Original Research

First Clinical Experiences with Microfocused Ultrasound in Infraorbital Rejuvenation: A Clinically and Scientifically Grounded Perspective

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ABSTRACT

Objectives & Hypotheses The infraorbital region is challenging to treat due to complex anatomy and issues like skin laxity, malar edema, and malar mounds. This study evaluates micro focused ultrasound with visualization (MFU-V) as a non-invasive treatment for infraorbital rejuvenation, hypothesizing improved skin tightening and contouring.

Study Design A case series with anatomical analysis and literature review.

Methods Five female patients (aged 42–54) with mild-to-moderate skin laxity underwent MFU-V treatment using 1.5, 3.0, and 4.5 mm transducers. Standardized photos and assessment scales (Merz Infraorbital Hollow Scale, GAIS) were used at baseline and 6 months.

Results MFU-V led to visible improvements in periorbital skin tightening and reduction of malar mounds, especially in more pronounced cases. No adverse effects occurred.

Conclusion MFU-V is a safe, effective, and non-invasive option for periorbital rejuvenation. It may serve as an alternative to surgical treatment for infraorbital skin laxity and malar deformities. Larger studies are needed to confirm efficacy.

Keywords malar mounds, facial rejuvenation, microfocused ultrasound

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Rejuvenation of the infraorbital region is a frequent reason for aesthetic consultations, driven either by aging-related soft-tissue changes or congenital predispositions that contribute to under-eye shadows or puffiness. In younger individuals, the transition between the infraorbital region and midcheek is smooth, but with aging, this boundary becomes more pronounced, leading to unwanted features such as tear troughs, palpebromalar grooves, and malar edema, mounds, or festoons[1,2] (**Table 1**). Some individuals are congenitally predisposed to these features, while others develop them over time due to factors such as skin and subcutaneous fat atrophy, displacement, repetitive muscle movements, and enlargement of the orbital bony space.[3,4] These changes can be exacerbated by external factors, including sun exposure and smoking.

The infraorbital region presents unique anatomical challenges due to its intricate structure, including septa, ligaments, fat compartments, muscles, vascularization, and lymphatic drainage.[5] Additionally, the thin, delicate skin in this area leaves little room for error during treatment. Hyaluronic acid (HA) fillers are commonly used to address hollows and grooves in the infraorbital region. For optimal results and to avoid visible material, fillers are typically placed deeply, directly on the periosteum below the orbicularis retaining ligament or in the preseptal fat deep to the orbicularis oculi muscle.[6] In patients with thin skin or for superficial indications such as dark shadows, fillers can also be placed in superficial planes, such as the superficial dermis or subcutaneous layer, using techniques like blanching to ensure seamless integration and natural outcomes.[7,8]

For patients with severe malar mounds or festoons, lower lid blepharoplasty is typically recommended.[9] However, complications from this surgical procedure may include undercorrection, where insufficient skin or fat is removed, or overcorrection, which can alter the lower eyelid contour, leading to eyelid retraction and increased scleral exposure. In both scenarios, additional surgery may be required to correct the lid–cheek junction.[10] Furthermore, surgical incisions and dissections may increase the risk of malar edema due to damage to the superficial lymphatic system in the infraorbital area.

While HA fillers and surgical techniques remain mainstays of treatment, several additional modalities have emerged as

Table 1 Definition of infraorbital defects

Term	Definition
Malar edema	Fluid that collects over the malar eminence, below the level of the infraorbital rim. It often varies in severity and can worsen after salty meals or in the morning.
Malar mound	Chronic soft tissue swelling or bulge over the malar eminence situated between the infraorbital rim and midcheek.
Malar festoon	Hammock of lax skin and orbicularis muscle that hangs between the medial and lateral canthi and may or may not contain herniated fat.

promising options for infraorbital rejuvenation. Radiofrequency microneedling combines controlled thermal energy with microneedling to stimulate collagen remodeling, improve skin laxity, and enhance texture without significant downtime.[11,12] Similarly, polynucleotide-based injectables offer a regenerative approach by enhancing hydration, fibroblast activity, and extracellular matrix integrity, improving fine lines and skin quality in the under-eye area.[13,14] Platelet-rich plasma, derived from autologous blood, promotes tissue regeneration and collagen production, effectively addressing pigmentation and skin texture irregularities.[15,16]

Other non-surgical approaches include laser resurfacing, which uses fractional or non-ablative lasers to target fine lines, pigmentation, and skin laxity by stimulating collagen synthesis.[17] Mesotherapy, involving microinjections of vitamins, enzymes, and HA, addresses puffiness and hydration, while thread lifting with biodegradable threads stimulates collagen production and provides a subtle lifting effect.[18,19] For patients seeking natural volume restoration, nano-fat grafting, which utilizes processed adipose-derived fat, can enhance skin quality and volume due to its rich stem cell content.[20] Emerging technologies like ultrasound-based devices (e.g., HIFU [high-intensity focused ultrasound], a medical treatment that uses focused ultrasound waves to heat targeted tissue or Ultherapy) use focused ultrasound energy to tighten deeper skin layers and stimulate collagen production.[21]

By integrating these innovative modalities with established treatments, practitioners can better address the complex anatomical and aesthetic challenges of the infraorbital region. A tailored approach that combines multiple techniques, depending on individual anatomical needs and aesthetic goals, offers the most effective path to achieving natural-looking, harmonious results.

Microfocused Ultrasound with Visualization

Given the complexities of the infraorbital region and the risks associated with surgical interventions, there is a growing demand for non-invasive methods to rejuvenate this area. One such method is microfocused ultrasound with visualization (MFU-V, Ultherapy, Merz, Frankfurt, Germany). MFU-V works by delivering precise ultrasound energy to targeted tissue layers beneath the skin. This energy is focused on creating thermal coagulation points (TCPs) at predetermined depths, typically 1.5, 3.0, and 4.5 mm, depending on the treatment area and desired results. At each TCP, the ultrasound energy raises the temperature to approximately 60 to 70 °C, inducing localized thermal injury without causing necrosis. This controlled heat causes immediate collagen denaturation while initiating a natural wound-healing response, which leads to the production of new collagen and elastin over time. This process, known as neocollagenesis, results in skin tightening and lifting without damaging the surface of the skin.[22,23]

Ultherapy is unique in its ability to visualize the underlying tissue using ultrasound imaging, ensuring accurate targeting of the deep layers of the skin, including the superficial muscular aponeurotic system, which is typically addressed in surgical facelifts. Studies have demonstrated that this treatment can produce significant improvements in skin laxity, with minimal downtime and a strong safety profile.[24,25] Ultherapy MFU-V has received FDA approval for non-invasive treatments in specific areas: Eyebrow lifting (2009), tightening of skin on the neck and under the chin (2012), and improving lines and wrinkles on the décolletage (2014). This treatment has since demonstrated skin-tightening and collagen-stimulating properties in various aesthetic indications. It has also been evaluated in three studies for off-label treatment of periorbital skin laxity.[26–28] To address the need for a non-invasive alternative to surgical treatments for the infraorbital area, this study outlines the application of MFU-V in patients with a range of under-eye conditions, including skin laxity and severe malar mounds. These patient profiles have not been widely explored in previous MFU-V studies but may benefit from its skin-tightening and tissue-lifting effects. This paper also discusses potential mechanisms underlying the observed treatment outcomes and aims to provide a reproducible protocol for clinicians.

Anatomical Overview of the Infraorbital Region

The infraorbital region is a complex anatomical area, bordered by the medial canthus medially, the lateral canthus laterally, and the inferior border of the orbicularis oculi muscle (**Fig. 1**).[29] This region is particularly challenging to treat due to its delicate structure and susceptibility to various anomalies that lead to aesthetic concerns, such as malar bulges or bags. These anomalies include malar edema, malar mounds, and malar festoons, which are often interconnected but can be distinguished by their underlying pathophysiological mechanisms.

Malar edema refers to the accumulation of fluid over the malar eminence, typically caused by compromised lymphatic drainage in the superficial suborbicularis oculi fat (SOOF). This compartment is separated from the deeper fat compartments by the malar septum, an impermeable fascial structure that influences fluid dynamics in the region. Malar edema may occur due to systemic conditions such as cardiac, renal, or hepatic insufficiency, hypothyroidism, allergies, or cosmetic interventions such as surgical procedures or periorbital injections.[29] When fillers or injectables are placed superficial to the malar septum, they can further block lymphatic drainage, exacerbating fluid retention and leading to the development of malar edema.[30] Additionally, some individuals may have congenital abnormalities that predispose them to lymphatic drainage issues in the infraorbital region. **Malar**

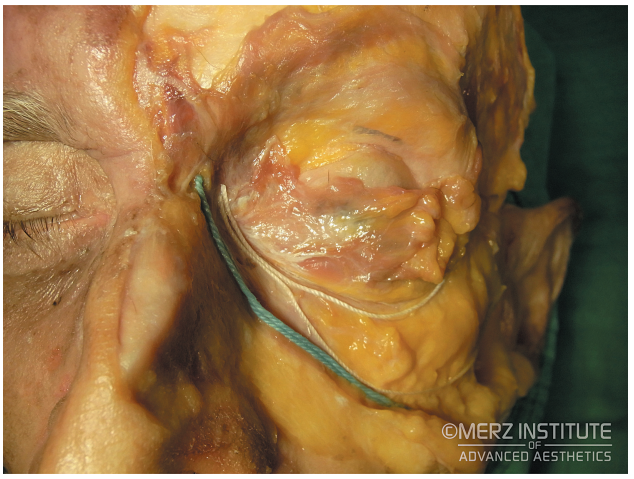

Fig. 1 Artwork depiction of the prezygomatic space bordered superiorly by the orbicularis retaining ligament and inferiorly by the malar septum and zygomaticocutaneous ligament. The malar septum courses inferiorly to a point just distal to the inferior border of the orbicularis. Sagittal section of the prezygomatic space. Reproduced with permission from artist Warren Noel, MD (plastic surgeon, Paris, France). SOOF, suborbicularis fat.

mounds, by contrast, are chronic swellings that occur between the infraorbital rim and the zygomaticocutaneous ligament.[1] These mounds consist of either displaced fat or hypertrophied orbicularis oculi muscle. Like malar edema, malar mounds can be congenital or develop over time due to changes in soft tissue structures. The descent or bulging of fat or muscle in this area creates a visible, permanent soft-tissue protrusion that can significantly impact the aesthetic appearance of the infraorbital region.[31] **Malar festoons** are acquired features typically associated with aging and represent an advanced stage of the anatomical changes seen in the infraorbital region. They appear as hammocks of lax skin and orbicularis oculi muscle hanging between the medial and lateral canthi, and they may or may not contain herniated fat. Malar festoons are more commonly seen in older individuals and are often considered a progression of both malar edema and malar mounds.[1]

The condition is exacerbated by age-related tissue laxity, contributing to the accumulation of fluid and the downward displacement of soft tissue. A key structure in the development of these infraorbital anomalies is the **malar septum**, which defines the inferior boundary where festoons typically form. This thin, impermeable membrane extends from the inferior orbital rim to the cheek skin, traversing the SOOF and the orbicularis oculi muscle. The malar septum's interaction with surrounding fibrous septa creates a relatively impermeable barrier, trapping tissue edema above its insertion in the midcheek dermis.[32] This unique fascial structure plays a central role in the accumulation of fluid and the structural changes that contribute to the formation of malar bulges, complicating both the natural aging process and the outcomes of aesthetic treatments in this region.[30]

Understanding the intricate anatomy of the infraorbital region, particularly the role of the malar septum, lymphatic drainage, and fat compartmentalization, is critical for devising effective rejuvenation strategies. The complexity of this area underlines the need for precision in treatment approaches, particularly with non-invasive methods like MFU-V, which can target deep tissue layers without disrupting the delicate surface anatomy.

Literature Review on Ultherapy (Microfocused Ultrasound with Visualization) Results

Search Strategy

To identify the available evidence on the efficacy of Ultherapy, we conducted an in-depth literature review utilizing the databases PubMed and Google Scholar. Anticipating that authors might use a variety of synonyms to express similar concepts, we selected a range of search terms for "Ultherapy" and combined them using Boolean operators. The complete search string is presented in **Table 2**.

Inclusion and Exclusion Criteria

The selection of literature was based on the year of publication, restricting to studies published from 2010 onwards. Given the rapid advancements in microfocused ultrasound technology, articles older than 10 years were deemed potentially outdated. Additionally, only peer-reviewed papers were included to ensure the quality and reliability of the findings. The articles were also required to be written in English to enhance accessibility. This strategy allowed for the comprehensive collection of relevant studies, facilitating a thorough analysis of Ultherapy's effects.

We included journal articles, encompassing case studies, reviews, qualitative and quantitative studies, clinical trials, and cohort studies. Articles were excluded if they addressed the use of microfocused ultrasound for purposes other than skin tightening or anatomical regions outside the facial area. Conversely, studies were included if they examined the use of microfocused ultrasound specifically for skin tightening within the facial region, including areas such as the infraorbital zone. Duplicate entries were excluded. The search terms were applied specifically within the Title and Abstract fields.

MFU-V, particularly under the brand name Ultherapy, has been extensively studied for its ability to non-invasively tighten skin and stimulate collagen production (**Table 3**). It works by delivering targeted ultrasound energy to specific tissue depths, causing controlled thermal damage that promotes tissue contraction

Table 2 Search strings

Academic database	Search string
PubMed	"Ulthera" [Title/Abstract] OR "Ultherapy" [Title/Abstract] OR "Intense-focused ultrasound" [Title/Abstract] OR "Microfocused ultrasound" [Title/Abstract] OR "Ultrasound" [Title/Abstract] AND "skin" [Title/Abstract]
Google Scholar	Intitle:"Ultraskin" OR intitle:"Ultherapy" OR" intitle: Ulthera" OR intitle:" Intense-focused ultrasound" OR intitle:"Ultrasound" AND intitle:"skin"

Table 3 Summary of studies/case reports of the use of microfocused ultrasound with visualization for facial skin therapy (based on reviews of Juhász et. al in 2018[52] and Wulkan et. al in 2016[53])

Study	Patients	Results	Area of treatment
Pak et al. (2014)[27]	7 patients; 25–50 years	Significant ($p < 0.0001$) reduction in the protrusion of orbital septum and flattening of skin surface	Infraorbital
Suh et al. (2012)[28]	15 Asian patients; 27–69 years	Objective: 86.66% improvement at 6 months; Subjective: 100% improvement at 6 months	Infraorbital
Alam et al. (2010)[33]	35 patients; 32–62 years	Significant ($p < 0.00001$) eyebrow lift at 90 days, average change in height: 1.7 mm.	Face and neck
Lee et al. (2012)[40]	10 female patients; 55–71 years	80% clinical improvement at 90 days; 80% subjective improvement	Lower face and neck
Fabi and Goldman (2014)[22]	45 patients 25–85 years	66.7% objective improvement at 180 days; 80% subjective improvement	Face and neck
Jung et al. (2016)[38]	20 patients 45–70 years	65% of patients reported similar efficacy between Ulthera and Ultra-Skin; 30% preferred Ulthera	Face
Suh et al. (2016)[45]	28 patients 29–74 years	42.9% of patients greatly satisfied at 3 months; 32.1% improvement confirmed by dermatologists	Face
Park et al. (2015)[44]	20 patients 37–75 years	Patients and physicians observed improvement at 3 months, with decline over time	Face
Oni et al. (2014)[43]	103 patients 35–60 years	65.6% patient-reported improvement; 58.1% reviewer-reported improvement at 90 days	Lower face
Suh et al. (2015)[23]	11 Asian patients 35–64 years	63.3% subjective improvement; 72.7% objective improvement at 2 months	Face
Pavicic et al. (2022)[25]	Review	Ulthera provides imaging capability; no significant temperature increases.	Review
Kerscher et al. (2019)[39]	22 patients 30–65 years	Significant ($p < 0.05$) increase in skin elasticity at 12 and 24 weeks; significant decrease in skin hydration.	Lower face + submental
Montes and Santos (2019)[42]	52 patients	41% satisfaction at 6 months	Lower face
Lowe (2021)[41]	9 patients 38–64 years	Objective improvement in all periorbital lines; 180 days posttreatment results	Periorbital and perioral
Bukhari et al. (2024)[34]	98 patients 35–60 years	Two-thirds of patients satisfied with treatment; significant ($p = 0.006$) higher satisfaction for periorbital region	Submental and periorbital
Chang et al. (2019)[35]	83 patients mean age 50.2 years	80% of patients noticed improvement; 53.1% reported satisfaction 4 months posttreatment	Face
Friedman et al. (2020)[37]	43 patients 24–80 years	51.2% evaluated as responders by physicians at 90 days; 47.1% patient-reported responsiveness	Lower face and neck
Chaves Bellote and Miot (2021)[36]	4 patients 29–36 years	Three-fourth of patients reported improvement 180 days posttreatment	Face
Koza et al. (2024)[2]	17 patients mean age 49 years	60–70% improvement in periorbital wrinkles at 1 and 3 months; less pain with Ulthera versus photothermolysis	Periorbital

and neocollagenesis. Subsequent studies have demonstrated its efficacy in treating skin laxity in various areas, including the face, neck, and, more recently, the infraorbital region.[2,22,23,31,33–43]

Efficacy in Skin Tightening and Collagen Stimulation

Several studies have shown that MFU-V is effective in improving skin laxity, enhancing skin texture, and reducing fine lines and wrinkles. For example, in a pivotal clinical trial by Pak et al. (2014),[27] MFU-V treatments of the infraorbital region were performed in seven patients aged 25 to 50. The primary objective was to evaluate changes in the lower eyelids using CT imaging. A baseline was established by drawing a line between the most inferior point of the supraorbital rim and the most superior point of the infraorbital rim. The distance from this baseline to the most protruding point of the orbital septum was measured. Changes in this distance before and after treatment were compared. Similarly, the distance from the baseline to the most protruding point of the skin was assessed. The treatment led to significant improvements in both the reduction of orbital septum protrusion and the flattening of the skin surface of the

lower eyelids, with results reaching high statistical significance ($p < 0.0001$). Furthermore, Suh et al. (2012) treated 15 Asian patients with infraorbital skin laxity. All patients were monitored for 6 months posttreatment. Standardized front and side-view photographs were taken at baseline and 6 months. Two blinded, non-treating physicians evaluated these photographs to assess clinical improvement in infraorbital laxity. Using a quartile grading scale (0 = worse, 1 = no change, 2 = improved, 3 = much improved), the blinded dermatologists and patients provided separate assessments of the outcomes. The average assessment scores were calculated and recorded. Scientists observed 86.66% objective improvement 6 months posttreatment along with 100% subjective improvement reported by the patients.[28] MFU-V has also shown notable results in broader facial rejuvenation studies. Alam et al. (2010) demonstrated significant eyebrow lifting in 35 patients, with an average eyebrow height increase of 1.7 mm observed 90 days after treatment. To determine eyebrow height, a standardized technique with fixed landmarks was used. Therefore, standardized photographs were taken of each patient. In 0-degree views of each eye, five measurements (in millimeters) were taken along a horizontal line connecting the medial canthi to the top edge of the eyebrow.[33] Additionally, Lee et al. (2012) investigated the long-term efficacy of MFU-V. Two blinded clinicians evaluated randomized pretreatment and posttreatment photographs of 10 subjects to assess clinical improvement. Each reviewer identified the posttreatment image or noted no difference, with assessments categorized as improvement, no change, or detriment based on agreement between reviewers. Images showing improvement were reevaluated and scored for skin laxity improvement as mild, moderate, or significant. Results showed that 80% (8 of 10 subjects) demonstrated clinical improvement in skin tightening 90 days posttreatment, confirming the long-term efficacy of MFU-V.[40] In a study by Fabi and Goldman (2014), 45 patients who underwent facial and neck treatments were examined. The primary efficacy measure was overall improvement in skin laxity (lifting, tightening, and texture) in areas treated with MFU-V, assessed by three blinded reviewers using randomized digital images taken before and 180 days after treatment. Reviewers determined improvement levels using a qualitative scale ranging from slight (1–25%) to excellent (76–100%). Secondary measures included the Physician Global Aesthetic Improvement Scale, which compared live assessments with pretreatment images, the Subject Global Aesthetic Improvement Scale, and patient satisfaction and lifestyle questionnaires. Patients showed 66.7% objective improvement at 180 days posttreatment and 80% subjective improvement.[22]

Ultherapy in Periorbital Rejuvenation

Specific studies addressing periorbital rejuvenation are more limited but promising. Park et al. (2015) examined the use of MFU-V for treating wrinkles and skin laxity in the periorbital region, noting significant improvement in six cases of periorbital lines, which persisted up to 180 days posttreatment.[44] Koza et al. (2024) further explored the efficacy of Ultherapy compared to fractional photothermolysis for treating periorbital wrinkles.[2] Both treatments produced similar outcomes in terms of wrinkle reduction, but patients rated Ultherapy as significantly less painful.

However, most of these studies have focused on moderate skin laxity and wrinkle reduction rather than the more severe manifestations such as malar mounds and festoons. This gap highlights the need for further investigation into the potential benefits of MFU-V for treating more pronounced infraorbital anomalies, which are often considered surgical cases.

Safety and Patient Satisfaction

MFU-V has consistently demonstrated a strong safety profile with minimal complications. Studies report high patient satisfaction rates, with relatively low pain levels compared to other energy-based devices. For instance, in the study by Suh et al. (2016), 42.9% of patients reported being greatly satisfied 3 months after treatment, and histological analysis showed increased and thickened collagen in the reticular dermis, supporting the long-term effects of collagen stimulation.[45] Additionally, Kerscher et al. (2019) confirmed the physiological safety of MFU-V, noting increased skin elasticity without significant adverse events.[39]

Gaps in the Literature and the Contribution of the Present Publication

MFU-V has been well-established as a safe and effective method for treating skin laxity and promoting collagen production in various facial regions. However, only a few studies specifically address the treatment of severe infraorbital anomalies, such as malar mounds and festoons, using MFU-V. These conditions, which are more challenging due to their anatomical complexity, have traditionally been managed through surgical means. The lack of extensive research on non-invasive alternatives for these severe cases suggests a significant gap in the literature. This study seeks to address this gap by evaluating the use of MFU-V in patients with more advanced infraorbital concerns, particularly malar mounds, thereby contributing new insights into its broader clinical applications.

Methods

This first-experiences paper describes the application of MFU-V in five patients with a range of periorbital concerns, including skin laxity, malar edema, and brow ptosis. The technique employed aims to provide a non-invasive alternative to traditional surgical approaches for the rejuvenation of the infraorbital region. Each patient received a single MFU-V treatment session, and the procedures were tailored to the individual anatomical characteristics and severity of the presenting conditions. Pain relief for all patients consisted of a combination of topical 10.5% lidocaine cream, oral 500 mg metamizole (Novalgin), and oral 500 mg paracetamol. Treatments were carefully restricted to areas outside the orbital rim.

The efficacy of the treatment was assessed using both objective and subjective measures. All patients were monitored for 6 months posttreatment. Standardized front and side-view photographs were taken at baseline and 6 months. For objective evaluation, the Merz

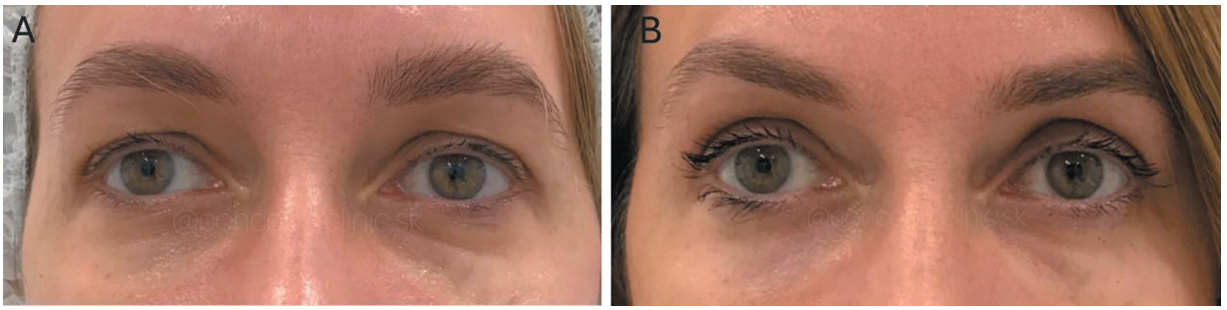

Fig. 2 Case 1: A 42-year-old woman before (**A**) and 2.5 months after MFU-V treatment (**B**) to the brow and periorbital area. MFU-V, microfocused ultrasound with visualization.

Infraorbital Hollow Assessment Scale was employed. The Merz Infraorbital Hollow Assessment Scale is a validated and globally accepted tool for proper assessment of the infraorbital hollow.[46] A blinded clinician, who was not an author of the study, performed the assessment. The clinician assigned scores ranging from 0 (no visible wrinkles) to 4 (very severe wrinkles) based on the appearance of facial wrinkles at baseline and follow-up visits.

For both objective and subjective outcomes, the Global Aesthetic Improvement Scale (GAIS) was used.[47] The GAIS was rated by the same blinded clinician to assess clinical improvement in skin appearance. This clinician evaluated changes in facial aesthetics on a scale from 1 (very much improved) to 5 (worse). Additionally, patients were asked to rate their own perceived improvement using the GAIS 6 months posttreatment, providing subjective feedback on their satisfaction with the treatment outcomes. This dual assessment allowed for a comprehensive evaluation of both clinical and patient-reported results.

Case 1

A 42-year-old female was treated with MFU-V for a brow lift and periorbital rejuvenation in February 2021. She had no prior history of malar edema but had received botulinum toxin treatment around the eyes 2.5 months prior to MFU-V. Her treatment involved the use of both 7 MHz/3.0-mm and 7 MHz/1.5-mm transducers. For the 7.0/3.0-mm transducer, 30 passes were applied in three columns from the eyebrow to the hairline between the mediopupillary line and the lateral canthus (10 passes per column). The periorbital region was treated with the 7.0/1.5-mm transducer, delivering 15 passes around the eye from the mediopupillary line to the zygomatic arch. Results from her 2.5-month follow-up visit showed considerable improvement (**Fig. 2**).

Case 2

A 47-year-old female with mild skin laxity, identified via a positive pinch test, received MFU-V treatment in November 2018. She had no history of prior aesthetic treatments and exhibited no signs of malar edema or mounds. A single session with the 7.0 MHz/3.0-mm transducer was administered with 50 passes around each eye, extending from the mediopupillary line to the lateral canthus and across the lower eyelid. Follow-up visits occurred at 3 and 6 months, with results at 11 months demonstrating sustained improvement (**Fig. 3**).

Case 3

A 49-year-old female with bilateral blepharochalasis, slight left brow ptosis, and mild skin laxity, indicated by a positive pinch test, underwent MFU-V treatment in June 2019. She had no prior aesthetic treatments and no malar edema. The left upper eye was treated with the 7.0/3.0-mm transducer using 40 passes, while the right eye received 35 passes. Both eyes were treated in four columns from the brow to the hairline. The 7.0/1.5-mm transducer was used to treat the periorbital region with 15 passes from the mid-pupillary line to the zygomatic arch. Results from the 8-month follow-up showed evident improvement (**Fig. 4**).

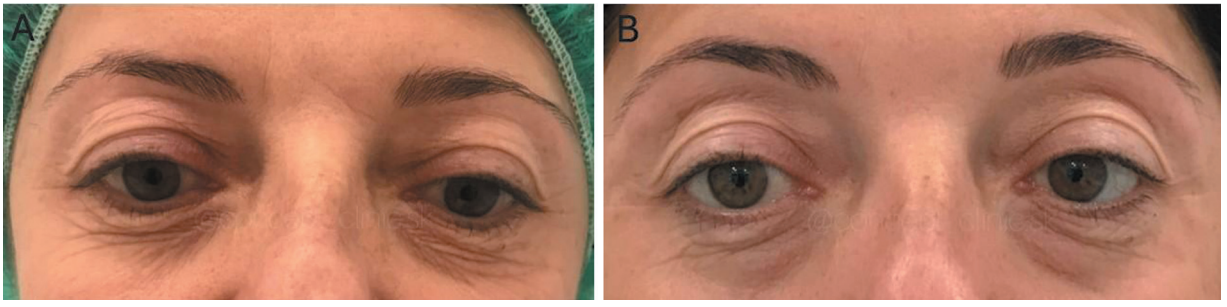

Fig. 3 Case 2: A 47-year-old woman showing the periorbital area before (**A**) and 11 months after MFU-V treatment (**B**). This patient was also treated for the infraorbital area. MFU-V, microfocused ultrasound with visualization.

Fig. 4 Case 3: A 49-year-old woman showing the periorbital area before (**A, B**) and 8 months after MFU-V treatment (**C, D**). MFU-V, microfocused ultrasound with visualization.

Case 4

A 46-year-old female, with a history of congenital malar edema that worsened in the mornings and improved throughout the day, received MFU-V treatment. She had no skin laxity and no previous aesthetic treatments. Her treatment involved both the 7.0/3.0-mm and 7.0/1.5-mm transducers, with 50 passes using the 7.0/3.0-mm transducer and 30 passes with the 7.0/1.5-mm transducer, applied to the area around the eyes from the mediopupillary line to the lateral canthus and the lower eyelid. At the 4-month follow-up, considerable improvement in the malar edema was observed (**Fig. 5**).

Case 5

A 54-year-old female with mild skin laxity, identified by a positive pinch test, but no malar edema, was treated with MFU-V. She had no prior aesthetic treatments. The procedure used both 7.0/3.0-mm and 7.0/1.5-mm transducers. The 7.0/3.0-mm transducer delivered 30 passes from the eyebrow to the hairline in three columns between the mediopupillary line and the lateral canthus (10 passes per column). The 7.0/1.5-mm transducer was used to treat the periorbital region with 15 passes from the mediopupillary line to the zygomatic arch. Results from her 7-month follow-up showed sustained improvement in periorbital skin tightening (**Fig. 6**).

Results

Safety and Tolerability

Across all cases, MFU-V was well-tolerated, and none of the patients reported adverse events.

Efficacy of Treatment

All patients showed a reduction in malar mound hollowness in the Merz Scale; in two patients, there was no hollowness at all at 6 months after treatment. Evaluation of the objective GAIS showed an improvement in facial aesthetics in all patients. Each patient experienced noticeable improvement in the periorbital region, including visible skin tightening and reduced skin laxity, with some reporting improvements in malar mounds or edema measured via subjective GAIS. The specific values for the Merz Score and the GAIS can be found in **Table 4**. All patients expressed satisfaction with the treatment results and either returned or were scheduled to return for repeat treatments in other facial areas.

Discussion

This study on the first clinical experiences demonstrated the potential of MFU-V for treating various periorbital concerns, including brow height, skin laxity, palpebromalar grooves, and malar mounds. Notably, visible improvements were observed after a single treatment session, with no other aesthetic procedures performed during or after the treatment. Pain management was effective, utilizing topical anesthetics and oral analgesics, and no adverse events were reported during follow-up. This aligns with other small-scale studies that have confirmed the safety profile of MFU-V in periorbital treatments.[26–28]

The anatomical complexity and thin skin in the infraorbital region make it a challenging area to treat for both aesthetic practitioners and plastic surgeons. Despite this, it is one of the most frequently requested areas for rejuvenation.[48] While botulinum toxin and HA fillers are effective in treating wrinkles,

Fig. 5 Case 4: A 46-year-old woman showing the periorbital area before (**A**) and 4 months after MFU-V treatment (**B**). MFU-V, microfocused ultrasound with visualization.

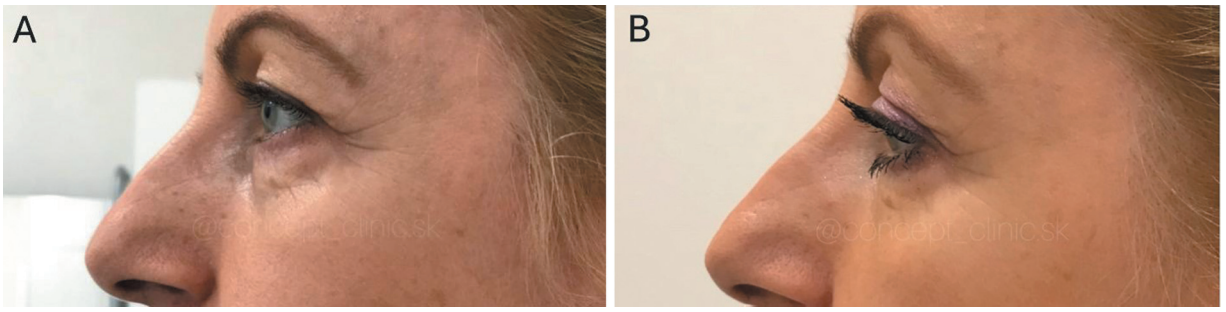

Fig. 6 Case 5: A 54-year-old woman showing the periorbital area before (**A**) and 7 months after MFU-V treatment (**B**). MFU-V, microfocused ultrasound with visualization.

addressing more complex issues such as fluid accumulation, excess tissue, and malar mounds is less straightforward. Surgical approaches, such as blepharoplasty with lipectomy, can be effective but come with a higher risk of complications, prolonged downtime, and inconsistent results.[1,29,31] Moreover, recurrence of these issues after surgery is not uncommon. As a result, there is no consensus on the optimal treatment approach, particularly for severe anomalies such as malar mounds and festoons.

MFU-V works by promoting neocollagenesis and elastogenesis, leading to improvements in skin tightness and tone.[24] Although its use in the periorbital region is currently off-label, studies have demonstrated its effectiveness in tightening the thin skin of the lower eyelid and targeting deeper structures like the orbicularis oculi muscle and orbital septum.[26–28,49] Studies in Asian patients have reported that the 1.5-mm MFU-V transducer is effective for tightening the thin skin of the lower eyelid,[27,49] while the 3-mm MFU-V transducer targets the orbicularis oculi muscle and the orbital septum.[27,28,49] Tightening of these structures was associated with improvements in the appearance of malar mounds and the contour of the lid–cheek junction. This was demonstrated subjectively based on the results of physician assessment and patient satisfaction questionnaires,[27,28] and objectively via measurements of the degree of malar mound protrusion on pre- and post-MFU-V CT images.[27] In studies that have performed pre- and posttreatment biopsies, histological analysis confirmed regenerated and increased collagen and elastin fibers in the reticular dermis.[28] The 3.0-mm transducer may also improve the appearance of malar mounds by condensing excess fat.

Case 4 showed that dual-depth MFU-V treatment was particularly effective in the patient with severe malar mounds. It is hypothesized that MFU-V tightens the suborbicularis oculi muscle and septum as well as the overlying skin, with the reduced tissue space limiting the area of lymphedema. The patients with less severe presentations (Cases 1, 3, and 5) received no under-eye treatment. In these cases, superficial skin-tightening treatment of the lateral periorbital area (from the mediopupillary line to the zygomatic arch) with the 1.5-mm transducer alone was sufficient to improve the patient's periorbital appearance.

Follow-up visits ranged from 2.5 to 11 months. While earlier follow-up times capture the initial effects of MFU-V, it is important to note that the full benefits of the treatment—driven by physiologic neocollagenesis—may take up to a year or more to manifest.[50] Previous studies evaluating MFU-V for periorbital rejuvenation assessed efficacy between 3 to 6 months posttreatment.[27,28] However, MFU-V has demonstrated efficacy in other facial areas for up to a year.[51]

While the current treatments focus on MFU-V as a standalone treatment, some studies suggest that a combination approach may further optimize periorbital rejuvenation. For example, a small case series that used MFU-V followed by the injection of cohesive polydensified matrix HA gel 3 months later

Table 4 Results of Merz Infraorbital Hollow Assessment scale (score range: 0 = no hollowness, 1 = mild hollowness, 2 = moderate hollowness, 3 = severe hollowness, 4 = very severe hollowness) and objective and subjective GAIS (score range: 1 = very much improved, 2 = marked improvement, 3 = improved, 4 = no change, 5 = worse)

Patient ID	Merz Infraorbital Hollow Assessment Scale at baseline (score 0–4)	Merz Infraorbital Hollow Assessment Scale 6 months posttreatment (score 0–4)	Global Aesthetic Improvement Scale reported by clinician (score 1–5)	Global Aesthetic Improvement Scale reported by patient (score 1–5)
Patient 1	2	0	3	2
Patient 2	4	3	2	1
Patient 3	2	0	3	3
Patient 4	4	2	1	1
Patient 5	3	2	3	2

Abbreviation: GAIS, Global Aesthetic Improvement Scale.

demonstrated even greater improvements in periocular skin laxity and tear trough appearance.[26] Both patients and physicians in this study reported high levels of satisfaction with the combined approach, suggesting that MFU-V can be effectively integrated with other treatments.

The five cases treated highlight the significant potential of MFU-V in treating a variety of periorbital indications, particularly in younger patients (aged 42–54) with minimal prior aesthetic treatments. Similar patient characteristics were noted in the study by Pak et al.,[27] where younger, treatment-naive patients also responded well to MFU-V for lower eyelid rejuvenation. However, further research is warranted to determine whether certain factors—such as age, skin type, gender, and the severity of the condition—affect treatment outcomes. Larger, controlled studies are necessary to validate these initial findings and define the optimal patient profile for MFU-V in treating infraorbital skin laxity and malar mounds.

Limitations

This study presents promising findings on the application of MFU-V for infraorbital rejuvenation; however, several limitations should be considered when interpreting the results. Firstly, the study sample was limited to five female patients aged between 42 and 54, which introduces potential selection bias and limits the generalizability of the findings to other demographics, such as males or individuals outside this age range. Secondly, the small sample size restricts the statistical power of the study and precludes definitive conclusions about the efficacy and safety of MFU-V for broader clinical populations.

Additionally, variation in follow-up intervals among participants poses a challenge in assessing the consistency and longevity of the treatment outcomes. Standardized and extended follow-up periods would provide more robust data on the long-term effects of MFU-V. Furthermore, the study's external validity is limited by the absence of a control group or comparative treatments, such as other non-invasive methods or surgical approaches, which could provide a clearer benchmark for evaluating the relative benefits of MFU-V.

These limitations highlight the need for larger, controlled studies with more diverse populations and standardized methodologies to validate and expand upon these preliminary findings. Despite these constraints, the study offers valuable insights and establishes a foundation for future research into non-invasive rejuvenation techniques for the infraorbital region.

Conclusion

MFU-V offers a non-invasive and well-tolerated option for rejuvenating the periorbital area, one of the most challenging regions of the face to treat. A single treatment session resulted in notable improvements in skin laxity and was particularly effective in reducing the appearance of severe malar mounds. These findings underscore the potential of MFU-V as a safe and effective alternative to surgical procedures, with minimal downtime and a favorable safety profile. Further research is needed to determine the long-term efficacy of MFU-V and its role in a combined treatment approach for optimal periorbital rejuvenation.

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Statements and Additional Information

Conflict of Interest A.S. is a consultant for Merz Aesthetics and declares no other financial disclosures related to this article. All other authors declare no conflicts of interest.

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Informed Consent All patients provided written informed consent.

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