15 min treadmill test. Materials and methods: We selected 40 volunteer subjects treated with ReadyWrap[®] Calf after randomization on one leg and on the other leg with 20 with Rosidal[®] Sys or 20 with Urgo K2[®]. We measured interface pressures in standing, lying position and during ankle dorsiflexion. We

calculated the SSI and Dynamic Stiffness Index (DSI) before and after a 15 min treadmill test. We also carried out a VAS on comfort. Results: Interface pressures decreased after the treadmill test with all three compression devices. ReadyWrap[®] Calf and Urgo K2[®] pressures, SSI and DSI before and after the treadmill test were not statistically different. Their static Stiffness Indices are in the order of 13-14 mmHg. Only Rosidal[®] Sys has a significantly higher SSI. Comfort is found very comfortable under the 3 compression devices. Conclusion: The adjustable compression wrap, Readywrap[®] Calf, behaves like a stiff bandage when applied with a pressure of around 40 mmHg. Its different pressures and stiffnesses are comparable to the bandage kit Urgo K2[®].

Keywords bandage, adjustable compression wrap, pressure, stiffness

Introduction

In healthy volunteers, pressure measurements and calculations of static stiffness index¹ are required to

evaluate a bandage or an adjustable compression wrap. These measurements are taken on the leg at point B1. This point is located at the junction of the medial gastrocnemius muscle and the Achille's tendon. The pressures are recorded using a Picopress[®] device.

These measurements provide a clinical assessment of the stiffness of the compression device called Static Stiffness Index or SSI¹⁻². This corresponds to the difference in mmHg between the interface pressure measured at point B1 in the upright position minus the interface pressure measured in the supine position. If the difference is greater than 10 mmHg, the device is considered to be stiff.

Several studies have shown that stiffness is an important parameter for measuring the effectiveness of a medical compression device. In patients with chronic venous insufficiency, devices with a stiffness greater than 10 mmHg have been shown to improve venous function³ and microcirculation^{4,5} during exercise compared to devices with a stiffness of less than 10 mmHg.

In clinical practice, stiffness is responsible for a massaging effect^{1,6}. Adjustable compression wraps (ACWs) could replace bandages for the treatment of chronic venous insufficiency (CEAP C3-C6) and lymphoedema in the near future⁷. They can be easily adjusted by the caregiver or the patient.

They were developed in the 1990s but, paradoxically, have been the subject of very little clinical research. Publications have focused mainly on venous ulcers⁸, venous and postural edema^{9,10}, lymphatic edema¹¹⁻¹⁴, ease and comfort of use¹⁵ and limitations of use in the elderly¹⁶.

A recent study using ReadyWrap[®] Calf estimated its stretch at 60%⁷. In another study, after 5 hours of wear in healthy volunteers, its SSI does not vary statistically and remains around 15-16 mmHg when initially applied with a resting pressure of around 40 mmHg¹⁷.

Jindal R. et al showed¹⁸ that the SSI of Rosidal[®] Sys and Urgo K2[®] remained constant after a 30-minute treadmill test (25 mmHg for Rosidal[®] Sys versus 15 mmHg for Urgo K2[®]).

These data come from different publications using different methods. It is therefore difficult to compare the consistency of the data obtained. It is therefore interesting to compare the performance of ReadyWrap[®] Calf with that of 2 bandages (Urgo K2[®] and Rosidal[®] Sys) under the same study conditions and using a common vocabulary (Table 1).

Stretch	Extension of a compression device to its maximum	
Elasticity	Capacity of a material, after being stretched, to return to its initial shape	
RP	Resting pressure	Interface pressure in a lying position at rest
WP	Working pressure	Interface pressure in a standing position
SSI	Static stiffness index	Interface pressure in a standing position minus interface pressure in a lying position at rest
DSI	Dynamic stiffness index	The difference between the maximal and minimal interface pressure during maximal foot dorsiflexion in the supine position

Table 1 - Definitions of the measurements and pressure indices in point B1

Aims of the study

Primary endpoint

The objective of this pilot study is to evaluate the evolution of the different interface pressures and stiffness indices of 3 compression devices (ReadyWrap[®] Calf, Urgo K2[®] and Rosidal[®] Sys) on volunteer subjects before and after a 15 min treadmill test.

Secondary endpoint

Visual analogic scale on comfort after the treadmill test.

Materials and Methods

The protocol and the principle of this study were approved on October 23th, 2023 by the advisory board of the Diabetic Foot Center (DFC), 15 Surayat Street, Cairo, Egypt, in accordance with the Egyptian Ministry of Health recommendations and with the principles set in the Declaration of Helsinki. The subjects were informed about the purpose of the study and signed a free and informed consent form.

Study Design

- Pilot study
- Single-center
- 40 healthy subjects
- ReadyWrap[®] Calf and bandages will be applied with a pressure of **40 +/- 3 mmHg** at point B1 by 2 different applicators. The applicators followed one another for each new subject.
- Selection based on a randomization table¹⁹ of 40 treated legs with ReadyWrap[®] Calf. 20 contralateral legs will be treated with Rosidal[®] Sys, 20 other legs with Urgo K2[®].

Number of subjects to be recruited

As the difference in resting pressure before and after treadmill testing in healthy subjects had not been published, and in the absence of data on the evolution of SSI for the three devices under similar conditions, it was decided to include 40 subjects in a pilot study. This number usually meets the requirements for a pilot study. The study took place over 4 days. Ten healthy volunteers were tested every day.

Materials

ReadyWrap® Calf (Lohmann & Rauscher GmbH & Co. KG): a short stretch adjustable compression wrap²⁰.

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). Urgo K2® was applied in accordance with the manufacturer's instructions, respecting the markings on the 2 bandages.

Rosidal® Sys (Lohmann Rauscher): a kit with 2 identical short-stretch (>10% and <100%) textile bandages (reusable). Rosidal® Sys bandage was applied in a spiral with 50% overlap and maximum traction.

ReadyWrap® Calf was applied according to the manufacturer's recommendations²⁰ (Instructions from the Lohmann-Rauscher's website)

Inclusion criteria

- Healthy volunteer subjects (males and females);
- CEAP classification C0a, C0s, C1a, C1s;
- Agree to take part in the test after explanations and signing the agreement;
- Age > 18 years and < 50 years;
- Ankle circumference > 18 cm and < 25 cm (point B).

Exclusion criteria

- BMI > 35;
- CEAP classification: C2as-C6;
- Pregnant or breast-feeding;
- Conditions preventing a quick standing up;
- Equilibrium impairment;
- Acute or chronic leg swelling.

Assessed criteria

Age, body weight, height, BMI, occupation, number of pregnancies.

Evaluation criteria

The interface pressures are measured at rest, in standing position and during foot dorsiflexion with the PicoPress²⁰®(21) (Microlab Elettronica s.a.s. di Bergamo

Giorgio & C. via G. Rossa, 35 35020 Ponte S. Nicolò (PD) – Italy).

The instrument uses a circular probe of 4.5 cm diameter made of ultra-thin biocompatible material into which a known amount of air is inserted. The probe is placed on the skin at point B1(21). This point B1 is located by echography.

A treadmill test is conducted for 15 min at a speed of 4 km/h on a treadmill with an 8% slope. The distance covered will be 1 km. We have estimated that a patient suffering from a venous leg ulcer walks no more than one kilometer a day. The slope only serves to make the test more sensitive, and 4 km/h is the subject's normal walking speed.

Visual Analogic Scale (VAS) is used to appreciate comfort of ReadyWrap® Calf and the 2 bandages: 10 was considered as very comfortable and 0 as very uncomfortable after the treadmill test.

Statistical analysis

JMP pro version 17(22) was used to assess the pressures changes on both legs with ReadyWrap® Calf and the 2 bandages, as well as the VAS. Means comparison was achieved with a Student t-test. The significance level with an error of 5% was used (P value <0.05).

Results

40 healthy subjects were included in the study from February 25th to February 28th 2024: 26 female (65%) and 14 males (35%). The subjects were classified with the CEAP clinical classification (23) as C0A (82,5%) and C1A (12,5%). Their average age was 31,5 years. Mean height was 165 cm and mean weight 75,2kg. Mean BMI was 27,6 (see details on table II).

N=40	Mean	standard dev.
Age in years	31,5	8,55
Height in cm	165 cm	8,21
Weight in kg	75,2 Kg	10,84
BMI (W/H ²)	27.6	3.3

Table II - Demographic data

Before the treadmill test

We used Picopress® to measure resting pressure, standing pressure and ankle dorsiflexion pressure. Each measurement was repeated three times.

	Resting pressure	Working pressure	Dorsiflexion	SSI	DSI
Ready Wrap® Calf	41,83 (1,5)	54,8 (5,3)	60,7 (12,1)	13,0 (5,3)	19,0 (12,0)
Urgo K2®	41,66 (2,15)	55,6 (6,0)	59,2 (6,8)	13,9 (5,5)	17,5 (6,7)
Rosidal® Sys	41,35 (3,0)	58,32* (7,3)	62,7 (9,6)	17,0* (6,8)	21,3 (8,4)

Table III - Means of interface pressures, SSI and DSI before the treadmill test in brackets: standard deviation. Resting pressure NS for all devices. * $p < .003$ Working pressure higher for Rosidal® Sys vs ReadyWrap® Calf. # $p < .01$ SSI higher for Rosidal® Sys vs ReadyWrap® Calf

The results (Table III, Figures 1 and 2) show a very homogeneous resting interface pressure (lying position) applied to all compression devices, measured with Picopress®, close to 40 mmHg.

Working pressures and SSI for ReadyWrap® Calf and Urgo K2® were not significantly different. Working pressure (standing position) was significantly higher with Rosidal® Sys ($p < 0.3$) than with the other two devices. Similarly, SSI was also significantly higher with Rosidal® Sys ($p < 0.1$).

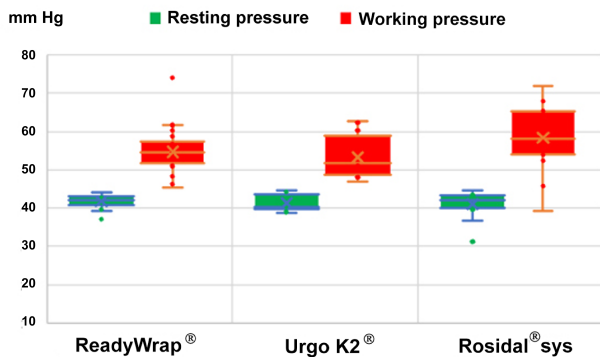


Figure 1 - Resting and working interface pressures before the treadmill test measured with Picopress®. Resting pressure NS for all devices. Working pressure higher for Rosidal® Sys compared to other devices ($p < .003$)

After the treadmill test

We observed a slight decrease in resting pressure and a non-significant increase in SSI for ReadyWrap® calf and for Urgo K2®.

This increase is significant with Rosidal® Sys $p < .0001$ (Table IV, figures 3, 4).

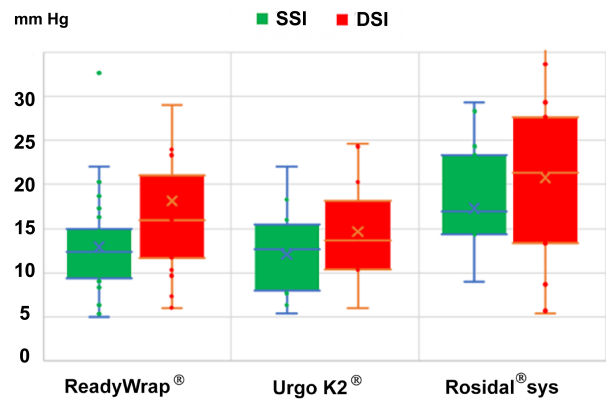


Figure 2 - SSI & DSI before the treadmill test measured with Picopress® SSI is significantly higher with Rosidal® Sys vs ReadyWrap® Calf ($p < 0.01$). Other indexes are NS.

	Resting pressure	Working pressure	Dorsiflexion	SSI	DSI
Ready Wrap® Calf	37,9 (4,2)	51,6 (6,6)	55,1 (9,6)	14,2 (6,0)	17,7 (9,2)
Urgo K2®	36,1 (3,0)	49,1 (4,9)	51,3 (4,4)	13,0 (5,3)	15,2 (4,7)
Rosidal® Sys	33,4* (6,6)	52,3 (9,4)	52,6 (8,9)	19,0* (7,2)	20,4** (7,9)

Table IV - Means of interface pressures, SSI and DSI after the treadmill test in brackets: standard deviation. * $p < .0001$ Lower resting pressure with Rosidal® Sys vs ReadyWrap® Calf and Urgo K2®; # $p < .005$ SSI of Rosidal® Sys vs ReadyWrap® Calf and Urgo K2®; ** $p < .005$ DSI of Rosidal® Sys versus Urgo K2®.

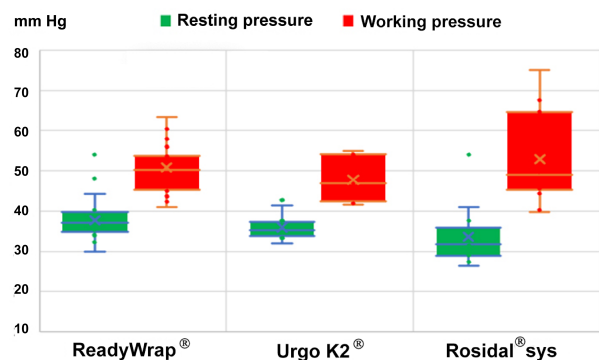


Figure 3 - Resting and working interface pressures after the treadmill test measured with Picopress®.

Resting pressure is lower for Rosidal® Sys compared to 2 other devices ($p < .0001$);

Working pressure is higher for Rosidal® Sys compared to 2 other devices ($p < .03$).

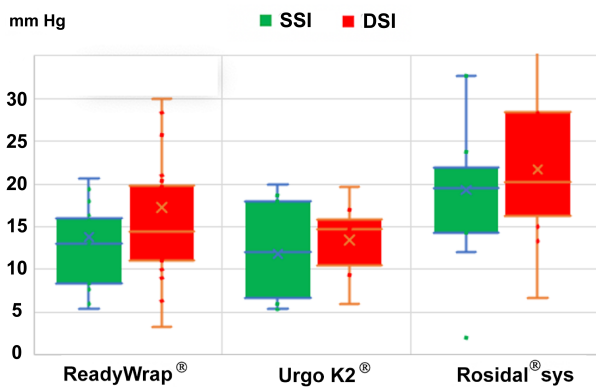


Figure 4 - SSI and DSI **after** the treadmill test measured with Picopress®;

SSI of Rosidal® Sys is higher than ReadyWrap® Calf and Urgo K2® ($p < 0.005$);

DSI of Rosidal® Sys is significantly higher than Urgo K2® ($p < 0.005$).

Comparison of pressures before and after the treadmill test

The drop of mean variations in % of resting pressure after treadmill test (figure 5) is similar for ReadyWrap® Calf and Urgo K2® (NS), but significantly higher for Rosidal® Sys ($p < .002$).

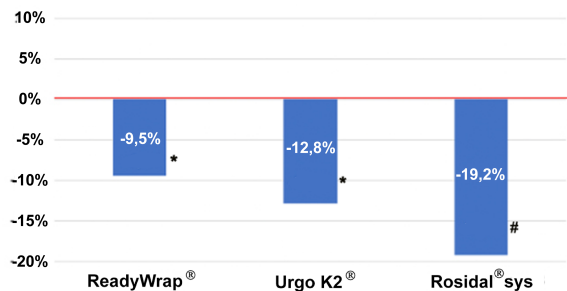


Figure 5 - Variations in resting pressure **before and after** the treadmill test (%).

* NS; # $p < 0.02$.

Correlation of SSI and DSI

We found a significant correlation between DSI and SSI with ReadyWrap® Calf ($R = 62\%$) (figure 6). The correlation was similar for Urgo K2® ($R^2 = 72\%$).

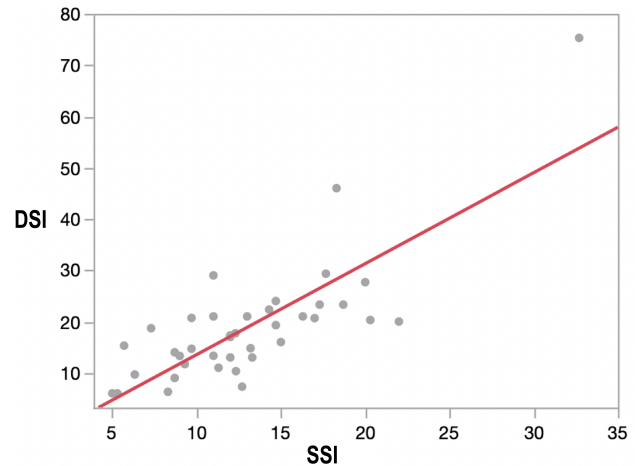


Figure 6 - High Correlation between SSI and DSI for ReadyWrap® Calf.

$$DSI = -4,183265 + 1,7731714 * SSI$$

Variability of pressure measurements

We assessed the variability (Table V) of the interface pressures measurements by the Variation Coefficient (VC) is the ratio of the standard deviation to the mean. The higher the VC, the greater the level of dispersion around the mean. If the variation coefficient is less than or equal to 15%, the statistical units form a homogeneous group with regard to the variable studied. If the VC is greater than 15%, the group is heterogeneous.

Picopress®	Treadmill test	Rest	Work
Overall VC 80 legs	Before	5,1%	11%
	After	14%	14%

Table V - Variation coefficients (VC) of the pressure measurements with Picopress® (80 legs)

Before treadmill test at rest, we observed a low VC for all devices (5.1%). At work in a standing position, a higher variation was found around 11%. The values form a homogeneous group.

After treadmill test at rest and at work, ReadyWrap® Calf and Urgo K2®, the values form a homogeneous group (14%).

	N	mean	Std dev.	t test of Student
Urgo K2®	20	7,42	2,09	NS
Rosidal® Sys	20	8,09	2,02	NS
Ready Wrap® Calf	40	8,17	1,44	NS

Table VI - Mean comparison of comfort score with the 3 devices

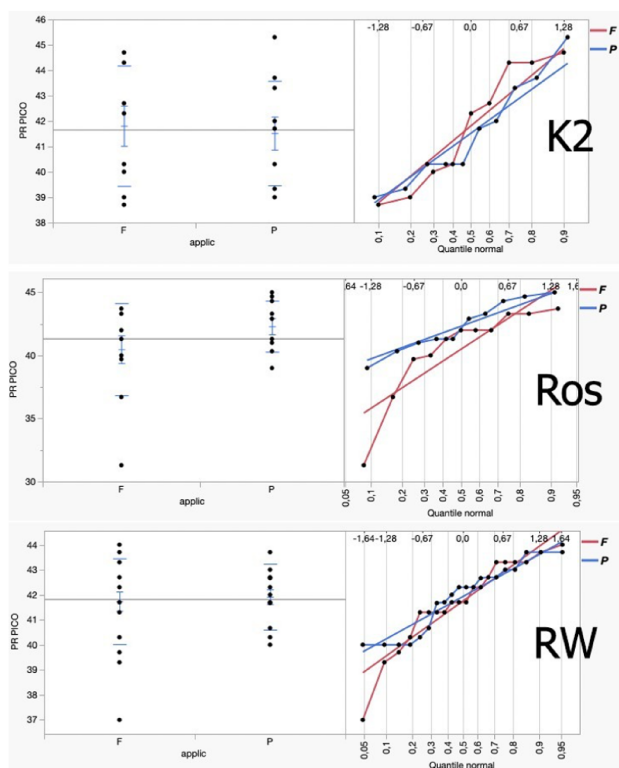


Figure 7 - Comparison between 2 applicators. (t-student test - 80 legs) Graphs of mean resting pressures by applicant and device: Mean comparison with t-student test shows no difference between the 2 applicators (NS).

Comparison between the 2 applicators (Picopress(®) pressures)

We found no difference in the mean comparison of resting pressures before the treadmill test between the 2 applicators for the three compression devices as shown in figure 7.

Visual analogic scale on comfort and tolerance

The comfort of the 3 devices assessed by a VAS (0 to 10) was very comfortable, with a mean of 8. There was no difference between the 3 devices. (Table VI)

Discussion

The data collected from these healthy subjects allows for a more accurate characterization of device behavior prior to use on pathological subjects. ReadyWrap® Calf did not differ significantly from Urgo K2®, but it was significantly different from Rosidal® Sys, which was found to be stiffer. that Rosidal® Sys had a significantly higher SSI than the other two devices.

Resting pressure decreased significantly under all devices, but the decrease was more significant with Rosidal® Sys. It is important to note that the higher SSI of Rosidal® Sys is related in a decrease in resting pressure rather than an increase in working pressure.

This phenomenon has been previously observed in a comparative clinical study¹⁷ following a treadmill test and an in vitro study²⁴.

Confirmation of the expected haemodynamic effects is crucial following the study published by Mosti and Partsch²⁵. It is worth noting that ReadyWrap® Calf and Urgo K2® exhibit a lower variability of resting pressures before and after the treadmill test compared to Rosidal® Sys, possibly due to their lower stiffness and higher elasticity. It is questionable to use the DSI due to the brief pressure display during muscle contraction ($R^2 = 33\%$), which can lead to assessment errors²⁶. The SSI is considered a reliable criterion, having been validated multiple times^{27,28}.

Another important point

The development of a compression device should respond to a precise process. An analysis of the literature shows that there are many biases²⁹ that make it difficult to conclude that the product studied is clearly effective, which is why registration and/or reimbursement with the relevant authorities is so difficult.

Unlike compression bandages, many elements are often missing for the wraps:

- The composition of the device;
- Stretching;
- *In vitro* stiffness;
- Comparative study on healthy subjects to better characterize the compression device;
- Unbiased comparative clinical studies to determine the most appropriate indication.

ReadyWrap® Calf is made of nylon, elastane, and polyurethane, with an estimated stretch of 60%⁵, which is

similar to that of a short-stretch bandage. In vitro stiffness assessment can be difficult, but the European Committee for Standardization (CEN) defines it as the increase in pressure resulting from a 1 cm increase in leg circumference³⁰.

Textile laboratories use various extensometers to measure stiffness and verify the relationship between stretch and force, which characterizes the elastic property of a device. It can be difficult to compare the results obtained with different extensometers. Hirai has developed an artificial leg model that eliminates variability of morphologic leg (figure 8). The model enables a significant increase of 1 cm in leg circumference, as previously published^{31,32}.

Device for stiffness determination. The leg mannequin was cut lengthwise on both sides (a), and the gap was enlarged by 5 mm by pushing the lever (b), leading to a 10-mm increase in circumference of the mannequin.

Interface pressures are accurately measured using the Picopress[®]. The pressures are recorded immediately after the compression device is applied, and the leg circumference increases as the lever is pushed down. It is important to note that the Hirai leg is specifically designed for studying the behavior of a bandage with a circumference of 20.5 cm (lever raised). Raising the lever increases (figure 9) the volume of the leg but does not change its shape like that of a human leg³².

Inside the leg mannequin, two rods (front and back) are connected by an oval cam at the top and bottom. When a lever is pushed, the connection rod moves both cams. This causes the cams to rotate, pushing the back rod outward and increasing the circumference of mannequin's leg.

Muscular contractions cause minimal volume changes, but significant shape changes due to muscle entrapment in the aponeurosis. Local radii variations in front of the probe cause pressure changes according to Laplace's law, which is particularly visible at point B1³³.

The SSI variations observed with Urgo K2[®] and Rosidal[®] Sys are consistent with the trends observed in Hirai's leg measurements. For example, in study realized with the Hirai leg²⁴, the SSI before and after 100 extensions varied little (figure 10) and the SSI of Rosidal[®] Sys was higher than that of Urgo K2[®].

This leg is only a theoretical model, but it should make it possible to compare different compression devices with each other.

The leg wrap used in the test was only partially adapted to the shape of Hirai's leg, and the measurements were taken only for an ankle with a circumference of 20.5 cm. It also tests the whole wrap with its seams, which can stiffen it.

Wouldn't it be more judicious to test the material used on cylinders of different circumferences capable of moving apart by 1 cm?

In this way, we could test the material at different pressures and also assess its fatigue over the course of the stretching maneuvers.

The test on healthy subjects provides precise indications of what ReadyWrap[®] Calf can achieve in chronic venous insufficiency and lymphedema. This comparative study in healthy subjects showed that the properties of ReadyWrap[®] Calf are close to those of Urgo K2[®]. All this data could appear in the registration file.

Comparative clinical trials³⁴ can be conducted against a reference bandage to assess a primary endpoint. For example in venous ulcer: complete wound healing.

Secondary endpoints: wound stage, healing %, age of the ulcer, recurrence, mixed ulcer, associated edema, topography, wound infection, cost of complete treatment. It turns out that comparing these multiple parameters can make this research difficult.

Conclusion

The interface pressures and SSI of Readywrap[®] Calf and two bandages (Rosidal[®] Sys, Urgo K2[®]) were studied before and after a treadmill test. The 3 devices have been applied with a pressure of 40 +/- 3 mmHg at point B1.

After the test, the interface pressures of the three devices decreased. The pressures and SSI under ReadyWrap[®] Calf and under Urgo K2[®], before and after the test, were not statistically different.

Only Rosidal[®] Sys had a significantly higher SSI before and after the test. ReadyWrap[®] Calf when applied in accordance with the manufacturer's recommendations, has physical properties similar to those of Urgo K2[®]. It is likely that the clinical indications will be similar.

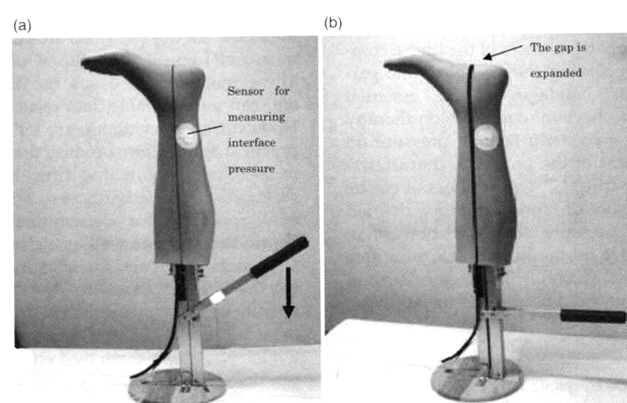


Figure 8 - Hirai plastic leg

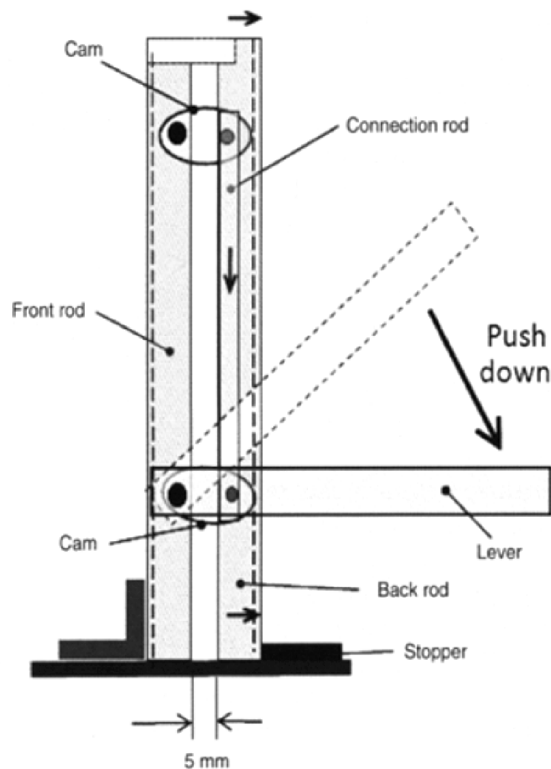


Figure 9 - Schematic diagram of Hirai leg for determining the stiffness.

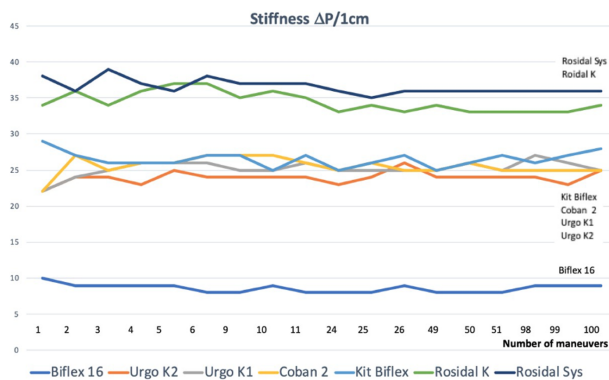


Figure 10 - Evolution of Stiffness Indices of several bandages calculated on Hirai leg.

Declarations

Disclosure

The content of this article was expressly written by the authors listed. No ghostwriters were used to write this article.

Ethical approval

The protocol and the principle of this study were approved on October 23th, 2023 by the advisory board of the Diabetic Foot Center

(DFC), 15 Surayat Street, Cairo, Egypt, in accordance with the Egyptian Ministry of Health recommendations and with the principles set in the Declaration of Helsinki. The subjects were informed about the purpose of the study and signed a free and informed consent form.

Contributorship

JPB organized the study

JPB & JFU conceived protocol and analyzed the results (statistical analysis)

JFU & JPB wrote the paper

FB, PF made the measurements

JPB, JFU, WT and PF reviewed the article

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

This project was funded by Lohmann & Rauscher company.

Acknowledgements

We would like to thank Dr. Rashad Bishara for his welcome to the diabetes center.

References

- 1) Partsch H, Schuren J, Mosti G, Benigni JP. The Static Stiffness Index: an important parameter to characterise compression therapy in vivo. J Wound Care. 2016 Sep;25 Suppl 9: S4-S10.
- 2) Partsch H, Bassez S, Benigni JP et al. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness: consensus statement. Dermatol Surg. 2006 Feb;32(2):22432; discussion 233. DOI [10.1111/j.1524-4725.2006.32039.x](https://doi.org/10.1111/j.1524-4725.2006.32039.x).
- 3) Mosti G, Mattaliano V, Partsch H. Inelastic compression increases venous ejection fraction more than elastic bandages in patients with superficial venous reflux. Phlebology. 2008;23(6):287-94.
- 4) Abu-Own A, Shami SK, Chittenden SJ et al. Microangiopathy of the skin and the effect of leg compression in patients with chronic venous insufficiency. J. Vasc. Surg. 1994 Jun;19(6):1074-83.
- 5) Grenier E, Gehin C, McAdams E, Lun B, Gobin J-P, Uhl J-F. Effect of compression stockings on cutaneous microcirculation: Evaluation based on measurements of the skin thermal conductivity. Phlebology. 2016;31(2):101-105. doi:10.1177/0268355514564175
- 6) Partsch H. Compression therapy: clinical and experimental evidence. Ann Vasc Dis. 2012;5(4):416-22.
- 7) Benigni JP, Uhl JF, Filori P, Balet F, Penoe L. Adjustable compression wraps: stretch, interface pressures and static stiffness indices. Int Angiol. 2023 Jun;42(3):247-253.
- 8) Mosti G, Mancini S, Bruni S, Serantoni S, Gazzabin L, Bucalossi M, Polignano R, Mariani F, Luca B, Partsch H; MIRACLE Trial investigators. Adjustable compression wrap devices are cheaper and more effective than inelastic bandages for venous leg ulcer healing. A Multicentric Italian Randomized Clinical Experience. Phlebology. 2020 Mar;35(2):124-133.
- 9) Mosti G, Cavezzi A, Partsch H. et al. Adjustable Velcro Compression Devices are More Effective than Inelastic bandages in

Reducing Venous Edema in the Initial Treatment Phase: A Randomized Controlled Trial. *Eur J Vasc Endovasc Surg*. 2015 Sep;50(3):368-74.

10) Benigni JP, Uhl JF, Balet F. et al. Treatment protocol on stasis edema in poorly mobile nursing home patients. *Int Angiol*. 2018 Oct;37(5):396-399.

11) Damstra RJ, Partsch H. Prospective, randomized, controlled trial comparing the effectiveness of adjustable compression Velcro wraps versus inelastic multicomponent compression bandages in the initial treatment of leg lymphedema. *J Vasc Surg Venous Lymphat Disord*. 2013 Jan;1(1):13-9.

12) Mestre S, Calais C, Gaillard G et al. Interest of an auto-adjustable nighttime compression sleeve (Mobiderm® Autofit) in maintenance phase of upper limb lymphedema: the MARILYN pilot RCT. *Support Care Cancer* 2017 Aug;25(8): 2455-2462.

13) Pujol-Blaya V, Salinas-Huertas S, Catasús ML, Pascual T, Belmonte R. Effectiveness of a precast adjustable compression system compared to multilayered compression bandages in the treatment of breast cancer-related lymphoedema: a randomized, single-blind clinical trial. *Clin Rehabil*. 2019 Apr;33(4):631-641.

14) Borman P, Koyuncu EG, Yaman A, Calp E, Koç F, Sargut R, Karahan S. The Comparative Efficacy of Conventional Short-Stretch Multilayer Bandages and Velcro Adjustable Compression Wraps in Active Treatment Phase of Patients with Lower Limb Lymphedema. *Lymphat Res Biol*. 2021 Jun;19(3):286-294.

15) Protz K, Reich-Schupke S, Klose K. et al. Compression devices for decongestion therapy : A cross-sectional observational survey of handling, pressure, and comfort. *Hautarzt*. 2018 Mar;69(3):232-241.

16) Balet F, Benigni JP, Uhl JF, Chahim M, Filori P. Limitations to self-management of adjustable compression wraps in the elderly: results of a prospective cohort study. *Int Angiol*. 2021 Jun;40(3):261-266. DOI [10.23736/S0392-9590.21.04580-6](https://doi.org/10.23736/S0392-9590.21.04580-6). Epub 2021 Mar 19. PMID: 33739073.

17) Taha W, Benigni JP, Uhl JF, Carpentier PH, Filori P, Bishara R. Performance of an adjustable compression wrap in occupational leg swelling. *Phlebology*. 2024 Jan DOI [10.1177/02683555231226385](https://doi.org/10.1177/02683555231226385).

18) Jindal R, Balet F, Filori P, Kaur T, Dhillon S, Thapa S, Chaudhary P. Interest of a Standardized Treadmill Test to Evaluate Pressure Drops and Stiffness Indices Under Short Stretch Bandages. *Indian Journal of Vascular and Endovascular Surgery* 7(4): 385-388, Oct-Dec 2020.

19) <http://www.random.org/lists/>

20) <https://lohmann-rauscher.co.uk/products/compression-wrap-systems/readywrap>

21) Partsch H, Mosti G. Comparison of three portable instruments to measure compression pressure. *Int Angiol*. 2010 Oct;29(5):426-30.

22) <https://www.jmp.com>

23) Lurie F, Passman M, Meisner M, Dalsing M, Masuda E et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg Venous Lymphat Disord*. 2020 May;8(3):342-352.

24) Benigni JP, UHL JF, Balet F, Filori, P. (2024). Interface pressures and stiffnesses of different bandages studied on a Hiraï leg. *Veins and Lymphatics*, 13(1). DOI [10.4081/vl.2024.12240](https://doi.org/10.4081/vl.2024.12240).

25) Mosti G, Partsch H. Inelastic bandages maintain their hemodynamic effectiveness over time despite significant pressure loss. *J Vasc Surg*. 2010 Oct;52(4):925-31.

26) Uhl JF, Benigni JP, Cornu-Thenard A. (2013). Where should stiffness be measured in vivo? *Veins and Lymphatics*, 2(1), e5-e5.

27) Wong I. K. Y, Man M. B. L, Chan O. S. H, Siu F. C, Abel M, Andriessen A. (2012). Comparison of the interface pressure and stiffness of four types of compression systems. *journal of wound care*, 21(4), 161-167.

28) Partsch H. (2012). Compression therapy: clinical and experimental evidence. *Annals of vascular diseases*, 5(4), 416-422.

29) Mosti G, Wittens C, Caggiati A. Black holes in compression therapy: A quest for data. *J Vasc Surg Venous Lymphat Disord*. 2024 Mar;12(2):101733.

30) European Committee for Standardization (CEN). Non active medical devices. Working Group 2 ENV 12718: European. Pre-standard 'Medical Compression Hosiery'. CEN TC 205. Brussels: CEN; 2001.

31) Hirai M, Niimi K, Miyazaki K, et al. Development of a device to determine the stiffness of elastic garments and bandages. *Phlebology*. 2011 Oct;26(7):285-91

32) Hirai M, Partsch H. (2013). The Mannequin-leg: a new instrument to assess stiffness of compression materials. *Veins and Lymphatics*, 2(1), e3-e3.

33) Chassagne F, Molimard J, Convert R, Helouin-Desenne C et al. Bandages Static Stiffness Index Is Not Influenced by Calf Mechanical Properties but Only by Geometrical Changes. *Biomechanics*, 2022 2(1), 87-94.

34) Mosti G, Namislo A, Da Matta E, Benigni JP et al. Indications, contraindications, side effects, general assessment and outlook for the future: an International Compression Club survey. *Phlebology*. 2024 Jun;39(5):342-352. DOI [10.1177/02683555241228899](https://doi.org/10.1177/02683555241228899).

