
Skin Tightening and Treatment of Facial Rhytides With Combined Infrared Light and Bipolar Radiofrequency Technology

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ABSTRACT

Background: The demand for non-invasive procedures for skin tightening and wrinkle reduction is increasing. Light-based therapies alone have limited efficacy due to the absorption of light by epidermal melanin and limited dermal remodeling.

Objective: To evaluate the efficacy and safety of the ReFirme™ ST Applicator (Syneron Medical Ltd., Yokneam, Israel), a novel combination of broadband IR light (700-2000 nm) and bipolar RF (electro-optical synergy [ELOS]) for the non-ablative treatment of skin laxity and mild to moderate rhytides.

Methods: Thirty-one patients (aged 45.1 ± 7.8 years, 26 women, skin types I-III) with skin laxity and facial wrinkles enrolled in a prospective study conducted at two clinical sites. Patients received 2 to 5 treatments at 3 to 4 week intervals with combined IR (700-2000 nm, 10 W/cm²) and RF energies (50-100 J/cm³) without anesthesia. Three blinded evaluators assessed percentage wrinkle clearance rates by comparing pre-treatment and post-treatment

photographs. Patients graded post-treatment satisfaction on the following scale: 1-2 not satisfied; 3-4 slightly satisfied; 5-6 moderately satisfied; 7-8 satisfied; and 9-10 exceptionally satisfied.

Results: The overall median wrinkle clearance rate for the 3 blinded evaluators was 50% (40.0-50.0 [97.1% CI]). The three median clearance rates did not differ significantly from one another ($p=0.1666$). The median patient satisfaction rate was 7.0 (6.0-8.0 [97.1% CI]) with 20 patients reporting 7 or greater. A Spearman rank correlation coefficient of 0.74 (0.53-0.87 [95% CI]) indicated a strong correlation ($p<0.0001$) between clearance rates and patient satisfaction levels. Adverse effects other than mild transient erythema or edema were not observed 1 to 2 days after treatment or 1 month after the final treatment.

Conclusion: The combination of broadband IR (700-2000 nm) and bipolar RF energies is a safe and effective treatment modality for improving the appearance of rhytides, skin texture, and laxity of the face.

INTRODUCTION

To meet the demand for safe, non-invasive procedures for the treatment of photo-damaged skin, a variety of light-based therapies have been developed. Although results are less impressive than those of surgical facelifts, adverse effects are few and post-treatment recovery time is short. For example, the use of non-ablative, infrared (IR) lasers with skin-surface cooling has been explored as a stimulus for dermal remodeling and clinical improvement of wrinkles with few adverse effects.¹⁻⁵

A major limitation of light-based therapies is that optical energy is absorbed by epidermal melanin, thus limiting the depth of light penetration, particularly in patients with dark skin. Another limitation is wrinkles respond minimally to this treatment because collagen contains no chromophores to absorb the light.⁵

To overcome these drawbacks, selective electro-thermolysis, in which electrical energy from radiofrequency (RF) current selectively heats target tissue without damaging the epidermis, has been introduced.⁶ RF current placed on the skin penetrates the epidermis and moves to tissues that offer high electrical conductivity. Since

conductivity varies inversely with temperature, cooling the epidermis guides the RF current to deeper tissues which, when pre-heated, has higher conductivity and thus a greater probability of receiving the RF current. The amount of heat generated in the pre-heated tissue varies with the tissue's resistance (impedance) to the RF current.

The Polaris WR™ Applicator (Syneron Medical Ltd., Yokneam, Israel) is a combination of 900 nm diode laser and RF technologies. The WR applicator can also be found on the Galaxy™, eLaser™, and eMax™. This WR device delivers optical energy to pre-heat the target and RF energy to heat the target (without injuring the epidermis) even more to a temperature that exceeds its therapeutic threshold. This combination of technologies is called electro-optical synergy (ELOS). The Polaris WR has shown efficacy and safety in the treatment of facial rhytides, skin laxity, and skin texture.^{7,8}

The purpose of this study is to evaluate the efficacy and safety of the broadband (700-2000 nm) ReFirme ST Applicator for the non-ablative treatment of skin laxity and mild to moderate rhytides.

METHODS

Thirty-one patients (aged 45.1 ± 7.8 years, 26 women, skin types I-III) with skin laxity and facial wrinkles enrolled in a prospective study conducted at two clinical sites (Brampton Cosmetic Surgery and Laser Clinic, Ontario, Canada [n=11], and Greenslope Plastic Surgery, Brisbane, Australia [n=20]). Patients received 2 to 5 treatments (median 3) at 3 to 4 week intervals with the combined IR (10 W/cm², 700-2000 nm) and RF (50-100 J/cm³) energies of the ReFirme ST Applicator device. Patients were treated on the full face (n=19), full face and neck (n=5), abdomen (n=3), neck (n=2), forehead (n=1), and LHS face (n=1). All patients gave informed consent to treatment.

The following exclusion criteria were met: pregnancy, photosensitivity, tanned skin, diabetes, use of isotretinoin within 6 months prior to study, use of pacemakers or internal defibrillators, concurrent treatments with other cosmetic modality.

Contact gel was applied before treatment to hydrate the treatment area and to assure proper conductivity. No anesthesia was used during treatments. Patients were instructed to apply a copper cream (Complex Cu₃ Post-Laser Lotion, Procyte Corp., Redmond, WA, USA) after treatment to reduce redness and dissipate heat from the treated zone. Photographs were taken at baseline and at each follow-up visit.

Treatment endpoints were the development of edema, radiant heat, and erythema. Faces were treated one side at a time with stacked pulses. During the initial regional pass, three pulses were stacked at each treatment site unless patient discomfort dictated fewer pulses. Passes were repeated on the wrinkles of the nasolabial, periorbital, forehead, glabellar, and upper lip areas and on areas of laxity such as the cheek and above the eyebrows. Sites on one side of the abdomen received two single-pulse passes. Typically, three to four total passes were made on the periorbital and forehead areas and six or more on the nasolabial folds, cheeks and abdomen.

Results were evaluated by three blinded independent medical evaluators and by patients participating in the study. Blinded evaluators assessed percentage wrinkle clearance rates by comparing pretreatment and post-treatment photographs. When the study was completed, patients graded satisfaction on the following scale: 1-2 not satisfied; 3-4 slightly satisfied; 5-6 moderately satisfied; 7-8 satisfied; and 9-10 exceptionally satisfied.

RESULTS

RF energies used with successive treatments are shown in Figure 1. Treatment energies increased with each treatment to a maximum of 100 J/cm³ for the third, fourth, and fifth treatments.

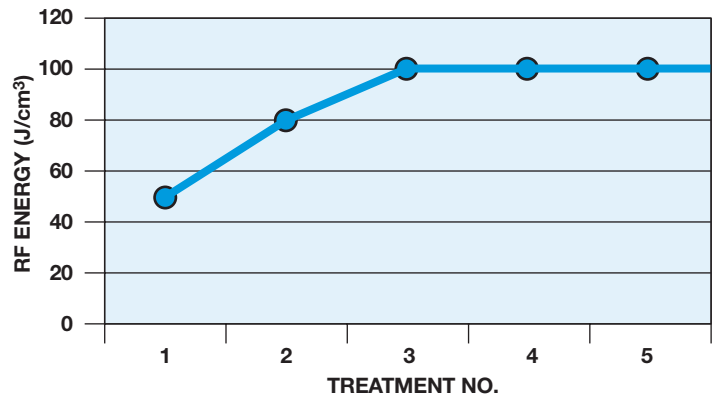
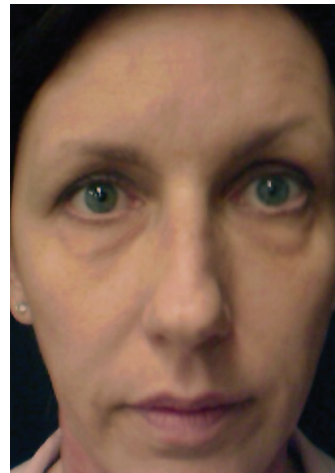
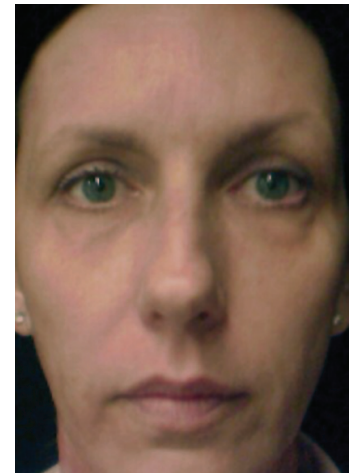


Figure 1. Median RF treatment energies used with successive treatments. Patients received 2 (n=3), 3 (n=8), 4 (n=13), or 5 (n=7) treatments.



Pretreatment



Immediately post one treatment



Three months post one treatment shows results are maintained



Immediately post second treatment



Pretreatment

Immediately post one treatment

Blinded evaluators compared pre-treatment and post-treatment photographs to assess wrinkle clearance rates. Clearance rates after the final treatment were not normally distributed, so the data was evaluated by non-parametric statistics. The overall median wrinkle clearance rate for the 3 blinded evaluators was 50% (40.0-50.0 [97.1% CI]). Individual median clearance rates were 40% (40-50 [97.1% CI]), 50% (40-60 [97.1% CI]), and 50%(40-60 [97.1% CI]). The three median clearance rates did not differ significantly from one another ($p=0.1666$, Kruskal-Wallis statistic = 3.58). The Kruskal-Wallis 1-way ANOVA tests for differences between medians; it is the non-parametric equivalent to a 1-way between-subject ANOVA.

The median patient satisfaction rate was 7.0 (6.0-8.0 [97.1% CI]) with 20 patients (64.5%) reporting satisfaction levels of 7 or greater. A Spearman rank correlation coefficient (a non-parametric alternative of the Pearson correlation coefficient) of 0.74 (0.53-0.87 [95% CI]) indicated strong correlation ($p<0.0001$) between clearance rates and patient satisfaction levels.

Adverse effects other than mild transient erythema or edema that resolved within 2-4 hours were not observed, 1 to 2 days after treatment, or 1 month after the final treatment.

Visible improvement in wrinkles was noticeable after the first treatment session. All patients noted immediate post-treatment tightening of lax skin that persisted for up to 48 hours and settled approximately two weeks later. Firmness persisted and was still increasing at the 3-month follow-up visit. The treatment was well tolerated and all patients were willing to continue treatments indefinitely.

Patients' overall improvement was on average 20% higher than with the investigator's assessment. Sensitivity was rated by study investigator slightly higher near the jaw line.

DISCUSSION

This is the first study to evaluate the safety and efficacy of this broadband IR-RF combination in the treatment of facial wrinkles and skin laxity. Two previous studies^{7,8} have evaluated the Polaris WR combination of diode laser (900 nm) and RF energies for the treatment of facial rhytides, skin laxity, and skin texture. As in the present study, treatment endpoints were mild erythema or edema, patients received three treatments at 2 to 3 week intervals, and patients were followed for at least 3 months.

In the study of Doshi and Alster,⁷ results were expressed as clinical improvement scores according to the following scale: 0 (no change from baseline), 1 (<25% improvement), 2 (26%-50% improvement), 3 (51%-75% improvement), and 4 (>75% improvement). Unlike in the present study, clinical scores were obtained for four specific locations: nasolabial/mesolabial, periocular, perioral, and cheeks (laxity). Three months after the final treatment, respective clinical scores were 2.0, 1.62, 1.38, and 1.85. The median of these four scores, 1.74, corresponds to less than 50% overall improvement but more than 25% overall improvement, which is roughly comparable to the 50% overall wrinkle clearance rate of the present study. Optical energies (900 nm) ranged from 32 to 40 J/cm², higher than the 10 W/cm² (700-2000 nm) used in the present study. RF energies ranged from 50 to 75 J/cm³ compared to 50 to 100 J/cm³ used in the present study.

In the study of Sadick and Trelles,⁸ physician-assessed improvement in facial wrinkles exceeded 50% in more than 50% of patients. In the present study, wrinkle clearance rates of at least 50% occurred in 17 of 31 patients (54.8%), which is comparable to the aforementioned results. Sadick and Trelles reported optical energies ranging from 30 to 50 J/cm² and RF energies from 80 to 100 J/cm³.

Wrinkle clearance rates in the present study were strongly correlated with patient satisfaction levels as shown by the 0.74 Spearman rank coefficient. In the study of Doshi and Alster, patient assessments of clinical improvement were similar to physician assessments. In the study of Sadick and Trelles, however, only 30% of patients rated clinical improvement higher than 50%, lower than the 50% of patients with this improvement level as rated by physicians. Sadick and Trelles attributed this difference to very high patient expectations.

Adverse effects in the two previous studies were limited to mild transient erythema and edema, as in the present study.

The present study suggests that the broadband ReFirme ST Applicator device provides clinical improvement in wrinkles and skin laxity at lower optical energy (10 W/cm²) than the optical energies used in 900-nm Polaris WR studies of Doshi and Alster (32-40 J/cm²) and Sadick and Trelles (30-50 J/cm²), thus increasing patient safety. This may be due to the broader IR spectrum (700-2000 nm).

CONCLUSION

The combination of broadband IR and bipolar RF energies is a safe and effective treatment modality for improving the appearance of rhytides, skin texture, and laxity of the face.

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