



Evaluation of efficacy and safety for the energy delivery and skin tightness of monopolar radiofrequency device in Asian

Mi Soo Choi¹ · Kyujin Yeom¹ · Myung Hwa Kim¹ · Byung Cheol Park^{1,2}

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Abstract

Monopolar radiofrequency(MRF) treatment is known to induce collagen contraction and remodeling in dermis. This study was conducted to evaluate safety of MRF in pre-clinical study first, and efficacy and safety in lifting and tightening of the face and upper neck in the clinical study. In pre-clinical setting, thermal imaging, and clinical and dermoscopic photography of after the procedure, and 7, 14, 30 days later were recorded. In clinical study, 23 subjects were enrolled and got 1 treatment. They were followed up at 4, 12, 24 weeks, and assessed using clinical photography. Changes in elasticity, pore number, wrinkle(%), and safety evaluation were also done. In the pre-clinical study, energy was safely delivered to the treatment area. In the clinical study, the clinical grades significantly decreased after 4, 12, and 24 weeks. Net and biological elasticity showed a significant increase at week 24. Pore count significantly decreased from week 12 and wrinkle started to decrease from week 4. Subjective satisfaction peaked in week 12. The average of pain score was 0.30 ± 0.63 , and only mild adverse events were recorded. This study found that MRF deliver stable energy to the skin and have significant effect in skin laxity without complications.

Keywords Monopolar radiofrequency · Asians · Radiofrequency · Facial laxity · Aging · Skin tightening

Introduction

The aging of the face and upper neck involves a complex interplay of various factors affecting the skin, subcutaneous tissue, and deeper structures. Over time, these structures undergo gradual degradation due to aging process, resulting in excessive skin laxity. Historically, surgical lifting has been the conventional treatment approach for skin laxity. However, this methods carries disadvantages such as scarring, nerve damage, and a lengthy recovery period. Consequently, non-invasive methods have gained popularity because of the safety, efficacy, and minimal downtime [1–3].

Non-invasive skin tightening methods generally spare the epidermis, targeting energy delivery directly to the dermis and subcutaneous layer. This energy creates heat within the skin, leading to controlled thermal injury in small, precise volumetric zones, with subsequently results in thermal necrosis. This process promotes collagen contraction through collagen denaturation [4], and induces shrinkage of the fibrous septae within fat lobules, causing compression of the subcutaneous layer [5, 6]. Infrared light, radiofrequency(RF), or ultrasound are the most common options for noninvasive skin tightening. Both ultrasound and RF are useful for skin tightening and widely used.

Monopolar radiofrequency(MRF) treatment specifically targets the dermis and fibrous septae, leading to immediate collagen contraction and subsequent collagen remodeling [1, 2, 4, 7]. This technique received FDA approval for treating periorbital wrinkles and all types of rhytids. MRF has been applied for skin tightening of the upper and lower face, neck, arms, abdomen, and even thighs [8–11].

This study consists of 2 separate components. The first involves a pre-clinical study using micropigs to assess the delivery of heat energy. The second is an open-label clinical trial aimed at evaluating the efficacy and safety of the MRF

✉ Byung Cheol Park
4exodus@hanmail.net

¹ Department of Dermatology, Dankook University Hospital, 201, Manghyang-ro, Dongnam-gu, Cheonan, Chungcheongnam-do, Republic of Korea

² Dankook University – Cheonan Campus, Beckman Laser Institute Korea, Cheonan, Chungcheongnam-do, Republic of Korea

device with resistive method (Oligio[®], Wontech, Daejeon, Republic of Korea) for non-invasive lifting and tightening of the face and upper neck.

Materials and methods

Pre-clinical study

We tried to verify the safety and efficacy according to the energy level of the procedure (level 2.5, level 4.5) using 1 micropig. The energy dependent on the treatment level is as follows: at level 2.5, the power is 45 W, fluence 12 J/cm²; at level 4.5, the power is 65 W, and fluence is 17 J/cm². After hair removal on the back of micropig, the radiofrequency (RF) irradiation sites were marked. Each divided area was irradiated with RF energy 4 times with the repetition rate of 0.5 s at 2 different treatment levels (level 2.5, level 4.5).

Immediately after the treatment (approximately half a second after treatment), the maximum surface temperature was measured with a thermal imaging camera (FLIR C2[®], FLIR systems OU, Estonia). Clinical and dermoscopic photography of treated area were taken immediately after the procedure, and 7, 14, 30 days later (EOS 50D[®], Canon, Japan; DL 200 h[®], DermLite, USA). The MRF device used in this study, which is the same as the one used in the clinical study, was manufactured by Wontech (Daejeon, Republic of Korea). This study was approved local institutional animal care unit committee (CRONEX-IACUC: 202106006).

Clinical study

Participants and demographics

This trial was conducted during June 2021~July 2022. This study enrolled both men and women between the ages of 25 and 70, who exhibited moderate skin laxity, wrinkles, and sagging (grade 2~3 on the modified Investigator Fasil Face/Upper Neck Laxity Scale). Individuals with underlying medical conditions or those taking medications that could impact the study were excluded. Participants who had undergone aesthetic procedures or received energy-based device treatments on their face and neck within the past 6 months were also excluded. A total of 23 participants were recruited, and informed consent was obtained from all subjects. A comprehensive history and physical examination were conducted. The study protocol adhered to the ethical guidelines outlined in the 1975 Declaration of Helsinki and received approval from the institutional review board (IRB No. DKUH 2021-04-023-001).

Treatment protocol and specifications of MRF

This study is a prospective study that compares pre- and post-treatment outcomes within the same group of participants. The treatment was administered once, and participants were followed up at 4, 12, and 24 weeks after the treatment. The MRF device used in this study was manufactured by Wontech (Daejeon, Republic of Korea). The device operates at a frequency of 6.78 MHz, with a maximum power of 400 W. It consists of a handpiece connected to a disposable treatment tip, which has a working area of 2 × 2 cm² (4 cm²). A hand switch is used to control the treatment shots. The treatment tip includes a sensor that continuously monitors skin temperature, a contact pressure sensor, and a skin impedance checking system to ensure proper contact between the tip and the skin. The device is equipped with a gas cooling system for safety with pre-cooling, parallel cooling (cooling during irradiation), and post-cooling system. Prior to the treatment, a grounding pad was attached to the lower back of each participant, and 60 to 90 ml of coupling fluid was applied to the face. The coupling fluid was reapplied regularly throughout the treatment. Participants received treatment on both sides of the periorbital area, temple area, cheeks, lower face, and double chin using a total of 600 shots (300 shots for each side of the face) of MRF, with an energy level ranging from 4.0 to 5.5 using the F4.0 tip (Energy level 4.0: fluence 16 J/cm², 4.5: fluence 17 J/cm², 5.0: fluence 18 J/cm², 5.5: fluence 20 J/cm²). Immediate repeated treatment of the exact same area was not allowed. Rather than repeatedly treating the same area consecutively, the entire treatment area was treated with a single pass first. This allowed sufficient time for spontaneous cooling to occur. However, slight overlap in the treatment area could result in immediate re-irradiation. In such cases, the repetition rate could be as short as half a second, similar to that observed in the preclinical study. The energy level was adjusted based on the tolerability reported by the participants using a patient feedback scale. After the procedure, the coupling fluid was completely removed with warm water. Patients were instructed to protect the treatment area by applying sunscreen of 30 SPF or higher daily.

Efficacy and safety evaluation

Global photographic assessment 2 dermatologic experts assessed the digital photographs at the baseline, and 4, 12, 24 week visits, about 3 items including cheekbone roundness, melolabial fold, and jowls with 6-grade scale (from -1 to +4 including 0). The digital images (DermaView-pro[®], Optobiomed, Wonju, Republic of Korea) were taken at every visit, and standardized for focus distance, bright-

ness, and white balance, angle, and position under identical conditions.

Changes of skin elasticity The skin elasticity of the participants were assessed with Cutometer® Dual MPA580 (Courage+khazaka electronic GmbH, Köln, Germany) at every visit. Using the probe in the instrument, investigators measured the skin elasticity at the same targeted area of the cheek at every visit.

Changes of pore number at cheek and wrinkle area of periorbita Using clinical photographs and the software of DermaView-pro® (Optobiomed, Wonju, Republic of Korea), investigators compare the number of pores at unit area of cheek and wrinkle area of periorbit before and after treatment.

Assessment of participant's subjective satisfaction The degree of subjective satisfaction that the subjects experienced was also surveyed. The survey (4 different questions) for subjective satisfaction was conducted using a 6-point scale ranging from -1 to 4 at the 4-, 12-, 24-week visits.

Safety evaluation Objective and subjective symptoms or adverse reactions were recorded at every visit. Pain was separately recorded at each visit using the numeral rating scale (NRS), and scored on a scale of 0 to 10.

Statistical analysis

Statistical analysis was conducted using SPSS version 20 (IBM, New York, U.S.A.). Paired t-test was used to compare the results of baseline and 4-, 12-, 24-week visit, including

global photographic assessment, cutometer change, pore count, degree of wrinkles, and participant's subjective satisfaction. For all tests, $p < 0.05$ was considered significant for the 2-sided test.

Results

Pre-clinical study

Changes in thermal energy at skin surface immediate after RF treatment

Average of surface temperature in control area was 33.4°C, and 35.8°C in the treatment area of level 2.5, 43.4°C in the treatment area of level 4.5 right after the quadruple stacking RF treatment (Fig. 1). The thermal image in Fig. 1 looks like ring shape because the thermal diffusion occurred due to time laps to take thermal image. Energy is safely delivered locally, and confined only inside the shape of the square tip of RF device. As the treated area is closer to the ground pad, surface temperature is inclined to increase slightly.

Chronological skin surface change after RF treatment

There were no adverse skin surface reactions in the treated area including erythema, purpura, wheal, swelling, erosion, scale, scar or bullae right after the procedure and 1, 7, 14, 30 days later. No specific skin surface change was observed on the dermoscopic examination until 30 days.

Clinical study

Demographics

A total of 23 patients were enrolled in this study. After initiation of the study, there were no one who failed to complete the treatment. 91.3% of study subject were female ($n=21$),

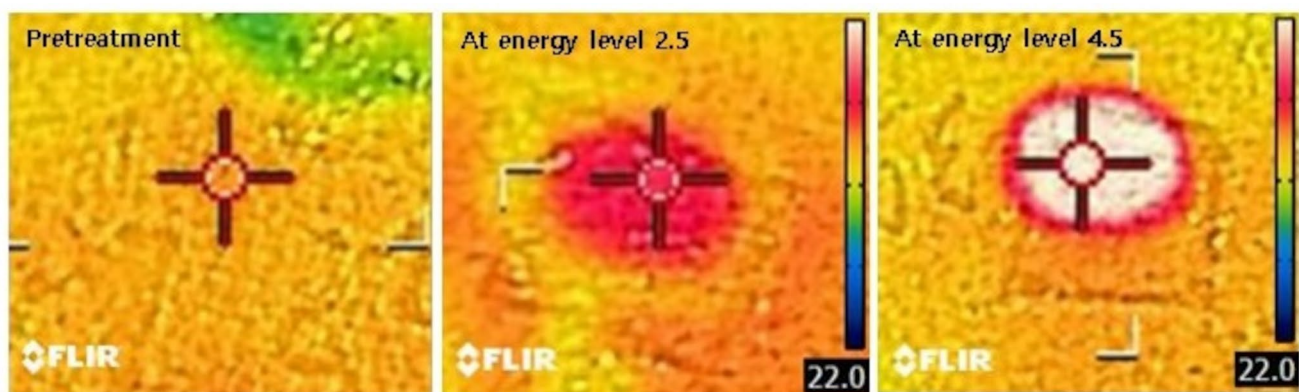
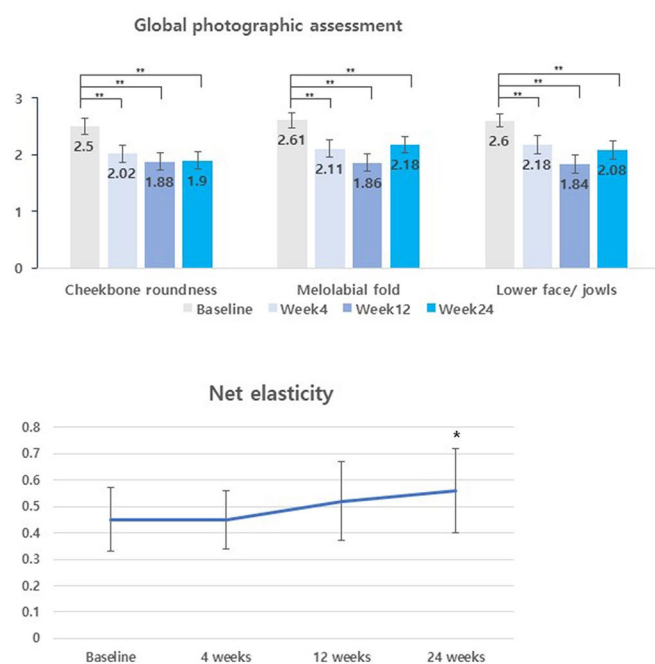


Fig. 1 Thermal change at skin surface of micropig after RF treatment (Pretreatment, at energy level 2.5, and at energy level 4.5)

Table 1 Results of global photographic assessment

Average of 2 experts		Before treatment	4 weeks (%improvement, <i>p</i> -value)	12 weeks (%improvement, <i>p</i> -value)	24 weeks (%improvement, <i>p</i> -value)
Middle face	Cheekbone roundness	2.50±0.65	2.02±0.72 (19.1%, <i>p</i> <0.01)	1.88±0.72 (24.8%, <i>p</i> <0.01)	1.90±0.70 (23.9%, <i>p</i> <0.01) **(<i>p</i> =0.78)
	Melolabial fold	2.61±0.65	2.11±0.74 (19.2%, <i>p</i> <0.01)	1.86±0.72 (28.8%, <i>p</i> <0.01)	2.18±0.69 (16.3%, <i>p</i> <0.01) **(<i>p</i> <0.01)
Lower face	Jowl	2.60±0.56	2.18±0.79 (15.9%, <i>p</i> <0.01)	1.84±0.79 (29.3%, <i>p</i> <0.01)	2.08±0.77 (20.1%, <i>p</i> <0.01) **(<i>p</i> <0.01)

Mean±Standard deviation(SD)

†*p*-value: statistically significant probability paired t-test (*p*<0.05, comparison to baseline)** this *p*-value was calculated by comparing the grades of week 24 with the grades of week 12* *p*=0.01
** *p*<0.01**Fig. 2** Changes in global photographic assessment, elasticity, pore count

and 8.7% (*n*=2) were male. 7 patients (30.43%) were in 40s, 12 patients (52.17%) were in 50s, and 4 patients (17.39%) were in their 60s. The age distribution ranged from at least 40 years old to 63 years old, and the subject's mean age is 53.09 ± 6.75 years old. All subjects received 600 shots of RF. The average energy level was 4.47 in cheek and lower face, 4.11 in double chin, 4.24 in periorbital and temple area. The average total energy delivered in a session was 58.67 ± 4.30 kJ.

Global photographic assessment (Table 1; Figs. 2 and 3)

We assessed factors of mid face (cheekbone roundness, melolabial fold) and lower face(jowls) using Global Aesthetic Improvement Scale by investigators. The grade of baseline, and 4, 12, 24 weeks after the treatment were recorded. For the all 3 items, the grades were statistically

significantly decreased after 4 weeks, 12 weeks, and 24 weeks compared to baseline (*p*<0.01). At week 12, in all 3 items, grades were highest decreased (24.8% in cheekbone roundness, 28.7% in melolabial fold, 29.2% in jowls), and the level of decrease slightly increased at week 24 (23.9% in cheekbone roundness, 16.3% in melolabial fold, 20.1% in jowls). The grade of cheekbone roundness did not show significant change from week 12 to week 24. The grades of melolabial fold and jowls showed significant increase at week 24 when compared to week 12. In Fig. 2., both subject 1 and 2 showed improvement in wrinkles and subject 2 showed improvement in laxity and jowls.

Changes of skin elasticity (Table 2)

R5 in Cutometer® means net elasticity which evaluated only the elasticity of the skin's solid components like

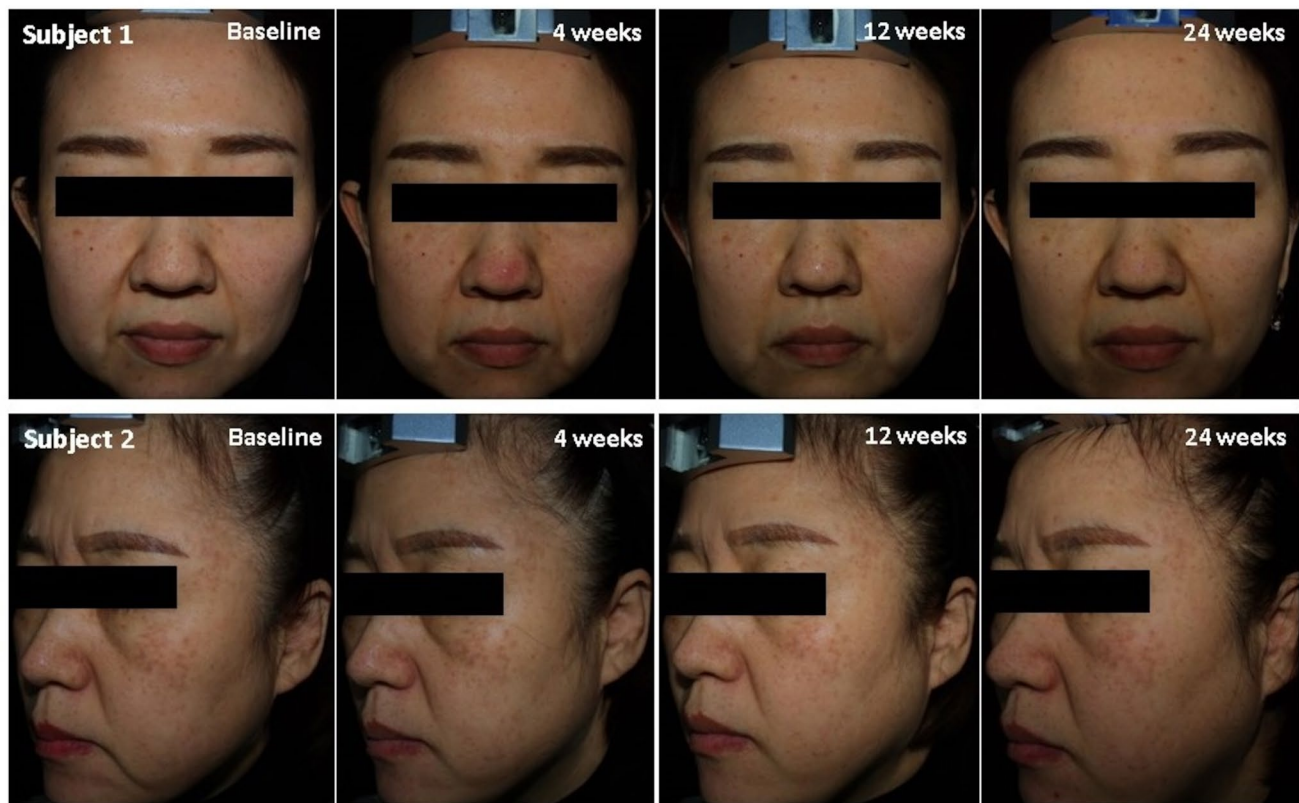


Fig. 3 The depth melolabial fold has decreased over time after treatment in subject 1, and the efficacy was highest after 12 weeks of treatment. Jowls and cheekbone roundness has improved over time after treatment, especially after 12 weeks of treatment in subject 2

Table 2 Results of Cutometer[®] measurement

	Baseline	4 weeks	12 weeks	24 weeks
	Mean±S.D	Mean±S.D	Mean±S.D	Mean±S.D
Mean±Standard deviation(SD)				
Net elasticity (Cutometer – R5)	0.45±0.12	0.45±0.11 (<i>p</i> =0.86)	0.52±0.15 (<i>p</i> =0.09)	0.56±0.16 (<i>p</i> =0.01)
† <i>p</i> -value: statistically significant probability paired t-test (<i>p</i> <0.05, comparison to baseline)				
Biologic elasticity (Cutometer – R7)	0.26±0.05	0.27±0.06 (<i>p</i> =0.32)	0.28±0.04 (<i>p</i> =0.24)	0.31±0.06 (<i>p</i> =0.01)

elastic fibers. The value of R5 was statistically significantly increased at week 12 and 24 when compared to baseline (*p*-value = 0.01 in both).

R7 in Cutometer[®] means biological elasticity, which checked the viscous and anatomical components of skin elasticity. It was statistically significantly increased at week 24 when compared to baseline (*p*-value = 0.01 in both).

Pore number of cheek and wrinkle area of periorbit (Table 3; Figs. 2 and 4)

Pore count and wrinkle area (%) in the same unit area was calculated using Derma-view pro[®] software. Pore count was 4536.65±625.29 at baseline, and 4452.61±648.90 at week 4, 4307.65±602.01 at week 12, and 4302.96±601.15 at week 24. When compared to baseline, statistically significant decreased was observed from week 12, and this change

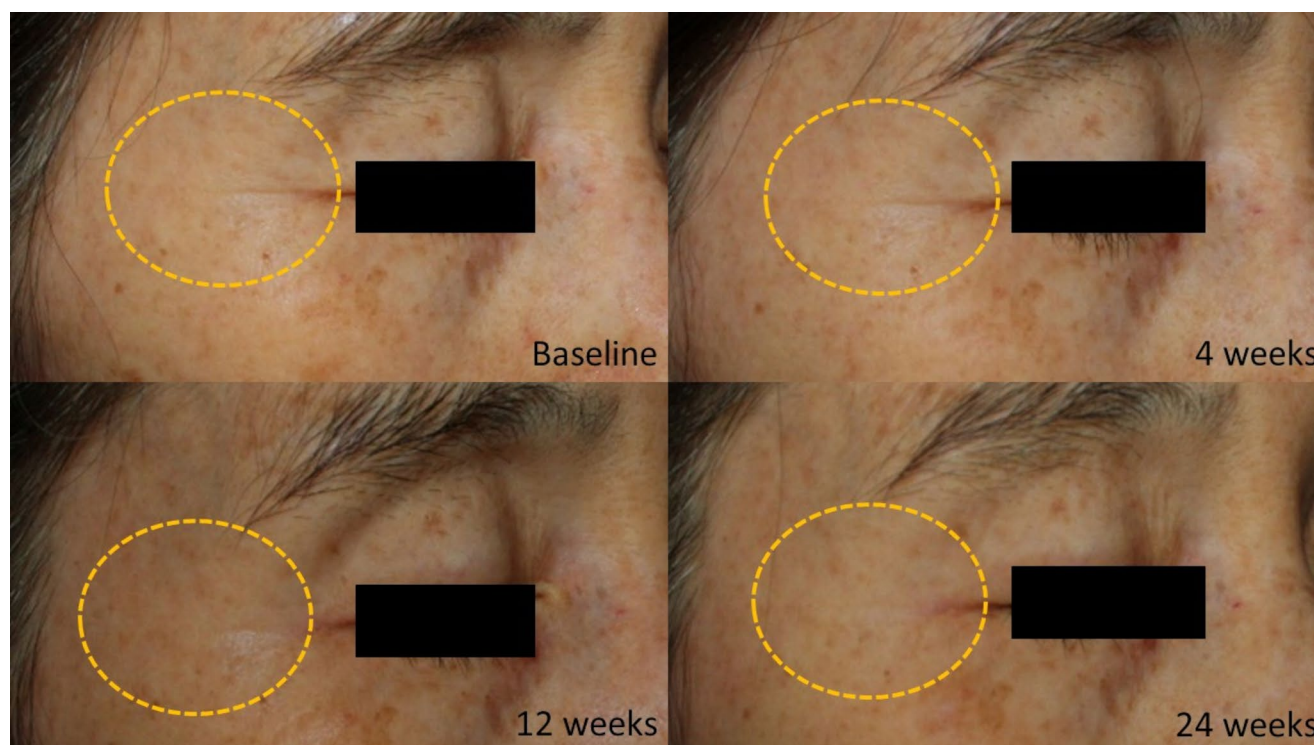
lasted up to week 24 (*p*-value < 0.01). Wrinkle area (%) in left periorbit was 43.04±3.82% at baseline, 41.06±3.81% at week 4, and 39.21±3.72% at week 12 at the left side of cheek. Wrinkle area (%) in right periorbit was 41.78±3.98% at baseline, 39.30±3.41% at week 4, and 37.94±3.94% at week 12. In both sides of periorbit, wrinkle area(%) started to decrease from week 4 (*p*-value<0.01) and lasted until week 24 compared to baseline.

Assessment of participant's subjective satisfaction (Fig. 5)

At week 4, 6 participants (26.09%) recorded no change, 6 participants (26.09%) recorded slight improvement, 9 participants (39.13%) recorded moderate improvement, and 2 participants (8.7%) recorded marked improvement. At week 12, number of participants who recorded subjective satisfaction as no change or slight change were decreased (no

Table 3 Changes in pore counts and area of wrinkle in clinical photography

	Baseline Mean±S.D	4 weeks Mean±S.D	12 weeks Mean±S.D	24 weeks Mean±S.D
Pore count at cheek	4536.65±625.29	4452.61±648.90 (<i>p</i> =0.08)	4307.65±602.01 (<i>p</i> <0.01)	4302.96±601.15 (<i>p</i> <0.01)
Mean±Standard deviation(SD)				
† <i>p</i> -value: statistically significant probability paired t-test (<i>p</i> <0.05, comparison to baseline)				
Wrinkle area Left (%)	43.04±3.82	41.06±3.81 (<i>p</i> <0.01)	39.21±3.72 (<i>p</i> <0.01)	40.40±6.77 (<i>p</i> =0.06)
Wrinkle area Right(%)	41.78±3.98	39.30±3.41 (<i>p</i> <0.01)	37.94±3.94 (<i>p</i> <0.01)	40.73±3.78 (<i>p</i> =0.51)

**Fig. 4** The decrease of the periorbital wrinkles lasted until 24weeks after treatment

change: 4 participants, slight improvement: 4 participants), and participants who recorded as moderate (11 participants), marked (3 participants), and excellent (1 participant) improvement were all increased than week 4. At week 24, 5 participants (21.74%) recorded no change, slight improvement in 8 participants (34.78%), moderate improvement in 6 participants (26.09%), marked improvement in 3 participants (13.04%), and excellent improvement in 1 participant (4.35%) were recorded. Subjective satisfaction score was highest in week 12, and this score slightly decreased in week 24 but overall 78% (18/23) have been still satisfied with the cosmetic result at 24 week.

Safety evaluation and pain assessment

The average of pain score (NRS, 0~10) assessed right after the treatment was 0.30 ± 0.63 , which was very low. No one discontinued the treatment due to pain during procedure. Only mild adverse events were recorded, including

tingling sensation (2 cases), 1 case of tingling sensation with 1st degree burn which recovered spontaneously without complication.

Discussion

This study represents the translational research encompassing both a pre-clinical animal study and a clinical human study to assess the efficacy and safety of the MRF device. For the pre-clinical study, micropigs were chosen due to their physiological resemblance to human skin. Utilizing a thermal imaging camera, we observed that RF energy was efficiently converted to thermal energy and effectively reached within a confined area. Even with multiple exposures, the temperature of the skin surface did not show a significant increase, demonstrating that the contact cooling system of this device functions in a stable and secure manner. It's worth noting that the surface temperature tends to

Subjective assessment of satisfaction

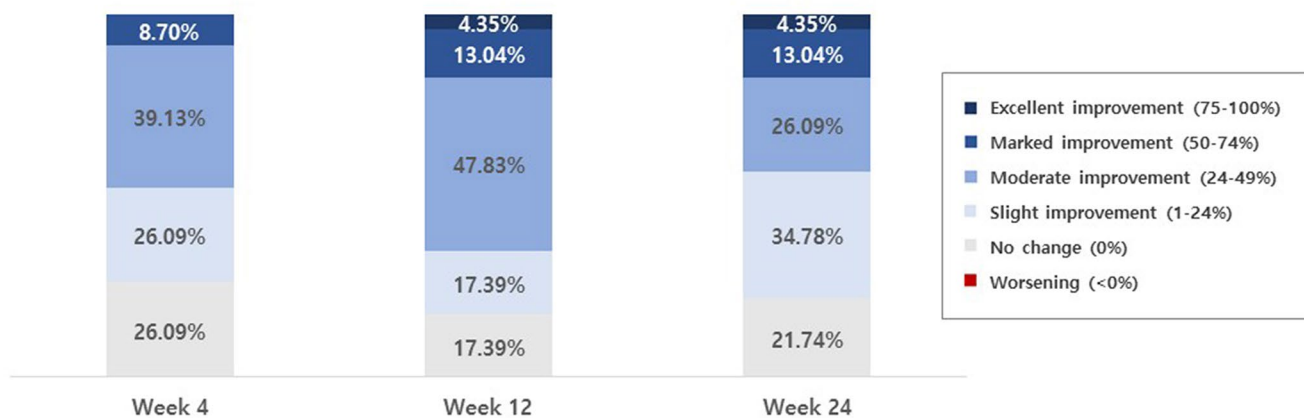


Fig. 5 Changes in subjective satisfaction assessment

rise when the treated area is closer to the grounding pad. With the cooling system, no complications were observed following multiple treatments.

Based on the clinical photos, the greatest effect was achieved at 12 weeks, and significant improvement continued until 24 weeks. One previous study using Thermage®(MRF) showed significant improvement of skin laxity in the 6 months post-treatment, especially in the jowls and melolabial folds, with the excellent adverse effect profile. The decreased rate of skin laxity in the middle face and lower face was higher in both week 4 and 12 in our study, but in week 24, the decreased rate(%improvement) was lower in this study than the previous study [12]. Also, this study showed slightly decreased improvement in week 24 than week 12. Although the both studies used similar global photographic assessment, absolute comparison between the previous study [12] and this study is meaningless because the head to head comparison study has not been done. In addition, the different efficacy of 2 studies, might be related to different treatment protocol (600 RF shots in this study and 900 RF shots in the previous study). Regarding ethnic differences, it is worth noting that individuals of East Asian descent typically exhibit wider and rounder faces, flatter malar prominence and midface, as well as a more recessed chin [13]. These distinct facial characteristics can potentially impact the photographic assessment when comparing the results between the two studies. Specifically, in this study, there may be a less pronounced change in cheekbone roundness compared to the findings of the previous study [12], which should be taken into consideration and interpreted accordingly.

We evaluated skin texture by assessing several quantitative factors like skin elasticity, pore counts of cheek, wrinkle area of periorbit using computer software and cutometer®. In the analysis of cutometer®, which has been

used for checking skin elasticity in the multiple studies, the net elasticity (R5) and biologic elasticity (R7) showed significant improvement in week 24. The R5 value (net elasticity) started to increase from week 12 to week 24, which means the RF energy constantly could affect the elastic fiber remodeling. The R7 value (biologic elasticity) increased only at 24 week after treatment, because the change of viscoelastic deformation usually takes more time.

The pore counts demonstrated a continuous and significant decrease until week 24, indicating the sustained improvement in pore size reduction. Additionally, the wrinkle area (%) exhibited a significant decrease by week 12, with the improvement maintained until week 24. The decrease in the number of pores can be attributed to the shrinkage of pore size resulting from the skin tightening of the treatment. It is important to note that the computer software used for counting pores can only detect and quantify pores above a pre-set default size, potentially resulting in the exclusion of pores that have become smaller. Therefore, the reduction in the number of pores indirectly signifies the positive effects of RF treatment on skin tightening and dermal elasticity. The wrinkle area(%) per unit area checked the degree of indentation or roughness of skin surface. The decrease of wrinkle area means the multiple minor indentation of skin surface by skin aging was flattened by the dermal remodeling.

Monopolar RF energy can heat only the dermis mainly targeting collagen and elastic fiber and sparing the epidermis [14]. The heat delivered to the dermis causes a controlled thermal injury, results in regeneration of the dermal matrix [1], makes recovery of skin laxity and texture.

Patient discomfort has been cited as a significant issue with MRF treatment [14–17], but this study relatively showed lower pain score right after the treatment than other studies without topical or injecting local anesthesia [12,

18, 19]. In this study, we performed RF treatment without the need for local anesthesia, and participants reported that the pain was tolerable. In another study that used the same device but employed topical local anesthesia and delivered a lower energy level compared to our study, the pain score during treatment was approximately 3.13, which was also deemed tolerable. It is hypothesized that the focal and targeted energy delivery to the dermis, as confirmed by the pre-clinical study, may contribute to the lower pain scores.

In the literature, the average satisfaction rate reported by patients was approximately 50% [11, 20, 21]. However, in our data, 73.9% of subjects was satisfied at week 4, 78.3% at week 24, with the highest satisfaction at week 12.

In conclusion, this prospective study provide evidence that MRF treatment delivers energy to the skin consistently and results in significant improvement in skin laxity, all while demonstrating a favorable safety profile.

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Author contributions Conceptualization: Byung Cheol Park. Methodology: Byung Cheol Park, Mi Soo Choi. Formal analysis and investigation: Myung Hwa Kim, Kyujin Yeom. Writing – original draft preparation: Mi Soo Choi. Writing – review and editing: Mi Soo Choi, Myung Hwa Kim, Byung Cheol Park. Funding acquisition: Byung Cheol Park. Resources: Byung Cheol Park. Supervision: Byung Cheol Park

Data availability The data underlying the findings in this manuscript are not publicly available to preserve participants' privacy. Access to the data may be granted upon request, subject to participants' approval and in compliance with applicable privacy regulations. For further information, please contact the corresponding author at 4exodus@hanmail.net.

Declarations

Ethics approval The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in its approval by the institutional review board (IRB No. DKUH 2016-09-005-001).

Conflict of interest There is no conflict of interest to declare.

Clinical trial number Not applicable.

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