Clinical Efficacy and Safety of Focused-Image Ultrasonography: A 2-Year Experience
Gordon H. Sasaki and Ana Tevez
Aesthetic Surgery Journal published online 23 April 2012
DOI: 10.1177/1090820X12445576

The online version of this article can be found at:
http://aes.sagepub.com/content/early/2012/04/23/1090820X12445576

Published by:
SAGE
http://www.sagepublications.com

On behalf of:
American Society for Aesthetic Plastic Surgery

Additional services and information for Aesthetic Surgery Journal can be found at:

Email Alerts: http://aes.sagepub.com/cgi/alerts
Subscriptions: http://aes.sagepub.com/subscriptions
Reprints: http://www.sagepub.com/journalsReprints.nav
Permissions: http://www.sagepub.com/journalsPermissions.nav

>> OnlineFirst Version of Record - Apr 23, 2012
What is This?
Clinical Efficacy and Safety of Focused-Image Ultrasonography: A 2-Year Experience

Gordon H. Sasaki, MD, FACS; and Ana Tevez, RN

Abstract

Background: Focused-image ultrasonography produces controlled waves that image dermal and subdermal structures in real time, with precise thermal coagulation points in a linear pattern, for eventual nonsurgical lifting.

Objectives: The authors evaluate the effectiveness of single and dual planes of ultrasound treatment by varying the directions of treatment lines, depths, and cumulative joule energies and compare the safety and efficacy of treatment with these variations.

Methods: In this prospective, 2-part study, patients were treated by single- or dual-treatment depth with differing directions of treatment lines while the number of treatment lines and amount of energy delivered to brows or marionette lines remained constant (Study 1) or with lower or higher joule energy to opposing areas while the dual depths and number of vectored lines remained constant (Study 2). Lifting was measured using the matched-orientation function of specific mirroring software. Clinical outcomes were assessed with global aesthetic improvement scales.

Results: Vertical vectoring of 15 treatment lines in both tissue depths produced significant lifting over the 15 horizontally-placed treatment lines in the opposing brows and marionette lines. Sites with more treatment lines and higher joule energy at dual depths resulted in significantly greater lifting (Study 2). Side effects were minimal.

Conclusions: Focused-imaged ultrasound therapy to facial tissues is safe and effective when performed as described.

Level of Evidence: 3

Keywords

cosmetic medicine, ultrasonography, focused-image ultrasound, marionette lines

Accepted for publication January 11, 2012.

Surgery to the ptotic face and neck remains the most effective method for achieving prolonged rejuvenation of the aging face. Despite the major efficacy advantage, informed patients often prefer noninvasive devices and procedures because they are associated with minimal posttreatment downtime and lower morbidity. Because the current non-invasive energy systems1-5 are unable to efficiently lift anatomical structures below the skin level, these devices are likely to be less effective than invasive procedures and the results are unpredictable. In contrast, focused ultrasound therapy6-10 produces precise, propagated ultrasonic waves that penetrate deeply and produce real-time imaging of the skin and subdermal structures. The targeted tissue levels are treated with a number of lines, each containing discrete separated thermal coagulation points (TCPs), which produces eventual nonsurgical tissue lifting without affecting the surface of the skin.

The objectives of the research described in this article were 3-fold. First, in Pilot Study 1, the effects of single/dual levels of treatment were assessed by varying the directions of treatment lines, depths of tissue treatments, and joule energies of the exposure lines to determine the optimal set of parameters for tissue lifting. Second, in Pilot Study 2, the lifting achieved in Study 1 was compared with that obtained with higher joule energies. Third, we compared the safety and efficacy between patients treated with lower versus higher numbers of treatment lines and at lower and higher joule energies.

Dr. Sasaki is Clinical Professor of Plastic Surgery at the Loma Linda University Medical School, Loma Linda, California. Ms. Tevez is a Registered Nurse in a plastic surgery private practice in Pasadena, California.

Corresponding Author:

Dr. Gordon H. Sasaki, 800 South Fairmount Avenue, Suite 319, Pasadena, CA 91105 USA.

E-mail: ghsasakimd@drsasaki.com
Of over 100 adults recruited in six months from the study site’s patient database, only 35 were qualified, provided written informed consents, and were randomized into the two Pilot Study Groups. Inclusion criteria were mild to moderate ptosis of skin and fibromuscular layers as well as mild to moderate fat thickness to the face and neck. Exclusion criteria included severely damaged actinic skin, thin porcelain-type skin, significant ptotic skin and fibromuscular units, active systemic or local infection, acne or keloidal scarring, skin diseases that altered wound healing, and hemorrhagic disorders or hemostatic dysfunctions. Women who were pregnant or breastfeeding were excluded from participation. Subjects who had undergone facial surgery, including ablative and nonablative skin procedures, were excluded until 1 year after their procedure. Study participants were treated in compliance with guidelines established by the International Organization for Standardization, US Food and Drug Administration, and Institutional Review Boards.

**METHODS**

**Patient Selection**

The process described above led to the selection of 35 patients who met the inclusion criteria and were randomized into the two Pilot Study Groups. The methodology adhered to the established guidelines to ensure the safety and efficacy of the treatment.

**Pretreatment Protocol**

One week before treatment, patients were asked to discontinue the use of topical skin care products such as isotretinoin, glycolic acid, and salicylic acid. On the day of treatment, they were asked to avoid application of facial creams, lotions, powders, and foundations. All metal jewelry was removed from the facial area. Patients washed their faces with a mild cleanser prior to their procedure. Patients who had a history of viral infections received a course of prophylactic antiviral medication, which lasted from 2 days before to 6 days after the procedure.

After photographic documentation, squares measuring $2.5 \times 2.5$ cm were marked at selected treatment sites such as the brow complex, crow’s feet, malar bag region, mid-face, and neck, as shown in Figures 1 and 2. The predicted pathways of the frontal nerve rami (1.5 cm superolateral to the orbital rim), the marginal mandibularis rami (medial to the marionette line), and the deep, long, lateral branch of the supraorbital sensory nerve (1-1.5 cm medial to the superior temporal crest line) were outlined as a reminder to (1) lower the quantity of delivered energy, (2) lessen the downward pressure of the transducer on the skin surface, (3) select a transducer associated with a higher level of tissue treatment, and/or (4) avoid placement of any treatment lines.

Treatment was avoided over areas containing mechanical implants, electrical devices, or soft-tissue augmentation materials. Treatment was not administered on tissues directly over a patient’s eyes or in any area where ultrasound energy could potentially reach the eyes. Ultrasound therapy should not be applied directly over the thyroid gland.
A full description of the ultrasound system used in this study (Ulthera System; Ulthera, Inc., Mesa, Arizona; approved by the US Food and Drug Administration in September 2009) is available in an online-only appendix at www.aestheticsurgeryjournal.com.

After a thin layer of ultrasound transmission gel was applied to the transducer’s window, the selected transducer was positioned onto the marked skin-treatment square and activated to begin imaging of the skin and subdermal structures. Upon activation of the transducer, a series of TCPs were deposited at the selected tissue level in a straight line. This sequence was repeated within each treatment square with the selected number, direction, and depth of treatment lines, according to the study protocols (described later), to complete the procedure. The ultrasound transmission gel was reapplied frequently to ensure proper tissue imaging and coupling. For the few patients who acknowledged a low pain threshold or who experienced moderate discomfort during treatment, a pain management program was initiated in a graded fashion. It consisted of administering oral analgesic or sedative medication, giving distractive hand and foot massages, reducing skin temperature with an air coolant device, lowering joule settings (by one level for each transducer or by shortening the length of treatment lines), and, if necessary, administering selective nerve blocks or limited amounts of buffered lidocaine (subcutaneously). The majority of patients who received treatment to the midface and neck did not require a local nerve block or lidocaine because of the adequate thickness of those tissues. A patient treated on the forehead/brow may require local anesthesia or nerve blocks because of the thinness of tissues overlying the frontal bone. After completion of treatment and removal of the ultrasound gel, patients were able to return immediately to their usual lifestyle and activities. Medical skin-care regimens resumed within 1 week. The entire 2-year study began in October 2009 and ended in October 2011. The Pilot Study 1 extended from October 2009 to April 2010, while Pilot Study 2 took place between April 2010 and October 2010.

**Figure 2.** (A, C) This 52-year-old woman presented with orbital hooding and ptosis of the lateral brows. The forehead tissue above her right lateral brow was treated with the 7 MHz, 4.5 mm (15 vertical lines; 267.8 joules) and the 7 MHz, 3.0 mm (15 vertical lines; 155.2 joules) and above her left lateral brow with 7 MHz, 4.5 mm (30 vertical lines; 535.6 joules) and 7 MHz, 3.0 mm (30 vertical lines; 310.5 joules). (B, D) Six months posttreatment. The left lateral brow demonstrates increased elevation compared with the right lateral brow.
Table 1. Pilot Study 1: Treatment Mapping of Depths, Number of Vector Lines, and Joule Energy

<table>
<thead>
<tr>
<th>Right Brow</th>
<th>Left Brow</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1</strong></td>
<td><strong>Group 2</strong></td>
</tr>
<tr>
<td>7 MHz, 3.0 mm (15 vertical lines)</td>
<td>7 MHz, 3.0 mm (15 horizontal lines)</td>
</tr>
<tr>
<td>4 MHz, 4.5 mm (15 vertical lines)</td>
<td>4 MHz, 4.5 mm (15 horizontal lines)</td>
</tr>
<tr>
<td>7 MHz, 3.0 mm (15 vertical lines)</td>
<td>7 MHz, 3.0 mm (15 horizontal lines)</td>
</tr>
<tr>
<td>7 MHz, 4.5 mm (15 vertical lines)</td>
<td>4 MHz, 4.5 mm (15 horizontal lines)</td>
</tr>
<tr>
<td>7 MHz, 4.5 mm (15 horizontal lines)</td>
<td>7 MHz, 4.5 mm (15 horizontal lines)</td>
</tr>
<tr>
<td><strong>Group 5</strong></td>
<td><strong>Group 6</strong></td>
</tr>
<tr>
<td>7 MHz, 3.0 mm (15 vertical lines)</td>
<td>7 MHz, 3.0 mm (15 superolateral lines)</td>
</tr>
<tr>
<td>7 MHz, 4.5 mm (15 horizontal lines)</td>
<td>4 MHz, 4.5 mm (15 horizontal lines)</td>
</tr>
<tr>
<td><strong>Group 8</strong></td>
<td><strong>Group 9</strong></td>
</tr>
<tr>
<td>7 MHz, 3.0 mm (15 superolateral lines)</td>
<td>7 MHz, 3.0 mm (30 superolateral lines)</td>
</tr>
<tr>
<td>4 MHz, 4.5 mm (15 horizontal lines)</td>
<td>4 MHz, 4.5 mm (15 superolateral lines)</td>
</tr>
<tr>
<td>7 MHz, 3.0 mm (15 horizontal lines)</td>
<td>4 MHz, 4.5mm (15 superolateral lines)</td>
</tr>
</tbody>
</table>

\[ a0.45 \text{ J/TCP} \times 23 \text{ TCPs/25-mm line} \times 15 \text{ lines} = 155.2 \text{ J}. \]
\[ b0.45 \text{ J/TCP} \times 23 \text{ TCPs/25-mm line} \times 30 \text{ lines} = 310.5 \text{ J}. \]
\[ c1.05 \text{ J/TCP} \times 17 \text{ TCPs/25-mm line} \times 15 \text{ lines} = 267.8 \text{ J}. \]
\[ d1.05 \text{ J/TCP} \times 17 \text{ TCPs/25-mm line} \times 30 \text{ lines} = 535.6 \text{ J}. \]
\[ e1.2 \text{ J/TCP} \times 17 \text{ TCPs/25-mm line} \times 15 \text{ lines} = 306 \text{ J}. \]
\[ f1.2 \text{ J/TCP} \times 17 \text{ TCPs/25-mm line} \times 30 \text{ lines} = 612 \text{ J}. \]

**Pilot Study 1**

Twenty-seven patients (9 groups of 3 patients each) received treatment to opposing brows and marionette folds by varying vector directions and single/dual tissue treatment depths, while keeping constant other aspects of the treatment map such as the number of lines (15, each 25 mm long) at the highest level of joules/TCP at each site (Table 1). For each group, the matching site on the opposing side of the face received identical total amounts of energy delivered at the same tissue depths; the only variation was the direction of the 15 lines of treatment.

The patients in Groups 1, 2, 3, 6, and 7 had their ipsilateral and contralateral brows and marionette lines treated at either the visualized dermal or fibromuscular layer, as determined by the transducer’s preset fixed focal depth, with 15 lines and equivalent joules per side (7 MHz, 3.0 mm, 15 lines, 155.2 J; 7 MHz, 4.5 mm, 15 lines, 267.8 J; 4 MHz, 4.5 mm, 15 lines, 306 J). Six months after treatment, the percentage of change in tissue lifting (vs baseline) was measured for each patient using Canfield Mirror software (Canfield Scientific, Inc., Fairfield, NJ).

**Pilot Study 2**

There were 2 groups in Study 2 (Table 2). The 4 patients in Group 1 had their ipsilateral brows treated with a lower number of lines and joule energy of vertical–vertical lines (7 MHz, 3.0 mm, 15 lines, 155.2 J; 7 MHz, 4.5 mm, 15 lines, 267.8 J) and their contralateral brows treated with a higher number of treatment lines and joule energy of vertical–vertical lines (7 MHz, 3.0 mm, 30 lines, 310.5 J; 7 MHz, 4.5 mm, 30 lines, 535.5 J). Similarly, the 4 patients in Group 2 had their ipsilateral marionette lines treated by a lower number of treatment lines and joule energy of superolateral–horizontal lines (7 MHz, 3.0 mm, 15 lines, 155.2 J; 4 MHz, 4.5 mm, 15 lines, 306 J) and their contralateral marionette lines treated by a higher number of treatment lines and joule energy of superolateral–horizontal lines (7 MHz, 3.0 mm, 30 lines, 310.5 J; 4 MHz, 4.5 mm, 30 lines, 612 J). Six months later, the percentage of change in tissue lifting (vs baseline) was measured for each patient with Canfield software.

**Clinical Experience With Vectored Lines and Joule Energy Levels**

Based on the results of Study 1, we treated 107 patients in our clinic between October 2009 and October 2010 with
Photographic and Statistical Analysis

In Studies 1 and 2, a custom-designed Canfield VISIA Analysis and Photographic System (Canfield Scientific, Inc, Fairfield, NJ) was used for baseline and follow-up photography with standardized lighting (0°, 45°, and 90° views). The matched-orientation function of the Mirror software was used to compare baseline and posttreatment distance changes (mm) between reference points on a standardized facial positioning table. Each photographic image was automatically tagged with a specific label that could not be edited.

An average of 3 vertical displacements of each brow (midpupil, lateral canthus, and lateral tail of brow) from the intercanthal horizontal axis, or the average of 3 superolateral displacements of each marionette line along a fixed reference line (extending from inferior tragal notch or midpoint of marionette line), was used to compare measurements for each subject and between each group. A disadvantage of using the brow or marionette fold as a reference point for measurements is the inherent vagary of mobile groomed structures. However, data were subjected to 1-way analysis of variance to test for significance between and within groups and for homogeneity of variances. Data were analyzed using Scheffé’s post hoc test for multiple comparisons of mean differences, standard errors, and 95% significance at the probability level of .05.

RESULTS

The cumulative demographic data for 27 patients in Pilot Study 1 included the following distributions: 27 females; average age 46.1 (range 25-67 years); 16 Caucasians and 11 Hispanics. The cumulative demographic data for 8 patients in Pilot Study 2 had the following distributions: 8 females; average age 49.6 (range 43-56); 5 Caucasians and 3 Hispanics.

Pilot Study 1

Groups 1, 2, 3, 6, and 7. Six months after treatment, the brows and marionette lines that had received superolaterally-placed treatment lines showed significantly higher lifting (vs baseline values) than the opposite sides treated by horizontal lines, according to post hoc testing analyses, independent of tissue depth or joule energy. The respective results were as follows: Group 1, 5.7 ± 1.2% vs 1.0 ± 0.3%; Group 2, 6.6 ± 0.5% vs 3.6 ± 0.7%; Group 3, 5.6 ± 1.3% vs 2.4 ± 0.8%; Group 6, 3.8 ± 0.7% vs 2.0 ± 0.5%; Group 7, 3.8 ± 0.7% vs 1.8 ± 0.2% (all P = .05).

Groups 4 and 5. Six months after treatment, post hoc testing analyses showed a significantly higher percentage of tissue lifting (vs baseline) for areas that had received dual-depth treatments in vertical–vertical directions compared with horizontal–horizontal directions (Group 4, 7.2 ± 1.4% vs 3.7 ± 0.7%, respectively; P = .05). Dual-plane treatment of opposing brows with crisscrossing lines resulted in significantly higher lifting for areas in which treatment lines had been applied horizontally to the fibromuscular layers and vertically to the dermis, compared with horizontal application to the dermis and vertical application to fibromuscular layers (Group 5, 6.0 ± 1.4% vs 3.1 ± 0.9%, respectively; P = .05).
Groups 8 and 9. Post hoc analyses at 6 months showed significantly higher tissue lifting (vs baseline) for dual-plane treatment given in the superolateral–superolateral direction (Group 8, 2.4 ± 0.2%; \( P = .05 \)) compared with horizontal–horizontal application (Group 8, 1.1 ± 0.3%; \( P = .05 \)). Similarly, dual-plane treatment of opposing marionette lines with crisscrossing lines resulted in significantly higher lifting for tissues in which the lines had been delivered horizontally to the fibromuscular layers and superolaterally to the dermis compared with the reverse of these procedures (ie, superolaterally to the fibromuscular layer and horizontally to the dermis) (Group 9, 2.7 ± 0.2% vs 1.4 ± 0.2%; \( P = .05 \)).

Pilot Study 2

At the 6-month evaluation, post hoc analyses showed that all patients in Group 1 had achieved significantly greater brow lifting from the higher number of lines and joule energy levels, delivered in dual planes (60 lines, 846 J, 4.3 ± 0.2%; \( P = .05 \)), compared with the lower number of lines and energy used to treat the opposite side (30 lines, 423 J, 1.9 ± 0.3%; \( P = .05 \)), also delivered in dual planes (Figure 2). Similarly, at the 6-month mark, all patients in Group 2 had achieved significantly greater lifting of the marionette lines (vs baseline) when more lines had been treated and higher joule energy applied in dual planes (60 lines, 922 J, 2.4 ± 0.3%; \( P = .05 \)), compared with the fewer lines and lower energy used in dual-plane treatment of the opposite side (30 lines, 461 J, 0.3 ± 0.2%; \( P = .05 \)).

Clinical Patients

The cumulative demographic data of patients in the 2 clinical groups (fewer treatment lines, lower joule energy; more treatment lines, higher joule energy) are summarized in Table 3. Two independent evaluators found that fewer than 2% of patients in these groups demonstrated mild improvements by IGAIS grading as early as 6 weeks. At 3 months, 51.4% of patients in the first group (fewer lines, lower energy) were classified as responders (mild, 47.2%; moderate, 52.8%). By 6 months, the percentage of responders in this group had increased to 70.3% (mild, 31.1%; moderate, 68.9%). In contrast, 71.2% of patients in the second group (more lines, higher energy) were judged to be responders at 3 months (mild, 34.0%; moderate, 47.6%; significant, 18.4%). By 6 months, the percentage of responsiveness in the higher-energy group had increased to 80.2% (mild, 31.1%; moderate, 68.9%). The FWFTLS classification at baseline of patients who experienced mild, moderate, or significant responses at 6 months, in either group, was as follows: Class I, 55%; Class II, 30%. The FWFTLS categorizations of patients who demonstrated negligible responses at 6 months (29.7% of the first group; 19.8% of the second group) were Class I, 15.5%, 17.8%; Class II, 41.1%, 33.7%; Class III, 43.4%, 48.5% (first and second groups, respectively). Clinical results of treatment to the brow complexes appear in Figures 3 and 4; the malar bags appear in Figure 5; and the midface and neck regions are shown in Figures 6 and 7.

Side Effects and Complications

No patient in Pilot Studies 1 or 2 or in the clinical study experienced any significant adverse event, such as long-standing sensory changes, permanent paresis/paralysis, blistering, ulceration, scarring, dyschromia, or fat atrophy during the 6-month follow-up period. However, 3 patients
had transient dysesthesia (numbness or hypersensitivity) to the deep branch of the supraorbital nerve, which lasted for 3 to 7 days. All patients experienced transient erythema for 1 to 2 hours and mild swelling for several days. Mild bruising generally resolved within 1 to 2 weeks. The uncommon occurrence of striated linear skin patterns spontaneously resolved within a few weeks.

Momentary discomfort (stinging, pain, heat) occurred during the procedure but dissipated immediately after the energy was deposited. According to patient ratings, the highest level of pain during the procedure was in the brow and periorbital areas (rated 5.7 out of 10). Pain to the face (3.7 out of 10) and neck (3.6 out of 10) was considered acceptable. Very few patients experienced pain or hypersensitivity during the first week.

**DISCUSSION**

Although patient selection remains fundamental to the success of any face- or neck-lifting procedure, candidates present with a range of variation in skin and soft-tissue characteristics that include, but are not limited to, gradations of skin aging, tissue laxity, and distributions of subcutaneous fat. Because less-impressive results are anticipated for nonsurgical lifting procedures (vs surgical
treatments), the presence of mixed anatomical findings becomes relevant in the interpretation of incremental outcomes in comparative studies of noninvasive techniques. Unlike surgical methods, noninvasive tissue lifting by heating mechanisms is believed to occur after application of sufficient thermal injury (65°C-70°C) to collagen fibers, which enables them to reorganize and contract later, usually by 3 months posttreatment, with results lasting up to 1 year. Temperatures higher than 80°C result in coagulation and fibrosis of collagen fibers. Therefore, the “ideal” candidates for nonsurgical thermal energy treatments should possess collagen fibers of optimal quantity and size as well as the most advantageous fiber orientation to allow maximal thermal absorption. In addition, the absence of tissue heaviness and fullness assists the lifting effects after thermally-induced collagen shortening. These attributes usually are characteristic of patients who have mild or moderate degrees of chronologic or photoactinic aging,
tissue ptosis, and facial heaviness. Most studies of non-invasive procedures have demonstrated modest to moderate subjective and objective results. The authors of these reports have noted wide variation in consistency and predictability of results (40%-80% response) 1 year after standardized noninvasive treatments in studies that used quantifiable methods of documentation and criteria of clinically relevant outcomes.

The onset of collagen denaturation after 60°C to 70°C exposure, the commencement of tissue contraction by 3 months, and the duration of clinical lifting responses (~1 year) appear to be similar after treatment by radiofrequency, ultrasonography, or laser energy sources. However, focused-image treatments represent a unique energy-based method that combines visualization of targeted structures beneath the skin surface and deliverance of either 17 or 23 TCPs in a single line or multiple lines to the fibromuscular and/or dermal levels of tissue.

Our pilot studies were designed to mitigate the effects of anatomical diversities by treating opposing brows or marionette lines in the same patient, with each site serving as its internal control over baseline values. In Pilot Study 1, vertical or superolateral vectoring at one brow or marionette line in the 3 patients in Groups 1, 2, 3, 6, and 7 resulted in statistically-significant percentages of change in tissue lifting in comparison to horizontal vectoring on the opposite side. Each corresponding site was treated at the same single-treatment depth, with an equal amount of joules and number of treatment lines. Comparisons of absolute percentage changes in tissue lifting (by matched Mirror imaging) between the groups demonstrated the difficulty of detecting significant clinical differences among small sets because of variations in patients and treatments. A more meaningful approach was to compare the effects of different treatments to opposing sides in the same patient.

Since the norm in clinical practice is to treat routinely at dual levels, each subject’s corresponding brows (lateral vs horizontal–horizontal) were treated at the fibromuscular and dermal layers, respectively. Dual-level treatments in vertical directions to brows (Group 4, vertical–vertical vs horizontal–horizontal) or marionette lines (Group 8, superolateral–superolateral) resulted in statistically-significant changes in tissue elevation compared with results after horizontal vectoring on the opposing side, with an equal number of treatment lines and joule energy. The objective results for patients from Groups 5 and 9, treated in criss-crossing dual-depth patterns to opposite sites with equal amounts of joules and treatment lines, emphasize the following: (1) the power of vertical- or superolateral-vectored lines applied to skin over similarly directed lines to the fibromuscular layer and (2) the less-dominant influence of horizontally (vs vertically) directed vector lines to the skin and fibromuscular layers. These cumulative findings emphasize the importance of selecting the appropriate number and direction of treatment lines, as well as treatment depth, to optimize clinical outcomes.

The purpose of Pilot Study 2 was not only to validate the importance of the number of vertical or superolateral vectors at both the dermal and fibromuscular levels but also to assess, by objective measurements, the potential value of increasing the amount of joule energy in each layer to improve outcomes. The data confirmed a direct correlation between the amount of tissue lifting (brow and marionette lines) and the quantity of energy deposited into the fibromuscular and dermal layers. Although each
The treatment parameters and outcomes of the 2 pilot studies were used as template guides to clinically treat 2 larger (but closely matched) groups of patients with different amounts of energy. This provided an opportunity to assess the safety and efficacy of treatment with lower versus higher numbers of lines and joule energies. After IGAIS assessments, observable positive responses in either group were difficult to discern within 6 weeks of treatment. After 3 months, approximately 51.4% of the first clinical group of patients and 71.0% of the second clinical group of patients (whose average age was 10 years older) were graded as showing a degree of response. It is noteworthy that 18.4% of the responders in the second group demonstrated significant changes. By 6 months, the percentages of responders had increased to 70.3% in the first group and 80.2% in the second. Although no patient in the first group exhibited a significant change, 26.2% of responders in the second group were found to have significant lifting at 6 months. Interestingly, the majority of patients in both groups (85%) who had responded by month 6 had been assigned to FWFTLS Class I or Class II at baseline. According to the 6-month SGAIS assessments, patients considered their improvement to be slightly better than that documented by the investigators (IGAIS evaluation).

Although favorable baseline clinical findings and optimal treatment parameters were associated with successful outcomes in some of our patients, little is known about which clinical factors are reliable predictors of desirable outcomes. A recent study suggests that there are few

Figure 6. (A, C) This 47-year-old woman desired a noninvasive procedure to lift and tighten her anterior midface, jowls, and neck. (B, D) One year after treatment at dual levels to the anterior midface with 4 MHz, 4.5 mm (30 horizontal lines/2.5 cm × 2.5 cm square; 2448 J in 4 squares) and 7 MHz, 3.0 mm (30 superolateral lines/2.5 cm × 2.5 cm; 1242 J in the same 4 squares). The neck received 4 MHz, 4.5 mm (30 horizontal lines/2.5 cm × 2.5 cm square; 3060 J in 5 squares) and 7 MHz, 3.0 mm (30 superolateral lines/2.5 cm × 2.5 cm square; 1552.5 J in the same 5 squares). Moderate tightening is evident in the nasolabial folds, jowls, lateral neck, and submentum.
baseline clinical indicators of success. In our study, responses were negligible in many patients who appeared to have favorable clinical prognosticators. Thus, patient selection is a challenging task. Realistic expectations remain the cornerstone for patient success and acceptance of this technique. Further studies are underway to optimize treatment maps for multiple tissue layers at labeled sites, and to treat unusual findings in off-label areas.

**CONCLUSIONS**

This research demonstrates the effectiveness of optimizing a single standardized treatment algorithm to lift tissues at 2 levels of the forehead, face, and neck by increasing the number of vectored lines and ultrasonic TCP of energy. In the pilot studies, vertical treatment lines and higher energy deposition increased the percentage of tissue lifting. In the larger clinical study, greater responses were achieved in the patients who had more lines treated and received higher joule energy (vs fewer lines and lower joule energy). Only minor side effects occurred. Further studies will be needed to optimize patient selection and to advance this technology for more effective outcomes in labeled and off-label sites.

**Acknowledgment**

The authors thank Margaret Gaston, BS, for creating the artwork and providing statistical and photographic assistance.

**Disclosures**

The authors declared no conflicts of interest with respect to the authorship and publication of this article.

**Funding**

The authors received no financial support for the research and authorship of this article.
REFERENCES