

Fractional, Non-Ablative Laser Therapy for the Treatment of Surgical and Trauma Scars

David B. Vasily, MD – Aesthetica Cosmetic and Laser Surgery Center, Bethlehem, PA 18018

Mary Cerino, RN - Aesthetica Cosmetic and Laser Surgery Center, Bethlehem, PA 18018

Overview

Until now, physicians have had limited options to address atrophic and hypertrophic scars. Treatment options include either traditional full-surface ablative therapy with its potential undesirable side effects and extended patient downtime or non-ablative therapy with only modest results. A new technology, fractional photothermolysis, has the potential to become the new gold-standard for scar treatment. Through photothermolysis, the non-ablative, fractional Erbium Glass laser (the Lux1540™ handpiece*, Palomar Medical Technologies, Inc. Burlington, MA) creates micro-columns of coagulated tissue that extend through the epidermis deep into the dermis. Over a course of well-tolerated treatments with minimal side effects and little to no downtime, this novel technique produces significant improvement in a broad range of surgical and post-trauma scars which may considerably enhance the patient's self esteem and quality of life.

Introduction:

Scars affect approximately 4.5 to 16% of the general population and, depending on the degree of disfigurement, can have a profound impact on the psyche of the patient (1). In addition to low self-esteem, patients may experience limited mobility, pruritus, pain, and/or dysesthesia (2-6). The two main types of scars include hypertrophic scars and atrophic scars. While hypertrophic scars often develop following surgical procedures, atrophic scars can result from traumatic injury to the tissue. Hypertrophic scars contain inappropriate accumulation of immature fibroblasts, elastin, collagen, and other cellular components and appear as either erythematous or hypo-pigmented raised bumps (7,8). Atrophic scars are dermal depressions caused by inflammatory destruction of dermal collagen (e.g. acne) or concomitant loss of dermis and thinning of epidermis following trauma (e.g. traumatic or splayed scars) (9).

* The Lux1540™ handpiece is pending US FDA clearance for the treatment of scars.

Early laser treatment of scars was performed with the continuous wave Nd:YAG laser or the CO₂ ablative laser, however, these treatments were associated with transient results, high rates of scar recurrence, extended downtime, and undesirable side effects (10-14). While the ablative, short-pulsed Er:YAG laser was developed to alleviate some of these shortcomings, these treatments yielded only modest clinical results. The current gold-standard for treating hypertrophic scars and keloids is the pulsed-dye laser in the 585 or 595 nm wavelength range (1,15). Although early studies with the 585 nm PDL demonstrated clinical improvements with minimal side effects and low recurrence rates, more recent studies have reported variable results for surgical and burn scars (16-24).

This report describes the use of a non-ablative, erbium laser (Lux1540). By creating micro-columns of coagulated tissue of approximately 150 μm in diameter that extend through the epidermis into the dermis, the Lux1540 evokes a wound healing response that removes the coagulated tissue and replaces it with healthy tissue. The intact, untreated tissue surrounding each microscopic wound allows for rapid re-epithelialization of the treated scar tissue. Because the 1540 nm wavelength is selectively absorbed by water in the tissue, it is safe for all skin types. The proximity of healthy tissue to the micro-column boundaries enables the migration of normal melanocytes which contributes to rapid pigment re-normalization. In contrast to side effects following traditional full-surface ablative therapies which may include oozing, crusting, infection, and hyper-pigmentation, subjects treated with the Lux1540 experience less pain and only transient edema and/or erythema lasting just a few days (13,14). One recent report describes the results of fractional photothermolysis for the treatment of one subject's surgical scar, stating clinical improvement of 75% (25). In this report, we present promising preliminary data from a clinical study examining the efficacy of Lux1540 treatments for the improvement of a broad range of surgical and trauma scars.

Scar Treatment Protocol

For optimal improvement of surgical and trauma scars, practitioners choose treatment parameters based on variables such as the type of scar, relief profile of the scar (indurated or raised), and any vascular or pigmentation components. For example, practitioners should use the 10 mm tip with energy settings of up to 70 mJ/microbeam (mb) to create the columns of coagulated tissue required for treating atrophic scars. In contrast, treatment of more superficial scars requires higher density/lower energy settings using the 15 mm tip. Hyper-pigmentation of a scar can be addressed with applications of the 10 mm tip (100 mb/cm²) at energies of 40-50 mJ/mb. Addressing scar microvasculature also requires the higher energy settings of the 10 mm tip. The versatility of the Lux1540 handpiece with interchangeable tips allows the practitioner to easily customize the treatment to the specific attributes of the scar.

Histology Characterization

To characterize the coagulation profile of the Lux1540 and to determine the appropriate treatment settings for our clinical study, we performed ex vivo histology with Hematoxylin and Eosin staining (H&E). As shown in Figure 1, ex vivo Yucatan abdominal skin was treated with a range of energy per microbeam with the Lux1540 device and then processed for histologic analysis to enable the correlation of energy to the resultant depth and width of thermal damage. Treatments at 66 mJ/mb resulted in deep coagulation columns of 800 μm depth and 160 μm width (panel A, dashed line). Increasing energy to 100 mJ/mb resulted in deeper and wider coagulation columns of 950 μm depth and 240 μm width (panel B, dashed line).

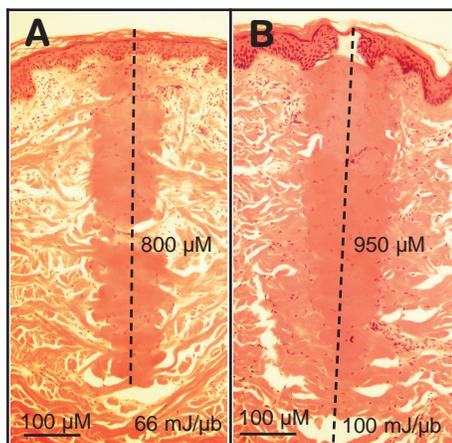


Figure 1. Ex Vivo Yucatan Pig Histology Showing Coagulation Profile Following Lux1540 Treatment at Varying Energy Levels. A) Treatments at 66 mJ/mb yield a 800 μm deep, 160 μm wide coagulation column while B) treatments at 100 mJ/mb yield a 950 μm deep, 240 μm wide coagulation column.

Results: Clinical Observations

In general, Lux1540 treatments are well-tolerated and result in only mild and transient side effects such as edema and erythema as opposed to the more extensive and persistent side effects of traditional full-surface ablative therapies. Results from our preliminary study investigating the use of the Lux1540 for scars demonstrate the efficacy of this device in successfully treating a broad diversity of Fitzpatrick skin types (II-V), scar types (burn scars, avulsion-like trauma scars, dog bites, post-surgical scars, tattoo-removal scars) as well as scars with varying degrees of dyspigmentation (hypo-pigmentation to hyper-pigmentation). Figures 2-4 illustrate examples of the observed significant clinical improvements.

The laceration scar of the right infra-orbital area shown in Figure 2 was previously treated with the onion-extract containing topical gel Mederma for 1 year, yet still appeared erythematous and raised (Figure 2, panel A). The 1 year-old scar received 5 treatments with the Lux1540 10 mm handpiece, at energy settings of 30-42 mJ/mb, a pulsewidth of 10 ms and coverage of 800 mb/cm². Within 2 months of the last treatment, the erythema is completely resolved and there is a much smoother transition from scar tissue to the normal surrounding skin (Figure 2, panel B).

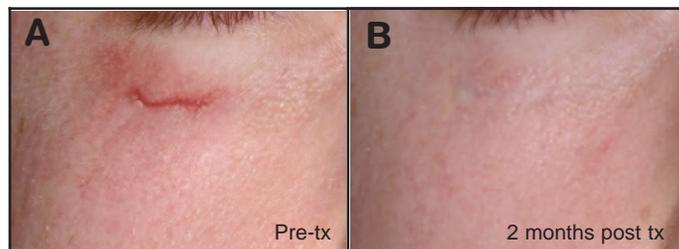


Figure 2. Significant Improvement in Laceration Scar. A) One-year old trauma scar appears erythematous and raised pre-treatment. B) By 2 months post-treatment, pigmentation has normalized and the scar appears flatter.

Figure 3 shows an example of a post-surgical scar following an avulsion-type injury which required microsurgery, nerve transplant and skin grafting. Prior to treatment, the scar appears hyper-pigmented with areas of depression (Figure 3, panel A). This subject received a total of 7 treatments with the Lux1540 10 mm handpiece at energy settings ranging from 30-38 mJ/mb, a 10 ms pulse width, and coverage of 600 mb/cm². At 6 weeks post-treatment, the hyper-pigmentation is drastically reduced and the scar appears softer and less-bound down (Figure 3, panel B).

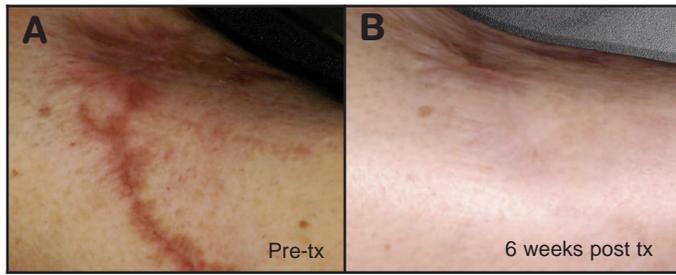


Figure 3. Lux1540 Treatment of Post-Surgical Trauma Scar. A) Before treatment, the scar is hyper-pigmented and depressed. B) Following treatment, the hyper-pigmentation and appearance are almost completely normalized.

The circular, hypo-pigmented scars shown in Figure 4 resulted from acute bullous dermatosis on the subject's arms (Figure 4, panel A). A total of 8 treatments were performed with the 10 mm handpiece at energy settings of 50-54 mJ/mb, a 10 ms pulse width, and coverage of 1000 mb/cm². Three weeks following treatment, the subject's scars are much less visible and pigmentation is close to normal (Figure 4, panel B).

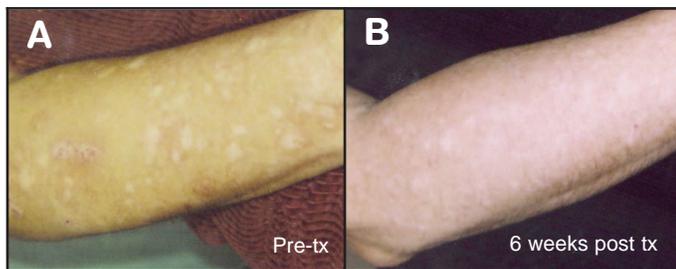


Figure 4. Normalization of Hypo-Pigmented Bullous Dermatitis Scars. A) The numerous circular, hypo-pigmented scars present on the subject's arm before treatment are almost completely resolved by B) 3 weeks after the 3rd treatment.

Discussion

Fractional photothermolysis using mid-IR wavelengths delivers clinically significant results for a variety of indications while minimizing the drawbacks associated with traditional full-surface ablative therapies including undesirable side effects and extended subject downtime. Indications successfully treated thus far with non-ablative fractional lasers include photodamaged skin (26), leucodermic scars (27), surgical scars (25), melasma (28,29) and non-facial skin rejuvenation (30). This report summarizes preliminary histologic and clinical data supporting the use of the Lux1540 in the treatment of post-trauma and post-surgical scars. Successful treatment of scars requires deep penetration through the epidermis and into the reticular dermis to evoke a dramatic healing response. Our ex vivo histology data confirm that, for particularly deep dermal scars, we can use settings as high

as 66 mJ/mb to 100 mJ/mb to produce coagulative depths ranging from 800 μ m to 950 μ m. Histology findings also confirm the close proximity of healthy tissue to coagulated tissue (i.e. column widths of 160 μ m for energy settings of 66 mJ/mb) which contributes to the rapid re-pigmentation of hypo-pigmented scars (Fig. 4B). Successful photothermolysis of scar microvasculature by the Lux1540 is illustrated by resolution of the redness present in erythematous scars prior to treatment (Figures 2B, 3B). The observed improvements in scar appearance and the softening in the transition from scar tissue to normal skin serve as evidence of the removal and replacement of the coagulated columns of tissue with new healthy tissue. Taken together, our histologic and clinical observations support the use of the Lux1540 as a preferred treatment alternative to the extensive downtime and side effects of CO₂ ablative lasers and the modest clinical improvements of 585 PDL lasers.

Conclusion

Over a course of well-tolerated treatments with minimal side effects and little to no downtime, the Lux1540 fractional non-ablative laser produces significant improvement in a broad range of scars. The Lux1540 offers a wide range of treatment options that can be tailored to the individual's skin type and nature of the scar to provide a safe and novel treatment modality.

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