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ORIGINAL ARTICLE

Treatment of periorbital wrinkles using multipolar fractional radiofrequency in Korean patients

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Abstract A limited number of studies have evaluated the efficacy and safety of electrode pin fractional radiofrequency (FRF) for periorbital wrinkle treatment in Asian patients, but none have measured noninvasive methodological objective parameters such as periorbital wrinkle area. This study aimed to investigate the efficacy and safety of electrode pin multipolar FRF for the improvement of periorbital wrinkles in Korean patients by using a noninvasive methodological objective parameter. Seventy female subjects with periorbital wrinkles (age range, 40–60 years) participated in this study. Each patient underwent three sessions of FRF treatment to the periorbital region separated by 2-week intervals. The area of periorbital wrinkles was analyzed by using a Robo Skin Analyzer CS50 at 4 weeks after the final treatment session. Periorbital wrinkle area was significantly decreased at 1-month follow-up (75.77 ± 29.46 mm^2) compared to baseline (94.74 ± 31.62 mm^2). The improvement ratio of periorbital wrinkle area was 20.02 %. Side effects were limited to transient mild erythema, swelling, and crusts. Pain was tolerable without local anesthesia. Our findings suggest that the multipolar electrode pin FRF can be an effective and safe method for reducing periorbital wrinkles in Asian patients.

Keywords Fractional · Radiofrequency · Periorbital wrinkle · Asian · Multipolar

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Introduction

Radiofrequency (RF)-based treatment first emerged in the 1990s as a minimally invasive procedure in the field of aesthetic medicine to improve skin aging [1]. RF induces volumetric heating through tissue resistance, and this heating effect stimulates initial collagen contraction and wound-healing response, which leads to remodeling of dermal collagen, tightening of skin tissues, and neocollagenesis [2]. These effects impact deeper tissue compared with laser-based treatment [3]. Since the US Food and Drug Administration (FDA) approved RF devices for the treatment of periorbital wrinkles in 2002 [1], they have been used for the improvement of skin tightening [4], wrinkles, and acne scarring [5–7] and also applied for the treatment of hyperhidrosis and paraffinoma [8, 9].

Fractional photothermolysis (FP) was developed in the field of lasers [7, 10, 11]. Fractionated ablative laser permits the formation of ablated microscopic zones of epidermis and dermis in a grid pattern while leaving the surrounding tissue intact. The reservoir of cells in the intact tissue promotes rapid healing. Thus, this method can achieve increased efficacy compared to nonablative laser and greater safety compared to ablative laser [12]. However, the risk for postinflammatory dyspigmentation is still present, especially in Asian patients with darker skin [11, 13–15].

Recently, fractional RF (FRF) was developed to further improve efficacy and safety. It is largely divided into electrode pin FRF and microneedle FRF [12, 16, 17]. Microneedle FRF creates thousands of microclefts in the papillary dermis invasively, creating nonhomogeneous fractional thermal wounds directly into the reticular dermis [18, 19]. Electrode pin FRF generates a thermal microwound to the epidermis with electrode stimuli and simultaneously delivers nonablative dermal heating [20].

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Few studies have investigated the efficacy and safety of electrode pin FRF level for the improvement of periorbital wrinkles in Asian patients, but none have used noninvasive methodological objective parameters such as periorbital wrinkle area to assess outcomes. In this study, we investigated the efficacy and safety of multipolar electrode pin FRF for the improvement in periorbital wrinkles in 70 Korean patients by using an objective parameter.

Methods

Patients

This study included 70 subjects ranging from 40 to 60 years of age who were deemed to have wrinkles at their periorbital regions. Exclusion criteria included active skin disease; cosmetic treatment including Botox, laser, or RF-based therapy to improve facial wrinkles within 6 months before enrollment; pregnancy; and the presence of implantable medical devices.

Materials

An electrode pin FRF device (DuetRF, Eunsung Global Inc., South Korea) was applied to periorbital wrinkles for treatment by using a disposable fractional RF tip. The fractional RF tip consisted of an 8×8 matrix array (10.5×10.5 mm) of 64 positively charged electrode pins, separated by 1.5-mm intervals, and four negatively charged electrode pins around the positive electrode matrix for delivering 4 MHz of conducted RF current (Fig. 1).

The minimal spot size of the fractional RF tip enabled the transfer and spread of heat energy through the epidermis and allowed the heat energy remained longer in the dermal layer.

Fig. 1 The fractional radiofrequency tip with a contact area of 10.5×10.5 mm^2

Protocols

The study protocol was approved by the Institutional Review Board of Konkuk University Hospital, Seoul, South Korea, and informed consent was obtained from all individual participants. The treatment area was randomly assigned to either the left or the right side. Each patient underwent three sessions of FRF treatment to the periorbital region at 2-week intervals. After removal of makeup and washing the face, the periorbital region was cleansed with an alcohol solution. Afterwards, a one-pass treatment was performed by applying six shots in a nonoverlapping motion covering a 30×30-mm^2 area of the lateral region of the eye, the treated area. An average treatment energy of 2.5 J was applied per shot (section 1, step 1, and level 7 of the duet RF program settings).

Assessments

The area of periorbital wrinkles was evaluated at baseline (visit 1) and 1 month (visit 4) after final treatment by using a Robo Skin Analyzer CS50 device (Inforward Inc., Japan). This device photographed the skin with a 3CCD digital camera, and the area of wrinkles was calculated by using the software provided by the manufacturer. The area of wrinkles was defined as regions in which pixels varied from the surrounding pixels of wrinkle-free regions in an image [21]. The improvement ratio of periorbital wrinkles was defined as follows:

$$\text{Improvement ratio }[\%] = (\text{area of wrinkles at baseline} - \text{area of wrinkles at 1-month follow-up}) \Big/ \text{area of wrinkles at baseline} \times 100.$$

Side effects were immediately reported for the safety evaluation.

Patients' satisfaction with periorbital wrinkle reduction on a five-point scale was also measured at the 1 month after the last treatment to assess the subjective efficacy and safety of FRF.

Statistical analyses

The data analyses were performed by using SPSS software (version 17.0, SAS Institute, Cary, NC, USA). Quantitative assessments of periorbital wrinkles were compared by paired *t* test. The threshold for statistical significance was a *P* value less than 0.05.

Results

Of the 70 included patients, 66 (mean age 54 years) completed the study. Four patients were excluded as they were lost to follow-up. The Robo Skin Analyzer CS50 presented the area

Table 1 Area of periorbital wrinkles (mean ± standard deviation)

Baseline (mm^2)	At 1-month follow-up (mm^2)	*P*
94.74 ± 31.62	75.77 ± 29.46	<0.001*

*$P < 0.05$, statistically significant

of wrinkles as red markers in the 30 × 30-mm^2 area of the periorbital region.

The area of periorbital wrinkles significantly decreased by about 19 mm^2 at 1-month follow-up (75.77 ± 29.46 mm^2) compared to baseline (94.74 ± 31.62 mm^2, Table 1). As shown in Figs. 2 and 3, a considerable reduction of periorbital wrinkles was observed after electrode pin FRF treatment compared to baseline. The improvement ratio of periorbital wrinkle area was about 20.02 %.

Side effects were limited to transient mild erythema and swelling lasting 1–12 days and crusts lasting 2–5 days. Pain was tolerable among all patients without local anesthesia. No burns, infections, scars, or postinflammatory hyperpigmentation were noticed at each visit. In total, 95.5 % of the patients scoring "neutral" or higher reported satisfaction with periorbital wrinkle reduction through FRF treatments (Fig. 4).

Discussion

The dermal layer preserves skin elasticity by an extracellular matrix comprising fibrous proteins including collagen, elastin rooted in fibroblasts, and mucopolysaccharides with hyaluronic acid [22]. Fibrous proteins such as collagen and extracellular matrix of tissues are decomposed by intrinsic and extrinsic factors, including increased age, ultraviolet (UV) radiation, and environmental pollution, thereby inducing skin aging with wrinkles and a loss of elasticity [22–25]. In particular, exposure to UV radiation causes papillary dermis and middermis to accumulate elastotic material [26], resulting in degradation of collagen and depletion of collagen synthesis via fibroblast damage and protein oxidation [27]. Periorbital wrinkles primarily emerge from natural facial expressions, such as smiling via orbicularis oculi muscle contraction as well as photoaging by UV radiation [28]. However, periorbital wrinkles are quite difficult to treat due to their delicate anatomical structure and function; complications, such as ectropion and scarring, can be caused by periorbital treatment [19].

RF is a noninvasive method for skin rejuvenation by using electrical current. Two typical electrode configurations of RF are available in medicine: monopolar and bipolar [2, 29]. In monopolar RF, electrical current from the active electrode passes through target tissue to a grounding pad. The electrical current of monopolar RF creates volumetric dermal heating in the tissue, but the depth of dermal heating cannot be controlled precisely [19]. In bipolar RF, electrical current passes between two active electrodes in contact with the skin [5, 19, 29]. The depth of penetration of bipolar RF energy is half the distance between the two electrodes [29]. Thus, bipolar RF can control the distribution of RF current inside the tissue and can be used more safely than monopolar RF with less pain.

Electrode pin FRF is a multipolar RF device made up of a large number of paired bipolar RF electrodes [5]. It simultaneously allows epidermal microablation and volumetric heating of the dermis [30]. Its mechanism of action involves RF energy acting on nitrogen gas to form high-energy foci called plasma sparks, resulting in a portion of the atoms being ionized and applied evenly onto the skin [31]. This phenomenon causes mild epidermal microablation with formation of microchannels [31], and the dermis is heated by rotational movement in water molecules by RF energy [29, 30]. Thus, FRF permits epidermal and dermal skin rejuvenation effects.

There have been some studies investigating the efficacy and safety of electrode pin FRF in the treatment of periorbital wrinkles in Asian patients. Lee et al. [11] observed significant improvement in fine lines, pores, smoothness, and tightness in the periorbital area in 26 Asian subjects after three sessions of electrode pin fractional RF treatments of using photographic evaluation. In this study, we investigated the effect of electrode pin FRF on periorbital wrinkles in Korean patients by calculating the area of periorbital regions. Using the objective parameter of periorbital wrinkle area, we could quantitatively observe significant improvement in periorbital wrinkles.

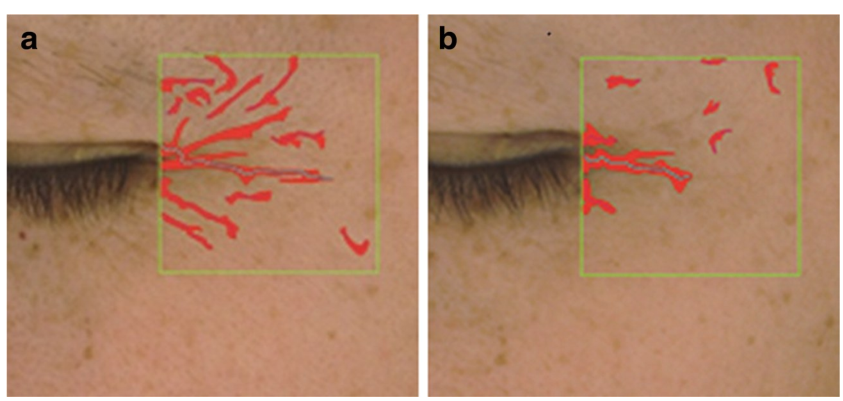

Fig. 2 The area of periorbital wrinkles of a 56-year-old female subject assessed by Robo Skin Analyzer **a** before treatment and **b** 4 weeks after the final electrode pin multipolar fractional radiofrequency treatment

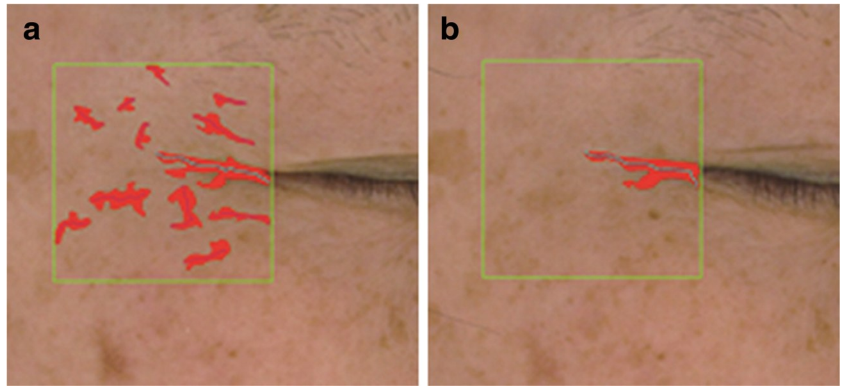

Fig. 3 The periorbital wrinkle area of a 59-year-old female subject assessed by Robo Skin Analyzer **a** before treatment and **b** 4 weeks after the final electrode pin multipolar fractional radiofrequency treatment

According to previous research, the RF device can produce conformational changes in collagen fibers immediately upon achieving temperatures within the dermis from 57 to 61 °C and long-term neocollagenesis starting at 4–6 weeks after treatment [2, 30]. The neocollagenesis is the result of dermal remodeling to decompose damaged collagen by collagenase and replace it with new collagen [32]. Fractional RF also provides minimal epidermal ablation as well as volumetric dermal heating [31]. Therefore, even though a low-energy level (an average of 2.5 J per shot) was applied, it seems that the effects of re-epithelialization and dermal remodeling could lead to significant improvement in periorbital wrinkles at 4 weeks after the last treatment session in this study.

Asian people have intrinsically darker skin and are susceptible to adverse events such as postinflammatory hyperpigmentation [11, 13–15, 33]. In spite of the development of fractional photothermolysis, darker skin is still at risk of these adverse events [11, 13, 19, 34]. In this study, side effects were limited to transient mild erythema and crusts lasting 1–12 days. Other adverse events, such as postinflammatory hyperpigmentation, burns, infections, and scars, were not observed at each visit. Consistent with our results, Lee at al. [11] applied a bipolar RF-based electrode pin fractional device to Asian subjects and observed that adverse events were limited to mild erythema, swelling, and scabs lasting an average of 3.9 days after treatment. Kim et al. [19] applied microneedle FRF to 11 female Asian subjects and found that no patients reported postinflammatory hyperpigmentation after the procedure, with skin crusts and scaling improved within 1 week. In contrast to laser energy absorbed by the chromophore, RF energy is independent of chromophores and instead dependent on the electrical properties of the target tissue and thus safer for darker-skinned populations [19, 35]. Furthermore, electrode pin FRF devices induce more minimal epidermal destruction, which is associated with postinflammatory dyspigmentation, than laser-based fractional ablative resurfacing [3, 12]. These scientific mechanisms of action support the lower risk of postinflammatory hyperpigmentation after FRF treatment observed in this study.

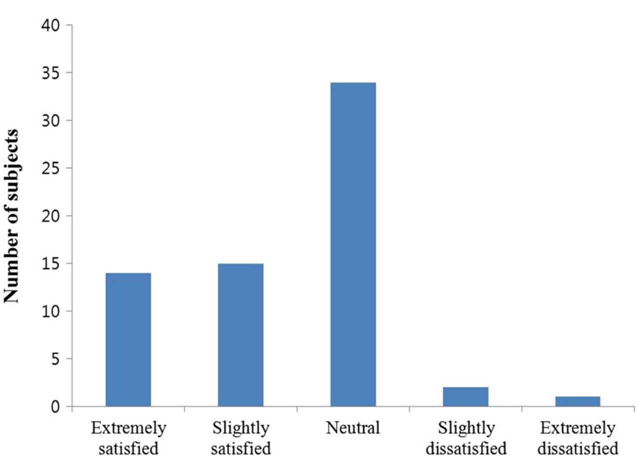

Fig. 4 Subjective satisfaction of patients

Pain is one of the crucial factors in treatment compliance. However, pretreatment with local anesthesia can change tissue impedance and is therefore not recommended for RF procedures [36]. We observed that pain was well tolerated without local anesthesia in this study. In contrast to our device setting, treatment of FRF using microneedles required local anesthesia to control the pain caused by the needling procedure; on occasion, even the local anesthesia cream was insufficient to control the pain [19, 37]. Lee et al. [11] applied electrode pin RF to facial skin at 4–25 J with 4- to 6-week intervals—a higher energy with longer treatment intervals than were used in the present study. Despite using local anesthesia, 88 % of patients reported moderate pain after the sessions [11]. According to this previous report [11], pain is associated with higher density rather than higher energy, but by evaluating the difference between previous study conditions and ours, it seems that the level of energy also influences pain. However, further study is needed to confirm the correlation between energy level and pain.

In conclusion, using an objective parameter for evaluation could strengthen the scientific evidence of this study. After FRF treatment, the area of periorbital wrinkles was significantly decreased, and the treatment was generally well tolerated. These findings suggest that electrode pin multipolar FRF treatment is an effective and tolerable treatment option for the treatment of periorbital wrinkles in Asian patients.

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Compliance with ethical standards

Conflict of interest Yeong Min Yoon is an engineer of Eunsung Global Corporation.

Informed consent and ethical approval The study protocol was approved by the Institutional Review Board of Konkuk University Hospital, Seoul, South Korea, and informed consent was obtained from all individual participants. All procedures conducted in this study were in accordance with the Helsinki Declaration.

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