

A VERY NEW TWO LAYER COMPRESSION SYSTEM* : PRESSURE INTERFACE RESULTS ON HEALTHY VOLUNTEERS AND CLINICAL EFFICACY IN THE MANAGEMENT OF VENOUS LEG ULCERS

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INTRODUCTION

Management of venous leg ulcers is based on compression therapy which disadvantages can limit patient's concordance. Similar efficacy between multilayer compression systems was confirmed by numerous randomized clinical studies : the different systems will differ one from other on their acceptability and ease of use for both practitioner and patients. In order to evaluate the interest of a new **two-layer compression system*** (2LB), two clinical studies were undertaken ; one randomized on healthy volunteers to compare the interface pressure between three different compression systems. Then after, a second open-label trial with patients presenting a venous leg ulcer was conducted to evaluate the efficacy, the tolerance and the acceptability of this new compression system.

MATERIALS AND METHODS

The first clinical trial (an open, german, monocentre one) has involved 24 young healthy volunteers wearing a compression therapy system : 2LB* (composed of two bandages: a viscose and polyester wadding within a knitted compression layer and a woven cohesive stretch system) (see photos), a 4-multilayer system** (4LB) and a short stretch bandage one (SSB) made up two separate bandage components : a padding bandage and short stretch cohesive bandage*** composed of cotton, polyamide and elastane.

The patients were randomized and bandaged with one of the three systems, on both legs. The interface pressures were measured at baseline, after one day (D1), three days (D3) and seven days (D7) with an air sensor system placed at B1 point, in different positions (sitting, supine and active standing position, and a dynamic one with the measurement of the maximal working pressure). The main judgement criteria was based on the loss of interface pressure for each of the tested systems (at D1, D3 and D7), as Acceptability and Tolerance were considered as secondary objectives. The second clinical trial (an open, French multicentre one) has involved 42 patients with venous leg ulcers (abpi>0.8, less than 24 months duration, between 2 and 20 cm², and non-infected), treated with 2LB* for a six weeks maximum period.

The primary endpoint of this trial (the efficacy) was based upon the reduction of the wound surface area over the follow-up period and the secondary endpoints included local tolerance (occurrence of local adverse events) and acceptability by the patient (impact of this compression system on his "quality of life" and the compression system concordance).

Clinical assessment, planimetric measurement and a photograph record were done at baseline and then after, every two weeks until the 6th week or healing, first occurred.

CONCLUSION

In the clinical study on healthy volunteers, the main point is that the performance for a week, with respect to the maximal working pressure, shows no statistically significant difference between 2LB* and the 4LB** system. 2LB* has reached a therapeutic level higher than 40 mmHg at all time points and the loss of maximal working pressure of 2LB* is significantly smaller than that of the SSB*** at Day 3, without difference at Day 7. The poor acceptability of the 4LB** in the german evaluation, is probably explained by the high level of the interface pressure in all positions, already reported

RESULTS

If considering the healthy volunteers, the following results were observed regarding to the pressure measurements:

- 2LB* has a significant lower loss of maximal working pressure than SSB***, at Day 3 (p=0.017), which was not observed at Day 7 (Figure 1).
- There is no significant difference at any time of the trial between the relative decrease (loss) of maximal working pressure for the 2LB* and 4LB**.
- There is no significant difference at any time of the evaluations between 2LB* and SSB*** considering the relative decrease of the interface pressures in supine position, sitting position and active standing position.

Considering the tolerance of the different systems it was noted that :

- 2LB* is equivalent to SSB*** on the following parameters : tightness, pain, burning, sweating and itching
- 2LB* is significantly better (p<0.0001) than SSB*** on the parameter of feeling heat
- 2LB* is equivalent to 4LB** on the burning and tickling parameters
- 2LB* is significantly better than 4LB** on the following parameters : tightness (p=0.0003), pain (p<0.0001), sweating (p=0.0005), itching (p=0.01) and heat feeling (p<0.0001).

In the second trial, the study population and leg ulcers are described in Table 1.

After the six weeks period treatment, a 58.5% mean surface area reduction was noted (Figure 4) and the mean surface area was 2.42 ± 3.60 cm² vs 6.97 ± 6.43 cm² at baseline (Anova. p<0.0001). 32 of the 42 (76%) leg ulcers showed a reduction of their initial surface area of 40 % or more, in a mean time of 18.8 days. Of the 42 treated ulcers, 10 leg ulcers healed and 26 others were considered improved by the investigators. Only 4 ulcers do not present any evolution and two others were worsened (55% of the treated ulcers at baseline considered not improved by their previous treatment). After the 6 weeks treatment, only 5 patients (12%) still present a clinical oedema of their lower limb (vs 70% at baseline. Figure 5), and 10 of the treated ulcers (30%) showed a healthy surrounding skin (vs 4% at baseline).

Impact of the 2LB* system on patient's daily quality of life

During the follow up period and beneath the tested system :

- pain was noted present in 53% of the documented cares vs 80% at baseline,
- less itchy feeling was perceived : none in 59 % of the cares vs 44 % at baseline,
- less heat sensation was perceived : none in 65 % of the cares vs 56 % at baseline,
- 84 % of the patients founded easy to put on their shoes vs 75 % at baseline,
- 95% and 92 % of the patients considered this system to be (very) comfortable during the day and the night vs 78 % and 81 % at baseline, respectively.

A very good concordance of this new compression system was observed, as no patient was withdrawn from the study because of a complain of bad tolerance or acceptability of the tested system.

in the literature with patients presenting leg ulcers.

The clinical results on leg ulcers show that this new two-bandage compression system* is effective in the management of venous leg ulcers. Compared to their previous compression therapy, it seemed that clinical relevant benefits were noted with regard to comfort, as reflected by the total concordance of the patients. Regarding these results, the 2LB* compression system seems to represent a suitable alternative to other compression systems, enabling an improvement of the patient's quality of life.

*Kiwo® trademark by the Laboratoires URGO (France) in Europe
 ** Proforo® trademark by the Smith and Nephew
 *** Actico® associated with Flexiban® trademark by the Activa Healthcare
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Figure 1. Relative maximal working pressure after 72h (Day 3) and 168h (Day 7) compared to baseline

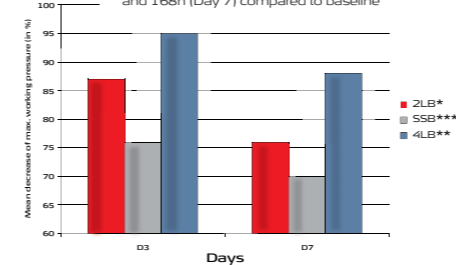


Figure 2. Tolerance of the tested bandages

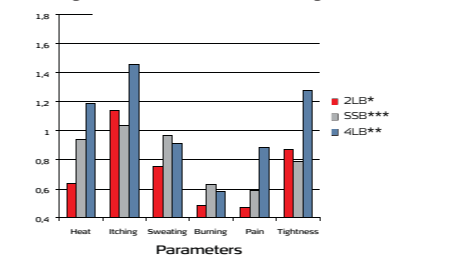


Figure 3. Comfort of the tested bandages

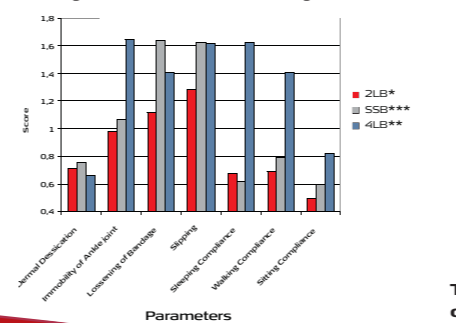


Figure 4. Percentage reduction in ulcer surface area after 6 weeks treatment

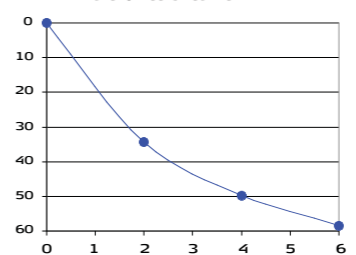


Figure 5. Percentage of clinical lower limb edema at each visit

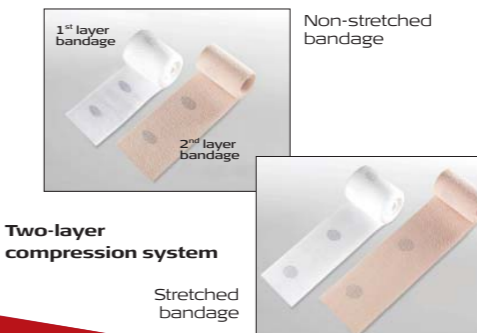


Table 1 Demographic data and Characteristics of the treated leg ulcers at baseline

Gender	
Female	22 (52.38%)
Male	20 (47.62%)
Age (years)	
	70.5 ± 14.1 [37.5 ; 92.9] Median = 73.9
Weight (kg)	
Female	78.3 ± 20.9 [52 ; 130]
Male	92.4 ± 24.9 [56 ; 140]
Height (cm)	
Male	162 ± 10 [142 ; 180]
Female	177 ± 7 [160 ; 195]
BMI ⁽¹⁾ (kg/m²)	
	29.5 ± 6.8 [19.8 ; 45.2] Median = 27.7
Medical history	
HBP (Hypertension)	18 (42.86%)
Heart Disease	9 (21.43%)
Smoking	9 (21.43%)
Diabetes Mellitus	8 (19.05%)
Duration of the ulcer (months)	
Mean [min ; max]	8.1 ± 10.4 [1 ; 60]
Recurrent nature of the ulcer (n.%)	
	26 (61.9%)
Initial surface area (cm²)	
Mean [min ; max]	6.97 ± 6.43 [0.78 ; 27.76]
Condition of the surrounding skin ⁽²⁾ (n.%)	
Healthy	3 (7.14%)
Erythematous	23 (54.76%)
Ecematous	10 (23.81%)
Edematous	18 (42.86%)
Irritated by the dressing(s)	7 (16.67%)
Macerated	6 (14.29%)
Other	3 (7.14%)
Ankle Brachial Pressure index (ABPI) ⁽³⁾	
	1.0 ± 0.1 [0.8 ; 1.3] [1 ; 60]
Edema in the lower limb under study (n.%)	
	29 (69.05%)
Response to previous treatment	
Clear improvement	5 (11.90%)
Moderate improvement	14 (33.33%)
Stagnation	11 (26.19%)
Worsening	12 (28.57%)

⁽¹⁾ Body Mass Index. ⁽²⁾ Total different from 100 % because several responses were possible. ⁽³⁾ Ankle Brachial Pressure Index.