Effectiveness of silicone superabsorbent polymer dressings for chronic wound management: a prospective single-arm clinical study

Objective: This study evaluated the effectiveness of silicone superabsorbent polymer (SAP) dressings in patients with venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs), with emphasis on wound area reduction (WAR) and improvement in wound bed characteristics over a six-week observation period.

Method: This prospective, single-arm study evaluated two silicone SAP dressings—RespoSorb Silicone Border (RSSB; also marketed as Zetuvit Plus Silicone Border) and RespoSorb Silicone (RSSil; also marketed as Zetuvit Plus Silicone) (both PAUL HARTMANN AG, Germany)—in patients with exuding VLUs or DFUs across eight clinical sites in Poland. The primary endpoint was relative WAR, measured using centralised digital planimetry, with ≥20% WAR defined as clinically meaningful. Secondary endpoints included: complete re-epithelialisation; changes in granulation and slough tissue composition; exudate management; periwound skin condition; dressing wear time; and safety.

Results: A total of 80 patients took part in this study. Participants were predominantly male (62.5%) with a mean age of 67.1 years; 53 received RSSB and 27 received RSSil. At the final visit, ≥20% WAR was achieved in 59/79 (74.7%) patients before cleansing/debridement and in 66/79 (83.5%) after cleansing/debridement ($p<0.001$ for superiority) (one baseline image for both before and after cleansing/debridement was missing and unavailable for planimetry assessment). The median relative WAR was 69.6% (interquartile range (IQR): 28.9–100%) following cleansing/debridement. The median granulation tissue coverage decreased by 75.2% (IQR: 24.3–100%) and slough coverage decreased by 98.6% (IQR: 46.7–100%) after cleansing/debridement, while median exudate volume reduced by 0.38ml (IQR: −0.1–1.75ml) from baseline (all $p<0.001$). Complete re-epithelialisation occurred in 21/80 (26.9%) patients. Median dressing wear time was four days (IQR: 3–6 days) over all six follow-up visits.

Conclusion: In this study, the two silicone SAP dressings used demonstrated clinically meaningful improvement in wound outcomes in chronic VLUs and DFUs, with most patients achieving ≥20% WAR alongside effective exudate management and improved wound bed quality.

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Chronic lower-extremity ulcers, particularly venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs), represent a persistent therapeutic challenge in everyday clinical practice. VLUs are among the most common chronic wounds and have been reported to affect approximately 0.3–1.0% of the general population, with higher prevalence in older adults and those with chronic venous insufficiency.[1] Such ulcers account for 60–80% of all lower-limb ulcerations and exhibit slow healing kinetics, with an average of only ~60% healing by 12 weeks and high recurrence rates of 50–76% after closure, with risk increasing with advanced age, obesity, hypertension and diabetes.[2] The '2025 SCAI [Society for

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Cardiovascular Angiography & Interventions] Clinical Practice Guidelines for the Management of Chronic Venous Disease'[3] highlight the substantial clinical burden of chronic venous disease and emphasise compression therapy as a strong recommendation for patients with VLUs, supporting its central role in achieving wound stability and promoting healing.[3]

Similarly, DFUs contribute a significant global burden, affecting an estimated 18.6 million people annually, largely among individuals with chronic diabetes.[4] The lifetime risk of developing a foot ulcer among patients with diabetes is substantial, estimated at 19–34%, and DFUs are a leading cause of lower-extremity amputation, accounting for up to 80% of diabetes-related amputations.[4,5] Following healing, DFU recurrence is common, with ~40% recurring within one year and up to 65% recurring within five years.[4] The 2023 International Working Group on the Diabetic Foot (IWGDF) and Infectious Diseases Society of America guidelines[6] emphasise early infection identification, debridement, offloading, and appropriate wound dressings as integral components of DFU care. The 2023 IWGDF global guidelines[7] further highlight the importance of selecting dressings that maintain moisture balance, manage exudate effectively, and protect the periwound skin to support optimal healing trajectories.

A key factor influencing VLU/DFU healing is wound exudate, the biological characteristics and clinical impact of which differ substantially between acute and chronic wounds. Compared with acute wound fluid, chronic wound exudate exhibits markedly elevated protease activity, including matrix metalloproteinases, human neutrophil elastase and polymorphonuclear elastase, along with increased levels of proinflammatory mediators, and reduced concentrations of growth factors and protease inhibitors. Mechanistically, sustained protease activity degrades essential extracellular matrix components, inactivates growth factors and their receptors, and maintains a proinflammatory milieu that disrupts granulation and re-epithelialisation, ultimately impairing wound repair.[8] Exudate control also serves as a marker of wound stabilisation, and objective assessment of exudate retention offers an additional perspective on dressing performance rarely captured in clinical studies.[9]

Building on this pathophysiological context, chronic VLU and DFU exudate not only impairs tissue repair but also contributes directly to prolonged healing trajectories, reduced patient quality of life (QoL), and substantial healthcare and economic burden.[10,11] As dysregulated, protease-rich exudate drives extracellular matrix degradation and perpetuates inflammation, effective local wound care becomes essential to counteracting these mechanisms. Clinically, this requires maintaining a controlled, moist wound environment while preventing periwound maceration. Excessive exudate can further amplify protease activity, promote tissue breakdown and increase susceptibility to bacterial colonisation, making high absorbency dressings with an atraumatic wound interface essential in chronic wound management.[12] Thus, the clinical need extends beyond simple fluid absorption to technologies capable of selectively sequestering the protease-rich exudate that characterises chronic VLUs and DFUs, while preserving a stable moist environment.

Within this therapeutic landscape, silicone superabsorbent polymer (SAP) dressings have garnered growing attention. Their design integrates a gentle silicone contact layer with a highly absorbent SAP core capable of sequestering large volumes of fluid, including protease-rich exudate, thereby helping to mitigate the biochemical drivers of chronic wound pathology. The silicone interface minimises trauma during dressing changes and protects fragile periwound tissue, while the SAP core supports effective exudate management and contributes to restoring a more physiologically balanced wound environment.[13,14] In practice, these attributes may reduce dressing change frequency, improve patient comfort and support more consistent progression toward healing. Despite their increasing adoption, however, prospective real-world evidence evaluating their clinical performance remains limited.[15,16]

This present study investigated two silicone SAP dressings—RespoSorb Silicone Border (RSSB; also marketed as Zetuvit Plus Silicone Border) and RespoSorb Silicone (RSSil; also marketed as Zetuvit Plus Silicone) (both manufactured by PAUL HARTMANN AG, Germany)—to evaluate their clinical effectiveness and safety in the management of exuding VLUs and DFUs.

In this manuscript, the results of the primary endpoint of relative wound area reduction (WAR) over time as well as secondary endpoints (such as wound healing, changes in granulation and slough tissues, exudate retention, frequency of dressing changes and wear time, improvement of periwound skin conditions over time and safety) are presented. Additional outcome results will be shared in subsequent publications.

Methods

Study design and intervention

This investigation was a prospective, non-randomised, single-arm, multicentre, clinical study conducted in accordance with International Organisation for

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Standardization (ISO) 14155. The design, conduct, analysis and reporting of the study followed the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) guidelines to ensure transparency and completeness of reporting.[14]

Patients were recruited between July 2024 and July 2025 and followed for up to six weeks, or until complete healing, withdrawal or discontinuation of dressing use if no longer clinically indicated. The study aimed to evaluate real world clinical performance and safety of SAP dressings under standard of care conditions. Random allocation and blinding of investigators or patients were not feasible given the observable product characteristics and the need to tailor dressing selection to wound characteristics.

Ethical approval and patient consent

The study, including all associated documents and procedures, received ethical approval from the Ethics Committee at the Lower Silesian Chamber of Physicians, Poland (approval no.: 03/05/2024; 8 May 2024), and all participants provided written informed consent prior to any study procedures.

Recruitment and setting

The study was conducted at eight wound care centres in Poland, each specialising in the management of chronic lower extremity ulcers. Recruitment followed a consecutive sampling strategy, whereby all eligible patients presenting at participating study sites during the enrolment period were screened for inclusion. Investigators identified candidates, confirmed eligibility, obtained written informed consent, and enrolled participants until the target sample size was reached. All study visits occurred at participating sites. For each participant, one target ulcer was selected based on clinical relevance and suitability for standardised measurement.

Participants

This prospective investigation enrolled adult patients (≥18 years) with a diagnosis of a single, chronic, exuding lower-extremity ulcer located on one limb, classified as either a VLU or DFU. Eligible ulcers had been present for 1–12 months prior to screening, were non-infected at inclusion, and extended through the full thickness of the skin without exposure of muscle, tendon or bone. Ulcer size was limited to ≤10cm for the longest dimension to allow standardised photographic documentation and digital planimetry. To ensure suitability for conservative wound management, vascular status was verified using ankle–brachial pressure index (ABPI) (normal range: 0.8–1.2); in cases where ABPI was >1.2, the toe–brachial pressure index (TBPI) was assessed and was required to be >0.6. Patients with VLUs were required to tolerate and comply with compression therapy, while patients with DFUs were required to use appropriate offloading devices throughout the study.

The exclusion criteria were: hypersensitivity to study product components; ischaemic DFUs; >2 full-thickness ulcers on one limb or >3 in total; recurrent ulcers; hypertensive leg ulcers; New York Heart Association class IV (severe) heart failure; severe deep vein thrombosis or contraindications to compression; clinical infection requiring antimicrobial therapy; significant ischaemia; clinically significant intermittent claudication; osteomyelitis; uncontrolled oedema; uncontrolled diabetes (glycated haemoglobin (HbA1c) ≥8.6%); severe malnutrition (albumin <3.5g/dl); severe obesity (body mass index (BMI) >40kg/m^2); immunosuppressive therapy; recent use of topical steroids, hyperbaric oxygen therapy or bioengineered tissue products; malignant wounds; pregnancy, breastfeeding, female patients of childbearing age not using contraception; and conditions preventing reliable wound assessment.

Patient involvement

Patients were not involved in the design or conduct of this study, nor in the selection of outcomes or interpretation of results. Patient involvement was limited to study participation following informed consent, including feedback on dressing comfort and usability collected during routine clinical assessments. The study results will be disseminated through scientific publication.

Investigational medical device

This study evaluated two SAP dressings for the management of exuding VLUs and DFUs: RSSB and RSSil. Both are CE-marked class IIa medical devices for the management of exuding acute and chronic wounds, and were used according to their intended purpose. The dressings have a multilayer design optimised for exudate control and periwound protection, including: a perforated silicone contact layer for atraumatic removal; a hydrophilic distribution layer for fluid dispersion; a cellulose/SAP absorbent core for high exudate retention; and a breathable backing layer that allows gas exchange while preventing contamination. RSSB additionally incorporates an adhesive polyurethane backing film that allows fixation of the dressing without the need for secondary materials and provides shower-proof protection. In contrast, RSSil requires secondary fixation according to routine clinical practice.[17,18] The dressing sizes used in the study were as follows:

- RSSB: 8×8cm; 10×10cm; 12.5×12.5cm; 17.5×17.5cm; and 13×15.5cm
- RSSil: 8×8cm; 12.5×12.5cm; and 10×20cm.

Assignment method and allocation constraints

No randomisation or comparator was included. Participants were allocated to receive one of the two dressings based on investigator clinical judgement and predefined feasibility targets. Dressing assignment (RSSB versus RSSil) to participants was determined by investigator judgement based on wound characteristics

and typical clinical practice, ensuring that dressing selection aligned with real-world clinical decision-making. The recruitment plan prospectively required that each cohort included ≥35% VLUs and ≥35% DFUs.

To mitigate bias inherent in a non-randomised design, several prospectively defined safeguards were implemented:

- Strict eligibility criteria
- Standardised co-interventions, including mandatory compression therapy for VLUs and defined offloading for DFUs
- Standardised photography procedures at each visit
- Centralised, blinded digital planimetry for wound area and tissue composition measurements
- Prespecified endpoints and statistical analysis plan, finalised prior to database lock (the point at which no further data modifications were possible and the analysis could begin)
- Harmonised site procedures through investigator training, ensuring consistent wound assessment, dressing weight measurement, and electronic case report form (eCRF) documentation.

Study procedures and visit schedule

Screening and enrolment (visit 1)

Potentially eligible patients with VLUs or DFUs were approached during routine care and informed about participation. After voluntary consent, site staff recorded patients': demographics; medical history; smoking and alcohol consumption; concomitant medications; ABPI or TBPI, prior wound treatments and full wound characterisation. Standardised wound photographs were obtained before and after cleansing/debridement by trained study personnel. The assigned investigational dressing (RSSB or RSSil) was applied after cleansing/debridement by trained physicians/nurses, and its pre-application weight was recorded in the eCRFs using the sponsor-provided calibrated scale. All patients with a VLU received standardised compression therapy (PütterPro 2 or Lite; PAUL HARTMANN AG, Germany), and all patients with a DFU used appropriate offloading devices. Patient diaries were issued with instructions to record dressing changes and compression/offloading reapplication between visits. Patient-reported outcomes (PROs), such as the Patient Benefit Index (which measures patient-relevant treatment goals and the degree to which therapy helps achieve those goals)[19] and Wound-QoL[20]) were collected during enrolment. A Social Support Questionnaire (which measures the perceived number of social supports and the satisfaction with available social support)[21] was collected once during the study, the results of which will be presented in a subsequent publication.

Scheduled visits: visits 2–7

Clinical assessments were performed weekly. At each visit, the patient diary was reviewed and used/unused dressings were reconciled. Adverse events (AEs) were recorded in the eCRF.

A dressing change was performed at each visit, with pre- and post-use dressing weights documented. The wound and periwound skin were assessed, compression or offloading were reapplied, and standardised photographs were taken before and after cleansing/debridement. All procedures were documented in the eCRF.

Unscheduled visits

Unscheduled visits occurred when an interim dressing change or compression reapplication was clinically required. For patients with a DFU, dressing changes could occur at home, if appropriate. At unscheduled visits, relevant procedures (dressing weights, exudate assessment, AE recording, compression/offloading) were documented in the eCRF.

End of study visit: visit 7 or earlier

The final study visit occurred at week 6 or earlier, for example, if complete healing occurred, or patient withdrawal or discontinuation of dressing use if no longer clinically indicated. All assessments performed during scheduled visits were repeated, and PROs (Patient Benefit Index, Wound-QoL) were readministered.

Study objectives and endpoints

Primary objective and endpoints

The primary objective was to evaluate the clinical effectiveness of silicone SAP dressings in the treatment of chronic VLUs and DFUs using objective wound area measurements obtained before and after cleansing/debridement, and assessed by centralised digital planimetry. The primary endpoint was the WAR from baseline to the final visit with a predefined threshold of ≥20% relative WAR considered clinically significant. To assess this, the proportion of patients meeting this predefined threshold (P(success)) was first tested for superiority against 22.5% evaluating the hypotheses (H): H_0: P(success) ≤22.5% versus H_1: P(success) >22.5%. If superiority was demonstrated, the study proceeded to test non-inferiority against 50.0%, with a non-inferiority margin of 7.56% (α=0.05), corresponding to the hypotheses: H_0: P(success)–50.0% <–7.56% versus H_1: P(success)–50.0% ≥–7.56%.

Early WAR has been consistently shown to be predictive of subsequent healing in chronic ulcers, with a continuous relationship between percentage area reduction and probability of closure rather than a single universal cut-off.[22] In the context of a six-week clinical study, a ≥20% reduction threshold was therefore selected as a clinically meaningful indicator of early healing trajectory.

Secondary objective and endpoints

The secondary endpoints assessed were: complete wound healing; changes in granulation tissue and slough tissue; exudate retention; frequency of dressing changes and wear time; improvement of periwound skin conditions over time; and safety. Complete re-epithelialisation at the final visit (week 6) was

reported as the proportion of patients achieving complete wound healing (wound area=0). The percentage changes in the granulation and slough tissue were categorised as: none; 1–24%; 25–49%; 50–74%; and 75–100% from baseline (visit 1) to final visit (visit 7), with assessments recorded both before and after cleansing/debridement. Changes in the exudate volume per dressing and daily exudate volume adjusted for wear time as well as changes in exudate amount from baseline to final visit were reported. Changes in periwound skin condition from baseline to the final visit were also reported. Practical usability outcomes included dressing change frequency and wear time, while safety endpoints comprised device-related AEs and device deficiencies.

Secondary objectives were to evaluate the potential effectiveness of silicone SAP dressings in terms of improvement of the wound and periwound area conditions.

Outcome measurement procedures

Digital wound images obtained before and after cleansing/ debridement at each visit were analysed by centralised digital planimetry (PictZar Digital Planimetry, US) for blinded measurement of wound area and wound tissue composition, including granulation and slough coverage. Digital planimetry is a validated method for wound measurement and has demonstrated high accuracy and reproducibility compared with contact- and ruler-based techniques, particularly for chronic ulcers.[23]

Periwound skin condition was assessed weekly using predefined clinical categories recorded by investigators, through visual inspection, as: 'healthy'; 'dry'; 'irritated'; 'macerated'; 'hyperhydrated'; 'eczematous'; 'squamous'; 'inflamed'; and 'erythema/redness'.

Objective assessment of exudate management was performed by weighing each dressing prior to application (m1) and again after removal (m2) during each study visit using a calibrated laboratory scale supplied to each site by the sponsor. The retained exudate volume (V) was calculated automatically as (m2–m1)/1.03, assuming an exudate density of 1.03g/ml, and expressed as daily exudate retention by dividing V by the recorded wearing time (days).[24] This density assumption is consistent with published biochemical analyses of wound exudate and serous fluid composition, which report densities slightly above water due to protein and electrolyte content.[25]

Sample size

The planned sample size was at least 80 evaluable patients, providing 80% power to demonstrate superiority over the predefined benchmark of 22.5%, assuming that approximately 70% of patients would achieve the prespecified endpoint (>20% ulcer size reduction at week 6 or last visit), using a one-sided test with $\alpha<0.05$. Participants were allocated into two dressing groups:

- 27 patients to the RSSil dressing group
- 53 patients to the RSSB dressing group.

To ensure adequate representation of clinically relevant wound aetiologies, eachdressing group was required to include a minimum of 35% participants presenting with either a VLU or DFU. This requirement was incorporated prospectively into the recruitment plan.

Statistical analysis

All statistical analyses were primarily performed in the intention-to-treat (ITT) population, defined as all eligible patients who had at least one investigational dressing applied and for whom at least one post-baseline (visit 1) assessment was available.

Clinical effectiveness of RSSB and RSSil was assessed as the proportion of patients achieving a ≥20% relative WAR. Superiority >22.5% was tested using a one-sided one-sample proportion test ($\alpha=0.05$). If superiority was confirmed, a subsequent non-inferiority analysis versus a 50% reference rate was performed, applying a non-inferiority margin of 7.56% and a one-sided test at $\alpha=0.05$. Additional analyses were primarily descriptive, aimed at characterising healing dynamics and overall dressing performance. Subgroup analyses by dressing group (RSSB and RSSil) were pre-specified in the statistical analysis plan and conducted as descriptive supportive analyses. No formal between-groups statistical comparisons were performed.

Continuous variables were summarised using mean±standard deviation, median and interquartile range (IQR); categorical variables as counts and percentages. Within-patient changes over time were assessed using paired Student's t-test or Wilcoxon signed-rank test, depending on distribution, and the McNemar test for categorical data. Normality was evaluated with the Shapiro–Wilk test, and a two-sided $p<0.05$ was considered significant. No multiplicity adjustments were applied due to the exploratory nature of the analyses.

For wounds that healed completely, missing values at subsequent visits were imputed as 0 for continuous variables and using last observation carried forward (LOCF) for categorical variables. For participants who discontinued for reasons other than healing, missing scheduled visit data for these variables were also imputed using LOCF. For intermittent missing data during follow-up (i.e., before healing or discontinuation), continuous variables were imputed using linear interpolation, while categorical and count variables were imputed using LOCF.

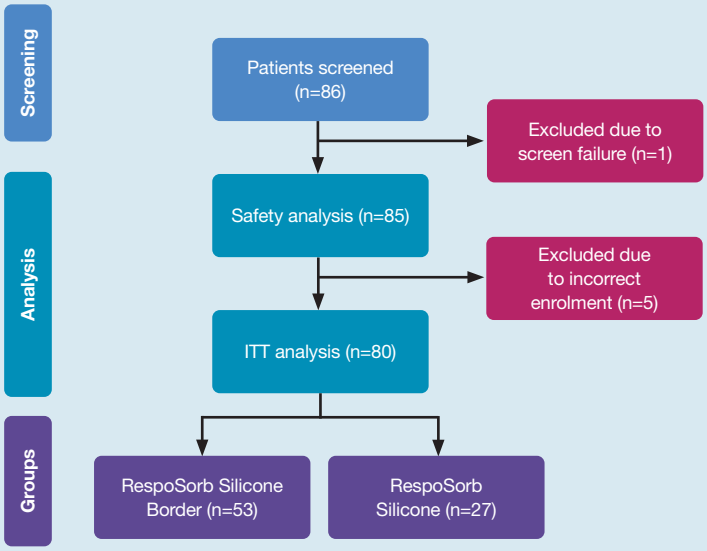
All statistical analyses were performed using R version 4.1.3 (R Foundation for Statistical Computing, Austria) or later.

Results

Study population

Of 86 screened patients, 85 were included in the safety population with one patient excluded due to screening failure (not meeting the eligibility criteria), and 80 patients were included in the ITT population, with five patients excluded due to incorrect enrolment. In all, 69 (81.2%) patients completed the study. The ITT group comprised 53 patients treated with RSSB and 27 with

Fig 1. Study flowchart. ITT—intention-to-treat. RespoSorb Silicone Border and RespoSorb Silicone are both manufactured by PAUL HARTMANN AG, Germany



RSSil (Fig 1). Participants were predominantly male (62.5%), with a mean age of 67.1±13 years and a BMI of 30.1±5.33kg/m². At baseline, 65% of patients had a VLU and 35% had a DFU, with a mean wound duration of 181 days and adequate perfusion (mean ABPI: 1.02), reflecting a typical chronic wound population (Table 1).

Wounds were almost evenly distributed between the left (52.5%) and right (47.5%) limbs, most commonly located on the calf (40.0%), followed by the foot (36.3%) and ankle (23.8%). Prior to inclusion, many patients had received various wound treatments, most frequently antibacterial dressings (50.0%), systemic agents (46.3%), compression therapy (63.8%), as well as gauze and foam dressings (each 27.5%) (Table 1).

During the study, wounds were managed primarily with the assigned investigational dressings selected according to ulcer size. Secondary dressing was rarely required (2/80 (2.5%) patients only at first visit), and routine wound rinsing was performed in nearly all cases (>95%). Adjunctive measures were common and reflected standard care, including fixation products in ~25.0% of cases, compression therapy in 60.0–65.0% of patients (mainly PütterPro 2), and offloading devices in ~35.0%.

Primary endpoint – WAR

Of the 80 patients included in the ITT population, wound area outcomes were analysed for 79 patients; this was due to one baseline image before cleansing/debridement and one baseline image after cleansing/debridement in one patient being absent and so unavailable for planimetry assessment.

The primary endpoint of achieving a ≥20% reduction in wound area from baseline to the final study visit was met by a substantial proportion of patients. When wound area was assessed before cleansing/debridement, the endpoint was met by 59/79 (74.7%) patients (with a two-sided 90% confidence interval (CI): 65.4, 82.5%). Corresponding rates were 71.7% (38/53; 90% CI: 59.8, 81.7%) in the RSSB group and 80.8% (21/26; 90% CI: 63.7, 92.1%) in the RSSil group. All results were statistically significant both for superiority versus the predefined reference value of 22.5% and for non-inferiority versus 50.0% (all p-values <0.001).

When wound area was assessed after cleansing/debridement, the proportion of patients achieving >20% WAR increased to 66/79 (83.5%) patients overall (90% CI: 75.1, 90.0%). The corresponding proportions were 82.7% (43/52; 90% CI: 71.7, 90.7%) in the RSSB group and 85.2% (23/27; 90% CI: 69.2, 94.8%) in the RSSil group. Again, results were statistically significant for both superiority and non-inferiority analyses in all populations (all p-values <0.001).

Wound area progressively decreased from baseline to final visit in both groups. At visit 2, median relative WAR values were modest (before debridement: 17.4% (IQR: –2.39–34.83); after debridement: 18.99% (IQR: 0.00–33.59)); however, by visit 7, the median relative WAR had reached 68.94% (IQR: 18.54–97.31) before debridement and 69.58% (IQR: 28.93–100.0) after debridement. This improvement was observed consistently in both groups (RSSB and RSSil) (Table 2).

Before cleansing/debridement, mean wound area in the overall population decreased from 5.4cm² at visit 1 to 3.0cm² at visit 7 (median reduction from visit 1 to visit 7: 2.2cm² to 0.4cm²), with similar trends in both treatment groups (Fig 2). Significant reductions from baseline were observed in the overall study population, beginning at visit 2 and continuing through to visit 7 (all p<0.001). In the RSSB group, mean area declined from 4.3cm² to 2.7cm², and in the RSSil group from 7.7cm² to 3.5cm² at final visit (p<0.001 for both groups), with median values falling below 1cm² by visits 6–7. After cleansing/debridement, comparable reductions were observed, with mean wound area decreasing from 5.5cm² at visit 1 to 2.8cm² at visit 7 in the overall study population (median reduction from visit 1 to visit 7: 2.4cm² to 0.5cm²) with significant reductions across all visits in the overall population (p<0.001). Consistent reductions in mean wound area were observed from baseline to final visit in both the RSSB (4.3cm² to 2.5cm²) and RSSil (7.7cm² to 3.4 cm²) groups (p<0.001) (Fig 2).

Secondary endpoints

Complete wound healing

By the final visit (visit 7), complete re-epithelialisation was documented in 21/80 (26.3%) patients. This included 12/53 (22.6%) patients treated with RSSB and 9/27 (33.3%) patients treated with RSSil. These findings indicate that >25.0% of patients with chronic ulcers achieved full re-epithelialisation within the six-week observation period.

Granulation tissue coverage

Evaluation of wound bed composition demonstrated consistent biological progression of healing throughout

Table 1. Baseline characteristics of the study population

Demographics	Overall (n=80)*	RSSB (n=53)*	RSSil (n=27)*
Male, n (%)	50 (62.5)	30 (56.6)	20 (74.1)
Age, years, mean±SD	67.1±13.0	65.8±13.3	69.6±12.1
BMI, kg/m², mean±SD	30.12±5.33	30.04±5.35	30.28±5.39
Target ulcer, n (%)			
VLU	52 (65.0)	34 (64.2)	18 (66.7)
DFU	28 (35.0)	19 (35.8)	9 (33.3)
ABPI, mean±SD	1.02±0.13	1.01±0.13	1.04±0.14
Wound duration, days, median (IQR)	173.5 (98.0–274.0)	180.0 (100.0–278.0)	156.0 (74.0–269.0)
Wound localisation limb, n (%)			
Left	42 (52.5)	23 (43.4)	19 (70.4)
Right	38 (47.5)	30 (56.6)	8 (29.6)
Wound localisation, n (%)			
Calf	32 (40.0)	19 (35.8)	13 (48.1)
Foot	29 (36.3)	20 (37.7)	9 (33.3)
Ankle	19 (23.8)	14 (26.4)	5 (18.5)
Previous wound treatment, n (%)			
Systemic agents	37 (46.3)	22 (41.5)	15 (55.6)
Topical agents	13 (16.3)	11 (20.8)	2 (7.4)
Gauze	22 (27.5)	16 (30.2)	6 (22.2)
Hydrocolloid dressings	2 (2.5)	0 (0.0)	2 (7.4)
Transparent film dressings	0 (0.0)	0 (0.0)	0 (0.0)
Gel dressings	0 (0.0)	0 (0.0)	0 (0.0)
Collagen dressings	0 (0.0)	0 (0.0)	0 (0.0)
Foam dressings	22 (27.5)	19 (35.8)	3 (11.1)
Silicone dressings	5 (6.3)	3 (5.7)	2 (7.4)
Alginate dressings	3 (3.8)	0 (0.0)	3 (11.1)
Antibacterial dressings	40 (50.0)	22 (41.5)	18 (66.7)
Negative pressure wound therapy	0 (0.0)	0 (0.0)	0 (0.0)
Accompanying measures (compression therapy)	51 (63.8)	33 (62.3)	18 (66.7)

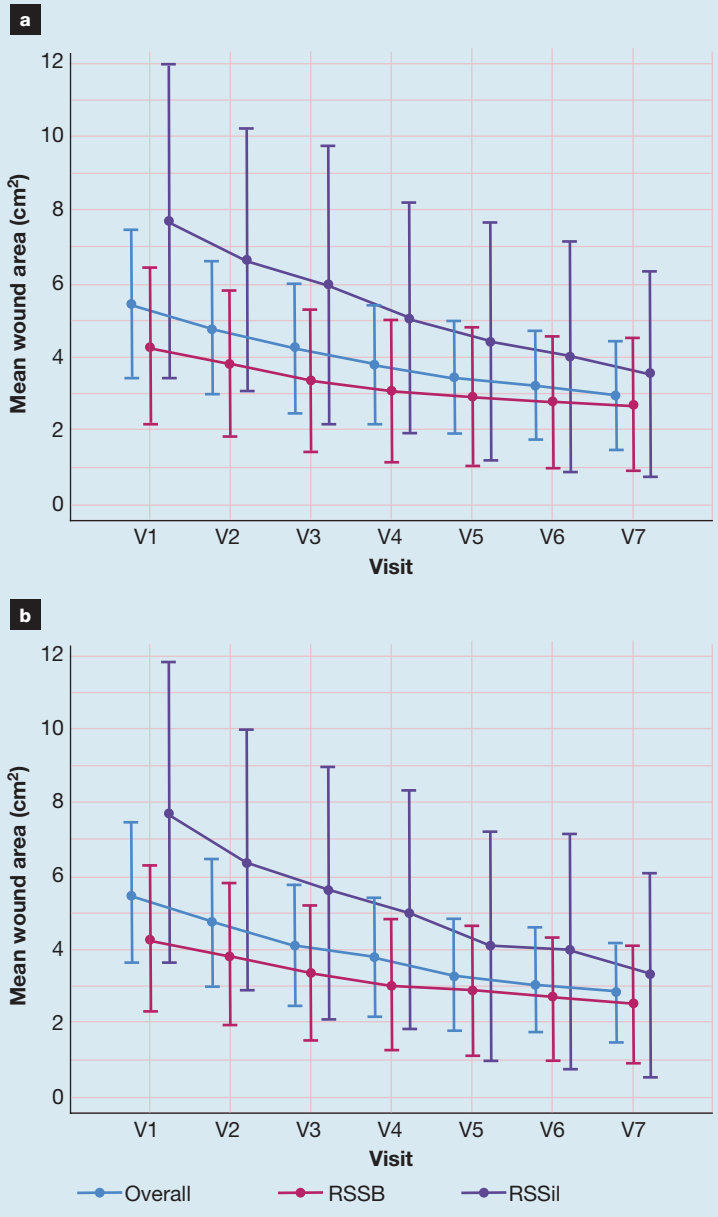
*Percentage calculated using a number of non-missing records in intention-to-treat population overall/in study arm as denominator. ABPI—ankle–brachial pressure index; BMI—body mass index; DFU—diabetic foot ulcer; IQR—interquartile range; RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany); SD—standard deviation; VLU—venous leg ulcer

the study. At visits 2 and 3, the relative change in granulation tissue coverage from baseline showed a mixed pattern. Although the mean values suggested overall increases in granulation tissue (visit 2: +21.7%; visit 3: +9.7%), the medians indicated decreases (visit 2: −32.0% (IQR: −64.5–40.7%); visit 3: −37.0% (IQR: −79.1–21.0%), with wide ranges indicating that a subset of patients experienced increases in granulation during the early follow-up period. From visit 4 onward, both the mean and median relative reductions in granulation tissue increased progressively.

By visit 7 (before cleansing/debridement), the median relative reduction in granulation tissue coverage from baseline was 85.6% overall (70.0% in RSSB and 97.2% in RSSil). More than half of patients (54.4%) demonstrated a 75.0–100.0% decrease in granulation coverage, with a higher proportion in the RSSil group (69.6%) compared with the RSSB group (46.7%). After cleansing/

debridement, the median reduction remained substantial at 75.2% overall (66.5% RSSB; 85.2% RSSil), with approximately half of patients (50.6%) showing a 75.0–100.0% decrease (Table 3). Overall, granulation tissue coverage at visit 7 was markedly reduced compared with baseline in both treatment groups. This progressive reduction in granulation tissue coverage towards later visits suggests advancement of the healing process beyond the proliferative phase, with transition toward re-epithelialisation and wound contraction. The observed pattern indicated continued wound bed maturation and progression towards closure during treatment.

Fig 2. Mean trend of wound area reduction (with 95% confidence interval) in the intention-to-treat population, before cleansing/debridement **(a)**, and after cleansing/debridement **(b)**. RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany)



Slough tissue reduction

Clear and progressive reductions in slough tissue coverage were observed from baseline, beginning at visit 2. At visit 7 (before cleansing/debridement), a marked reduction in slough tissue coverage from baseline was observed, with a median decrease of 87.0% overall (74.4% RSSB; 100.0% RSSil). The majority of patients (60.7%) demonstrated a 75.0–100.0% reduction in slough coverage, particularly in the RSSil group (78.3%). After cleansing/debridement, the reduction was even more pronounced, with a median decrease of 98.6% overall (96.3% RSSB; 100% RSSil), and approximately two-thirds of patients (67.9%) achieving a 75.0–100.0% reduction. These findings indicate substantial removal of non-viable tissue and progression towards a cleaner wound bed by study completion (Table 3).

Exudate volume reduction

Objective assessment of exudate management showed a time-dependent reduction in both daily exudate retention volume and total exudate volume compared with baseline. By the final visit, the median reduction in daily exudate retention volume from baseline was 0.09ml (IQR: −0.03–0.43ml) (p=0.004) and the median reduction in exudate volume from baseline was 0.38ml (IQR: −0.10–1.75ml) (p<0.001), with statistically significant reductions observed from visit 5, reflecting improved control of wound exudation during the course of treatment. In the RSSB group, the final visit median daily exudate retention volume from baseline was 0.09ml (IQR: 0.00–0.43ml) (p=0.002) whereas the median total exudate volume reduction was 0.29ml (IQR: −0.10–1.75ml) (p=0.005). In the RSSil group, the final visit median daily exudate retention volume was 0.07ml (IQR: −0.32–0.30ml) (p=0.442), whereas the median total exudate volume reduction was 0.54ml (IQR: −0.20–2.04ml) (p=0.125). In parallel, changes in exudate type were observed, with serous exudate predominating. Notably, absence of exudate at the final visit was documented in 22.5% of patients versus none at baseline (Table 3).

Periwound skin condition

Improvements were also noted in the periwound skin condition, with the proportion of patients presenting healthy periwound skin increasing from 26.3% at baseline to 36.3% at the final visit, while signs of dry skin, squamous changes, erythema/redness showed a slight decline at the final visit. Other categories of periwound skin, such as irritated, hyperhydrated, macerated, eczematous and inflamed, remained stable or varied minimally at the final visit. Overall, no evidence of progressive periwound skin deterioration was observed (Table 4).

Frequency of dressing changes and wear time

Across visits, the dressing change frequency remained low throughout the study. The median was consistently 1 dressing change (IQR: 0–1 dressing changes) between

Table 2. Relative wound area reduction (WAR) by visit in intention-to-treat (ITT) population*

Measurement before cleansing/debridement	Overall (n=80)	RSSB (n=53)	RSSil (n=27)
Visit 2			
n	79	53	26
Mean±SD	13.33±37.87	16.33±36.60	7.22±40.39
Median (Q1, Q3)	17.42 (–2.39, 34.83)	19.66 (0.00, 37.05)	11.41 (–5.27, 27.74)
Min, Max	–116.2, 100.0	–81.3, 100.0	–116.2, 70.9
Missing data	1	0	1
Visit 3			
n	79	53	26
Mean±SD	27.40±46.47	24.16±46.72	34.03±46.16
Median (Q1, Q3)	29.95 (1.34, 61.49)	29.01 (0.00, 58.75)	40.39 (12.55, 66.49)
Min, Max	–133.3, 100.0	–130.4, 100.0	–133.3, 94.6
Missing data	1	0	1
Visit 4			
n	79	53	26
Mean±SD	34.92±45.10	35.41±42.16	33.92±51.45
Median (Q1, Q3)	39.18 (1.50, 71.37)	34.30 (0.00, 67.67)	41.69 (5.87, 71.75)
Min, Max	–141.1, 100.0	–64.6, 100.0	–141.1, 100.0
Missing data	1	0	1
Visit 5			
n	79	53	26
Mean±SD	44.75±49.08	42.16±46.65	50.04±54.29
Median (Q1, Q3)	52.85 (20.85, 82.11)	47.70 (20.85, 80.10)	66.70 (21.04, 86.07)
Min, Max	–147.4, 100.0	–133.1, 100.0	–147.4, 100.0
Missing data	1	0	1
Visit 6			
n	79	53	26
Mean±SD	48.13±51.04	44.05±47.55	56.43±57.61
Median (Q1, Q3)	57.18 (15.26, 95.27)	47.94 (12.49, 90.39)	81.34 (46.12, 95.57)
Min, Max	–139.4, 100.0	–82.7, 100.0	–139.4, 100.0
Missing data	1	0	1
Visit 7			
n	79	53	26
Mean±SD	52.29±56.93	48.39±52.88	60.25±64.81
Median (Q1, Q3)	68.94 (18.54, 97.31)	58.48 (17.65, 90.39)	85.08 (58.39, 100.00)
Min, Max	–165.2, 100.0	–138.0, 100.0	–165.2, 100.0
Missing data	1	0	1

*Percentage WAR (ulcer size reduction at visit X), calculated as (wound area at baseline (V1) – wound area at visit X)/wound area at baseline (V1)×100. Wound area analyses included 79 ITT patients because one baseline image before cleansing/debridement and one image after cleansing/debridement in one patient were missing and unavailable for planimetry assessment. IQR—interquartile range; max—maximum; min—minimum; Q—quarter; RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany); SD—standard deviation

Table 2. Relative wound area reduction (WAR) by visit in intention-to-treat population* (continued)

Measurement after cleansing/debridement	Overall (n=80)	RSSB (n=53)	RSSil (n=27)
Visit 2			
n	79	52	27
Mean±SD	19.12±31.37	19.12±32.11	19.11±30.50
Median (Q1, Q3)	18.99 (0.00, 33.59)	16.36 (-0.19, 41.11)	23.81 (11.59, 31.70)
Min, Max	–90.9, 100.0	–46.2, 100.0	–90.9, 74.4
Missing data	1	1	0
Visit 3			
n	79	52	27
Mean±SD	33.29±42.09	29.81±44.36	39.99±37.18
Median (Q1, Q3)	36.72 (10.38, 58.92)	29.64 (8.89, 58.28)	40.41 (28.18, 58.92)
Min, Max	–152.4, 100.0	–152.4, 100.0	–94.8, 100.0
Missing data	1	1	0
Visit 4			
n	79	52	27
Mean±SD	40.68±41.76	39.54±42.40	42.89±41.20
Median (Q1, Q3)	42.04 (10.40, 76.14)	41.48 (9.96, 77.10)	52.60 (22.36, 70.48)
Min, Max	–98.1, 100.0	–90.3, 100.0	–98.1, 94.5
Missing data	1	1	0
Visit 5			
n	79	52	27
Mean±SD	47.85±44.67	44.09±43.04	55.08±47.64
Median (Q1, Q3)	54.68 (17.48, 83.49)	43.32 (12.04, 84.70)	70.44 (39.84, 82.02)
Min, Max	–104.0, 100.0	–73.9, 100.0	–104.0, 100.0
Missing data	1	1	0
Visit 6			
n	79	52	27
Mean±SD	53.15±47.53	48.80±45.38	61.54±51.25
Median (Q1, Q3)	63.01 (26.97, 92.53)	50.82 (25.31, 91.62)	80.13 (37.95, 97.62)
Min, Max	–120.4, 100.0	–113.5, 100.0	–120.4, 100.0
Missing data	1	1	0
Visit 7			
n	79	52	27
Mean±SD	56.60±51.99	53.16±48.43	63.22±58.65
Median (Q1, Q3)	69.58 (28.93, 100.00)	62.46 (25.72, 96.31)	85.23 (38.54, 100.00)
Min, Max	–168.6, 100.0	–115.7, 100.0	–168.6, 100.0
Missing data	1	1	0

*Percentage WAR (ulcer size reduction at visit X), calculated as (wound area at baseline (V1) – wound area at visit X)/wound area at baseline (V1)×100. Wound area analyses included 79 ITT patients because one baseline image before cleansing/debridement and one image after cleansing/debridement in one patient were missing and unavailable for planimetry assessment. IQR—interquartile range; max—maximum; min—minimum; Q—quarter; RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany); SD—standard deviation

Table 3. Change in granulation, slough tissue and exudate type from baseline to final visit

Parameter	Overall (n=80)*	RSSB (n=53)*	RSSil (n=27)*
Relative change in coverage by granulation tissue from baseline (%) at V7 (measurement before cleansing/debridement)			
Median (IQR)	85.59 (10.28–100.00)	69.96 (13.80–100.00)	97.20 (6.77–100.00)
None, n (%)	16 (23.5)	11 (24.4)	5 (21.7)
1–24%, n (%)	3 (4.4)	2 (4.4)	1 (4.3)
25–49%, n (%)	4 (5.9)	3 (6.7)	1 (4.3)
50–74%, n (%)	8 (11.8)	8 (17.8)	0 (0.0)
75–100%, n (%)	37 (54.4)	21 (46.7)	16 (69.6)
Relative change in coverage by granulation tissue from baseline (%) at V7 (measurement after cleansing/debridement)			
Median (IQR)	75.21 (24.32–100.00)	66.51 (16.29–97.41)	85.23 (33.82–100.00)
None, n (%)	12 (15.2)	10 (19.2)	2 (7.4)
1–24%, n (%)	8 (10.1)	7 (13.5)	1 (3.7)
25–49%, n (%)	10 (12.7)	3 (5.8)	7 (25.9)
50–74%, n (%)	9 (11.4)	8 (15.4)	1 (3.7)
75–100%, n (%)	40 (50.6)	24 (46.2)	16 (59.3)
Relative change in coverage by slough tissue from baseline (%) at V7 (measurement before cleansing/debridement)			
Median (IQR)	87.0 (51.42–100.00)	74.40 (37.48–100.00)	100 (79.50–100.00)
None, n (%)	8 (13.1)	7 (18.4)	1 (4.3)
1–24%, n (%)	1 (1.6)	1 (2.6)	0 (0.0)
25–49%, n (%)	6 (9.8)	3 (7.9)	3 (13.0)
50–74%, n (%)	9 (14.8)	8 (21.1)	1 (4.3)
75–100%, n (%)	37 (60.7)	19 (50.0)	18 (78.3)
Relative change in coverage by slough tissue from baseline (%) at V7 (measurement after cleansing/debridement)			
Median (IQR)	98.63 (46.67–100.00)	96.32 (6.04–100.00)	100 (58.33–100.00)
None, n (%)	4 (14.3)	4 (21.1)	0 (0.0)
1–24%, n (%)	2 (7.1)	1 (5.3)	1 (11.1)
25–49%, n (%)	1 (3.6)	0 (0.0)	1 (11.1)
50–74%, n (%)	2 (7.1)	1 (5.3)	1 (11.1)
75–100%, n (%)	19 (67.9)	13 (68.4)	6 (66.7)

*Percentages are calculated using number of non-missing records in intention-to-treat population overall/in study arm as denominator. Relative change (%), calculated as (Values at baseline (visit 1) – Values at final visit)/Values at baseline×100. IQR—interquartile range; RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany); V—visit

scheduled visits, with no statistically significant differences compared with baseline in the overall population (visits 3–7: p=0.276–0.754) or within RSSB (visits 3–7: p=0.356–0.824) and RSSil (visits 3–7: p=0.166–0.627). The median wear time was consistently ~4 days (IQR: 3–6 days) across visits, with no significant change compared with baseline overall (visits 3–7: p=0.380–0.993), in RSSB (visits 3–7: p=0.232–0.982) or RSSil (visits 3–7: p=0.086–0.976). This indicated a stable dressing wear time and effective exudate handling in a clinical setting.

Safety profile

Overall, 10 potentially device-related AEs were reported in seven (8.2%) patients during the study period. These events were observed with similar frequency in both dressing groups and were predominantly mild to moderate, consisting mainly of localised periwound skin reactions typical for chronic wound care. No potentially device-related serious AEs occurred, and no systemic safety concerns were identified. Importantly, no device deficiencies were reported throughout the study (Table 5).

Table 3. Change in granulation, slough tissue and exudate type from baseline to final visit (continued)

Parameter	Overall (n=80)*	RSSB (n=53)*	RSSil (n=27)*
Exudate quality at V1, if exudate present, n (%)			
Serous	68 (85.0)	47 (88.7)	21 (77.8)
Sanguineous	0 (0.0)	0 (0.0)	0 (0.0)
Serosanguineous	8 (10.0)	5 (9.4)	3 (11.1)
Seropurulent	2 (2.5)	0 (0.0)	2 (7.4)
Fibrinous	0 (0.0)	0 (0.0)	0 (0.0)
Purulent	2 (2.5)	1 (1.9)	1 (3.7)
Haemopurulent	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhagic	0 (0.0)	0 (0.0)	0 (0.0)
Exudate quality at V7, if exudate present, n (%)	**(n=62)**	**(n=41)**	**(n=21)**
Serous	53 (85.5)	34 (82.9)	19 (90.5)
Sanguineous	1 (1.6)	1 (2.4)	0 (0.0)
Serosanguineous	2 (3.2)	2 (4.9)	0 (0.0)
Seropurulent	4 (6.5)	3 (7.3)	1 (4.8)
Fibrinous	0 (0.0)	0 (0.0)	0 (0.0)
Purulent	2 (3.2)	1 (2.4)	1 (4.8)
Haemopurulent	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhagic	0 (0.0)	0 (0.0)	0 (0.0)

*Percentages are calculated using number of non-missing records in intention-to-treat population overall/in study arm as denominator. IQR—interquartile range; RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany); V—visit

Discussion

This prospective single-arm cohort study assessed the clinical performance of silicone SAP dressings in the treatment of VLUs and DFUs. In line with the study hypothesis that treatment with the dressings would be associated with early WAR and measurable improvements in wound bed condition, participants demonstrated a consistent pattern of healing-related changes over the six-week observation period. A key predefined endpoint was the proportion of patients achieving ≥20% relative WAR by week 6, a threshold reached by 74.7% of patients before and 83.5% after cleansing/debridement. These findings represent both statistically and clinically meaningful early improvement. Additional parameters, including reductions in granulation tissue and slough, improvements in exudate characteristics, and improved periwound skin condition, supported the internal consistency of the observed healing trajectory. Notably, 26.9% of ulcers achieved complete re-epithelialisation within six weeks, an outcome that would not typically be expected in chronic ulcers of this duration (mean baseline wound duration: 181 days).

The patterns observed over the study period, early mean increases in granulation during the first two weeks, followed by steady reductions in granulation tissue as the wounds contracted and re-epithelialised, are biologically consistent with progression through the proliferative and maturation phases of healing.[26] Improvements in wound area and tissue composition, combined with favourable changes in exudate and periwound skin condition, suggest that many ulcers were moving away from a chronic inflammatory plateau and towards an active healing trajectory.

The dressings were applied in accordance with the manufacturer instructions, and clinicians selected specific products within the SAP range based on individual wound characteristics, mirroring routine clinical decision-making. As part of standard multidisciplinary care, all patients received appropriate co-interventions—compression therapy for VLUs and offloading for DFUs—which are recognised as central components of effective wound management and inevitably interact with dressing-related outcomes. Throughout the study, dressing changes were infrequent, with the majority of participants requiring ≤1 change between scheduled visits. This pattern suggests that the absorbency and exudate handling capacity of the dressings were adequate under typical outpatient conditions. Collectively, these aspects of intervention delivery reflect real-world practice and support the reproducibility of the study conditions in comparable clinical settings.

Table 4. Changes in periwound skin condition from baseline to final visit

Improvement of periwound skin condition by visit	Overall (n=80)*, n (%)	p-value†	RSSB (n=53)*, n (%)	p-value†	RSSil (n=27)*, n (%)	p-value†
Healthy at visit 1	21 (26.3)		15 (28.3)		6 (22.2)	
Healthy at visit 7	29 (36.3)	0.118	18 (34.0)	0.579	11 (40.7)	0.131
Dry at visit 1	12 (15.0)		11 (20.8)		1 (3.7)	
Dry at visit 7	6 (7.5)	0.149	6 (11.3)	0.228	0 (0.0)	>0.999
Irritated at visit 1	6 (7.5)		5 (9.4)		1 (3.7)	
Irritated at visit 7	6 (7.5)	>0.999	3 (5.7)	0.683	3 (11.1)	0.617
Macerated at visit 1	11 (13.8)		5 (9.4)		6 (22.2)	
Macerated at visit 7	13 (16.3)	0.773	9 (17.0)	0.289	4 (14.8)	0.617
Hyperhydrated at visit 1	4 (5.0)		4 (7.5)		0 (0.0)	
Hyperhydrated at visit 7	4 (5.0)	>0.999	3 (5.7)	>0.999	1 (3.7)	>0.999
Eczematous at visit 1	2 (2.5)		2 (3.8)		0 (0.0)	
Eczematous at visit 7	4 (5.0)	0.617	3 (5.7)	>0.999	1 (3.7)	>0.999
Squamous at visit 1	12 (15.0)		8 (15.1)		4 (14.8)	
Squamous at visit 7	5 (6.3)	0.146	2 (3.8)	0.114	3 (11.1)	>0.999
Inflamed at visit 1	1 (1.3)		1 (1.9)		0 (0.0)	
Inflamed at visit 7	3 (3.8)	0.480	2 (3.8)	>0.999	1 (3.7)	>0.999
Erythema/redness at visit 1	37 (46.3)		22 (41.5)		15 (55.6)	
Erythema/redness at visit 7	31 (38.8)	0.211	21 (39.6)	>0.999	10 (37.0)	0.131

*Percentages are calculated using number of non-missing records in intention-to-treat population overall/in study arm as denominator; †p-value for comparison between the visit and baseline (V1) values; McNemar test; RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany)

Participant retention varied across the study period, largely because some patients achieved complete re-epithelialisation earlier or discontinued follow-up, resulting in differing numbers of observations at later visits. Although standardised photography and digital planimetry were used to ensure measurement consistency, missing data in the later stages of follow-up may influence the interpretation of temporal trends. Importantly, early healing reflects a genuine clinical outcome rather than a methodological limitation, and its occurrence naturally reduces the availability of repeated measurements in those participants.

Changes in wound bed composition provided additional insight into the healing process. By the final visit, 50.6% of wounds showed a 75.0–100.0% reduction in granulation tissue, following a brief early increase consistent with the proliferative phase of healing. Slough decreased by 75.0–100.0% in 67.9% of participants after debridement, illustrating substantial improvement in tissue quality. Exudate levels also declined, with a median reduction of 0.38ml; by week 6, 22.5% of wounds produced no exudate and the character of fluid shifted toward predominantly serous. The proportion of wounds with healthy periwound skin increased from 26.3% to 36.3%, indicating improved moisture balance and reduced local irritation. Collectively, these changes support the interpretation that the dressings contributed to a more stable wound microenvironment, including more effective sequestration of inflammatory exudate and protection of surrounding skin.

Table 5. Adverse events

Incidence	Overall (n=85)*, n (%)	RSSB (n=58)*, n (%)	RSSil (n=27)*, n (%)
Skin and subcutaneous tissue	7 (8.2)	5 (8.6)	2 (7.4)
Skin inflammation/irritation	3 (3.5)	2 (3.4)	1 (3.7)
Contact dermatitis	1 (1.2)	1 (1.7)	0 (0.0)
Eczema	2 (2.4)	1 (1.7)	1 (3.7)
Wound odour	1 (1.2)	1 (1.7)	0 (0.0)
Itching sensation	1 (1.2)	1 (1.7)	0 (0.0)
Skin erosion	2 (2.4)	1 (1.7)	1 (3.7)
Skin infection	1 (1.2)	0 (0.0)	1 (3.7)
Generalised disorders	2 (2.4)	2 (3.4)	0 (0.0)
Pain	2 (2.4)	2 (3.4)	0 (0.0)

*Percentages are calculated in terms of incidence, i.e., taking the size of the safety population or its subpopulation as denominator and number of unique patients with the event as numerator. RSSB—RespoSorb Silicone Border; RSSil—RespoSorb Silicone (both PAUL HARTMANN AG, Germany)

The observation that 26.9% of chronic ulcers achieved complete re-epithelialisation within six weeks is clinically significant, particularly given the mean baseline wound duration of 181 days. Such rapid closure is typically observed in only a minority of chronic VLUs and DFUs.[4,27] However, closure in this context should be regarded as remission rather than a definitive cure, as recurrence remains common in these patient populations. Pooled data demonstrate that three-year recurrence rates for DFUs reach 58%, comparable to recurrence rates observed in advanced-stage cancers.[28] Indeed, 42% of DFUs recur within one year and 65% within five years.[4,29] Long-term management strategies, including control of exudate, protection of the periwound area, and appropriate biomechanical or vascular support, are essential to reduce the risk of recurrence. Dressings that effectively manage exudate may therefore have relevance not only during active healing but also in the maintenance phase following closure.

The dressings were generally well tolerated. AEs were infrequent, mild and localised, occurring in 8.2% of participants, and no device deficiencies were reported. Events such as irritation, dermatitis or discomfort are consistent with known profiles of advanced wound dressings[30] and were manageable through standard adjustments to wound care. The silicone interface likely supported atraumatic removal, an important consideration for patients with fragile periwound skin and a factor that may help maintain uninterrupted healing.

The findings are broadly consistent with published economic[31–34] and clinical evaluations[35] indicating that SAP dressings can be cost-effective or cost-saving compared with standard dressings. Although this study did not assess economic outcomes directly, the low dressing change frequency and measurable improvements in wound area align with the mechanisms described in those analyses. The results are most generalisable to outpatient wound care settings that employ structured multidisciplinary care, including appropriate compression or offloading. Caution should be exercised when applying these findings to settings lacking such infrastructure, as healing trajectories may differ in the absence of standard supporting therapies.

Limitations

Given the prospective, non-randomised, single-arm design, findings should be interpreted as within-person associations rather than device-attributable effects.[36] Regression to the mean,[37] the natural course of healing that can occur when hard-to-heal ulcers are managed with optimised SoC, secular trends, and mandated co-interventions (compression/offloading, debridement)[38,39] may contribute to the observed changes. Allocation by investigator judgement and eligibility criteria introduce selection bias and may limit transportability to other patient populations or care settings.[40,41] Standardised photography with centralised, blinded planimetry[42] reduces, but cannot eliminate, measurement error. Early healing and attrition raise the possibility of informative censoring despite ITT analyses and prespecified missing data rules.[43,44] The six-week horizon captures early dynamics only and does not address durability or recurrence, and the effects of compression/offloading cannot be disentangled from dressing effects.

Conclusions

This prospective single-arm cohort study found that silicone SAP dressings were associated with meaningful improvement in chronic VLUs and DFUs over six weeks. Most participants achieved at least a 20% WAR, with a median reduction of almost 70%, alongside consistent improvements in wound bed quality, exudate control and periwound skin condition. More than 25% of ulcers reached complete re-epithelialisation despite their long duration at baseline. The dressings supported effective exudate management, required infrequent changes, and showed a favourable safety profile with only mild local reactions and no device deficiencies.

Overall, the findings of this study provide concise real-world evidence that these dressings are safe, well-tolerated, and clinically useful as part of routine management for exuding chronic lower extremity ulcers, while acknowledging that the single-arm design limits causal interpretation. **JWC**

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The authors used Microsoft 365 CoPilot (Microsoft Corp., US) to review language, spelling and grammatical errors.

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Reflective questions

- What additional insights would a 24-week (and, ideally, 52-week) follow-up yield on durability of closure and time to first recurrence, using competing risk methods to handle events, such as amputation or death?
- How might early wound area reduction correlate with meaningful change in wound-specific quality of life?
- To what extent do objectively measured activity levels (steps/day, heel raise sets, or wearable derived walking/standing time) modify healing rates in venous leg ulcers, beyond dressing plus compression?