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ORIGINAL CONTRIBUTION

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Clinical efficacy and safety evaluation of a novel fractional unipolar radiofrequency device on facial tightening: A preliminary report

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Summary

Background: Previous studies have shown that radiofrequency (RF) energy is safe and effective for improving skin laxity. Unlike monopolar and bipolar devices, little has been studied with the unipolar hand piece.

Objectives: We sought to evaluate the safety and efficacy of a novel fractional unipolar RF device on facial tightening.

Patients and Methods: This was a retrospective, single-center study of 14 subjects with age-related facial laxity who underwent five sessions of fractional unipolar RF at an interval of 2 weeks, and then followed-up for 3 months. Standardized photos were taken at baseline and at 3-months follow-up, and were assessed by two independent dermatologists using a 4-point scale (0=no improvement, 1=mild improvement, 2=moderate improvement, 3=significant improvement). Punch biopsies (2 mm) were performed and a questionnaire was used to evaluate the patient's satisfaction and the incidence of adverse reactions.

Results: Fourteen subjects with mild to moderate age-related facial laxity were included in the study. The mean age of the subjects was 49.7 years (range 32-80). 35.7% of the subjects showed significant improvement, 50% moderate improvement, and 14.3% slight improvement of facial laxity in their follow-up photos. About 85.7% of the patients replied that they were either greatly satisfied or satisfied with the results at 3-months follow-up. Skin biopsies revealed an increase in collagen in the dermis. None of the subjects experienced any serious adverse events during or after the procedure.

Conclusion: Our findings suggest that fractional Unipolar RF can be safely performed on the face and is effective in skin tightening. It has a great advantage over other forms of RF by being entirely painless.

KEYWORDS
efficacy, facial skin tightening, fractional unipolar RF device, novel

1 | INTRODUCTION

Facial skin tightening by collagen regeneration secondary to thermal injury was first observed using ablative laser resurfacing. More recently, non-ablative technologies have been employed for treatment of lax skin, and among the non-ablative skin tightening technologies, radiofrequency (RF) devices have been the most extensively studied.[1]

The medical use of RF is based on an oscillating electrical current that forces collision between charged molecules and ions, which are then transformed into heat.[2] RF heating is associated with a wide range of biological and clinical effects and has been proposed as a method for contracting loose, lax skin. In the dermis, RF-mediated thermal stimulation results in an immediate and temporary change in the helical structure of the collagen. It is also believed that RF heating stimulates fibroblasts with subsequent production of new collagen (neo-collagenesis), as well as other proteins that enhance the dermal structure.[3]

Currently, a number of RF devices are available in the market where RF is delivered in one of the three forms: monopolar, bipolar and unipolar.[1] The first RF to attain approval by the US Food and Drug Administration (FDA) for facial rhytides was a monopolar device (ThermaCool, Thermage, Hayward, CA) in 2002.[3,4] Bipolar devices were subsequently developed, attaining FDA approval in the following years.[5-8] A newer application of RF involves the emission of electromagnetic radiation (EMR) rather than current. When RF is delivered as EMR, the delivery is called unipolar and no grounding pad is necessary.[9] Recently, additional modalities such as fractional RF was developed to further improve the efficacy and safety. It is largely divided into electrode pin fractional RF and microneedle fractional RF with most being bipolar or multipolar.[10-14] In this study, we investigated the facial skin tightening effect of a new RF device with a fractional unipolar hand piece and vacuum for the first time.

FIGURE 1 A cooled, vacuum-assisted unipolar RF hand piece (6 pins, each with a diameter of 5 mm are situated within the area of 5 cm^2)

2 | SUBJECTS AND METHODS

This was a single-center study where data were collected retrospectively using electronic medical record entries and coding information. An informed consent was obtained from all patients. Telephone calls were placed to patients requesting additional information or photography taken when appropriate. The study was performed in accordance with the Declaration of Helsinki (1975) and approved by the institutional review board of the university hospital.

Patients who received five sessions of fractional unipolar RF (Tune Face™, Accent Prime, Alma Lasers, Caesarea, Israel) on the face by a single physician between 12/11/2015 and 22/04/2016 and then followed-up for 3 months were identified. Subjects who received other skin rejuvenation procedures during the follow-up period were excluded. All patients who fulfilled the inclusion and exclusion criteria were selected as study subjects in a consecutive manner. Information gathered through patient questionnaire at 3-months follow-up included the overall degree of satisfaction (unsatisfied, slightly satisfied, satisfied, and greatly satisfied); and the pain or discomfort associated

TABLE 1 Summary of the patients' characteristics and treatment outcome following treatment with a novel unipolar RF device

	Gender	Age	Skin type	Objective score	Subjective score	Pain score
1	F	46	II	3	2	0
2	F	80	II	2	2	0
3	F	40	IV	3	3	0
4	F	53	III	2	2	0
5	F	57	III	3	3	0
6	F	48	III	2	2	0
7	F	47	II	3	3	0
8	F	57	III	3	3	0
9	F	48	II	1	2	0
10	F	50	II	1	1	0
11	F	43	III	2	1	0
12	F	32	III	2	2	0
13	F	47	II	2	2	0
14	F	48	III	3	3	0

Objective scores; 0=no improvement, 1=slight improvement, 2=moderate improvement, 3=significant improvement.
Subjective scores; 0=not satisfied, 1=slightly satisfied, 2=satisfied, 3=greatly satisfied.
Pain score (VAS); 0=no pain, 10=worst pain imaginable.

with unipolar RF (visual analog scale (VAS); 0- no pain, 10- worst pain imaginable). Standardized photographs, taken initially and at 3-months follow-up were compared by two blinded dermatologists where the degree of improvement in facial laxity was analyzed using a 4-point scale (0=no improvement, 1=mild improvement, 2=moderate improvement, 3=significant improvement). Punch biopsies (2 mm) taken from nine patients at 1 month follow-up visit after the final treatment were evaluated. Any adverse effects (fat atrophy, erythema, edema, and paresthesia, etc.) were assessed up to 3-months post-treatment.

The treatments were performed without any anesthesia. A cooled, vacuum-assisted unipolar RF applicator was applied to the face. The forehead, temples and the malar area were treated with a 40.68 MHZ, 5 cm^2 hand piece (6 pins, each with a diameter of 5 mm are situated within the 5 cm^2 area) (Figure 1) at a setting of power: 60-65 Watts (W), on/off time: 2 seconds (heating)/3 seconds (cooling), high vacuum and phase shifter: superficial. The cheeks and submentum were treated with the same probe with the power set at 65-75 W, on/off time: 2 seconds (heating)/3 seconds (cooling), high vacuum and phase shifter: superficial. A total of seven passes were applied and five treatments at 2 week intervals were performed.

3 | RESULTS

A total of 14 female patients with age-related facial laxity who underwent treatment with a novel unipolar RF device were evaluated. The mean age of the subjects was 49.7 years (range 32-80) and Fitzpatrick skin types 2 through 4 were represented in our cohort. All subjects completed five treatments at 2-week intervals.

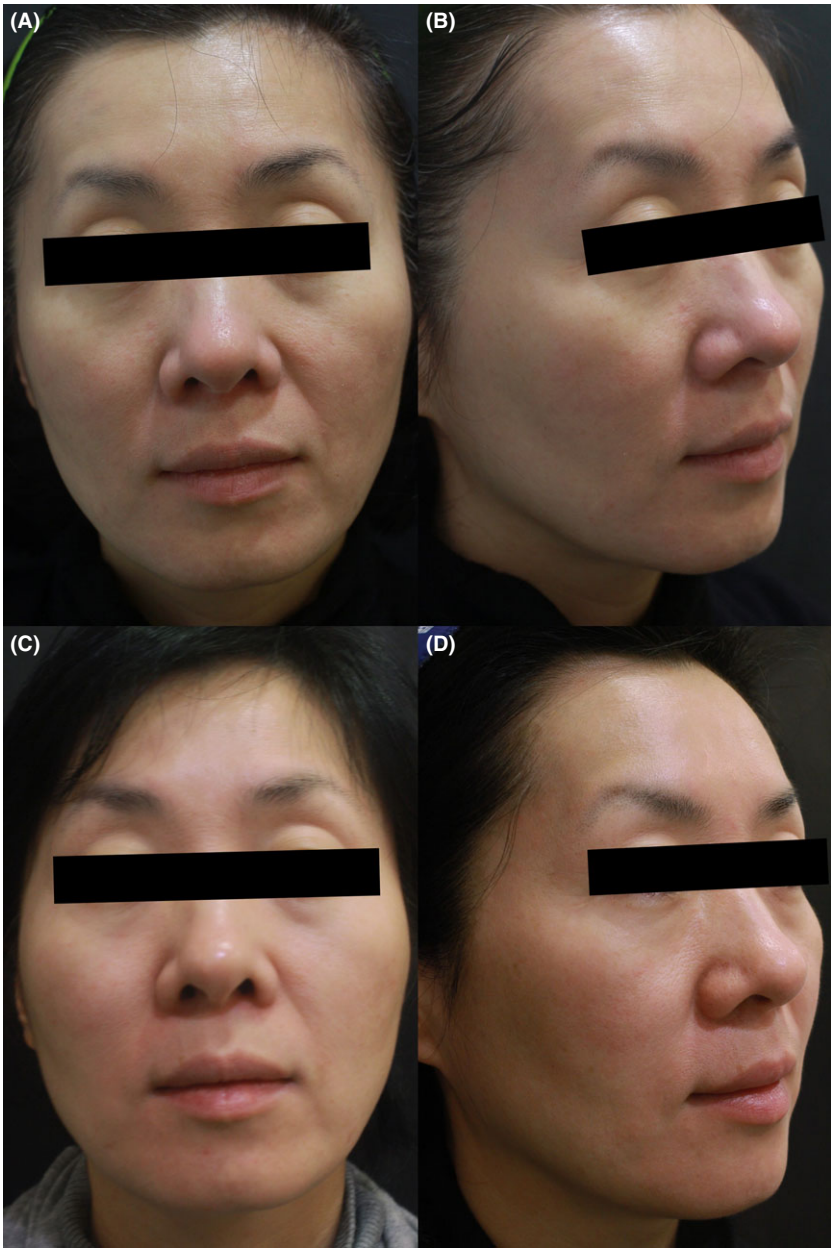

FIGURE 2 Initial (A,B), Photographs taken at 3 mo follow-up after receiving five sessions of unipolar RF to the face, each sk apart (C,D)

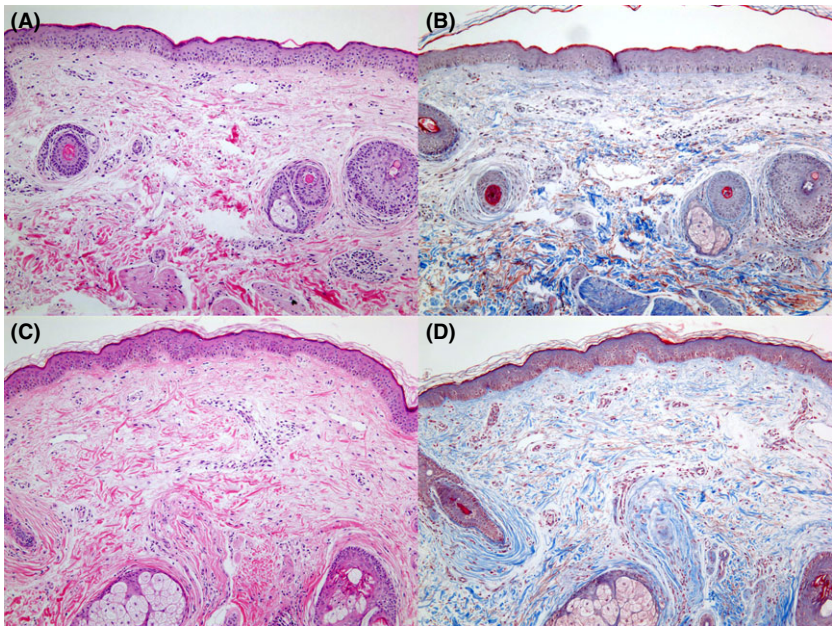

FIGURE 3 The histology of the facial skin before unipolar RF (A) with significant loss of collagen in the reticular dermis (B). Findings after unipolar RF with a cooled, vacuum-assisted hand piece (C) with increase in collagen density and distribution in the reticular dermis (D). (A, C: H&E ×200; B,D: Masson's trichrome, ×200)

According to the results of the questionnaire taken at 3-months follow-up, subjects reported that they were either greatly satisfied (42.9%) or satisfied (42.9%) with unipolar RF treatment. During the procedure, patients felt no pain, with an average pain score being 0 based on the VAS (Table 1).

Two blinded dermatologists identified significant improvement of skin laxity in 35.7%, moderate improvement in 50% and slight improvement in 14.3% of subjects at 3-months follow-up compared with the baseline (Figure 2). No serious adverse event including facial fat atrophy was observed.

Hematoxylin and eosin (H&E) staining of the skin before treatment revealed significant fragmentation and loss of dermal collagen in the reticular dermis, which was confirmed by Masson's trichrome staining (Figure 3A,B). Post unipolar RF biopsy specimens showed an increased number of thick collagen bundles in the reticular dermis under H&E and Masson's trichrome staining (Figure 3C,D).

4 | DISCUSSION

Since its introduction in aesthetic medicine, RF technology has been used for many indications which includes skin tightening and wrinkle reduction. Being non-ablative, RF has proved itself in daily practice as a safe and efficient way to stimulate collagen contraction and neo-collagensis with minimal downtime.[15] Lack of chromophore dependence makes the system appropriate for all skin types,[16] and as a result, RF has been widely performed in Asians.

A unipolar device emits an electromagnetic field which produces heat in the area adjacent to the hand piece with a predictable depth of penetration. It does not require any grounding because it produces dielectric heating while the other RF systems use resistive heating. Dielectric heating occurs when the frequency goes above 10 MHz with the rotation and friction of water molecules. The advantage of dielectric heating is fast and uniform heating of the skin. The first Unipolar RF approved by the FDA for skin tightening was in 2005.[17,18] In this study, we used an updated version of the device with a specialized treatment tip for the face to find it safe and effective in facial skin tightening.

RF devices have evolved over the years. At first, RF treatment caused a great deal of pain,[3,5,6] on many occasions requiring anesthesia of some variety for the procedure to be successfully performed. Notably, RF treatment in our study was painless and was highly appreciated by all patients.

The device adopted in this study is the newest unipolar RF applicator developed for facial skin tightening which uses contact cooling and a vacuum (for better cooling and deeper RF penetration). It is also differentiated from prior unipolar RF hand pieces by being fractional. The first fractional unipolar RF technology was invented in 2005 where the electrode organized micro-sparks (microplasma)

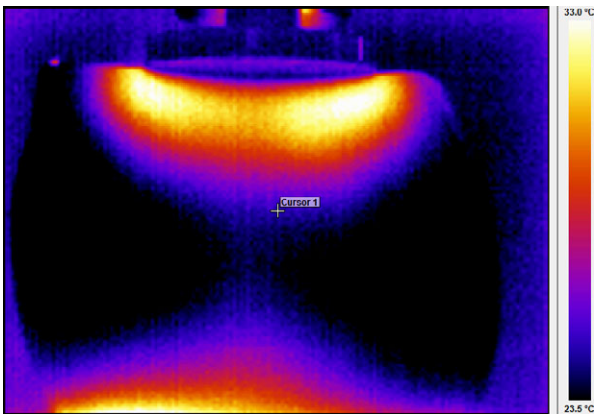

FIGURE 4 A thermography showing the edge heating at extended unipolar electrodes

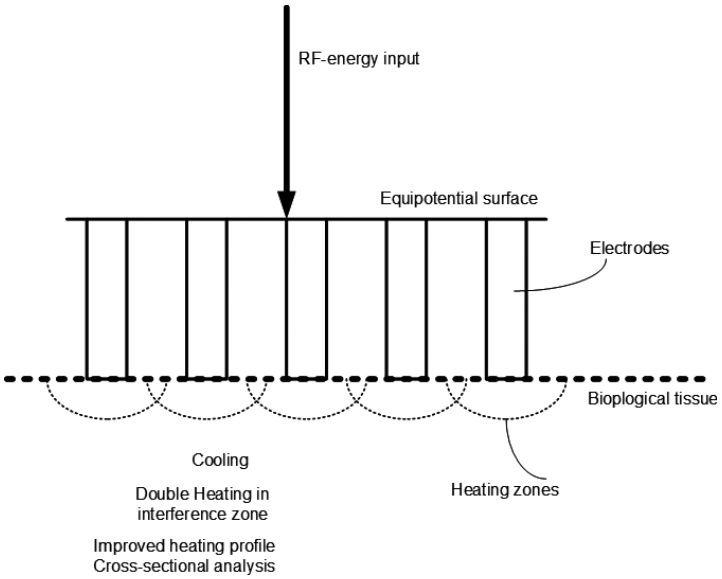

FIGURE 5 A drawing of partition unipolar electrode providing several contact areas with the biological tissue being treated

causing superficial skin ablation.[19] The current applicator is non-ablative and has a fractional heating electrode. Increasing the unipolar RF electrode dimension is time-saving and convenient for practitioners but has been limited because of its skin effect. The RF current which flows through the extended area go to the electrode edge causing intense heating of the biological tissue near the edges (Figure 4). To overcome the limitation of the unipolar RF-energy coupling system, this new device provides several contact areas with uniform heating of the skin (Figure 5), and has allowed an increase in hand piece diameter up to five times. Our novel RF tip appears to be painless without adverse events such as burns, because peak temperatures at the dermo-epidermal junction (DEJ) do not increase to the same extent as prior RF delivery methods.[1] Free nerve endings, the most prominent sensory receptors in the skin are most common in the papillary dermis beneath the DEJ and most pain fiber terminals are located at or within 25 μm of the DEJ.[20]

One should understand that appropriate patient selection is the key for success in tissue tightening.[21] With our unipolar RF device, we noticed that patient satisfaction and results of objective assessment were best in those with oily skin. The penetration depth of unipolar RF (superficial mode: 5-8 mm) is claimed to be slightly deeper than both monopolar and bipolar devices (2-4 mm),[1,2] and it has been noted that with the unipolar RF, the highest temperature achieved is located several millimeters beneath the skin. Sebaceous glands absorb a substantial amount of RF energy delivered to the deeper dermis and it would be natural to see greater heating (also greater remodeling and greater neo-collagenesis) of the dermis in those with active or hyperplastic sebaceous glands.

As RF technology continues to rapidly advance, physicians and patients can choose from a sophisticated selection of treatment techniques to improve skin appearance. The current device is an advance in that the RF is EMR, not current (unipolar RF), and with a novel applicator, the treatment is entirely painless with little-to-no recovery and no adverse effects. It therefore offers an additional step in non-ablative treatment for skin laxity.

These advances along with future developments, and the selection of appropriate patients will continue to keep RF technology at the forefront of the dermatologist's armamentarium for skin tightening and rejuvenation- however, more randomized controlled trials are needed to increase the knowledge on this relatively new and rapidly developing technology.

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