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 3LB system.* This reaches a statistical level higher than 4% at all levels, and the loss of maximal working pressure of a 3LB is significantly smaller than that of the 2LB system on Day 3, without difference at Day 7. The poor acceptability of the 4LB on the German evaluation, and the loss of maximal working pressure of 2LB is significantly smaller than 3LB on the parameter of burning heat.

In order to evaluate the interest of a new compression system, a new experimental model was proposed that allows for the intuitive pressure between these 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.

The main criterion of the trial was the rate of improvement of the venous leg ulcers at baseline considered as not improved by their previous treatment. After the 6 weeks treatment, 5 patients (19.05%) did not present a clinical improvement of their lesions than 50% at baseline.

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.

In the second trial, all 42 patients showed a reduction of their initial surface area of 40% or more, in a mean time of 16.4 days. Of the 42 evaluated patients, 10 leg ulcers treated with 2LB and 26 others with 4LB were assessed by the investigators. Only 4 of 26 do not present any evolution and two others were worsened (15% of the treated ulcers at baseline considered not improved by previous treatment). After the 6 weeks treatment, 5 patients (19.05%) did not present a clinical improvement of their lesions than 50% at baseline.

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

During the follow up period and throughout the studied period:

• pain was noted present in 53% of the documented cases vs 80% at baseline,
• less itching feeling was perceived: none in 59% of the cases vs 44% at baseline,
• less heat sensation was perceived: none in 65% of the cases vs 56% at baseline,
• 84% of the patients battled easy to put on their shoes vs 75% at baseline,
• 88% and 98% of the patients considered the system to be very comfortable during the day and night 78% and 81% at baseline respectively.

A very good concordance of the new compression system was observed, as no patient was withdrawn from the study because of a complaint of bad tolerability or acceptability of the tested system.

CONCLUSION

Management of venous leg ulcers is based on compression therapy which diarrhoea not can limit patient’s concordance. Similar efficacy between multilayer compression systems was confirmed by numerous randomized clinical studies. The different systems will offer different or their acceptability and ease of use for both practitioners 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 these 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.

The first clinical trial, open, German multicentre study has involved 24 young healthy volunteers wearing a compression therapy system: 2LB (*two-bandage system*), a visceral and a stretch bandage combined in a viscoelastic and a stretch compression system, on both legs. The patients were randomized and bandaged with one of the three systems, on both legs.

The interferential pressure were measured at baseline, one day after (D1), three days after (D3) and seven days after (D7) with an air sensor system placed at B1 point, in different positions (sitting, supine and standing positions). The interferential pressure is the measurement of the interferential pressure. The main judgment criteria was based on the loss of interferential 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 at baseline. The patients were randomized and bandaged with one of the three systems, on both legs.

There is no significant difference at any time of the trial between the relative difference of maximal working pressure for the 2LB and 4LB. However, there is no significant difference at any time of the trial between the relative difference of interface pressure in supine position, sitting position and active standing position.

Considering the脸颊ness of the different systems it was noted that:

• 2LB is equivalent to 3LB** in the following parameters: pain, burning, itching and burning 3LB is significantly better (p=0.0001) than 3LB in the parameter of burning heat.

• 2LB is equivalent to 4LB** on the burning and itching factors.

2LB is significantly better than 4LB** on the following parameters: pain (p=0.003), burning (p=0.001) and heat feeling (p=0.001).

In the second trial, the study population and leg ulcers are described in Table 1. After the six weeks period treatment, 105.5% mean area surface reduction was noted on the total 42 leg ulcers. A mean of 16.4 days of treated ulcer, 10 leg ulcers treated with 4LB and 26 others with 2LB were assessed by the investigators. Only 4 of 26 do not present any evolution and two others were worsened (15% of the treated ulcers at baseline considered not improved by their previous treatment). After the 6 weeks treatment, 5 patients (19.05%) did not present a clinical improvement of their lesions than 50% at baseline.

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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 3LB system. This reaches a statistical level higher than 4% at all levels, and the loss of maximal working pressure of a 3LB is significantly smaller than that of the 2LB system on 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 interferential pressure in all positions, already reported in the literature with patients presenting leg ulcers. The clinical results on leg ulcers show that this new two-layer 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 patients’ quality of life.