Promotion of healing, pain relief, tolerability and quality of life: results of a prospective, controlled, randomized comparison study with two wound dressings in out-patients with non-infected leg ulcers

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Introduction

In a pilot study with CE-marked medical devices (applied in their intended use) the efficacy and tolerability of different short stretch multilayer compression systems as well as of two different wound dressing systems in out-patients with non-infected leg ulcers over three months were proven. The aim was to compare the efficacy of two different wound dressings, a Hydrobalanced cellulose based dressing* versus a Foam Wound Dressing** with Ibuprofen.

Material & Methods

- Clinical, experimental, randomized, bicentric, prospective, controlled comparison study with out-patients (see fig 1, 2)
- Proof of concept study (feasibility study)
- Main parameters: pain reduction (Visual Analogue Scale 0-10), quality of life, wound size reduction or healing time

Group 1 – Suprasorb® X + Lomatuell® + short stretch multilayer system:

Sex (N)		Age (year)	Wound age (months)	Pathophysiology					
Men	Women	(mean ± SD)	(mean ± SD)	SVI	DVI	Vasculitis	Arterial	Mixed	No vasculopathy
13	30	73 ± 8.8	57.5 ± 31.7	20	6	2	4	3	3

Group 2 – Biatain® IBU + short stretch multilayer system :

Sex (N)		Age (year)	Wound age (months)	Pathophysiology					
Men	Women	(mean ± SD)	(mean ± SD)	SVI	DVI	Vasculitis	Arterial	Mixed	No vasculopathy
2	16	75.3 ± 4.7	118.5 ± 167.5	6	4	3	2	0	1

Fig. 1: *Anamnesis of the out-patients. Dressing change every 7 days (depending upon wound condition)*

mean (± SD)	lying	standing	SSI
Suprasorb X + Lomatuelle	51,3 (± 8.5)	67 (± 8.6)	15,7 (± 3.4)
Biatain IBU	50,7 (± 6.3)	67,4 (± 7.8)	16,6 (± 4.8)

Fig. 2: *Comparable interface pressure at position B1 with PicoPress in both groups.*

Results

In general, a fast shift of the wound phases from inflammation via granulation to epithelisation was observed, but by the treatment with the HydroBalance Wound Dressing* a faster onset of wound healing, a shorter healing time and a faster pain reduction were seen (fig 3-5). Furthermore, the HydroBalance Wound Dressing* showed an excellent tolerability in comparison to the foam with ibuprofen**.

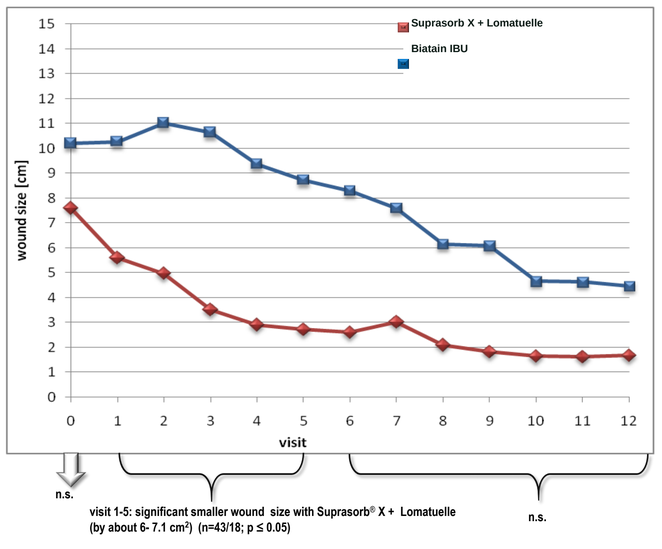


Fig. 3 *Reduction of wound size over time*

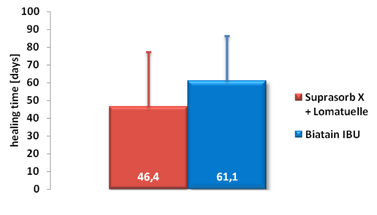
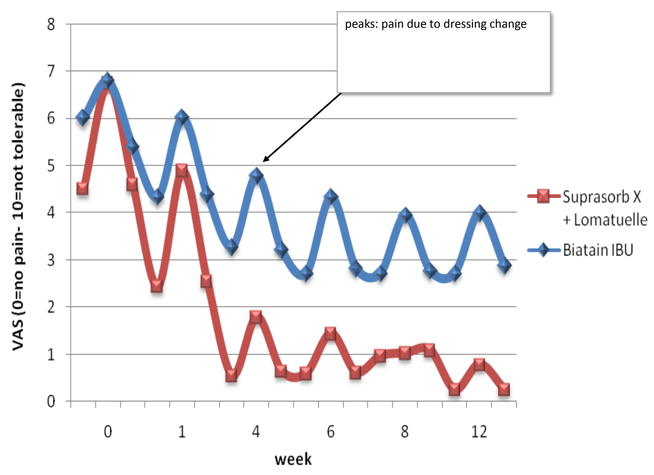


Fig. 4 *Healing time*

1.Suprasorb® X + Lomatuelle: 6.6 weeks (± 4.4) / 46.4 days (± 30.8) (n=43)
2.Biatain® IBU: 8.7 weeks (± 3.6) / 61.1 days (± 5.2) (n=18)

→ significant faster healing when treated with Suprasorb® X + Lomatuelle (p<0,05)



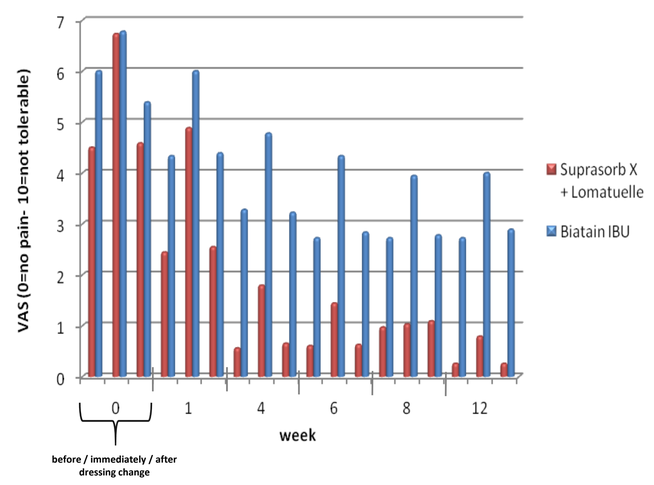


Fig. 5 *Pain Development*

Treatment with

- Suprasorb® X + Lomatuelle®:
  →fast pain reduction
  →fast reduction of the pain peaks due to dressing change
- Biatain® IBU:
  →slower pain reduction
  →less reduction of pain peaks at dressing change

Conclusions

The combination of wound moist dressing and a compression device exerting a strong interface pressure was effective in promoting wound healing. In this respect the HydroBalance Wound Dressing* seems to produce a better outcome.

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*** Suprasorb® X + Lomatuell® (secondary dressing) (Lohmann & Rauscher)**
**** Biatain® IBU (Coloplast)**

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