A Fractional Bipolar Radiofrequency Device Combined with a Bipolar Radiofrequency and Infrared Light Treatment for Improvement in Facial Wrinkles and Overall Skin Tone and Texture

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Abstract

Background: A variety of techniques and energy-based technologies are currently utilized for the treatment of facial wrinkles. Fractional bipolar radiofrequency treatment and treatment with bipolar radiofrequency combined with infrared light have both been reported to be safe and effective for the non-invasive treatment of wrinkles and overall facial rejuvenation.

Objectives: A multicenter, prospective clinical trial evaluated a protocol of treatment with a device incorporating bipolar radiofrequency and infrared light followed by treatment with a fractional bipolar radiofrequency device for facial wrinkle reduction and improvement in the overall appearance of aged facial skin.

Methods: Fifty-six patients with mild to moderate facial wrinkles received three full-face treatments (forehead, nose, cheeks, periorbital, and perioral areas) at 4 to 6 week intervals and were evaluated at 12 and 24 weeks after the last treatment. Clinical photographs at baseline and follow-ups were assessed by both the investigators and patients using the Global Aesthetic Improvement scale. Treatment safety was evaluated. Study participants also completed a satisfaction and improvement questionnaire.

Results: Fitzpatrick Wrinkling and Elastosis Score was decreased significantly at three months (P < .01; paired t test) and at six months (P < .001; paired t test) after the final treatment. Investigators’ assessments of overall improvement in facial appearance, demonstrated 88% improvement at 12 weeks and 82% at 24 weeks after the final treatment. Subject evaluations were similar, consistently reporting improvement in wrinkles and overall facial skin appearance throughout the study, and high a degree of satisfaction with their final results. Subjects tolerated the procedures well, with only transient mild to moderate erythema and edema occurring in most patients, and without complications.

Conclusions: A combined protocol of bipolar radiofrequency and infrared light treatment followed by fractionated bipolar radiofrequency treatment results in safe, well tolerated, and effective improvement in overall skin tone and texture and reduction of facial wrinkles.

Level of Evidence: 4

With both genetic (intrinsic) and environmental (extrinsic) factors contributing to the relentless chronological aging process and its visible signs, non-invasive energy-based procedures designed to improve facial wrinkles and the overall appearance and “quality” of the facial skin, are becoming an increasingly more popular and important part of many cosmetic medicine practices. Although more invasive approaches, such as varying techniques of facelift

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surgery, result in the most dramatic cosmetic outcomes with restoration or repositioning of facial volume and the removal of lax skin, and even an improvement in the appearance of facial wrinkles, there are of course inherent risks of surgery, as well as associated prolonged recovery times.\(^4,5\) Additionally, and perhaps most importantly, our surgical procedures alone do not address the also desirable changes in the “quality” of the skin. These limitations of surgical procedures in part have helped popularize more non-invasive techniques among cosmetic patients and practitioners alike.

Minimally-invasive non-surgical techniques, such as injection of neurotoxins and a multitude of filler products of varying compositions or micro-needling techniques that heat the dermis from within, and non-invasive energy-based and light-based modalities are currently being used for the treatment of wrinkles and improvement in the appearance of facial skin.\(^6-11\) Ideally, such non-invasive facial rejuvenation techniques would be safe and effective with minimal pain and little to no associated downtime, but although they can sometimes offer cosmetic patients a viable alternative to surgical procedures, they may all be associated with their own risks.

Ablative radiofrequency (RF) energy delivered to the skin in a non-homogenous manner has resulted in improvement of skin texture and reduction of wrinkles\(^2\) with the results of fractional RF treatment generally observed after two to three months. Although associated with less downtime and fewer potential complications than surgery, there are indeed some transitory risks associated with RF, including localized areas of acneiform subcutaneous erythematous papules, superficial crusting,\(^6,7\) and exacerbation of latent melasma-like hyperpigmentation with light-based modalities.\(^8\)

We hypothesized, however, that despite those transitory risks, combining a modality that delivered both fractional RF energy and non-fractional RF energy to the superficial dermis and also created thermal injury to deep dermal layers, might maximize patient benefit and result in improved long-term clinical outcome with a shorter treatment course, while hopefully maintaining the safety profile of non-ablative procedures. In the current multicenter study, we evaluated a combined approach of delivering a broadband infrared (IR) light and bipolar RF treatment followed by a fractional bipolar RF treatment to reduce facial wrinkles and improve the overall appearance of the skin.

METHODS

Patients

This was a prospective clinical study performed at three United States sites that enrolled 60 patients (20 from each site), from November 2011 to January 2013, with appreciable facial wrinkles, to receive three facial treatments to the forehead, nose, cheeks, periorbital, and perioral areas. Subjects were eligible to participate if they were healthy, at least 35 years of age, Fitzpatrick skin type I to VI, and score of 2 to 7 in the Fitzpatrick Classification and Wrinkling and Degree of Elastosis scale. Pregnant women and subjects with a pacemaker or an internal defibrillator or permanent implant in the treated area; use of a retinoid within two weeks or oral Isotretinoin within six months; resurfacing procedure within 12 months; and a history of poor wound healing or active lesion in the treated area were excluded from participation. The study was approved by the Essex Institutional Review Board (Lebanon, NJ), and all participants signed a informed consent form. Subjects were free to discontinue their participation at any time during the study. One patient was excluded from the study because he did not return after the first treatment, while three additional subjects were lost to follow-up before the completion of the study, with the remaining 56 patients completing the study. Clinical assessment was carried out by the physicians, using the pre- and post-treatment photographs of their own patients. They were not blinded for Global Aesthetic Improvement (GAI) and Fitzpatrick Wrinkle and Elastosis Score assessments. Patient self-assessment was recorded on a standardized questionnaire approved by the Essex Institutional Review Board, Inc. It was provided to the patients after treatment, and was initiated by each patient on completion. A blank copy of this questionnaire is available as Supplementary Material at www.aestheticsurgeryjournal.com.

Device Description and Treatment Protocol

All subjects were treated with the eTwo system (Syneron Medical Ltd., Yokneam, Israel). There are movable “applicator” handpieces controlled by the operator to deliver each treatment, and to which a variety of disposable electrode “tips” may be attached. Two different “applicators” were utilized for the noninvasive treatment of facial rhytides; one using both IR light (700-2000 nm wavelengths) combined with bipolar RF, and one using fractional bipolar RF alone. The IR light combined with bipolar RF procedure was performed first, followed immediately by a fractional bipolar RF treatment. Three treatments were performed at 4 to 6 week intervals.

Fractionated bipolar RF energy was delivered to the targeted skin via a matrix of multi-electrode pins fitted at the distal end of the applicator, as disposable tips.

The RF current flows at the electrode-skin contact points where spots of demarcated ablation are created and resurfacing of the skin takes place. The impact of the emitted energy depends on the pre-designated energy for the individual patient, power (depending on the tip type and skin impedance), and the electrode-pin density. A 64-pin tip was used
to treat larger surface areas of targeted skin (forehead and cheeks), while a 44-pin tip was used to treat smaller and more difficult to contact areas such as the periorbital, perioral, and paranasal areas.

Immediately prior to treatment, the area was prepared by applying a topical anesthetic cream of 20% Betacaine (containing lidocaine, prilocaine, and phenylephrine) or BLT (consisting of 10% benzocaine, 6% lidocaine, and 4% tetracaine) for 45 to 60 minutes, and then thoroughly cleaning and drying the area. Additionally, air cooling (Zimmer Cryo Chiller, CryoTec, Allentown, PA) was used during the majority (84%) of treatments. A thin layer (1-2 mm) of conducting gel was applied to the face, which was then treated with the IR and bipolar RF applicator, using energy levels of 80, 90, 100, 110, or 120 J/cm² for skin types I to III and 100, 110, or 120 J/cm² for the five patients with skin type IV to VI. Generally, 100 J/cm² was used for the first treatment, 110 J/cm² for the second treatment and 110 or 120 J/cm² for the third treatment for both skin types. Following that procedure, fractional bipolar RF treatment was performed with energy ranging from 36 to 65 mJ per pin for skin types I to III and 30 to 60 mJ per pin for skin type IV to VI. Treatment was performed with 50% overlapping of each applicator pattern and 2 to 3 passes with the 64-pin tip on the forehead and cheeks, and 1 to 3 passes with the 44-pin tip on the nose, periorbital and perioral regions (36%, 64/176 of treatments with 44-pin tip were performed with only 1 pass).

Outcome Assessments

All study participants were evaluated one week after the first baseline treatment for safety and tolerability. Clinical assessment was carried out by the physicians at 12 and 24 weeks after the last treatment session. Full-face frontal and lateral clinical photographs were taken in a standardized fashion at baseline and at each treatment and follow-up visit. Investigators performed treatment efficacy assessments, using the pre- and post-treatment photographs to determine the Fitzpatrick Wrinkle and Elastosis Score and the GAI scale (0 = no difference; 1 = slight improvement; 2 = moderate improvement; and 3 = marked improvement), considering aspects of skin tone, texture, and pore size. Treatment safety was evaluated by the frequency and severity of adverse events reported throughout the study. Study participants also completed a self-assessment questionnaire to assess improvement and satisfaction with treatment (beginning from the second treatment visit). A blank copy of this questionnaire is available as Supplementary Material at www.aestheticsurgeryjournal.com.

Immediately following each treatment session, the study participants reported tolerability for each treatment phase separately, as well as for the overall/combined treatment using the Visual Analogue Scale (VAS). The scale is a continuous 0% to 100% range (0% = no discomfort and 100% = extreme pain). For analysis, the pain level was categorized to 4 quartiles (0%-24%: none to minimal discomfort; 25%-49%: mild discomfort; 50%-74% moderate pain; 75%-100% severe pain). In addition, patients were asked to rate their discomfort and severity of erythema, edema, crustung, and blistering, daily for the first week following the treatment.

RESULTS

Of the 60 subjects enrolled and treated at least once, 56 subjects (52 females and 4 males; mean age, 50 ± 7 years; age range, 35-60 years) completed the treatment course of three treatments and were evaluated at 12 and 24 weeks after the final treatment. One patient was excluded from the study because he did not return after the first treatment, while three additional subjects were lost to follow-up before the completion of the study.

Fitzpatrick skin types for the 56 subjects included I (n = 4), II (n = 28), III (n = 20), IV (n = 1), V (n = 0) and VI (n = 3). Most subjects (70%, 39/56) had moderate to severely rough skin texture at baseline. Mean Fitzpatrick Wrinkling and Elastosis Score was 3.45 ± 1.4 (range, 2-7) at baseline.

Treatment Efficacy Assessments

Study investigators assessed the facial wrinkle reduction and overall appearance by comparing before and after photos, using the Fitzpatrick Wrinkle and Elastosis Scale and the GAI scale. Most of the subjects (63%, 35/56) already experienced improvement four weeks following the first treatment (before the second treatment). This rate increased to 86% (n = 48/56) after the second treatment and to 88% (n = 49/56) after the third treatment. Treatment efficacy remained stable during follow-up (85% at 24 weeks following end of treatments; Table 1 and Figure 1). Furthermore, the Mean Fitzpatrick Wrinkling and Elastosis Score was decreased significantly from 3.45 ± 1.4 (range, 2-7) at baseline to 3.12 ± 1.3 (range, 2-6) at three months (P < .01; paired t test) and to 2.96 ± 1.3 (range, 1-6) at six months (P < .001; paired t test) after the final treatment.

At the second and third treatment visits and at 12 and 24 weeks after the last treatment, the study participants rated their satisfaction and improvement. As shown in Figure 1, subjects and physicians reported similarly high levels of improvement, which increased with multiple treatments. Furthermore, nearly all patients (98%) reported improvement at 12 weeks following the three treatments, which was maintained in 89% (n = 50/56) of subjects at 24 weeks (Table 2 and Figure 1). Figures 2 to 5 and Supplemental Figure S1 demonstrate variable results of the combined treatments.
After one treatment, 64% (n = 36) of patients reported satisfaction (Table 3 and Figure 1). This increased to the majority of subjects (86%, n = 48) reporting “satisfied” or “very satisfied” at 12 weeks following the three treatments and 80% (n = 45) at 24 weeks.

Safety Assessments

Patients reported daily on the severity of any anticipated treatment-associated responses experienced, during the first week of the study following treatment, including: erythema, edema, crusting, and/or blistering. The most common response following treatment was transient erythema (99% of treatments, generally mild-moderate in severity), followed by edema, generally mild and occurring in 91% of patients; both treatment responses resolved within 3 ± 2 days (range, 1-7 days for erythema and 1-5 days for edema). Minimal crusting and blistering was seen in two patients, both with skin type I. In one patient, transitory crusting was observed at the 1-week follow-up, but resolved spontaneously after one week. Treatment energy was lowered for the second treatment; immediate post-treatment crusting was noted, but resolved spontaneously before the third treatment. Mild blistering occurred following the third treatment, but resolved spontaneously by the 1-month follow-up after treatment. There were no lasting effects observed at the 3-month and 6-month follow-ups. In another patient with skin type I, immediate mild blistering was observed after the second treatment that resolved spontaneously 2 days post-treatment. Mild crusting developed and was observed before the third treatment in this patient. The crusting resolved spontaneously after three days, and there were no lasting effects observed at the 3-month and 6-month follow-ups. There were no permanent side effects associated with treatment.

Treatment Tolerability

Subject tolerability assessments showed that 93% (n = 154) and 46% (n = 78) of the IR and bipolar RF treatments and fractional bipolar RF treatments, respectively, were associated with none to mild discomfort. In addition, 74% (n = 125) of all combined procedures were reported as being associated with none to mild discomfort. The average pain level of the IR and bipolar RF procedure was 18% ± 17% (categorized as minimal discomfort) with a range of 0% to 78% (1 patient experienced severe pain, 78% on VAS, following the second treatment, but none to minimal pain, 20% on VAS, following the third treatment). The fractional bipolar RF procedure and combined treatment assessments were associated on average with moderate discomfort (49% ± 21% and 39% ± 19%, respectively; range 0%-97%). Severe discomfort with treatment was reduced to moderate or mild discomfort the following day.

In addition to the subjective evaluation of discomfort immediately after treatment, patients were also asked to rate the severity of discomfort up to seven days after the treatment. Discomfort with treatment decreased with time with 77% (n = 41) and 93% (n = 52) of subjects reporting no discomfort or mild discomfort one day and three days after treatment, respectively.

DISCUSSION

In this multicenter study with 56 subjects treated during three sessions, the pairing of an initial treatment with bipolar RF combined with IR light followed immediately by
Figure 2. A 57-year-old woman with Fitzpatrick skin type II presented with baseline Elastosis score of “4” and slightly visible photodamage. (A, C) Before treatment and (B, D) 6 months after 3 treatments showing marked improvement by Investigator Assessment. Her Elastosis score reduced from “4” at baseline to “2” at the 3-month and 6-month follow-up evaluations.

Table 2. Subject Evaluation (N = 56) of Improvement in Overall Appearance Compared to Baseline, Using the GAI Scale

<table>
<thead>
<tr>
<th>Improvement (score)</th>
<th>4 Weeks Tx. 2% (n)</th>
<th>8 Weeks Tx. 3% (n)</th>
<th>20 Weeks (12-week follow-up) % (n)</th>
<th>32 Weeks (24-week follow-up) % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difference (0)</td>
<td>23% (13/56)</td>
<td>9% (6/56)</td>
<td>2% (1/56)</td>
<td>9% (6/56)</td>
</tr>
<tr>
<td>Slight improvement (1)</td>
<td>45% (25/56)</td>
<td>47% (26/56)</td>
<td>25% (14/56)</td>
<td>29% (16/56)</td>
</tr>
<tr>
<td>Moderate improvement (2)</td>
<td>14% (8/56)</td>
<td>11% (6/56)</td>
<td>42% (24/56)</td>
<td>20% (11/56)</td>
</tr>
<tr>
<td>Marked improvement (3)</td>
<td>18% (10/56)</td>
<td>32% (18/56)</td>
<td>31% (17/56)</td>
<td>42% (23/56)</td>
</tr>
</tbody>
</table>
treatment with fractionated bipolar RF, produced improvements in wrinkles and overall facial skin appearance in 88% of subjects evaluated at three months after the last treatment. Results were maintained at when the subjects were reevaluated six months after treatment, with 85% of subjects demonstrating improvement.

Treatment procedures were well tolerated with 74% associated with no to mild discomfort. Immediate response of mild to moderate erythema and edema were observed in 99% and 91% of the subjects, respectively, and resolved completely within one week (mean, 3 ± 2 days) without medical intervention. The presence of mild erythema and edema after treatment were considered as endpoints of therapy. None of the subjects experienced any complications that might have been associated with more ablative treatment, such as hyperpigmentation, acne flares, infection, prolonged erythema, or scarring.

Significant improvements in the reduction of wrinkles and overall facial skin appearance were observed with investigator-rated improvement of 63%, 86%, 88%, and

Figure 3. A 50-year-old woman with Fitzpatrick skin type II presented with baseline Elastosis score of “2” and somewhat visible photodamage. (A, C) Before treatment and (B, D) 6 months after 3 treatments showing slight improvement by Investigator Assessment. Her Elastosis score remained “2” at the 3-month and 6-month follow-up evaluations.
85% at 4, 8, 20, and 32 weeks after the first treatment, respectively. Patients’ assessments correlated with physicians’ assessment with overall improvement of 77%, 91%, 98%, and 91% at 4, 8, 20, and 32 weeks after the first treatment, respectively. Patient satisfaction with treatment was also high with overall satisfaction of 64%, 85%, 85%, and 80% reported at 4, 8, 20, and 32 weeks after the first treatment, respectively. Throughout the study, both investigators and patients consistently reported improvement in wrinkles and overall facial skin appearance, including skin tone and texture, compared to baseline, and patients generally expressed a high degree of satisfaction and tolerance of the treatment.

Numerous energy-based devices are currently being used for the treatment of wrinkles and overall improvements in facial skin rejuvenation, with each modality having varying degrees of success and safety. Radiofrequency-based devices in particular have become popular due to the significant cosmetic outcomes they can achieve, in association with an excellent safety profile. RF-generated tissue heating has unique biological and clinical effects, and RF can be used at lower frequencies to penetrate more deeply.

Figure 4. A 39-year-old woman with Fitzpatrick skin type II presented with baseline Elastosis score of “2” and slightly visible photodamage. (A, C) Before treatment and (B, D) 6 months after 3 treatments showing moderate improvement by Investigator Assessment. Her Elastosis score remained “2” at the 3-month and 6-month follow-up evaluations.
to target tissues. Fractionated bipolar RF energy is delivered deep into the dermis, resulting in a high dermal impact with low epidermal disruption. The non-homogenous micro-epidermal ablative injuries and wider spread dermal coagulation subsequently induce a robust dermal tissue healing response, resulting in a more diffuse therapeutic effect in the dermis that leads to significant improvements in wrinkles and sagging skin.

**Figure 5.** A 60-year-old woman with Fitzpatrick skin type II presented with baseline Elastosis score of “3” and slightly visible photodamage. (A, C) Before treatment and (B, D) 6 months after 3 treatments showing moderate improvement by Investigator Assessment. Her Elastosis score remained “3” at the 3-month and 6-month follow-up evaluations.

**Table 3.** Patients’ (N = 56) Satisfaction Over Time

<table>
<thead>
<tr>
<th>Satisfaction</th>
<th>4 Weeks Tx. 2% (n)</th>
<th>8 Weeks Tx. 3% (n)</th>
<th>20 Weeks (12-week follow-up) % (n)</th>
<th>32 Weeks (24-week follow-up) % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsatisfied</td>
<td>0% (0/56)</td>
<td>0% (0/56)</td>
<td>7% (4/56)</td>
<td>7% (4/56)</td>
</tr>
<tr>
<td>Having no opinion</td>
<td>36% (20/56)</td>
<td>14% (8/56)</td>
<td>7% (4/56)</td>
<td>13% (7/56)</td>
</tr>
<tr>
<td>Satisfied</td>
<td>57% (32/56)</td>
<td>64% (36/56)</td>
<td>55% (31/56)</td>
<td>54% (30/56)</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>7% (4/56)</td>
<td>21% (12/56)</td>
<td>31% (17/56)</td>
<td>26% (15/56)</td>
</tr>
</tbody>
</table>
safety profile associated with the device used in this study is most likely due to the nature of RF thermal heating, which is independent of tissue diffraction and chromophore absorption. Thus, unlike laser or optical light, RF energy may be used on any skin type. The combination of bipolar RF energy with the IR light in the same applicator enables the use of lower levels of the optical energy, reducing the risk to the epidermis in darker Fitzpatrick skin types.8,12

Previous studies have demonstrated the safety and efficacy of treating photo-damaged skin with combined RF and IR light treatments and with fractional bipolar RF treatment.2,8,12-19 in one study of 35 subjects treated for wrinkle reduction and skin rejuvenation with fractional RF treatment, clinical assessment by physicians at one month after three treatments showed improvement in wrinkling/smoothness in 90% of subjects.2 Similar results with overall improvement in 86% of subjects at one month after two treatments were observed in the current study. Furthermore, treatments results improved to 88% at 12 weeks after completing all three treatments. At 24 weeks after completing treatments, results were similar with 85% of subjects demonstrating improvement.

It is important to note that significant limitations of this study are the potential bias of the investigators’ association with the sponsor of the study and the lack of patient masking for objective measurements. However, since patient satisfaction is the primary goal of any of our treatments, it is perhaps even more important to note that the patients’ own assessments of overall improvement correlated with the physicians’ assessments, and that patients consistently reported improvement in wrinkles and overall facial skin appearance, including skin tone and texture, throughout the study as compared to baseline.

CONCLUSION

This study demonstrated in a large sample of 56 treated subjects that three monthly treatments with a protocol of initial treatment with IR light combined with bipolar RF, followed immediately by treatment with fractional bipolar RF, is safe, easily tolerated, and effective in producing reduction of facial wrinkles and an overall improvement in skin appearance lasting up to six months after treatment. Patient self-assessment of improvement (98%) and satisfaction (85%) were high following three treatments, suggesting that the clinical outcome met the overwhelming majority of patient expectations for improvement in wrinkles and overall skin appearance, including tone and texture. Investigator (GAI) assessment rate of improvement was 85% at six months after three treatments (week 32), while subject assessment rate of improvement was even higher (91%) at the same evaluation point. Future studies should include additional objective measurements to evaluate clinical efficacy.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr Gold is Chairman of the Syneron-Candela Medical (Yokneam, Israel) Advisory Board, performs research and evaluates devices for Syneron-Candela, and may be provided with devices at a discount. Dr Pozner is also a member of the Syneron-Candela Medical Advisory Board. Drs Pozner and Weiss perform research and evaluate devices for Syneron-Candela, and may be provided with devices at a discount.

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