

Clinical Observations Using Spectricept™ Skin and Wound Cleanser

Authors

Dr. David Allie
Louisiana Cardiovascular & Limb
Salvage Center

Dr. Jerry Stonemetz
CMO
Spectrum Antimicrobials

Mitchell Sanders, PhD
CEO
ProDevLabs, LLC

Abstract

This post-market clinical study assessed the use of Spectricept™ Skin and Wound Cleanser (Spectricept™) and additional medical intervention in 15 patients with 20 chronic arterial or venous ulcers that presented long standing challenges despite prior treatments (failed wounds). These wounds demonstrated eschar formation and were accompanied by significant comorbidities, including complex vascular disease. The treatment protocol consisted of weekly in office debridement of the eschar using a cotton applicator saturated with Spectricept™, supplemented by limited instrumental surgical debridement in 36% of visits. In addition, patients performed twice-daily self-application of Spectricept™ at home.

Study findings described wound changes overtime within a protocol that included Spectricept™ to debride and maintain an optimal moist wound bed environment as part of a broader medical care plan that addressed underlying comorbidities.

Introduction

Spectricept™ Skin and Wound Cleanser Rx contains hypochlorous acid (HOCl) while incorporating zinc, copper, and iron chlorides. Spectricept™ has received FDA 510(k) clearance for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from wounds, and dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post surgical wounds, superficial second-degree burns, abrasions, minor irritations of the skin, ingrown toenails, grafted/donor sites and exit sites. Spectricept™ has been classified as a device-led combination product.

This clinical study evaluated the use of Spectricept™ as part of a comprehensive medical intervention designed to debride and moisten non-healing chronic arterial and venous ulcers that had not respond to treatment.

Patient Population and Clinical Protocol

Fifteen patients (6 female, 9 male; mean age 73) with 20 chronic arterial/venous ulcers were enrolled. The treatment protocol eliminated standard compression therapy and included weekly in-office spraying of the wound with Spectricept™ followed by selective debridement using a cotton swab soaked in Spectricept™, minimal surgical debridement as needed, and twice-daily patient-applied Spectricept™ at home. Compression therapy was not part of this site's protocol for observational cohort. This does not imply replacement or comparison with standard compression therapy.

Patients reported that Spectricept™ was easy to apply and no serious adverse event was experienced.

Clinical Observations

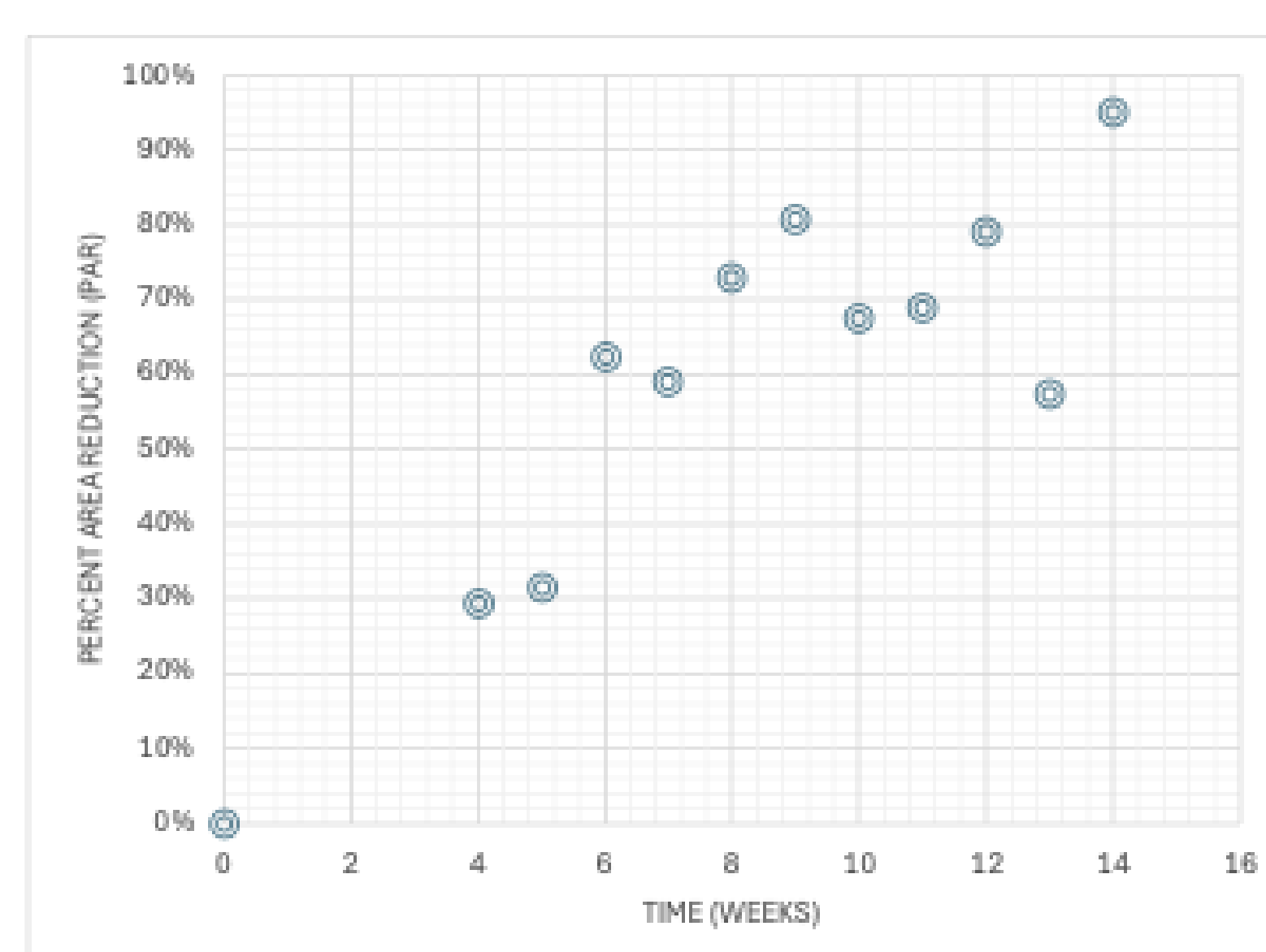


Figure 1. Average percent area reduction (PAR) trend over 14 weeks in the observational cohort. Exploratory descriptive data and not based on randomized controlled trial to support clinical performance.

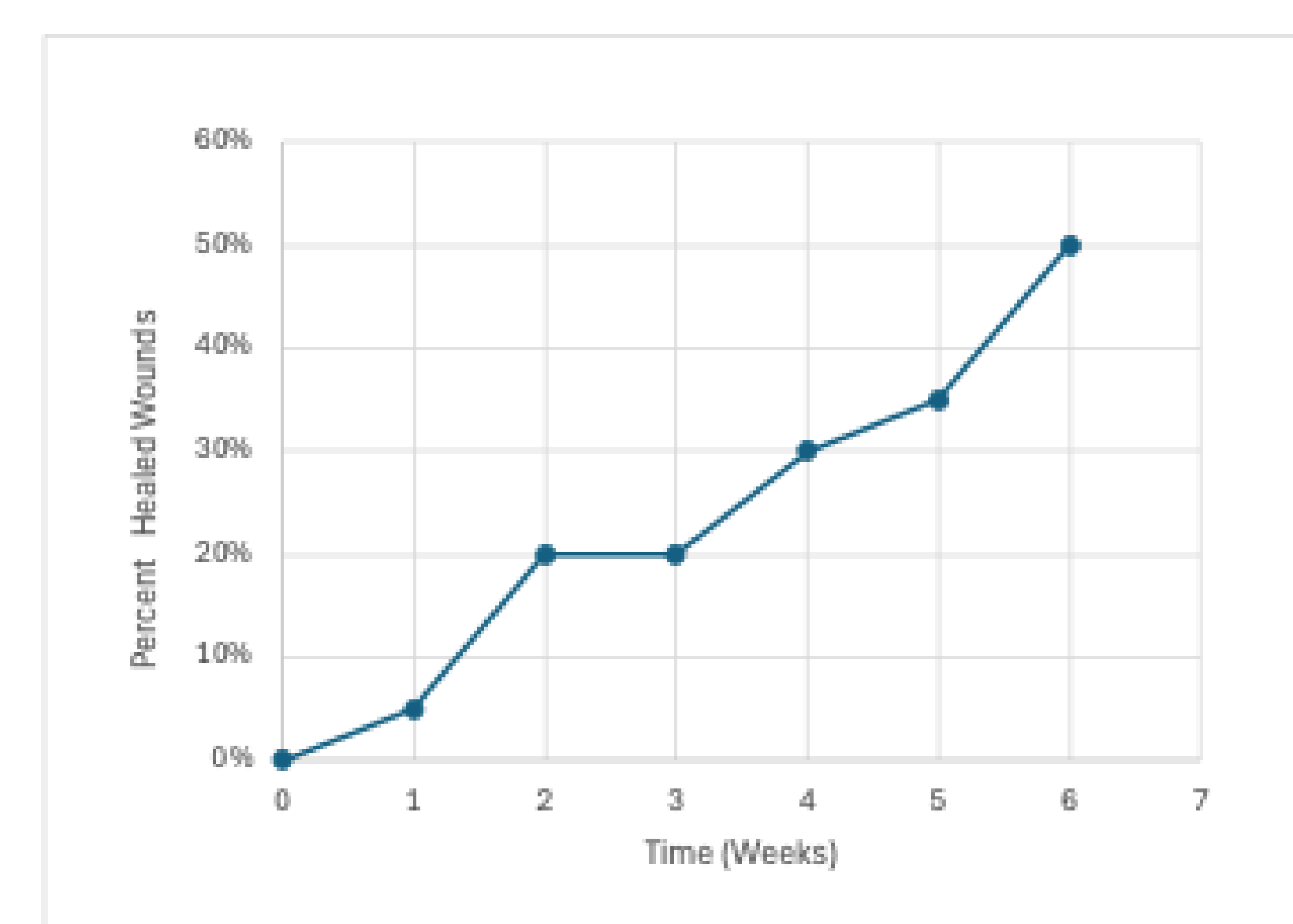


Figure 2. Reported wound closure status at 6 weeks. The outcome is observational and not powered to establish clinical performance.

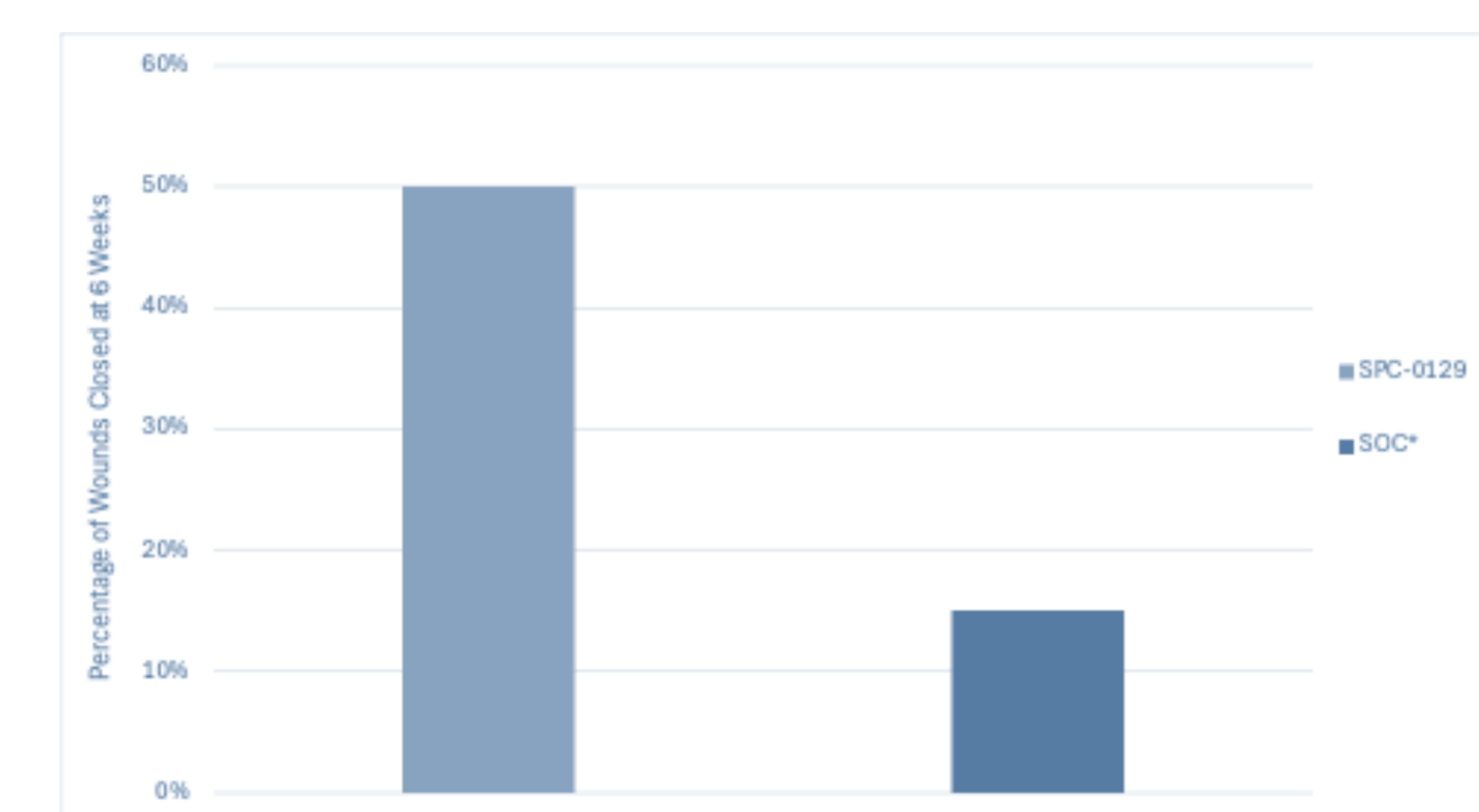


Figure 3. Historical standard of care using compression data is shown for context only (Serena et al. 2022). No direct comparative study was performed.

Limitations and Future Studies

Limitations of this study were the small sample size, the uncontrolled design and comparison of historical standard of care. Outcome should not be interpreted as demonstrating effectiveness. Larger randomized controlled studies are recommended.

Reference

Serena, et al., 2022. A Multicenter, Randomized, Controlled, Clinical Trial Evaluating Dehydrated Human Amniotic Membrane in the Treatment of Venous Leg Ulcers. *Plastic and Reconstructive Surgery* 150(5):p 1128-1136, November 2022.

Disclosures

Dr. David Allie is a director and shareholder in Spectrum Antimicrobials, Inc. The product used in this study was provided by the company at no charge.

Dr. Jerry Stonemetz is the CMO of Spectrum Antimicrobials, Inc.

Dr. Mitch Sanders is a paid consultant of Spectrum Antimicrobials, Inc.

DISCLAIMER

Spectricept™ Skin and Wound Cleanser is a medical device cleared under 510(k) K243875 for the mechanical cleansing, irrigation, and debridement of wounds. It has not been FDA-approved or cleared for the treatment of pain, inflammation, or to accelerate wound healing. The clinical observations presented are from a small, non-randomized, uncontrolled cohort and are intended for descriptive purposes only; they do not establish safety or effectiveness for any specific clinical outcome.

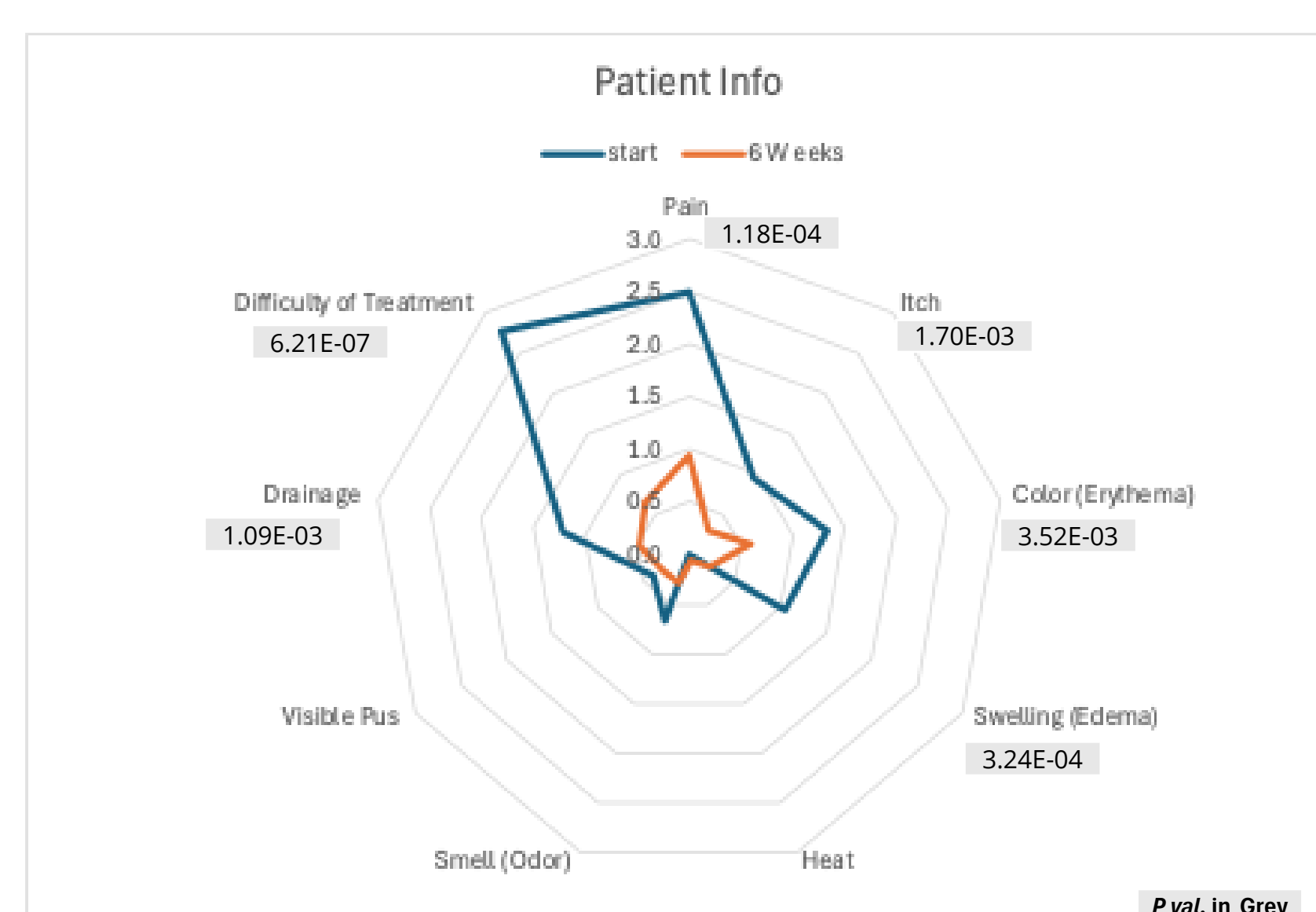


Figure 4. Patient-reported symptom scores showed a downward trend by Week 6. These self-reported outcomes were exploratory in nature.

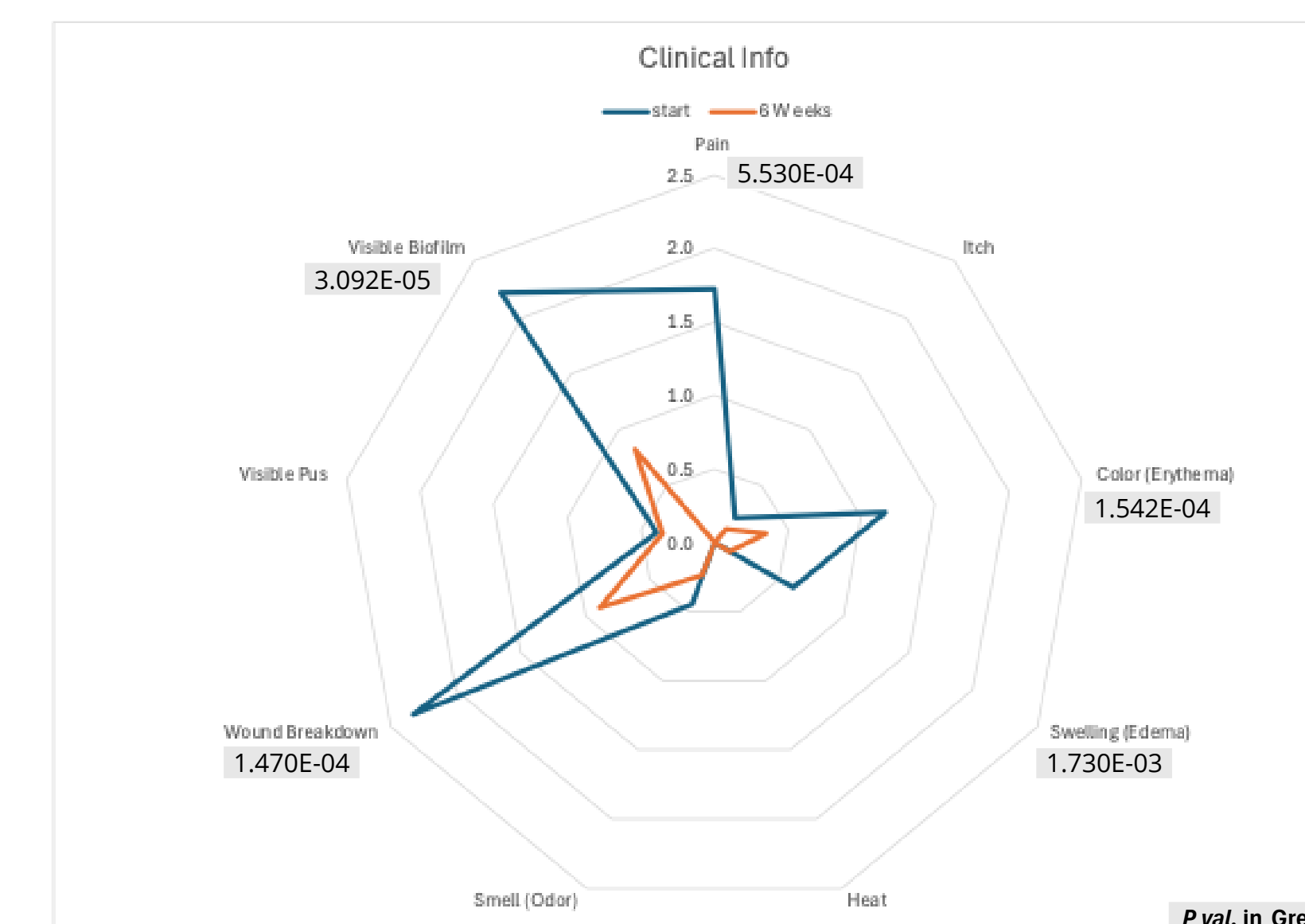


Figure 5. Observed clinical parameters (maceration, eschar and erythema) declined over the treatment period. The observations are from a non-randomized descriptive data set.

Results - Descriptive Observations Only

Percent area reduction (PAR), wound status, patient-reported outcomes, and clinical appearance parameters were recorded over time.

- PAR values fluctuated initially and increased over the 14-week observation period (Fig. 1).
- At week six, a subset of wounds had reached closure during care; closure cannot be attributed to Spectricept™ alone and may reflect multidisciplinary wound management (Fig. 2).
- Published venous leg ulcer compression therapy results are shown only for context; no comparative conclusions should be drawn (Fig. 3).
- Patients reported decreases in pain, itch, swelling, edema, erythema, drainage, and treatment difficulty from baseline to Week 6. These self-reported observations are exploratory only (Fig. 4).
- Clinical observations of maceration, eschar presence, and erythema trended downward during care. Statistical outputs reflect within-group change and do not establish product effectiveness (Fig. 5).

Conclusion

Controlled, prospective clinical studies are recommended to further evaluate outcomes associated with Spectricept™ within comprehensive wound care protocols.