Adjustable compression wraps

Correlation between performances *in vitro* (Hiraï leg) and *in vivo:*
A mandatory step before clinical development ?

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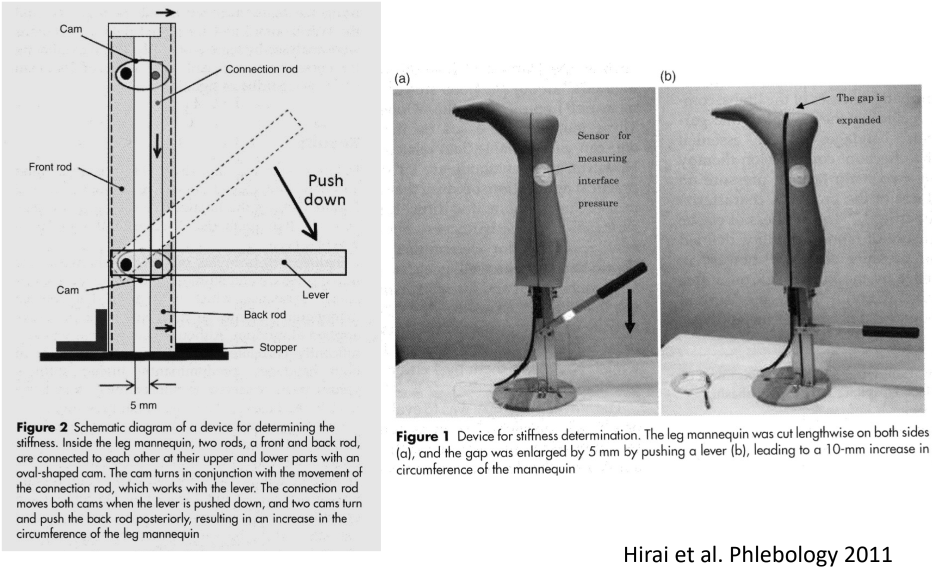
In the medium term, wraps will probably replace bandages. Their ease of use and the lack of nursing staff will justify the use of wraps by less qualified personnel or by the patient's entourage. This is definitely one of the reasons why the wraps are developed based on the performance of the bandages. But is comparison accurate? Their development is based on that of the bandages (stretch, stiffness and static stiffness index).

Juzo compression wrap 6000

Is the study of wraps and bandages comparable? An adaptation is necessary to evaluate the performance and specificity of the wraps. Is there a correlation between the in vitro properties and the properties evaluated in healthy subjects?

The evaluation of the stretch is finally simple to evaluate. The study of the stiffness requires the use of a specific device allowing to measure the pressure variation for one cm increase in circumference ($\Delta P/\Delta C$). The use of a leg model, the Hirai leg (figure 1), should make it possible to study pressure and stiffness variations with greater precision and less variability than in the healthy subject (static stiffness index).



Hirai et al. Phlebology 2011

Figure 1 Evaluation of stiffness with Hiraï leg

But this method of evaluation is only valid if there is a correlation between the data collected on the Hirai leg and the data collected on healthy volunteers in order to extrapolate the behavior of the wraps in clinic.
The objective of this study is to investigate for each interface pressure (from 20 mmHg to 60 mmHg maximum) the in vitro stiffness and the in vivo static stiffness index.

Five wraps tested

We tested five different wraps on the Hiraï leg and on five normal legs:

- With a 50 and 60% stretch (Juzo compression wrap 6000, Readywrap)
- with a 70, 80% and 124% stretch (Circaid Juxtafit, Circaid Juxtalite , Compreflex)

We measured the interface pressures at point B1 on the Hirai leg and on the leg of the healthy subject with a Picopress. The wraps were applied from 20 mmHg to 60 mmHg for Circaid Juxtafit, Circaid Juxtalite, Compreflex and to 50 mmHg for Juzo and ReadyWrap. The pressures were increased from 5 mmHg to 5 mmHg.

Stiffness with Hiraï leg

Stiffness curves assessed with the Hirai leg make possible to characterize the wraps in relationship with their stretching (fig 2)

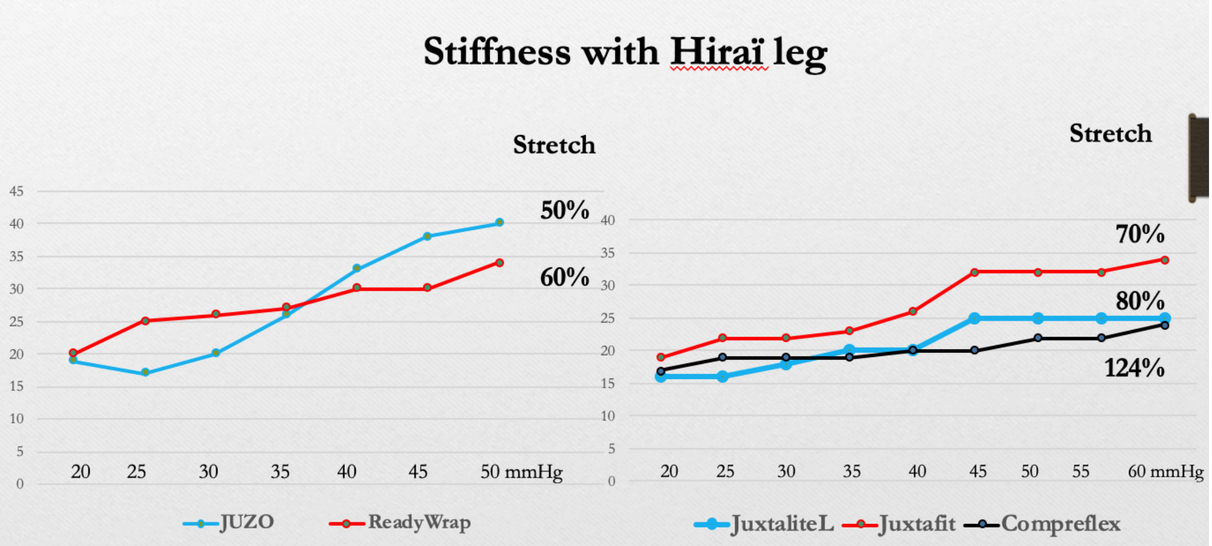
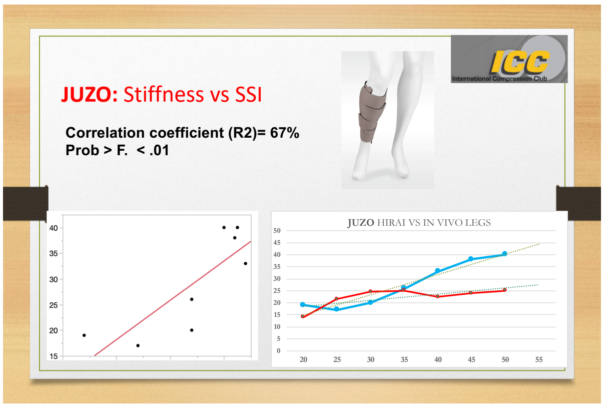
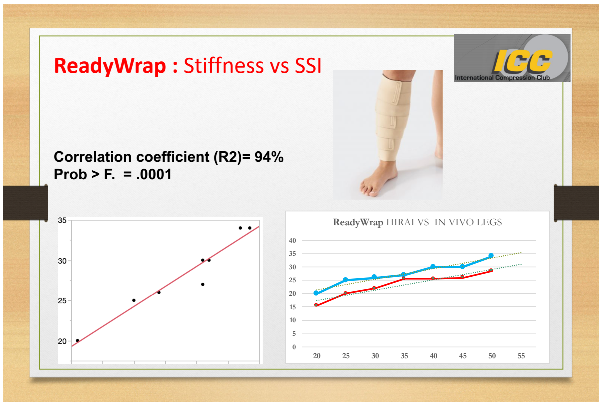


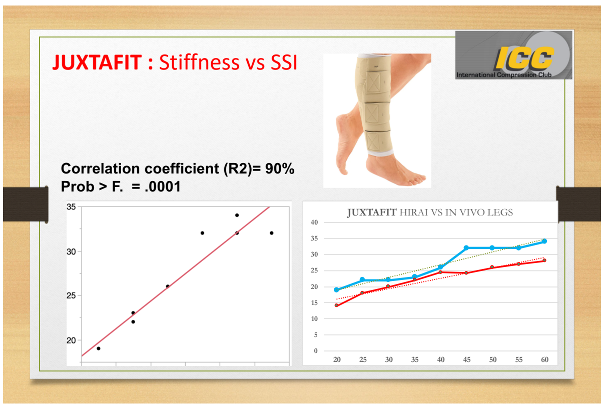
Fig. 2 stiffness curves of the wraps with the Hiraï leg according to pressure

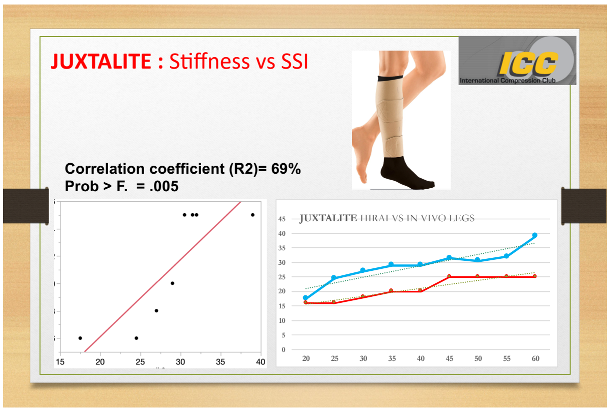
What correlation with Static stiffness index (SSI) in healthy subjects ?

A correlation between the SSI and stiffness was demonstrated for all wraps.









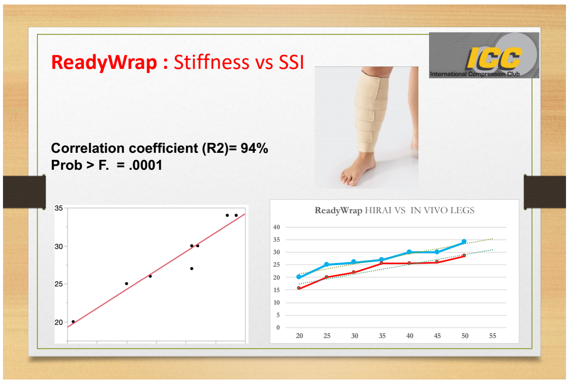
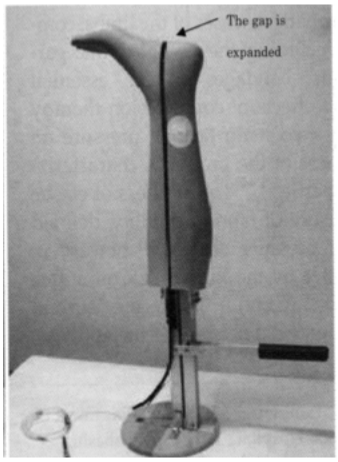


Fig 3. Correlation curves and correlation coefficient (R^2) SSI (red line) -Stiffness (blue line) of the wraps

There is a very good correlation (mean R2 = 79%) between the results measured on the Hirai leg and those measured in healthy volunteers, but a larger scale study is needed to confirm the results of this assessment method.

What to remember?

The use of a Hiraï leg should help to anticipate the performances expected in wrap developments, clinical trials and finally in daily practice.



A breakthrough in limb volume measurement?

Methodology and validation of a new technique of limb volumetry by 3D surface scanning.

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Introduction

The tools for studying the volume of lower-limb edema are debatable. The accuracy of the measurements varies according to the methods currently used

We explain here this new technique of limb volumetry, more accurate, easier and so more reproducible.

We tested this new technique through a clinical study lower extremity edema at an early stage

Methodology of leg volumetry

The use of a portable 3D scanner (Figure 1) allows a quick, reproducible and very accurate measurement of the volume of the lower limbs. The other methods are either tedious: the water boot although accurate or inaccurate / time consuming like opto-electronic measurement, photogrammetry (Bodytronic 600), leg-o-meter. Precise volume reduction has not been quantitatively evaluated.
The new 3D handyscan (Peel 2 from Creaform) was used to measure leg volumes.

Figure 1: 3D Handyscan device (Peel 2 from Creaform)

After calibration of the device, several targets are placed on the skin. These enable an easy 3D vectorial reconstruction of the whole limb and accurate location of the cutting planes (figure

3,4). For this reason, each group of 3 targets have to define a plane parallel to the ground in standing position.
According the the desired segmentation, the number of targets could vary between 6 to 18.
Skin marks are drawn around the target in order to avoid lost of target position. (figure 2)

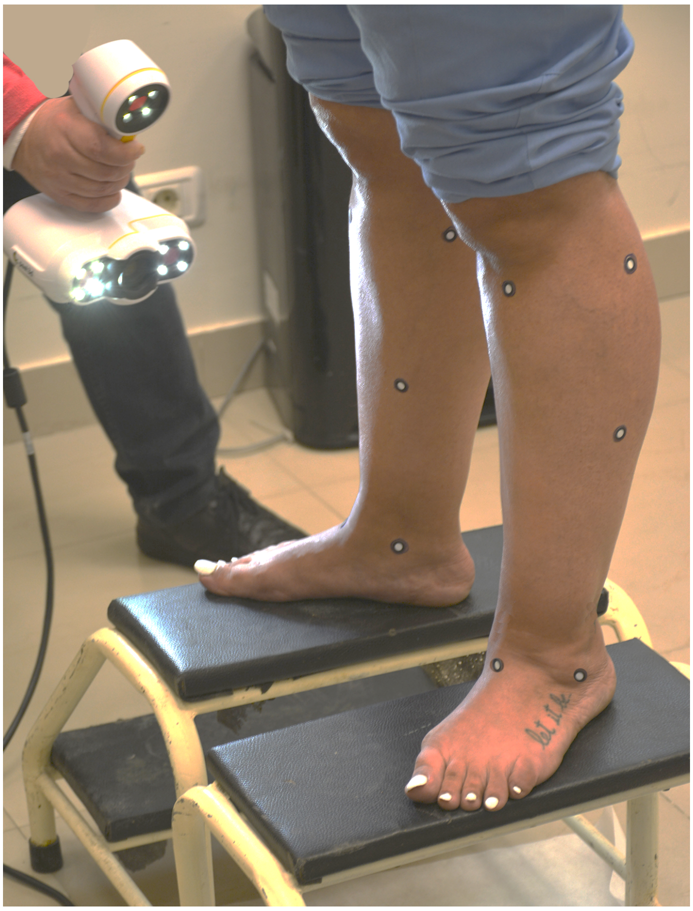

Figure 2: Scanning of a patient (right leg) in standing immobile position

3d surface scanning and technique of limb reconstruction
The subject is standing immobile on a stool, the 2 feet separated by 40 cm with a free space of 2 m around the subject, so as to allow to freely go around the legs. (figure 2
Scanning parameters are: resolution 2 mm, fill the targets, targets geometry, texture on.
During the scanning, the user slowly turns around the subject and has to follow the limb reconstruction on the computer screen, to be sure the surface is complete (no holes). After reconstruction, the user checks the completion of the limb surface and the correct identification of all targets. Otherwise, the limb scanning has to be done again.
The mean time of scanning (one leg) was about 90 seconds. This acquisition is done 3 times, in order to compute a median volume.
Computation of volumes from the 3D mesh with the dedicated software takes about 2 minutes.

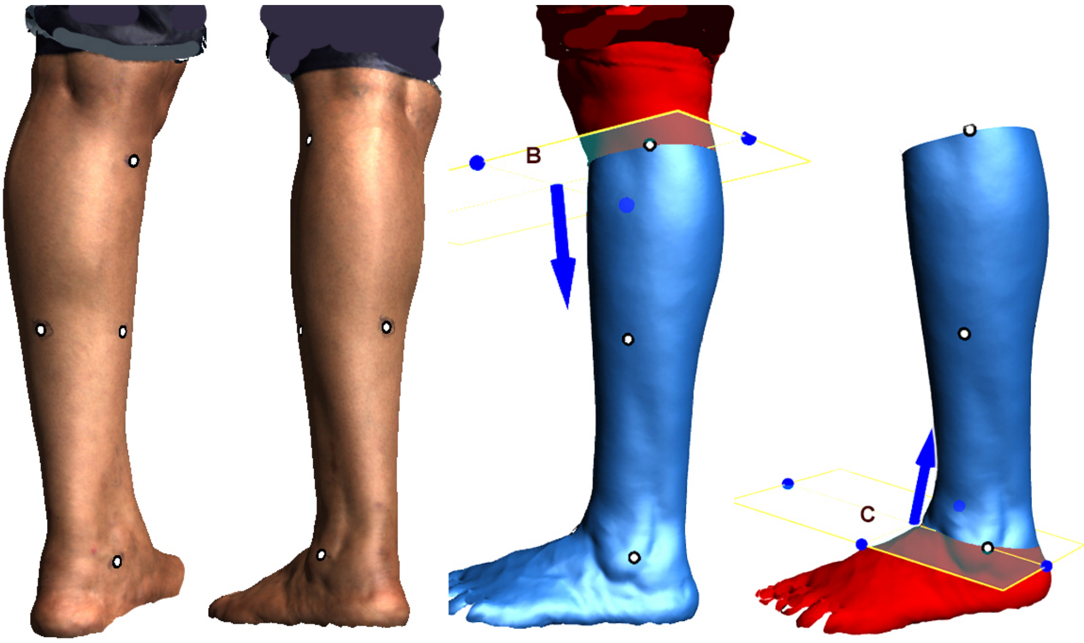

Figure 3: Volumetric computation by 3D modeling.
First step: segmentation of the leg by 2 cutting planes automatically drawn by the 3 targets below knee (B) and ankle below the malleolas (C)

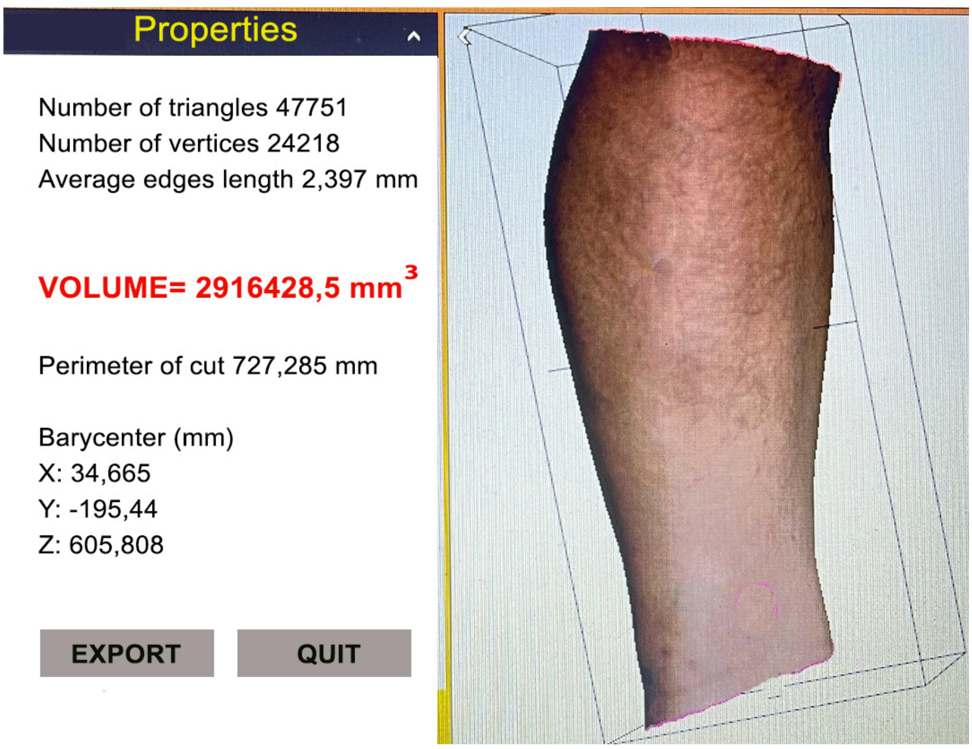

Figure 4 Computation of the leg volume with mesh option "properties".

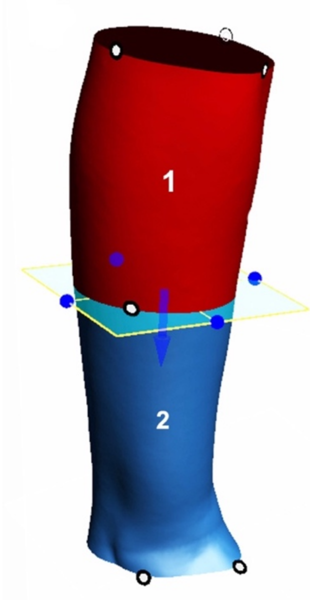

Figure 5 Volumetric computation by 3D modeling.
Second step: division of the leg in several parts. Here 2 parts : upper leg (calf) and lower leg by a mid-leg cutting plane using 3 targets.

- Accuracy and reproductibility:

The device used to study the volume is very precise with an accuracy of 0.5% of the leg's volume, that is about 12.5 ml. Moreover, this method allows a very fine analysis of the volume variations, including the segmental variations of the leg. The use of this new 3D handyscan offers new perspectives in the exploration of chronic venous disease and lymphedema of upper & lower limbs.

figure 11 Scanning technique for upper limb lymphedema

Conclusion

This technique uses a new device which makes possible to accurately assess limb volumetry by surface scanning.
This method is very accurate and quickly repeatable to assess the leg's volume evolution during day, making possible to better define edema during CVD.
It makes also possible to assess segmental volume of the upper and lower limb.

Effectiveness of an adjustable compression wrap

Testing of pressure, stiffness and comfort

Assessment by 3D volumetry technique in the control of leg volume.

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Introduction:

Venous edema is an early sign of chronic venous insufficiency. Most patients develop pitting edema in the evening or after prolonged sitting or standing. The aims of compression in these patients are the prevention and/or reduction of edema, and the improvement of QoL.

The tools for studying the volume of lower-limb edema are debatable. The accuracy of the measurements varies according to the methods currently used .

For these reasons, we found it useful to innovate on a pauci-symptomatic pathology. We decided to study lower extremity pitting edema.

Unlike bandages an adjustable compression wrap allows a standardized application without compressing the ankle and foot.

Previously published results showed the wrap to be effective in treating edema, leg ulcers and lymphoedema . Pressure and stiffness are key parameters of the effectiveness of wraps.

The use of a portable 3D scanner allows for a quick, reproducible and very accurate measurement of the volume of the lower limbs

The aims of this study are:

- To test the pressure and stiffness performance and the comfort of the adjustable compression wrap Readywrap® (Lohmann Rauscher®).

- To evaluate leg volume reduction in ten nurses with pitting edema treated with the wrap on one leg, compared to no compression on the other leg, using a new 3D Scan volumetric technique.

Material and methods:
The wrap was applied with an interface pressure (median of 42 mmHg) at point B1. We calculated the static stiffness index.

A 3D Handyscan from Creaform® was used to measure leg volumes. Volumetry was computed on both legs 3 times before and after a 5-hour compression using the Readywrap® applied on one leg. The contralateral leg was used as the control.

Legs were segmented in 2 parts: upper-leg and lower-leg. Leg volume changes were assessed by median comparison with non-parametric Mann-Whitney U Test.

Results :

We noted a decrease of resting pressure (median of 28 mmHg) with a maintenance of the stiffness (mean 16 +/-3.2 mmHg to 15 +/- 3.7 mmHg) after 5 hours of application. This type of performance is close to that of a short-stretch bandage. The comfort of the wrap showed that it was very well accepted (mean VAS: 8.5 +/- 1.2).
The 3D Handyscan (Creaform®) is extremely accurate in calculating leg volume (CV 0.5%).
We observed a highly significant whole leg volume decrease in the wrap group and an increase in the control group ($p < 0.001$). This was true for the upper-leg ($p = 0.001$) and the lower-leg ($p = 0.001$). fig 1 and table I.
In both groups, volume changes in % were greater in the upper-leg than in the lower-leg, but not significantly so.

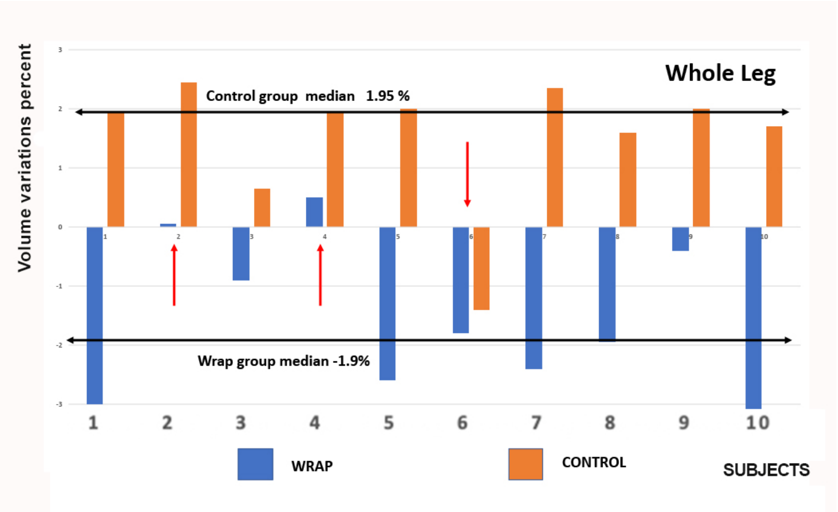

Figure 1: Volume variations in % of whole-leg for each subject

	N	Whole leg	Upper leg	Lower leg
Wrap group	10	-1.95 %	-2.45 %	-1.4 %
Control group	10	1.9 %	1.95 %	1.5 %

p-value		p < 0.001	p = 0 .001	p =0.001

Table I. shighly significant volume changes in % of wrap group vs. control group

Conclusion:

This pilot study confirms that:
- Readywrap® performs like a short stretch bandage with better comfort.
- This innovative surface scanning device allows accurate assessment of limb volume.

Wearing Readywrap® significantly reduces leg volume.
Surprisingly, the volume changes were not only observed in the lower-leg, as previously thought, but also in the upper-leg (calf). (see table I.)