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ORIGINAL ARTICLE

Usefulness of Monopolar Thermal Radiofrequency Treatment for Periorbital Wrinkles

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Background: Over the past 10 years, monopolar radiofrequency (MRF) technology has been widely used by dermatologists as a valuable modality to effectively tighten and rejuvenate photoaged skin. It also has the benefit of a short recovery time. **Objective:** Using an objective parameter, this study aimed to assess the efficacy and safety of MRF, which is the basic modality of radiofrequency technologies, for treatment of periorbital wrinkles in Korean patients. **Methods:** We enrolled 70 middle-aged female patients with periorbital wrinkles for this study. Each patient underwent triple sessions of MRF treatment in the periorbital region, separated by 2-week intervals. Clinical photographs were obtained, and the areas of wrinkles were measured using a Robo Skin Analyzer CS50 (Inforward Inc., Japan) at baseline and 4 weeks after the final treatment session. **Results:** Significant reduction in the mean area of periorbital wrinkles was detected at 1-month follow-up (80.64 ± 28.96 mm^2) compared to baseline (95.08 ± 31.93 mm^2). The improvement ratio of the wrinkle area was 15.19%. Pain during procedure seemed to be tolerable without any local anesthesia for all patients. Transient mild erythema was the only side effect reported during the study. **Conclusion:** In conclusion, MRF could still be an attractive modality for Korean patients with periorbital wrinkles if the treatment is conducted repeatedly with sufficient energy and proper intervals. **(Ann Dermatol 30(3) 296~303, 2018)**

-Keywords-
Monopolar radiofrequency, Periorbital wrinkles, Photoaging

INTRODUCTION

As the demand for cosmetic intervention has increased, nonsurgical anti-aging treatments requiring less recovery time have gained popularity. Ablative and nonablative laser devices have been the main anti-aging tools used to improve skin laxity and rhytides[1]. However, these modalities have some limitations. Ablative lasers are associated with some side effects, including oozing, bleeding, and infection, and they require considerable recovery time[2]. Although nonablative lasers were developed to overcome the disadvantages of ablative devices, they also have some problems, such as scattering and suboptimal energy penetration[3]. Over the past 10 years, nonablative radiofrequency (RF) has been actively used as an innovative technology and is anticipated to become an alternative to laser treatments[4].

RF-based treatments have broad medical applications beyond cosmetic uses. Since RF technology was first developed for electrocautery in the 1920s, it has been widely used for purposes ranging from joint capsular tightening to neoplasm eradication in the prostate and liver[5,6]. Monopolar radiofrequency (MRF) was the first RF system introduced for esthetic purposes. It was approved by the U.S. Food and Drug Administration in 2002 (Thermacool; Thermage Corporation, Haywood, CA, USA) for the treatment of periorbital wrinkles[4]. Since then, many kinds of RF instruments have been widely used in cosmetic dermatology.

Although MRF devices are still widely used in cosmetic

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dermatology, there have been few clinical studies on them, especially with regards to their use in Asian patients. Guidelines presenting standardized treatment protocols have not been established. Nevertheless, it seems that efforts to verify the actual efficacy and safety of MRF have rapidly decreased because many other anti-wrinkle instruments have been developed. In this study involving Korean patients, we investigated the efficacy and safety of MRF, which is the basic modality of RF technologies and the most commonly, used modality for the treatment of periorbital wrinkles.

MATERIALS AND METHODS

Patients

Seventy Korean patients ranging in age from 40 to 60 years with periorbital wrinkles gave informed consent for the study. Patients who had active skin diseases or who were pregnant were not included. The study also excluded patients with a history of concomitant cosmetic procedures to treat facial wrinkles, including botulinum toxin injections, laser therapy, or other RF-based therapies, within 6 months before enrollment. Presence of an implantable medical device such as a pacemaker was also an exclusion criterion.

This study protocol received approval from the Institutional Review Board of the Konkuk University Medical Center, Seoul, South Korea, and all participants provided informed consent prior to enrollment (IRB no. KUH 1120047).

Treatment protocols

An MRF device (Duet RF; Eunsung Global Inc., Wonju, Korea) was used in this study. The surface of the thermal RF tip is described in Fig. 1A. The thermal RF system consists of a positively charged tip (Fig. 1A) and a separate negatively charged ground pad (Fig. 1B) that delivers 4 MHz of RF energy. The surface area of the tip in contact with the skin is 18.4×18.4 mm, and it is composed of a 13×13 matrix array of 169 positively charged electrodes placed at 0.7-mm intervals.

We randomly assigned the treatment region to either the right or the left periorbital region. After patients removed their cosmetics and washed their faces, we cleansed the target periorbital region (more accurately, the lateral portion of an eye) with alcohol solution. Then, we attached the ground pad to the anterior trunk in the supine position and applied electrically conductive viscous fluid to the target region. Then, RF energy was delivered using 20 passes with an average of 2.5 J per shot (Section 1, Step 1, and Level 7 of Duet RF) covering an area of 30×30 mm^2. We conducted a total of three sessions at 2-week intervals. No topical anesthesia or sedative drug was provided before the procedure.

Assessments

To evaluate the wrinkle-reducing effects of 4-MHz RF, we measured the area of periorbital wrinkles using a Robo Skin Analyzer CS50 device (Inforward Inc., Tokyo, Japan), which photographed the skin with a 3CCD digital camera and calculated the area using software. The software provided by the manufacturer distinguished the area containing wrinkles from the wrinkle-free regions by using different image pixels[7]. All patients underwent assessment at baseline (visit 1) and 1 month after the last treatment (visit 4). The evaluations during pretreatment and post-treatment were compared. Post-procedural follow-up was scheduled after 8 weeks from the first session, or 4 weeks from the last session, as collagen remodeling induced by thermal stimulation, such as RF treatment, is known to last for 4～6 weeks[8]. Improvement in periorbital wrinkles was assessed with the following ratio: improvement ratio [%]=(area of wrinkles at baseline−area of wrinkles at 1-month follow-up)/area of wrinkles at baseline×100. In addition, all subjects were asked to respond to the patient self-satisfaction survey that assessed subjective efficacy of MRF in regard to periorbital wrinkle reduction on a 5-point scale (extremely satisfied, slightly satisfied, neutral, slightly dissat-

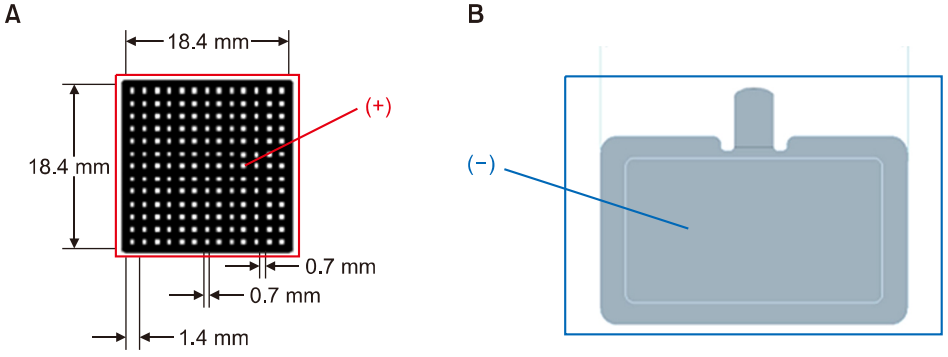

Fig. 1. Mimetic diagram of the contact area of the tip (A) and ground pad of the monopolar radiofrequency device (B) used in this study.

isfied, and extremely dissatisfied) at 1 month after the last treatment (visit 2).

We educated patients to immediately inform us of any discomfort that occurred during the study. Symptoms or signs regarded as side effects and complications were reported for safety evaluation.

GraphPad Prism ver. 5 (GraphPad Software, La Jolla, CA, USA) was used for statistical analyses. We compared the means of pre-RF and post-RF treatment evaluations using the paired t-test. The authors referred to statistical significance as $p<0.05$.

RESULTS

Because four patients were lost to follow-up, a total of 66 out of the 70 included patients completed the study. The mean age was 54 years.

The mean area of periorbital wrinkles significantly decreased by 14.4 mm^2 at the 1-month follow-up evaluation: mean, 80.64 ± 28.96 mm^2 compared with the baseline mean of 95.08 ± 31.93 mm^2; $p<0.0001$ (Fig. 2A). The calculated improvement ratio was approximately 15.19%. Fig. 3 and 4 show the remarkable improvement in periorbital wrinkles after treatment with 4-MHz MRF.

Subsequently, we analyzed the involvement of age as a factor in the effectiveness of MRF on periorbital wrinkles. We classified the patients into two groups, by age, and compared the change in the area of periorbital wrinkles after MRF. A total of 34 patients were included in the old-age group (≥55 years) and 32 patients were included in

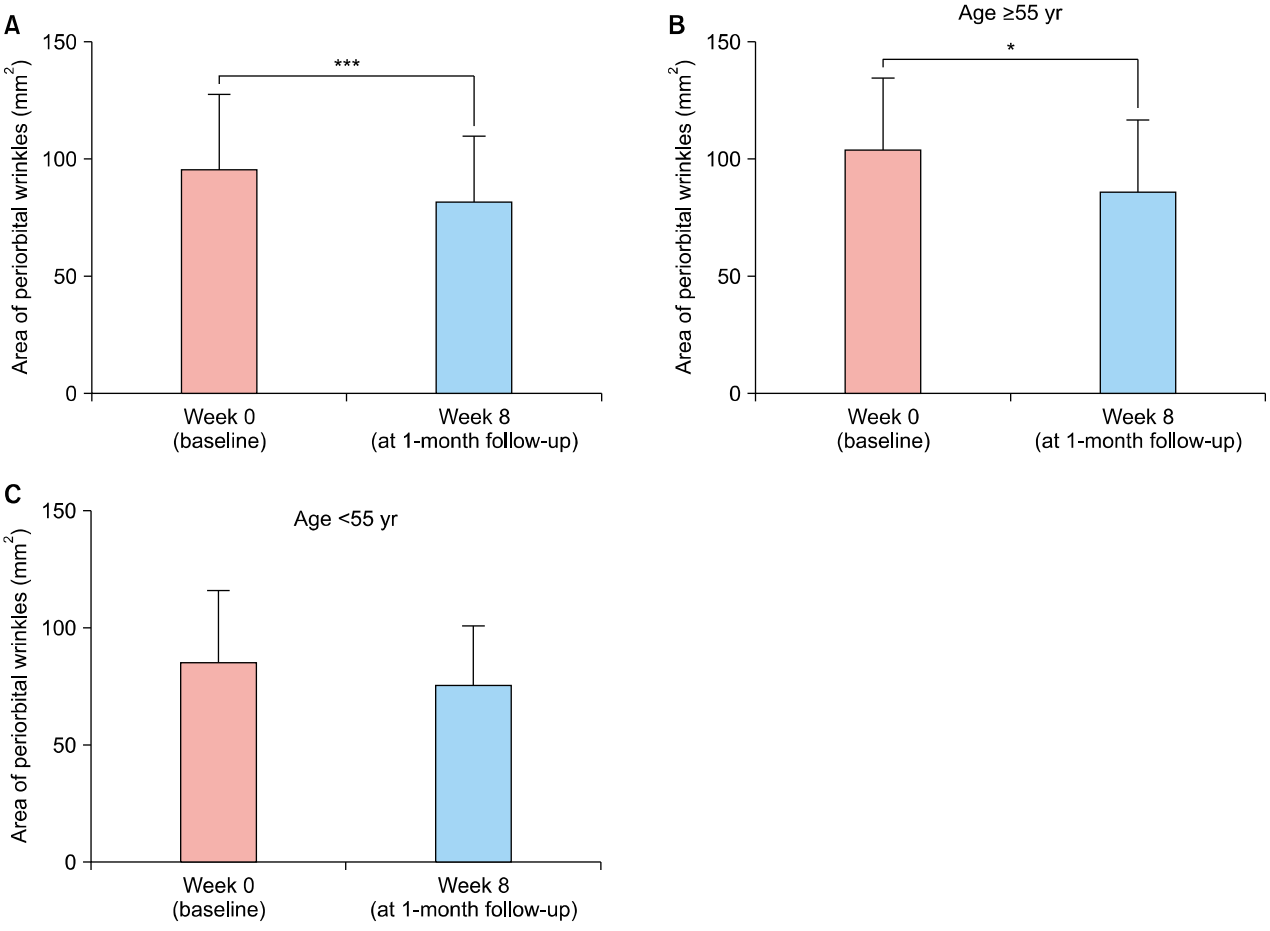

Fig. 2. (A) The mean area of periorbital wrinkles measured using the Robo Skin Analyzer (Inforward Inc., Japan) at baseline and at the 1-month follow-up. The area of periorbital wrinkles significantly decreased (80.64 ± 28.96 mm^2) compared with baseline (95.08 ± 31.93 mm^2). (B, C) Age as a factor in the effect of monopolar radiofrequency on periorbital wrinkles. The mean area of periorbital wrinkles at baseline and at the 1-month follow-up in two groups: the older group (B, ≥55 years) and the younger group (C, <55 years). In the older group, at the 1-month follow-up, the mean area had decreased to 89.82 ± 30.80 mm^2 compared with the baseline of 104.03 ± 30.89 mm^2. In contrast, in the young-age group, the mean area of 75.13 ± 26.22 mm^2 at the 1-month follow-up was not a substantial decrease from the baseline mean of 85.56 ± 30.67 mm^2. Unpaired t-test was applied for statistical analyses. Statistically significant, $*p<0.05$. $***p<0.0001$.

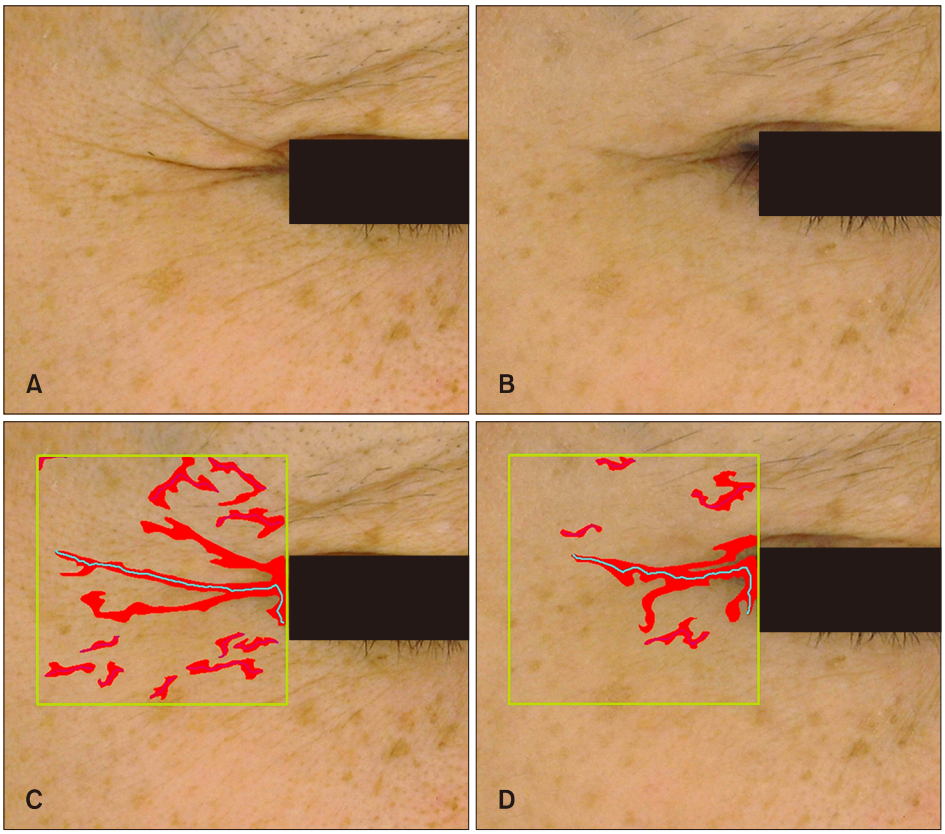

Fig. 3. A 56-year-old female patient assessed by the Robo Skin Analyzer (Inforward Inc., Japan). The periorbital wrinkle area was decreased at 4 weeks after the final treatment (B, D) compared to at baseline (A, C).

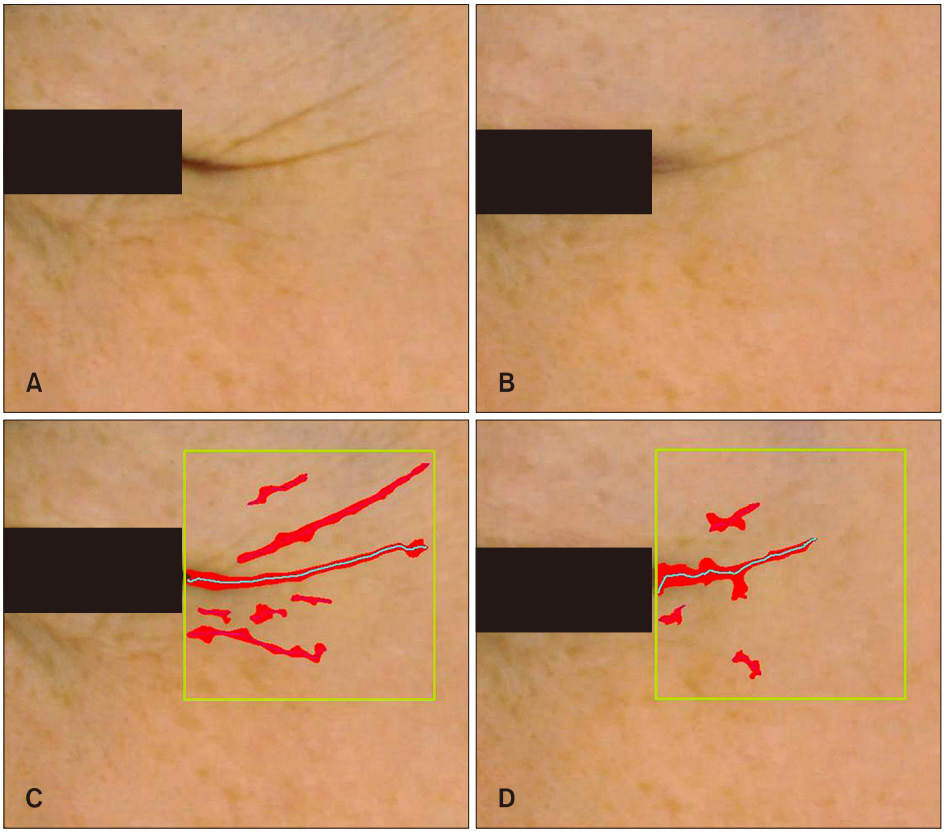

Fig. 4. A 52-year-old female patient assessed by the Robo Skin Analyzer (Inforward Inc., Japan). The periorbital wrinkle area was decreased at 4 weeks after the final treatment (B, D) compared to at baseline (A, C).

the young-age group (<55 years). In the old-age group, the mean area of periorbital wrinkles significantly decreased at the 1-month follow-up evaluation to 89.82±30.80 mm^2 compared with the baseline mean of 104.03±30.89 mm^2; $p<0.05$ (Fig. 2B). In contrast, in the young-age group, MRF did not decrease the mean area of periorbital wrinkles at the 1-month follow-up; 75.13±26.22 mm^2 compared with the baseline mean of 85.56±30.67 mm^2 (Fig. 2C).

As we detected a meaningful difference in the baseline area of periorbital wrinkles between two age groups, as depicted in Fig. 5A, we considered that not only was age a factor, but also the baseline wrinkle severity might influence the treatment results. Thus, we conducted an additional sub-analysis dividing the patients into two groups based on the baseline wrinkle area. A total of 34 patients had wrinkles over an area ≥91 mm^2 (severe group) and 32 patients had wrinkles over an area <91 mm^2 (mild group). As described in Fig. 5B, the results showed a general tendency of more improvement in the severe group compared with the mild group. In the severe group, improvement of periorbital wrinkles was present, to varying degrees, in most patients (82.4%). In contrast, in the mild group, numerous patients (37.5%) showed an increase in periorbital wrinkles resulting in a negative improvement ratio, in spite of the MRF treatment. The variation between individual patients in the mild group was also more prominent than in the severe group, which suggests a comparatively consistent therapeutic effect for patients with severe wrinkles.

The only side effects or complications noticed were transient erythema and swelling, which were immediately caused by thermal stimulation. They were mild and lasted approximately 1~3 days. Burns, scars, any signs of infection, and postinflammatory hyperpigmentation were not reported at 1-month follow-up. Pain seemed to be tolerable because all subjects completed the treatment without requesting local anesthesia. In patient satisfaction surveys, 63 patients (95.5%) chose a score of "neutral" or higher

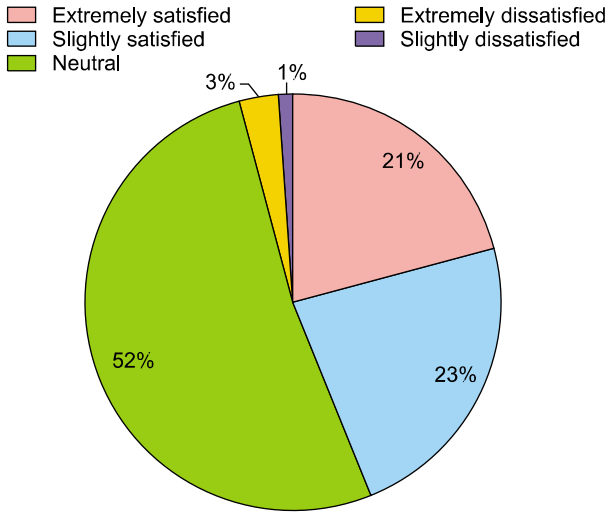

Fig. 6. Results of the subjective satisfaction survey on periorbital wrinkle reduction.

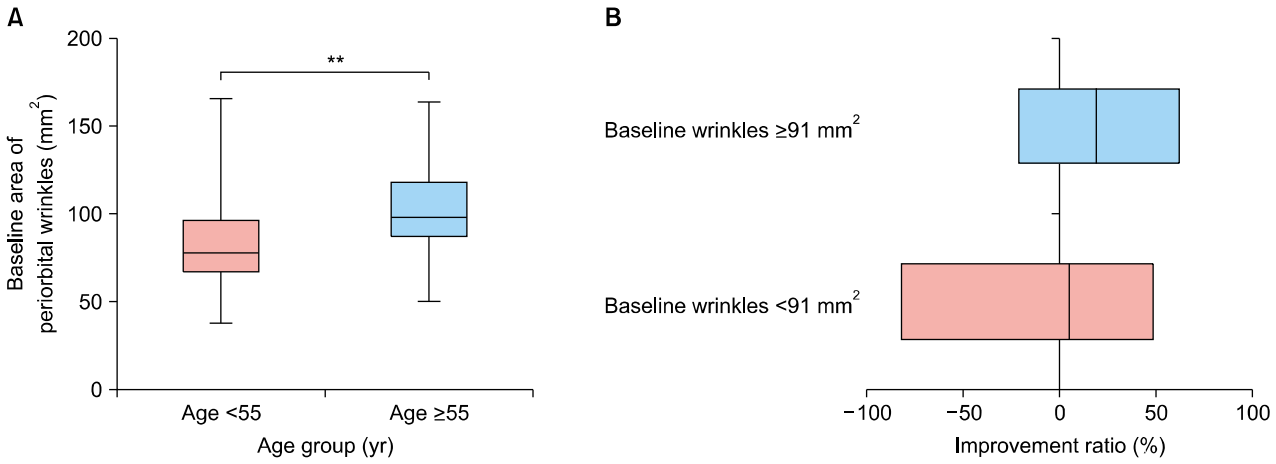

Fig. 5. (A) The baseline areas of periorbital wrinkles in the older group (≥55 years) and the younger group (<55 years): 80.56±30.67 mm^2 and 75.13±26.22 mm^2, respectively. The difference between the two groups was statistically significant. Mann Whitney test was applied. **Statistically significant, $p<0.01$. (B) Baseline severity as a factor in the effect of monopolar radiofrequency (MRF) on periorbital wrinkles. The improvement ratio was determined for two groups: the severe group (baseline wrinkle area ≥91 mm^2) and the mild group (baseline wrinkle area <91 mm^2). The results show the general tendency for more improvement in the severe group compared with the mild group. In the severe group, most patients had improvement in periorbital wrinkles. In contrast, in the mild group, numerous patients had an increase in periorbital wrinkles, resulting in a negative improvement ratio despite the MRF treatment.

for periorbital wrinkle improvement with 4-MHz MRF treatments (Fig. 6).

DISCUSSION

As interest in aging and skin rejuvenation has increased over the past few decades, noninvasive or minimally invasive treatment modalities are now being developed; these include dermal fillers, lasers, light source technologies, and RF technologies[9]. The RF device uses electromagnetic radiation to produce electric currents. When a rapidly oscillating electromagnetic field causes rotatory movement of water molecules within a closed tissue, thermal energy is formed via friction. In addition, passing current induces displacement of charged particles through tissue. The electric current is subsequently converted to heat energy. As a result, RF devices cause focal thermal damage to the dermis. In several previous studies, the histologic and molecular effects of RF technology have been reported[3,8]. As collagen fibers have a triple helix structure of protein strands containing hydrogen bonds, the application of the thermal energy causes changes in the collagen fibers. Collagen shrinkage by denaturation is the key mechanism for cosmetic results, which is triggered by an 'ideal' heat applied to the dermis[10]. The collagen remodeling is a phenomenon that lasts up to 4～6 months following treatment[8].

However, excessively high heating temperatures can cause pain, scarring, burns, or necrosis[4]. Recent clinical studies on RF have demonstrated that multiple-pass low-energy protocols are more efficacious and tolerable compared with single-pass high-energy protocols[8,11]. Thus, we used 20 passes with an average of 25 J per shot in this study, although the actual energy delivery per unit of target tissue was not quantifiable as the tip of the hand piece was applied in a continuous motion during the procedure. In addition, when an RF device is applied to the skin, a reverse thermal gradient is formed in which the epidermis is cooled and preserved (typically heated from 35°C to 45°C) while the deeper tissue is heated (typically from 65°C to 75°C at a controlled depth of 3 to 6 mm). This technology is associated with fewer complications and shorter recovery times[12-15]. On the basis of the "reverse thermal gradient" principle, we monitored the surface temperature of the treated area using a non-contact infrared thermometer to keep the surface at approximately 40°C, which should provide the optimal aesthetic result.

There are several RF-based systems: MRF, bipolar RF, and multipolar RF; we investigated the MRF system. The configuration of electrodes determines the difference between MRF and the other types. MRF devices deliver current through one active electrode that is in direct contact with the skin and another that is a ground pad. In contrast, bipolar RF and multipolar systems use a current between two or more electrodes, which makes the energy more controlled (less pain) but less penetrating (less effective)[1,16]. To overcome the limited penetration depth of the energy, bipolar and multipolar RF usually needs to be combined with other modalities: bipolar RF with optic-based devices or vacuum therapy, and multipolar RF with a pulsed electromagnetic field[16]. Thus, we considered the traditional MRF system to be the most suitable for evaluation of the actual efficacy and usefulness of RF technology. MRF also has the advantage of being simpler and more user-friendly than the other RF systems. Although pain during the procedure has been raised as a major limitation of MRF[1], we confirmed that the pain was not noteworthy and no patient needed topical anesthesia or pain control. Therefore, we evaluated the usefulness of MRF as a basic modality for wrinkle reduction.

Globally, results from clinical trials which have been reported indicate that MRF is effective for various applications, including treating wrinkles on the periorbital and forehead regions, lower face and neck laxity, nasolabial folds, and even acne vulgaris with atrophic scarring[12,17,18]. MRF is also a common modality in dermatologic settings in Asia. However, little is known about its efficacy and safety in Asian populations. A study by Suh et al.[19] reported the long-term effects of multi-session MRF in eight Korean patients, but it was an observational study with a retrospective review of charts and clinical photographs. Interpersonal and intrapersonal variability were unavoidable in the treatment regimens. In addition, they evaluated improvements in wrinkles using the Glogau classification, in which investigator subjectivity could easily be reflected. Our prospective study is meaningful in that we used a systematic treatment protocol for a much larger Korean subject group, with a relatively objective parameter to evaluate the treatment effect, the area of wrinkles calculated using the Robo Skin Analyzer CS50[20]. Consequently, we have quantitatively confirmed a clinical improvement of periorbital wrinkles in Korean patients by using MRF.

Periorbital rhytides and lines are unavoidable changes associated with aging because they result from natural facial expressions over the long term and because the periorbital region is easily exposed to ultraviolet radiation. However, periorbital wrinkles are difficult to manage because of their delicate nature and complicated anatomical structure attributable to their position adjacent to the orbit. Complications can be critical (e.g., scarring, ectropion, and even impaired vision) when the surgical procedure or laser

treatment is conducted improperly[21]. In this study with MRF, the only side effect reported was transient mild erythema. On the one hand, as neither chromophore absorption nor tissue diffraction affects the energy from RF devices, RF technology could be a useful and safe treatment option for any skin type, which is in contrast to laser devices[3]. Thus, MRF may be a more suitable treatment method than other surgical approaches and laser therapies, especially for the periorbital region.

This study has a limitation in that we did not show the tissue changes resulting from RF treatment using skin biopsy. Instead, we used the Robo Skin Analyzer CS 50, a non-invasive measuring instrument, which presents objective results. The Robo Skin Analyzer CS 50 is considered capable of providing facial images with a high level of reproducibility. In addition, according to previous studies, even small changes can be detected and analyzed with the Robo Skin Analyzer CS 50[20]. Another limitation of this study is that we only investigated the short-term effect of RF. Evaluation of the serial changes of the treated area over a long-term should also be considered.

Overall, our data suggest that MRF technology could be a useful and safe treatment choice for Korean patients with periorbital wrinkles. Although many other anti-wrinkle interventions are being developed, MRF is still an attractive modality for both young patients, who must immediately return to their daily life activities, and patients of advanced age who prefer a stable procedure with minimal complications. Our data indicates that the therapeutic effect seems to be more favorable for older patients with more severe wrinkles at baseline. Although we did not verify histologic evidence corresponding to these clinical results, we presume that older patients and patients with severe wrinkles might have more capacity for dermal collagen shrinkage and remodeling under the same level of thermal stimulation. These patients have a large amount of elongated and lax collagen fibers compared with younger patients and those with mild wrinkles. This means there is more room for improvement and the changes in the treated area will be more evident.

We encourage further studies to establish an ideal and standardized treatment protocol that can maximize the aesthetic effects of MRF such that MRF devices could be more extensively used. These studies should be conducted by dermatologists to determine the appropriate energy, treatment intervals, and follow-up periods for Asian populations.

CONFLICTS OF INTEREST

Yeong Min Yoon is an engineer of Eunsung Global Corporation. The other authors have nothing to disclose.

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