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RESEARCH ARTICLE



A multicenter pilot study of the effectiveness and safety of a monopolar radiofrequency device for improving periorbital and facial fine wrinkles

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ABSTRACT

Purpose: This study aimed to investigate the effectiveness and safety of a new monopolar radiofrequency device equipped with a 5 cm² tip, against fine wrinkles around the eyes and cheeks.

Materials and methods: This multicentered, prospective pilot study involved treating participants with mild-to-moderate wrinkles on both periorbital areas and cheeks using the monopolar radiofrequency device for one session. One and four months after treatment, wrinkle reduction, overall esthetic improvement, adverse events, and vital signs were evaluated.

Results: The study involved 13 participants (age: 35–62 years) and on a five-point scale, periorbital wrinkles showed a significant reduction at 4 weeks (0.96 ± 0.65) and 16 weeks (1.04 ± 0.59). On a five-point scale, cheek wrinkles also decreased at weeks 4 and 16 (1.00 ± 0.55 and 1.12 ± 0.64 , respectively). On a five-point scale (range: –1–3), overall global esthetic improvement was rated by the participants at weeks 4 and 16 to be 2.23 ± 0.80 and 2.31 ± 0.61 , respectively. Adverse events were not observed during the follow-up.

Conclusion: A single session using the new monopolar radiofrequency device equipped with a 5 cm² tip safely and effectively improves mild-to-moderate periorbital and facial wrinkles.

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Introduction

Topical agents, injectables, and energy devices have been used to slow skin aging (1). Because of their benefits of short downtimes, good safety profiles, and minimal side effects, minimally invasive procedures that use energy devices, such as radiofrequency (RF), micro-focused ultrasound, and non-ablative lasers, have garnered interest for skin rejuvenation (2,3). RF, which is part of the electromagnetic spectrum, ranges from 0.5–40 MHz, and various RF devices, including monopolar, bipolar, and multipolar devices, have been developed and are in use (3). In monopolar devices, current flows through the patient from a single active electrode to a distant return electrode, and bulk heating is generated when electron flow between the electrodes encounters tissue resistance (4).

Two decades ago, non-ablative monopolar RF treatment was shown to achieve skin tightening esthetic improvement (5). Since the US Food and Drug Administration first approved monopolar RF for wrinkle treatment in 2002, mounting evidence has been reported on its use for wrinkles (6,7), skin tightening (7), and eyebrow heightening (8), as well as laxity (8), pore size (8), and acne (9) reduction. Because RF generates heat through tissue resistance rather than a chromophore, individuals with lighter and darker

skin types (Fitzpatrick type V and VI) have been reported as RF rejuvenation candidates (10).

Since monopolar RF's larger, 4 cm² tip is reported to penetrate deeper into the tissue when compared with conventional smaller tips (11), we applied a novel, larger than conventional, 5 cm² face tip to monopolar RF and evaluated the effectiveness and safety of this novel device on mild-to-moderate periorbital and cheek wrinkles.

Materials and methods

Study design and medical device

Participants (aged 30–70 years) with mild-to-moderate wrinkles in both Crow's feet and cheek wrinkles were recruited at Asan Medical Center, Severance Hospital, and Chung-ang University Gwangmyeong Hospital from July 2023 to August 2023. The selection of participants was based on assessments using the Crow's Feet Grading Scale (CFGs) and Cheek Line Grading Scale (CLGS) to ensure eligibility within the mild-to-moderate wrinkle range. Participants who met the following criteria were excluded: 1) those who had undergone cosmetic procedures, including laser treatment, phototherapy, and surgery or filler injection within the

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previous 6 months, 2) those who had received radiotherapy, chemotherapy, or facial cancer diagnosis, 3) those with facial infection, dermatitis, rash, or a history of facial herpes simplex or herpes zoster, 4) those with a history of keloid, hypertrophic scars, or abnormal wound healing, 5) those who used whitening agents, including hydroquinone and tranexamic acid, isotretinoin, photo-sensitizing drugs, or steroids within the previous 6 months, and 6) pregnant or lactating women.

A 10THERMA® monopolar RF device (Tentech, Seoul, Republic of Korea) was equipped with a 5 cm² tip and used at a 6.78 MHz frequency. Before RF treatment, a coupling fluid was applied on both sides of the cheeks and periorbital areas. Each participant underwent one monopolar RF device session, with the energy (range: 2.0–3.0) set at the highest level tolerable to the participant, adjustable in 0.5-unit increments (e.g., 2.0, 2.5, 3.0). The 5.0 cm² tip was used to treat all areas, with multiple overlapping passes. In total, the periorbital area was treated with 50 shots, and the remaining facial area, excluding the periorbital region, was treated with 550 shots, resulting in a total of 600 shots. The participants were followed up 4 and 16 weeks following treatment. At each visit, a digital camera was used to take clinical standardized photographs. Mark-Vu® (PSI PLUS, Suwon-si, Republic of Korea) and Antera 3D® (Miravex, Dublin, Ireland) were also used on available patients.

Outcome evaluation

Treatment effectiveness was evaluated based on the degree of wrinkle reduction and overall esthetic improvement. Periorbital and cheek wrinkles were evaluated using the previously validated, CFGS and CLGS (12), respectively (Table 1). Both are five-point scales, with 4, 3, 2, 1, and 0 indicating extreme or diffuse wrinkles, severe wrinkles, moderate wrinkles, mild or minimal wrinkles, and no wrinkles, respectively. In this study, to grade CLGS, facial area superficial lines, which are defined as the areas between 1 cm lateral to the nasolabial fold to the preauricular cheek, and the inferior orbital rim to the mandible, were counted (12). CFGS and CLGS were evaluated by physicians on the left and right sides 4 and 16 weeks after treatment. Overall esthetic improvement was evaluated using a five-point Global Esthetic Improvement Scale (GAIS), with 3, 2, 1, 0, and –1 indicating very much improved, much improved, improved, no change, and worse, respectively (Table 1). GAIS was evaluated by the participants and physician on

weeks 4 and 16. During the procedure, participants reported pain severity on a 0–10 Visual Analogue Scale (VAS).

Skin texture was examined in periorbital and cheek areas using Antera 3D.

Safety evaluation

During each visit, treatment-associated adverse events, vital signs (systolic/diastolic blood pressure, pulse, and body temperature), and body weight were examined.

Statistical analyses

All statistical analyses were conducted using R, version 4.2.2 and GraphPad Prism, version 8.0.1. Wrinkle grades before and after treatment were compared using paired *t*-tests. *p* < 0.05 was considered statistically significant.

Results

Assessment of effectiveness against periorbital and cheek wrinkles

The study involved 13 Asian female participants (age: 35–62 years, mean age: 50.2 years). The baseline right and left eye wrinkle CFGS scores measured by the physician were 1.85 ± 0.36 and 1.69 ± 0.46 (mean $\pm$ standard deviation [SD]), respectively. The right and left eye wrinkles measured by the physician were 0.85 ± 0.77 and 0.77 ± 0.70 in week 4 respectively, and 0.77 ± 0.70 and 0.69 ± 0.61 in week 16, respectively (Figure 1A). Week 4 and 16 CFGS scores had decreases of 0.96 ± 0.65 and 1.04 ± 0.59 , respectively (Figure 1B). When compared with the baseline, there was statistically significant eye improvement in weeks 4 and 16 (both *p* < 0.01).

The mean right and left cheek CLGS scores measured by the physician before treatment were 1.54 ± 0.50 and 1.46 ± 0.50 , respectively, and they had decreased to 0.54 ± 0.50 and 0.46 ± 0.50 respectively, in week 4, and 0.38 ± 0.49 for the right and left cheeks in week 16 (Figure 1C). On weeks 4 and 16, the CLGS improvement scores were 1.00 ± 0.55 and 1.12 ± 0.64 , respectively, which was statistically significant (*p* < 0.01, Figure 1D).

At weeks 4 and 16, the investigator-determined GAIS scores were 2.31 ± 0.61 and 2.46 ± 0.63 , respectively, whereas the participants-determined GAIS scores were 2.23 ± 0.8 and 2.31 ± 0.61 , respectively (Figure 2).

Figure 3 shows a representative face photograph obtained using a Mark-vu. Sagging jowl improvement continued during the follow-up periods. Figure 4 is a representative photograph obtained using an Antera 3D. Four weeks after treatment, based on a Wilcoxon rank-sum test, the Antera 3D revealed a significant decrease in the roughness index of the periorbital areas and cheeks (Figure 5). The decreased cheek roughness index remained significant 16 weeks after treatment.

Safety assessment

The VAS score of the pain during monopolar RF treatment was 5.46 ± 1.99 (pain score range: 3–8, Figure 2B). During the procedure, the pain level was tolerable to the participants. Moreover, no severe adverse events were observed during the study period, and after RF treatment, none of the participants had facial burns or scars. The participants' vital signs were stable and at each follow visit, significant body weight changes were not observed.

Table 1. Grading scales for outcome evaluation in the present study.

Crow's Feet Grading Scale (CFGS)		
4		Extreme wrinkles
3		Severe wrinkles
2		Moderate wrinkles
1		Mild wrinkles
0		No wrinkles
Cheek Line Grading Scale (CLGS)		
4	Diffuse wrinkles	Diffuse superficial lines; cross-hatching
3	Severe wrinkles	Greater than 5 superficial lines; no cross-hatching
2	Moderate wrinkles	3–5 superficial lines
1	Minimal wrinkles	1–2 superficial lines
0	No wrinkles	No fine lines
Global Esthetic Improvement Scale (GAIS)		
3		Very much improved
2		Much improved
1		Improved
0		No change
–1		Worse

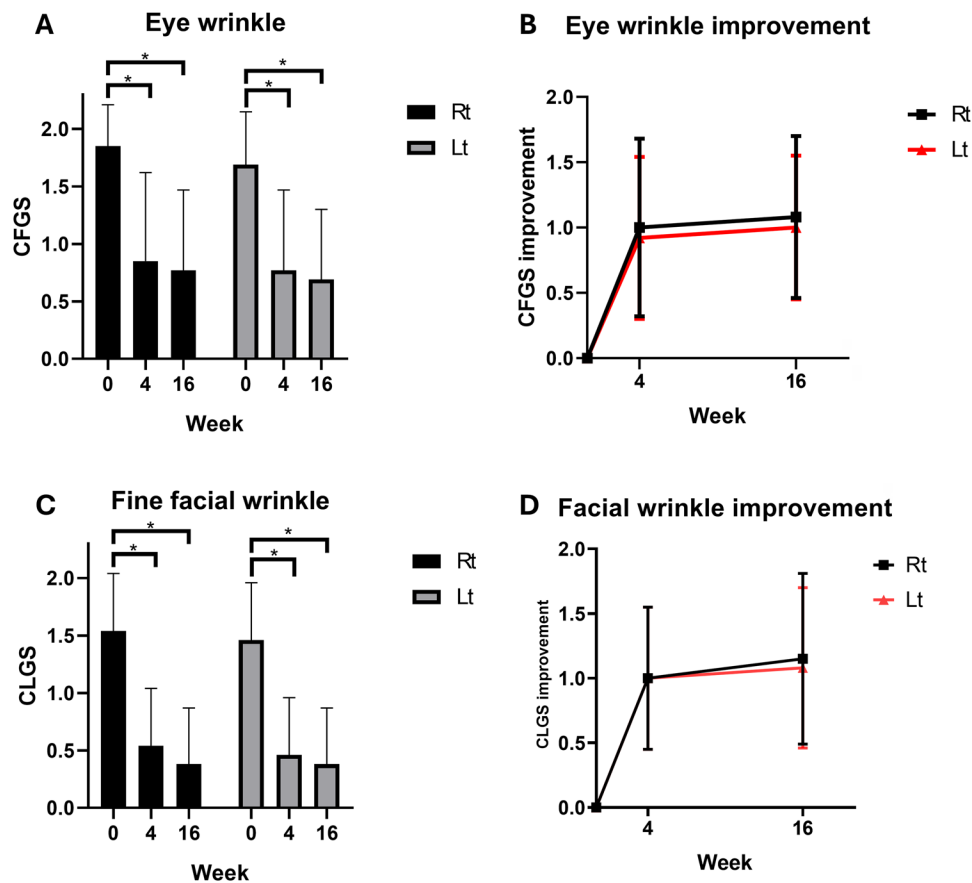


Figure 1. (A) Eye wrinkle severity based on the Crow's Feet Grading Scale (CFGs) during follow-up; (B) Eye wrinkle improvement based on CFGs scores; (C) Fine facial wrinkles based on the Cheek Line Grading Scale (CLGS) during follow-up; (D) Facial wrinkle improvement based on CLGS scores. Rt: right, Lt: left

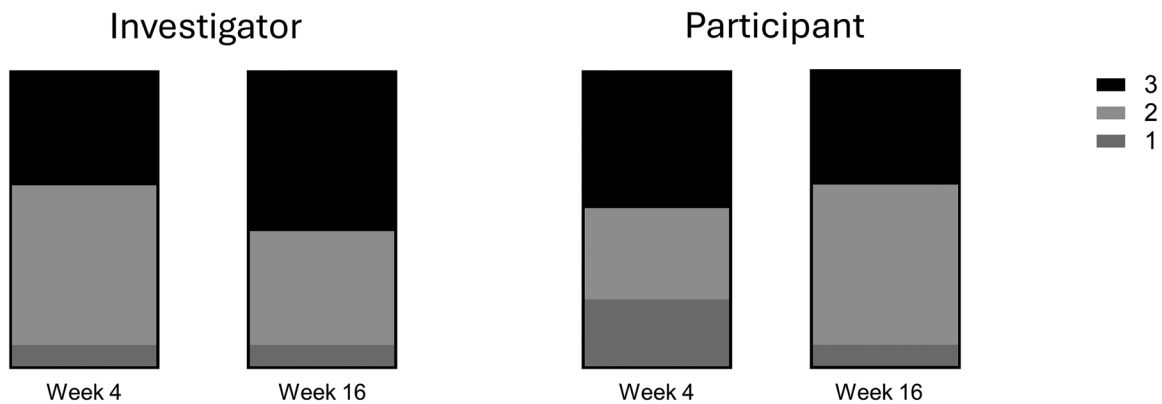


Figure 2. Investigator and participant Global Aesthetic Improvement Scale (GAIS) scores (3: very much improved, 2: much improved, 1: improved, 0: no change, -1: worse).

Additionally, there were no mild to adverse events including erythema, abnormal sensations, or bullae throughout the entire study period.

Discussion

Previously, a single RF treatment has been proven to be effective at reducing periorbital wrinkles, with the effect lasting 6 months in >80% of the participants (7). Consistently, in this study, follow-up at 4 and 16 weeks after treatment revealed that one RF treatment session resulted in significant wrinkle reduction. While multiple RF

sessions are reported to have better esthetic results when compared with one session (13), in this study, wrinkle improvement lasted 16 weeks after one treatment with our monopolar RF device.

Collagen synthesis may explain the mechanism underlying the effects of RF on wrinkle reduction. Previously, animal and human studies have proven that monopolar RF plays a role in increased collagen synthesis at the mRNA (14) and protein levels (11,15). Immunohistochemical Masson's trichrome staining revealed that when compared with baseline levels, collagen fiber density was significantly elevated in the papillary dermis and lower reticular dermis 6 months after one monopolar RF session, but they were

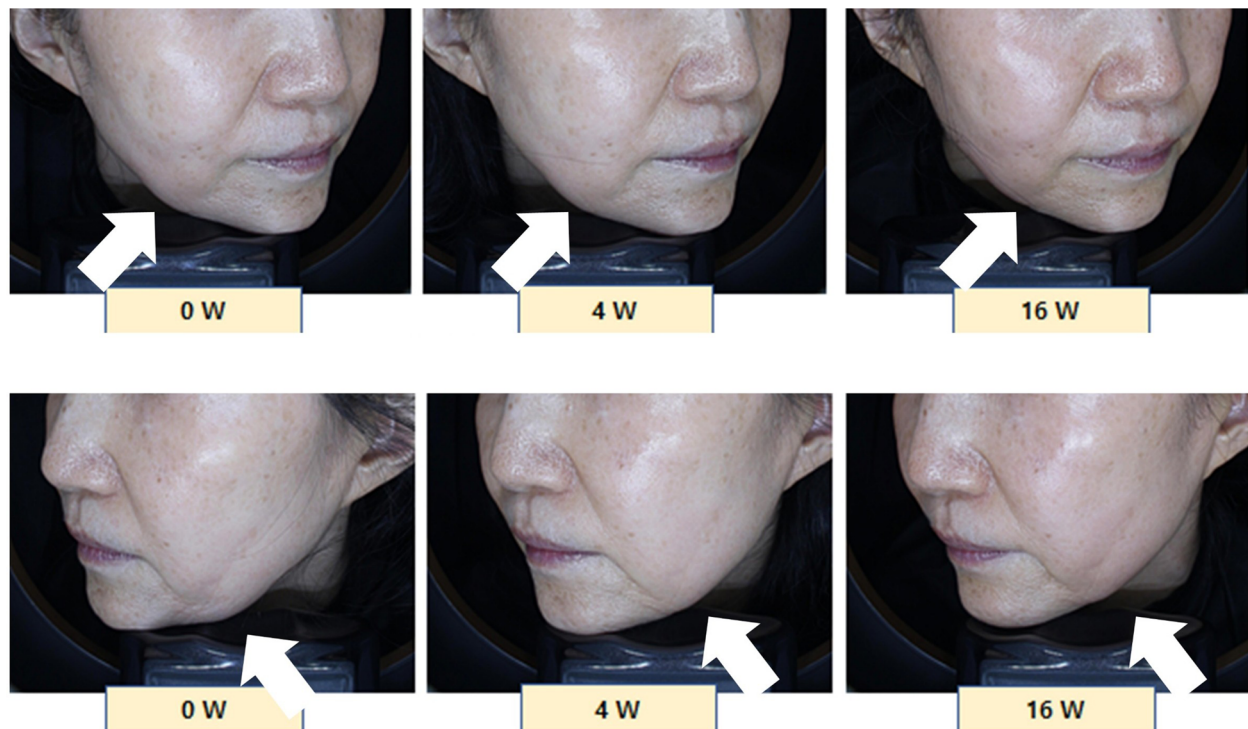


Figure 3. A clinical photograph of a representative case face lift acquired using Mark-Vu. White arrows indicate sagging jowl improvement.

not significantly different 2 months after treatment (11). In this study, the significant increase in collagen fiber density after 2 months may explain the lower CFGS and CLGS scores in week 16, when compared with week 4.

A previous study examined laxity improvement in patients immediately after RF treatment, and after 1 week, 1 month, 3 months, and 6 months, and found that some patients improved immediately after the treatment (16), probably because RF is associated with immediate collagen shrinkage (17). However, a previous study observed decreased esthetic scores after 1 week and an increase after 1 month, which then persisted until 3 months (16), we therefore focused on RF treatment's collagen neosynthesis and monitored the participants at 1 month and 4 months after treatment. However, because a previous study suggested that wrinkle reduction after monopolar RF may last for years (18), future studies should involve longer follow-ups.

A previous study of monopolar RF treatment-associated improvement based on a four-point scale of 0–3 found that the lower lid had better results (mean±SD: 2.8 ± 0.6) when compared with Crow's feet and jowl line (2.7 ± 0.6 and 2.4 ± 0.7 , respectively) (6). However, in this study, fine facial wrinkle scale improvement was higher than the periorbital wrinkle scale improvement in week 4 (1.00 ± 0.55 vs 0.96 ± 0.65) and 16 (1.12 ± 0.64 vs 1.04 ± 0.59), probably because the large tip size used in the study enables heat delivery deep enough into the lower face's dermis. A split-face study that used a 3 cm^2 tip on one side of the face and a 4 cm^2 tip on the other found that the 4 cm^2 tip reduced lower face wrinkles more effectively (19).

Although not statistically significant, right-side wrinkles exhibited better improvement when compared with left-side wrinkles. This is probably because most people are right-handed, making it easier for physicians sitting at the patient's head to perform procedures on the right side. Wrinkle improvement differences between the sides were

more noticeable in periorbital areas, in which left-side procedures involve a more uncomfortable posture when compared with cheeks. Moreover, when compared with the right cheek, the left cheek has a thicker dermal layer (20), which may partially contribute to the wrinkle improvement differences observed between the sides in this study.

A recent survey reported that 82% of patients treated with monopolar RF were satisfied (21). Similarly, the participants in this study had high GAIS scores (all >2, much improved) at 4 and 16 weeks after treatment. Moreover, when compared with 4 weeks after treatment, GAIS scores were higher after 16 weeks (2.23 ± 0.8 vs 2.31 ± 0.61 , respectively), which is consistent with the greater wrinkle reduction indicated by the CFGS and CLGS scores.

Previously, using monopolar RF for skin tightening, the patient's report about heat was suggested as a valid indicator for energy adjustment (22). In this study, the mean VAS score was 5.46 ± 1.99 (SD), which is consistent with the average pain score of 6.06 reported by a study conducted without anesthesia (23), and relatively higher than in previous studies that reported scores ranging between 1.94 and 3.13 (21,24), with topical anesthesia cream application. The lack of anesthetic conditioning may explain the high pain score reported in this study. However, when compared with the incidence of 0.36% reported for secondary-degree burns (7), none of the patients in this study experienced burns or scars after treatment. The monopolar RF device is considered safe for individuals with darker skin because the epidermis is relatively spared (14) and its mechanism of action does not involve a chromophore (10). Although participants in this study did not complain of hyperpigmentation, it has been reported in Asians after monopolar RF treatment (10). Moreover, although a monopolar RF complication rate of about 10% has been reported (25), no complications were observed in this study.

Although mandibular line improvement was reported in 2003 to be less visible when compared with cheek contour or nasolabial

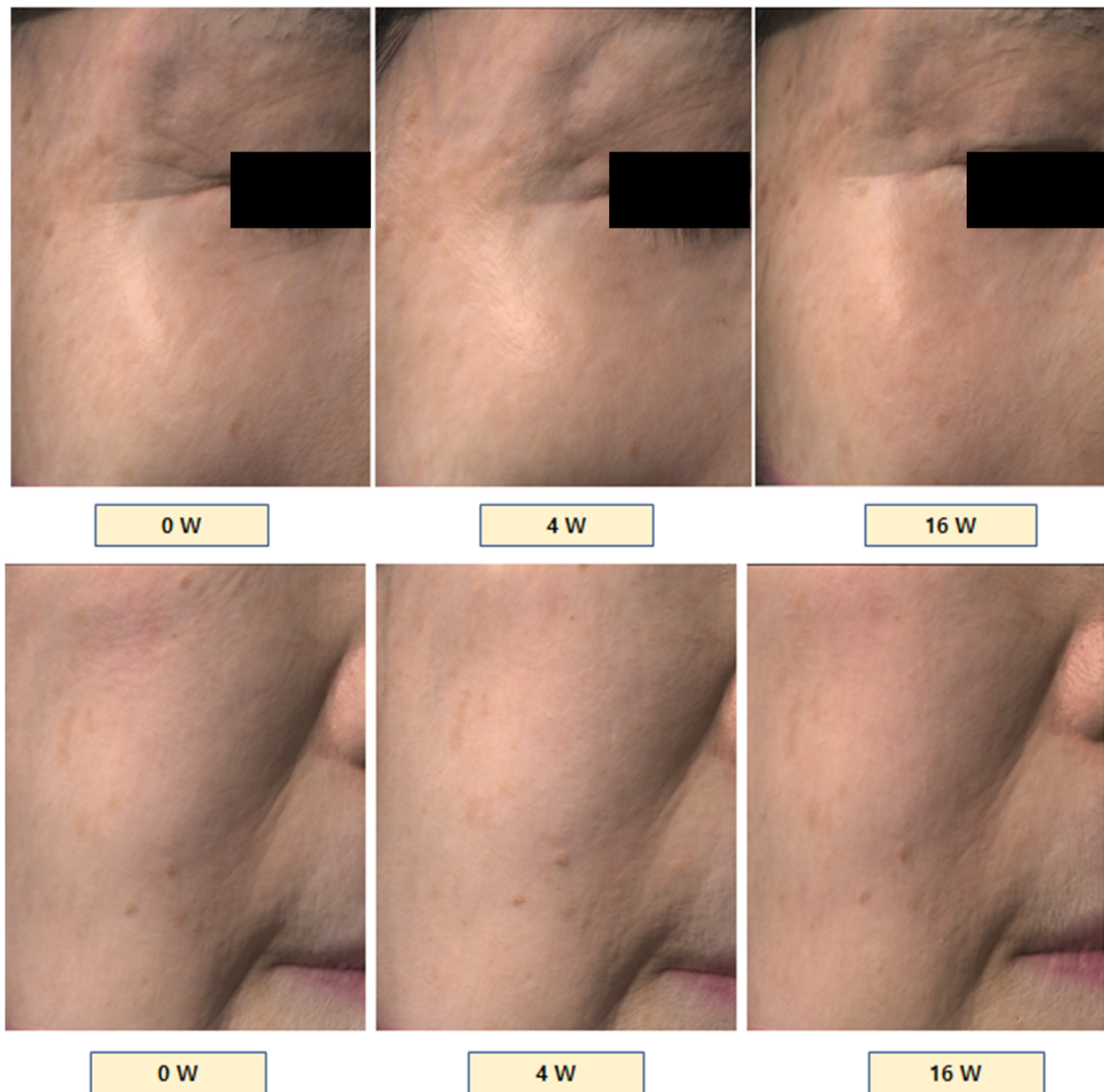


Figure 4. An Antera 3D representative case photograph of the eye and fine facial wrinkles during follow-up.

fold after using a 1 cm² tip⁵, follow-up studies reported that monopolar RF had a lifting effect on sagging jowls, with a surface area reduction of about 22% (10,26). Consistent with a previous report that sagging jowls exhibited greater improvement in 6 months after treatment than after 3 months (10), this study found that sagging jowls were more improved in week 16 when compared with week 4 (Figure 3). Based on the Antera 3D imaging system, non-ablative monopolar RF was previously reported to effectively make the skin smoother (27). In this study, skin texture examination using Antera 3D revealed that in the cheeks and periorbital skin, roughness decreased in week 4, although the trend was more consistent in the cheeks.

The limitation in periorbital skin may be because of the use of the 5 cm² tip on eyelids, which have a thin dermal thickness. Indeed, a recent split-face study showed that a smaller tip was better at treating periorbital wrinkles, whereas larger tips achieved better results for lower face wrinkles (19). Future studies, using

smaller tips on periorbital areas, may yield different results. The use of the 5 cm² tip allows for efficient and effective treatment over larger areas of the face within a shorter duration while achieving sufficient therapeutic outcomes. However, as mentioned in the limitation, the periorbital area, due to its smaller size and thinner dermal thickness, may benefit more from a smaller tip that can adhere better to the skin's contours. Based on this, we are currently planning a blinded, controlled study using a smaller, eye-specific tip to evaluate its efficacy in the periorbital region. Additionally, there are other limitations to this study. These include a small sample size, the absence of comparison with a conventional 4 cm² tip, and the inclusion of only female participants. To address these issues, future research will involve a large-scale, multicenter study incorporating both male and female participants. The study will also adopt a split-face design to compare the 5 cm² tip with other conventional tips and include blinded assessments to ensure objective evaluation.

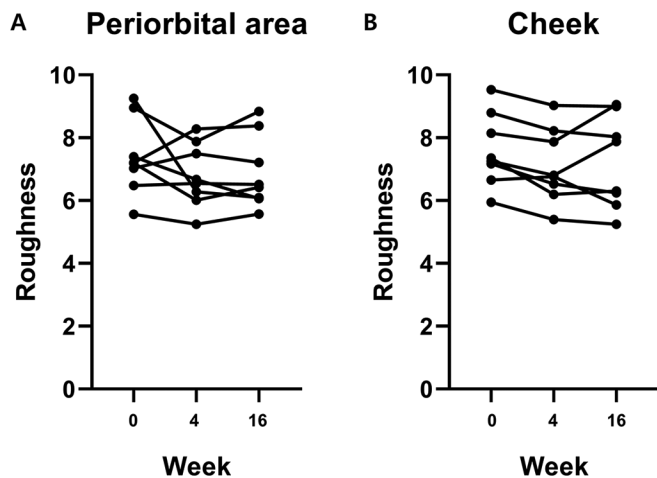


Figure 5. Roughness index based on Antera 3D. (A) Periorbital area. (B) Cheek area.

In conclusion, our findings indicate that until 4 months of follow-up, the monopolar RF device with a 5 cm² tip is safe and effective at fine wrinkle reduction in periorbital areas and cheeks. Esthetic satisfaction by physicians and participants, as well as objective jowl sagging and texture improvement, were observed.

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Ethical approval

The study was approved by the institutional review board (IRB numbers S2023-1025-0002, 1-2023-0037, and 2305-092-051). All participants signed a photo release consent form authorizing the reproduction and distribution of any images acquired during the study.

Disclosure statement

The authors declare no conflict of interest.

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Data availability statement

The data underlying the study are available from the corresponding author upon reasonable request.

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