PATIENT-REPORTED OUTCOMES AND WOUND-SPECIFIC QUALITY OF LIFE IN DIABETIC FOOT ULCERS AND VENOUS LEG ULCERS: A PROSPECTIVE SINGLE-ARM STUDY OF SILICONE SUPERABSORBENT POLYMER DRESSINGS

PCR164

HARTMANN
Helps. Cares. Protects.

TERESA SZENK[1], AGNIESZKA SEGIET-ŚWIĘCICKA[1], V. VELICKOVIC[2,3], ANITHA PITCHIKA[2], SEBASTIAN PROBST[4], DAVID G. ARMSTRONG[5]

1 Clean Data Labs, Warsaw, Poland; 2 HARTMANN GROUP, Heidenheim, Germany; 3 Institute of Public Health, Medical Decision Making and HTA, UMIT, Hall i.T., Austria; 4 HES-SO, Geneva, Switzerland; 5 Keck School of Medicine of University of Southern California, California, United States

INTRODUCTION

Diabetic foot ulcers and venous leg ulcers are chronic lower-extremity wounds that impose substantial physical, psychological, and daily-life burden. Although wound area reduction and healing remain important clinical endpoints, patient-reported outcomes provide complementary evidence on treatment value by capturing wound-related impairment, perceived benefit, and the lived experience of care. This analysis evaluated wound-related quality of life and patient-perceived treatment benefit in adults with DFU or VLU treated with silicone superabsorbent polymer dressings in routine specialist wound care.

OBJECTIVE

To describe changes in wound-related quality of life, patient-perceived treatment benefit, wound outcomes, and safety over 6 weeks in adults with DFU or VLU treated with silicone superabsorbent polymer dressings as part of standard care.

METHOD

This was an exploratory, prospective, multicenter, nonrandomized, single-arm cohort study conducted in eight specialist wound care centers in Poland. Adults with superficial, noninfected DFUs received silicone superabsorbent polymer dressings with standard offloading, while adults with chronic, noninfected, exuding VLUs received the same dressing class under compression therapy. Patient-reported outcomes were assessed using the Wound-QoL-17 and the Patient Benefit Index for wounds. Wound-QoL scores range from 0 to 4, with lower scores indicating less impairment; PBI-W scores range from 0 to 4, with higher scores indicating greater patient-perceived benefit. Wound area was measured using centralized digital planimetry, and analyses were descriptive and exploratory.

RESULTS

The DFU cohort included 28 participants, 75.0% of whom were male, with a mean age of 63.4 years and median wound duration of 166 days. The VLU cohort included 52 participants, 44.2% of whom were women, with a mean age of 69.1 years and median ulcer duration of 180.5 days. Baseline characteristics are summarized in Table 1.

Table 1. Cohort overview and baseline characteristics for a combined DFU/VLU cohorts

Characteristic	DFU cohort	VLU cohort
Analysis population	28 participants (ITT subgroup)	52 patients (full analysis subgroup)
Dressing-use context	Silicone SAP dressing + standard offloading	Silicone SAP dressing + standardized compression
Follow-up	Up to 6 weeks	Up to 6 weeks
Age, years	63.4 +/- 11.0	69.1 +/- 13.6
Sex	21/28 male (75.0%)	23/52 female (44.2%)
BMI, kg/m2	30.34 +/- 4.79	30.00 +/- 5.64
Key comorbidity	Hypertension 71.4%; dyslipidemia 42.9%; obesity 46.4%	Hypertension 63.5%; obesity 40.4%; diabetes 19.2%; DVT 13.5%
Ulcer duration, days	166 (IQR 96.5-273.5)	180.5 (IQR 98.0-278.0)
Wound location/features	Foot 100%; PEDIS D1 100%; loss of protective sensation 85.7%	Calf 61.5%; ankle 36.5%; ABPI 1.02 +/- 0.13

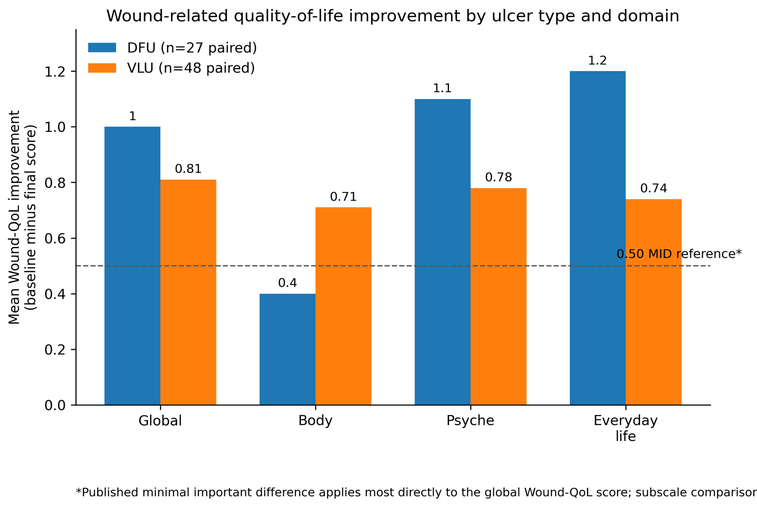
Clinical wound outcomes improved in both cohorts. In the DFU cohort, 77.8% of evaluable participants achieved at least 20% wound area reduction before cleansing or debridement, 85.7% achieved this threshold after cleansing or debridement, and 22.2% achieved complete epithelialization by the final visit. In the VLU cohort, wound area reduction progressed over follow-up, and 29.4% of evaluable ulcers were completely healed by Visit 7.

In the DFU cohort, mean global Wound-QoL decreased from 2.4 at baseline to 1.5 at the final visit, corresponding to a mean improvement of 1.0 point. Improvements were greatest in the psyche and everyday-life domains. Mean PBI-W increased from 2.44 to 2.94, indicating greater patient-perceived benefit at follow-up.

Table 2. Exudate severity and healing hazard

Measure	DFU cohort	VLU cohort
PROM analysis sample	Paired baseline and final questionnaires: n=27	Paired Wound-QoL/final PBI-W analyses: n=48
Global Wound-QoL	2.4 +/- 0.6 to 1.5 +/- 1.0; improvement 1.0 +/- 0.8; P<0.001	2.03 +/- 0.78 to 1.18 +/- 0.80; improvement 0.81 (95% CI 0.49 to 1.12); P<0.001; SRM 0.74
Body subscale	Improvement 0.4 +/- 0.8; P=0.009	Improvement 0.71 (95% CI 0.43 to 1.00); P<0.001; SRM 0.72
Psyche subscale	Improvement 1.1 +/- 1.1; P<0.001	Improvement 0.78 (95% CI 0.33 to 1.23); P<0.001; SRM 0.51
Everyday-life subscale	Improvement 1.2 +/- 1.1; P<0.001	Improvement 0.74 (95% CI 0.37 to 1.11); P<0.001; SRM 0.58
Wound-QoL clinically relevant improvement	Not reported as responder analysis	Global MID responder: 27/48 (56.3%); stable 16/48 (33.3%); worsened 5/48 (10.4%)
PBI-W	2.44 +/- 0.94 to 2.94 +/- 0.87; change +0.45 +/- 1.10; P=0.043	Final attained benefit: 2.92 +/- 0.97 (95% CI 2.63 to 3.20); median 3.07 (IQR 2.15 to 3.78); >=3 in 28/48 (58.3%)

In the VLU cohort, mean global Wound-QoL improved from 2.03 to 1.18, with a mean improvement of 0.81 points; 56.3% of patients achieved a clinically relevant improvement of at least 0.50 points. Final PBI-W benefit was favorable, with a mean score of 2.92 and a median score of 3.07. These patient-reported outcomes are summarized in Table 2 and displayed in Figures 1 and 2.



*Published minimal important difference applies most directly to the global Wound-QoL score; subscale comparisons are exploratory.

Figure 1. Wound-QoL improvement by ulcer type and domain

Safety findings were favorable. No potentially device-related adverse events were reported in the DFU subgroup. In the VLU subgroup, no dressing-related serious adverse events were reported, and no withdrawals were attributed to the study dressings.

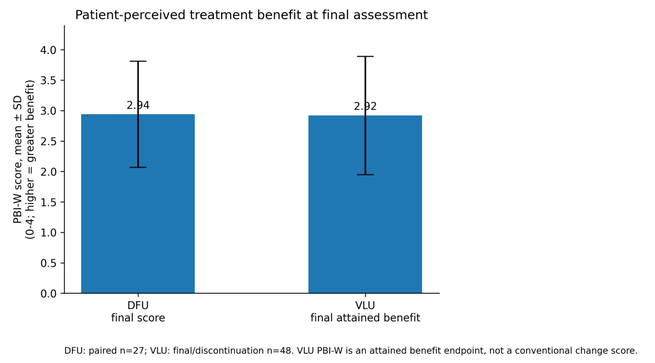


Figure 2. Final patient-perceived treatment benefit by ulcer type

CONCLUSIONS

In this exploratory prospective cohort, adults with DFU or VLU treated with silicone superabsorbent polymer dressings within standard care showed improvement in wound-related quality of life and favorable patient-perceived treatment benefit over 6 weeks. The findings support the inclusion of validated wound-specific patient-reported outcome measures alongside wound healing endpoints in chronic wound studies. Because the study was open-label, nonrandomized, and single-arm, the results should be interpreted as supportive patient-centered outcomes evidence rather than comparative proof of dressing superiority or cost-effectiveness. Future studies should include comparator groups, longer follow-up, and prospective resource-use data to better define the clinical and economic value of exudate-management strategies.

REFERENCES

1. Blome C, Baade K, Debus ES, Price P, Augustin M. The Wound-QoL: a short questionnaire measuring quality of life in patients with chronic wounds. Wound Repair Regen. 2014;22:504-514.
2. Augustin M, Blome C, Zschocke I, et al. Benefit evaluation in the therapy of chronic wounds from the patients' perspective: development and validation of the Patient Benefit Index for wounds. Wound Repair Regen. 2012;20:8-14.
3. Topp J, Blome C, Augustin M, et al. Determining the minimal important difference for the Wound-QoL questionnaire. Patient Prefer Adherence. 2021;15:1571-1578.
4. Staniszewska A, Game F, Nixon J, et al. Development of a core outcome set for studies assessing interventions for diabetes-related foot ulceration. Diabetes Care. 2024;47:1958-1968.
5. Hallas S, Nelson EA, O'Meara S, Gethin G, et al. Development of a core outcome set for interventions in venous leg ulceration. J Tissue Viability. 2024;33:324-331.
6. Velickovic VM, Macmillan T, Lones E, et al. Systematic review and quality assessment of clinical and economic evidence for superabsorbent wound dressings in chronic ulcers. Int Wound J. 2024;21:e14750

CONTACT INFORMATION

Corresponding author contact: vladica.velickovic@hartmann.info