

Improvement of treatment in patients with venous leg ulcer by a new pain-reducing wound dressing with HydroBalance

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Introduction:

The aim of this study is to investigate the influence of a HydroBalanced wound dressing* (HWD) on wound size reduction, pain control and properties of the wound surrounding skin, before and after treatment with the bio-cellulose based HWD* by means of non-invasive objective skin techniques in patients with venous leg ulcers. The bio-cellulose based HWD* can absorb exudate and donate moisture.

Material and Methods

A single-blinded, monocentric, prospective, controlled, randomized, explorative comparison trial of HWD* and foam** (secondary dressing) versus foam** alone over 3 months (interim evaluation), with ambulatory leg ulcer patients (n=50) has been conducted. As non-invasive parameters transepidermal water loss (vapometer, for skin barrier), redness (chromametry, for inflammation) and skin hydration (corneometry) were additionally used. The wound size was analyzed by a digital wound documentation software with 2D-3D measurement device. The pain measurement was carried out by a Visual Analogue Scale (VAS, 0-10). For the compression therapy a short stretch compression system*** were applied.

Results

Up to now 25 patients (Day 0: HWD*+Foam** n=12, Foam* n=13) were recruited and evaluated for interim results. The dressings were changed every 3 days. During the period of four weeks treatment the healing of the wounds started in both groups. A higher reduction of the wound size and faster onset was seen with HWD*+Foam** (49.4%, n=10) vs Foam** alone (26.1%, n=8) after 4 weeks (Fig 1).

The patients reported a subjective better pain control during application and the whole period of treatment. The pain - reported in the Quality of Life (QoL) form - decreased in both groups - after three months for

HWD*+Foam**	from 7.5 (n=12)	to 2.3 (n=10)	and for
Foam**	from 7.8 (n=13)	to 3.6 (n= 7).	

The transepidermal water loss TEWL (for skin barrier) of the surrounding skin decreased and the skin hydration increased in both groups.

Conclusions

After four weeks treatment the HWD*+Foam** demonstrated a very good wound size reduction, pain control, skin barrier improvement as well as comfort in application and formability as interim result. The HWD*+Foam** showed a very good tolerability.

* HWD = Suprasorb® X; ** Foam = Suprasorb® P; *** Rosidal® sys; Lohmann & Rauscher products

Case 1:

Female patient, 79 years old with venous leg ulcers on her right leg. Persisting for 8 months. Treated with HWD*+Foam**.



Day 0 (30.11.07):

Wound area: 78.5 cm²
Moderate to heavy exudation
Moderate wound odour
Coated with fibrin
QoL-VAS: 9
TEWL (g/h • m²): 44
Corneometry (mm): 16



Day 28 (03.01.08):

Wound area: 76.4 cm²
Slight exudation
Wound bed completely granulated
QoL-VAS: 7
TEWL (g/h • m²): 32.8
Corneometry (mm): 20



After 3 months (22.03.08):

Wound area: 59.1 cm²
Slight exudation
Wound bed completely granulated
QoL-VAS: 0
TEWL (g/h • m²): 26.6
Corneometry (mm): 37



Case 2:

Female patient, 43 years old with venous leg ulcers on her left leg. Persisting for 11 months. Treated with HWD*+Foam**



Day 0 (15.02.08):

Wound area: 362 cm²
Heavy exudation
Tendon exposed
QoL-VAS: 9
TEWL (g/h • m²): 35.3
Corneometry (mm): 43



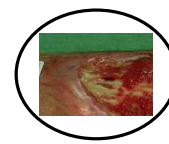
Day 28 (18.03.08):

Wound area: 198 cm²
Heavy exudation
Tendon covered with granulation tissue
QoL-VAS: 8
TEWL (g/h • m²): 53.7
Corneometry (mm): 18



After 2 months (14.04.08):

Wound area: 175.5 cm²
Slight exudation
Wound bed completely granulated
QoL-VAS: 0
TEWL (g/h • m²): 11.1
Corneometry (mm): 14



Case 3:

Female patient, 80 years old with venous leg ulcer on her right leg. Persisting for 2 years. Treated with HWD*+Foam**.



Day 0 (22.11.07):

Wound area: 12.8 cm²
Moderate exudation
QoL-VAS: 5
TEWL (g/h • m²): 88.66
Corneometry (mm): 5.33



Day 28 (21.12.07):

Wound area: 6.9 cm²
Slight exudation
QoL-VAS: 5
TEWL (g/h • m²): 67.9
Corneometry (mm): 50



After 3 months (21.02.08):

Wound area: 2.7 cm²
QoL-VAS: 4
TEWL (g/h • m²): 21.7
Corneometry (mm): 19



After aprox. 4,5 months (07.04.08):

Wound area: healed (0 cm²)

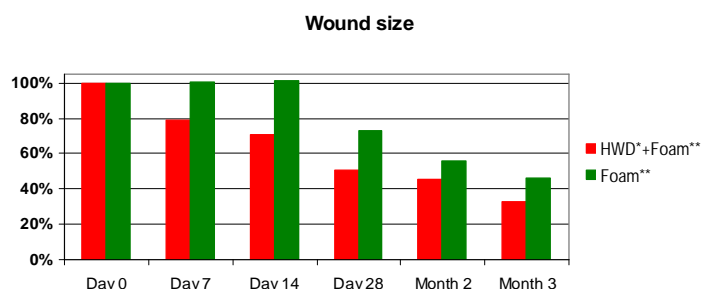


Fig 1