

The Efficacy of High-Intensity Focused Ultrasound Treatment for Sagging Upper and Lower Eyelids

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Background and Objectives

Eyelid sagging is a common complaint in aging patients. Although various attempts have been made to treat this condition, obtaining satisfactory results in patients without causing adverse effects has been challenging. The study demonstrated that high-intensity focused ultrasound (HIFU) can be a valuable tool for the treatment of eyelid sagging.

Materials and Methods

Twenty Korean women aged 35 to 57 years with mild to moderate upper and lower eyelid sagging were enrolled. The periocular area of the participants was treated with a 2.0-mm, 4-MHz HIFU probe. Photographs were taken before and 12 weeks after the treatment. Two clinicians who were blinded to participant recruitment evaluated improvements. Perceived improvement was rated by both patients and clinicians on a 4-point scale. The eyelid length was measured and compared before and after treatment.

Results

The results showed that 17 patients (85%) experienced some clinical improvement. In 15 of the 20 cases, clinicians were able to detect improvement. In addition, the mean eyelid length was reduced 12 weeks after treatment, indicating that the treatment is a potentially effective method for successfully treating eyelid aging.

Conclusion

HIFU is a useful method for improving upper eyelid sagging.

Key words

High intensity focused ultrasound, Eyelid sagging, Skin lifting

Received September 21, 2022

Accepted November 1, 2022

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INTRODUCTION

The periocular region shows the most prominent and early facial signs of aging [1]. The eyelid is one of the thinnest areas of the face [2], and aging eyelids show a decrease in elastic fibers with ultrastructural abnormalities and overexpression of elastin-degrading enzymes, which can result in prominent sagging [3]. As cutaneous changes and subsequent skin sagging can cause significant distress [4], the clinical management of this problem can enhance emotional well-being. Various surgical procedures, such as upper eyelid blepharoplasty, eyelid reconstruction, and eyebrow lifting, have been used widely to address these issues. However, because of the invasive nature of the surgery and its possible side effects, the demand for non-invasive treatment options is high [5]. Therefore, diverse non-invasive procedures have been introduced to restore youthful facial appearance [6]. In addition to botulinum toxin, fillers, radiofrequency treatment, and lasers [7], high-intensity focused ultrasound (HIFU) is a popular treatment modality with the treatment goal of rejuvenating and tightening the skin [8]. Ultrasound energy penetrates the subcutaneous tissue to several millimeters in depth, producing thermal coagulation points that cause collagen fiber synthesis in the superficial muscular aponeurotic system and platysma [9]. A meta-analysis of the efficacy of HIFU for the face and neck showed moderate improvement in objective and subjective measurement scores [10]. However, despite the positive results of HIFU treatment for skin rejuvenation and face and neck tightening [8,11], its effectiveness on the eyelids has not yet been established. We hypothesized that HIFU may not only be a good treatment for tightening the mid and lower facial skin but also for tightening the eyelids. Here, we report the effectiveness of HIFU treatment for the eyelids and how we were able to safely treat this part of the eye.

MATERIALS AND METHODS

1. Patients

Twenty Korean women aged 30-60 years (Fitzpatrick skin type III and type IV) who complained of mild to moderate skin laxity of the eyelids were enrolled in the study. The exclusion criteria included active infection or skin diseases in the periocular area, pregnancy, history of keloidal scarring, and history of anti-aging procedures within 12 months prior to the study. All the patients provided informed consent at the time of enrollment.

2. Treatment Protocol

For each patient, a topical anesthetic cream (5% lido-

caine-prilocaine) was applied to the periocular area, including the upper and lower eyelids and crow's feet area, for 40 min before the procedure after their faces had been cleansed. One HIFU device (Ultraformer III, Classys Inc.) was used for treatment because of its 2.0-mm probe that was specially designed to treat the periocular area. The energy parameter for the treatment was set at 0.3 J. For every patient, 40 treatments shot were applied to the upper eyelids, lower eyelids, and crow's feet (20 shots on each side). Therefore, a patient received 120 shots in total. During the entire procedure, the probe was firmly positioned perpendicular to the skin surface with constant movement to ensure appropriate energy delivery into the tissue. Corneal protectors were applied to each patient's eyes to ensure safety.

3. Outcome evaluation

Participants were evaluated on the day of treatment and 12 weeks after treatment. Digital photographs were obtained under similar lighting conditions. Photographs of the frontal view of the face as well as of the face at an angle of 45° on each side were obtained. The photographs obtained before and after the 12 weeks treatment were assessed by two clinicians who were blinded, and they were asked to choose a post-treatment image to assess the overall improvement, tightening of sagging eyelids, and improvement of crow's feet using a 4-point scale ranging from 1 to 4 (1 = little or no improvement [$< 25\%$], 2 = mild improvement [26%-50%], 3 = moderate improvement [51%-75%], and 4 = marked improvement [76%-100%]). Each patient was also asked to rate their perception of the overall improvement in the periocular area, tightening of sagging eyelids, and improvement of crow's feet using the same scale. Any side effects or discomfort during treatment, after treatment, and at the follow-up visit were recorded.

In addition, to objectively assess improvements, a perpendicular line was drawn which passed through the midline between the medial and lateral canthus and measured the distance between the point at which the line met the eyebrow and the point at which the line met the upper rim of the eye. The average of the right and left side distances was calculated for each patient as the average lid length (ALL). ALL was calculated immediately before treatment and 12 weeks after treatment. After recording all the ALLs of the 20 participants, the mean ALL before and after the treatment was each calculated to determine the significant difference the two measurements.

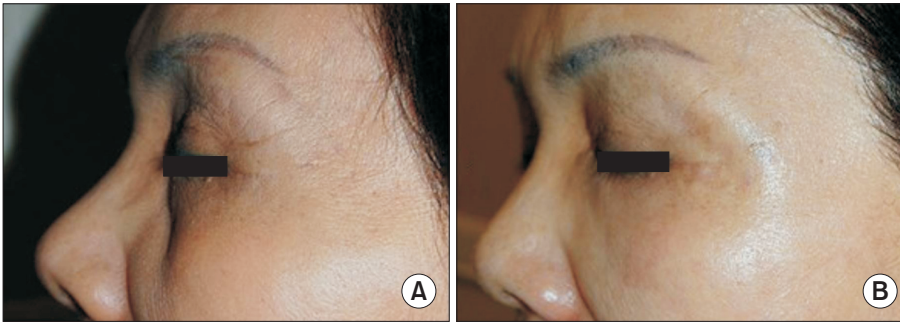


Fig. 1 . Lateral view of a patient before (A) and 12 weeks after treatment (B) showing crow's feet.

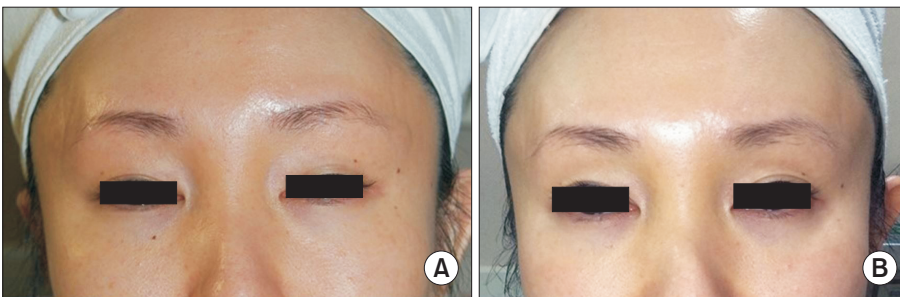


Fig. 2. Frontal view of a patient before (A) and 12 weeks after treatment (B).

RESULTS

All the 20 patients (all female) completed the treatment program and were available for the follow-up assessment after 12 weeks.

Their ages ranged from 35 to 57 years (mean: 46.00 ± 7.41 years); 15 patients had Fitzpatrick skin type III, and 5 had Fitzpatrick type IV.

Seventeen patients reported a degree of overall improvement in the periocular area 12 weeks after the treatment. Their average 4-point scale score for the overall improvement was 2.35 (mean: 2.35 ± 0.81). The average eyelid skin tightening score was 2.30 (mean: 2.30 ± 0.86). The average crow's feet score was 2.25 (mean: 2.25 ± 0.97). The mean VAS score was 4.45 ± 1.10 . Sixteen patients (80%) indicated that they would consider undergoing HIFU treatment again in the future.

When the clinicians compared the photographs obtained before and 12 weeks after treatment, they could choose appropriate post-treatment images in 15 cases (75%). They did not identify any difference between the photographs before and 12 weeks after the treatment in five cases, and none of the clinicians chose wrong post-treatment photos. Therefore, a score of 1 was assigned to each of the five cases. The clinicians rated the average score on the overall improvement, skin tightening of the eyelids, and improvement of crow's feet as 2.30 (mean: 2.30 ± 0.86), 2.15 (mean: 2.15 ± 0.81), and 2.16 (mean: 2.16 ± 0.93), respectively (Fig. 1).

After then it was assessed whether the ALL changed significantly 12 weeks after treatment ($p < 0.0001$). The mean

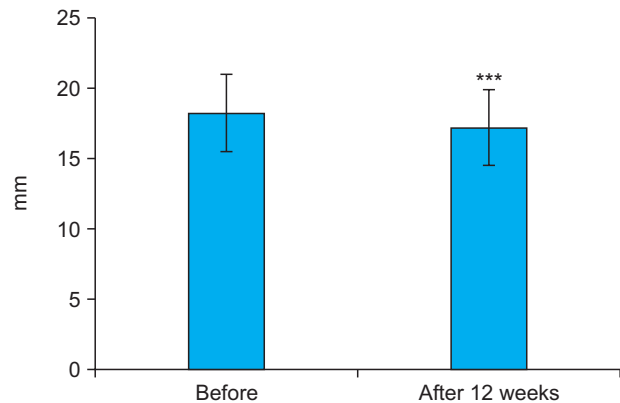


Fig. 3. The mean ALL before and 12 weeks after treatment (C). ALL: average lid length, which is the distance from the upper rim of the eye to the eyebrow along the midline between the medial and lateral canthus. ***Significant difference, $p < 0.0001$ vs before using paired t-test.

ALL decreased at 12 weeks post-treatment compared with that at baseline (Fig. 2). The mean ALL was 18.3 ± 2.75 mm immediately after treatment and was 17.2 ± 2.69 mm at week 12. The difference between the mean ALL at baseline and at 12 weeks after the treatment was 1.05 ± 0.94 mm (Fig. 3).

DISCUSSION

Various attempts have been made to treat eyelid sagging, which can lead to eyelid ptosis. Depending on the severity of the condition, surgical options such as Müller's muscle conjunctival resection, shortening of the levator

palpebrae, or brow/frontalis suspension are used [10,12]. However, these surgeries lead to common complications such as scarring, infection, bleeding, over- or under-correction, and reduced vision. Therefore, noninvasive procedures such as fractional lasers, intense pulse light, and radiofrequency treatment, which are designed to enhance collagen remodeling, have emerged [13,14]. Among the various noninvasive techniques, HIFU is a unique technique that can induce collagenesis by causing thermally induced collagen contraction and tissue coagulation without damaging the epidermis [15]. Many studies have reported favorable outcomes regarding the safety and efficacy of HIFU [16]. However, to the best of our knowledge, only a few studies have reported a positive effect of HIFU treatment on the perioral area [7,17]. Another study demonstrated that HIFU could be effective for eyebrow lifting [18] although their result was achieved by treating only the forehead. Moreover, no study has investigated whether HIFU treatment can safely tighten the eyelids through direct application on the eyelids.

Therefore, in this study, it was assessed the effect of HIFU treatment on the periocular area (around the eye) and were particularly interested in determining the tightening effect of HIFU on the eyelids. The results of this study showed that HIFU was effective for the overall rejuvenation of the periocular area. Both the patients and clinicians evaluated the average 4-point scale score for the overall improvement as higher than 2 (2.35 and 2.30, respectively), indicating that a mild-to-moderate level of improvement was achieved by HIFU treatment. Some tightening and improvement of crow's feet were also reported by both patients and clinicians. Although the ratings by the patients were slightly higher than those by the clinicians, the difference was not statistically significant.

After examined the changes in the mean ALL of the patients, authors observed a significant reduction after the treatment, implying that HIFU had a tightening effect on the sagging eyelids.

Several studies have explained the mechanism by which HIFU induces skin tightening. After some changes in living tissues caused by exposure to high-intensity and high-frequency sound waves were reported as early as 1928, the biological effect of high-intensity acoustic waves has been investigated with the development of ultrasound imaging techniques. When ultrasound waves propagate through tissues, a portion of the wave energy is converted into heat energy. The heat energy increases the temperature of the targeted tissue to 60°C, which results in coagulation necrosis. Therefore, HIFU was initially applied in clinical practice for the treatment of tumors such as uterine fibroids and prostate, breast, liver, and esophageal tumors. Ultrasound

waves cause thermal and mechanical effects [19]. In 2008, White et al. [20] first proposed the dermatological and aesthetic use of HIFU by examining cadaveric specimens after HIFU exposure. Histological analysis of the specimens after HIFU exposure showed marked collagen contraction at a given depth without affecting superficial thermal injury. After this observation, it was concluded that HIFU has significant potential effect on aesthetic facial rejuvenation [21], and subsequently, many commercially available HIFU devices have emerged in the market. Ultraformer is one of the noninvasive ultrasound device designed to remodel collagen and tighten and lift the face. A special feature of Ultraformer is its MF2 cartilage with a targeted depth of 2.0 mm and its slim design that allows clinicians to treat narrow and sensitive areas of the face such as the eyes and mouth. In this study, authors successfully treated all the participants with the Ultraformer HIFU device without significant complications.

One concern with HIFU treatment is that the improper use of the device may damage a patient's vision. However, the application of corneal protectors and the pulling up of the eyebrow by the clinician to avoid any contact of the device with the cornea during treatment can successfully prevent the above risks. Similarly, stretching the lower eyelids downward, which expands the wrinkles and separates the lower eyelids from the cornea, makes the procedure easier and safer. By adhering to these safety tips, none of the participants experienced extreme levels of pain, discomfort in the cornea, or loss of vision. The only notable side effects reported were mild pain and erythema that lasted for 3-4 days.

Finally, it is worthwhile to address several limitations of this study. First, as authors were not able to perform histological analysis, the investigation of cellular changes that occur due to HIFU treatment was limited. Second, the small sample size of this study might have limited the statistically significant results authors obtained. Third, Ultraformer is yet to be approved by the FDA and the only FDA-approved device, Ultherapy (Ulthera, Merz Inc.) was not used in this study. Investigating whether Ultherapy can reproduce results similar to those in this study can increase the reliability of our study.

CONCLUSION

HIFU treatment can be a feasible method to treat signs of aging in the periocular area, and it can tighten and lift the eyelids as well as improve crow's feet without causing serious complications.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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