Blinded, Randomized, Quantitative Grading Comparison of Minimally Invasive, Fractional Radiofrequency and Surgical Face-lift to Treat Skin Laxity

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Objectives: To quantify the improvements in laxity from the surgical face-lift and to perform a randomized, blinded comparison with the clinical effects of a novel, minimally invasive fractional radiofrequency (FRF) system.

Study Design: Randomized, blinded, comparative trial.

Patients: Fifteen sequential patients with facial skin laxity enrolled in the trial and completed FRF treatment and follow-up. Baseline and follow-up digital photographs of patients undergoing FRF were randomly mixed with 6 sets of baseline and follow-up images of patients undergoing surgical face-lift with equivalent baseline facial laxity grades.

Main Outcome Measures: Five independent blinded evaluators graded randomized baseline and 3- to 6-month follow-up photographs using a comprehensive quantitative 4-point laxity grading scale. Quantitative changes in laxity grades were calculated and compared statistically for FRF treatment vs surgical face-lifts. Patient satisfaction and adverse events were also evaluated.

Results: Blinded grading of unmarked, randomized baseline and follow-up photographs of patients undergoing FRF treatment randomized with baseline and follow-up photographs of patients undergoing surgical face-lift demonstrated statistically significant improvement in facial laxity, with a mean grade improvement of 1.20 for patients in the surgical face-lift group and of 0.44 for FRF-treated patients on a 4-point laxity grading scale (P < .001). The improvements relative to baseline were 16% for FRF treatment compared with 49% for the surgical face-lift. The mean laxity improvement from a single FRF treatment was 37% that of the surgical face-lift. Patient satisfaction was high (dissatisfied, 0%; neutral, 7%; satisfied, 60%; and very satisfied, 33%). All participants in the FRF treatment group experienced transient erythema, mild edema, and mild to moderate purpura that resolved in 5 to 10 days, and they returned to normal activities within 24 hours. There were no adverse events or complications in the FRF group. All patients in the surgical face-lift group experienced scarring at surgical margins, erythema, edema, and ecchymosis, and they returned to normal activities on suture removal at 7 to 10 days.

Conclusions: This randomized, blinded, quantitative assessment using a validated grading scale of skin laxity improvement from the gold standard treatment, the surgical face-lift, and comparative analysis to a novel, minimally invasive FRF treatment has demonstrated 49% improvement in skin laxity relative to baseline for the surgical face-lift, compared with 16% for FRF. The surgical face-lift resulted in a mean 1.20-grade improvement on the 4-point laxity grading scale. In comparison, a single, minimally invasive FRF treatment demonstrated a 0.44–laxity grade improvement, or 37% that of the surgical face-lift, without the adverse effects and complications of surgical procedures. This study provides a basis for quantifying cosmetic outcomes from novel treatments with comparative analysis to the gold standard. It also suggests that minimally invasive FRF treatment may provide an important nonsurgical option for the treatment of facial skin laxity.

Trial Registration: clinicaltrials.gov Identifier: NCT00791414

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to our knowledge, has a valid comparative study to the gold standard of surgical face-lifts ever been conducted. The Miratone minimally invasive bipolar fractional RF (FRF) system (Primaeva Medical, Inc, Pleasanton, California) heats the dermis from within using a microcrone needle electrode array. The microcrone needle electrodes are arranged in pairs between which bipolar RF energy is delivered. Thermal lesions are fractionally generated directly within the reticular dermis. The volume of each lesion is defined by the geometry of the microcrone needle electrode pairs. Real-time feedback of lesion temperature from sensors in the tips of the microcrone needle electrodes allows energy delivery to be precisely modulated so that lesions are created at a specific preselected temperature and for defined time periods. The fractional pattern of injury, wound healing, and dermal remodeling processes induced following treatment were recently described histologically in skin to be excised in subsequent abdominoplasty or face-lift procedures. Fractional thermal injury of deep dermal collagen induced a vigorous wound healing process leading to dermal remodeling and the generation of new collagen, elastin, and hyaluronic acid, suggesting the device could become an effective treatment option with predictable outcomes for the treatment of laxity and rhytids associated with intrinsic aging. To date, there remain no published reports quantifying the laxity improvements from the gold standard treatment, the surgical face-lift, or comparatively analyzing the clinical outcome of noninvasive or minimally invasive nonsurgical treatment of skin laxity with surgical face-lift outcomes. In prior studies evaluating outcomes from surgical face-lifts, descriptive impressions were used, including “poor, good, or excellent.” In contrast, the present study is the first to use quantitative, blinded evaluations with a tested laxity grading scale. In this investigational study, we evaluate the clinical effects of FRF for the treatment of facial laxity and compare the outcomes with surgical face-lift results through randomized, blinded assessment of digital baseline and follow-up clinical photography.

METHODS

The study protocol was approved by the Western Institutional Review Board. All participants provided verbal and written consent before enrollment. Patient consent for digital photography was also obtained before treatment. Randomized (not paired in sequence) digital baseline and 3- to 6-month follow-up images of 15 sequential patients completing FRF treatment and follow-up were intermixed with 6 sets of randomized baseline and 3- to 6-month follow-up images of surgical face-lift patients with equivalent baseline facial laxity selected from a surgical face-lift pool by one of us, a plastic surgeon (D.R.). The FRF treatment and surgical face-lift photographs were equivalently cropped and randomly intermixed. Pretreatment and posttreatment photographs were not in sequence, but randomly assorted throughout the intermixed FRF and surgical photographs. Blinded grading was performed by 5 independent evaluators (J.D., K.A., and 3 others), including dermatologists and plastic surgeons, who were unaware of the nature or types of treatments being tested, using a quantitative 4-point grading scale assessing changes in skin laxity. The blinded evaluators were unaware that surgical face-lift photographs were included in this study, nor were they privy to the type of nonsurgical treatment being tested.

FRONTAL RF

Patient Selection

The FRF treatments were performed by the lead author (M.A.-A.) using a study protocol approved by an institutional review board. Inclusion criteria were being older than 18 years, in good health, and with mild to severe facial rhytids or laxity (minimum baseline laxity, grade 2). Exclusion criteria consisted of history of injection with silicone, fat, collagen, or a synthetic material in the intended treatment area, bleeding disorder, hypertrophic scar or keloid formation, isotretinoin treatment in the past 12 months, anaphylaxis, or lidocaine hypersensitivity. Other exclusion criteria included prior, current, or anticipated treatment with anticoagulants; thrombotic; chemotherapeutics; systemic corticosteroids; or anabolic steroids. Patients with a compromised immune system, impaired wound healing (eg, patients with diabetes mellitus), collagen vascular disease, an implantable electronic device (eg, pacemaker), or active infection were also excluded. Participants were required to be available for posttreatment follow-up evaluation.

FRF Treatment Protocol

Patients undergoing FRF received fixed-temperature symmetrical treatment of the lateral mid and lower face with the Miratone system. The FRF energy was delivered through 3 microcrone needle electrode pairs deployed in the reticular dermis at an angle of 20° to the skin surface, with the exposed electrode length extending from 0.75 to 2 mm below the skin surface (Figure 1). The precise intradermal location of the electrode tips was determined by real-time impedance measurements, such that impedance measurements between 300 and 2000 Ω were used to define ideal intradermal placement. Typical dermal impedance measurements were between 500 and 1500 Ω. Software built into the device precluded energy delivery if impedance between an electrode pair measured less than 300 or more than 3000 Ω, thereby restricting energy delivery to proper intradermally placed electrodes. Software was also programmed to deliver energy until a preselected intradermal target temperature was attained and for a specified duration in seconds (Figure 2). Epidermal cooling was achieved by positioning a cooling device maintained at a temperature of 15°C directly on the skin above the exposed electrode length. The spacing of the bipolar needle pairs and the spacing during successive applications of the device were selected to give 15% to 35% fractional skin coverage by surface projection. Patients 1 through 5 received topical anesthesia (EMLA cream; APP Pharmaceuticals, LLC, Schaumburg, Illinois) only, applied for 45 to 60 minutes before treatment. Conservative treatment parameters of 62°C and 3 seconds were selected for these patients. Patients 6 through 15 received additional local infiltration with diluted lidocaine (0.2% with 1:400 000 epinephrine). A local anesthetic (mean quantity, 18 mL of 0.25% lidocaine) was used in both cheeks and in the submental and lateral neck regions. For these patients, more aggressive treatment parameters of 68°C to 78°C and 5 seconds were selected. A representative real-time temperature curve for a preselected target temperature of 70°C for 5 seconds is shown in Figure 2. Before treatment, the patient’s skin was cleansed with Betadine (Purdue Pharma, Stamford, Connecticut), and treatments were delivered medial to lateral in rows following anatomical margins. Postoperatively, the patient’s skin was cleansed with isotonic sodium chloride solution, and a thin coat of white petrolatum was applied. Patients were allowed to resume normal activities immediately and were instructed to wash the skin with mild cleansers, to avoid makeup for 24 hours, and to minimize sun exposure for 14 days. Patients were required to report any discomfort, ad-

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verse effects, and complications during or following treatment and completed questionnaires at each follow-up visit. Patients were followed up at 1, 3, and 6 months following treatment. During 3- and 6-month follow-up visits, patients were asked to rate their overall satisfaction and their impression of wrinkles and laxity improvement using a 5-point scale.

SURGICAL FACE-LIFT PROCEDURE

Surgical face-lifts were performed by one of us (D.R.). Each patient received general endotracheal and local anesthesia. The procedure consisted of submentoplasty, suction and excisional lipectomy, and deep-plane plication. The incision and dissection extended from the malar eminence and mandibular angle into the neck in the preplatysmal plane to the midline and submental incision. The deep-plane dissection extended deep to the jowl fat and inferiorly to 2 cm below the mandibular angle and continued anteriorly within the fibroadipose tissues of the melolabial fold and deep to the superficial muscular aponeurotic system of the jowl. The melolabial fold was approached by undermining the fibroadipose layer of the cheek overlying the zygomatic muscles and anteroinferiorly to the nose and lip. The superficial muscular aponeurotic system of the jowl was undermined from the parotid gland to the masseter. The dissection continued anteriorly over the masseter muscle border and inferiorly over the lower border of the mandible, extending anteriorly to where the facial artery crosses. The cheek flap was closed by suturing the superficial muscular aponeurotic system flap to the preauricular tissue and anchoring the flap posteriorly, just anterior to the tragus. The platysmal flap, beginning at the mandibular angle, was sutured to the mastoid peristeum. Redundant preauricular tissue was excised. Excision and closure of the skin flap commenced at the apex of the postauricular incision, followed by skin excision and closure anteriorly and posteriorly. The postauricular, hair-bearing region and temporal incision were closed superficially with staples and sutures. A compression head dressing was placed and secured with burn netting. Patients received treatment overnight by a registered nurse, were instructed about wound care, and had sutures removed 7 to 10 days posttreatment.

QUANTITATIVE LAXITY GRADING, ASSESSMENTS, AND STATISTICAL ANALYSIS

Standardized photographs were taken for the FRF patient group at baseline on the day of treatment and during each follow-up visit. Standardized photographs were taken for the surgical face-lift pool during their preoperative office visit and during routine 3- to 6-month follow-up visits. Six sets of baseline and follow-up surgical face-lift images with baseline facial laxity spanning mild (n=1), moderate (n=3), and advanced (n=2) categories were selected by one of us (D.R.) as representative surgical face-lift patients. Photographs were taken...
using a digital single-lens reflex camera (model E-500; Olympus America, Central Valley, Pennsylvania) fitted with an external shoe-mounted electronic flash (model FL-50, Olympus America) and a fixed focal length 50-mm 1:2 macro lens (Olympus ED), using standardized settings (F9.0, 1/125, ISO400) from a 1-m distance and in a photography room with set lighting for every patient. The FRF treatment and surgical face-lift photographs were equivalently cropped and randomized. Five independent blinded evaluators graded the unidentified images using a Quantitative Comprehensive Grading Scale for facial and neck laxity8-10 (Table 1). The grading system is binary, and blinded evaluators determine the patient’s laxity grade category based on the presence or absence of a given finding (eg, melolabial folds). Two of the blinded evaluators (J.D. and K.A.) have used this grading scale in a prior study.12 The evaluators were not informed of the randomized comparison to the surgical face-lift or of the nature of the intervention. Upon unblinding, the results were tabulated, grouped, and analyzed. Mean baseline and follow-up grades with standard deviations were calculated for each patient. The reliability of the grade assignment agreement of independent evaluators was assessed by calculating a Fleiss $\kappa$ statistic using each one-half point grade assignment from 0 to 4 of the laxity scale as categorical ratings. The improvement for each patient was calculated as the difference between the mean baseline and mean follow-up grades, and a paired $t$ test was used to assess statistical significance. The mean baseline and follow-up grades for each treatment modality group were then averaged and compared using a paired $t$ test. The percentage FRF to surgical face-lift result and the percentage improvement over baseline for each patient pool were calculated.

RESULTS

DEMOGRAPHIC CHARACTERISTICS

Fifteen sequential patients completing treatment and follow-up were included in the FRF group. All patients were women, and the mean (SD) age was 59.7 (8.9) years. Two patients (13%) were Fitzpatrick skin type I, 8 (53%) were type II, 4 (27%) were type III, and 1 (7%) was type IV. In the surgical face-lift group (6 patients), all patients were women, and the mean (SD) age was 54.0 (9.2) years. Three patients (50%) were Fitzpatrick skin type I and 3 (50%) were type II. The baseline mean laxity grades were similar: 2.76 for
by blinded evaluators to assess the baseline and follow-up laxity grades following surgical face-lift and FRF treatment in the present study. Photographic examples of typical patient outcomes from patient pools were 0.44 (0.20) improvement for the FRF treatment and surgical face-lift patient groups are shown. The mean (SD) laxity grade improvement for the FRF treatment was 37% that of the surgical face-lift. There was good agreement between the laxity grades assigned by all independent evaluators (Fleiss $\kappa = 0.45$), with standard errors less than or equal to the laxity scale resolution. The mean (SD) laxity grade improvement for the FRF treatment and surgical face-lift patient pools were 0.44 (0.20) ($P < .001$) and 1.20 (0.44) ($P < .001$), respectively. The percentage improvements relative to mean baseline for the FRF treatment and surgical face-lift patient pools were 16% and 49%, respectively. The mean percentage improvement for FRF treatment was 37% that of the surgical face-lift.

Patient self-assessments of clinical improvements from FRF yielded a mean rating of moderate for rhytids and moderate to significant for laxity. Patient satisfaction with FRF treatment was high: 0% were dissatisfied; 7%, neutral; 60%, satisfied; and 33%, very satisfied.

### EFFICACY

Photographic examples of typical patient outcomes from surgical face-lift and FRF treatment are shown in Figures 3, 4, 5, 6, and 7. The results of the blinded grading evaluation and statistical analysis for the FRF treatment and surgical face-lift patient groups are shown in Table 2. These results are summarized and compared in Table 3. There was good agreement between the laxity grades assigned by all independent evaluators (Fleiss $\kappa = 0.45$), with standard errors less than or equal to the laxity scale resolution. The mean (SD) laxity grade improvement for the FRF treatment and surgical face-lift patient pools were 0.44 (0.20) ($P < .001$) and 1.20 (0.44) ($P < .001$), respectively. The percentage improvements relative to mean baseline for the FRF treatment and surgical face-lift patient pools were 16% and 49%, respectively. The mean percentage improvement for FRF treatment was 37% that of the surgical face-lift.

### ADVERSE EVENTS

There were no adverse events or complications in the FRF treatment group. All participants experienced transient erythema, swelling, and ecchymoses, which resolved in 5 to 10 days. On a scale of minimal, mild, moderate, advanced, and severe, the erythema was mild to moderate and resolved within 24 hours in the vast majority of patients. The edema varied from minimal to moderate among the patients and resolved gradually in 5 to 10 days. Ecchymoses varied from minimal to advanced and resolved within 24 hours in the vast majority of patients. The edema varied from minimal to moderate among the patients and resolved within 24 hours. There were no adverse events or complications in the FRF treatment group. All participants experienced transient erythema, swelling, and ecchymoses, which resolved in 5 to 10 days. On a scale of minimal, mild, moderate, advanced, and severe, the erythema was mild to moderate and resolved within 24 hours in the vast majority of patients. The edema varied from minimal to moderate among the patients and resolved gradually in 5 to 10 days. Ecchymoses varied from minimal to advanced and resolved within 24 hours in the vast majority of patients. The edema varied from minimal to moderate among the patients and resolved within 24 hours.

### Table 1. Quantitative Comprehensive Grading Scale of Rhytids, Laxity, and Photoaging

<table>
<thead>
<tr>
<th>Grading Scale</th>
<th>Descriptive Parameter</th>
<th>Rhytids</th>
<th>Laxity</th>
<th>Elastosis</th>
<th>Dyschromia</th>
<th>E-T</th>
<th>Keratoses</th>
<th>Texture</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild</td>
<td>Wrinkles in motion: few, superficial</td>
<td>Localized, NL folds</td>
<td>Yellow hue or early localized PO EB</td>
<td>None</td>
<td>Few (1-3) discrete, small (≤ 5 mm) lentigines</td>
<td>Pink E or few T, localized to a single site</td>
<td>None</td>
</tr>
<tr>
<td>1.5</td>
<td>Mild</td>
<td>Wrinkles in motion: multiple, superficial</td>
<td>Localized, NL and early ML folds</td>
<td>Yellow hue or early localized PO EB</td>
<td>None</td>
<td>Few (1-3) discrete, small (≤ 5 mm) lentigines</td>
<td>Pink E or few T, localized to 2 sites</td>
<td>Several</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>Wrinkles at rest: few, localized, superficial</td>
<td>Localized, NL/ML folds, early jowls, early submental/SM</td>
<td>Yellow hue, localized PO EB</td>
<td>None</td>
<td>Multiple (7-10) small lentigines</td>
<td>Red E or multiple T, localized to 2 sites</td>
<td>Multiple, small</td>
</tr>
<tr>
<td>2.5</td>
<td>Moderate</td>
<td>Wrinkles at rest: multiple, localized, superficial</td>
<td>Localized, prominent NL/ML folds, jowls and SM</td>
<td>Yellow hue, PO and malar EB</td>
<td>None</td>
<td>Multiple small and few large lentigines</td>
<td>Red E or multiple T, localized to 3 sites</td>
<td>Multiple, large</td>
</tr>
<tr>
<td>3</td>
<td>Advanced</td>
<td>Wrinkles at rest: multiple forehead, periorbital, and perioral sites, superficial</td>
<td>Prominent NL/ML folds, jowls and SM, early neck strands</td>
<td>Yellow hue, EB involving PO, malar and other sites</td>
<td>None</td>
<td>Many (10-20) small and large lentigines</td>
<td>Violaceous E or many T, multiple sites</td>
<td>Many</td>
</tr>
<tr>
<td>3.5</td>
<td>Advanced</td>
<td>Wrinkles at rest: multiple generalized, superficial; a few deep</td>
<td>Deep NL/ML folds, prominent jowls and SM neck strands</td>
<td>Deep yellow hue, extensive EB with little uninvolved skin</td>
<td>None</td>
<td>Numerous (&gt;20) or multiple large lentigines with little uninvolved skin</td>
<td>Violaceous E and numerous T, little uninvolved skin</td>
<td>Little uninvolved skin</td>
</tr>
<tr>
<td>4</td>
<td>Severe</td>
<td>Wrinkles throughout: numerous, extensively distributed, deep</td>
<td>Marked NL/ML folds, jowls and SM, neck redundancy and strands</td>
<td>Deep yellow hue, EB throughout, comedones</td>
<td>None</td>
<td>Numerous, extensive lentigines; no uninvolved skin</td>
<td>Deep, violaceous E and numerous T throughout</td>
<td>No uninvolved skin</td>
</tr>
</tbody>
</table>

Abbreviations: EB, elastotic beads; E-T, erythema-telangiectasia; FRF, fractional radiofrequency; ML, melolabial; NL, nasolabial; PO, perio-orbital; SM, submental/submandibular.

*This 4-point grading scale has been extensively tested and used for evaluating laser and energy-based cosmetic treatments.*

The laxity category was used by blinded evaluators to assess the baseline and follow-up laxity grades following surgical face-lift and FRF treatment in the present study.
posterior-auricular regions. These were treated postoperatively with intralesional triamcinolone acetonide and pulsed dye laser localized to the scar margins. Ecchymoses and edema were present in all patients postoperatively for 2 to 4 weeks. The ecchymoses were mild to advanced and resolved by the 4-week follow-up visit. The edema varied from mild to advanced and resolved within 2 to 4 weeks. Among the 6 patients selected, no patients experienced hematoma formation, flap necrosis, or infection. Patients returned to normal activities within 7 to 10 days.

### COMMENT

In evidence-based medicine, it is generally agreed that the validity of a novel treatment is best tested by comparative trial to the gold standard. Until now, such a comparative trial had not been performed for nonsurgical treatments of skin laxity, owing to the absence of a quantitative measure for the outcome of the surgical face-lift. In this study, a quantitative blinded graded value in laxity improvement has been assigned to the gold standard surgical face-lift, allowing for comparison with a minimally invasive nonsurgical FRF treatment.

| Table 2. Blinded Grading Data of 15 FRF and 6 Surgical Face-lift Patients* |
|-----------------------------|---------------------|---------------------|---------------------|---------------------|
| **Patient No.** | **Grade (SD)** | **Grade (SD)** | **Laxity Change** | **P Value** |
| FRF Treatment Group | | | | |
| M01 | 2.7 (0.3) | 2.1 (0.4) | 0.6 | .004 |
| M02 | 3.0 (0.0) | 2.4 (0.2) | 0.6 | .004 |
| M03 | 2.4 (0.2) | 1.9 (0.2) | 0.5 | <.001 |
| M04 | 2.3 (0.4) | 1.7 (0.3) | 0.6 | .004 |
| M05 | 3.0 (0.5) | 2.6 (0.5) | 0.4 | .02 |
| M06 | 3.3 (0.3) | 3.1 (0.5) | 0.2 | .18 |
| M07 | 3.4 (0.4) | 3.0 (0.4) | 0.4 | .10 |
| M08 | 2.3 (0.3) | 1.7 (0.3) | 0.6 | .004 |
| M09 | 2.4 (0.4) | 2.0 (0.4) | 0.4 | .10 |
| M10 | 2.0 (0.0) | 1.5 (0.0) | 0.5 | <.001 |
| M11 | 2.2 (0.3) | 1.5 (0.0) | 0.7 | .005 |
| M12 | 3.8 (0.3) | 3.3 (0.3) | 0.5 | <.001 |
| M13 | 3.5 (0.0) | 3.5 (0.0) | 0.0 | NA |
| M14 | 2.5 (0.5) | 2.4 (0.2) | 0.1 | .70 |
| M15 | 2.4 (0.4) | 1.9 (0.4) | 0.5 | <.001 |
| Mean | 2.75 | 2.31 | 0.44 | <.001 |

| Surgical Face-lift Group | | | | |
| P1 | 2.8 (0.4) | 1.3 (0.4) | 1.5 | <.001 |
| P2 | 3.4 (0.4) | 1.8 (0.4) | 1.6 | <.001 |
| P3 | 2.0 (0.4) | 1.4 (0.2) | 0.6 | .03 |
| P4 | 3.2 (0.3) | 1.7 (0.3) | 1.5 | .001 |
| P5 | 2.0 (0.4) | 1.3 (0.3) | 0.7 | .005 |
| P6 | 1.4 (0.2) | 0.1 (0.2) | 1.3 | <.001 |
| Mean | 2.47 | 1.27 | 1.20 | <.001 |

Abbreviations: FRF, fractional radiofrequency; NA, not applicable.

*Each randomized digital baseline and follow-up image was evaluated by 5 blinded evaluators using the quantitative 4-point laxity grading scale. Upon unblinding, the mean baseline and follow-up laxity grades were calculated for each FRF and surgical face-lift patient, and the mean change in laxity grade was calculated. In both groups, the mean laxity grade change was statistically significant ($P < .001$).

When assessed by 5 blinded evaluators of randomized photographs, the mean laxity grade improvement from the surgical face-lift in this cohort of patients was 1.20 on a 4-point laxity grading scale, with FRF treatment achieving a 0.44-grade improvement (Table 3). The improvement in skin laxity relative to baseline from a surgical face-lift was calculated as 49%, and FRF treatment resulted in a 16% improvement over baseline, or 37% of a surgical face-lift result from a single minimally invasive treatment. A 16% laxity improvement above the baseline from a single nonsurgical intervention is a significant improvement, considering that the gold standard treatment with its associated risks and complications yielded a 49% improvement.

The laxity improvements quantified here for the surgical face-lift and this novel RF device provide needed evidence-based outcome measurements for what has been a largely descriptive field and will assist in managing patient expectations. The mean improvement in laxity grade of 1.20 for the surgical face-lift indicates that this gold standard procedure can provide a reduction in a patient’s laxity grade from severe to advanced, advanced to moderate, or moderate to mild, but will not, on average, improve laxity from severe to moderate, advanced to mild, or moderate to none. By placing patients in a specific laxity grade category, it is now possible to show them on the grading table what outcome to expect from a single grade

Figure 3. Surgical face-lift patient (P2) at baseline (A) and at the 6-month follow-up visit (B). Blinded grading by 5 independent physicians resulted in a mean improvement in skin laxity of 1.60 grades on the 4-point grading scale. Blinded evaluators were unaware of the types of treatments being evaluated (fractional radiofrequency or surgical face-lift) and were also blinded to pretreatment and posttreatment photographs.
reduction following a surgical face-lift, thereby tempering expectations in specific terms. Of equal importance, the quantitative measure of relative outcome of nonsurgical alternatives enables patients to make more informed choices from among different treatment modalities based on their baseline condition and treatment expectations. The findings and methods presented herein provide a basis for future studies to test the validity of novel therapies and to quantitatively assess and compare changes in skin laxity from surgical and nonsurgical treatments alike to the gold standard treatment.

Two important aspects of the methods used in the present study were the rigor of randomization and blinded evaluation and the use of a quantitative grading scale. Base-line and follow-up photographs from patients undergoing both surgical face-lift and FRF were randomly assorted, then sent to 5 independent evaluators who were blinded to which image was baseline or follow-up and to the types of treatments being compared. The evaluators were unaware that photographs of 2 different treatment modalities were randomly intermixed or that surgical face-lift photographs were included in the study. The use of 5 evaluators, including dermatologists and plastic surgeons, allowed for greater statistical accuracy of laxity grades.

Given the rigor of blinding and the inclusion of dermatologist and plastic surgeon graders, the benefits of grading to a quantitative scale was demonstrated by the strong agreement between laxity grades assigned by all independent evaluators. The grading system resulted in narrow standards of error and a Fleiss \( \kappa \) statistic of 0.45, consistent with strong agreement given the nine 1⁄2-grade categories and 5 graders. The baseline mean laxity grades in the 2 groups were similar, with a slightly higher baseline grade for the FRF group (2.76 vs 2.47 for surgical face-lift), therefore eliminating bias toward more advanced cases in the surgical face-lift group. The extent of change in laxity from surgical treatment is greater than that from FRF; therefore, fewer surgical than FRF participants were required to achieve statistical significance. Statistical significance was achieved in both patient pools, suggesting that the number of patients in each pool was appropriate for the degree of improvement achieved.

This study is the first to use a reproducible, quantitative grading scale for the evaluation of skin laxity by blinded evaluators to assess the clinical outcome from the surgical face-lift and to compare it with an alternative, nonsurgical therapy. Nonsurgical skin tightening...
techniques have previously been quantitatively assessed using this grading scale; however, the current device demonstrated much higher efficacy in treating skin laxity. These prior device studies reported 0.075 to 0.236 mean laxity grade improvement per treatment.\(^9,11-13\) All of these previously tested techniques were skin-surface applied RF or infrared laser or light devices. The current device demonstrated a mean grade improvement of 0.44, significantly higher than all prior studies following a single treatment. Prior skin-surface RF devices have been observed to yield lower efficacy in reducing laxity in fat faces; in contrast, the FRF treatment demonstrated similar laxity grade reductions among the thin vs fat faces in the present study, although the numbers were too small for statistical comparison.

To date, there has been no prior report of surgical face-lifting evaluated with quantitative grading scales by blinded evaluators. Prior studies evaluating the improvements from surgical face-lifts have used subjective, descriptive grades of “poor,” “good,” or “excellent” in an unblended manner.\(^5,7\) In addition, it is important to note that the surgical face-lift entails treating the subcutaneous and deeper tissues, including lipectomy and platysmal flaps, in contrast to FRF, which only targets the dermis (see the “FRF Treatment Protocol” sub-subsection of the “Methods” section). Thus, the results of the quantitative, blinded, and randomized study design presented here provide the first quantitative measure of laxity improvements from the surgical face-lift and a basis for comparison of this novel FRF technology with prior skin-tightening technologies. The findings presented here also now make possible further research into translation of clinical laxity grade reductions from these “turn-back-the-clock” treatments into age-specific reductions. The rationale for such an analysis is that the current laxity grading scale with its small margins of error among 5
back, allowing a specific target temperature of 62°C to
technological advantage of real-time temperature feed-
output. The current FRF device has the
advantage of prior modalities is that temperature at-
ment in the dermis is theoretical based on Monte-
significant clinical results that can be compared with the gold standard
and that can be designed rationally to target specific bio-
logical end points.

In conclusion, the gold standard treatment, the sur-
gical face-lift, has been quantified in its degree of im-
provement in skin laxity and compared with a novel, mini-
mally invasive FRF treatment using randomized, blinded
grating with a previously tested laxity grading scale. This
randomized, blinded, quantitative comparative study pro-
vides a basis for quantifying cosmetic outcomes from novel
treatments with valid comparative analysis to the gold
standard. It also suggests that minimally invasive FRF
treatment may provide an important nonsurgical op-
tion for the treatment of facial skin laxity.

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REFERENCES

