Enhanced high-energy protocol using a fractional bipolar radiofrequency device combined with bipolar radiofrequency and infrared light for improving facial skin appearance and wrinkles

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Funding information
Syneron Candela;

Summary

\textbf{Background:} Fractional bipolar radiofrequency treatment and treatment with bipolar radiofrequency combined with infrared light have been shown in previous trials to safely and effectively improve the appearance of facial wrinkles.

\textbf{Aims:} To evaluate a high-energy protocol with combined bipolar radiofrequency and infrared light energies for improvement in photoaged facial skin.

\textbf{Patients/Methods:} Seventy-two patients presenting with mild to moderate facial wrinkles underwent a single full-face treatment (n=54) or two treatments (n=18) at 6-week intervals. Independent blinded assessment and investigator assessment were performed, using the Fitzpatrick Wrinkle and Elastosis Scale (0-9) and the Global Aesthetic Improvement scale. Patients also completed a self-assessment questionnaire concerning satisfaction with the treatment.

\textbf{Results:} All patients achieved some degree of improvement in their wrinkles and skin appearance, following a single treatment or two treatments with the enhanced-energy protocol. Blinded evaluation demonstrated 71\% and 70\% of the patients showing improvement of one unit or greater on the Fitzpatrick Scale, at the 12-week and 24-week follow-ups post-treatment, respectively. Similar results were reported by investigators. Under the Global Aesthetic Improvement scale, investigators observed 87\%, 91\% and 81\% of patients showing improvement at the 6-, 12-, and 24-week post-treatment end, respectively. Patients tolerated the treatments well and were satisfied with the clinical results.

\textbf{Conclusion:} The enhanced-energy treatment protocol, with fractional bipolar radiofrequency treatment and treatment with bipolar radiofrequency combined with infrared light applications, yields significant improvement of skin texture, wrinkling, and overall appearance following a single treatment. The results appear gradually over time and are maintained for at least 6 months’ post-treatment.

\textbf{KEYWORDS}
Bipolar radiofrequency, laser treatment, photoaging, photorejuvenation, wrinkle treatment
INTRODUCTION

Characterized in part by skin laxity, photodamage, the appearance of fine lines and wrinkles, as well as the overall gradual decline in skin texture and tone, aging skin and its optimal treatment is a very common concern in the aesthetic practice. Whether it is because of intrinsic (genetic) factors or extrinsic (environmental) factors, optimal treatment solutions for the improvement in the signs of skin aging remain elusive.

Traditionally, more invasive approaches, such as varying techniques of facelift surgery, often result in the most pronounced cosmetic outcomes in respect to the reduction of wrinkles and skin tightening, leading to a refreshed, more youthful appearance of the face. However, these procedures are also associated with the inherent risks of surgery, as well as prolonged recovery times. The limitations of surgical techniques including those patients who are skeptical of or contraindicated for having a surgical procedure, in part have paved the way for alternative, less invasive avenues of treatment. A number of minimally invasive, nonsurgical treatment techniques and approaches have been tried and used to improve the cosmesis of facial wrinkles, as well as the overall appearance of the skin, including skin resurfacing modalities, such as ablative and nonablative lasers, chemical peels, dermabrasion, as well as a variety of injectables ranging from botulinum toxin to a multitude of filler products of varying compositions. Many of these treatment techniques that penetrate deeper in the dermis, however, are associated with adverse events, such as postinflammatory hyperpigmentation (PIH), with the injectables having their own distinct set of adverse events; thereby, underscoring the need for safer, more effective skin rejuvenation approaches.

Radiofrequency (RF) based treatment modalities, including fractional RF techniques, have enjoyed a surge in popularity in aesthetic medicine primarily because of their noninvasive nature, coupled with the excellent cosmetic outcomes that they can achieve. In addition, treatments with RF devices are associated with minimal downtime, a high tolerability, and an excellent safety profile, even in challenging to treat darker Fitzpatrick Skin Types. This mode of energy delivery has been shown in previous clinical trials to be very effective in addressing the many different signs of skin aging such as wrinkles and fine lines, as well as skin texture and tone.

In this study, we evaluated an enhanced-energy protocol, using higher combined bipolar RF and infrared (IR) light energies than previously reported for facial wrinkle reduction and improvement in the overall appearance of aged facial skin. We proposed that fewer treatments with higher energy would yield similar results, while decreasing overall downtime and the duration of the treatment process.

MATERIALS AND METHODS

Patients

This was a prospective, multi-center, clinical study that enrolled healthy patients with appreciable facial wrinkles and a Fitzpatrick Wrinkle and Elastosis Scale (FWES) score of 2 or greater. Subjects received a single full-face treatment or two treatments at 6-week intervals. All patients met the inclusion/exclusion criteria and provided written informed consent prior to the initiation of treatment.

Device Description

All of the patients in this study received treatment with the bipolar RF applicator (Sublative™ RF) and combined RF and IR energies (Sublime™ applicator) on the eTwo™ system (Syneron Medical, Ltd., Yokneam, Israel). The Sublime applicator combines pulsed infrared light (700 nm-2000 nm wavelengths) and bipolar RF energy, while the Sublative RF applicator delivers fractionated bipolar RF energy to the skin via a matrix of multi-electrode pins. The RF current flows between the internal electrode pins and the larger return electrodes. The highest impact occurs at the electrode-skin contact points, where spots of demarcated ablation are created and skin resurfacing takes place. The impact of the emitted energy depends on the pre-designated energy for the individual patient, power, and the electrode-pin density. The 64-pin tip (12 × 12 mm treatment area) is used to address larger surface areas, while the 44-pin tip (11 × 3 mm treatment area) is used to reach more difficult-to-reach anatomical areas, such as the periorbital, perioral and paranasal regions.

Treatment Protocol

Each patient was assessed at baseline and at each follow-up visit following treatment. Pulses with combined pulsed IR and bipolar RF were applied first, immediately followed by the bipolar RF treatment in one treatment session. Patients’ treatment results at each follow-up visit were compared with baseline to determine the level of improvement with the combined therapy. At the 6-week follow-up visit, if the investigator determined that an additional treatment was needed, a second treatment session was performed at this visit. The enhanced-energy protocol consisted of using higher energies for treatment than that was previously reported. Combined pulsed IR and bipolar RF energies (energy range of 120-200 J/cm²) were applied and followed by bipolar RF treatment (energy range of 62-100 mJ/pin).

Outcome assessments

All patients were evaluated for efficacy, safety and tolerability of the combined treatment. Clinical photographs were taken in a standardized manner at baseline and at each of the follow-up time points, and comparisons were made at the end of the study. Treatment efficacy assessments were made using the FWES (0-9) and the Global Aesthetic Improvement (GAI) scale (0=no difference; 1=slight improvement; 2=moderate improvement; and 3=marked improvement), considering aspects of skin tone, texture, and pore size, as well as visual assessment of wrinkle and skin quality improvement. Three independent, blinded investigators, the study investigators and the study subjects reported outcome at the 6-, 12-, and 24-week
follow-ups, compared to baseline. Any adverse events were reported. Patients also completed a self-assessment questionnaire to evaluate the tolerability of treatment, the improvements achieved and overall satisfaction from treatment. For treatment tolerability assessment, the Visual Analogue Scale (VAS) (continuous 0-100% range: 0%=no discomfort and 100%=extreme pain) was used. For analysis, the pain level was categorized to four quartiles (0-24%=none to minimal discomfort; 25-49%=mild discomfort; 50-74%=moderate pain; 75-100%=severe pain).

3 | RESULTS

A total of 72 healthy patients (67 females, 5 males), ranging in age from 35 to 59 years (mean age of 49±6 years) with Fitzpatrick Skin Types II-V and appreciable facial wrinkles (FWES of 2-6), received a single full-face treatment (n=54) or two treatments (n=18) at 6-week intervals. The majority of patients were Caucasian (n=55; 76%), while the remaining non-Caucasian patients were Asian (24%), noting that one site was located in Hong Kong. At baseline, the majority of the patients (78%) had a Fitzpatrick Wrinkle and Elastosis Scale (FWES) in class II (moderate elastosis, moderate number of lines), and most of the patients (71%) had moderate to high skin roughness.

Subjects underwent a single (n=54) or two treatments (n=18) with combined pulsed IR and bipolar RF energies (mean 140±16 J/cm²), followed by bipolar RF treatment (mean 75±9 mJ/pin with 64 pin tip; 67±19 mJ/pin with 44 pin tip). The energy level for the combined pulsed IR and bipolar RF treatment to the jawline was reduced to 100 J/cm² for the 17 Asian subjects in the study.

All patients achieved some degree of improvement in their wrinkles and skin appearance, following a single treatment or two treatments with the enhanced-energy protocol. Logistic regression analyses demonstrated no significant differences between clinical outcome following one or two treatments, and therefore, the findings were combined. Blinded evaluation demonstrated 71% and 70% of patients showing improvement of one unit or greater on the FWES Scale (0-9), at the 12-week and 24-week follow-ups post-treatment, respectively (Figure 1).

As assessed by the study investigators, 78% of the patients showed improvement of at least one unit on the FWES Scale as early as 6 weeks following a single treatment at baseline (Figure 1). Similar to blinded evaluator results, investigators reported 77% and 72% of patients showing improvement at the 12-week and 24-week follow-ups, respectively (Figure 1). Inter-reader variability results between the three reviewers demonstrated high agreement for baseline and post-treatment assessments with an intraclass correlation coefficient (ICC) of .859 and .874, respectively. Figures 2 and 3 represent examples of various results.

Under the GAI Scale, the investigators observed that greater than 80% of the patients showed some degree of improvement at each follow-up visit, with 87%, 91%, and 81% of patients showing improvement at the 6-, 12-, and 24-week post-treatment visits, respectively. Furthermore, logistic regression analyses supported poolability of study results across sites and between the United States and foreign populations.

At the 6, 12, and 24-week follow-up time points, 84%, 78%, and 68% of patients reported positive changes in overall appearance with the GAI scale. The patient self-assessment questionnaire reflected satisfaction from the treatment, with the majority of patients reporting that they were satisfied or very satisfied with the treatment results at each of the follow-up visits, including 71% of the study patients at the primary endpoint visit of 12 weeks’ post-treatment end.

3.1 | Safety assessment

Transient post-treatment erythema and edema were common, occurring in 99% and 76% of the subjects, respectively. Crusting occurred in 28% of the subjects and purpura in 13%. Very mild blistering occurred in three subjects. Treatment responses were transient, generally lasting only several days, mild to moderate in severity and resolving without intervention. No post-inflammatory hyperpigmentation (PIH) or scarring was observed in any patient.

3.2 | Treatment comfort

Discomfort associated with application of bipolar radiofrequency combined with infrared light was minimal (mean score of 39%±22%, based on the 100% VAS scale). As expected, greater discomfort was associated with application of fractional bipolar radiofrequency and was considered as moderate (mean score of 57%±23%).

4 | DISCUSSION

The results of this multicenter clinical study demonstrated that an enhanced-energy protocol, using higher combined bipolar radiofrequency and infrared light energies than previously reported, was safe and effective for the improvement of facial wrinkles, as well as overall facial skin rejuvenation. Blinded evaluation demonstrated 71% and 70% of the patients showing improvement of one unit or greater on the FWES scale, at the 12-week and 24-week follow-ups post-treatment, respectively. Similar results of 77% and 72% of
patients showing improvement at the 12-week and 24-week follow-up were reported by investigators. This study further supports the therapeutic benefit associated with radiofrequency treatments in the aesthetic field.

According to the design of the study, patients were scheduled to receive a single high-energy sequential combination treatment and would only receive a second treatment at the 6-week follow-up, at the discretion of the study investigator. Of the 72 patients included in the study, 54 patients received one treatment session, while only 18 patients received a second treatment. The premise behind performing high-energy treatment, as opposed to using lower energy settings, is to achieve comparable clinical outcomes with potentially fewer treatment sessions, while maintaining a good safety profile.

In a similar study, 56 patients presenting with mild to moderate facial wrinkles underwent three full-face treatments, spaced 4-6 weeks apart, using the combination approach of broadband IR light and bipolar RF, followed by fractional bipolar RF treatment. Lower energy settings were used compared with our treatment protocol. Combined pulsed IR and bipolar RF energies ≤120 J/cm² were followed by bipolar RF treatment with ≤62 mJ/pin. With the enhanced-energy protocol, the energy range was 120-200 J/cm² for combined pulsed IR and bipolar RF energies and 62-100 mJ/pin for bipolar RF treatment. Regarding overall improvement in facial appearance (GAI scale), the investigators reported 88% and 82% improvement at 12 and 24 weeks after the third treatment, respectively. These findings are very similar to those reported in the current study with investigators’ GAI scale assessments demonstrating 91% and 81% improvement at 12 and 24 weeks after treatment, respectively.

The efficacy results of both the lower energy settings and the enhanced-energy protocol were comparable at 12 and 24 weeks after treatment. However, three treatment sessions at 4-6 week intervals were performed to achieve a similar effect with the lower energy settings. Of importance, tolerability with treatment and incidence of transient side effects of treatment were similar with both energy protocols. Furthermore, there was no PIH incidence,
prolonged erythema or scarring observed in our study population including Asian patients and Fitzpatrick Skin Types IV-V. The advantage of fewer treatments with the enhanced-energy protocol is that overall the treatment course and accumulated downtime is reduced.

In conclusion, regardless of treatment strategy, both studies show that whether using moderate or enhanced-energy level settings, fractional bipolar RF treatment and treatment with bipolar RF combined with IR light yields significant improvement of skin texture, wrinkling, and the overall appearance of the skin. Those patients treated with higher energy levels achieved marked clinical results in fewer treatment sessions and benefited from a shorter treatment course because of the higher energy parameters used. Treatment results were maintained at 6 months’ post-treatment.

REFERENCES


How to cite this article: Gold MH, Biesman BS, Taylor M. Enhanced high-energy protocol using a fractional bipolar radiofrequency device combined with bipolar radiofrequency and infrared light for improving facial skin appearance and wrinkles. J Cosmet Dermatol. 2017;00:1–5.