

Quality of Life Improvement in Patients with Chronic Leg Wounds that were Treated with Wound Irrigation Solution* and Wound Gel+ each Containing Polyhexanide (PHMB) and Betaine



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INTRODUCTION

- Improving health-related quality of life (QoL) is important for patients living with chronic wounds.
- The physical symptoms of chronic wounds can dominate everyday living, affecting mobility, causing sleep disruption, and affecting work and social activities.
- Chronic leg wounds are those that do not progress through the normal healing process in a timely manner; these wounds affect approximately 2.4 – 4.5 million patients in the United states alone and last on average 12 – 13 months with a reoccurrence rate of 60-70%.^{1,2}
- The study consisted of a screening period (Week 0), a baseline assessment (Week 1), and 4 weeks of treatment with Wound Irrigation Solution* and Wound Gel+ (each containing Polyhexanide [PHMB] and Betaine).
- Polyhexanide (PHMB), also found in contact lens solution, functions as a preservative and Betaine is a surface-active cleanser (Surfactant), see Figure 1.

Figure 1. PHMB and Betaine Application



OBJECTIVES

- Primary Objective:** to assess the overall change in the QoL after 4 weeks of treatment in patients with chronic leg wounds, determined by the change from baseline in the global score of the Wound-QoL questionnaire.
- Secondary Objective:** to assess the changes in the Body, Psyche, and Everyday Life (EDL) subscores of the Wound-QoL questionnaire after 4 weeks of treatment, determined by changes from baseline in the subscores of the Wound-QoL questionnaire
- Exploratory Objective:** to assess the change in appearance and size of the wounds by direct evaluation and photographic measurements after 4 weeks of treatment, evaluated by assessing the change from baseline to Week 5.

METHODS

- Prospective, open-label, single-arm study to evaluate the change from baseline (Week 1) in Wound-QoL after 4 weeks of treatment in adult patients with chronic leg wounds.
- Non-hospitalized patients with no more than 2 wounds below the knees were recruited into the study; wounds were ≥5 to ≤50cm² and present for ≥4 weeks.
- Investigator or designee applied the PHMB and Betaine to the wound(s) at the clinic visits and patients/caregivers applied the PHMB and Betaine at home. The frequency and method of PHMB and Betaine applications were per institutional guidelines and instructions for use (IFU) for the individual patient wounds.
- Validated Wound-QoL questionnaires were obtained at Screening and each week of treatment.³ Wound size and photographs were obtained at pre- and post-treatment during clinic visits.
- Completer Population**- patients completing the 4-week treatment period (Week 5). The analyses of the primary, secondary, and exploratory endpoints were conducted using this population.

RESULTS

Table 1. Characteristics of the Subjects in the Completer Population at Baseline (Week 1)

Characteristics	Completer Population (N=36)
Mean age (SD) – years	63.2 (15.34)
Sex – no. (%)	
Male	17 (47.2)
Female	19 (52.8)
Race – no. (%)	
Asian	1 (2.8)
Black/African American	15 (41.7)
White	17 (47.2)
Not available	3 (8.3)
Hispanic or Latino ethnicity – no. (%)	8 (22.2)
Mean body weight (SD) – kg	95.3 (21.48)
Mean height (SD) – cm	169.3 (10.92)
Mean body mass index (SD) – kg/m2	33.3 (6.8)

Table 1. Characteristics of subjects in the Completer Population. The mean age was ~63 years old, mean BMI was ~33 kg/m² and a majority of subjects were White or African American females.

Table 2. Statistical Summary for Global QoL Scores and Body, Psyche, and EDL QoL Subscores – Completer Population

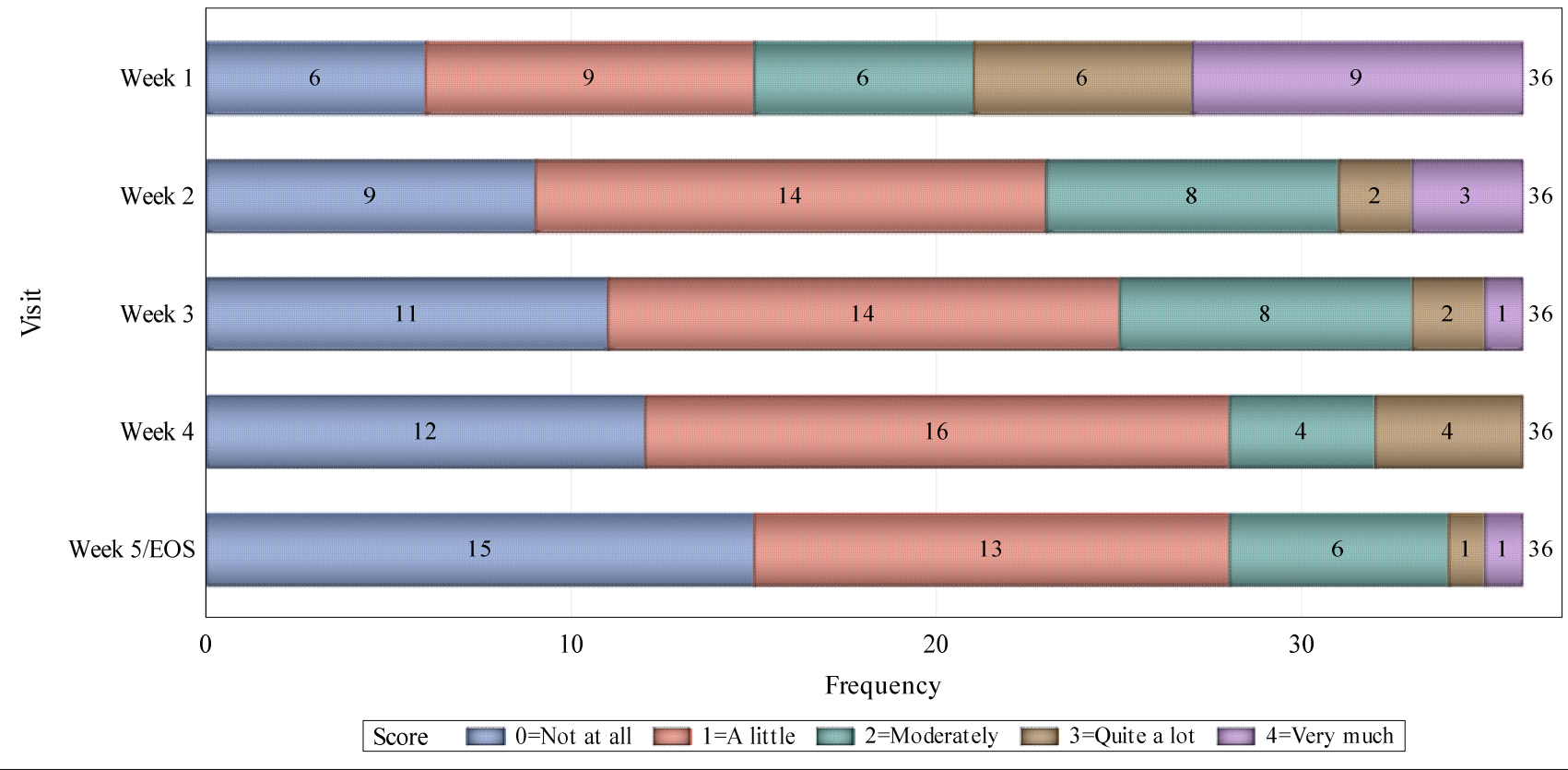
Global Score						
Visit	N	Mean	Numerical change from baseline	% change from baseline	P-value	95% CI
Baseline (Week 1)	36	2.413	NA	NA	NA	NA
Week 2	36	1.735	-0.677	28.1%	0.0001	-1.001 to -0.354
Week 3	36	1.506	-0.906	37.6%	<0.0001	-1.235 to -0.578
Week 4	36	1.253	-1.160	48.1%	<0.0001	-1.507 to -0.813
Week 5/EOS	36	1.301	-1.112	46.1%	<0.0001	-1.425 to -0.799
Body Subscore						
Visit	N	Mean	Numerical change from baseline	% change from baseline	P-value	95% CI
Baseline (Week 1)	36	1.956	NA	NA	NA	NA
Week 2	36	1.193	-0.763	39.0%	0.0003	-1.150 to -0.375
Week 3	36	1.025	-0.931	47.6%	0.0001	-1.363 to -0.498
Week 4	36	0.767	-1.189	60.8%	<0.0001	-1.629 to -0.749
Week 5/EOS	36	0.783	-1.172	60.0%	<0.0001	-1.583 to -0.761
Psyche Subscore						
Visit	N	Mean	Numerical change from baseline	% from baseline	P-value	95% CI
Baseline (Week 1)	36	3.017	NA	NA	NA	NA
Week 2	36	2.250	-0.767	25.4%	0.0002	-1.144 to -0.389
Week 3	36	1.979	-1.038	34.4%	<0.0001	-1.421 to -0.654
Week 4	36	1.774	-1.243	41.2%	<0.0001	-1.673 to -0.813
Week 5/EOS	36	1.756	-1.261	41.8%	<0.0001	-1.647 to -0.875
EDL Subscore						
Visit	N	Mean	Numerical change from baseline	% change from baseline	P-value	95% CI
Baseline (Week 1)	36	2.375	NA	NA	NA	NA
Week 2	36	1.797	-0.578	24.3%	0.0022	-0.933 to -0.223
Week 3	36	1.558	-0.818	34.4%	<0.0001	-1.170 to -0.45
Week 4	36	1.268	-1.107	46.6%	<0.0001	-1.482 to -0.731
Week 5/EOS	36	1.372	-1.003	42.2%	<0.0001	-1.339 to -0.668

Wound Characteristics: Baseline (Week 1)

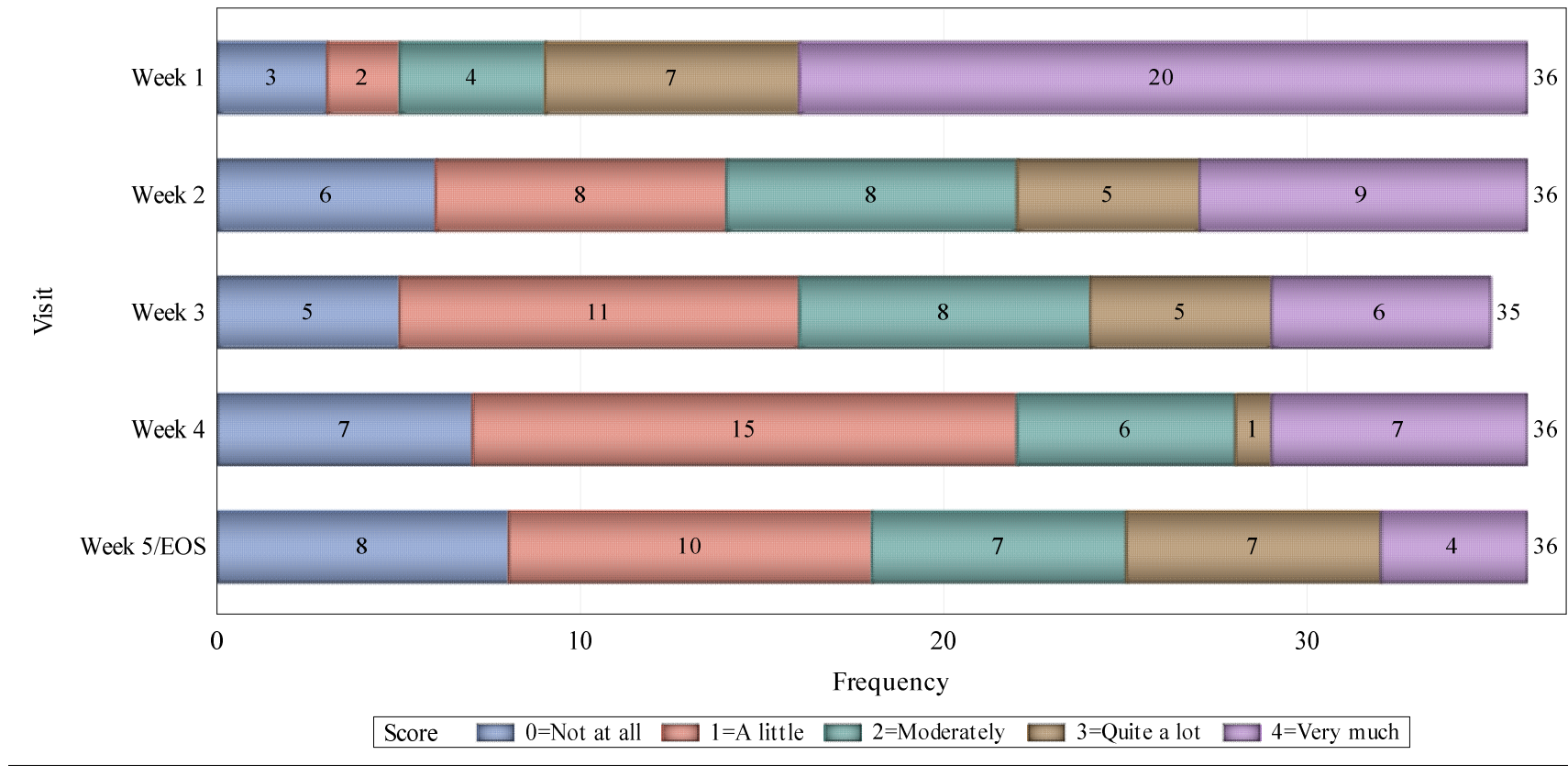
- Primary wound type: venous ulcer (69.4%), diabetic ulcer (13.9%), neuropathic ulcer (5.6%), and traumatic ulcer (11.1%)
- Wound age ranged from 4 – 1,613 weeks with a median of ~20 weeks
- Wounds were located on the left leg (41.7%), right leg (47.2%), left foot (5.6%), and right foot (5.6%)
- Past wound complications included infection (27.8%) and recurrent hospitalizations (8.3%)
- Calculated wound surface area⁴ ranged from 5 – 48 cm² with a median of ~14 cm²

Figure 2. Representative Bar Charts and Statistical Analyses for Individual QoL Subscores – Body , Psyche, and EDL

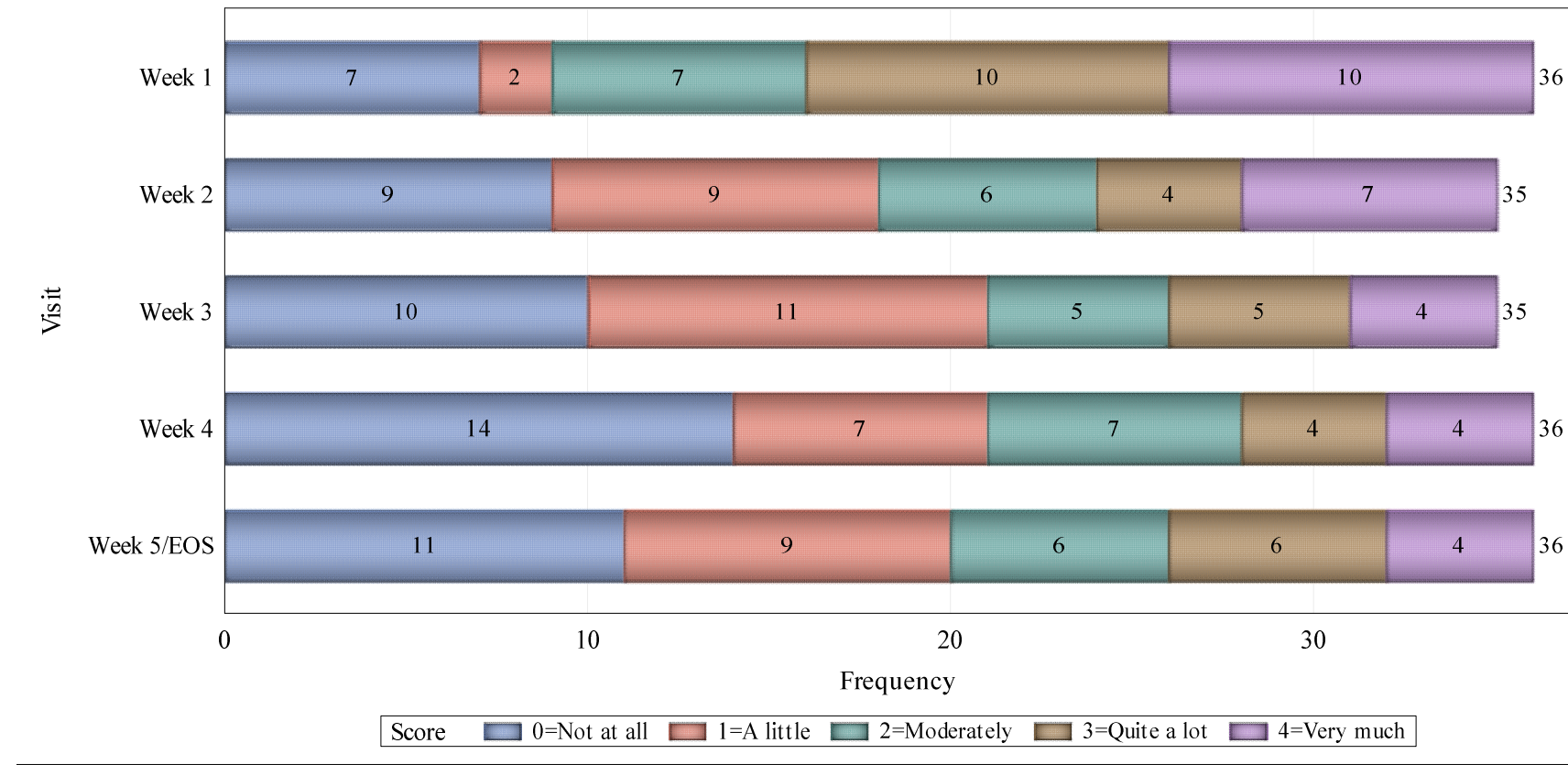
a. Body: My wound hurt



b. Psyche: The wound has made me unhappy



c. EDL: I have trouble moving around because of the wound



d. Body: My wound hurt

Visit	N	Mean	Change from baseline	% change from baseline	P-value	95% CI
Baseline	36	2.083	NA	NA	NA	NA
Week 2	36	1.333	-0.750	36.0%	0.0045	-1.251 to -0.249
Week 3	36	1.111	-0.972	46.7%	0.0001	-1.433 to -0.511
Week 4	36	1.000	-1.083	52.0%	0.0002	-1.622 to -0.545
Week 5/EOS	36	0.889	-1.194	57.3%	<0.0001	-1.73 to -0.659

e. Psyche: The wound has made me unhappy

Visit	N	Mean	Change from baseline	% change from baseline	P-value	95% CI
Baseline	36	3.083	NA	NA	NA	NA
Week 2	36	2.083	-1.000	32.4%	0.0005	-1.53 to -0.47
Week 3	36	1.886	-1.171	38.8%	0.0001	-1.721 to -0.622
Week 4	36	1.611	-1.472	47.7%	<0.0001	-1.98 to -0.964
Week 5/EOS	36	1.694	-1.389	45.1%	<0.0001	-1.915 to -0.863

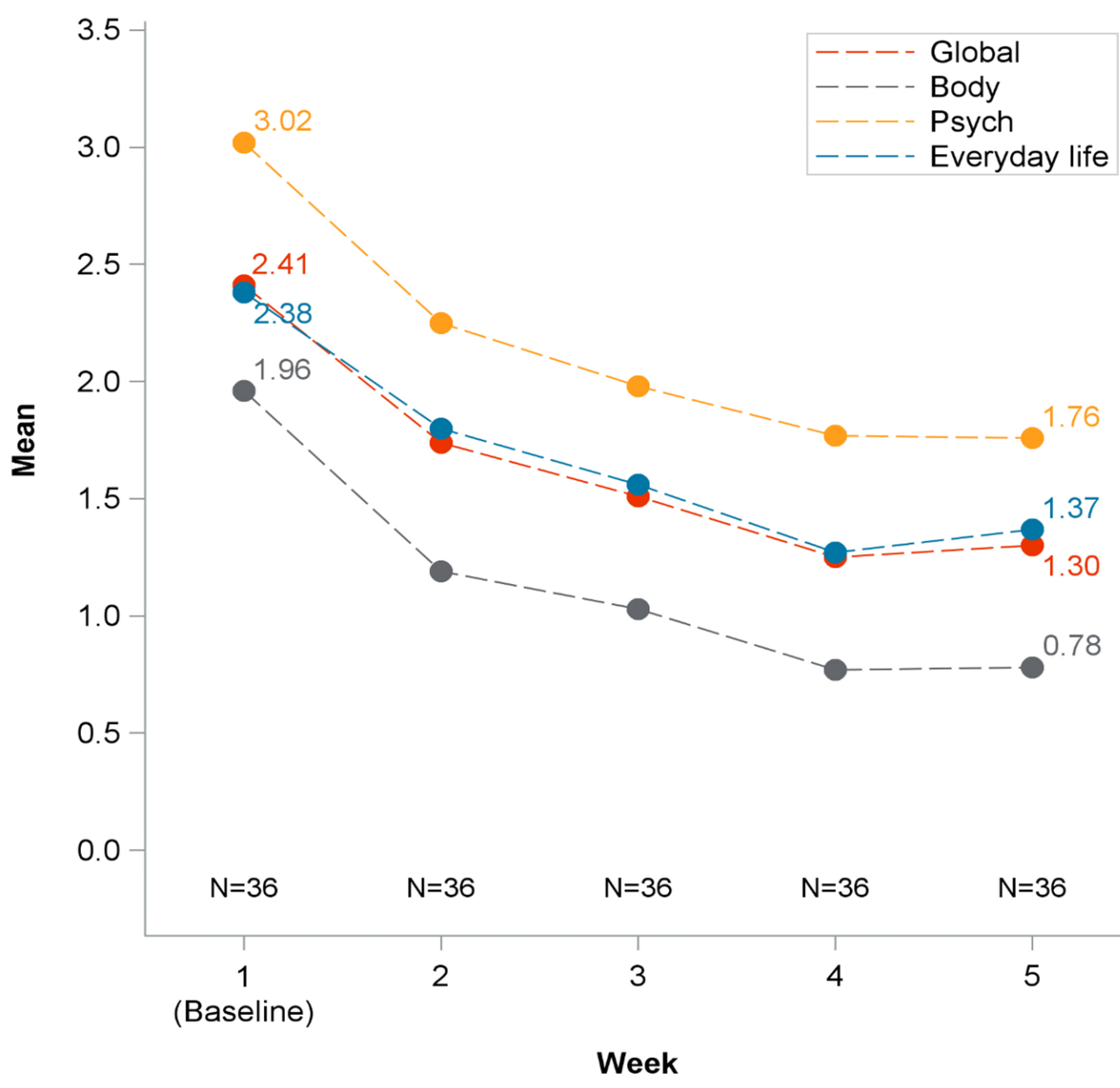
f. EDL: I have trouble moving around because of the wound

Visit	N	Mean	Change from baseline	% change from baseline	P-value	95% CI
Baseline	36	2.389	NA	NA	NA	NA
Week 2	36	1.743	-0.600	27.0%	0.0204	-1.101 to -0.099
Week 3	36	1.486	-0.857	37.8%	0.0014	-1.358 to -0.356
Week 4	36	1.361	-1.028	43.0%	0.0005	-1.567 to -0.488
Week 5/EOS	36	1.528	-0.861	36.0%	0.0007	-1.334 to -0.388

Figure 2: The Wound-QoL measures the health-related quality of life of patients with chronic wounds via 17 statements. Five (5) statements were assigned to the Body subscores, 5 statements were assigned to the Psyche subscores, 6 statements were assigned to the EDL subscores, and 1 statement was unassigned. **Panels a, b,** and **c** display representative bar charts for statements in the Body, Psyche, and EDL subscores. **Panels d, e,** and **f** display the statistical analysis for the corresponding bar charts, panels a, b, and c, respectively. There was a clear improvement in scores of all 3 Wound-QoL subscores, as seen by decreases in mean scores over time. These improvements were gradual until Week 4 – mean changes in scores of the 3 subscores from baseline to Week 5 differed only little from the mean changes from baseline to Week 4.

Figure 3. Global, Body, Psyche, and EDL Wound-QoL Scores - Completer Population

a. Mean Global, Body, Psyche, and EDL Wound-QoL Scores



b. Absolute Mean Changes in Global, Body, Psyche, and EDL Wound-QoL Scores

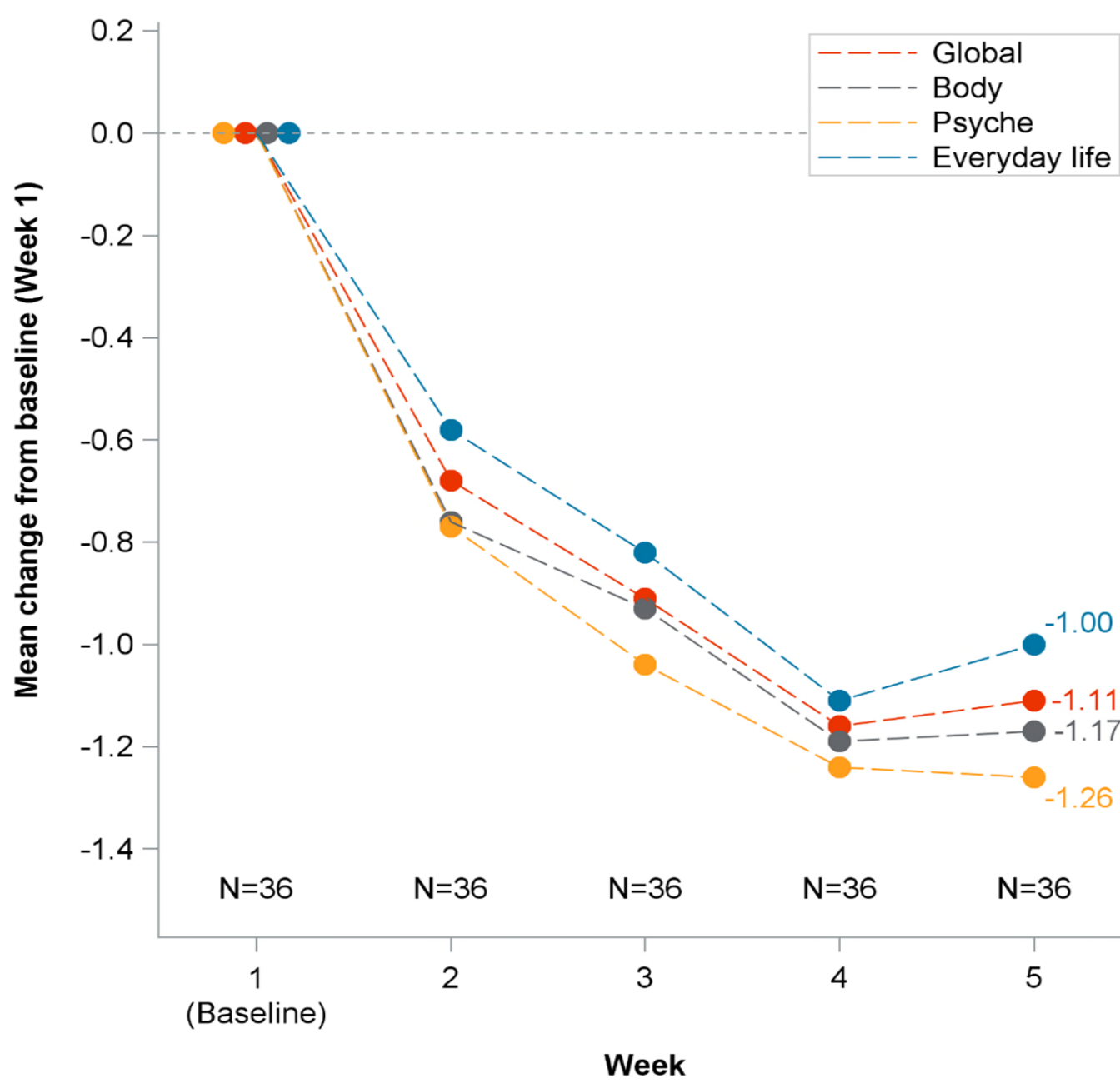


Figure 3: **Panel a** displays the mean global QoL scores decreased by 1.112 (46.1%). Body, Psyche, and EDL decreased by 1.172 (60.0%), 1.261 (41.8%), and 1.003 (42.2%), respectively. **Panel b** displays the absolute mean global QoL scores decreased by 1.11. Body, Psyche, and EDL decreased by 1.17, 1.26, and 1.00, respectively. All p-values were <0.0001.

DISCUSSION

- Clinically meaningful improvements in QoL were demonstrated by reductions in QoL scores during the first 3 weeks of treatment which appeared to stabilized at the 4th week.
- Wounds showed improvement in odor, appearance, and size.
- Proportion of patients with erythematous wound surroundings decreased and wound swelling improved.
- Improvements in: physical and psychological impairments, performing leisure activities and dependency on others.

CONCLUSIONS

- Marked improvement in the global QoL score as well as Body, Psyche, and EDL QoL subscores in patients with 1 or 2 chronic legs wounds below the knees following 4 weeks of treatment with PHMB and Betaine.
- Wounds showed improvement in odor, size and appearance.
- Safety**
- All adverse events were minor and mild in intensity. PHMB and Betaine were well tolerated by patients.
- Adverse device reactions with 10 or more events were: burning sensation (11 subjects), paraesthesia (4 subjects), pain (3 subjects), and pain of skin (1 subject).

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