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The efficacy of micro-insulated needle radiofrequency system for the treatment of lower eyelid fat bulging

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Summary

Background and objectives: Conventional treatment options for eyelid fat bulging are generally limited to surgical approaches. However, many attempts have been made recently to manage this disfigurement using non-surgical interventions. The purpose of this study was to evaluate the efficacy and safety of a micro-insulated needle radiofrequency system for the treatment of lower eyelid fat bulging.

Methods: This is a single center pre-post comparative study. Twenty-two subjects with lower eyelid fat bulging were treated twice using the needle radiofrequency system, at an interval of four weeks. Two types of partially insulated needles with different lengths were used in each session. A three-dimensional photogrammetry system was used to objectively measure changes in the extent of the fat bulge. The investigator's global assessment (IGA) of the severity of fat bulging was also evaluated.

Results: The average extent of fat bulging was decreased significantly after twelve weeks, and was maintained until 24 weeks. The IGA score was significantly decreased after four weeks and further decreased after twelve weeks, and then maintained until 24 weeks. There were no side effects, except for lower eyelid swelling and bruising that lasted for about a week.

Conclusion: The micro-insulated needle radiofrequency system can be a beneficial and well-tolerated treatment for lower eyelid fat bulging.

Introduction

Lower eyelid fat bulging, also known as infraorbital fat pad herniation or eye bags, is one of the characteristics of aging. Loosening of the orbital septum and orbicularis oculi muscle are the most important factors leading to herniation of orbital fat. These result in a tired, sunken, and older-looking facial appearance. The traditional treatment for lower eyelid fat bulging is surgical lower eyelid blepharoplasty via a percutaneous or transconjunctival approach [1–3]. However, invasive surgery evokes unnecessary anxiety in many patients for reasons including pain, long downtime, and possible complications such as diplopia, chemosis, ectropion, corneal abrasion, and overcorrection [4–6].

In recent decades, many attempts have therefore been made to develop non-surgical and minimally invasive approaches; the radiofrequency (RF) technique has shown high efficacy and safety in improving lower eyelid fat bulging [7–9]. Radiofrequency devices use electric current to create a thermal effect that results in collagen contraction and neocollagenesis [10], as well as fat cell apoptosis and fatty tissue reduction [11]. More recently, a fractional RF microneedle device has been introduced. This device allows the operator to control the depth and intensity of thermal lesions, delivering focused RF energy without epidermal damage by using insulated needles [12].

In the present study, we evaluated the efficacy of the needle RF system in treating lower eyelid fat bulging with the use of two types of insulated microneedle: one targeting the orbital fat and the other targeting the overlying connective tissues, including the orbital septum. We used a three-dimensional (3D) surface imaging system to objectively measure the change in extent of fat bulging.

Patients and methods

Subjects

A total of 24 volunteers with lower eyelid fat bulging were enrolled in this prospective non-controlled clinical trial. The study protocol was approved by the institutional review board of the Seoul National University Bundang Hospital. Informed consent was obtained from all subjects prior to participation. The exclusion criteria were: prior cosmetic facial surgery within the past year, placement of tissue fillers within the last six months, neurotoxin injections around the eyes, laser therapy or chemical peeling of the midface within the preceding three months, and the use of topical retinoids on the face within the past month.

Treatment protocol

All treatments were performed under local anesthesia with 1 % lidocaine and 1 : 100,000 epinephrine. To minimize the impact on the treatment area, the least amount of anesthesia required was injected. AGNES™ micro-insulated needles with RF applicators (Gowoonsesang Cosmetics Co, Seongnam, Gyeonggi, Korea) were used to treat the fat bulges. The device that we used is a monopolar RF system with a frequency of 1 MHz. The needles were composed of two parts: a proximal insulated area and a distal non-insulated area. Proximal insulation protects the epidermis against thermal damage, allowing the procedure to be non-ablative and minimally invasive. In addition, the needle has shoulders that function as a stop, allowing the operator to insert the needle to a consistent depth and avoid deep tissue injuries (Figure 1a, c).

Subjects were treated in two separate sessions at an interval of four weeks. Two types of needle tip were used sequentially in each session: a tip with three short needles 1.5 mm in length with proximal insulation of 0.3 mm (Figure 1a), and another tip with a single long needle 5 mm in length with proximal insulation of 2.5 mm (Figure 1c). The periorbital area was treated with the short needles first (exposure time 150 ms, power 9 W) to tighten the overlying dermis (Figure 1b). A fat pocket was then treated with the long needle as well (exposure time 400 ms, power 9 W) to tighten the orbital septum and damage the fat cells directly (Figure 1d). The insertion sites were about 2 mm apart from one another. When using the long needle, the following method was applied to avoid eyeball injuries (Figure 2). The operator used the second to fourth fingers of his non-dominant hand to gently press the patient's eyeball, causing posterior displacement of the eyeball in its socket; this led to protrusion of the infraorbital fat pads. The operator then moved his fingers slightly downwards until his fingertips touched the inferior orbital rim, so that the fingers completely covered the eyeball. The assistant then pulled down the lid/cheek junction, where the orbitomalar ligament is attached, so that the infraorbital fat pads could be placed on the maxillary bone, where the operator could insert the needle without the risk of eye damage. After treatment, the treated areas were compressed gently and cooled with ice packs for 20 min and a topical antibiotic (mupirocin ointment) was applied. All subjects were instructed to cleanse their face gently with tap water and to avoid sun exposure until the next day.

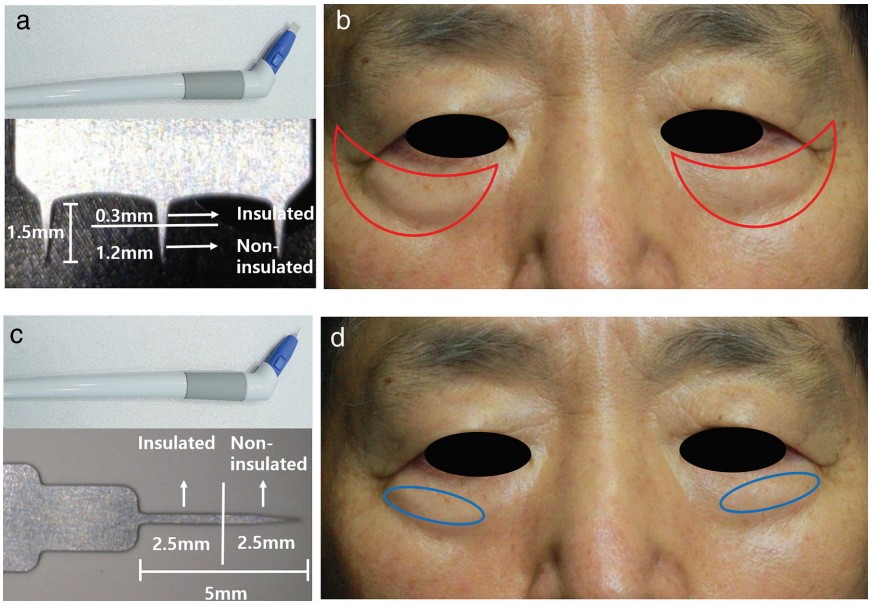

Figure 1 Two types of needle tip and the treated area. A tip with three short needles 1.5 mm in length with 0.3 mm of proximal insulation (a). Areas treated with the three short needles (b). A tip with a single long needle 5 mm in length with 2.5 mm of insulation proximally (c). Areas treated with the single long needle (d).

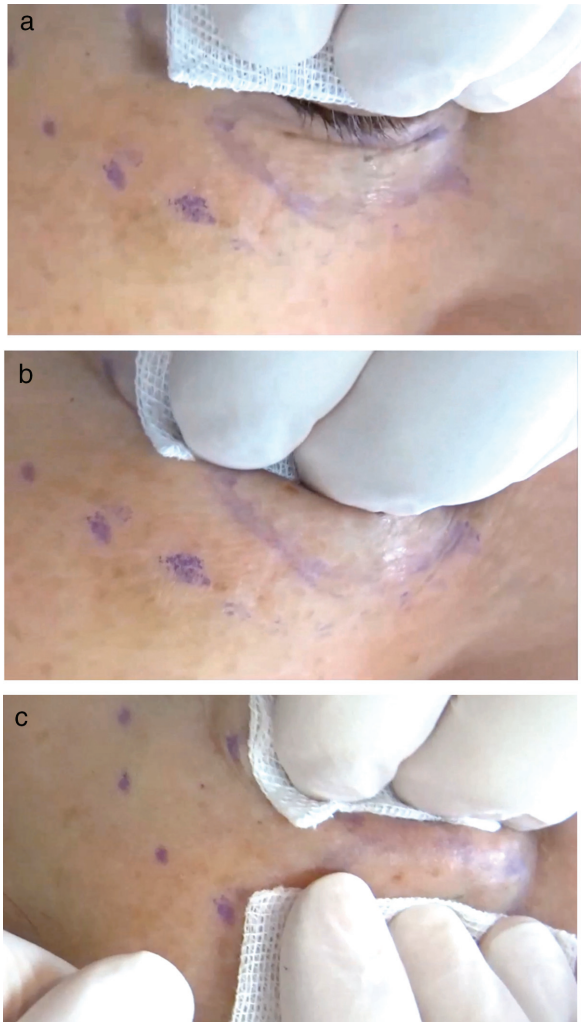

Figure 2 Technique used to avoid eyeball injuries during treatment with the long needle. The operator uses the second to fourth fingers of the non-dominant hand to gently press the patient's eyeball (a). The operator moves his/her fingers downwards until the fingertips touch the inferior orbital rim and the fingers completely cover the eyeball (b). The assistant pulls down the eyelid/cheek junction where the orbitomalar ligament is attached (c).

Assessment

Changes in fat bulging were observed objectively using 3D photogrammetry. The 3D surface data of each subject's face was acquired at baseline, 4, 12, and 24 weeks after treatment, using a Morpheus 3D® scanner (Morpheus Co., Seongnam, Gyeonggi, Korea). To measure the extent of fat bulging, we determined an arbitrary reference plane that linked three points: two points where the right and the left mid pupillary lines met at each lower eyelid, and another point at the pogonion (the most anterior part on the chin) (Figure 3). The distance from this reference plane to the greatest extent of fat bulging was defined as the extent of fat bulging.

All subjects were photographed using a digital camera at baseline, 4, 12 and 24 weeks; the same conditions – standardized brightness and distance – were applied at each photo shoot. For the investigator's global assessment (IGA) of infraorbital fat herniation, we used a four-point scale: 0 for no herniation, 1 for mild herniation, 2 for moderate herniation and 3 for severe herniation (Figure 4).

The patient's satisfaction score was evaluated at 4, 12, and 24 weeks with a questionnaire using a ten-point scale: from 0 (very unsatisfied) to 10 (very satisfied) for all aspects of treatment. Furthermore, patients were asked to report any adverse effects at any time during and after the treatment. The investigators also checked for adverse effects at each follow-up visit.

Statistical analysis

We performed a paired t-test and used a generalized linear model for the data at baseline and at each subsequent visit using SPSS software, version 20.0 (SPSS, Chicago, IL, USA). A *P*-value of less than 0.05 was considered statistically significant.

Results

Subject characteristics

Of the 24 volunteers, 22 subjects successfully completed this study; two were excluded for personal reasons. Eighteen subjects were female and four were male. The average age was 56.1 years (range: 42 to 69).

Shot numbers

The average number of applications with the short and long needles during the first visit was 91.65 ± 18.38 and 36.42 ± 11.12, respectively. During the second visit, the average number of applications with the short and long needles was 82.20 ± 13.94 and 32.22 ± 6.46, respectively.

Extent of fat bulging

Forty-four lower eyelid fat bulging lesions from 22 patients were evaluated individually. The average extent (mm) of fat bulging at baseline, 4, 12 and 24 weeks was 1.76 ± 1.23, 1.64 ± 1.07, 1.34 ± 1.09, and 1.32 ± 0.18, respectively (Figure 5). The extent continued to decrease throughout the study period, and the extents measured at 12 weeks and 24 weeks were significantly less than those measured at baseline and four weeks ($p < 0.001$).

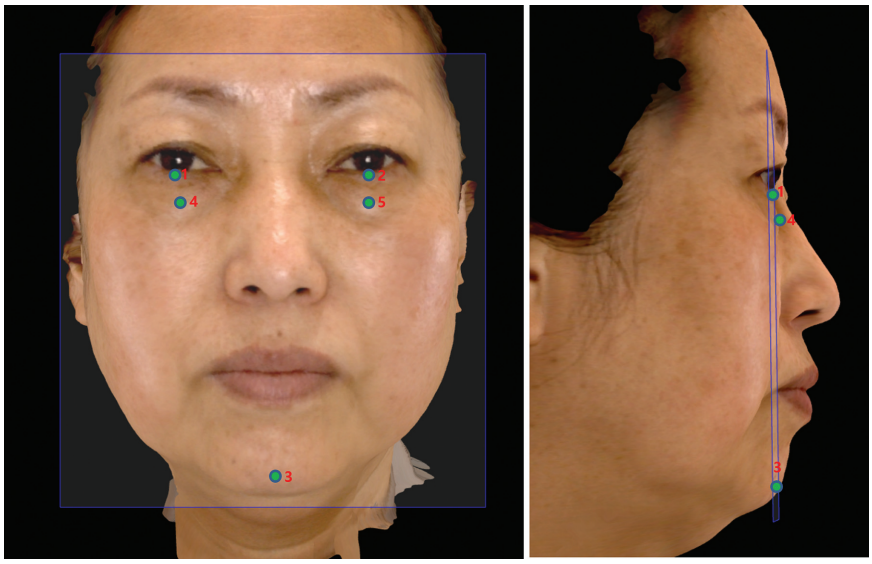

Figure 3 Three-dimensional photographs obtained by Morpheus 3D® and landmarks required for analysis. The point where the right mid-pupillary line meets the lower eyelid (1). The point where the left mid-pupillary line meets the lower eyelid (2). Pogonion of the chin (3). Greatest extent of fat bulging on the right (4). Greatest extent of fat bulging on the left (5).

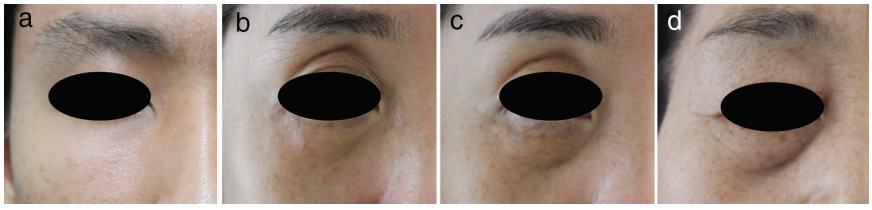

Figure 4 Investigator's global assessment (IGA) of infraorbital fat herniation. 0 = none (a), 1 = mild (b), 2 = moderate (c), 3 = severe (d).

IGA score

Subjective assessment of the patients showed a clinical improvement after the treatment (Figure 6). The average IGA score for the 44 lower eyelid fat bulging lesions at baseline, 4, 12 and 24 weeks was 1.99 ± 0.60, 1.07 ± 0.44, 0.71 ± 0.50, and 0.82 ± 0.55, respectively (Figure 7). After the first session (at week 4), the average score had decreased remarkably and the decrease was statistically significant ($p < 0.001$). The average score decreased further to 0.71 until week 12, and was significantly lower than at week 4 ($p < 0.001$); at week 24, the average score was maintained, and was similar to that at week 12.

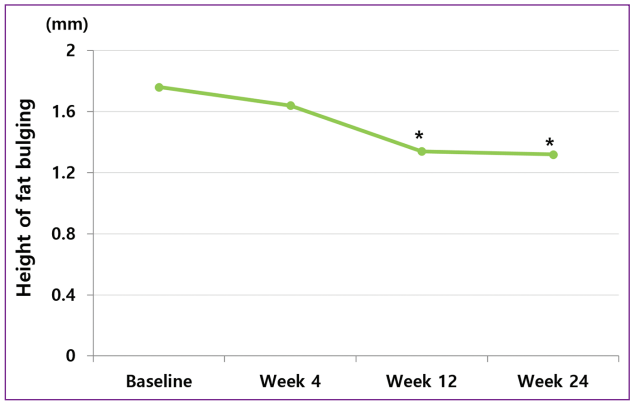

Figure 5 The extent of reduction of lower eyelid fat bulging, measured with Morpheus 3D® The average extent of fat bulging was decreased at week 12 and maintained until week 24. *$p < 0.001$ compared with baseline and week 4.

Patient satisfaction

The average patient satisfaction at weeks 4, 12 and 24 was 5.61 ± 2.31, 6.51 ± 2.35, and 6.58 ± 2.55, respectively. All these values were greater than 5, and peaked at week 24 with a score of 6.58. The proportion of patients with a score of greater than 6 gradually increased with time (Figure 8).

Safety assessment

Except for transient pain during the injection of anesthetic and subsequent swelling and bruising, which usually disappeared within the first week, no severe adverse effects (such as burns, ectropion, diplopia or prolonged dysesthesia) were reported.

Discussion

The results of this study demonstrate that the micro-insulated needle RF system can successfully reduce lower eyelid

Figure 6 Clinical photographs of patients before and after the procedures.

fat bulging without any serious adverse effects. Unlike lasers, which use light energy to heat and target a specific superficial structure or chromophore, RF produces heat when the electrical energy is converted to thermal energy in the deeper dermis and subcutaneous tissue [13]. Initially, RF was used to destroy tissues or coagulate vessels with ablative electrosurgery. It was shown later that low-energy RF was applicable for cosmetic purposes [14–16], although it could only achieve superficial cutaneous changes. Then, with greater advancements in the late 2000s, non-ablative RF devices were developed, allowing for the tightening of deeper dermal structures without epidermal damage. Non-ablative RF devices use a unique capacitor membrane at the treatment tip, allowing uniform and volumetric application of heat [17].

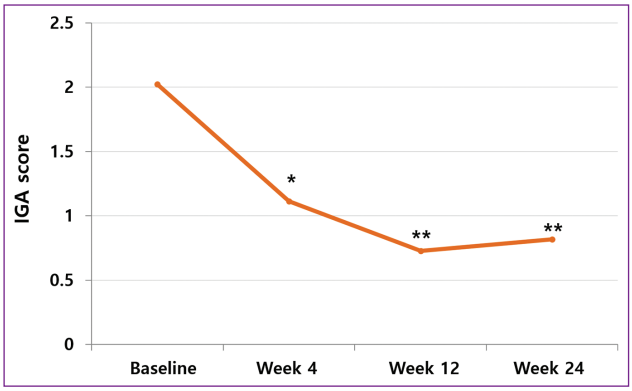

Figure 7 The investigator's global assessment (IGA) score. The average IGA score decreased after the procedures and was maintained until week 24. *$p < 0.001$ compared with baseline, **$p < 0.001$ compared with baseline and week 4.

The epidermis is protected by simultaneous cryogen cooling during the procedure. These devices have been widely used to rejuvenate and lift aging skin without surgical removal [7–9, 14, 17–21]. Since the effects of these devices are not affected by skin chromophores, they can be used safely for any skin type. For delivery of more heat to deeper areas in order to achieve more successful outcomes, the exposure time and power need to be increased; however, these increases can elevate the risk of thermal burns [22]. In fact, in an early clinical study, about 17 % of subjects were reported to have at least one grid-spot of second-degree burn [14]. Subsequent protocol modifications and technical improvements can decrease the burn rate [11, 23, 24], but if such burns do occur they can result in serious cosmetic disfigurement. More recently, fractional RF devices using microneedles were developed to deliver more heat to deeper skin tissues while reducing the risk of side effects such as thermal burns. With fractional RF devices and microneedle RF electrodes, one can deliver focused RF energy and control the depth, area, and intensity of treatment [12]. Fractional RF devices with microneedle RF electrodes can therefore be applied for non-invasive treatment of wrinkles, skin laxity, atrophic scars, and acne scars [25–29].

In the present study, we used two types of needle tip to treat lower eyelid fat bulging. Anatomically, the infraorbital fat pad is covered by the orbital septum, orbicularis oculi muscle, dermis, and deep epidermis. Previously, we measured the depths of various layers overlying the fat pad in 17 normal Koreans using DermaScan® C USB (Cortex Technology, Hadsund, Denmark). We found that the average depth of the epidermis, dermis, and orbital septum was 0.12 mm, 1.79 mm, and 3.13 mm, respectively (unpublished data). We were therefore able to tighten the overlying dermis using a

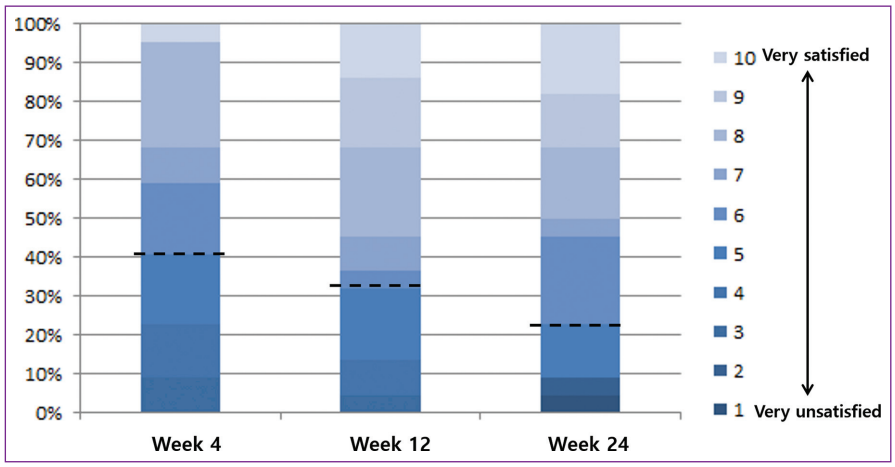

Figure 8 The average patient satisfaction score. The broken lines are placed between the scores 5 and 6. The percentage of patients who scored higher than 6 gradually increased over time.

tip with three short needles and a length of 1.5 mm, while preserving the epidermis from thermal damage due to its proximal insulation of 0.3 mm. We were also able to tighten the orbital septum while destroying the fatty tissues, using the tip with a single long needle, with a length of 5 mm and proximal insulation of 2.5 mm. Unlike other fractional RF devices with square tips, the needle radiofrequency system used in this study has a single short, linear needle tip that can be used to treat the periorbital area more selectively and effectively.

The main etiologies of lower eyelid fat bulging are thought to be loosening of the orbital septum and prolapse of the underlying orbital fat. Hence, these two types of target-specific needles may provide better results than conventional RF methods. Furthermore, due to the partial insulation of these needles, this approach can be regarded as minimally invasive compared with surgical blepharoplasty. The approach can also improve laxity and wrinkles of the overlying skin, which commonly get worse after surgical fat removal.

The severity of fat bulging decreased significantly after the first session, decreased further after the second session and maintained this level throughout the 24-week period (Figure 7). Moreover, the mean satisfaction score of all subjects was greater than five out of ten throughout the study period, and only increased over time (Figure 8). In this study, we used the Morpheus 3D® scanner (a 3D photogrammetry system) to objectively evaluate the extent of reduction of fat bulging. This scanner uses a structured light scanning system, making it possible to quantify angles, surface areas and volumes, as well as providing linear distances, user-guided interactive landmark localization, and the potential to extract the x, y, and z coordinate data for a wide variety of statistical analyses. In a previous study, the Morpheus 3D® device was used to obtain facial volumetric data [30]. The extent of fat bulging was obtained by calculating the distance between the reference plane and the greatest extent of fat bulging. The extent of fat bulging was significantly decreased at twelve weeks and maintained until 24 weeks (Figure 5).

Some risks are involved with the use of a needle 5 mm in length. Firstly, there is a possibility of an eyeball injury. To avoid this complication, the operator used the second to fourth fingers of the non-dominant hand to protect the eyeball during the procedure (Figure 2). Secondly, bleeding is possible. The angular vein is located in the medial part of the infraorbital fat pad, so that any procedure in this area can cause venous bleeding. Nonetheless, it is extremely rare for such bleeding to cause a concealed hematoma that could lead to blindness due to compression of the optic nerve. Moreover, the electrical conductivity of the vessels is much higher than that of fatty tissues. Hence, if the long needle of the RF system contacts a vessel, it would probably result in coagulation of vessels rather than bleeding. In other words, the probability of venous bleeding is less with the RF procedure than with conventional surgery. However, compression of the treated area for 5 minutes is recommended after the procedure to prevent this rare but critical complication.

A major limitation of this study is the non-controlled nature of the study. Randomized controlled trials are necessary to confirm our results. Nevertheless, to the best of our knowledge, this is the first clinical investigation proving the efficacy of the needle RF system as a treatment for lower eyelid fat bulging. Moreover, we also proved its efficacy objectively with the 3D photogrammetry system. This system should be able to provide objective evaluations of quantitative volume changes after various procedures in future studies.

The needle radiofrequency system used in this study has some advantages over other conventional fractional RF systems. Firstly, it has two types of tip with different needle lengths to reduce fat volume and tighten the overlying connective tissues. In particular, the long needle with a length of 5 mm can effectively target the orbital fat and induce its destruction, and can also be used to tighten the

orbital septum. Secondly, the small and simple needles can be used to target the curved periorbital surface precisely and treat infraorbital fat bulging more effectively. Although surgical blepharoplasty of the lower eyelid is still regarded as the standard treatment for infraorbital fat bulging, we believe that the micro-insulated needle RF system is an effective but much less invasive alternative. Further investigations with larger sample sizes and long-term follow-up are needed to provide additional information on the safety and efficacy of the micro-insulated needle RF system.

Conclusion

The micro-insulated needle RF system is a beneficial and well-tolerated treatment option for lower eyelid fat bulging. This minimally invasive method uses two types of insulated needle to target the fat deposit and surrounding tissues, and can correct the deformity more effectively than other methods. We were able to demonstrate its efficacy in an objective manner with the 3D photogrammetry system.

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