

Subject Satisfaction of Wrinkle Reduction Following Treatment with Fractional Radiofrequency: A Prospective Study

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ABSTRACT

Background: Fractional radiofrequency (FRF) technology reduces skin laxity and treats aging-related skin disorders such as wrinkles. The objective of this study was to evaluate participant satisfaction of FRF for the treatment of facial wrinkles.

Methods: A total of 25 male and female patients (average age 60.5 years) were enrolled in this prospective, single center study. Patients received 3 FRF treatments at 3- to 5-week intervals on both sides of the face, using 80-pin (up to 124 millijoule/pin) or the 160-pin tip (up to 62 millijoule/pin) applicator. Follow-up visits were conducted at 6 and 12 weeks after the last treatment. Participant satisfaction was evaluated by individual self-assessment of wrinkle reduction and a patient satisfaction questionnaire. Pain, tolerability, and safety were monitored throughout.

Results: The individual satisfaction was high with participants giving an average satisfaction score of 2.8 ("satisfied") out of 4. Pain was rated "mild" with an average of 4.0 on a 10-point Visual Analog Scale (VAS). Tolerability was rated 3.3 out of 4.0, correlating to "very tolerable." Ninety percent (90%) of subjects reported a mild or moderate improvement in their treatment area at 12-week follow-up.

Conclusion: This study demonstrates that under the FRF pre-sets used, patients are satisfied with results of FRF modality for improvement of their wrinkles. No unanticipated side effects were observed. Treatment was tolerable, and individuals had high levels of satisfaction and tolerability with the results at last follow-up.

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INTRODUCTION

Both intrinsic and extrinsic factors contribute to skin aging; smoking and UV radiation are well-known extrinsic risk factors.¹⁻³ Fine and coarse rhytids, xerosis, sallowness, roughness, loss of tone, and resiliency are all indications of photodamaged skin.⁴ Atrophic or hyperplastic epidermis, flattened dermo-epidermal junction, decreased cell turnover, upregulated melanocytes, and inflammatory cells are phenotypical features.^{5,6} The phenotype of the dermis is characterized by fragmented collagen as well as dysfunctional glycosaminoglycans (GAGs) and proteoglycans.⁷

Minimally invasive procedures are frequently preferred above surgical options for skin aging. Topical retinoids, chemical peels, dermabrasion, microneedling, and ablative and non-ablative lasers are common treatments for aged skin.⁸ Ablative laser skin resurfacing has produced significant results, but at the expense of undesirable side effects such as pigmentary changes, scarring, infection, and delayed healing. As a result, methods with lower risk profiles were developed.⁹

Fractional radiofrequency (FRF) has become popular as a next-

generation strategy for wrinkle reduction. To achieve dermal effects, electrode pins (that do not "penetrate" the skin) or needles create ablative and coagulative micro-injuries in the epidermis and dermis, interspersed among areas of unaffected skin. This causes a dermal wound healing response, which consequently stimulates fibroblasts. This is supported by higher levels of Type I and Type III procollagen and elastin found in skin biopsy samples following FRF treatment.^{4,10} The increased collagen volume and elasticity contribute to the improvement of rhytids and wrinkles.

It has been established that FRF can reduce wrinkles.¹¹ However, a patient-centered satisfaction metric is critical for cosmetic treatments, as patients have alternatives when picking a practitioner. Therefore, the objective of this clinical trial was to establish participant satisfaction with FRF for wrinkles in a variety of skin types and both genders.

MATERIALS AND METHODS

Participants

This was a prospective, evaluator-blind study conducted at

one clinical center between March 2019 and April 2021. The study protocol complied with the CONSORT 2010 statement for reporting a randomized controlled trial (see Supplementary Material), and the trial was conducted according to the Declaration of Helsinki and all its revisions. This study was registered to the ClinicalTrials.gov Registry (ID number: NCT03776461). All participants provided written informed consent to participate in the trial.

Male or female individuals over 21 years of age with moderate to severe wrinkles were enrolled. Women of childbearing age were required to be using a reliable method of birth control at least 3 months prior to study enrolment 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 the area of treatment, therapies or medications that may have interfered with the treatment or healing process, recent surgery in the 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 3 months, use of isotretinoin (Accutane) or other systemic retinoids within 6 months prior to treatment, and tattoo or permanent makeup in the treatment area.

Treatment Description

Test spots were performed in the intraarticular and postauricular areas 10 to 14 days before initial full-face treatments. They were carried out over a range of stacked and non-stacked passes. Skin was cleansed and dried prior to treatment. A topical anesthetic cream (5% lidocaine cream) was applied for 1 hour prior to the procedure. Additionally, refrigerated air (Cryo 6 Cold Air Chiller Device, Zimmer Medizin Systems) was applied at level 2 to 3. In selected patients who noted more severe discomfort, and with higher settings, we injected 1 cc of 1% lidocaine 1:200,000, buffered, along the supraorbital supratrochlear, infraorbital, and mental nerves.

Treatments were performed using the Venus VivaMD (Venus Concept). The study involved 3 treatments to the entire face at 3- to 5-week intervals. The distal section of the applicator on the device was cleaned and fitted with a new tip (80-pin or 160-pin) for each 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. Each treatment consisted of 1 to 5 passes over the designated area in a range (voltage: 240 V or 280 V; pulse duration: 28 ms to 30 ms). Tip selection was determined by the principal investigator. Average settings per area of the face are described in Table 1. If the test spot settings showed healing results by day 4 to 5, those settings were used for the entire face. Typically, more passes were applied in the perioral area where the skin was thicker.

The 80-pin and 160-pin applicators do not penetrate the skin but are able to deliver energy into the epidermis and superficial dermis through application of the RF energy at the surface. In general, in more severe wrinkles the 80-pin tip was used, and for milder wrinkles, the 160-pin tip was used. Participants were instructed to use a high factor of sunscreen (SPF \geq 30) to protect the treated area from direct sunlight for the entire period of the study. Patients were followed at 6 and 12 weeks after their last treatment.

Outcome Measures

Performance outcomes were determined by using a Subject Satisfaction Scale (SSS) at 6 and 12 weeks post-treatment. Each patient's SSS was evaluated using the following 5-point Likert scale: (4) very satisfied, (3) satisfied, (2) no opinion, (1) unsatisfied, and (0) very unsatisfied. Immediately after each treatment, participants were assessed for treatment pain/discomfort using a 10 cm Visual Analog Scale (VAS)^{17,18} on a scale from 0 cm (no pain) to 10 cm (pain as bad as it can be). Participants were not permitted to view their previous VAS or SSS treatment scores. Additionally, following treatment, each patient's treatment tolerability was recorded using a scale: (4) very tolerable, (3) tolerable, (2) having no opinion, (1) intolerable, and (0) very intolerable. All adverse events (AEs) were recorded up to the 12-week post-treatment visit.

Additional analysis of satisfaction was performed using a treatment evaluation questionnaire conducted at the 6-week and 12-week follow-ups. Participants were asked what level of improvement they experienced (mild, moderate, or significant), whether they would recommend this treatment to a friend (yes or no), how soon after the start of treatments they started noticing changes to their skin (after the first treatment, after the second treatment, after the third treatment, or during the follow-up period). Patients with wrinkles were asked what specific changes they saw in their skin (smoother skin, softer skin, firmer skin, and overall improvement in wrinkles and fine lines) and which areas of the face had the most improvement of wrinkles (forehead, perioral area, and oral area).

Statistical Analysis

Quantitative data are presented as mean, median, standard deviation (SD), standard error (SE), and/or range, as applicable, while qualitative data are presented as percentages (%). 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

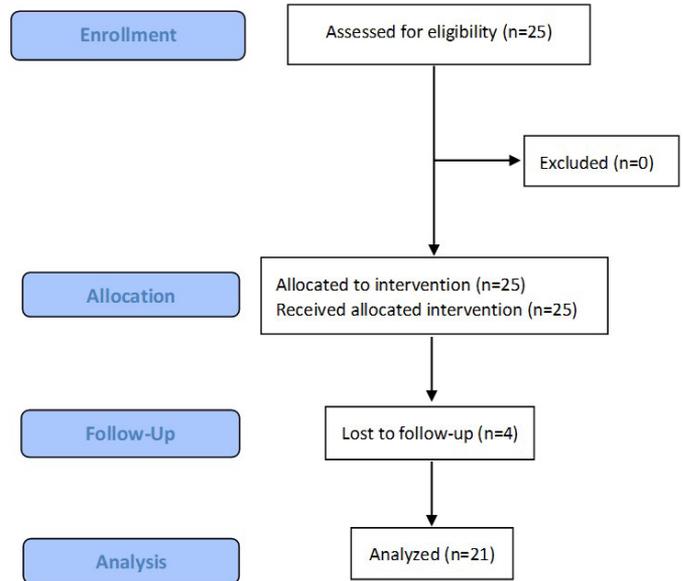
Patient Demographics

Twenty-five (25) participants were enrolled in the study. The mean age at consent was 60.5 years. Twenty-four (24) participants

TABLE 1.

Average Settings of Device Per Facial Area			
Area	Voltage (V)	Pulse Duration (ms)	Number of passes
Eyes and nose	280.0	28.0	2
Forehead	280.0	28.0	1
Full face	280.0	28.0	1
Nose	280.0	28.0	2
Lower lip and chin	278.2	28.4	4
Eyelids	277.4	28.6	2
Upper lip	276.6	28.8	3
Cheeks	275.2	29.1	3
Chin	274.4	29.3	5
Perioral	271.7	28.7	5
Cheeks and nose	271.6	29.9	2
Periorbital	269.4	29.0	2
Forehead	264.8	29.0	2

FIGURE 1. Study overview. A flow chart representing patient enrollment.



(96%) were female and 1 (4%) was male. All participants were White (14 participants being Fitzpatrick skin type II (56%), 11 type III (44%)). Nine (9) participants were treated with the 160-pin applicator and 16 were treated with the 80-pin applicator (Table 1, Figure 1). Twenty-five (25) participants were assessed for eligibility and treated, but 4 were lost to follow-up, therefore, 21 participants completed the study.

Participant Satisfaction

Participants were satisfied with their treatment, with mean scores of 2.6 (SE 0.1) at 6 weeks and 2.8 (0.1) at 12 weeks after the last treatment. At the 6-week follow-up, 66.7% reported being either “satisfied” (60.0%) or “very satisfied” (6.7%), with 20.0% reporting they had “no opinion.” By the 12-week follow-up visit, 71.4% of the participants reported satisfaction due to

FIGURE 2. Subject Satisfaction Score distribution at 6-week and 12-week follow-up.

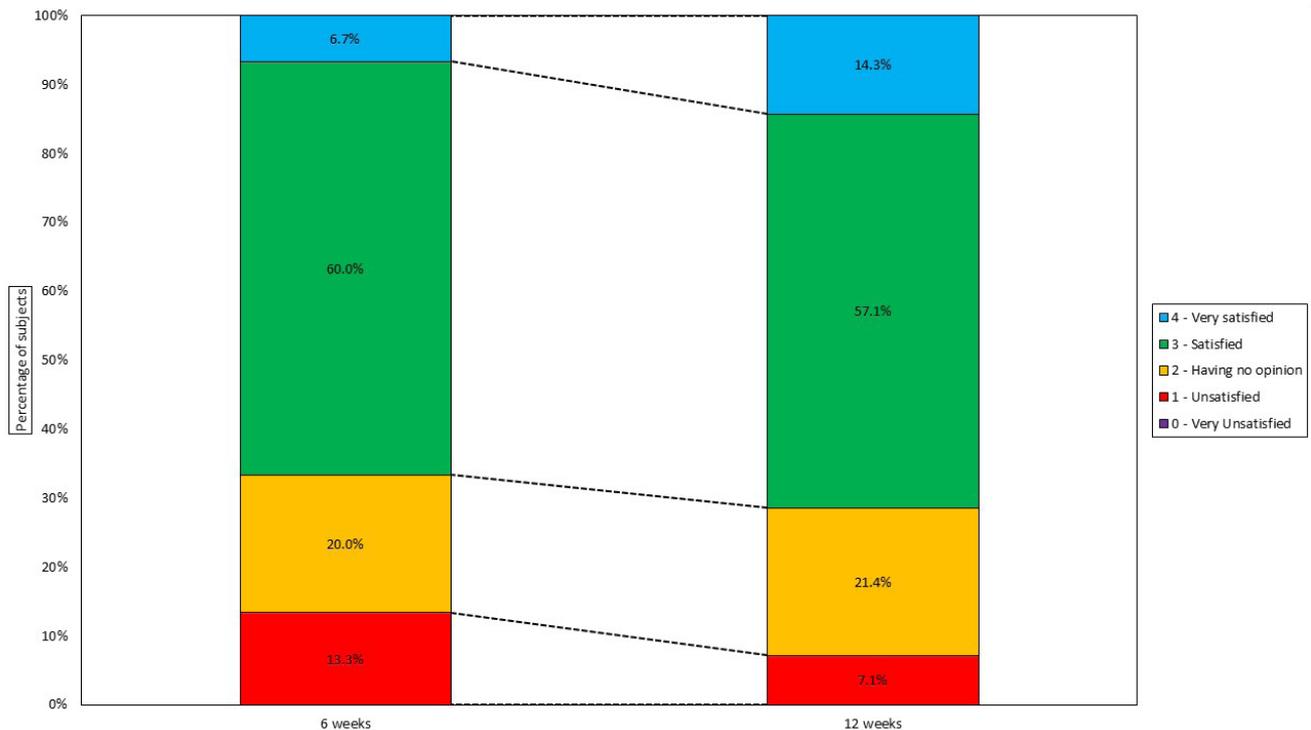


TABLE 2.

Demographic Data and Adverse Events of Participants	
Demographic data	Results (N = 25)
Age, mean (SD) (years)	60.5 (7.7)
Age, range (years)	44 – 79
Gender, n (%)	
Female	24 (96%)
Male	1 (4%)
Race	74
Caucasian	25 (100%)
Ethnicity	12
Not Hispanic or Latino	25 (100%)
Fitzpatrick skin type	1
II	14 (56%)
III	11 (44%)
Applicator	14
160-pin	9 (36%)
80-pin	16 (64%)
Adverse events (events)	2
Mild	
Cold sores	3
Pseudomonas aeruginosa	1
Moderate	
Swelling	1

their treatments, of which 57.1% reported: “satisfied” and 14.3% reported being “very satisfied” (Figure 2).

All participants reported some level of change at the follow-up visits compared to baseline. At the 6-week follow-up, 40% of participants reported a moderate or significant level of positive change. By the 12-week follow-up, 58% of participants reported a moderate or significant level of change. For 20% of participants, changes were noticed as soon as after 1 treatment, but most participants (47%) noticed the change after the second treatment (3 to 5 weeks post previous treatment). The most common specific changes in skin reported by participants at 12 weeks was smoother skin, improvement of fine lines, and firmer skin. At 12 weeks post final treatment, the most common specific changes in skin were improvement in fine lines, smoother skin, softer skin, and firmer skin. At 6 weeks post the last treatment, most participants reported the most significant area of wrinkle reduction around the eyes and at 12 weeks around the mouth (Table 2).

Safety Outcomes: Pain, Tolerability, and Adverse Events

Treatments were well tolerated at all treatment sessions. The average tolerability level of all 3 treatments was 3.2 out of a possible total of 4.0 (80-pin tip average 3.3 out of 4.0 and 160-pin tip 3.2 out of 4.0), correlating to “very tolerable,” and there was no significant difference of tolerability between treatments with 80-pin versus 160-pin tips ($P=0.42$; Figure 3).

FIGURE 3. Tolerability distribution as measured using a Tolerability scale for subjects who received treatment using the 80-pin and 160-pin tips.

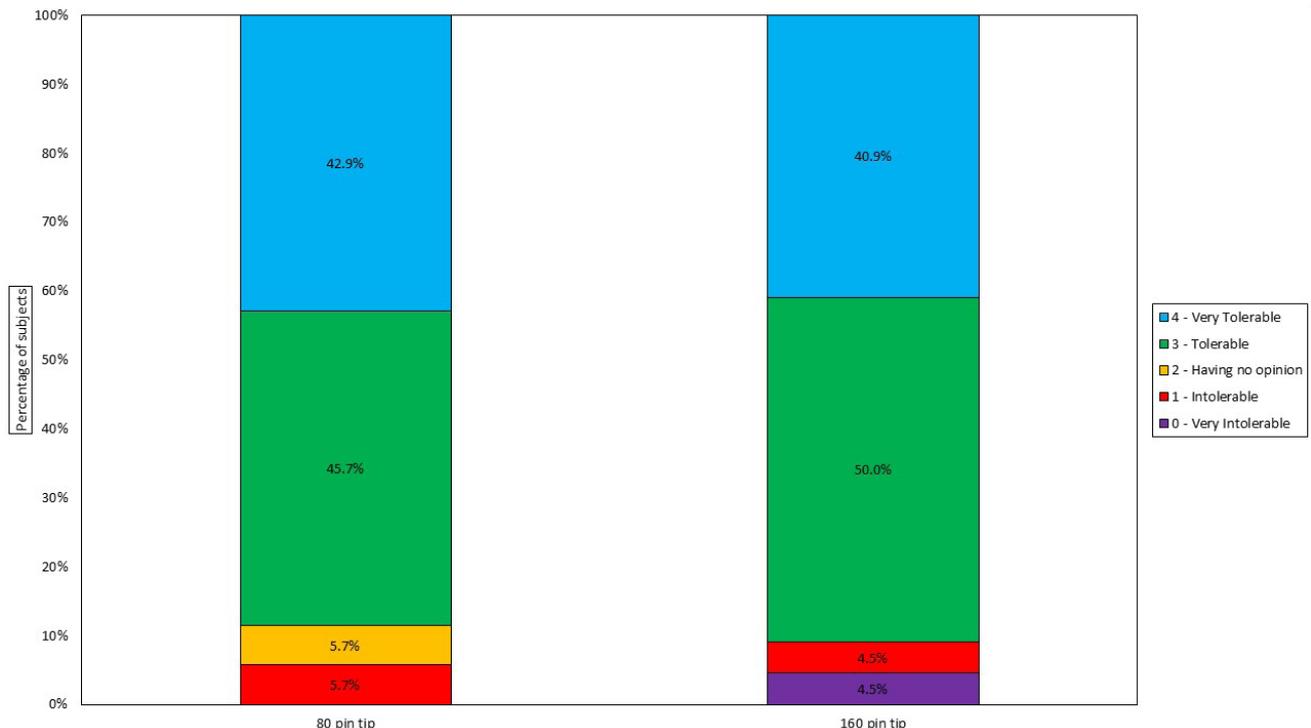


TABLE 3.

Treatment Evaluation Questionnaire for Wrinkles		
Question asked	Answer recorded	12-Week Follow-Up
What was the level of change? (percent)	Mild change	42%
	Moderate change	58%
When did you begin to notice changes? (percent)	At follow-up period	50%
	End of treatments	25%
	After first treatment	25%
What were the specific changes in skin? (events)	Improvement of fine lines	6
	Smoother skin	5
	Softer skin	4
	Firmer skin	4
	Decreased hyperpigmentation	1
	Plumper upper lip	1
	Lessened dark circles under eyes	1
Where was the specific area of wrinkle reduction? (percent)	Mouth	45%
	Around eyes	33%
	Cheeks	22%

The mean pain of all 3 treatments as measured using VAS was 4.0 cm out of 10.0 cm, which correlates to “mild pain.” There was no statistically significant difference in pain VAS scores between the 3 treatment visits ($P=0.67$), however, pain did on average decrease from 4.3 at the first treatment to 3.8 at the second treatment and to 3.5 at the third treatment.

Blinded Review of Photographs

A series of before and after photos were included for blinded review, using a global aesthetic improvement scale (GAIS), with -3=very much worse and +3=very much improved; with 1=being improved and 2=being much improved (Figure 4, 5). The GAIS incorporates characteristics such as wrinkling and pigmentation

FIGURE 4. Representative before and after photographs of a study subject using the 80-pin applicator.



FIGURE 5. Representative before and after photographs of a study subject using the 80-pin applicator.



FIGURE 6. Close image of the 80-pins on the applicator, pins do not penetrate the skin but rather sit on top of the skin and deliver energy.



and grades the overall aesthetic improvement of the subject. For the 21 patients who completed the study, photographs were reviewed in a blinded fashion where the pre-treatment and post-treatment photographs were not ordered. Nine (9) patients were noted to have improvement. In no case were the after photographs designated as worse than the before photographs.

DISCUSSION

Treatment sessions using FRF were well tolerated, and only 1 moderate adverse event was reported. Patients were satisfied with the results. After 3 treatment sessions at medium to high energy settings, the treatment showed subjective improvement in skin texture and wrinkles, with the improvements remaining for at least 3 months after the last session.

Patient satisfaction is increasingly recognized as a critical factor in determining the quality of care.¹²⁻¹⁷ Higher patient satisfaction has been shown to have a positive effect on patient retention, compliance, and reduce medical malpractice claims.¹⁸ Moreover, in aesthetic operations, patient satisfaction may be an outcome indicator in deciding whether patients return for subsequent procedures.¹⁹ Several other clinical studies have indicated that FRF technologies are successful in the treatment of skin laxity and wrinkles.^{15,20-25} Using the FRF technology described in this study, columnar quantities of tissue can be ablated with a zone of residual surrounding coagulation. This allows for highly customizable treatments, depending on the severity of wrinkles. FRF at various energy levels triggers a wound healing response with resolution within a 1-week period.²⁶ Additionally, FRF volumizes the dermis by stimulating endogenous formation of 3 key dermal constituents: collagen, elastin, and hyaluronic acid.

Many other FRF devices include sharp needles that are mechanically inserted into the skin before FRF energy is discharged. The insertion of these needles into the skin contributes to discomfort. The method we describe here is micro "pinning," which uses FRF to ablate fractions of the epidermis and external papillary dermis, without physical needle insertion into the dermis. The pins are placed against the skin during the energy delivery (Figure 6). This reduces the level of pain and the incidence of adverse events such as bleeding and post treatment

hyperpigmentation. In our analysis, there was no difference in satisfaction results or aesthetic outcomes between the 80-pin applicator and 160-pin applicator. Although the difference was not statistically significant, with more participants, a significant effect may be noted. The 80-pin tip can deliver double the amount of energy per pin compared to the 160-pin tip (up to 124mJ/pin for the 80-pin tip compared to up to 62mJ/pin for the 160-pin tip), which results in increased depth of ablation.

One sign of aging is rhytids in the perioral region. Dermal fillers can improve rhytids in that region; however, perioral rejuvenation with FRF has advantages over fillers, including a more natural appearance and longer duration.²⁷ Patients often experience improvement 6 to 8 weeks following FRF treatment and continue to improve for up to a year.²⁸ Most investigations on the lifespan of hyaluronic filler in the perioral area use a 3-month primary endpoint.²⁹⁻³¹ In comparison, maintenance treatment with FRF may only be necessary every 2 to 5 years.^{27,32-36} Following filler injection in the lips, the filler treatment of the upper lip tends to lengthen the top lip and can exacerbate wrinkling that area. FRF on the other hand, due to its coagulative impact, may result in shrinkage of the skin and moderate shortening of the upper lip. Our study found that participants saw most improvement around their mouth (45%) and around their eyes (33%), supporting FRF as an effective option for perioral/periorbital aging (Table 2).

CONCLUSION

Our results suggest that per treated participants' opinions, FRF is effective in improving wrinkles. Also, FRF treatments resulted in prolonged improvements in overall skin quality. The FRF device may be a viable alternative for patients desiring fast results and wanting to avoid the drawbacks of fractional laser treatments and dermal fillers.

DISCLOSURES

ER and BW have no conflict of interest.

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