

Treatment of Periorbital Wrinkles With a Novel Fractional Radiofrequency Microneedle System in Dark-Skinned Patients

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BACKGROUND Periorbital wrinkles as a result of photoaging are a frequent cosmetic concern. Recently, the fractional radiofrequency microneedle system was introduced as a new device for facial rejuvenation, and it has received much recognition for its unique “deep dermal heating with epidermal sparing” feature.

OBJECTIVE The purpose of this study was to examine the clinical efficacy and safety of the system for the treatment of periorbital wrinkles in Korean patients.

MATERIALS AND METHODS Twenty Korean patients (Fitzpatrick skin Type IV–V) with varying degrees of periorbital wrinkles were enrolled in this study. The patients were treated 3 times at 4-week intervals with the system. Changes in periorbital wrinkling were evaluated by 2 independent experts with digital images of the subjects’ faces using a 5-point Wrinkle Assessment Scale. At the end of the study, the patients rated their satisfaction with the overall treatment outcome on a numerical scale.

RESULTS All patients completed the treatment regimen and were satisfied with the treatment. Most patients improved according to clinical and photographic assessments performed 6 months after the treatment. Two patients (10%) reported mild hyperpigmentation.

CONCLUSION The system may be an effective and safe treatment option for periorbital wrinkles in dark-skinned Korean patients.

The authors have indicated no significant interest with commercial supporters.

Therapeutic approaches to periorbital wrinkles are unique because of the delicacy of the anatomic structures and the possibility of adverse events.¹ Topical agents (including tretinoin), chemical peels, botulinum toxin, dermal filler injections, dermabrasion, and laser therapy are some of the therapeutic resources that have been used alone or in combination, but the efficacies of these techniques are limited and no ideal procedure exists.^{2,3}

There have been recent reports on the use of deep dermal heating by radiofrequency (RF) equipment, also known as bipolar fractional radiofrequency (FRF), which involves the insertion of needles. This technique was developed specifically

for tightening deeper dermal structures with minimal epidermal damage.⁴

In the system, 10 needles are inserted obliquely with long RF emission times (up to 4 seconds). The fractional radiofrequency microneedle system employed in this study is very similar to FRF, but there are several differences: (1) the number of needles is 49 (Figure 1), (2) needles are inserted vertically, and (3) RF emission time and the depth of needle insertion can be changed easily at the operator’s discretion. Although the differences between the two systems are not fully clarified, the former targets only deeper dermal areas for skin lifting, whereas the latter targets superficial to deep dermis for various dermatologic conditions.

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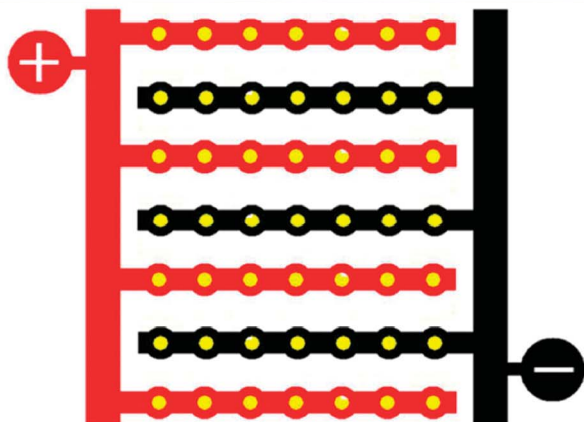


Figure 1. Illustration of microelectrode assembly containing 49 bipolar RF needles.

The objective of this study was to examine the clinical efficacy and safety of the system for the treatment of periorbital wrinkles in Korean patients.

Materials and Methods

Subjects

Twenty Korean patients (Fitzpatrick skin Type IV–V) with varying degrees of periorbital wrinkles were enrolled in the study. This prospective study was performed according to the guidelines of the 1975 Helsinki Declaration, and the Institutional Review Board of Kangbuk Samsung Hospital approved this clinical study protocol. Before inclusion in the study, all patients had to provide written informed consent. The mean patient age was 48.5 years (range, 37–61 years), and the patient group consisted of 19 women and 1 man. Patients undergoing

concomitant treatments of the involved skin areas, a history of medical or surgical facial wrinkle treatments within the past 6 months, a history of keloid formation, or pregnancy were excluded. Table 1 summarizes the characteristics of the patients included in this study.

Treatment Protocol

Before treatment, the periorbital area was gently cleansed with a mild cleanser, and a topical anesthetic cream (EMLA; AstraZeneca, Wilmington, DE) was applied to minimize treatment discomfort. Eyes were protected with eye shields. In all subjects, the area was treated 3 times at 4-week intervals with the FRM system (INTRAcel, Jeisys, Korea). The treatment parameters were: bipolar mode, needle insertion to 0.8 mm depth, power 12.5 W, and duration 100 milliseconds. After treatment, the area was cooled with ice packs for 20 minutes and topical antibiotics were applied. The authors advised all subjects to avoid sun exposure and wear broad-spectrum sunscreen during and after the treatment period.

Assessment

High-resolution digital photographs were taken before each treatment session and 6 months after the last treatment using a Nikon DSLR camera (Nikon, Tokyo, Japan). To compare the efficacy of treatment, the authors assessed the same areas containing wrinkles using dermoscopy (Aramo TS; Aram Huvis Co., Ltd., Seongnam, Korea) and acquired magnified images.

The wrinkle grade and overall clinical efficacy were assessed by 2 blinded dermatologists who observed

TABLE 1. Subject Demographics

Sex	
Female	19
Male	1
Mean (range), years	48.5 (37–55)
Fitzpatrick skin type	
IV	18/20 (90%)
V	2/20 (10%)

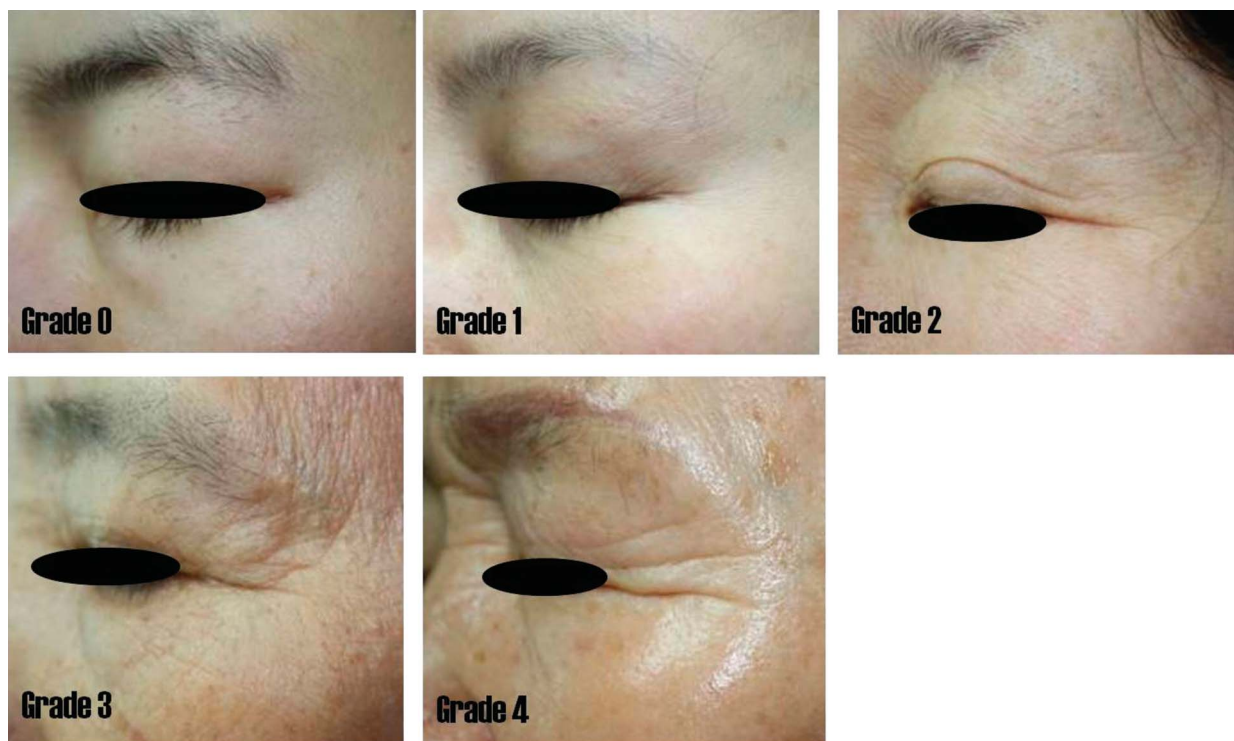


Figure 2. Illustration of the 5-point WAS.

nonconsecutive comparative photographs. Patients' wrinkles were graded using the 5-point wrinkle assessment scale (WAS), which ranges from 0 to 4 (Figure 2, Table 2). Treatment efficacy was assessed by subtracting the baseline score from the score at 6 months after the last treatment. When the post-treatment scores were smaller than the baseline scores, the treatment was considered effective. At the end of the study, the patients rated their satisfaction with the overall treatment outcome on a numerical scale (poor = 1, fair = 2, good = 3, and excellent = 4).

At each visit, a medical examination and adverse effects related to laser treatment including erythema, erosion, edema, hyperpigmentation, hypopigmentation, and scarring were recorded. The Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL) was used for statistical analysis. Data were evaluated using a paired *t*-test and statistical significance was defined as a $p < .05$.

Results

All subjects completed the study. Intraoperative and postoperative discomfort was described as moderate (using the visual analog pain scale) by most of the patients. All patients reported mild erythema and edema after the treatment, but the symptoms disappeared within 3 days. Subsequently, superficial crusting occurred and sloughed off in 7 days without scarring.

Follow-up results 6 months after the final treatment showed statistically significant improvements in periorbital wrinkles based on a quantitative assessment by a physician using the 5-point WAS (Table 3). The mean treatment efficacy was

TABLE 2. Five-Point WAS

Score	Description
0 (none)	No wrinkles No visible wrinkles; continuous skin line
1 (mild)	Fine wrinkles Visible wrinkles and slight indentation
2 (moderate)	Moderate wrinkles Clearly visible wrinkles
3 (severe)	Deep wrinkles Deep and furrowed wrinkles
4 (extreme)	Extremely deep wrinkles Extremely deep and long folds

TABLE 3. Summary of Patient Outcomes

Patient	Physician Assessment (WAS)			Global Aesthetic Improvement Scale	
	Baseline*	After Treatment* (6 Months)	Efficacy (After Baseline)	Patient (6 Months)	Adverse Effect
1	2 (2.2)	1.5 (1.2)	−0.5	3	None
2	3.5 (3.4)	1.5 (2.1)	−2.0	4	None
3	2.5 (2.3)	1 (1.1)	−1.5	3	None
4	3.5 (3.4)	2 (2.2)	−1.5	3	None
5	3 (3.3)	1.5 (1.2)	−1.5	3	Mild PIH
6	3 (3.3)	2 (2.2)	−1	3	None
7	2 (2.2)	1 (1.1)	−1	3	None
8	3.5 (3.4)	2 (2.2)	−1.5	3	None
9	2 (2.2)	0 (0.0)	−2	4	None
10	2 (2.2)	1.5 (1.2)	−0.5	2	None
11	2 (2.2)	1 (1.1)	−1	3	None
12	3 (3.3)	1.5 (1.2)	−1.5	3	Mild PIH
13	2 (2.2)	1 (1.1)	−1	3	None
14	2 (2.2)	1.5 (2.1)	−0.5	3	None
15	2 (2.2)	1.5 (1.2)	−0.5	3	None
16	2 (2.2)	1.5 (2.1)	−0.5	3	None
17	2.5 (2.3)	1.5 (2.1)	−1	4	None
18	3.5 (3.4)	2 (2.2)	−1.5	3	None
19	2 (2.2)	1.5 (2.1)	−0.5	2	None
20	2 (2.2)	1.5 (2.1)	−0.5	3	None
Mean efficacy	−1.075 ± 0.52 (<i>p</i> < .001)	—	—	—	—

*Average of the 2 raters' scores (first rater's score and second rater's score).

−1.075 ± 0.52 (*p* < .001), and the mean participant satisfaction score for the procedure was 3.05 (Figure 3). Comparisons of the photographs taken before and after treatment confirmed significant improvements in periorbital wrinkles (Figures 4–6). Two patients (Fitzpatrick skin Type IV–V) reported mild hyperpigmentation of the treated area after the treatment, which resolved within 4 weeks after the last treatment.

Discussion

Aging of the periorbital area is a complicated biological process and occurs through 2 distinct processes. Intrinsic aging is the natural aging process that results from slow irreversible tissue degeneration including thinning of the epidermis and changes in collagen and elastic fibers.¹ Extrinsic aging, often coinciding with the normal aging process, is influenced

by several types of external exposure (such as sun exposure and mechanical stress).¹ A wide array of techniques has been used to improve the appearance of periorbital wrinkles.



Figure 3. Patient satisfaction scores 6 months after the last treatment.



Figure 4. A 55-year-old woman before treatment and 6 months after the last treatment. A significant improvement was observed.

Over the last few decades, techniques for nonsurgical wrinkle reduction have advanced significantly with the emergence of resurfacing lasers. Ablative lasers, such as carbon dioxide and erbium:yttrium aluminum garnet lasers, have been used as treatment options for periorbital wrinkles.^{5–8} However, the annual number of treatment sessions has declined because of significant downtime and unacceptable risk profiles including edema, long-standing

erythema, hyperpigmentation, hypopigmentation, infection, and scarring.⁹ Thus, patients are seeking procedures without risks and the prolonged recovery of ablative laser treatment. This demand has led to the development of nonablative devices that minimize risk profiles. Nonablative devices such as pulsed dye laser (585–595 nm), intense pulsed light sources (585–1,100 nm), neodymium:yttrium aluminum garnet laser (1,064/1,320 nm), and other



Figure 5. A 48-year-old woman before treatment and 6 months after the last treatment. A significant improvement was observed.

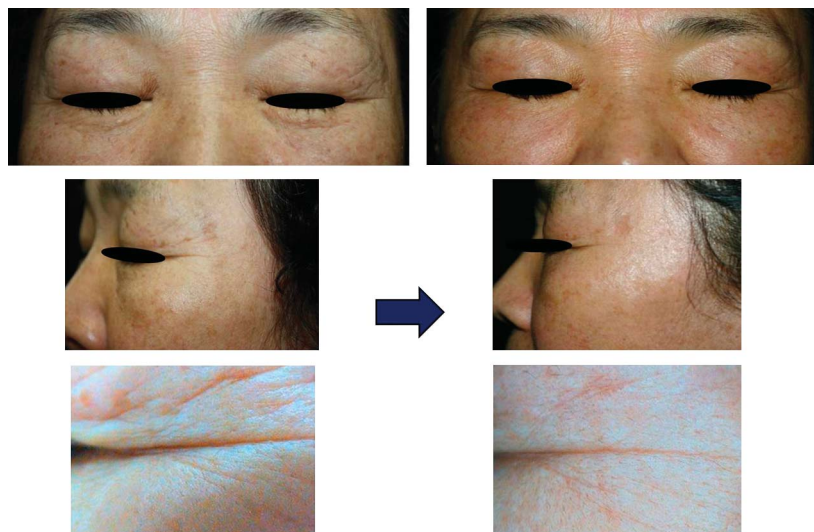


Figure 6. A 61-year-old woman before treatment and 6 months after the last treatment. A significant improvement in the infraorbital area was observed.

infrared lasers (1,450, 1,550, 1,927 nm) have been developed. However, the degree of improvement seems to be limited and unsatisfactory for some patients.¹

Fractional photothermolysis (FP) was developed recently and it sensationalized the field of laser skin remodeling. Fractional photothermolysis delivers thermal energy into multiple noncontiguous arrays of microscopic treatment zones (MTZ) surrounded by intact nonirradiated skin. Nonablative FP triggers collagen synthesis and dermal remodeling, and minimal epidermal injury reduces the risk for side effects such as long-standing erythema, hyperpigmentation, and scarring.^{9–12} Therefore, this system ensures shortened recovery period and fewer adverse effects compared with ablative lasers.^{9–12} However, several treatment sessions are required to achieve tangible cosmetic improvement and therapeutic results are still inferior to traditional ablative lasers.^{9–12} Ablative FP systems such as 10,600-nm CO₂ or 2,940-nm erbium-yttrium aluminum garnet are available and are used for more effective treatments than nonablative FP. Ablative FP laser treatment creates real skin ablative holes rather than MTZ. The effect of ablative FP is stronger than nonablative FP and safer than conventional ablative laser treatment. However, despite some advantages of ablative FP, it is not an incontrovertible alternative.^{13,14}

Although postinflammatory hyperpigmentation (PIH) is much less frequent with fractional laser treatment than with other ablative procedures, it is observed in 1% to 32% of patients.^{13,14} Asian patients in particular have a higher likelihood of developing PIH.^{13,14}

As an alternative to nonablative laser technology, RF tissue tightening was introduced and has been increasing in popularity recently.^{15,16} The electrical resistance of tissue converts the electrical current of RF to thermal energy deeper within the dermis. Therefore, RF causes skin tissue tightening through collagen denaturation, contraction, and fibroblast stimulation. The collagen remodeling process continues for a period of 4 to 6 months.¹⁶ Because of its high efficiency and safety, noninvasive nonablative RF systems have many esthetic applications, including skin lifting and tightening, body contouring, and cellulite reduction.^{16–18} A combination of the fractional technique with a classical nonablative RF device has been introduced and applied in the field of skin rejuvenation.^{16,17}

Fractional radiofrequency microneedle therapy was developed as a minimally invasive and unique system that delivers bipolar RF current through a microneedle electrode assembly.¹⁹ This system efficiently delivers bipolar RF current to the deep dermis and creates a controlled RF thermal zone while

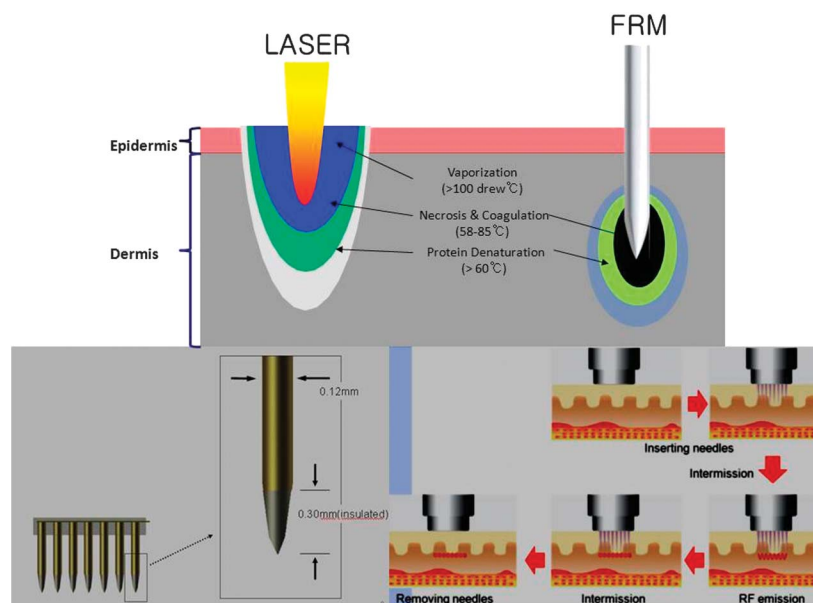


Figure 7. Illustration of what is the fractional radiofrequency microneedle system, differences between laser and the fractional radiofrequency microneedle system, and schematic operation system of the fractional radiofrequency microneedle system.

sparing the epidermis and key adnexal structures that contribute to rapid wound healing.^{19,20}

The histopathologic changes after the treatment are unique and different from those of laser treatment (Figure 7). In a preliminary study, the authors demonstrated the effectiveness of the system in dermal remodeling by showing increased production of HSP47 and procollagen and the full replacement of denaturalized collagen with new collagen.²⁰ The study confirmed the actual volume effect by showing increased production of procollagen and elastin based on immunohistochemistry and reverse transcription polymerase chain reaction.²⁰

In this study, the system induced significant improvements in periorbital wrinkles. The improvement in wrinkle appearance reduction was superior to that afforded by other nonablative fractionated lasers, which resulted in limited and inconsistent cosmetic improvement. One of the advantages of the system is its powerful thermal damage of the deep dermis while sparing the epidermis and key adnexal structure that contribute to rapid healing. In this study, only 2 patients experienced reversible PIH, which is very impressive results considering all patients were dark skinned.

In conclusion, the system may be an effective and safe option for the treatment of periorbital wrinkles especially in dark-skinned patients. Additional controlled trials with large patient samples and more extensive follow-up are needed to confirm the safety and effectiveness of the procedure and to evaluate the duration of results.

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