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ORIGINAL ARTICLE NON-SURGICAL AESTHETIC

Clinical Outcomes and Complications Associated with Fractional Lasers: A Review of 730 Patients

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Abstract

Background Fractional lasers were introduced to provide increased safety, while maintaining high efficacy and patient satisfaction. Patients with virtually all Fitzpatrick skin types could be safely treated using a wide spectrum of wavelengths and a broad array of skin conditions, and aging could be addressed. Although safety studies have been reported for ablative CO_2 and erbium lasers, surprisingly few data are available on adverse events and complications associated with fractional lasers.

Objective We report the frequency of adverse events, skin improvement and complications in a broad range of skin types using a standardized protocol that can be safely tailored to the patient's presenting complaints by varying the laser wavelength and number of treatments.

Materials and Methods The medical records of 730 patients (>90% females, age ranged from 50.5. to 59.9 years.) who had been treated at FACES+ Aesthetic Facility were reviewed. Patients were followed from 1 to 10 months and were reviewed to determine the frequency of complications, as well as their frequency, type, cause, treatment and resolution thereof. Patients were categorized by Fitzpatrick skin type (I–IV) to determine whether skin type was related to the frequency of complications. Improvement in skin condition (wrinkles, nasolabial folds and pigment) was rated by a technician before and after treatment using a Likert scale, 0–5, with 0 being no change and 5 being the most improvement.

Results Seven hundred thirty patients underwent procedures using fractional lasers in our center. Procedures were carried out with 3 different laser wavelengths, depending on the condition(s) treated (wrinkling vs. pigmentation issues, etc.) and the patients' desired length of downtime. The fractional Fraxel 1927-nm laser was used in 224 patients [Fitzpatrick skin type I (2.2%), II (38.4%), III (46.0%), IV (12.5%)]; the fractional Fraxel 1550-nm laser was used in 334 [type I (4.5%), II (31.9%), III (50.0%), IV (13.3%)], and the fractional Fraxel CO_2 laser was used in 172 [type 1 (4.7%), II (49.7%), III (41.5%), IV (4.1%)]. The Fraxel CO_2 laser showed greater improvement in wrinkles and naso-labial fold ($p < 0.001$). The greatest improvement in pigmentation was seen with the Fraxel 1927-nm laser ($p < 0.001$). Adverse events and complications occurred in 31 of 730 patients (4.2%). There was no significant difference in the rate of complications among the three treatments ($p = 0.26$). Complications were generally minor, and all resolved completely with treatment. Complications occurred in 4.0% of patients having the fractional Fraxel 1927-nm laser, 3.3% of patients having the fractional Fraxel 1550 nm and 6.4% of patients having the fractional Fraxel CO_2 laser. Complications included 5 herpes simplex virus breakouts, 13 acne eruptions, 1 abrasion, 1 bacterial infection, 9 dermatitis, 1 drug eruption, 4 prolonged erythema, 1 hyperpigmentation, 1 increased swelling and 1 telangiectasia. There was no significant relationship between Fitzpatrick skin type and incidence of complications ($p = 0.37$).

Conclusions Fractional lasers in general have reduced complication rates, while maintaining high degrees of patient satisfaction. Since their inception in early 2004, our clinic has utilized fractional lasers to treat patients from a variety of ethnic backgrounds and diverse skin types with an overall complication rate of 4.2%, all of which resolved. Comprehensive care of

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patients with facial aging is not limited to surgery alone and should include these types of strategies to appropriately and safely address photo-damage and photo-aging.

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Keywords Fractional lasers · Complications · Outcomes

Manuscript

Lasers have been part of dermatology and plastic surgery practices for over a decade to improve tissue tone and texture, laxity, treatment of digital cutis laxa [1], rhinophyma [2], melasma [3], pigmentation [4], acne scarring [5, 6] and atrophic scars [7] as well as surgical scars [8] and depressed alar scars [9] following surgery. Carbon dioxide (CO_2) and erbium ablative lasers were previously considered the gold standard; however, after fractionated resurfacing was introduced, fractional lasers became the most commonly used laser due to decreased recovery time and risk of adverse events [10]. The introduction of fractionated lasers offered increased safety while maintaining high efficacy. An additional benefit is that darker Fitzpatrick skin types IV and V could be safely treated [20].

The Fraxel Restore laser (Solta Medical Inc. Haywar, CA 94545) was introduced to plastic surgeons in 2004 [11]. The Restore model is a 1550 wavelength fractionated erbium laser, which creates microthermal zones (MTZ's) in a targeted fraction of the epidermis and mid-dermis layer while leaving surrounding tissue intact and minimizing downtime [12]. This laser will be referred to as the Fraxel 1550-nm laser for the remainder of this manuscript. The intensity of treatment is varied based on the total density (total number of MTZ's deposited per square centimeter) and energy (expressed in millijoules) applied for each treatment. The expected reaction for each treatment is pigment reduction, increased tone and texture as well as collagen remodeling within the tissue (Figs. 1, 2, 3).

The Fraxel Repair was introduced in 2007. The Repair model is a 10,600 wavelength fractionated CO_2 laser that creates microscopic zones of thermal injury at different depths of the dermis to treat pigmentation, tissue laxity, texture and collagen stimulation [13]. This laser will be referred to as the Fraxel CO_2 laser for the remainder of this manuscript. This laser is more aggressive and therefore provides greater results per treatment with moderate downtime and low risk of adverse events [10].

In 2009, the dual platform was introduced which included both a 1927 and 1550 wavelength fractionated erbium/thulium laser that creates microthermal zones in a targeted fractionation of the epidermis. This laser will be referred to as the Fraxel 1927-nm laser for the remainder of

Fig. 1 A 48-year-old female, treated with Fraxel 1927 nm, developed post-treatment prolonged redness that was treated conservatively with moisturizers. One month post-complication photograph showing significant improvement

Fig. 2 A 47-year-old female, treated with Fraxel 1927 nm, developed chest skin staphylococcal infection that was treated with Bactrim for 1 week. Two-week follow-up showing significant improvement

Fig. 3 A 36-year-old female, treated with Fraxel 1927 nm, developed acneiform eruption that was treated with Bactrim for 1 week. One-month f/up photograph showing significant improvement

this manuscript. Depending on the surface area the individual wants to treat, changes in both total density and energy will be made. Both the Fraxel 1927-nm and 1550-nm lasers allow individuals to be treated efficaciously with minimal downtime and a low risk of adverse events. Within our practice, many patients prefer the Fraxel 1550-nm and 1927-nm laser due to the lack of downtime, despite the need for more treatments to replicate results similar to the Fraxel CO_2.

Though fractionated lasers have less patient recovery time than full ablative CO_2 lasers, they still are associated with some short-term complications [10, 14]. The most common complications of fractionated skin resurfacing are prolonged erythema, acne and milia, delayed purpura, superficial erosions, contact dermatitis and recall phenomenon. Moderately severe complications include infection, pigmentary alteration, anesthesia toxicity and eruptive keratoacanthomas, whereas severe complications include hypertrophic scarring, ectropion formation and disseminated infections [13, 14]. Brauer et al. evaluated 39 patients after treatment with the Fraxel 1927-nm laser and found 68% at 1 month and 51% at 3 months had overall moderate to very significant improvement in lentigines and ephelides after two treatments. Patients had moderate erythema, mild edema and mild skin roughness throughout all treatments; however, investigators reported that no serious adverse events related to treatment were observed or reported [16]. Naouri et al. discussed in their article the side effects and immediate complications following ablative fractional CO_2 resurfacing utilizing a laser other than the Fraxel CO_2. In their retrospective study, they evaluated 46 treatments and reported 21.7% complications. A total of 10.6% of complications were due to facial herpes, 8.7% of complications occurred from inflammatory reactions, which included severe facial swelling, and 2.2% were due to acne. They discussed that even though none of their complications were particularly severe, they were high when evaluated in comparison to the Fraxel [17]. Manstein et al. described in their article the effects of multiple passes on cadaver abdominal tissue using nonablative fractional resurfacing. Results indicated that the thermal injury zone was directly related to the pulse energy, and therefore, as more passes were completed, there was an increased number of microscopic treatment clusters. They reported that more studies are needed to accurately determine the impact of these results [18]. In the particular study examined in this paper, we used the scale presented by Metelitsa and Alster to format our complications and rate as short term or long term [14, 15].

The purpose of this study was to evaluate the safety and efficacy of three types of lasers (Fraxel 1550 nm, Fraxel 1927 nm and Fraxel CO_2) used to treat patients with Fitzpatrick skin types I–IV. After reviewing patient records, Fitzpatrick skin types V–VI were excluded due to a lack of statistically significant number of participants with these skin types.

Materials and Methods

The results of treating 730 patients undergoing fractional laser treatments were examined retrospectively using a chart review from 2004 to 2014. Their medical records were examined to identify the Fitzpatrick skin type, laser energy used (millijoules), and treatment level (percentage of fractionation). The frequency of complications, the cause, treatment and resolution were also identified. Pre- and post-treatment photographs were reviewed to evaluate wrinkles, naso-labial fold and pigmentation improvement. Most of the patients treated were female for all 3 types of lasers. The energy treatment range for Fitzpatrick skin types I–III using the Fraxel 1550-nm laser was 40–50mj, treatment level 7 with 8 passes, and for skin types III–IV between 30 and 40mj, treatment level 5, also with 8 passes. The average energy used to treat for Fitzpatrick skin types I–III using the Fraxel 1927-nm laser was 10mj, treatment level 3, and for skin type III–V was 5mj, treatment level 1 with 8 passes. The average energy used for Fitzpatrick skin type I–III using the Fraxel CO_2 laser was 40mj, treatment level 10 with 4 passes. The energy treatment protocols for different Fitzpatrick skin types are delineated in Figs. 4, 5 and 6.

Patient Selection

Patients were selected for the three different lasers based on the condition the patient was most concerned about (pigmentation vs wrinkles) and length of downtime. Fraxel 1927 nm is used for fine lines and pigmentation, the Fraxel 1550 nm for deeper wrinkles and acne scarring, and the

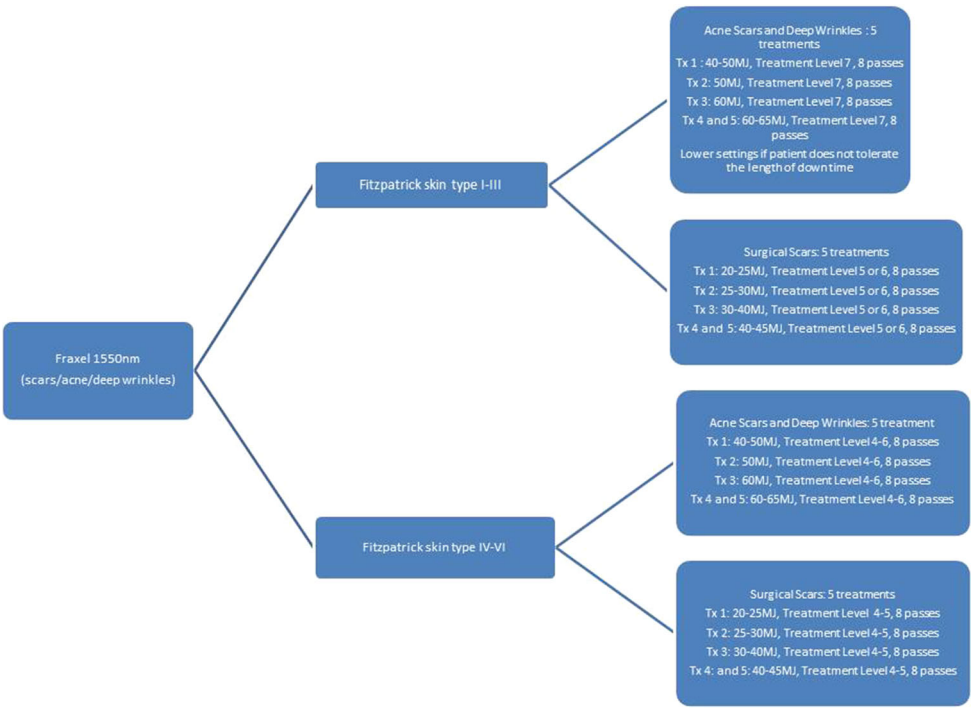

Fig. 4 Protocol for Fraxel 1550 nm

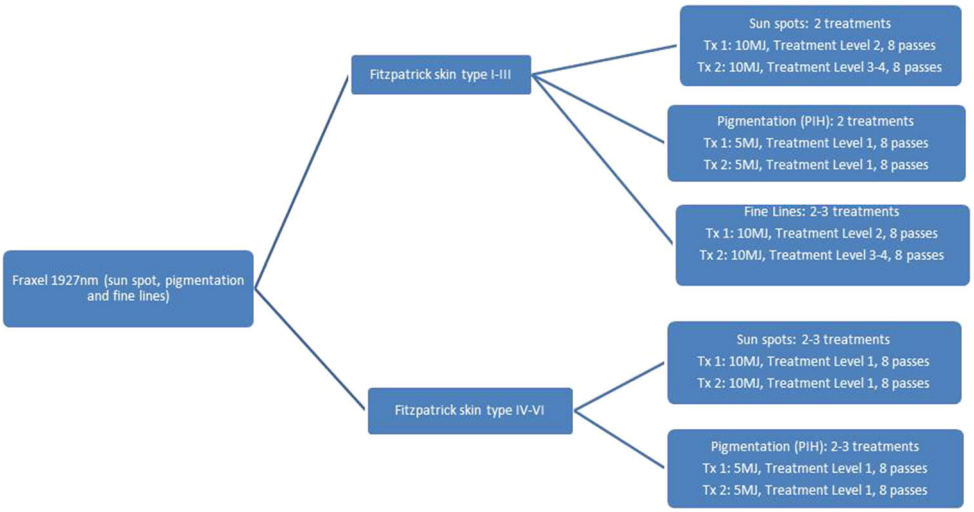

Fig. 5 Protocol for Fraxel 1927 nm

Fraxel CO_2 for any of these target conditions when greater results from fewer treatments are desired. A laser nurse, physician assistant or plastic surgeon initially evaluated the patients. Settings and number of treatments were jointly determined by the patient, nurse, physician assistant and physician, depending on the complexity of the case. Number of treatments was determined based on achievement of esthetic outcome wanted by the patient, as well as finances and occurrence of complications. Treatment settings were based on Fitzpatrick skin type and desired outcome. A pre-treatment appointment was made 1–2 weeks prior to the procedure to answer all patients' questions, give patients prophylactic medication, take pre-treatment photographs and discuss skin care prior to and after treatment as well as expectations.

Standardized Protocol

Prophylactic Valtrex (GlaxoSmithKline, Research Triangle Park, NC) 500 mg 1 tab PO BID was started 48 h prior to treatment administration in all patients with a history of herpes simplex virus (HSV) when using the Fraxel 1927-nm or 1550-nm lasers. Administration of prophylactic antiviral and antibiotic (Keflex, unless allergy was noted; then, clindamycin was given) medication was given to all Fraxel CO_2 laser patients regardless of HSV history.

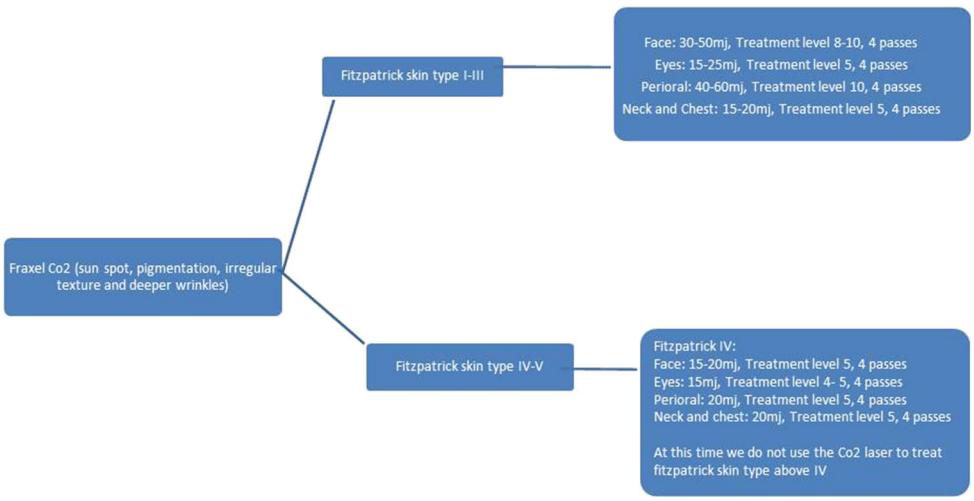

Fig. 6 Protocol for Fraxel Co_2

Instructions were given to discontinue all irritating or abrasive products (Retina-A, glycolic, salicylic, lactic acids, benzol-peroxides or any facial cleansing scrubs) 3 weeks prior to treatment and 6 weeks post-treatment.

Patients arrived 1 h prior to treatment to sign informed consent forms, discuss any questions they might have and apply lidocaine–tetracaine 23/7% ointment (La Vita Compounding Pharmacy, San Diego, CA). The ointment was removed after an hour, and the skin thoroughly cleansed (Neocleanse, gentle cleanser, Neocutis Inc., San Francisco, CA) without the use of acetone or alcohol.

Fraxel 1927-nm and 1550-nm Laser Protocol

Treatment settings (energy in millijoules (mj) and treatment level) were selected based on Fitzpatrick skin type, indication of treatment and area of treatment. All patients were treated with eight passes. An estimated amount of kilojoules (kj) was determined prior to treatment, and the actual kj were recorded in the patient's chart. Patients were treated concomitantly with a Zimmer cooler attached to the Fraxel laser. An epidermal cream [Sente (Sente Inc, Carlsbad, CA)] and sunscreen [Faces+ Sunscreen, (La Vita Compounding Pharmacy, San Diego, CA)] were applied to the skin post-treatment. Patients were also evaluated for discomfort on a subjective scale of 0–10 during the treatment where 0 represents no pain and 10 represented the highest amount of pain. Immediately post-treatment, patients were evaluated for erythema, edema, pinpoint bleeding and exudates present using a scale of 0–3 (0 = none 1 = mild 2 = moderate 3 = significant). Patients were then able to have an oxygen facial post-treatment (Intraceuticals, Long Beach, CA) by an esthetician immediately following the laser treatment. Oxygen treatments hydrate tissue and promote healing [19]. A phone call was made to each patient during the first week after treatment to follow-up on their healing. Patients who did not have any complications were brought back to the office at 4–6 weeks for follow-up photographs and further evaluation. Patients with complications were seen regularly until resolution of the adverse event.

Fraxel CO_2 Laser Protocol

CO_2 lasers were performed under Monitored Anesthesia Care (MAC) at an American Association for Accreditation of Ambulatory Surgery Facility (AAAASF). The anesthesiologist evaluated all CO_2 laser patients 1–2 weeks prior to the treatment to make sure they were good candidate for MAC. Treatment settings were charted in the same way as described above. Four passes were used for each treatment. Estimated kj were determined before the treatment was performed and actual kj were recorded in the chart. The Zimmer cooler was attached to the laser during treatment to alleviate discomfort and burning. Application of Aquaphor (Beiersdorf Inc, Wilton CT) was applied post-treatment. Patients were recovered and released once vital signs were stable and the patient was ambulatory and cleared by the anesthesiologist. Patients were evaluated for discomfort within the first hour post-treatment in the manner described above. Fraxel CO_2 laser patients underwent an oxygen treatment at day 10, with an average of three treatments between days 10–21. Patients were contacted by phone 1 day post-treatment and with in-office evaluations at days three, five and ten, and again at 3 and 6 months. If complications occurred, patients were seen as soon as possible and regularly until problem resolved.

Results

A total of 730 patients (three of which provided incomplete data and three were eliminated due to insufficient number of subjects for skin type V) that included Fitzpatrick skin

types I–IV were reviewed and included in the study analysis (Table 1). For the Fraxel 1927 nm, a total of 224 patients were treated, 101 of these patients had only one treatment, but the numbers ranged up to 10 treatments per patient. Three hundred thirty-four patients were treated with the Fraxel 1550 nm, 34 of whom had only one treatment, and the numbers ranged up to 12 treatments performed per patient. Follow-up treatments with the 1927-nm and 1550-nm lasers occurred at 6–8 weeks. For the Fraxel CO_2 laser, 172 patients were treated, and in the majority of patients a single treatment was done and continued maintenance was provided by the Fraxel 1927 nm or Fraxel 1550 nm, depending on desired outcome. At least 1 year is allowed before follow-up treatments to the Fraxel CO_2. The treatment of 154 patients (21.1%) used more than one type of laser for treatment. Of the 730 patients, age range was between 20–88 years (mean age 52.7) for the Fraxel 1927 nm, 17–72 years (mean age 54.3) for the Fraxel 1550 nm and 25–85 years (mean age 61.5) for the Fraxel CO_2. They were followed post-treatment anywhere from 1 to 10 months after the initial treatment. Fitzpatrick skin types ranged from I–IV. The majority of patients treated with the Fraxel 1927 nm and 1550 nm were type III. The majority of patients treated with the Fraxel CO_2 were type II.

Improvement in skin condition was determined by a technician rating the before and after photographs of patients on a scale of 0–5, 0 indicating no improvement and 5 indicating full improvement. Statistical analysis using the Kruskal–Wallis Test gives the median improvement index of three skin conditions treated by the Fraxel lasers—wrinkles, naso-labial fold (NLF) and pigment. Results indicate that the Fraxel CO_2 has the highest rate of improvement for wrinkles and NLF, while the Fraxel 1927 nm has the highest rate of improvement for pigmentation (Table 2).

Complications occurred in 31 of the 730 patients, with 26 patients reporting 1 complication, 4 patients reporting 2 complications and 1 patient reporting 3 complications. The total number of patients with complications from the Fraxel 1927-nm laser was 9, with 11 patients reporting complications with the Fraxel 1550 nm and 11 also reporting complications with the Fraxel CO_2.

Patients were categorized into two groups—complications that were short term, resolving in 20 days or less, or complications that were long term, resolving in a period of time greater than 20 days (Fig. 7). Of the 31 patients that had complications occur, 23 had mild short-term complications which resolved within 1–16 days and 5 had moderate short-term complications which took 1–18 days to resolve. Only 2 had mild long-term complications which resolved in 20–57 days and 1 had a moderate long-term complication (hyperpigmentation) which took 60 days to improve, with application of hydroquinone.

Of the 224 patients treated with the Fraxel 1927-nm laser, 4.0% ($n = 9$) had a complication. With the Fraxel 1550-nm laser, 334 patients were treated with a 3.3% ($n = 11$) complication rate. Of 172 patients treated with the Fraxel CO_2 laser, the complication rate was 6.4% ($n = 11$). The Fraxel CO_2 laser had the highest

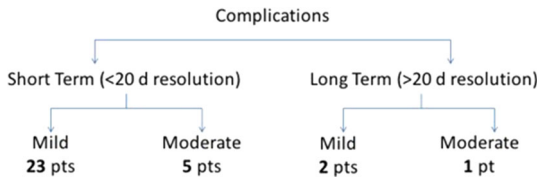

Fig. 7 Complications short term versus long term

Table 1 Fitzpatrick skin type and number of patients

Fitzpatrick skin type	Number of Fraxel 1927-nm patients (% within treatment type)	Number of Fraxel 1550-nm patients (% within treatment type)	Number of Fraxel CO_2 patients (% within treatment type)
I	5 (2.2%)	16 (4.5%)	8 (4.7%)
II	86 (38.4%)	106 (31.9%)	85 (49.7%)
III	103 (46.0%)	166 (50.0%)	71 (41.5%)
IV	28 (12.5%)	44 (13.3%)	7 (4.1%)
Total	222	331	171

Table 2 Median improvement index of targeted skin conditions

	Wrinkles	Naso-labial fold	Pigment
Fraxel 1927 nm	1 (min 0, max 4)	0 (min 0, max 4)	3 (min 0, max 5)
Fraxel 1500 nm	2 (min 0, max 5)	2 (min 0, max 5)	1 (min 0, max 4)
Fraxel CO_2	3 (min 0, max 5)	3 (min 0, max 5)	2 (min 0, max 5)

Table 3 Incidence of complications

Complication	Fraxel 1927 nm (number of patients)	Fraxel 1500 nm (number of patients)	Fraxel CO_2 (number of patients)
HSV	1	1	3
Acneiform eruption	2	6	5
Abrasion	0	1	0
Bacterial infection	1	0	0
Dermatitis	3	3	3
Drug eruption	0	0	1
Prolonged erythema	2	0	2
Hyperpigmentation	1	0	0
Swelling	0	0	1
Telangiectasia	0	1	0
Total	10	12	15

complication rate at 6.4%; however, the differences between these complication rates are not statistically significant ($p = 0.26$).

The most common complication among all three lasers was acneiform eruptions ($n = 13$, 1.8%), dermatitis ($n = 9$, 1.2%), HSV ($n = 5$, 0.7%). Each of the following complications only occurred once: abrasion, bacterial infection, drug eruption, hyperpigmentation, swelling and telangiectasia (Table 3). The acneiform eruption was treated with either doxycycline or clindamycin for 7–10 days. Patients who developed herpetic outbreaks were treated with valacyclovir and followed up regularly. The one patient that developed a staphylococcal bacterial infection was treated with a 1-week course of trimethoprim/sulfamethoxazole. The rest of the patients who developed complications were followed up with regularly until their signs and symptoms resolved.

When we compared the incidence of total complications between the Fitzpatrick skin types, we did not find statistically significant differences ($p = 0.36$).

Discussion

Lasers with fractional capability have become increasingly favorable to patients due to decreased downtime and improved outcome for skin concerns. The risk of complication, though present, is slight.

Previous studies have demonstrated the rate of side effects with carbon dioxide and erbium fractionated lasers and length of time for resolution of complications [13, 16, 17, 21]; however, this is the first large-scale paper to show a very small complication rate and significant improvements achieved with the Fraxel 1927-nm, Fraxel 1550-nm and Fraxel CO_2 lasers. Significant improvements were noted for wrinkles, naso-labial fold and pigment in patients. The greatest improvements seen with the Fraxel CO_2 laser were wrinkle and naso-labial fold reduction. The Fraxel 1927 nm showed the greatest improvement in pigmentation. There was no significant difference in the percentage of complication among the 3 laser treatments ($p = 0.26$), and efficacious results were attained.

In a study by Graber et al. [21], a complication rate of 7.6% was reported when treating with a 1550-nm laser, whereas the complication rate observed in patients treated with the equivalent Fraxel 1550-nm laser was only 3.3%. The complication rate reported with the Fraxel CO_2 laser was 6.4%, significantly lower than what was observed by Manuskiatti et al., who reported a complication rate of 92% [13]. Their higher rate of complications was likely due to a very small population size, as well as the treatment of Fitzpatrick skin type IV only to specifically improve atrophic acne scars in Asian patients. Nanni et al. also reported a higher incidence of side effects and complications with treatment of the CO_2 laser on 500 patients. One hundred percent of patients experienced erythema, 37% hyperpigmentation, 15% acne exacerbation, 10% contact dermatitis and 7.4% herpes simplex virus [22]. The complication rate observed with the Fraxel 1927-nm laser was 2.5% (9 of the total 361 treatments). Brauer et al. reported no serious adverse events related to the treatment; however, no complication rates were reported [16].

The overall complication rate of treatments performed with all three lasers Fraxel 1550 nm, Fraxel 1927 nm and Fraxel CO_2, was 4.2%. The most common complications encountered in 31 of the 730 patients treated were acneiform eruptions ($n = 13$, 1.8%), dermatitis ($n = 9$, 1.2%) and HSV ($n = 5$, 0.7%). Patients that presented with acne prone skin prior to treatment were more likely to have an eruption post-treatment. All eruptions were transient and resolved. Dermatitis was the second most common complication encountered by patients. This was most likely due to patient's reaction to the topical anesthetic used prior to treatment or other products the patient used post-treatment. The reported cases of dermatitis were transient and resolved. HSV outbreak was the third most common complication seen in our patient population. All HSV outbreaks were treated and resolved with no scarring. As a practice, we adopted a protocol of pre-treating our patients with valacyclovir if they had a history of herpetiform outbreaks. We did not encounter any severe side effects, which would include hypertrophic scarring, ectropion or disseminated infection. Metelitsa et al. [14] reported that as many as 10% of the patients reported acne eruptions after fractionated laser and 80% after traditional resurfacing. They also reported that contact dermatitis is uncommon,

but is likely found when a patient has sensitivity to a topical product [14]. Additionally, they reported that 0.3–2% of all fractional lasers and 2–7% of traditional laser resurfacing, patients would encounter reactivation of the HSV infection [14].

Conclusion

All three fractional lasers demonstrated significant improvement in targeted skin conditions. Ninety-five percent of the 730 patients treated had no complications from any of the three lasers that were used (Fraxel 1550 nm, Fraxel 1927 nm and Fraxel CO_2). The greatest numbers of complications were found in the patient population treated with the Fraxel CO_2 laser although the number of patients treated was the smallest of all three lasers. Most complications reported were short term and resolved after treatment.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest to disclose.

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