

# A single-center, randomized, investigator-blinded comparative trial, topical proprietary Procedure Enhancement System (PES) vs. a basic regimen (bland ointment and cream) pre and post-fractional non-ablative laser resurfacing treatment to the face/décolleté.

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## Introduction

Fractional non-ablative lasers have become increasingly popular over the last few years to improve the appearance of skin rhytides, texture, dyspigmentation, and scarring. Traditional ablative laser resurfacing can involve significant downtime comprising erythema, dyspigmentation, pain, and a more labor intensive postoperative wound care regimen. Fractional laser treatment to the face or décolleté has an improved side effect profile which includes a decreased downtime of approximately 3-7 days, less pain, erythema, and dyspigmentation. Postoperative wound care regimens also tend to be less labor intensive due to the overall decreased side effect profile compared to nonfractional ablative lasers.<sup>1</sup>

However, additional improvements in recovery times, healing outcomes and symptomatology are still being sought by patients and clinicians particularly as many of these procedures are repeated as a series. In this regard, continuing to enhance the patient experience and decreased downtime are important parameters to treatment continuity and patient satisfaction.

## Objectives

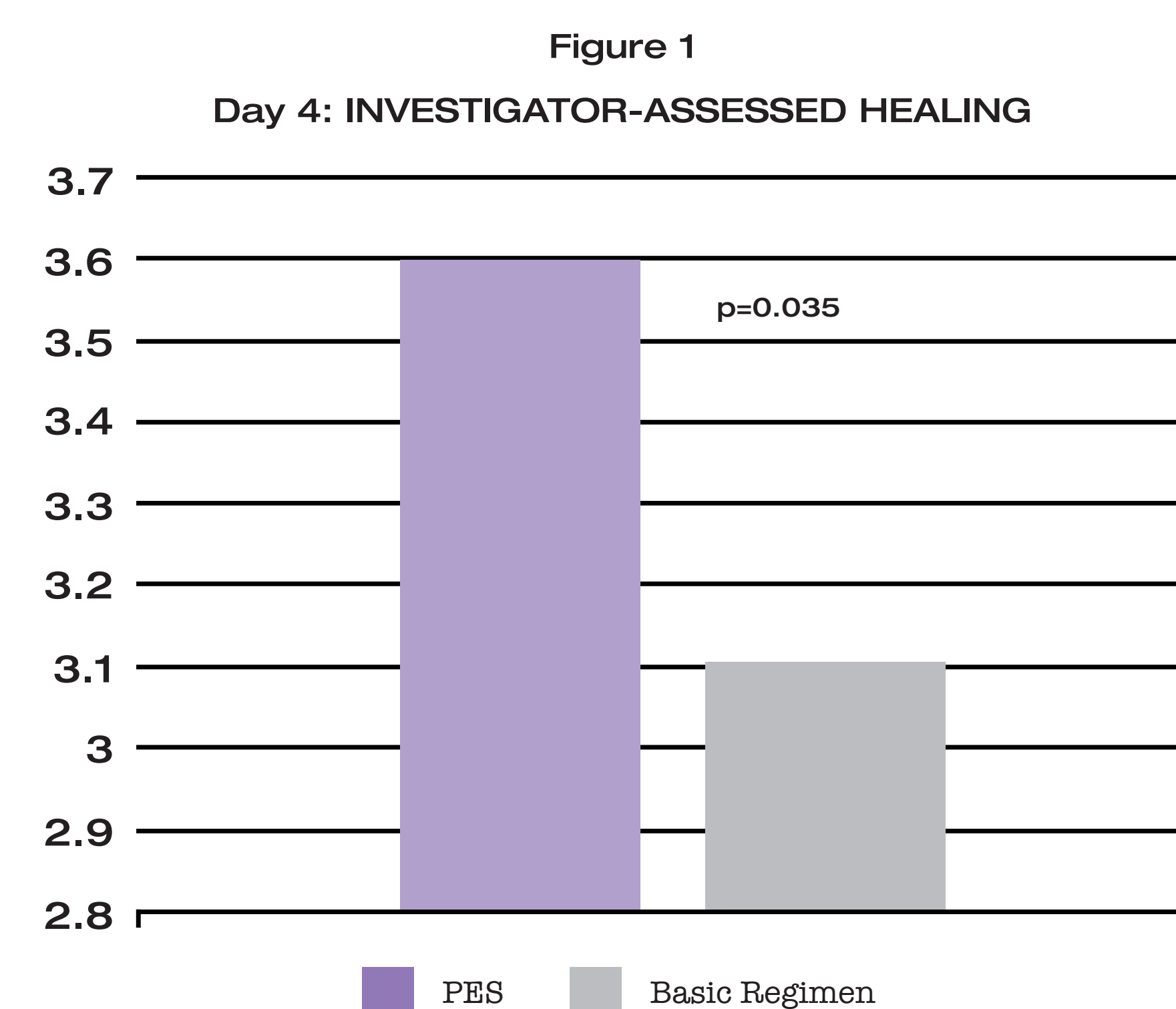
The objectives of this study were to evaluate the initial healing time and symptomatology with a new pre/post-laser resurfacing topical Procedural Enhancement System (PES) (Gentle Cleanser, Regenerating Skin Nectar (anhydrous gel) with TriHex Technology™, Ultra Nourishing Moisturizer with TriHex Technology™, Soothe + Protect Recovery Balm, Broad Spectrum 30+ Sunscreen) following Fraxel® Dual Skin Resurfacing treatment to the face or décolleté compared to a basic regimen (Aquaphor™ ointment, Cerave™ cleanser, Vanicream™, Broad Spectrum 30+ Sunscreen). This was assessed over the two week post-laser follow-up period.

## Materials and Methods

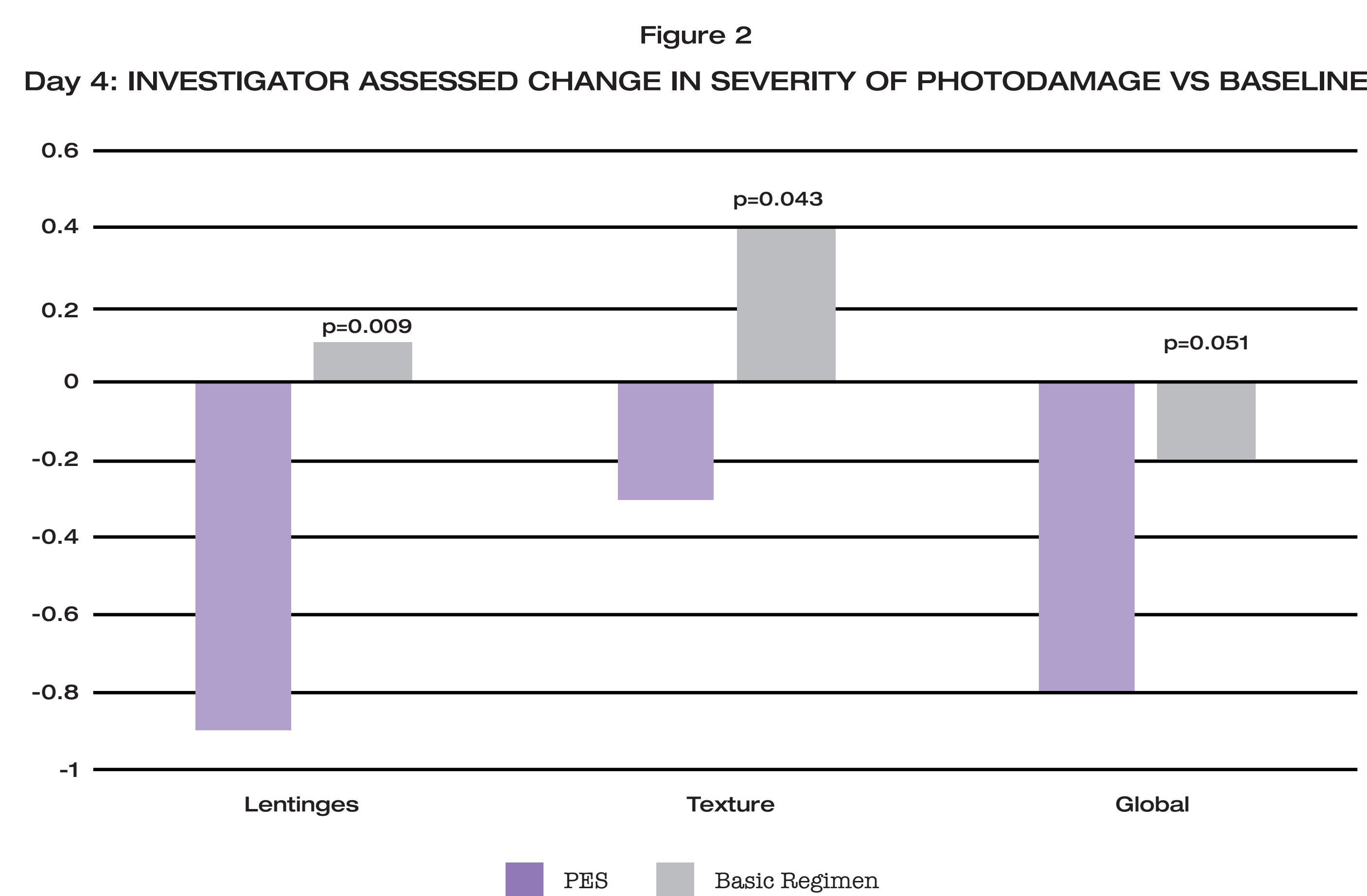
- Comparative split face/décolleté investigator-blinded randomized clinical study with a single study site.
- Ten (10) subjects were randomized to receive the PES on one side of their face or décolleté and the basic regimen on the other side of the face or décolleté pre and post fractional non-ablative laser resurfacing treatment.
- Two weeks (-17 to -14 days) prior to the procedure, subjects were randomized to receive the PES (minus the balm) on one side of their face or décolleté (right or left) and the basic regimen (minus the ointment) on the opposite side to be used twice daily until their next scheduled appointment.
- Following topical anesthesia application, the subjects underwent fractional non-ablative thulium doped 1927 nm Fraxel Dual; (Fraxel; Solta Medical Inc., Hayward, CA, USA).
- Immediately following the procedure (Day 1), postoperative randomized topical product (PES or basic regimen) was applied to the randomized side of the subject's face or décolleté by a non-blinded coordinator.
- The ointment was applied immediately postoperatively to the basic regimen side and PES anhydrous gel was applied to the PES side first followed approximately 2 minutes later with the balm.
- The subjects returned for follow up on postoperative days 2, 4, and 14.
- PES or basic regimen was applied as instructed to cleansed skin from days 1 to 14. The evaluating investigator was blinded to randomization schedule (performed by an unblinded coordinator). Standardized photography with DSLR system was utilized at all visits.

## Results

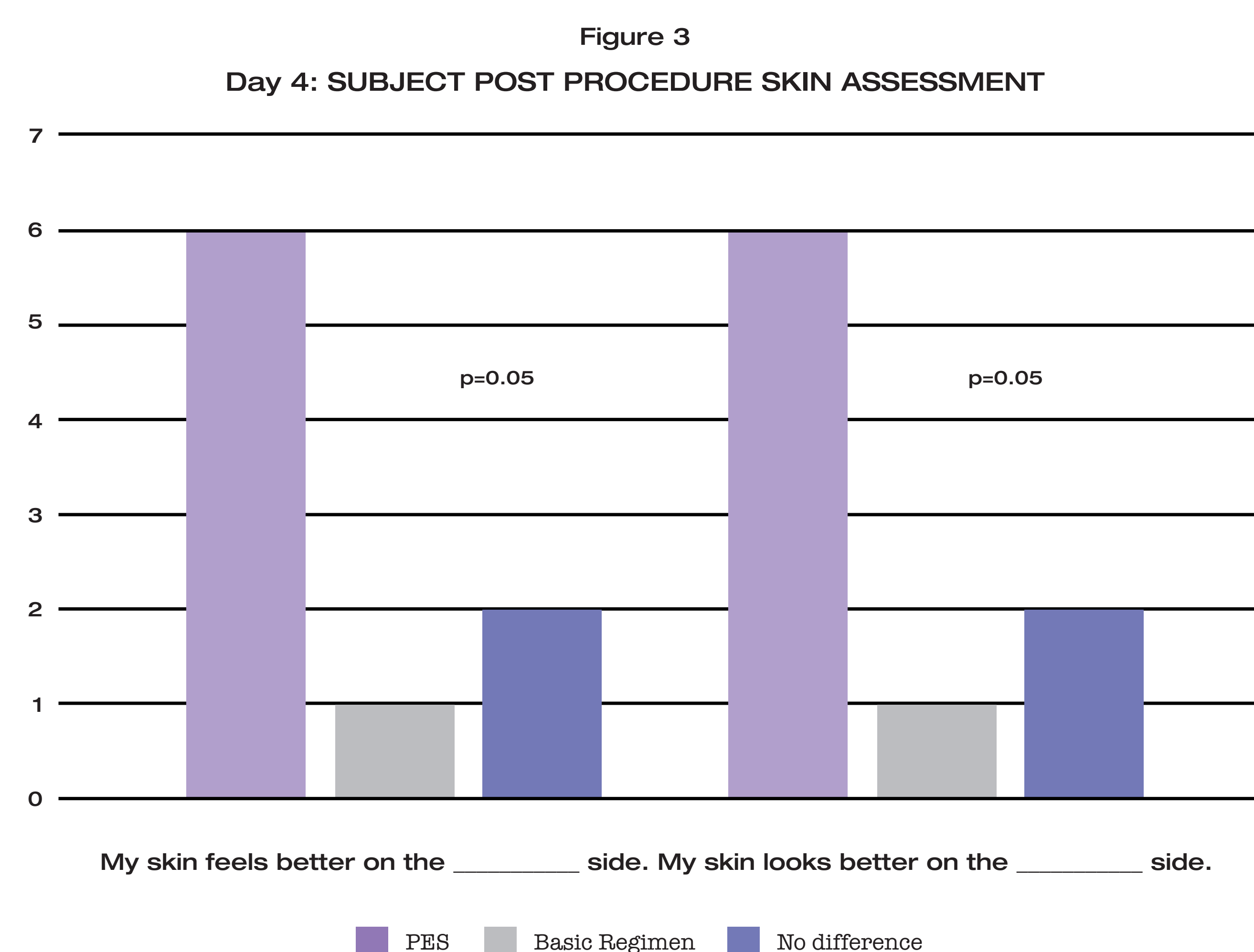
The blinded Investigator rated the PES, using a 5 point Healing Assessment Scale (0-4), as statistically superior ( $p=0.035$ ) to the basic regimen on healing post-laser treatment on Day 4 (Figure 1).



When compared to baseline values, using a 10-point Photodamage Scale, the blinded Investigator rated the PES as superior to the basic regimen on Day 4 on the following skin quality parameters: Lentigines ( $p=0.009$ ), Texture ( $p=0.043$ ) and Global Photodamage Assessment ( $p=0.051$ ) (Figure 2).



From the patients' perspective, on Day 4, subjects reported that their "skin looked better on the PES side" and "felt better on the PES side" ( $p=0.05$  on both parameters) based on a Subject Post Procedure Skin Assessment Questionnaire (Figure 3).



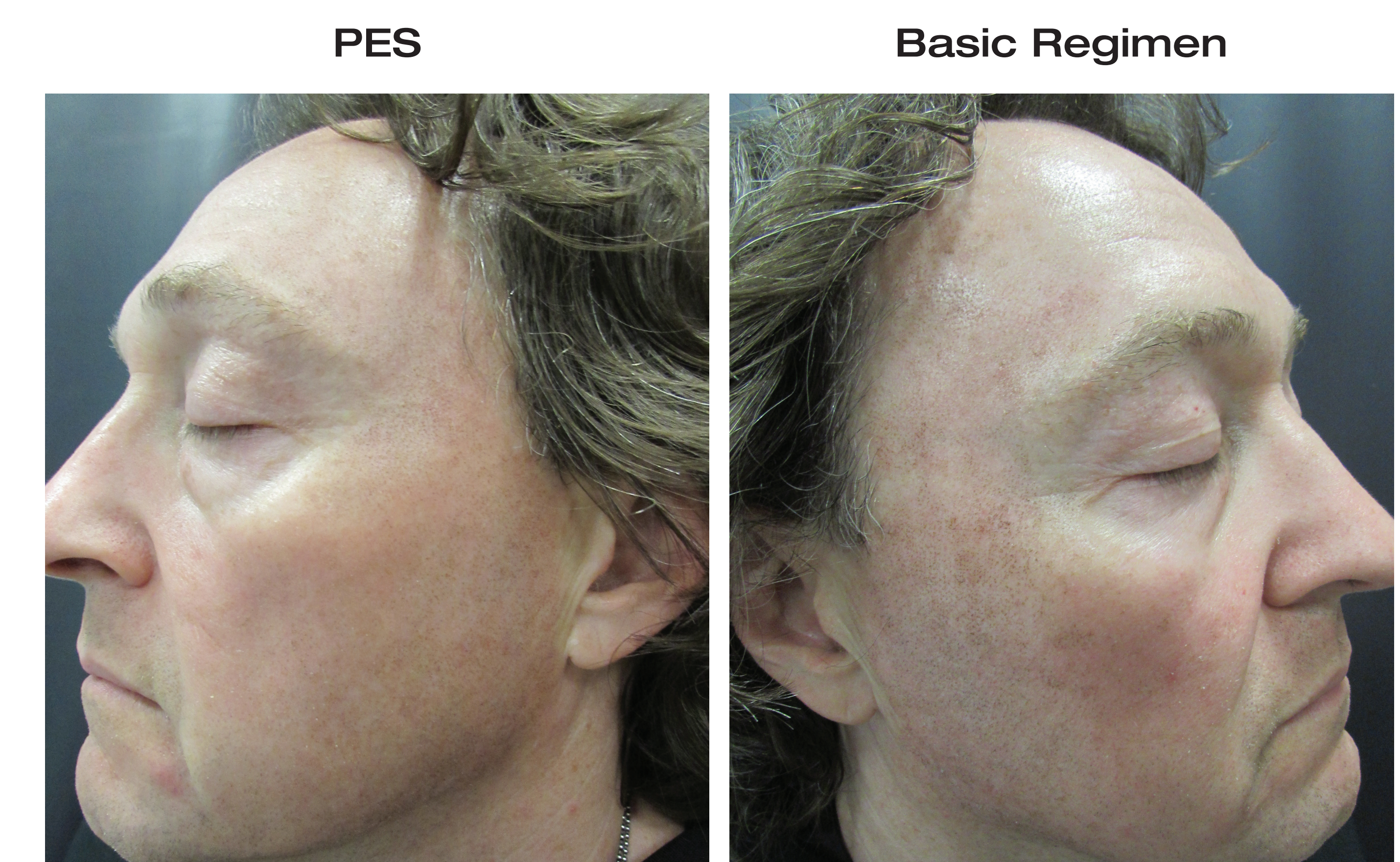
## Discussion

The Procedure Enhancement system (PES) with TriHex Technology has been designed as an adjunct to skin resurfacing and a variety of other rejuvenating procedures. The premise behind the technology is the clearing of the extracellular matrix (ECM) of the by-products of extrinsic photodamage and intrinsic aging<sup>2,3,4</sup>. These 'by-products' take the form of collagen and elastin fragments which 'clog' the ECM and disrupt cell to cell and cell to protein communication resulting in senescent non-productive fibroblasts<sup>4</sup>. The PES TriHex formulation clears the matrix in a pre-conditioning phase and then stimulates new collagen and elastin formation creating the ideal framework for regeneration following resurfacing procedures. Clinically this manifests in hastened healing and improved symptomatology.

In this series, healing was hastened in all cases and side effects were diminished. The cut off day when this was readily apparent appeared to be day 4, which is typical of the experiences seen in other trials<sup>5</sup>. Day 3 to 4 is typically distinguished by decreased erythema, crusting and finalization of epithelialization. Within a day or two, subjects are then able to enter society and continue with their lifestyle.

In this era of workplace pressures or purely from the impact on personal lifestyle, a day or two less in recovery phase can be very meaningful for a patient. Couple with this an improved procedure and recovery experience, the return rate and compliance for another session is thus improved.

Figure 4  
TYPICAL EXAMPLE OF IMPROVED HEALING SEEN AT DAY 4



## Conclusion

In keeping with other trial results with PES<sup>5</sup>, these products appear to improve healing post non-ablative fractional laser resurfacing treatment to the face/décolleté with Day 4 heralding the start of improved healing in the PES group and demonstrating the greatest overall difference between the PES and a basic regimen. In addition, the PES also improved overall skin quality more significantly than a basic regimen at the same timepoint, while maintaining overall greater subject satisfaction at study end on Day 14.

## REFERENCES

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