A prospective, multi-centre, clinical evaluation of an innovative, non-bordered foam dressing in the management of exuding chronic wounds

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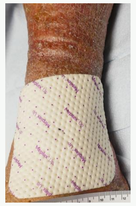
Background

- High exudation is a key challenge in chronic wound management.
- Exudate flows in the direction of gravity and leads to leakage, increasing the risk of maceration, especially for patients with venous leg ulcers (VLUs).
- Dressings that can handle large quantities of exudate, while maintaining a moist wound environment, can help minimize the risk of moisture-related damage.
- A **highly conformable, dimpled, soft silicone-coated, non-bordered foam dressing*** has been developed, that can manage exudate corresponding to **low-to-high exuding wounds**, as well as absorbing both **low and high viscous exudates.**



STUDY AIM

To investigate the effectiveness of a dimpled, non-bordered foam dressing in the management of VLUs and diabetes-related foot ulcers (DFUs).

Methods

Prospective, non-comparative, multi-center, clinical study conducted across four specialist centers in the United States.

Inclusion/exclusion criteria

- Adults with a VLU (3-30 cm^2) or DFU (≥1 cm^2);
- Moderate-severe exudate at baseline;
- Included VLUs: normal distal arterial flow (e.g. ABPI within 3 months >0.7) and willingness to comply with compression therapy.
- Infected ulcers excluded per clinician judgement

Wound Management

Managed according to study centre standard of care, including wound cleansing and/or debridement and the application of compression or off-loading, when indicated.
The dimpled, non-bordered foam was used as the primary absorbent dressing.

Key outcome measures:

Wound progress#, dressing performance, and patient experience were assessed at each visit for up to 6 weeks or until the wound had healed, whichever occurred sooner, and were based on:

- ✓ Clinical assessment
- ✓ Measurement of wound area (and wound volume for DFUs)
- ✓ Evaluation of wound and peri-wound condition as compared to the previous visit
- ✓ Quality of life (QoL) assessments
- ✓ Technical performance of the dressing

#Wound progress based on objectively measured wound area and subjectively evaluated wound condition and rated as 'Deteriorated', 'No change', 'Improved' or 'Healed'

Results

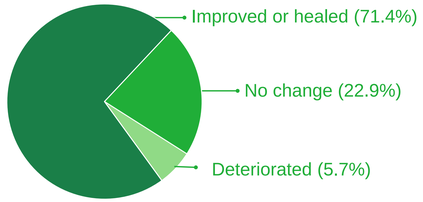
Baseline wound characteristics:

- 68 patients were included in the full analysis set (34 in the VLU group and 34 in the DFU group).
- The percentage of improved or healed wounds with large exudate levels at baseline was 56%.

Characteristic	All (n = 68)	DFU (n = 34)	VLU (n = 34)
Duration (weeks) mean [range]	74.9 [1-780]	73.9 [1-780]	75.8 [5-416]
Area (cm^2) mean ± SD	6.4 ± 6.1	4.2 ± 4.4	8.2 ± 6.7
Exudate amount			
None/Scant/Small	0%	0%	0%
Moderate	85.3%	88.2%	82.4%
Large	14.7%	11.8%	17.6%
Exudate Viscosity			
Low	89.7%	97.1%	82.4%
High	10.3%	2.9%	17.6%

PRIMARY OUTCOME

- DFUs and VLUs **showed significant progress with the dimpled, non-bordered foam dressing,** 71.4% being noted as improved or healed (n=367 follow-up visits).
- Nine (13.2%) patients completed the study with healed wounds.



92.15% decrease in median **DFU volume** compared to baseline (mean: -65.43%)

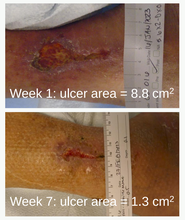
63.07% decrease in median wound **area** compared to baseline (mean: -47.14%)

Consistent, linear **wound closure rate** over time (0.07 to 0.12cm/day using Gilman's formula)

Strong technical performance

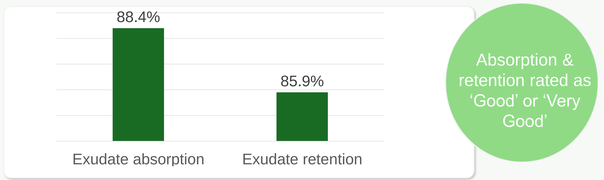
- Adherence to the healthy skin and non-adherence to a moist wound bed rated as '**Good**' or '**Very Good**' at most visits; close to no occurrences of product residue noted in wounds or peri-wound skin upon removal.
- Mean dressing wear time was 5.0 days (range 1-14). Primary reason for change was 'routine change' in 99.1% of the 452 total changes.

3 month-old VLU



Decreased exudate & slough; improved granulation

- By the final visit, the proportion of wounds with moderate and large exudate volumes **reduced substantially** to 40.4% and 7.0%, respectively, while 5.3% of wounds exhibited no exudate and 10.5% exhibited scant.
- Slight **reduction in slough** noted by investigators (e.g. 7.4% with no slough at baseline vs. 17.6% at final visit).
- Area covered by **granulation tissue increased** (76.5% with 75-100% coverage at baseline vs. 80.9% at final visit).
- Dressings were not saturated at **71.9%** of changes.



Patient-reported experience

- The dressing was reported to be comfortable to wear, both with compression (VLU) and without compression (DFU).
- Substantial improvement in wound-related quality of life (QoL).
- Little or no reported trauma or pain during dressing removal, pain during wear, or peri-wound skin itch

- Safety data: no unknown or unexpected safety concerns raised

Conclusions

In a population of moderately-to-heavily exudating wounds of long duration, study data demonstrate:

Favourable performance of the dimpled, soft silicone-coated non-bordered foam dressing to manage large amounts of exudate and support wound progress to healing and improved patient QoL.

Safety, generally positive patient experience (e.g. little or no pain or trauma at removal), and encouraging wear time were also reported.

*Mepilex® Up, Mölnlycke Health Care.

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