A face appears “aged” when it has undergone loss of volume, surface changes, reduced elasticity, and increased skin laxity. The goal of antiaging therapies is to create a more youthful, rejuvenated appearance through lifting, tightening, and excising redundant tissues in the face and neck. Therapies that address the lower half of the face, which bears the brunt of gravitational forces, can improve outcomes. Although rhytidectomy remains the gold standard for consistent long-term results in facial rejuvenation, many patients have sought alternatives to this procedure.

Abstract
Background: The Ulthera System (Ulthera, Inc, Mesa, Arizona) employs microfocused ultrasound to cause discrete focal heating of the dermis and stimulate neocollagenesis and elastin remodeling.
Objectives: The authors investigated tightening and lifting of cheek tissue, improvement in jawline definition, and reduction in submental skin laxity in patients treated with the Ulthera System.
Methods: A total of 103 adults were enrolled in this prospective nonrandomized clinical trial. Three-dimensional photographs obtained at baseline and 3 months posttreatment were assessed qualitatively by 3 blinded reviewers and quantitatively with AutoCAD software (Informer Technologies, Redwood City, California). The relationship between outcomes and body mass index (BMI) was examined as well. Patients rated pain during the procedure and provided subjective assessment of their outcome at 90 days. Adverse events were documented.
Results: Ninety-three patients were evaluated. Blinded reviewers observed improvement in skin laxity in 58.1% of patients. During quantitative assessments, overall improvement in skin laxity was noted in 63.6% of evaluated patients. No change was detected in 54.5% of patients whose BMI exceeded 30 kg/m² or in 12.2% of patients whose BMI was ≤30 kg/m². At day 90, 65.6% of patients perceived improvement in the skin laxity of the lower half of their face/neck. The average procedural pain scores for the cheek, submental, and submandibular regions were 5.68, 6.09, and 6.53, respectively. Wheals, which resolved without intervention or long-term sequelae, were reported for 3 patients.
Conclusions: To the authors’ knowledge, this is the largest clinical study of the effectiveness of the Ulthera System for rejuvenation of the lower face. At day 90, improvements were reported by two-thirds of patients and by nearly 60% of blinded reviewers. Outcomes were better in patients with BMI ≤30 kg/m².

Level of Evidence: 2

Keywords
microfocused ultrasound, nonsurgical skin rejuvenation, facial rejuvenation, Ulthera

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because of the associated recovery times, morbidity rates, financial implications, and/or concerns about surgery in general. Chemical peels, injectables, and light-based and laser (ablative and nonablative) therapies are the main nonsurgical options for facial rejuvenation; however, these treatments are not effective for lifting or tightening tissue. Moreover, their clinical outcomes are variable and their side effect profiles have not proven superior to those of surgical facelifts.1-4

Another nonsurgical alternative for facial rejuvenation is high-intensity focused ultrasound (HIFU) therapy, a common treatment for solid malignant and benign tumors.5,6 The HIFU devices heat tissue with acoustic energy in a focused, controlled manner. The thermal injury within the tissue leads to focal necrosis and cellular damage, initiating an inflammatory cascade that culminates in tissue remodeling, similar to changes that occur after ablative or nonablative laser treatments.7-9 Ultrasonic energy not only penetrates deeper into the tissue, causing thermal coagulation, but also avoids the adverse posttreatment effects of more superficial treatments. These HIFU characteristics have piqued interest in its application for rejuvenating facial skin and deep tissue.

The Ulthera System (Ulthera, Inc, Mesa, Arizona) integrates microfocused ultrasound (MFU) therapy with high-resolution ultrasound imaging to deliver energy to precise depths (up to 5 mm) within dermal layers of the skin and superficial musculoaponeurotic system (SMAS), while sparing the epidermal layers (Figure 1). In previous clinical trials, the noninvasive system was shown to be a safe and effective method of improving skin laxity through subdermal tissue coagulation and tightening.10,11 The Ulthera System works by potentiating thermally induced contraction of tissue and a “wound-healing” response that stimulates the formation of new tissue as well as collagen and elastin remodeling.12 The heat is confined to small focal regions within the dermis, sparing the overlying epidermis and intervening tissue. The system is similar to a fractional ablative laser, in that thermally injured areas are bridged by undamaged skin.13

The goal of this study was to investigate the clinical effectiveness of the Ulthera System (an MFU device) for tightening and lifting cheek tissue, improving jawline definition, and reducing submental skin laxity. As part of this study, a mathematical method was applied to calculate neck and submental lift, which has been accepted by the US Food and Drug Administration (FDA, reference K121700).

METHODS

Institutional review board approval was granted by the University of Texas Southwestern (UTSW) Medical Center in accordance with regulations of the US Department of Health and Human Services (HHS) (45 CFR46) and the US FDA (21 CFR 50 and 21 CFR 56). Between July 6, 2010, and August 21, 2010, a total of 103 adults were enrolled in this single-site prospective, nonrandomized, clinical trial with masked evaluation. The inclusion and exclusion criteria are summarized in Table 1.

Before treatment, 3-dimensional baseline photographs were taken of each patient’s face. For the efficacy analysis, additional 3-dimensional photographs were obtained immediately after the MFU procedure and during the 3-month follow-up visits.

Pretreatment Medication

All patients received some form of pretreatment medication to control pain. Oral medications (5-10 mg of diazepam and 5/325 mg of hydrocodone/acetaminophen [1 or 2
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Table 1. Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male or female</td>
<td>Pregnant or lactating</td>
</tr>
<tr>
<td>Aged 35-60 years</td>
<td>Presence of any active systemic or local skin disease that may alter wound healing</td>
</tr>
<tr>
<td>In good health</td>
<td>Severe solar elastosis</td>
</tr>
<tr>
<td>Desires lifted and tightened cheek tissue, and/or desires improved jawline definition, and/or desires reduction of submental skin laxity</td>
<td>Excessive subcutaneous fat on the cheeks</td>
</tr>
<tr>
<td>Willing and able to provide informed consent</td>
<td>Excessive skin laxity on the lower face and neck</td>
</tr>
<tr>
<td>Willing and able to attend follow-up visits</td>
<td>Significant scarring in areas to be treated</td>
</tr>
<tr>
<td></td>
<td>Significant open facial wounds or lesions</td>
</tr>
<tr>
<td></td>
<td>Severe or cystic facial acne</td>
</tr>
<tr>
<td></td>
<td>Presence of a metal stent or implant in the facial area</td>
</tr>
<tr>
<td></td>
<td>History of smoking in past 10 years</td>
</tr>
<tr>
<td></td>
<td>Inability to understand the protocol or to give informed consent</td>
</tr>
<tr>
<td></td>
<td>Mental illness</td>
</tr>
<tr>
<td></td>
<td>History of cosmetic treatments in the facial area to be treated, including facial skin tightening procedure within the past year; injectable filler of any type within the past year; Botox in the lower face within the past 6 months; ablative or nonablative resurfacing/rejuvenating laser treatment or light treatment within the past 6 months; dermabrasion or deep facial peels within the past 6 months; facelift, blepharoplasty, or browlift (including contour threads) within the past 6 months</td>
</tr>
<tr>
<td></td>
<td>Taking isotretinoin or other retinoids within the past 2 weeks; taking psychiatric drugs, warfarin, or heparin within the past 2 weeks</td>
</tr>
</tbody>
</table>

Outcome Analyses

**Patient Assessments**

During treatment, the patient was asked to rate sensation on a scale of 0 to 10, with 0 denoting no sensation and 10 denoting the worst possible pain. At the 90-day follow-up visit, participants were asked to complete a patient satisfaction questionnaire, which entailed recording their perception of the clinical outcome and indicating whether they would be interested in receiving more such treatments in the future (see Appendix A available online at aesthetic surgeryjournal.com/supplemental).

**Qualitative Masked Assessment**

Most patient data were obtained from projected digital images: 5 pretreatment views and 5 posttreatment (day 90) views were examined for each patient. Each set comprised 1 frontal, two 45-degree (left and right), and 2 lateral (left and right) views, all prepared with Canfield Digital Software (Canfield Imaging Systems, Fairfield, New Jersey). Three physicians based in the plastic surgery department at UT SW but not involved in the recruitment, treatment, or postprocedure follow-up of the patients served as independent blinded reviewers. To permit direct comparisons, the 5 pretreatment images were grouped

tables]) were administered at least 30 minutes before treatment. Intramuscular medication (60 mg of ketorolac tromethamine) was given 60 minutes prior.

**Treatment and Aftercare**

During the procedure, ultrasound gel was applied to the patient’s face, and the transducer was placed on the skin to obtain an ultrasonographic image of each section of the proposed treatment area and to ensure adequate coupling between the device and the skin. The physician placed multiple exposure lines 2 to 4 mm apart, each up to 25 mm long, in the selected area. The placement of each line took approximately 3 seconds. All facial regions were treated in this standardized pattern (Figure 2); approximately 295 exposure lines were placed on each patient’s face and neck. Therapy was delivered by advancing the transducer 2 to 4 mm along each line in the matrix (17 individual ultrasound pulses per line). All treatment areas received 2 passes: the Ulthera DeepSee 4-4.5 transducer (deeper penetration) was employed for the first pass, followed by the DS 7-3.0 transducer (more superficial penetration) for the second pass. Upon completion of treatment, patients were advised to resume their normal skincare regimens.
together and presented alongside the 5 corresponding posttreatment images. However, the sides of placement varied so that reviewers would be unaware of which images were pretreatment and which were posttreatment. The reviewer also was provided with printed pre- and posttreatment photographs. In accordance with the validation protocol, only 1 viewing session of each patient’s images was allowed.

**Evaluation of 90-day results.** Before viewing the images of evaluable patients, the 3 blinded reviewers had been informed that right/left positioning of the pre- and posttreatment images had been randomized. For each patient, they rated the images as “changed” or “not changed”; if change was observed, the reviewer was asked to identify the posttreatment image.

For all evaluable patients, the reviewers’ assessments were recorded on a data sheet. Each reviewer’s results were then compared with the reference key. If the correct posttreatment image was identified based on the reference key, the patient’s result was considered improved. If the reviewer did not observe a change, the result was considered unchanged. If the reviewer identified the wrong photograph as the posttreatment image, the result was considered worsened. All results were then collated on a Microsoft Excel spreadsheet (Microsoft Corp, Redmond, Washington), and trends were analyzed.

**Quantitative Assessment**

For this assessment, the true lateral images obtained at baseline were compared with the corresponding 90-day images by measuring an area defined by fixed points. Both left and right lateral images were analyzed for each patient. The fixed points were the lateral canthus, the point where the nostril meets the columella, and the point where the
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chin meets the neck (Figure 3). For each lateral image, a line was first drawn horizontally from the lateral canthus (line a); a vertical line was then dropped down through the point where the columella meets the nostril. A second horizontal line (c) is drawn from line b to the point where the chin meets the neck; this line was then extended an additional 35 mm. A second vertical line (d) is then drawn downward from this terminus. The resulting area (x) bounded by line c, line d, and the natural line of the neck is then calculated with AutoCAD software (Autodesk, Version 17.0, 2007; Informer Technologies, Redwood City, California).

Figure 3. The objective assessment methodology developed for this study. Fixed points are the lateral canthus, the point where the nostril meets the columella, and the point where the chin meets the neck. Line a is drawn horizontally from the lateral canthus, and then a vertical line (b) is dropped down through the point where the columella meets the nostril. A second horizontal line (c) is drawn from line b to the point where the chin meets the neck and then extended an additional 35 mm. A second vertical line (d) is then drawn downward from this terminus. The resulting area (x) bounded by line c, line d, and the natural line of the neck is then calculated with AutoCAD software (Autodesk, Version 17.0, 2007; Informer Technologies, Redwood City, California).

Table 2. Summary of Baseline Demographics of Enrollees (N = 103)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (range), y</td>
<td>49.2 (35-60)</td>
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<tr>
<td>Sex, No.</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
</tr>
<tr>
<td>Female</td>
<td>87</td>
</tr>
<tr>
<td>Fitzpatrick skin type, No.</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>12</td>
</tr>
<tr>
<td>II</td>
<td>66</td>
</tr>
<tr>
<td>III</td>
<td>15</td>
</tr>
<tr>
<td>IV</td>
<td>5</td>
</tr>
<tr>
<td>V</td>
<td>3</td>
</tr>
<tr>
<td>VI</td>
<td>2</td>
</tr>
<tr>
<td>Body mass index, mean (range), kg/m²</td>
<td>25.6 (18.7-36.5)</td>
</tr>
</tbody>
</table>

Adverse Events

An unanticipated device-related adverse effect was defined as “any serious adverse event on health or safety, or any life-threatening problem or death caused by, or associated with, a device; if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or application (including supplementary application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of patients.” For example (and not limited to), events related directly to the device such as changes in skin pigmentation, erythema, swelling, or bruising were considered to be adverse events. Events not directly related to the device were also recorded, for example (and not limited to), unrelated admissions to the hospital or infections such as pneumonia.

RESULTS

Eighty-seven (84.5%) of the 103 enrollees were women. The mean patient age was 49.2 years (range, 35-60 years), and the mean body mass index (BMI) was 25.6 kg/m² (range, 18.7-36.5 kg/m²). Most patients had Fitzpatrick skin type II. Patient demographics are summarized in Table 2.

Of the 103 enrollees, 93 completed the study and could be evaluated. Ten patients were excluded because of incomplete treatment (n = 1), self-withdrawal from the study (n = 3), or failure to attend the 90-day follow-up assessment (n = 6).

In the remaining 93 participants, skin surface remained intact, and there was no damage to the epidermis. Throughout the study, there were no reports of acute skin damage or long-term sequelae such as scarring, burns, hypopigmentation, hyperpigmentation, or ulceration.
At the 90-day follow-up visit, 61 (65.6%) of the 93 evaluable patients reported improvement in the lower half of their face/neck; 32 patients (34.4%) felt there had been no improvement in this area. Of those who saw no improvement, 14 (43.8%) indicated they would undergo another treatment.

With respect to pain during the procedure, patients noted that the most comfortable treatment area was the cheek, followed by the submental region and then the submandibular area (Table 3). Average pain scores were 5.68 (range, 1-10) for the cheeks, 6.09 (range, 2-10) for the submental area, and 6.53 (range, 2-10) for the submandibular region.

Assessments by Masked Reviewers

According to assessments of masked reviewers, improvements in skin laxity of the lower two-thirds of the face and the neck occurred in 54 (58.1%) of the 93 patients. No change was observed for 16 patients (17.2%), and the result was worse for 23 patients (24.7%). Pre- and posttreatment images of several patients appear in Figures 4 to 6.

Effect of BMI

BMI exceeded 30 kg/m² for 11 of the 93 patients evaluated. According to clinical assessments, 3 (27.3%) of these patients had improvement, 6 (54.5%) remained unchanged, and 2 (18.2%) worsened. When these 11 patients were excluded from the overall analysis, the percentage of reviewer-assessed improvements increased to 62.2%, the percentage of patients with no change was reduced to 12.2%, and the number of patients with a worse result remained essentially the same.

Quantitative Assessments

Of the 103 enrollees, 78 satisfied the criteria for objective quantitative assessment. The 25 patients who were excluded had failed to complete treatment or follow-up (n = 10), or their photographs had lighting problems or other issues that rendered them inadequate for analysis (n = 15).

Correlation between the left and right lateral images was good (P = .522). The average amount of lift was 45.2 mm², reflecting improvement in skin laxity for 71.8% (56 of 78) of seventy-eight assessed patients. Of the patients who experienced a quantitative lift, 82.1% (46 of 56) were deemed improved according to the masked qualitative assessment, and 75.0% (42 of 56) noted improvement in their face and/or neck at day 90 (per the patient satisfaction survey).

Among patients with BMI > 30 kg/m² (n = 8 [after exclusions]), the average amount of lift was 24.3 mm². This finding correlates with the improvement in skin laxity observed for 50% (4 of 8) of these patients.

Adverse Events

Seven adverse events were reported during the study (Table 4), 5 of which were deemed mild and 2 moderate. Four of these events were considered unrelated to the device or the procedure. All 3 device-related adverse events were wheals on the cheek or neck, all of which were rated as mild and resolved spontaneously with no sequelae. The adverse event profile with the Ulthera System compares favorably with that of traditional laser treatments. The duration of facial swelling did not exceed 7 to 10 days in any patient, and there were no reports of crusting, pigment changes, or persistent pain.

DISCUSSION

Rejuvenation of the neck and lower two-thirds of the face, particularly skin tightening and lifting, is a goal of many nonsurgical and surgical cosmetic procedures. Although surgical rejuvenation remains the gold standard for many patients and physicians, MFU devices have clear advantages. These devices provide dermal heating to induce collagen denaturation and subsequent synthesis. The epidermis is spared, and patient downtime is minimized.14 When epidermal tissue is disrupted, crusting and peeling often occur for a lengthy period, and the protective barrier may be lost.

The epidermal-sparing properties of fractionated MFU devices such as the Ulthera System were demonstrated in a clinical study by Gliklich et al,12 who also reported that the area damaged by thermal ablation from intense ultrasound exposure was approximately 1 mm³. In a cadaveric study, White et al15 found that ultrasonic energy deposited deep within the SMAS induces the most effective skin tightening.

Similar to other MFU devices, the Ulthera System is designed and configured to produce small (approximately
1 mm³) microthermal lesions in the mid to deep reticular dermis and subdermis, while sparing the overlying papillary dermis, the epidermis, and the intervening tissue between the lesions. Thermal damage to the dermis stimulates collagen neosynthesis, leading to clinically observed skin tightening. The device also enables visualization of the tissue, which permits its evaluation and ensures proper transducer contact. Four Ulthera transducers are available: the
Figure 5. (A, C, E) Images of this 52-year-old white woman (Fitzpatrick skin type I; body mass index, 26 kg/m²) before treatment to the cheeks, jawline, and neck with the Ulthera System (Ulthera, Inc, Mesa, Arizona). Note the substantial laxity of the neck and submental area. (B, D, F) Ninety days after treatment, her average lift was 181.7 mm².
Figure 6. (A, C, E) Images of this 52-year-old white man (Fitzpatrick skin type II; body mass index, 27 kg/m²) before treatment to the cheeks, jawline, and neck with the Ulthera System (Ulthera, Inc, Mesa, Arizona). (B, D, F) Ninety days after treatment, his average lift was 91.8 mm².
DS 4-4.5 and DS 7-4.5 (which target subdermal tissues, including the SMAS), the DS 7-3.0 (which targets the dermis to a depth of ~3 mm), and the newer DS 10-1.5 (which targets the upper dermis).

Suh et al. obtained biopsy specimens from 11 patients who had undergone treatment with the Ulthera device 2 months earlier and reported a statistically significant increase in dermal thickness secondary to increased dermal collagen fibers. Moreover, they found no evidence of epidermal changes or inflammatory reactions. These results support previous findings of White et al., who reported sparing of the epidermis and focused thermal microablative damage, characterized histologically in human cadaveric skin.

In a pilot study, Gliklich et al. demonstrated that intense focused ultrasound had no effect on structures such as the facial nerve or its branches and produced discrete areas of coagulative damage. Furthermore, no thermal injury was apparent from histologic examination conducted 4 to 12 weeks posttreatment.

By contrast, traditional laser devices can induce epidermal injury that results in postprocedural morbidities such as prolonged erythema, scarring, pigmentary changes, and, rarely, infection or an unpredictable clinical result. Monopolar and bipolar radiofrequency devices, which tighten the skin through volumetric heating, have shown variable efficacy over the past decade. Clinical results with these devices have been inconsistent and largely anecdotal. For example, during a review of efficacy studies of nonablative radiofrequency devices, Atiyeh et al. noted low levels of evidence. Fractionated MFU differs from older radiofrequency devices in that it causes very little epidermal heating, with most of the energy deposited in the dermis (Figure 7).

To our knowledge, the present study is the largest to date of patients treated with an MFU device irrespective of anatomic region. Our results compare favorably with those of smaller published studies. Lee et al. examined the efficacy of Ulthera treatment and found that at 90 days, 80% of blinded assessors saw some clinical improvement in the 10 patients who completed the study, and 90% of patients noted improvement in skin laxity. The side effect profile was similar to that of our study, with all patients reporting slight erythema and edema but no lasting sequelae. In a recent publication, Suh et al. reported that all 15 of their patients treated by intense focused ultrasound had improvement in eyebrow lift, according to objective and subjective evaluation. In a blinded, prospective, cohort study, Alam et al. evaluated the outcome of Ulthera treatments to the forehead in 35 patients. All patients experienced erythema after treatment, which was transient and resolved within 7 days. Wheals on the neck

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Days After Treatment</th>
<th>Adverse Event Description</th>
<th>Severity</th>
<th>Action Taken</th>
<th>Relationship to Investigational Device</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Wheals on right cheek and right side of neck</td>
<td>Mild</td>
<td>None</td>
<td>Possible</td>
<td>Resolved; no sequelae</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>Wheal on left cheek</td>
<td>Mild</td>
<td>None</td>
<td>Possible</td>
<td>Resolved; no sequelae</td>
</tr>
<tr>
<td>3</td>
<td>84</td>
<td>Common cold</td>
<td>Mild</td>
<td>Medication</td>
<td>Unrelateda</td>
<td>Resolved; no sequelae</td>
</tr>
<tr>
<td>4</td>
<td>78</td>
<td>Pneumonia</td>
<td>Moderate</td>
<td>Medication</td>
<td>Unrelateda</td>
<td>Resolved; no sequelae</td>
</tr>
<tr>
<td>5</td>
<td>78</td>
<td>Cracked rib</td>
<td>Moderate</td>
<td>Medication</td>
<td>Unrelateda</td>
<td>Resolved; no sequelae</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>Wheal on left side of neck</td>
<td>Mild</td>
<td>None</td>
<td>Probable</td>
<td>Resolved; no sequelae</td>
</tr>
<tr>
<td>7</td>
<td>79</td>
<td>Influenza</td>
<td>Mild</td>
<td>None</td>
<td>Unrelateda</td>
<td>Resolved; no sequelae</td>
</tr>
</tbody>
</table>

aAdverse event was not related to the study device.

Figure 7. Depth of energy penetration with laser, radiofrequency, and Ulthera devices. The Ulthera transducer (DS 7-3.0) delivers peak energy at a depth of 2 to 4 mm, in contrast to traditional radiofrequency and laser energy sources, which delivers peak energy at the epidermis. (Reprinted with permission from Ulthera, Inc, Mesa, Arizona.)
developed in 2 patients and resolved within 7 days of topical steroid use. At the 90-day evaluation, 86% of patients were assessed as having statistically significant eyebrow lift, with a mean elevation of 1.7 mm.

Microfocused ultrasound compares favorably with lasers and radiofrequency devices. First, any evidence of edema produced by the Ulthera device subsided within 7 to 10 days—a result comparable to those of studies of radiofrequency devices such as Thermage (Solta Medical, Hayward, California).18,21 The specific targeting of the dermis by MFU should help ensure consistent clinical results. Second, the Ulthera system allows direct visualization of the treatment area to ensure that energy is delivered to the targeted location/depth within the dermis and that proper contact is achieved between the transducer and the skin. Third, unlike many laser devices, ultrasound therapy does not target melanin and therefore is safe for all skin types. Chan et al12 used this device for skin tightening in Asian patients (Fitzpatrick skin type III or IV) and found that only 2 (4%) of 49 patients experienced postinflammatory hyperpigmentation, which resolved fully within 9 months of treatment.

We quantitatively and qualitatively assessed the effect of Ulthera treatment on skin lifting, tightening, and laxity. On the basis of these assessments, nearly two-thirds of the patients had improvement in skin laxity. Improvement from baseline was noted by two-thirds of the patients at day 90. These findings compare favorably with results of other skin rejuvenation procedures that are maximized around the 3-month mark.2,3,17,23,24 However, appropriate patient selection is essential for a successful outcome. In our study, patients whose BMI exceeded 30 kg/m² tended to have less perceptible improvement (clinically and quantitatively) than those with lower BMI. Most likely, this finding is due either to excess fat deposition within the face or to excess skin laxity, neither of which would improve substantially with this procedure. Brobst et al25 also emphasized the importance of proper patient selection for maximizing aesthetic outcomes with an MFU device. Physicians should consider this finding when determining which patients are suitable for Ulthera treatment.

Patient Experience

In a study of focused intense ultrasound therapy in 36 patients, Alam et al10 reported results similar to ours, with no adverse events other than erythema and edema that resolved within 7 days. Pain perception is very subjective, and the range of sensory responses to MFU treatments is broad. Patients who have undergone previous cosmetic procedures often have a higher pain threshold than treatment-naive individuals. In our study, patients experienced greater pain in the submental and submandibular regions than in the cheek. This is likely attributable to the bony prominences/dentition underlying these areas, and greater pain in the periorbital/brow region has been reported by other authors.26 In our study, oral or intramuscular pain medication was administered to all patients before treatment. Local anesthesia such as nerve blocks or topical applications may improve the somatic experience during an MFU procedure.

Study Limitations, Future Directions, and Clinical Applications

This nonrandomized, noncomparative clinical study had several limitations. New technologies such as the Ulthera System also should be assessed in a randomized comparative manner, which will be implemented in future research. Because patients with excessive skin laxity and/or high BMI are not likely to benefit from this treatment, such characteristics should be incorporated into the exclusion criteria of future studies. Our objective method for assessing results with this device can now supplement subjective assessments, which remain useful but do not permit rigorous statistical scrutiny. Longer follow-up would enable evaluation of the long-term outcomes of Ulthera treatment.

Because MFU remains an emerging technology, few relevant clinical studies exist. When our study was designed, the number of treatment lines placed in the face and neck was somewhat arbitrary, and we erred on the side of caution. However, from subsequent studies we have learned that the treatment density applied in our study was only 40% of the currently recommended company guideline.22,26 The next step is to examine the effect of a greater number of treatment lines on outcomes.

Investigations of the effects of local anesthesia on pain management and efficacy are needed to improve the patient experience. Future studies involving full-face rejuvenation, multiple treatments in responders and nonresponders, and targeted areas such as periorbital rhytides would be beneficial as well.

Conclusions

The thermal damage to tissue produced by MFU creates microcoagulative zones and stimulates collagen neosynthesis and subsequent skin tightening. Even though the treatment densities in our study were 40% lower than currently recommended values, promising results were achieved in the lower face and neck, equal to those of ablative or nonablative laser treatments, and side effects were minimal and transient. Additional studies are needed to assess the efficacy of Ulthera treatment for a broader range of clinical indications.
Disclosures
The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding
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REFERENCES