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1440 nm and 1927 nm Nonablative Fractional Diode Laser: Current Trends and Future Directions

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The 1440 nm and 1927 nm Nonablative Fractional Diode Laser: Current Trends and Future Directions

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ABSTRACT

Clinical characteristics of skin exposed to ultraviolet and infrared radiation include dryness, dyschromia, laxity, roughness, sallowness, scaling, telangiectasia, and wrinkles. Fractional photothermolysis promotes skin remodeling by formation of new dermal collagen. The nonablative fractional diode laser (NFDL) system employs fractional photothermolysis to rejuvenate the skin, using 2 distinct handpieces for wavelengths of 1440 nm and 1927 nm. Fractional photothermolysis from nonablative fractional diode lasers facilitates delivery of small molecular-weight compounds, such as L-ascorbic acid, through the skin without compromising barrier function of the stratum corneum. Both handpieces of the NFDL system are effective for rejuvenation of photodamaged facial skin, providing clinical improvement in skin tone, skin texture, fine lines, and dyschromia and reducing the number of detectable skin pores. Application of the 1927 nm wavelength handpiece has shown clinical improvement of hyperpigmentation, melasma, and postinflammatory hyperpigmentation, which have been challenging to treat effectively with other laser devices. With a target chromophore of water, the infrared energy of the 1440 nm and 1927 nm NFDL system is appropriate for skin rejuvenation and treatment of dyschromia in skin of color, with a reduced risk of the adverse events observed with other nonablative and ablative fractional lasers. Clinical data have demonstrated that both the 1440 nm and 1927 nm wavelengths are effective, with high levels of patient satisfaction, transient side effects, and minimal patient downtime.

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INTRODUCTION

Skin exposure to ultraviolet (UV)B and UVA light and infrared radiation contributes to photoaging.[1] Irradiated skin is metabolically hyperactive with epidermal hyperplasia and neoplasia, increased production of elastic fibers and glycosaminoglycans, accelerated breakdown and synthesis of collagen, and proinflammatory processes.[1] Historically, skin rejuvenation of photoaged skin has involved invasive procedures.[2] Over time, demand has grown for less invasive treatments and reduced patient recovery time.[2,3] Moreover, procedures catering to all skin types are becoming increasingly popular. Mainstays include topical treatments such as retinoids, hydroquinone, and antioxidants. Nonablative fractional lasers for facial rejuvenation use midinfrared wavelengths ranging from 1320 nm to 1927 nm, which target water as a chromophore and preserve the corneal barrier. Treatment with a nonablative fractional laser may be performed in a clinical setting by a healthcare provider or, for some devices approved for patient use, at home.[4] Advantages of nonablative fractional lasers include rapid skin healing, as well as reduced risk of dyschromia, scarring, and infection.[2]

A nonablative fractional diode laser (NFDL) system with a 1440 nm wavelength handpiece (Clear + Brilliant® laser system, Solta Medical, Inc., Bothell, WA) was approved by the US Food and Drug Administration (FDA) in 2011 for general skin resurfacing. The 2.5 W 1440 nm wavelength handpiece has 3 fixed energy levels: low energy achieves a depth of 280 μm and 2% coverage (assuming 4 total passes across the treatment area); medium energy achieves a depth of 340 μm and 3.5% coverage; and high energy achieves a depth of 390 μm and 4.5% coverage. In 2012, the FDA approved the 1927 nm wavelength handpiece as an addition to this NFDL system (Clear + Brilliant Perméa®, Solta Medical, Inc., Bothell, WA). The 1 W 1927 nm wavelength handpiece has a fixed energy level (5 millijoule [mJ]/pulse) achieving a depth of 170 μm and a coverage of 2.5% (low), 3.75% (medium), or 5% (high), assuming 4 total passes. The Intelligent Optical Tracking® System (Solta Medical, Inc., Bothell, WA), a feature of both handpieces, ensures activation only when the handpiece scanner senses contact with skin, along with proper handpiece movement and velocity.

The 1927 nm wavelength handpiece of the NFDL system described above differs from another device, the 1550 nm erbium-doped and 1927 nm thulium laser system (Fraxel® Dual laser system, Solta Medical, Inc., Bothell, WA) in that the latter

TABLE 1.

Beam Profile Differences Between the 1927 nm Wavelength Handpiece of the Nonablative Fractional Diode Laser System* and the 1550 nm and 1927 nm Laser System†

Parameter	Nonablative fractional diode laser system 1927 nm wavelength handpiece*	1927 nm thulium laser†
Beam cross-section	Elliptical; nominal aspect ratio, 2.5:1	Circular
Spot size, µm	110-180‡	85-620
Pulse energy, mJ	Maximum, 5	5-20
Maximum pulse duration, ms	5	10
Pulse repetition rate, Hz	<150§	0-3000§
Treatment density per pass, MTZs/cm^2	Maximum, 50	8-850

*Clear + Brilliant Perméa® (Solta Medical, Inc., Bothell, WA).
†Fraxel® Dual laser system (Solta Medical, Inc., Bothell, WA).
‡Calculated by circle of equivalent area.
§Determined by handpiece velocity.
MTZs = microscopic treatment zones.

system employs higher power that is delivered through one handpiece (Table 1). The 1927 nm wavelength handpiece of the NFDL system produces an elliptical- to rectangular-shaped beam (Figure 1A) with an aspect ratio of about 2.5:1, and has a fixed spot size of between 110 and 180 µm (calculated by circle of equivalent area). The 1927 nm laser of the 1550 nm erbium-doped and 1927 nm thulium laser system produces a circular beam (Figures 1B and 1C) with a variable beam size, ranging from 85 to 620 µm. In addition, the higher powered 1550 nm erbium-doped and 1927 nm thulium laser system offers variable energy settings, in contrast to the maximum 5 mJ energy level of the 1927 nm wavelength handpiece of the NFDL system (Table 1). When using the NFDL system, topical anesthesia is optional, though recommended, and downtime for the patient is minimal.

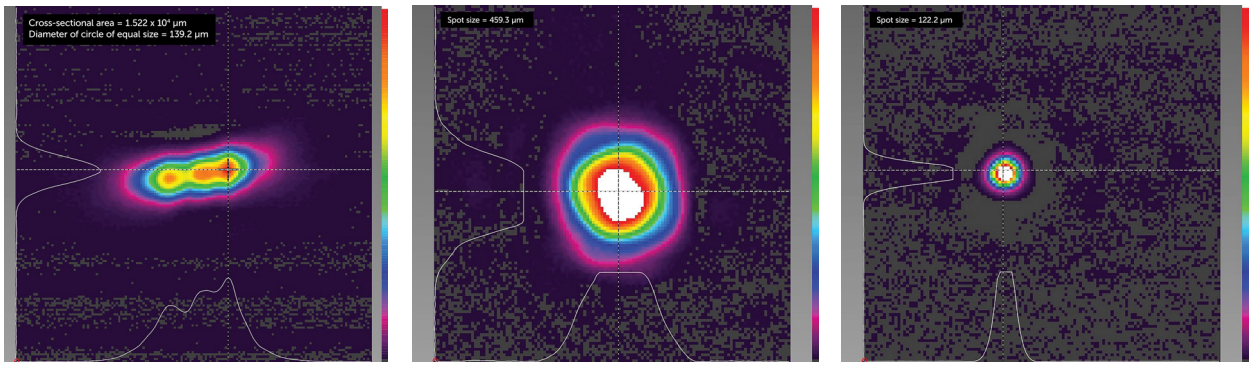
Patient satisfaction has been high with the 1927 nm wavelength handpiece of the NFDL system, and treatment has been well tolerated. In a study of 78 patients with Fitzpatrick skin type I–V and mild to moderate photodamage and/or dyspigmentation, patients received treatment every 2 weeks for a total of 6 treatments with the 1927 nm wavelength handpiece (4 passes; 5 mJ/pulse; treatment coverage: low, 2.5%; medium, 3.75%; high, 5%), combined with a topical serum containing 15% L-ascorbic acid, 1% alpha-tocopherol, and 0.5% ferulic acid.[5] Patients rated treatment satisfaction using a 5-point scale (1 = very satisfied; 5 = very dissatisfied). Most patients (86%) reported high satisfaction ("satisfied" to "very satisfied") with treatment at 2 weeks posttreatment (mean score, 1.7 ± 0.7). Patients observed improvement in skin texture, skin tone, and dyschromia. Furthermore, the treatment regimen was well tolerated, with transient erythema and edema lasting ≤24 hours; on an 11-point pain scale (0 = no pain; 10 = worst pain), the mean ± SD pain score immediately posttreatment across 6 treatment visits was 3.6 ± 1.7.

The objective of this manuscript is to provide an overview of the 1440 nm and 1927 nm Clear + Brilliant laser system and discuss current trends and future directions for its use.

Fractional Photothermolysis Promotes Skin Rejuvenation

Fractional photothermolysis as a mechanism for skin rejuvenation generates an array of microscopic areas of thermal injury to the skin (ie, microscopic treatment zones [MTZs]).[3,6] These zones of thermal injury induce focal dermal wounds while sparing surrounding tissue.[3] In a study of 12 individuals, a single treatment was performed on the forearm using a 1500 nm

FIGURE 1. Laser beam profile of the 1927 nm handpiece of the nonablative fractional diode laser system* (A) and the large beam (B) and small beam (C) of the 1927 nm thulium laser of the 1550 nm and 1927 nm laser system.†



*Clear + Brilliant Perméa® (Solta Medical, Inc., Bothell, WA).
†Fraxel® Dual laser system (Solta Medical, Inc., Bothell, WA).
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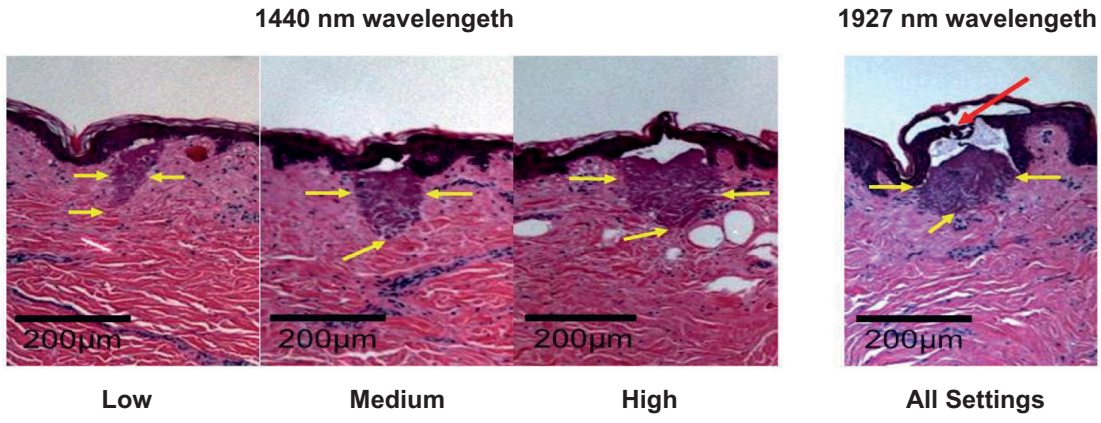
TABLE 2.

Measurement of Lesion Size Posttreatment With the 1440 nm and 1927 nm Nonablative Fractional Diode Laser System Obtained From Abdominal Skin Grafts[10]

Treatment*	Width, µm		Depth, µm	
	1440 nm wavelength handpiece	1927 nm wavelength handpiece	1440 nm wavelength handpiece	1927 nm wavelength handpiece
Low	120.1	220.7	281.8	167.4
Medium	163.1	220.7	339.3	167.4
High	201.6	220.7	384.2	167.4

*For a total of 8 passes, treatment levels (coverage) for 1440 nm wavelength handpiece were low, 4 mJ/pulse (4%); medium, 7 mJ/pulse (7%), or high, 9 mJ/pulse (9%) and for 1927 nm wavelength handpiece, with fixed energy (5 mJ/pulse), were low (5%); medium (7.5%); or high (10%).
Table reprinted with permission from Solta Medical, Inc.

FIGURE 2. Histology of microscopic treatment zone after treatment with the 1440 nm and 1927 nm wavelength handpieces of the nonablative fractional diode laser system.[10*]



*Ex vivo abdominal skin samples were treated with the 1440 nm wavelength handpiece (8 passes; energy level [treatment coverage]: low, 4 mJ/pulse [4%]; medium, 7 mJ/pulse [7%], or high, 9 mJ/pulse [9%]) and the 1927 nm wavelength handpiece (8 passes; 5 mJ/pulse; settings [treatment coverage]: low [5%]; medium [7.5%]; high [10%]), then subsequently paraffin embedded, sectioned, and stained with hematoxylin and eosin stain. Yellow arrows indicate borders of microscopic treatment zone and red arrow indicates a potential laser-tissue interaction.
mJ = millijoule.
Figure reprinted with permission from Solta Medical, Inc.

fractional erbium-doped laser prototype (5 mJ/pulse), with biopsies at 1 hour; 1, 3, 5, and 7 days; and 3 months after treatment.[7] Microscopic epidermal necrotic debris containing melanin and thermally damaged keratinocytic debris formed in the subgranular space within 1 day posttreatment and was intracorneal or shed from the epidermis by 7 days posttreatment.[7] Formation of new dermal collagen, to replace the thermally damaged collagen, was observed 3 months posttreatment.[7] Histologic assessments were consistent with this timeline of pigment migration and epidermal recovery in a study of 18 individuals treated on the forearm with the 1927 nm wavelength handpiece of the NFDL system (5 mJ/pulse; coverage, 5%–10%).[8]

As mentioned previously, an important advantage of nonablative fractional infrared lasers is that they target water molecules rather than melanin, and this improves safety profiles for use on Fitzpatrick skin type III–VI (darker skin types).[2,9] With the 1440 nm and 1927 nm NFDL system, the 1927 nm wavelength, compared with the 1440 nm wavelength, confers a higher absorption coefficient for water, thus generating wider and shallower MTZs independent of treatment coverage (Table 2; Figure 2).[10] Notably, interaction of the 1927 nm wavelength handpiece with the skin leaves the stratum corneum structurally intact, with a zone of subepidermal clefting and thermally altered dermal collagen (Figure 2).[10]

Fractional Photothermolysis Enhances Skin Permeability

Nonablative fractional photothermolysis thermally damages the epidermis in a pixilated pattern and enables laser-assisted topical drug delivery as an adjunct in the treatment of photoaging.[11,12] Topical uptake experiments (n=3) with the 1440 nm and 1927 nm NFDL system were performed on abdominal skin grafts (500-µm thickness) with an antioxidant serum contain-

TABLE 3.

Clinical Facial Applications of 1440 nm Nonablative Fractional Diode Laser[14,15]

Clinical Application	Study Design	Control	Patients, N	Treatment Protocol*	Results	Evidence†
Facial pores[14]	OS	Uncontrolled	20	8 passes; 6 treatments	++	4
Photodamage, Asian skin[15]	OS	Uncontrolled	10	8 passes; 4 treatments	++	4

*Treatment was at the highest tolerable energy level (4, 7, or 9 mJ/pulse).
†1a = systematic review of RCTs; 1b = individual RCT (with narrow confidence intervals); 1c = all or none study; 2a = systematic review of cohort studies; 2b = individual cohort study (including low-quality RCTs); 2c = "outcomes" research; 3a = systematic review of case-control studies; 3b = individual case-control study; 4 = case series; 5 = expert opinion without explicit critical appraisal or based on physiology bench research or "first principles."
+ = nonsignificant improvement; ++ = significant improvement; +++ = significant improvement over control; – = no improvement from baseline.
OS = observational study.
Table created with data from Saedi N, et al. *J Am Acad Dermatol.* 2013;68:113-118; and Marmon S, et al. *Lasers Surg Med.* 2014;46:375-379.

ing 15% L-ascorbic acid, 1% alpha-tocopherol, and 0.5% ferulic acid ± skin exposure to the 1927 nm wavelength (8 passes; 5 mJ/pulse; settings [treatment coverage]: low [5%]; medium [7.5%]; high [10%]), with assessment of permeation via high-performance liquid chromatography.[11,12] A dose-dependent uptake of the serum was observed, with an 8-, 12-, and 17-fold increase in enhancement ratios with low, medium, and high energy laser settings, respectively (Figure 3).[10-12] In another skin permeability experiment with different donor tissue, compared with skin not exposed to laser treatment, a 5-fold increase in the uptake of the serum was observed with the 1927 nm wavelength handpiece and a 2.7-fold increase with the 1440 nm wavelength handpiece (Figure 4).[10] These results indicate that the 1927 nm and 1440 nm handpieces can facilitate delivery of small molecular weight compounds through the skin without compromising the barrier function of the stratum corneum.

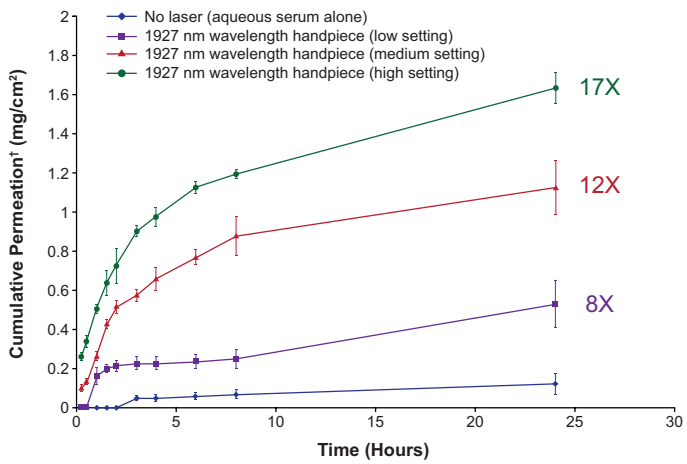
Clinical Applications

The 1440 nm and 1927 nm NFDL system has been studied for a wide range of applications. Studies have found a reduction in the number of detectable skin pores and improvement in photodamaged skin, melasma, postinflammatory hyperpigmentation (PIH), and hyperpigmentation (including ethnic/periorbital) following treatment (Tables 3 and 4).[13-20]

Skin Texture or Textural Changes

The safety and efficacy of the 1440 nm wavelength handpiece of the NFDL system for improving overall skin appearance and reducing detectable pores was demonstrated in a study in 20 patients[14] with Fitzpatrick skin type I–VI.[14] Patients received 6 treatments 2 weeks apart (± 3 days) at the highest tolerable energy level (8 passes; 4, 7, or 9 mJ/pulse). Digital imaging was used to determine a pore score (percentage of skin surface with detectable pores). Clinicians and patients also

FIGURE 3. Dose-dependent uptake of topical serum* after treatment with 1927 nm handpiece of the nonablative fractional diode laser system.[11]



*Contained 15% L-ascorbic acid, 1% alpha-tocopherol, and 0.5% ferulic acid.
†Cumulative permeation of L-ascorbic acid was determined by high-performance liquid chromatography.
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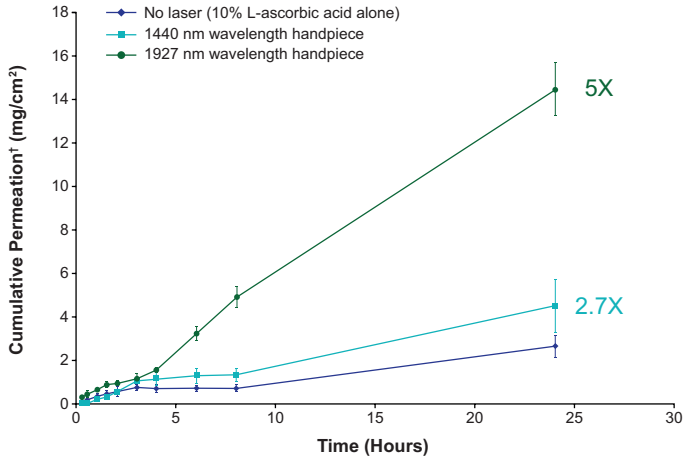
FIGURE 4. Uptake of topical serum* posttreatment with the 1927 nm and 1440 nm handpieces of the nonablative fractional diode laser system.[10]



*Contained 10% L-ascorbic acid.
†Cumulative permeation of L-ascorbic acid was determined by high-performance liquid chromatography.
Figure reprinted with permission from Solta Medical, Inc.

TABLE 4.

Current Clinical Applications of 1927 nm Nonablative Fractional Diode Laser[13,16-20]

Clinical Application	Study Design	Control	Patients, N	Treatment Protocol*	Results	Evidence†
Photodamage[13]	RCT	No serum	40	Multiple passes; 5%-10% coverage; 6 treatments	+	1b
Photodamage[20]	RCT	No laser	14	5% coverage; 3 treatments	+	1b
Photodamage/ Melasma/PIH[16]	OS	Uncontrolled	23	≤8 passes; 5%-10% coverage; 4-6 treatments	+	4
Melasma[17§]	R	Uncontrolled	11	8 passes; 5% coverage; ≤11 treatments	+	4
Melasma/ hyperpigmentation[18]	RCT	Bland moisturizer (no HQ cream)	40	8 passes; 5% coverage; 4 treatments	++	1b
PIH[19]	R	Uncontrolled	61	5% coverage; ≥2 treatments	+	4

*1927 nm wavelength handpiece fixed at 5 mJ.
†1a = systematic review of RCTs; 1b = individual RCT (with narrow confidence intervals); 1c = all or none study; 2a = systematic review of cohort studies; 2b = individual cohort study (including low-quality RCTs); 2c = "outcomes" research; 3a = systematic review of case-control studies; 3b = individual case-control study; 4 = case series; 5 = expert opinion without explicit critical appraisal or based on physiology bench research or "first principles."
‡1927 nm wavelength laser immediately followed by photodynamic therapy with topical ALA.
§595 nm pulsed dye laser followed by same-day treatment with 1927 nm wavelength laser for majority of patients.
+ = nonsignificant improvement; ++ = significant improvement; +++ = significant improvement over control; – = no improvement from baseline.
ALA = aminolevulinic acid hydrochloride; HQ = hydroquinone; PIH = postinflammatory hyperpigmentation; OS = observational study; R = retrospective; RCT = randomized controlled trial.
Table created with data from Elford EL, et al. Presented at American Society for Laser Medicine and Surgery Annual Meeting; April 20-22, 2012; Kissimmee, FL.; Brauer JA, et al. *J Drugs Dermatol.* 2015;14:1262-1267; Geddes ER, et al. *Lasers Surg Med.* 2017;49:20-26; Vanaman Wilson MJ, et al. *Dermatol Surg.* 2018;44:1304-1310; Bae YC, et al. *Lasers Surg Med.* 2020;52:7-12; Croix J, et al. *Lasers Surg Med.* 2020;52:53-60.

assessed pore appearance, skin texture, and overall appearance. A quartile improvement scale (0 = no improvement; 4 = very significant improvement [76%–100%]) was used to quantify changes posttreatment. A significant mean reduction from baseline of 17% ($P \leq 0.002$) in the pore score was observed 2 weeks after treatment 6. The clinician-rated mean improvement scores for pore appearance and overall appearance were 1.95 ± 0.3 and 2.75 ± 0.2, respectively; patient efficacy ratings were similar to clinician ratings. Patient satisfaction ratings were significantly associated with improvement in overall facial appearance ($P=0.001$). During treatment, the mean (± SD) pain discomfort score (0 = no pain; 10 = most painful) was 4.6 ± 0.1. Two weeks after treatment 6, 30.0% of patients (6/20) had mild erythema; there were no reported cases of edema, hyperkeratosis, hyperpigmentation, or hypopigmentation.

Photodamage

Skin damage related to chronic UV radiation exposure is characterized by actinic keratosis, atrophy, dyspigmentation, loss of dermal elasticity, lentigines, rhytids, and telangiectasia.[21,22] Other skin conditions that can be exacerbated by UV light include melasma and PIH.[16] Forty women with Fitzpatrick skin type I-IV received 6 treatments over the entire face with the 1927 nm wavelength handpiece of the NFDL system (multiple passes [number dependent on patient tolerability]; 5 mJ/pulse; coverage, 5%–10%) ± an aqueous serum containing 15% L-ascorbic acid, 1% alpha-tocopherol, and 0.5% ferulic acid.[13] Clinicians assessed improvement in fine lines, skin texture, dyschromia, and overall appearance at 1 week, 1 month, and 3 months posttreatment using a 5-point quartile improvement scale (0 = none; 4 = very significant). Women assessed side effects on a 4-point scale (0 = none; 3 = marked) and pain on an 11-point scale (0 = no pain; 10 = worst pain). Overall satisfaction was evaluated using a 5-point scale (range, 1 = very dissatisfied; 5 = very satisfied) at 1, 4, and 12 weeks posttreatment. Mild to moderate improvement (scores of 1–2) from baseline in all areas assessed was reported for the laser alone and laser + aqueous serum groups, with patients in both groups showing clinician-rated improvement in fine lines, skin texture, and dyschromia. Slightly larger improvements in dyschromia and overall facial appearance were observed with the 1927 nm wavelength handpiece + serum versus the 1927 nm wavelength handpiece alone. Numeric improvements from baseline in skin tone and skin texture were observed with the 1927 wavelength handpiece alone (Figure 5A), and improvements in skin tone, skin texture, and dyschromia were observed with the 1927 nm wavelength handpiece + serum (Figure 5B). Averaging data over 6 treatments for the

FIGURE 5. Example of skin improvement with 1927 nm handpiece of the nonablative fractional diode laser system (A) or 1927 nm handpiece of the nonablative fractional diode laser system in combination with aqueous serum* (B) assessed at baseline and 3 months posttreatment.

*Contained 15% L-ascorbic acid, 1% alpha-tocopherol, and 0.5% ferulic acid.
Data on file, Solta Medical, Inc. 2020.
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40 patients, a mean of 37 patients self-reported side effects on day 1 posttreatment, including redness (mean percentage of patients over 6 treatments, laser: 89%; laser + serum: 84%), edema (laser: 67%; laser + serum: 63%), and heat sensation (laser: 56%; laser + serum: 63%), which were scored as mild to moderate in intensity. Mean duration of these 3 side effects was shorter with the 1927 nm wavelength handpiece + serum versus the 1927 nm wavelength handpiece alone (5 days vs 7 days, respectively). Mean pain score across 6 treatments was 3.9 ± 0.2. On average, patients in both treatment groups reported being "satisfied" or "very satisfied" at each of the 3 follow-up visits (average score, 4.4), supporting ongoing patient satisfaction through 12 weeks posttreatment.

Pigmentary skin changes on cheeks are a predominant feature of aging skin in individuals of East Asian descent.[23] Treatment with the 1440 nm wavelength handpiece of the NFDL system has been shown to be safe and to improve photodamaged skin in an Asian population.[15] Ten Asian patients with Fitzpatrick skin type III–V received 4 treatments over the face at 2-week intervals with the highest tolerable energy level (8 passes; 4, 7, or 9 mJ/pulse). Two clinicians independently assessed digital images using an 11-point scale (0 = absent; 10 = severe) for each parameter (ie, skin roughness, wrinkles, dyspigmentation, pore size, skin laxity). Significant improvements from baseline were observed for skin roughness (P=0.006), wrinkles (P=0.046), and dyspigmentation (P=0.01) at 4 weeks posttreatment; no significant improvements from baseline were observed for pore size and skin laxity. Four of the 10 patients reported being satisfied with the treatment. After the final treatment session, most of the 10 patients reported mild to moderate treatment-related erythema (n=9), edema (n=10), and pain (n=9). One patient developed transient PIH that resolved by the follow-up visit (4 weeks posttreatment).

Dyschromia

The 1927 nm wavelength handpiece of the NFDL system has demonstrated efficacy in facial resurfacing for photodamage, melasma, and PIH.[16] In a prospective, noncomparative study, 23 women with facial photodamage, melasma, or PIH and Fitzpatrick skin type I–VI received 4 to 6 treatments with the 1927 nm wavelength handpiece over the face (≤8 passes; 5mJ/pulse; coverage, 5%, 7.5%, or 10%) 2 weeks apart (± 3 days). Density coverage and number of passes were established by the clinician, taking into consideration skin type, clinical diagnosis, and treatment response. Women were offered a choice of topical anesthesia prior to treatment. Digital images using standardized settings and conditions were obtained at baseline, and 1 and 3 months posttreatment. Baseline and follow-up photographs were randomized, and 3 independent clinicians blindly graded digital images for facial skin appearance using a quartile scale (0 = no improvement; 4 = very significant improvement [76%–100%]). If the baseline photograph was identified as best, the score was negative. Patient satisfaction was rated at 3 months posttreatment using a 5-point scale (1 = very dissatisfied; 5 = very satisfied). After each treatment, adverse events (AEs) and side effects were reported on a 4-point scale (0 = none; 3 = marked) and pain assessment on an 11-point scale (0 = no pain; 10 = intolerable pain).

The results of this study showed mean improvement at 1 and 3 months posttreatment (range 1.8 ± 1.5 [mild to moderate] to 2.3 ± 1.5 [moderate to marked]) according to the independent clinicians' assessment of photographs.[16] In addition, 55% of women reported marked to very significant improvement in overall facial skin appearance (51%–100%) at the 1-month and 3-month posttreatment follow-up visits. At 3 months posttreatment, 85.0% of the women (17/20) were "satisfied" or "very satisfied" with treatment results. The mean pain score

across 6 treatments was 3.4 ± 2.0, and 57% to 74% of women (depending on number of treatments) requested topical anesthesia. Side effects observed immediately posttreatment by most patients over the 6 treatments included mild edema and mild to moderate erythema and heat sensation. While severe edema was not observed, a few patients experienced severe erythema and heat sensation posttreatment. Desquamation (eg, flaking) was observed at 1 (n=1) and 3 months (n=2) posttreatment. PIH was observed on one Asian woman with Fitzpatrick skin type IV and resolved within 2 months posttreatment.

A retrospective analysis assessed 11 patients (Fitzpatrick skin type II [n=4], III [n=3], IV [n=4]) with melasma who had ≥1 treatment during a 2-year period with a 595 nm pulsed dye laser in combination with the 1927 nm wavelength handpiece of the NFDL system.[17] Patients were treated at 4 to 6 week intervals with the 595 nm pulsed dye laser (10 mm spot size; 10–20 ms pulse duration; 7.5–8.5 J/cm^2 fluence; dynamic cooling device spray duration 30 ms and delay 30 ms) followed, after ~10-15 minutes for skin cooling, by treatment over the entire face with the 1927 nm wavelength handpiece of the NFDL system (8 passes; 5 mJ/pulse; depth, 170 μm; coverage, 5%). An independent clinician assessed photographs and measured improvement in melasma and erythema using a 4-point scale (1 = 0 to <25%; 2 = 25% to <50%; 3 = 50% to <75%; 4 = 75% to 100%); patient-rated treatment satisfaction was assessed using a 3-point scale (0 = not satisfied; 2 = very satisfied). The mean number of combined treatments was 4 (range, 2–11), and the mean length of follow-up posttreatment was 96 days (range, 21–249 days). A >50% improvement from baseline in melasma and erythema was observed in 54.5% (6/11) and 63.6% (7/11) of patients, respectively. The 10 patients who had satisfaction data reported being "satisfied" or "very satisfied" with treatment (overall mean score, 1.6). No rebound melasma, PIH, postinflammatory hypopigmentation, or other AEs were observed. Of note, interim results from a separate clinical trial found improvements at 6 months posttreatment in 25 patients with melasma treated with the 1927 nm wavelength handpiece of the NFDL system in combination with topical tranexamic acid (personal communication, Roy G. Geronemus).

A randomized study was conducted with 40 patients with Fitzpatrick skin type III–V and moderate to severe facial hyperpigmentation (≥4 hyperpigmentation scale) related to photodamage or melasma.[18] Patients received 4 treatments at 2-week intervals with the 1927 nm wavelength handpiece of the NFDL system and were randomly assigned to apply topical hydroquinone 2% cream or bland moisturizer immediately after laser treatment with the 1927 nm wavelength handpiece (8 passes; spot size, 140 μm; 5 mJ/pulse; depth, 170 μm; coverage, 5%). Clinicians blinded to treatment evaluated digital images using the Mottled Pigmentation Area and Severity Index (MoPASI),[24] a 10-point scale (0 = none; 9 = severe) for hyperpigmentation and photodamage and the 5-point (1 = very much improved; 5 = worse) Global Aesthetic Improvement Scale (GAIS).[25] Additionally, patients rated satisfaction with their appearance using a 6-point scale (1 = extremely satisfied; 6 = extremely dissatisfied).

Results from this study showed significant improvements from baseline for both treatment groups at week 4 posttreatment in blinded clinician-assessed MoPASI scores (P≤0.001 for both groups), hyperpigmentation (P≤0.001 for both groups), and photodamage (hydroquinone, P=0.01; moisturizer, P=0.02).[18] Significant improvements from baseline were maintained through week 12 (P≤0.001 for both groups) for all 3 assessments. Compared with baseline, patients from both treatment groups were significantly more satisfied with their facial appearance at week 4 (hydroquinone, P=0.003; moisturizer, P≤0.001) and week 12 (P≤0.001 for both groups). When comparing the treatment groups, there was a significant difference in improvement from baseline in GAIS score favoring the laser + hydroquinone group at week 12 (P=0.02). Though patients in the laser + moisturizer group were significantly more satisfied with their appearance compared with those in the laser + hydroquinone group (P=0.02), overall 88.2% (30/34) of patients included in the study felt satisfied with their appearance at week 12.

A retrospective study was conducted with 61 patients with Fitzpatrick skin type IV (n=45), V (n=10), and VI (n=6) who had PIH. Patients received monthly treatments with the 1927 nm wavelength handpiece of the NFDL system (fixed spot size, 140 μm; 5 mJ/pulse; depth, 170 μm; coverage, 5%).[19] Determination of the number of treatments required for improvement of PIH and evaluation of response based on Fitzpatrick skin type were among the objectives of the study. Patients received 2 (n=15), 3 (n=14), 4 (n=16), or ≥5 (n=16) treatments. Two independent clinicians, who had a statistically significant correlation between their grading during the study, assessed improvement in pigmentary clearance from photographs taken prior to each treatment using a 0 to 100% numeric scale. Overall, the mean percentage (± SD) improvement in pigmentary clearance was 43.2% ± 25.4%. No significant differences in mean improvement from baseline were observed among patients receiving different numbers of treatments or across Fitzpatrick skin types, although authors noted a trend favoring darker skin types and suggested the study may have been underpowered to fully assess this parameter. There were no reported side effects or worsening of PIH with treatment. The 1927 nm wavelength handpiece of the NFDL system was safe and demonstrated at least moderate improvement for the treatment of PIH in darker skin types.

CONCLUSIONS

The technology of the Clear + Brilliant NFDL system employs fractional photothermolysis to rejuvenate the skin, using 2 distinct handpieces each with a different wavelength, 1440 nm and 1927 nm. Compared with the 1440 nm wavelength handpiece, energy from the 1927 nm wavelength handpiece is more efficiently absorbed by water, producing shallower, wider MTZs. Regardless of the mechanism, data demonstrate that both lasers are effective in a variety of settings, are well tolerated, and provide high levels of patient satisfaction. The generally mild and transient nature of side effects reported posttreatment suggests limited downtime for patients.

Both lasers have demonstrated efficacy for rejuvenation of photodamaged facial skin, clinical improvement in skin tone, skin texture, fine lines, and dyschromia, and reduction of the number of detectable skin pores. Application of the 1927 nm wavelength handpiece improved skin appearance in conditions such as hyperpigmentation, melasma, and PIH, which have been challenging to treat safely and effectively with other laser approaches. The infrared energy generated by the Clear + Brilliant NFDL system targets water, rather than melanin, as a chromophore, so this system is appropriate for skin rejuvenation in Asian skin and for treatment of hyperpigmentation and PIH in skin of color, with a reduced risk of the AEs associated with other nonablative fractional treatments.

Future studies for the NFDL system should consider a split-face prospective study design, which would allow for comparative analysis. Given most published studies have limited follow-up to ≤3 months posttreatment, long-term durability of this therapy is unclear. Patients are encouraged to continue with maintenance treatments to ensure longevity of results and address future cumulative damage. This is especially true with clinical studies focusing on patients with melasma. When assessing combination treatment regimens, it can be difficult to ascertain whether the effect is synergistic or due to a single laser. Future studies with controls or split-face design would best further our knowledge on this modality. Other potential areas of research with the NFDL system include use of modified protocols, administered in combination with other devices or with topical agents (eg, tranexamic acid), and identification of optimal re-treatment strategies. Finally, additional studies would be valuable to expand the current dataset of the NFDL system for the treatment of facial pores, a common complaint among patients.

DISCLOSURES

Paul M. Friedman has served on advisory boards for Allergan plc, Solta Medical, Inc., and Candela Corp, and as a consultant for Merz North America, Inc; has received grant funding from Sienna Biopharmaceuticals, Inc. and Candela Corp; has served as a principal investigator for Sienna Biopharmaceuticals, Inc.; and has received speaker honoraria from SkinCeuticals.

Kristel D. Polder has served on advisory boards for Allergan plc, Solta Medical, Inc., L'Oréal USA and has served as a principal investigator for Galderma and Allergan plc.

Pooja Sodha reports being a consultant for Solta Medical, Inc.

Roy G Geronemus has served on advisory boards for Allergan plc, Candela Corp, Cearna Inc., Cynosure, Cytrellis Biosystems, Inc., Lutronic, Soliton Inc.; has served as an investigator for Allergan plc, Candela Corp, Cynosure, Cytrellis, Biosystems, Inc., Endo Pharmaceuticals Inc., Kerastem, Lutronic, New York Stem Cell Foundation, Sciton, Inc.; and is a stockholder of Cytrellis Biosystems, Inc.

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