

# Randomized, Split-Face/Décolleté Comparative Trial of Procedure Enhancement System for Fractional non-Ablative Laser Resurfacing Treatment

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## ABSTRACT

**Introduction:** A topical proprietary procedural enhancement system (PES) containing a combination of active ingredients including a tripeptide and hexapeptide (TriHex Technology™, Alastin Procedure Enhancement Invasive System, ALASTIN Skincare™, Inc., Carlsbad, CA) has been used successfully to aid in healing and improve symptomatology following resurfacing procedures.

**Methods:** PES (Gentle Cleanser, Regenerating Skin Nectar with TriHex Technology™, Ultra Nourishing Moisturizer with TriHex Technology™, Soothe + Protect Recovery Balm, Broad Spectrum 30+ Sunscreen) was compared to a basic regimen (Aquaphor™, Cerave™ cleanser, Vanicream™, Alastin Broad Spectrum 30+ Sunscreen) in a split face/ décolleté trial following fractional non-ablative thulium-doped resurfacing treatment to the face or décolleté. The skin was pre-conditioned and treated during and after the procedure using the two regimens.

**Results:** A blinded investigator rated the PES statistically superior to the basic regimen on healing post-laser treatment on day 4 based on lentigines, texture, and Global Skin Quality. Subjects also reported 'better looking and feeling' skin on the PES side.

**Conclusion:** PES appears to improve healing post-non ablative thulium-doped resurfacing treatment to the face/décolleté in comparison with standard of care.

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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 of about 14 days comprising erythema, dyspigmentation, pain, and a more labor intensive postoperative wound care regimen. Fractional 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 fractional or fully 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. The proprietary procedural enhancement system (PES) is a kit that includes a series of topical skincare products containing an innovative blend of peptides and other ancillary actives (TriHex Technology™, Alastin Procedure Enhancement Invasive System, ALASTIN Skincare™, Inc., Carlsbad, CA) that clear the extracellular matrix and stimulate the skin to produce new collagen and elastin. Tripeptide, hexapeptide, and

other important actives in the PES also have antioxidant properties to decrease inflammation and irritation resulting in an accelerated epidermal healing process. In addition, the skin bed preparation pre-treatment regimen used for a period of two weeks prior to the procedure is expected to optimize procedure healing and outcome. The PES may therefore shorten downtime following fractional non-ablative laser resurfacing treatment to the face or décolleté. Additionally, there may be a cumulative effect with neocollagenesis and elastogenesis to improve overall skin quality.<sup>2,3</sup>

## MATERIALS AND METHODS

The objectives of this study were to evaluate the initial healing time and symptomatology with a new pre/post-laser resurfacing topical PES (Gentle Cleanser, Regenerating Skin Nectar 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™, Cerave™ cleanser, Vanicream™, Alastin Broad Spectrum 30+ Sunscreen). This was assessed over the two week post-laser follow-up period.

This was a comparative split face/décolleté investigator-blinded randomized clinical study with a single study site. Ten (10)

TABLE 1.

Investigator Healing Assessments at Days 2, 4, and 14								
Category	Visit	Treatment	No. of Subjects	Mean (SD)	Median	Range (Min, Max)	Mean Difference	P-value <sup>a</sup>
Skin healing post laser treatment with post laser skin care system	Day 2	PES	9	3.3 (0.71)	3	2, 4	0.11	0.594
		SOC	9	3.2 (0.44)	3	3, 4		
	Day 4	PES	9	3.6 (0.53)	4	3, 4	0.44	0.035*
		SOC	9	3.1 (0.33)	3	3, 4		
	Day 14	PES	9	3.9 (0.33)	4	3, 4	0.33	0.081
		SOC	9	3.6 (0.53)	4	3, 4		

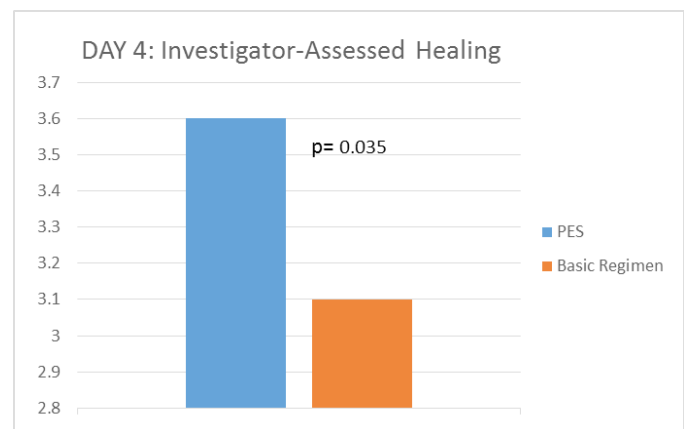
Blinded Investigator Healing Assessments			
Right		Left	
4	Excellent	4	Excellent
3	Very Good	3	Very Good
2	Good	2	Good
1	Fair	1	Fair
0	Poor	0	Poor

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 underwent screening and a pre-treatment visit where they were randomized to receive the PES on one side of their face or décolleté (right or left) and the basic regimen on the opposite side. Subjects were instructed to follow the pre-treatment application regimens to the corresponding side of the face or décolleté twice daily until their next scheduled appointment.

Following a single application of topical anesthesia for 30 minutes, 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), some components from the postoperative randomized topical product regimens (PES or basic regimen) were applied to the randomized side of the subject's face or décolleté by a non-blinded coordinator. The Aquaphor was applied immediately postoperatively to the randomized basic regimen side and for the PES regimen, the Regenerating Skin Nectar with TriHex Technology was applied first and approximately 2 minutes later the Soothe + Protect Recovery Balm.

The subjects returned for follow up on postoperative days 2, 4 (+/- 1 day), and 14 (+/- 2 days). PES or basic regimen was applied as instructed to cleansed skin from days 1 to 14. The modified regimens (omission of Aquaphor and Soothe + Protect Recovery Balm in each regimen accordingly were applied pre-treatment days -14 to 0 and days 4 to 14). The evaluating investigator was

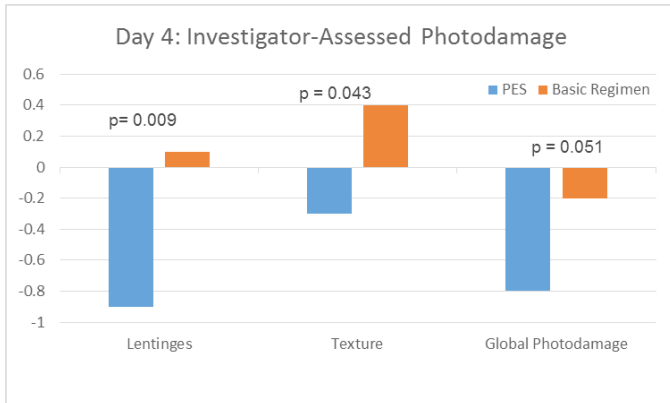
FIGURE 1. Improvement of healing starting at day 4.



blinded to randomization schedule (performed by an unblinded coordinator). Standardized photography with DSLR system was utilized at all visits.

## RESULTS

In this series, assessment of healing within the first week post-procedure was the primary endpoint. In particular, it was important to determine if a difference in healing and patient experience was evident from a particular day within the time span of that week. This appeared to be the case from day 4 post-laser treatment. The blinded Investigator rated the PES statistically superior ( $P=0.035$ ) to the basic regimen on healing post-laser treatment on day 4 onwards (Table 1; Figure 1). When compared to baseline values, the blinded Investigator rated the PES as superior to the basic regimen starting on day 4 on the following skin quality parameters: Lentigines ( $P=0.009$ ), Texture ( $P=0.043$ ) and Global Skin Quality ( $P=0.051$ ; Figure 2). From the patients' perspective on day 4, "skin looked better on the PES side" and "felt better on the PES side" ( $P=0.05$  on both parameters; Figure 3). Although day 4 is too early to assess long-term effect on lentigines, there was already improvement observed at 4 days. The long-term effect on lentigines was not followed as the final endpoint of the study was 14 days.

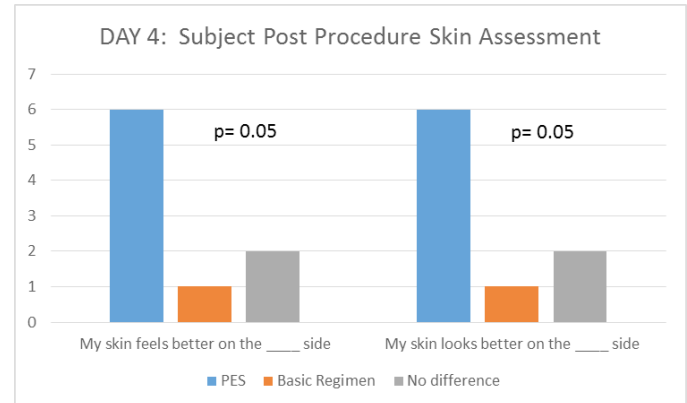
**FIGURE 2.** Photodamage parameters also improved in test group from day 4.

In addition to improved early healing, subjects reported that the PES significantly improved tone better than the basic regimen when compared to baseline values on day 14 ( $P=0.052$ ), the final study visit. Subjects also reported higher satisfaction with the PES with a desire to continue using the treatment regimen and recommend treatment regimen to others ( $P=0.016$  for both parameters).

## DISCUSSION

The proprietary PES has been designed as an adjunct to skin resurfacing and a variety of other rejuvenating procedures. The premise behind the technology utilizing tripeptide/hexapeptide and other critical synergistic ingredients is their combined ability to clear the extracellular matrix of the by-products of extrinsic photodamage and intrinsic aging.<sup>4</sup> These by-products take the form of collagen and elastin fragments, which 'clog' the extracellular matrix and disrupt cell to cell and cell to protein communication resulting in senescent non-productive fibroblasts. The proprietary technology 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 (Figure 4) and side effects were diminished. The first indication of apparent healing was day 4, which is typical of the experiences seen in other trials.<sup>5</sup> Day 3 to 4 was distinguished by decreased erythema, crusting, and finalization of epithelialization. Within 1-2 days, subjects were able to continue with their lifestyle. In this era of workplace pressures or purely the impact on personal lifestyle, a day or two less in recovery phase can be very meaningful to a patient. When coupled with an improved procedure outcome and recovery experience, it is likely that patients will be more receptive to continuing with a recommended series of treatments, and compliance for future session should also be

**FIGURE 3.** Subjective assessment – preferences for test product from day 4 onwards.

improved. Day 4 was chosen as the logical comparator as day 2 was felt to be too early to assess meaningful differences and by day 14 all patients had healed completely.

## CONCLUSION

This study was aimed primarily at examining healing and patient experience in the early stages of non-ablative resurfacing therapy. The final endpoint was therefore established at 14 days. In keeping with other trial results with PES, these products appear to improve healing post fraxel non-ablative thulium-doped 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

**FIGURE 4.** Cases at day 4 comparing split face/decollete results (PES=test product side).

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.

### DISCLOSURES

Study funded and materials provided by Alastin. Dr. Robinson is a Consultant for Alastin.

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