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Clinical Evaluation of Fractional Radiofrequency for the Treatment and Reduction of Wrinkles: A Prospective Study

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ABSTRACT

Background: Fractional radiofrequency (FRF) technology has been shown in clinical studies to improve skin laxity, and to treat various skin conditions related to aging and alternate collagen structures such as rhytids. The objective of this clinical study was to evaluate the safety and performance of FRF (up to 124 mJ per pin) for the treatment of facial rhytids, emphasizing the upper lip and perioral areas.
Methods: Enrolled subjects received a series of 3 FRF treatments to the full face, 3 to 5 weeks apart. Immediately after treatment, the subjects were given a scale to assess pain and tolerability of the treatment. Subject satisfaction questionnaires were completed at follow-up visits at 6 and 12 weeks post final treatment. Before and after photographs were graded for change by three blinded evaluators using the Fitzpatrick Wrinkle and Elastosis Scale (FWES) and the Global Aesthetic Improvement Scale (GAIS).
Results: Image sets of 10 enrolled subjects (average age 62.7 years) were assessed by blinded evaluators. The overall face FWES score improved from 5.97 (SE 0.20) at baseline to 5.78 (SE 0.22) at 12-week follow-up. The GAIS improved by 0.4 points and was significant compared to baseline ($P = 0.0004$). Subject satisfaction was high with subjects giving an average satisfaction score of 3.2 ("satisfied") out of 4. Pain was rated "mild to moderate" with an average of 3.9 on a 11-point Wong Baker FACES Scale. Ninety percent (90%) of subjects reported either a mild, moderate, or significant improvement to their treatment area. Eighty percent (80%) of subjects reported that they would recommend the treatment to a friend. There were no reports of adverse events or unanticipated side effects during the duration of the study.
Conclusion: A statistically significant reduction in rhytids of the upper lip and the perioral area, was found, as evaluated by independent blinded evaluators. There were no adverse events. Treatment pain was low and tolerable, and subjects had high levels of satisfaction with the results at last follow-up.

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INTRODUCTION

Skin laxity and facial wrinkles, clinically referred to as rhytids, are common skin conditions in both men and women and are most commonly found in aging skin.[1–4] Skin aging is a complex biological process, influenced by combination of intrinsic (genetics, cellular metabolism, hormone and metabolic processes) and extrinsic (chronic light exposure, pollution, ionizing radiation, chemicals, toxins) factors.[5] These factors lead together to cumulative structural and physiological alterations and progressive changes in each skin layer as well as changes in skin appearance.[6–9] Gradual loss of skin elastosis leads to the phenomenon of skin sagging.[10] The aging of one's skin contributes to one's external appearance, making skin health an important component of facial aesthetics.

The desire to preserve youth is prevalent in modern society, as a youthful appearance is associated with perceived well-being and physical attractiveness.[11–13] The appearance of rhytids can lead to negative psychological impact on patients, causing patients to seek cosmetic treatments.[14] Traditionally, rhytids have been treated with surgery, such as rhytidectomy, blepharoplasty, and brow lifts. More recently, however, minimally invasive procedures have gained popularity. Consequently, lasers and light therapy for facial rejuvenation were one of the most common five procedures performed in the USA in 2019.[15]

Conventionally, ablative and non-ablative laser systems have been used to boost skin laxity, but additional technologies have been developed that utilize energy sources to combat aging skin, such as fractional radiofrequency (FRF). This method utilizes electrodes or needles to deliver energy to the tissue to achieve targeted predetermined fractional epidermal and dermal injury. The injury causes damage to the dermal collagen, which initiates a wound healing response including formation of new collagen, elastin and hyaluronic acid resulting in dermal remodeling and skin tightening.[16] The tissue located between

the targeted predetermined fractional impacted tissue zones, maintains skin integrity and serves to promote and accelerate wound healing. Fractional radiofrequency was developed with the same conceptual framework as fractional lasers, which is to provide focal, high-energy treatment zones within intact skin for the purpose of reduced downtime and risk. Furthermore, FRF is not selectively absorbed by chromophores, so it is considered safe to use in darker skin.[1]

Fractional radiofrequency technology has been shown to improve skin laxity, and to treat various skin conditions related to aging and alternate collagen structures resulting in appearance alterations such as rhytids. The objective of this study was, therefore, to evaluate the safety and efficacy of using an FRF device with an 80-pin tip (up to 124 mJ per pin) to reduce moderate to severe facial rhytids and elastosis.

MATERIALS AND METHODS

Participants

This was a prospective, evaluator-blind, study conducted at one clinical center between August 2019 and January 2020. The study protocol complied with the CONSORT 2010 statement for reporting randomized controlled trial, and the trial was conducted according to the Declaration of Helsinki and all its revisions. It was approved by the Western Institutional Review Board (IRB approval number: 1262764). This study was registered to the ClinicalTrials.gov Registry (ID number: NCT04057768). All subjects provided written informed consent to participate in the trial.

Male or female subjects over 21 years of age with moderate to severe rhytids who were seeking treatment and reduction of their wrinkles were enrolled. Women of child-bearing age were required to be using a reliable method of birth control at least three months prior to study enrollment and for the duration of the study and have a negative urine pregnancy test at baseline.

The exclusion criteria were: the presence of pacemaker or defibrillator, metal implants, pregnancy, any past or current significant systemic illness, illness localized in area of treatment, therapies or medication that may have interfered with the treatment or healing process, recent surgery in treatment area, acute or chronic infection in the area, any active condition in the treatment area, any history of skin disorders, facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, use of isotretinoin (Accutane®) or other systemic retinoids within six months prior to treatment, and tattoo or permanent makeup in the treatment area.

Description of Treatment

Skin in the treatment area was cleansed and dried prior to treatment. Treatments were performed using the Venus VivaMD™ (Venus Concept, Toronto, Canada). The study involved three treatments on both sides of the face with 3 to 5-week intervals between each treatment. Subjects were followed at 6- and 12-weeks after their last treatment. To begin the treatment, subjects lay in a supine position. The distal section of the applicator on the device was cleaned and fitted with a new tip (80 pins) per patient. The applicator was then held perpendicular to the skin, and with the distal part of the tip in close contact with the skin for the application of the treatment. Treatment consisted of two passes over the designated area in a range of energies (voltage: 240 or 260, pulse duration: 15 or 30 milliseconds). Subjects were advised to avoid possible thermal or mechanical damage after the treatment. Subjects were also instructed to use a high factor of sunscreen (SPF ≥ 30) to protect the treated area from direct sunlight for the entire period of the study.

Outcome Measures

All evaluations were conducted with blinded evaluation of clinical photography as well as investigator and patient assessments. Clinical photographs were taken at each treatment and follow-up visit. Photographs were taken with standardized photography equipment including stool height and anatomical alignment, illumination, and background throughout the study.

The primary outcome measures was the Fitzpatrick Wrinkle and Elastosis Scale (FWES): (1–3) mild, meaning fine texture changes with subtly accentuated skin lines, (3–6) moderate, meaning distinct papular elastosis (individual papules with yellow translucency under direct lighting) and dyschromia, (6–9) severe, meaning multipapular and confluent elastosis (thickened, yellow and pallid) approaching or consistent with cutis rhomboidalis.[17] The FWES was used to assess the wrinkles on the face overall, the upper lip, perioral area, and crow's feet. The other primary outcome measure was improvement in acne scarring at 6- and 12-weeks post-treatment, compared to baseline, as assessed by blinded evaluators by photographic assessment utilizing the Global Aesthetic Improvement Scale (GAIS): (3) very much improved, (2) much improved, (1) improved, (0) no change, and (-1) worse.

Secondary performance outcomes were the subjects' assessments of satisfaction with the treatment using a Subject Satisfaction Scale at 6- and 12-weeks post-treatment. Subject satisfaction was evaluated with the following 5-point Likert scale: (4) very satisfied, (3) satisfied, (2) no opinion, (1) unsatisfied, (0) very unsatisfied. Immediately after each treatment, subject discomfort was assessed using a 11-point Wong Baker FACES Pain Scale (WBFS) on a scale from 0 (no pain) and 10 (worst pain imaginable).[18] Subjects were not permitted to view their previous WBFS treatment scores. All adverse events (AEs) were recorded up to the 12-week post-treatment visit.

Statistical Analysis

Quantitative data are presented as mean, median, standard

deviation (SD), standard error (SE) and/or range, as applicable, while qualitative data is presented as percentage (%). Two-sided Student's paired t-test was used to test for changes from baseline to follow up visits at 6 and 12 weeks after the last treatment. *P* values less than 0.05 were considered statistically significant.

RESULTS

Patient Demographics

Ten (10) subjects were enrolled and completed the study (Figure 1). The mean age at study consent was 62.7 (±8.4 (SD)) years (range, 49.8 to 77.9 years). Nine (9) subjects (90%) were female and 1 (10%) was male. All subjects were Caucasian. Eight (8) subjects had Fitzpatrick's skin type II (80%) and 2 had type III (20%; Table 1).

FIGURE 1. Study design flowchart.

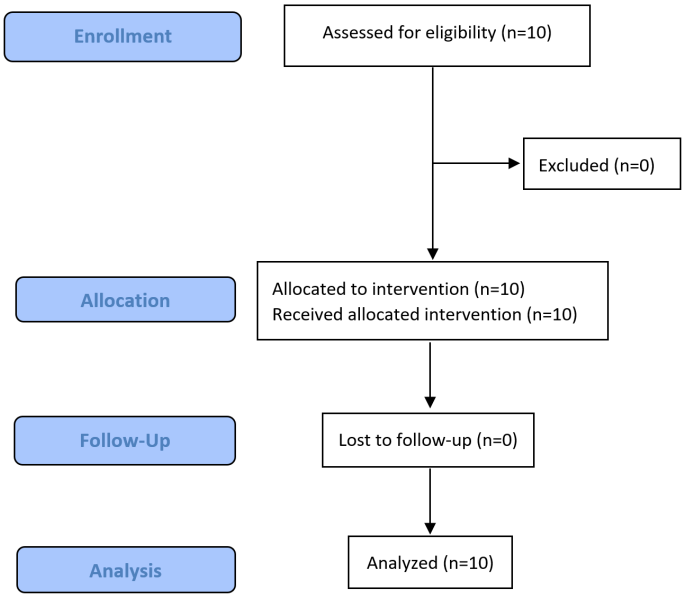

TABLE 1.

Demographic Data of Participants	
Demographic Data	**Results (N=10)**
Age, mean (SD) (years)	62.7 (8.4)
Age, range (years)	49.8 - 77.9
Gender, *n* (%)	
Female	9 (90%)
Male	1 (10%)
Race	
Caucasian	10 (100%)
Ethnicity	
Not Hispanic or Latino	10 (100%)
Fitzpatrick skin type	
II	8 (80%)
III	2 (20%)

Primary outcome: Fitzpatrick Wrinkle and Elastosis Scale (FWES) and Global Aesthetic Improvement Scale (GAIS)

Three blinded evaluators evaluated the FWES score for the overall face as well as specific areas of the subjects' upper lip, crow's feet, and perioral area. The overall face FWES score improved from baseline from 5.97 (SE 0.20) to 5.78 (0.22) at 12-week follow-up, which was a mean change of -0.18 (0.10). The crow's feet FWES score improved from 5.75 (0.20) to 5.65 (0.22) which was a mean change of -0.10 (0.12). The upper lip FWES score improved from 4.96 (0.24) to 4.63 (0.27) which was a mean change of -0.30 (0.13) and was statistically significant (*P*=0.02). Finally, the perioral FWES score improved from 6.77 (0.27) to 6.33 (0.32), which was a mean change of -0.43 (0.12) and was statistically significant (*P*=0.002) (Table 2, Figure 2).

The same blinded evaluators evaluated the GAIS for changes in overall skin quality, pigment, and visible vascular regions. The score improved by 0.4 (SE 0.1) points at 12 weeks post treatment, which was a statistically significant improvement when compared to baseline (*P*=0.0004). Representative before and after photographs of a study subject are shown in Figure 3.

Secondary Outcomes: Subject Satisfaction

Subjects were on average more than satisfied with their treatment, with a mean score of 3.20 (0.25) at 12-weeks after the last treatment, which meant that on average subjects chose a score slightly higher than 'satisfied'. At the 6-week follow-up visit, 88.9% reported being at least 'satisfied' (55.6%) or 'very satisfied' (33.3%). By the 12-week follow-up visit, the percentage of subjects who were 'very satisfied' with the treatment, went up to 40%. No subjects reported dissatisfaction at either the 6- or 12-week follow-up.

Ninety percent (90%) of subjects reported either a mild (50%), moderate (20%) or significant (20%) improvement to their treatment areas at 12 weeks. The most common specific textural skin change was smoother skin (58% reported a noticeable change). The two most noticeable areas of improvement according to subjects at 12 weeks post last treatment were the periorbital (44.4%) and the peri-oral (44.4%). Eighty percent (80%) of subjects would recommend this treatment to a friend, per response at final follow-up of 12-weeks post last treatment.

Safety Outcomes: Pain, Tolerability, and Adverse Events

The treatments were well tolerated, with an average tolerability score of 3.1 (0.1) for all three treatments which corresponds to "tolerable" to "very tolerable". The average WBFS for all three treatments was 3.9 (0.4) out of 10, which corresponds to "mild" to "moderate" pain. There were no reports of adverse events or unanticipated side effects during the duration of the study.

TABLE 2.

Average Aesthetic Improvement in Photographs from Baseline to the 12-week Post Last Treatment as determined by independent evaluators using photographs and measured using the Fitzpatrick Wrinkle and Elastosis Scale (FWES).

Location of Wrinkles	Baseline, Mean (SE)	12-weeks, Mean (SE)	Difference of Means, Mean (SE)
Overall face	5.97 (0.20)	5.78 (0.22)	-0.18 (0.10)
Upper lip	4.96 (0.24)	4.63 (0.27)	-0.30 (0.13)*
Perioral	6.77 (0.27)	6.33 (0.32)	-0.43 (0.12)*
Crow's feet	5.75 (0.20)	5.65 (0.22)	-0.10 (0.12)

*statistically significant FWES:
I: Mild (1–3) fine wrinkles, fine texture changes with subtly accentuated skin lines.
II: Moderate (4–6) fine to moderate depth wrinkles, moderate number of lines, distinct papular elastosis (individual papules with yellow translucency under direct lighting), and dyschromia.
III: Severe (7–9) fine to deep wrinkles, numerous lines, with or without redundant skin folds, multipapular and confluent elastosis (thickened, yellow, and pallid) approaching or consistent with cutis rhomboidalis.

FIGURE 2. Three blinded evaluators evaluated the FWES score for the overall face as well as specific areas of the subjects' upper lip, crow's feet, and perioral area.

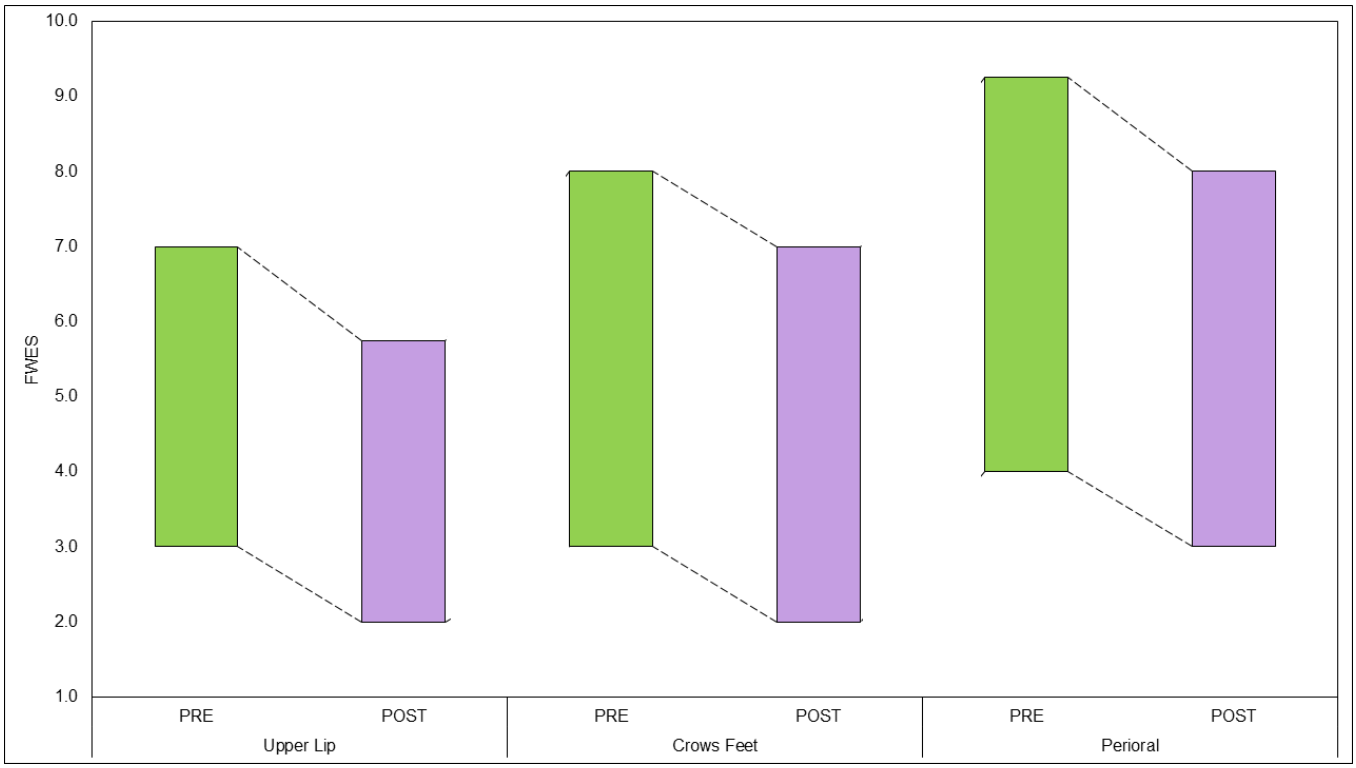

FIGURE 3. Representative before and after photographs of a study subject.

DISCUSSION

This was a prospective, evaluator-blinded study of the performance of FRF for the treatment and reduction of wrinkles for 10 subjects. Wrinkles, as assessed by the evaluators blinded to the treatment who reviewed the before and after treatment images, were reduced and showed improvement over the time-period studied. Moreover, none of the subjects experienced any adverse events, pain was rated low to moderate, and majority of subjects were satisfied or very satisfied with the treatment and outcomes achieved.

The FRF technology uses an array of electrodes that produce ablative and coagulative micro-thermal injuries to the epidermis and dermis with interspersed areas of unaffected skin. This provokes a significant dermal wound healing response, resulting in fibroblast stimulation and subsequent collagen remodeling. This is demonstrated by the increased levels of Type I and Type III procollagen and elastin found in skin biopsy samples post FRF treatment.[1,9] The added collagen volume, the improvement in elasticity along with melanin/erythema index, contributes to improvement of rhytids. The FRF device used in this study is different than microneedling FRF, as the pins do not penetrate the skin. Energy is distributed through small footprint per pin at variable energy densities in a single tip, reducing the risk of post-inflammatory hyperpigmentation and leaving sufficient intact tissue in between, for faster wound healing, uniform post-treatment tissue appearance, and low downtime.

Photoaging caused by cumulative UV exposure and intrinsic aging process results in thinned skin and reduced quantity and quality of collagen in the dermis and hypodermis.[20,21] Furthermore, skin starts producing an estimated 1 percent less collagen every year once a person turns 20 years old.[22] The perioral area of the face is one of the foremost areas on the face that may develop rhytids. Part of this is due to the thinness of the skin, which already has less collagen compared to other areas of the face. Although lifting procedures, such as face-lift and thread lift, are effective for treatment of skin laxity, they cannot improve skin texture or achieve skin rejuvenation. Fractional radiofrequency treatments have been proved to stimulate collagen and elastin production while safely and effectively promoting long-lasting skin rejuvenation results that treat laxity.[23] Additionally, an advantage of FRF treatment is the small treatment tip, which makes this area accessible, and the high variable fluence for safe specific targeting of skin depth.
The FWES was used in this study to measure wrinkle reduction. Results showed key areas of the face, the upper lip and perioral area, were statistically significantly improved (P<0.05) after treatment with FRF. When stratifying areas of the face, the perioral area and upper lip area were the most improved areas of focus (P<0.05), furthering the evidence that FRF is a strong choice in skin rejuvenation in the lower two-thirds of the face. Interestingly, subjects reported seeing a substantial difference in their peri-orbital area post treatment (44.4% reported a change post treatment), whereas expert graders did not notice as significant a change in photographs. That may be explained by that crow's feet are an example of a dynamic wrinkle which tend to show when the muscles are in use (for example when someone smiles). The treatment may have had a more measurable effect on the dynamic crow's feet that the patient noticed, but it was not visible in 2D static photographs to the graders. The GAIS also showed significant improvement in skin texture and appearance (P<0.05) 12-weeks post last treatment. Satisfaction was consistent over the two follow-up visits; the satisfaction scores at the 6-week follow-up did not differ significantly from the 12-week follow-up (P>0.05). Subjects reported the most common specific textural skin change was smoother skin (58% reported a noticeable change) and most subjects (80%) would recommend this treatment to a friend. The reported pain was rated as moderate (3.93 out of 10) and not as low pain. This treatment did not use any kind of anaesthetic or pain treatment. This value would potentially be much lower with numbing agents involved. In subjects who tend to feel more pain, pre-treatment anesthesia is recommended.

A further advantage of FRF is that FRF does not show evidence of hyaluronic acid filler disruption, a common concern amongst potential patients.[24] Additionally, FRF does not target specific chromophores in the skin and therefore is safe in darker skin types because the risks of pigmentary changes post-treatment are minimal, while helping to maintain healthy skin texture.[25] Fractional radiofrequency has been shown to improve skin texture.[26] Additionally, FRF has been shown to improve skin roughness in over 70% of patients,[27] which was similar to the results shown in this study, where 58% reported a noticeable change in skin smoothness.

Limitations of the study included the relatively small sample size that limited the power of the study. Additionally, a shorter time follow-up period of FWES could have shown results much faster than at 6 or 12 weeks, while a longer follow-up period could have allowed for the assessment of the longevity of all the outcomes (for example 6 or 12 months after treatment). More treatments may result in greater improvements in some patients' rhytids. Finally, inclusion of a wider range of skin types would have been beneficial to show the safety and efficacy of FRF for facial rhytids in darker skin types.

CONCLUSION

In conclusion, our results suggest that FRF is effective in the treatment of wrinkles, without significant adverse events. Moreover, FRF treatments showed improvements in overall skin quality and pigmentation. The FRF device may be a viable alternative for fractional laser devices for the treatment of rhytids for subjects looking for shorter recovery times and looking to avoid the drawbacks of fractional laser treatments.

DISCLOSURES

Dr. Suzanne Kilmer serves on the advisory board for Venus Concept and received research support for this study. Dr. Alison Kang has no disclosures.

The research was conducted at Laser and Skin Surgery Center of Northern California, Sacramento, California.

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