

Experimental study on efficacy of compression systems with a high static stiffness index for treatment of venous ulcer patients

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Abstract

The experimental study measured interface pressure and static stiffness index of four different compression systems in fifty-two healthy volunteers. For the study interface pressure (3 cm ø probe was placed at the anatomical B1 point) was recorded on application of the compression systems every 15 min for 4 h, in supine, standing, while sitting and during walking. For this purpose a portable Kikuhime (Harada Corp., Osaka, Japan) device was used. Further static stiffness index (SSI) was calculated. The evaluated systems were: short stretch bandage system (SSB) Rosidal sys (Lohmann & Rauscher, Rengsdorf, Germany), multi-layer bandaging (LSB) Profore (Smith & Nephew, Hull, UK), vari-stretch bandage (VSB) Proguide (Smith & Nephew) and tubular compression (CS) Rosidal mobil (Lohmann & Rauscher). The mean interface pressure of SSB, LSB and VSB was significantly higher ($P < 0.05$) in each position measured over 4 h, compared to CS. In supine VSB showed high-pressure levels, up to 60 mmHg, which remained high. The other

systems had more tolerable levels of about 30 mmHg. Interface pressure exerted on limbs is an indicator of their clinical effect. The experimental study results showed different patterns of interface pressure and SSI, which may enable clinicians to predict the frequency of bandage application, supporting an adequate and safe choice of bandage system.

Introduction

The paper was presented at the *International Compression Club Meeting* in Vienna 2012 and discussed an experimental study that was previously published.¹ The study aimed to compare interface pressure and static stiffness index (SSI) of four different compression systems that are currently in use for venous leg ulcer and lymphedema treatment of the lower limbs.

Materials and Methods

For the experimental study fifty-two ambulatory adults with healthy legs, were recruited at random in the study center, after they had given informed consent.¹ Excluded were those with an allergy against one of the used materials; arterial occlusive disease (ABPI less than 0.8); ulcers on the lower limb; lower limb edema; known history of dermatological problems such as eczema or cellulites. The evaluated systems were: short stretch bandage system (SSB) Rosidal sys (Lohmann & Rauscher, Rengsdorf, Germany), multi-layer bandaging (LSB) Profore (Smith & Nephew, Hull, UK), vari-stretch bandage (VSB) Proguide (Smith & Nephew) and tubular compression (CS) Rosidal mobil (Lohmann & Rauscher).

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Key words: interface pressure, static stiffness index, compression for venous leg ulcers.

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Contributions: the authors contributed equally.

Conflict of interests: MA is an employee of Lohmann & Rauscher (Rengsdorf, Germany), the company that provided the study products. A limited educational grant was received from Lohmann & Rauscher for conducting the study.

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Interface pressure (IP) (3 cm ø probe was placed at the anatomical B1 point) was recorded on application of the compression systems and every 15 min for 4 h, in supine, standing, while sitting and during walking. For this purpose a portable Kikuhime (Harada Corp., Osaka, Japan) device was used. Measurements during walking were recorded while subjects walked on a treadmill for at least 5 min at normal pace.

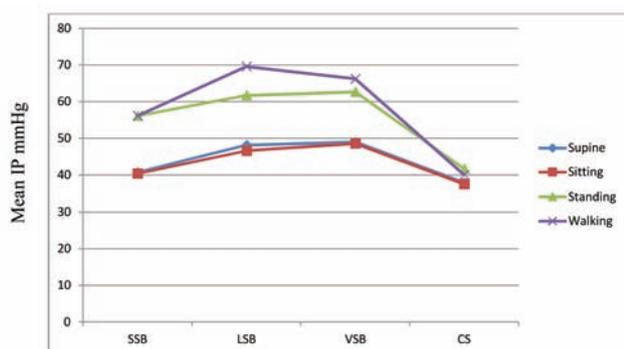


Figure 1. Mean interface pressure in supine, sitting, standing and walking (N=52). IP, interface pressure; SSB, short stretch bandage system; LSB, multi-layer bandaging; VSB, vari-stretch bandage; CS, tubular compression.

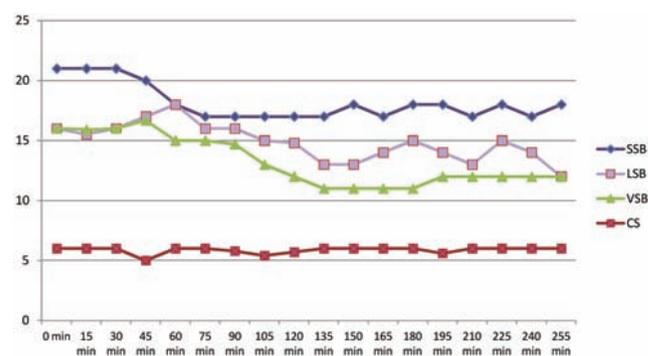


Figure 2. Static stiffness index (N=52). SSB, short stretch bandage system; LSB, multi-layer bandaging; VSB, vari-stretch bandage; CS, tubular compression.

Primary outcome measure

Interface pressure measured in supine, sitting, standing and walking and SSI. Parametric or non-parametric tests (SPSS: IBM Corp., Armonk, NY, USA) were used where appropriate. Mann-Whitney U or paired T-test were used for intragroup and per group comparisons of the IP measured in the different positions and over time.

Results

The mean interface pressure of SSB, LSB and VSB was significantly higher ($P < 0.05$) in each position measured over 4 h, compared to CS (Figure 1). In supine VSB showed high-pressure levels, up to 60 mmHg, which remained high. The other systems had more tolerable levels of 30 mmHg. Measurements in sitting showed similar trends. All compression

systems maintained pressure levels in walking of at least 40 mmHg (Table 1). The SSI was the highest for SSB with 20 and remained 19 throughout the study period. LSB followed with an SSI of 18, reduced to 15, where the SSI for VSB went from 17 to 12 and CS with an SSI of 6 lagged behind (Figure 2).

Discussion

The IP for LSB and VSB in supine of ± 60 mmHg were higher than usually reported. LSB and VSB are defined systems, SSB is a variety of compression systems. LSB has an elastic layer (extensibility $> 100\%$), SSB consists of short-stretch materials (extensibility $\pm 70\%$). By applying LSBs' elastic layers over each other, with a cohesive bandage as the outer layer, the final system is stiffer.² This was also shown in our study¹ and is in line with what was demonstrated by Mosti and Partsch.^{2,5}

In a clinical study⁶⁻⁸ two groups were treated with compression and one group received no compression. In selected patients IP and SSI was measured for the two compression systems LSB and SSB. The static stiffness index remained higher than 10 in both compression groups for one week, the duration of bandage application, despite of bandage pressure loss (Figure 3). The reduction in ulcer area from weeks 12 to 24 in the LSB group and usual care group (moist wound healing dressings, no compression) was not significant ($P = 0.67$ and $P = 0.16$), where a statistically significant reduction in ulcer area was observed in the SSB group ($P = 0.047$) (Figure 4). Both compression systems treated groups showed effective ulcer healing with faster and better ulcer area and pain reduction for SSB, which may be explained by the higher SSI of the system.

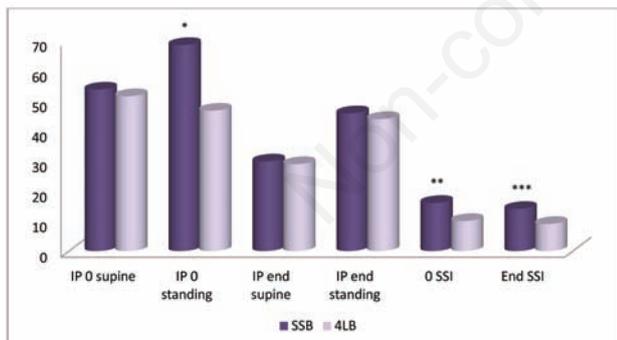
Limitations

This was an experimental study on healthy

Table 1. Experimental study (N=52): interface pressure measured in supine and walking.

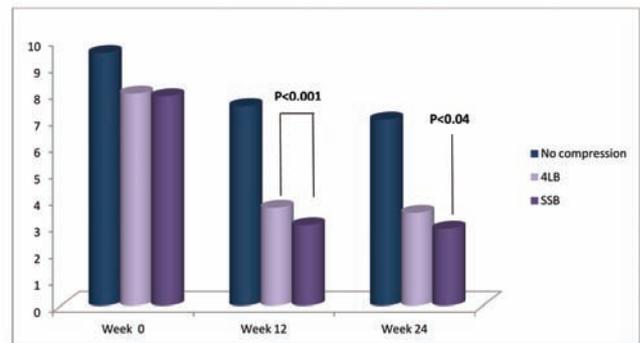
mmHg	SSB		LSB		VSB		CS		Paired T-test
	Supine	Walking	Supine	Walking	Supine	Walking	Supine	Walking	
Mean (\pm SD)	40.68 (± 5.01)	56.11 (± 5.01)	48.12 (± 4.57)	69.59 (± 6.24)	48.96 (± 3.99)	66.21 (± 4.02)	37.82 (± 0.58)	40.04 (± 1.77)	Supine: SSB, LSB, VSB vs CS: $P = 0.05$
Median (range)	41 (39-60)	57 (52-80)	50 (44-59)	73 (64-90)	51 (46-60)	69 (64-80)	40 (39-41)	42 (40-45)	Walking: SSB, LSB, VSB vs CS: $P = 0.05$

SSB, short stretch bandage system; LSB, multi-layer bandaging; VSB, vari-stretch bandage; CS, tubular compression; SD, standard deviation.



	SSB	4LB	Paired-T-test
Upon application IP supine: mean (\pm SD)	53.7 (7.5)	51.5 (6.8)	$P = 0.693$
Upon application IP standing: mean (\pm SD)	68.5 (8.5)	46.7 (7.5)	** $P = 0.041$
Before bandage removal IP supine: mean (\pm SD)	29.8 (3.7)	28.9 (4.7)	$P = 0.763$
Before bandage removal IP standing: mean (\pm SD)	45.8 (4.6)	43.9 (4.4)	$P = 0.693$
Upon application SSI: mean (\pm SD)	16	10	** $P = 0.036$
Before bandage removal SSI: mean (\pm SD)	14	9	*** $P = 0.037$

Figure 3. Clinical study (N=321): interface pressure and static stiffness index. IP, interface pressure; SSI, static stiffness index; SSB, short stretch bandage system; 4LB, four-layer bandage system; SD, standard deviation.



Ulcer area cm ²	SSB	4LB	UC	ANOVA
Week 0: mean (\pm SD)	7.56 (10.43)	7.54 (9.95)	9.23 (12.50)	$P = 0.493$
Week 12: mean (\pm SD)	3.00 (8.40)	3.48 (8.54)	7.54 (12.45)	$P < 0.001$
Week 24: mean (\pm SD)	*2.85 (8.18)	3.39 (8.64)	6.90 (10.62)	* $P = 0.047$

Figure 4. Clinical study (N=321): ulcer area reduction at 12 and at 24 weeks. SSB, short stretch bandage system; 4LB, four-layer bandage system; UC, usual care (a moist wound healing dressing and no compression); ANOVA, analysis of variance; SD, standard deviation.

legs over a 4-h period where typically the systems are left in place for 3-4 days up to 1 week. Moreover the device that was used to measure IP is not suitable to leave in place for over 4 h. Based on our results it is not possible to predict what the pressure levels would be over this period on for instance venous leg ulcer patients with edema.

However the reported results from a clinical study,^{6,7} suggest that when using the SSB and LSB compression systems in venous leg ulcer patients with edema, the IP levels are maintained at a therapeutic level over a week. For this study another, more suitable measurement device [Picopress®, Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò (PD), Italy]³ was used to measure IP levels. This device can be left in place for several days up to a week, providing clinically relevant information.³

Conclusions

Interface pressure exerted on limbs is an indicator of their clinical effect. The study results showed different patterns of interface

pressure and SSI, which may enable clinicians to predict the frequency of bandage application, supporting an adequate and safe choice of bandage system. This approach may increase the patients' participation in, and compliance with, compression therapy, thereby saving on costs and nursing time.

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