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ORIGINAL RESEARCH

Patient-Reported Outcomes and Wound-Related Quality of Life in Adults with Diabetic Foot Ulcers Treated with Silicone Superabsorbent Polymer Dressings: Exploratory Results from a Prospective Multicenter Nonrandomized Cohort Study

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Background: Diabetic foot ulcers (DFUs) are associated with substantial clinical and economic burden and impaired health-related quality of life (HRQoL). Although wound healing remains a core endpoint, recent consensus work identifies HRQoL as an essential outcome in DFU studies. This study describes wound healing, patient-reported outcomes, function, and safety in adults with DFU treated with silicone superabsorbent polymer (SAP) dressings.

Methods: This exploratory prospective, multicenter, nonrandomized cohort study reports the DFU subgroup from a broader single-arm investigation conducted at eight specialist centers in Poland. Adults with superficial, noninfected DFUs received silicone SAP dressings for up to 6 weeks with standard offloading. Prespecified patient-reported outcome measures were the Patient Benefit Index for wounds (PBI-W) and the Wound Quality of Life questionnaire (Wound-QoL-17). Additional endpoints included wound area reduction (centralized digital planimetry), complete epithelialization, accelerometry-based activity, offloading adherence, and safety.

Results: Twenty-eight participants were included (75.0% male; mean age, 63.4 years), with a median wound duration of 166 days. By the final visit, 21 (77.8%) achieved at least 20% wound area reduction before cleansing/debridement and 24 (85.7%) after cleansing/debridement; 6 (22.2%) achieved complete epithelialization. Mean global Wound-QoL improved from 2.4 ± 0.6 to 1.5 ± 1.0 (mean change, −1.0 ± 0.8; $P < 0.001$), with greatest improvements in psyche and everyday-life domains. Mean PBI-W increased from 2.44 ± 0.94 to 2.94 ± 0.87 (mean change, 0.45 ± 1.10; $P = 0.043$). Activity intensity remained stable, offloading adherence exceeded 95%, and no device-related adverse events were reported.

Conclusion: In this prospective DFU cohort, use of silicone SAP dressings within a structured care setting was associated with improvements in wound area reduction and wound-related quality of life over 6 weeks. These results highlight the feasibility of integrating patient-reported outcomes in DFU studies and provide a clinically relevant platform for future comparative and health-economic evaluations.

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Plain Language Summary: Diabetic foot ulcers are open wounds on the foot that can last for months and can affect far more than the skin. They can make walking harder, limit daily activities, increase anxiety, and require repeated clinic visits and dressing changes. Because of this, it is important to measure not only whether a wound becomes smaller, but also whether people feel and function better during treatment.

We followed 28 adults with diabetic foot ulcers who were treated with 2 silicone dressings designed to absorb wound fluid and protect the surrounding skin. Patients were observed for up to 6 weeks and were also asked to complete questionnaires about quality of life and perceived treatment benefit.

Most wounds improved during follow-up. Around 78% to 86% of patients achieved at least a 20% reduction in wound area, depending on whether the wound was measured before or after cleansing and debridement, and about 1 in 5 ulcers healed completely. Patients also reported meaningful improvements in wound-related quality of life, especially in emotional well-being and everyday life. Perceived treatment benefit also improved. Physical activity remained broadly stable, patients followed offloading recommendations closely, and no dressing-related safety concerns were identified.

These findings suggest that silicone superabsorbent polymer dressings may support both wound improvement and patient well-being. Future studies should test these results against comparator dressings and should also measure costs and resource use so that the full value of treatment can be evaluated.

Keywords: diabetic foot ulcer, patient-reported outcomes, quality of life, wound healing, superabsorbent dressing, outcomes research

Introduction

Diabetic foot ulcers (DFUs) are among the most serious complications of diabetes mellitus and are associated with recurrence, amputation, premature mortality, and substantial healthcare use.[1–3] Normal wound healing follows a coordinated sequence of overlapping phases, including inflammation, proliferation, and remodeling. In DFUs, this process is frequently disrupted due to underlying pathophysiological factors often resulting in chronic, non-healing wounds.[4] Meta-analytic and cross-sectional evidence consistently shows that people living with DFUs experience markedly impaired health-related quality of life (HRQoL), particularly in mobility, emotional well-being, and everyday functioning.[5,6]

Despite this burden, studies evaluating dressings for DFU have historically focused on objective wound endpoints such as change in wound area, time to healing, and complete epithelialization. Patient-reported outcome measures (PROMs) have been less consistently selected, measured, and reported, and a systematic review found considerable heterogeneity in the instruments used across studies of diabetic foot disease.[7] A broader review of PROM use in diabetes likewise emphasizes the need to measure outcomes that matter to patients and to report them rigorously enough to inform clinical decisions, health technology assessment, and policy discussions.[8]

These issues are now reflected in the recently developed core outcome set for diabetes-related foot ulceration, which identified eight outcomes that should be reported in interventional studies: wound healing, time to healing, new or recurrent ulceration, infection, major amputation, minor amputation, HRQoL, and mortality.[9] For chronic wounds, this shift is especially important because treatment benefit depends not only on whether a wound heals, but also on exudate control, comfort, dressing burden, mobility, and the overall experience of care.[10,11]

Silicone superabsorbent polymer (SAP) dressings are intended to manage moderate-to-high exudate, protect the peri-wound skin, and reduce leakage and dressing-change burden.[12,13] Their design combines a soft silicone contact layer with a highly absorbent SAP core capable of retaining substantial volumes of exudate, including biologically active components such as proteases, thereby contributing to modulation of the wound environment. These properties are clinically relevant in DFU, where exudate management and adherence to offloading both influence healing trajectories and patient experience.[14,15] However, DFU-specific evidence on PROMs with SAP dressings remains limited. The present manuscript therefore describes clinical outcomes and patient-reported outcomes in adults with noninfected DFU treated with silicone SAP dressings in a prospective multicenter nonrandomized cohort study.

Patients and Methods

Study Design and Reporting

We conducted an exploratory, prospective, multicenter, nonrandomized cohort study at eight specialized wound care centers in Poland. This manuscript reports the DFU cohort from a broader study of exuding chronic lower-extremity ulcers. Further information on the parent study can be found in the Supplementary Material and the previous publication.[16] Reporting was structured to align with the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement[17] and the CONSORT-PRO extension[18] items most relevant to studies that include patient-reported outcomes, including prespecification of PRO endpoints, instrument selection, missing data reporting, and interpretation of PRO findings where applicable to nonrandomized designs. The study protocol, informed consent form, case report forms, insurance conditions, and related study documents were approved by the Independent Ethics Committee of the Lower Silesian Medical Chamber in Wroclaw (Komisja Bioetyczna przy Dolnośląskiej Izbie Lekarskiej we Wrocławiu) on May 8, 2024 (approval No. 03/05/2024), based on protocol version 1.0 dated March 26, 2024. All participants provided written informed consent before study-specific procedures. This study is registered at ClinicalTrials.gov (Identifier: NCT07549737).

Participants were recruited between July 2024 and July 2025 and were followed for up to 6 weeks, or until complete epithelialization, withdrawal, or discontinuation of the study dressing if its use was no longer clinically indicated. Study conduct followed site standard operating procedures, centralized review of wound images, and sponsor/CRO monitoring with source data verification to support data completeness, plausibility, and protocol adherence.

Participants and Setting

Eligible participants were adults aged 18 years or older with a single chronic, exuding DFU located on one foot. Ulcers were required to have been present for 1 to 12 months, to involve the full thickness of the skin without exposed muscle, tendon, or bone, to measure no more than 10 cm in the longest dimension, and to be free from clinical infection at enrollment. To confirm suitability for conservative wound care, vascular status was assessed by ankle-brachial index or toe-brachial index when appropriate.

Key exclusion criteria included critical limb ischemia, osteomyelitis, active infection requiring antimicrobial treatment, severe edema, immunosuppressive therapy, poorly controlled diabetes (HbA1c 8.6% or higher), severe obesity (body mass index greater than 40 kg/m^2), pregnancy or breastfeeding, malignant wounds, and the recent use of advanced local treatments that could confound wound assessment. Consecutive sampling was used at participating sites to reduce selection bias.

Treatment and Co-Interventions

Participants were treated with either RespoSorb Silicone Border (also marketed as Zetuvit Plus Silicone Border) or RespoSorb Silicone (also marketed as Zetuvit Plus Silicone) (PAUL HARTMANN AG, Germany). Dressing selection was determined by the investigator based on clinical judgement and wound characteristics including exudate level, wound size, and anatomical location. Predefined study-level allocation targets required that at least one-third of patients receive RespoSorb Silicone, with investigator-led selection at the patient level. Both products are commercially available and CE-marked silicone SAP dressings intended for the management of exuding wounds and incorporate a silicone wound contact layer with a highly absorbent core to support exudate management and peri-wound skin protection.[12,13,19,20]

Dressings were applied after wound cleansing and debridement, with mechanical techniques (eg, gauze pads or sponges) used as part of routine clinical practice, consistent with clinical practice guidelines emphasizing regular wound bed preparation. All participants with DFU received standard offloading interventions consistent with contemporary guideline recommendations[14,15] with the specific device and approach determined by the treating investigator based on clinical judgement and wound characteristics. Patient diaries were used to document interim dressing changes and offloading use between visits.

Visit Schedule and Assessments

Baseline assessment (Visit 1) included demographics, comorbidities, glycemic control, vascular evaluation, prior wound treatment, and detailed wound characterization. A single target ulcer per participant was selected for follow-up. Standardized wound photographs were obtained before and after cleansing or debridement at baseline and at weekly visits thereafter (Visits 2–7).

At each scheduled visit, investigators assessed wound status and peri-wound skin, reviewed diaries, recorded dressing use and adverse events, reapplied the assigned study dressing, and re-established offloading as appropriate. Patient-reported outcome measures (PBI-W and Wound-QoL-17) were collected at baseline and at the final visit, while perceived social support was assessed once during follow-up. At the baseline visit, participants were fitted with a wrist-worn accelerometer (GENEActiv, ActivInsights, UK), which they were instructed to wear continuously throughout the study until the final visit. The technical reliability and validity of the accelerometer has been reported in detail elsewhere.[21] The final study visit occurred at week 6 or earlier in the event of complete healing, withdrawal, or dressing discontinuation.

Endpoints and Outcome Measurement

The primary patient-centered outcomes were change from baseline to the final visit in the Patient Benefit Index for wounds (PBI-W) and the Wound Quality of Life questionnaire (Wound-QoL-17). The PBI-W is a wound-specific goal-attainment measure scored from 0 to 4, with higher scores indicating greater patient-perceived benefit.[22] The Wound-QoL-17 measures wound-related HRQoL on a 0 to 4 scale, with higher scores indicating greater impairment, and provides a global score plus body, psyche, and everyday-life subscales.[23] Published work has provided estimates for the Wound-QoL, including estimation of a minimal important difference of approximately 0.50 for the global score and content validation in people with leg ulcers and DFUs.[24,25]

Clinical effectiveness endpoints included the proportion of participants achieving at least 20% wound area reduction from baseline to the final visit and the proportion achieving complete epithelialization within 6 weeks. Wound area was quantified by centralized digital planimetry using standardized photographs taken before and after cleansing or debridement, a method with established validity and reliability in chronic wounds.[26]

Exploratory supportive endpoints included accelerometry-based physical activity and sleep metrics, offloading adherence, perceived social support measured with the Multidimensional Scale of Perceived Social Support (MSPSS),[27] and safety. Accelerometer-derived outcomes were captured continuously and summarized over consecutive 24-hour periods using predefined proprietary algorithms. Daily measures of physical activity and sleep were derived for each participant. Active intensity per day was defined as the mean activity intensity of all periods classified as active (light, moderate, or vigorous activity) within a 24-hour period and expressed in metabolic equivalents (METs). Active volume per day represented the cumulative activity dose over a 24-hour period, calculated by integrating activity intensity across all recorded activity events and expressed as MET-minutes per day. Moderate-to-vigorous physical activity (MVPA) duration was defined as the total daily time spent in activity exceeding predefined intensity thresholds and reported in hours. The active-to-inactive duration ratio was defined as the ratio of total daily active time (light, moderate, and vigorous activity) to total daily inactive time, excluding sleep periods. Sit-to-stand transitions per day were defined as the total number of daily posture changes from sitting or lying to standing, derived from posture and movement pattern recognition. Sleep outcomes were derived from detected sleep periods within the nightly rest interval. Total sleep duration was defined as the cumulative duration of all detected sleep events within a 24-hour period and reported in hours. Sleep efficiency was defined as the percentage of time spent asleep relative to the total duration of the rest interval. Sleep onset latency was defined as the time elapsed between the start of the rest interval and the onset of the first detected sleep episode and reported in hours.

Offloading adherence was categorized as fully compliant (7 of 7 days), moderately compliant (1–3 days without offloading per week), or non-compliant (more than 3 days without offloading per week).

Sample Size, Bias Mitigation, and Statistical Analysis

The parent cohort study targeted at least 80 evaluable participants overall;[16] no formal sample size calculation was performed specifically for the DFU cohort or for the PROM endpoints reported here. Accordingly, analyses in this manuscript should be interpreted as exploratory and descriptive rather than confirmatory.

Several prespecified measures were used to improve internal consistency and reduce bias in the absence of randomization: consecutive recruitment, strict eligibility criteria, standardized co-interventions, standardized photography procedures, centralized blinded planimetry, investigator training, and a prespecified statistical analysis plan finalized before database lock. The parent study also incorporated centralized monitoring and source data verification; identified protocol deviations were predominantly operational and were not judged to compromise subject safety or the overall interpretability of the data. Because dressing allocation followed primary care settings clinical judgment, no formal between-dressing comparison was planned for this manuscript.

Analyses were conducted in the intention-to-treat (ITT) population, defined as eligible participants who received at least one application of the study dressing and had at least one post-baseline assessment. Continuous variables are summarized as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate, and categorical variables as counts and percentages. Relative wound area reduction was calculated as [(wound area at baseline – wound area at visit X)/ wound area at baseline] *100. The proportions of participants achieving at least 20% wound area reduction and complete epithelialization by the final visit were summarized. Changes from baseline to the final visit in PBI-W and Wound-QoL-17 scores were evaluated using paired Student t tests or Wilcoxon signed-rank tests according to data distribution. Daily accelerometer metrics were first derived for each participant and subsequently aggregated to obtain weekly summary values for each assessment period. Weekly average values were summarized at the group level using medians and IQRs and are reported for Week 1 and Week 6. Data from the days at which device recorded less than 16 hours out of 24 hours were excluded from the analysis. Given the exploratory nature of the study and small sample size, statistical tests are descriptive and should not be interpreted as confirmatory. PROMs were not imputed and analyses were based on observed paired questionnaires, and denominators are reported for each endpoint. For wounds that achieved complete healing, missing values at subsequent scheduled visits were handled according to predefined rules: wound area was imputed as 0, and weekly aggregated activity and sleep metrics were imputed using the last observation carried forward (LOCF) method. For participants who discontinued the study for reasons other than wound healing, missing scheduled visit data for wound area and missing weekly aggregated activity and sleep metrics were imputed using LOCF. For intermittent missing data during follow-up (i.e., prior to wound healing or study discontinuation), both wound area and weekly aggregated activity and sleep metrics were imputed using linear interpolation. No sensitivity analyses were performed.

All statistical analyses were performed using R version 4.1.3 (R Foundation for Statistical Computing, Austria) or later.

Patient and Public Involvement

Patients and members of the public were not involved in the design, conduct, reporting, or dissemination plans of this study. The selection of patient-reported outcome measures was informed by prior literature and consensus recommendations emphasizing the importance of capturing outcomes that matter to patients with diabetic foot ulcers.

Results

Participant Flow and Baseline Characteristics

Of 86 screened subjects, 85 entered the safety population and 80 met criteria for the ITT population. Twenty-eight participants had DFU and form the cohort reported in this study (DFU subgroup of the parent cohort); 19 received RespoSorb Silicone Border and 9 received RespoSorb Silicone. Figure 1 shows the flow of participants from screening to analysis.

The cohort was predominantly male (21 of 28, 75.0%), with a mean age of 63.4 ± 11.0 years and a mean body mass index of 30.34 ± 4.79 kg/m2. Cardiometabolic comorbidity was common, including arterial hypertension in 71.4% and

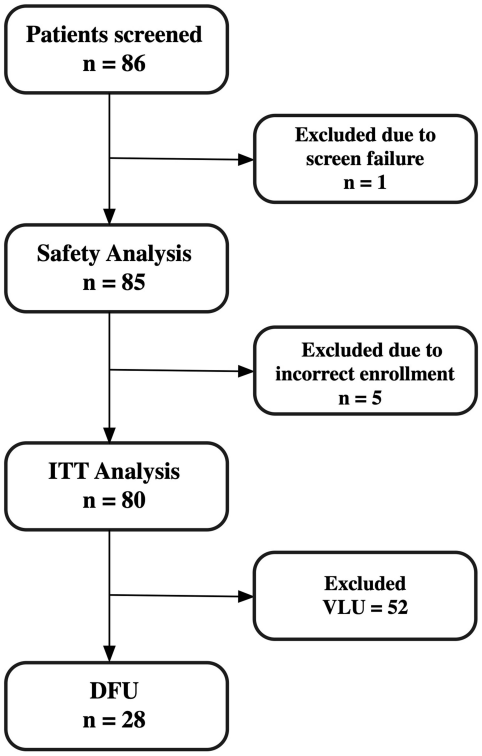

Figure 1 Flow of participants from screening to the diabetic foot ulcer analysis cohort.

dyslipidemia in 42.9%. The median ulcer duration at study entry was 166 days (IQR, 96.5–273.5), all ulcers were located on the foot, and all were classified as superficial full-thickness wounds (PEDIS depth D1). Most ulcers were nonischemic at baseline (PEDIS perfusion P1, 89.3%), and 85.7% of participants had loss of protective sensation. Detailed baseline characteristics are shown in Table 1.

Table 1 Baseline Characteristics of the DFU Cohort

Characteristic	Value
Male sex	21/28 (75.0%)
Age, years	63.4 ± 11.0
Body mass index, kg/m2	30.34 ± 4.79
Arterial hypertension	20/28 (71.4%)
Dyslipidemia	12/28 (42.9%)
Obesity	13/28 (46.4%)
Peripheral artery disease	7/28 (25.0%)
Chronic venous insufficiency	7/28 (25.0%)
HbA1c, %	7.35 (IQR, 6.40–7.75)
Wound duration, days	166 (IQR, 96.5–273.5)

(*Continued*)

Table 1 (Continued).

Characteristic	Value
Wound localization	
Foot	28/28 (100.0%)
PEDIS perfusion	
P1: no signs of peripheral arterial disease	25/28 (89.3%)
P2: peripheral arterial disease without critical ischemia	3/28 (10.7%)
P3: critical limb ischemia	0/28 (0.0%)
PEDIS wound size	
<1 cm2	7/28 (25.0%)
1–3 cm2	12/28 (42.9%)
>3 cm2	9/28 (32.1%)
PEDIS depth/tissue loss	
D1: superficial full-thickness ulcer	28/28 (100.0%)
D2: deep ulcer	0/28 (0.0%)
D3: bone or joint involved	0/28 (0.0%)
PEDIS infection	
I1	28/28 (100.0%)
I2–I4	0/28 (0.0%)
PEDIS sensation	
S1: no loss of protective sensation	4/28 (14.3%)
S2: loss of protective sensation	24/28 (85.7%)

Notes: Values are n/N (%), mean ± SD, or median (IQR), as appropriate. PEDIS indicates perfusion, extent/size, depth/tissue loss, infection, and sensation.

Clinical Outcomes

By the final visit, 21 of 27 evaluable participants (77.8%; 90% CI, 60.8%-89.9%) achieved at least 20% wound area reduction before cleansing and debridement; one participant was not evaluable for this analysis because a usable baseline image before cleansing/debridement was unavailable (Table 2). After cleansing and debridement, 24 of 28 participants (85.7%; 90% CI, 70.2%-95.0%) achieved at least 20% wound area reduction. Complete epithelialization within the 6-week follow-up period was documented in 6 of 28 participants (22.2%) (Table 2).

Median relative wound area reduction increased over follow-up. At Visit 2, the median relative wound area reduction was 21.87% (IQR, 2.41%-42.42%) before debridement and 24.27% (IQR, 14.25%-52.62%) after debridement. By Visit 7, the corresponding medians were 70.73% (IQR, 23.87%-86.11%) and 72.46% (IQR, 34.86%-93.12%), respectively. Figure 2 illustrates the mean wound area reduction trajectory over time before (Figure 2A) and after (Figure 2B) cleansing/debridement. Figure 3 shows the individual patient-level wound area reduction at 6 weeks, before (Figure 3A) and after (Figure 3B) cleansing/ debridement.

Table 2 Summary of Clinical Healing Outcomes

Outcome	Result
≥20% wound area reduction at final visit, before debridement	21/27 (77.8%)
≥20% wound area reduction at final visit, after debridement	24/28 (85.7%)
Complete epithelialization at final visit	6/28 (22.2%)
Median relative wound area reduction at Visit 2, before debridement	21.87% (IQR, 2.41–42.42%)
Median relative wound area reduction at Visit 2, after debridement	24.27% (IQR, 14.25–52.62%)
Median relative wound area reduction at Visit 7, before debridement	70.73% (IQR, 23.87–86.11%)
Median relative wound area reduction at Visit 7, after debridement	72.46% (IQR, 34.86–93.12%)

Notes: Clinical outcomes are reported for the intention-to-treat diabetic foot ulcer cohort. Values are n/N (%), or median (IQR), as appropriate.
Abbreviation: IQR, indicates interquartile range.

Patient-Reported Outcomes

Paired baseline and final questionnaires were available for 27 participants. Mean PBI-W increased from 2.44 ± 0.94 at baseline to 2.94 ± 0.87 at the final visit, corresponding to a mean change of +0.45 ± 1.10 (P = 0.043) (Table 3). Median PBI-W increased from 2.35 (IQR, 1.95–3.00) to 3.00 (IQR, 2.70–3.60).

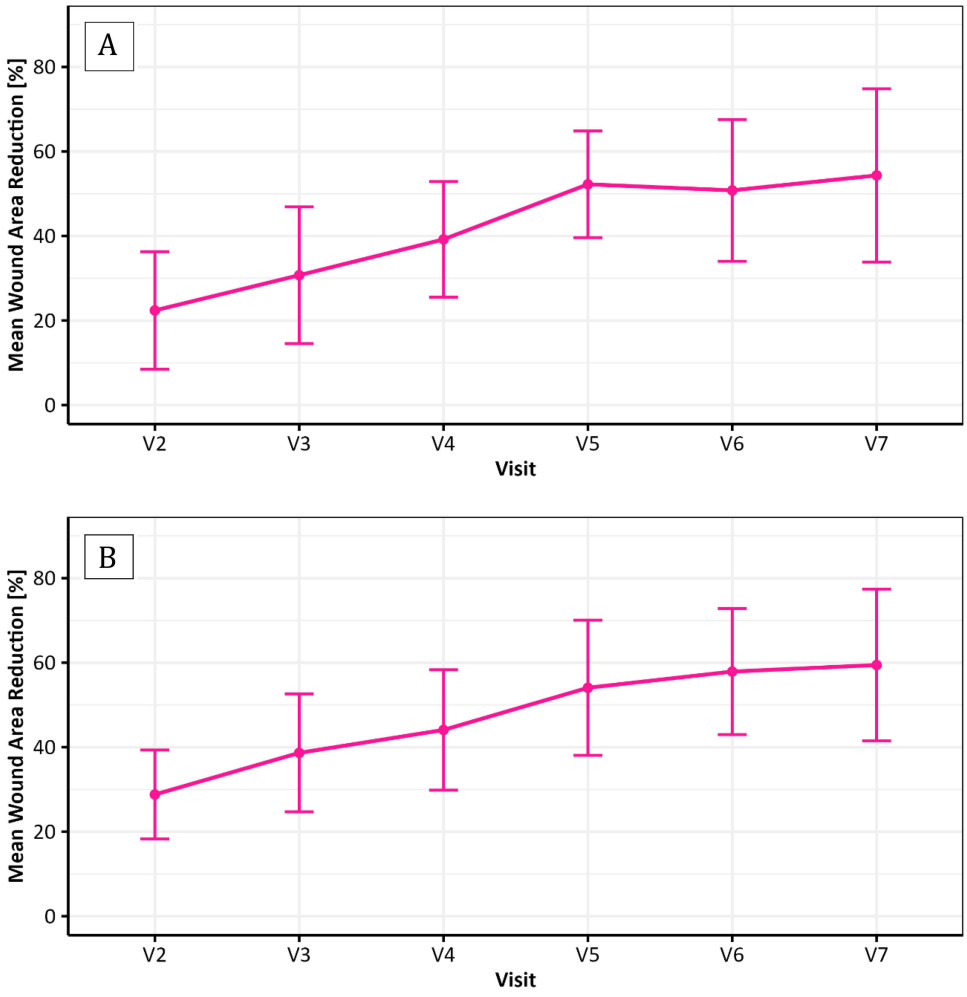

Figure 2 Mean percentage wound area reduction over time (**A**) before and (**B**) after cleansing/debridement, with 95% confidence intervals. Values are shown at each study visit from Week 1 (Visit 2) to Week 6 (Visit 7). Error bars represent 95% confidence intervals at each time point.

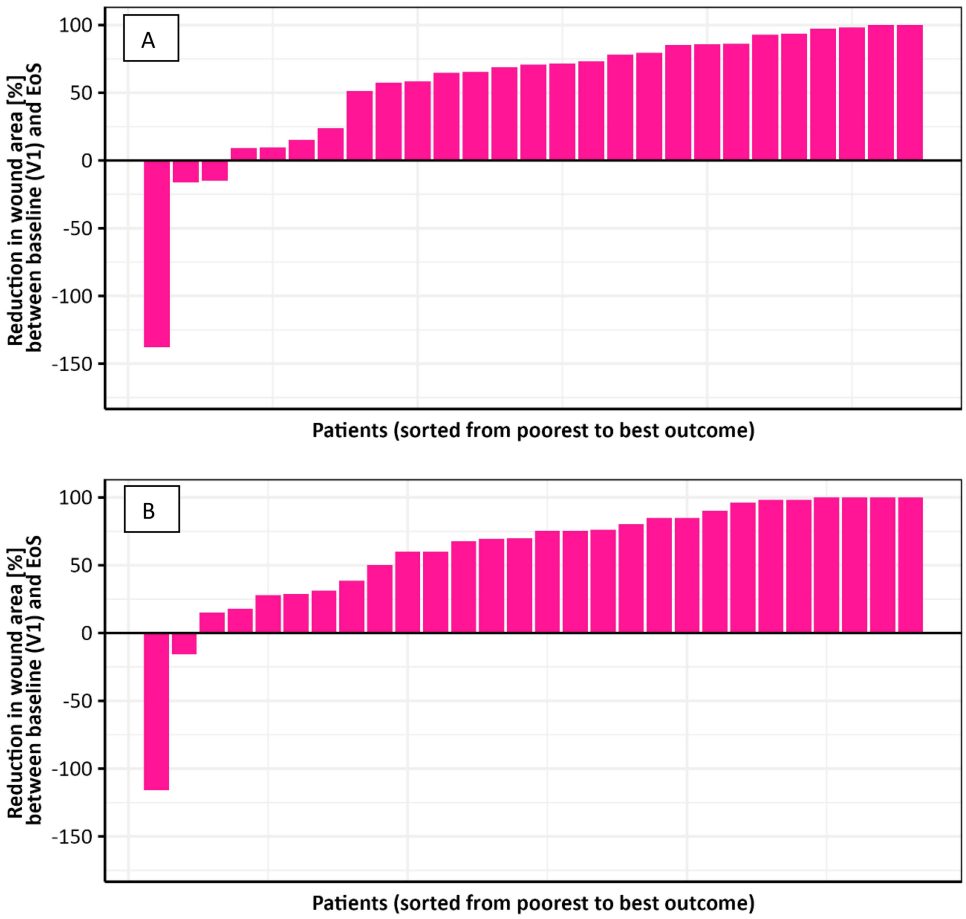

Figure 3 Distribution of Individual Patient–Level Wound Area Reduction from baseline (Visit 1) to end of study (EOS) at 6 Weeks, (**A**) before and (**B**) after cleansing/debridement. Patients are ordered from poorest to best outcome to illustrate the distribution and heterogeneity of treatment responses.
Abbreviation: EoS, End of study.

Mean global Wound-QoL improved from 2.4 ± 0.6 at baseline to 1.5 ± 1.0 at the final visit, for a mean change of −1.0 ± 0.8 ($P < 0.001$) (Table 3). Improvements were observed across all Wound-QoL domains: body, −0.4 ± 0.8 ($P = 0.009$); psyche, −1.1 ± 1.1 ($P < 0.001$); and everyday life, −1.2 ± 1.1 ($P < 0.001$).

Physical Activity, Offloading Adherence, Social Support, and Safety

Accelerometry-based activity metrics showed similar values at week 1 and week 6 (Table 4). Median active intensity per day was 0.0995 MET (IQR, 0.0937–0.1122) at week 1 and 0.0982 MET (IQR, 0.0937–0.1121) at week 6. Median

Table 3 Patient-Reported Outcome Measures

Instrument/Scale	Baseline	Final Visit	Mean Change	P value
PBI-W global score	2.44 ± 0.94	2.94 ± 0.87	+0.45 ± 1.10	0.043
Wound-QoL global score	2.4 ± 0.6	1.5 ± 1.0	−1.0 ± 0.8	<0.001
Wound-QoL body subscale	1.4 ± 0.7	1.0 ± 0.9	−0.4 ± 0.8	0.009
Wound-QoL psyche subscale	2.9 ± 0.9	1.8 ± 1.3	−1.1 ± 1.1	<0.001
Wound-QoL everyday-life subscale	2.8 ± 0.7	1.6 ± 1.2	−1.2 ± 1.1	<0.001

Notes: PROM analyses used paired observed questionnaires (n = 27). Values are mean ± SD. Higher PBI-W indicates greater perceived benefit; higher Wound-QoL indicates worse impairment.

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Table 4 Physical Activity and Sleep Metrics

Metric	Week 1	Week 6
Active intensity per day, MET	0.0995 (0.0937–0.1122)	0.0982 (0.0937–0.1121)
Active volume per day, MET	1542.0 (1263.5–2025.8)	1667.9 (1266.3–2113.8)
MVPA duration, hours	1.12 (0.69–2.12)	1.23 (0.66–1.83)
Active/inactive duration ratio	0.3638 (0.2533–0.4313)	0.3666 (0.2706–0.5080)
Sit-to-stand transitions per day	149.8 (128.2–171.2)	154.0 (128.8–163.4)
Total sleep duration, hours	3.90 (3.07–5.09)	4.04 (2.95–4.92)
Sleep efficiency, %	53.45 (41.13–60.63)	53.85 (39.84–56.44)
Sleep onset latency, hours	0.14 (0.10–0.21)	0.16 (0.05–0.25)

Notes: Values are median (IQR). MET indicates metabolic equivalent.
Abbreviation: MVPA, moderate-to-vigorous physical activity.

active volume per day was 1542.0 MET (IQR, 1263.5–2025.8) at week 1 and 1667.9 MET (IQR, 1266.3–2113.8) at week 6, and median sit-to-stand transitions per day were 149.8 (IQR, 128.2–171.2) at week 1 and 154.0 (IQR, 128.8–163.4) at week 6.

Offloading adherence exceeded 95% at all assessed visits (Supplementary Table S1). Full compliance was observed in 27 of 28 participants (96.4%) at Visit 2 and in 26 of 27 participants (96.3%) at Visit 7; all evaluable participants were fully compliant at Visits 3 to 5, and no participant was classified as non-compliant at any assessed visit. The mean total MSPSS score was 6.8 ± 0.3 (Supplementary Table S2) with high scores for support from a significant other, family, and friends. No potentially device-related adverse events or device deficiencies were reported in the DFU subgroup. In the parent study overall, device-related adverse events were infrequent, non-serious, and predominantly local skin reactions.

Discussion

This prospective multicenter cohort describes clinically relevant wound improvement observed in a cohort treated with silicone SAP dressings over a 6-week period in adults with selected DFUs. Most participants achieved at least 20% wound area reduction, approximately one in five achieved complete epithelialization, and both wound-related quality of life and patient-perceived treatment benefit improved over the follow-up period.

The study is relevant to current outcomes research because it addresses a gap repeatedly identified in the DFU literature. PROM use in diabetic foot disease has been heterogeneous, and the new core outcome set for diabetes-related foot ulceration specifically identifies HRQoL as an outcome that should be reported alongside wound healing and other hard clinical endpoints.[7–9] By combining wound area reduction, complete healing, Wound-QoL, and PBI-W in the same cohort, the present study provides a more patient-centered description of outcomes alongside conventional wound measures.

The Wound-QoL findings are notable in both statistical and clinical terms. The mean improvement in the global Wound-QoL score was 1.0 points, which is approximately double the published minimal important difference of 0.50 for the instrument.[25] This suggests that the observed change exceeds the established minimal important difference and is likely meaningful to patients. In addition, recent validation work has proposed score bands that classify global Wound-QoL scores into clinically interpretable levels of impairment.[28] Using these bands, baseline mean scores in the present study (2.4) corresponded to the category “quite a lot impaired,” whereas scores at the final visit (1.5) corresponded to “moderately impaired.” This shift represents an improvement of approximately one impairment level and further supports the clinical relevance of the observed reduction in Wound-QoL scores.

The pattern of improvement, with the largest gains in psychological and everyday-life domains, is also plausible in light of the broader DFU literature, which shows that emotional distress, dependence, and disruption of daily activities contribute substantially to burden.[5,29–32]

The PBI-W result complements the Wound-QoL signal by indicating that participants perceived greater treatment benefit at the end of follow-up. Because the PBI-W is goal based and patient defined, it helps capture dimensions of treatment benefit that may not be fully represented by anatomical healing alone.[22] However, the clinical interpretability of the change in PBI-W is less well established than for Wound-QoL, and with the nominal p-value (0.04) for the absolute change between baseline and final visit, the observed improvement should therefore be interpreted cautiously. Nevertheless, the PBI-W and Wound-QoL findings together support the view that objective healing and patient-centered outcomes can be considered complementary measures of benefit in DFU care.[29,32]

The clinical results are directionally consistent with the rationale for SAP dressings and with the broader wound-dressing literature. Superabsorbent dressings are intended to retain exudate, protect the peri-wound skin, and reduce leakage and dressing burden.[12,13] Observational evidence in chronic wound populations has suggested favorable effects on exudate handling, pain, and wound-related QoL with superabsorbent dressings or other high-absorbency technologies.[19,20,33] However, systematic review indicates that comparative and economic evidence remains limited and often of low certainty.[12] The 22.2% complete epithelialization rate at 6 weeks should be interpreted in the context of established prognostic factors for diabetic foot ulcer healing. A meta-analysis[34] showed that wound duration is one of the independent predictors of delayed closure. Although the ulcers in this study were superficial, noninfected, adequately-perfused, and optimally offloaded, the median baseline wound duration of 166 days indicates a predominantly chronic population. Given the negative impact of chronicity on early healing, the observed 6-week epithelialization rate appears to be consistent with expected healing trajectories. In broader DFU populations, particularly those with infection or ischemia, healing rates are typically lower, which may limit comparability. In that context, the present prospective PROM-inclusive dataset is useful, even though it does not resolve comparative effectiveness.

The supportive findings on physical activity and offloading adherence also deserve attention. Activity intensity remained stable, with modest increases in activity volume and sit-to-stand transitions, suggesting that functional status was at least preserved during treatment. This matters because offloading can create trade-offs between wound healing and day-to-day mobility or convenience.[35] At the same time, the very high offloading adherence observed here likely contributed substantially to the favorable healing trajectory, which is consistent with evidence and guideline recommendations that effective offloading is central to healing neuropathic DFUs.[14,15,36] Given that effective offloading is one of the strongest determinants of DFU healing, the near-complete adherence observed in this study may represent a major driver of outcomes, and the independent contribution of the dressing intervention cannot be disentangled.

Strong perceived social support may have contributed to adherence and engagement with care, which could have influenced outcomes. The uniformly high MSPSS scores suggest that many participants had access to family or partner support that may have facilitated adherence to offloading, clinic attendance, and wound care routines. This psychosocial context is important because QoL in DFU is shaped not only by wound severity but also by anxiety, depression, self-care capacity, and social resources.[27,31]

Several limitations should be considered. First, this was a single-arm, nonrandomized cohort, and the present manuscript reports the DFU cohort from a broader parent study; the study design precludes causal inference and prevents attribution of observed effects specifically to the study dressings. Second, the sample size was small and the analyses were exploratory. Third, the cohort was relatively selected, with ulcers that were superficial, noninfected, and mostly nonischemic ulcers, which may not reflect the broader DFU population encountered in routine clinical practice. Fourth, follow-up was limited to 6 weeks, capturing only short-term wound healing trajectories and early patient-reported outcomes, and precluding conclusions about recurrence, durability of HRQoL improvement, or longer-term resource use. Additionally, the exceptionally high adherence to offloading observed in this study may not be reproducible in less controlled settings and likely influenced outcomes. Fifth, MSPSS scores were uniformly high across the cohort, suggesting a selection effect whereby patients with strong support networks may be more likely to attend specialist centers, adhere to treatment recommendations, and complete study procedures. Taken together, these factors may limit generalizability to broader DFU populations characterized by lower adherence, reduced social support, and greater clinical complexity. Sixth, the accelerometer-derived sleep metrics should be interpreted with caution. The low median sleep duration and sleep efficiency observed may reflect, at least in part, measurement characteristics of wrist-worn devices and algorithm-based sleep classification in a population with limited mobility. However, substantial sleep

fragmentation is also common in patients with diabetic foot ulcers, and the findings may therefore represent a combination of measurement effects and true sleep disturbance. Accordingly, these results are presented descriptively and should not be interpreted as definitive measures of sleep quality.

Seventh, missing data handling relied on pre-specified LOCF and interpolation approaches without sensitivity analyses, which may influence the robustness of the findings. Eighth, no direct cost, dressing utilization, or formal healthcare resource-use endpoints were collected, which limits economic interpretation despite the relevance of the findings for future studies. Finally, because dressing allocation followed clinical judgment, no between-product comparison should be inferred. The parent study recorded protocol deviations, but these were predominantly operational and were not considered to undermine subject safety or overall interpretability. Further information can be found in the Supplementary Material.

Even with these limitations, the study provides practical insights into the feasibility of integrating wound-specific PROMs into DFU research. The findings suggest that a concise set of wound-specific PROMs can be implemented in a multicenter DFU cohort and can generate interpretable results alongside conventional healing outcomes. Future comparative studies should align with the DFU core outcome set and extend this framework by prospectively collecting dressing-change frequency, clinic contacts, caregiver burden, and cost data so that the clinical and economic value of SAP dressings can be assessed more directly.

Conclusion

In adults with diabetic foot ulcers treated in routine specialist care, silicone superabsorbent polymer dressings were associated with clinically meaningful wound improvement, significant gains in wound-related quality of life, and better patient-perceived treatment benefit over 6 weeks. The study reinforces the importance of integrating PROMs with wound healing outcomes in DFU research and highlights the need for future comparative studies that also incorporate resource-use and cost endpoints.

Abbreviations

DFU, diabetic foot ulcer; HRQoL, health-related quality of life; ITT, intention-to-treat; IQR, interquartile range; MET, metabolic equivalent; MSPSS, Multidimensional Scale of Perceived Social Support; MVPA, moderate-to-vigorous physical activity; PBI-W, Patient Benefit Index for wounds; PEDIS, perfusion, extent/size, depth/tissue loss, infection, and sensation; PROM, patient-reported outcome measure; SAP, superabsorbent polymer; SD, standard deviation; Wound-QoL, Wound Quality of Life questionnaire.

Data Sharing Statement

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request. Data will be shared in a form that protects participant confidentiality and complies with applicable data protection requirements.

Ethics Approval and Informed Consent

The study protocol, informed consent form, case report forms, insurance conditions, and related study documents were approved by the Independent Ethics Committee of the Lower Silesian Medical Chamber in Wroclaw (Komisja Bioetyczna przy Dolnośląskiej Izbie Lekarskiej we Wrocławiu) on May 8, 2024 (approval No. 03/05/2024). All participants provided written informed consent before the initiation of study-specific procedures. The study was conducted in accordance with the Declaration of Helsinki and applicable local requirements.

Consent for Publication

Not applicable. The manuscript does not contain identifiable individual participant data or images.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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