

Radiofrequency Treatment for Middle and Lower Face Laxity

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Objective: To compare the effectiveness of 1 and 2 radiofrequency (RF) treatments with the ThermoCool TC system (Thermage Inc, Hayward, Calif) on middle and lower face laxity.

Methods: Twenty patients with mild to moderate laxity of the middle and lower face were randomly assigned to receive either a single RF treatment or 2 treatments spaced 1 month apart. Treatment energy levels were titrated to patient tolerance and ranged from 85 to 135 J/cm². Acute clinical response was recorded after each session. Standardized photographs were taken before treatment and at 1 and 4 months after the last treatment. Using a percentage scale, 4 blinded physicians experienced in dermatologic laser therapy independently rated improvement in nasolabial folds, marionette lines, jowls, laxity under the chin, and overall appearance. In addition, subjects completed quality-of-life surveys 1 and 4 months after treatment. Each patient paid the same fee for involvement in the study.

Results: Eleven patients received a single RF treatment, and 9 patients underwent 2 treatments. All subjects experienced mild edema and mild to moderate erythema as an acute clinical response; no patients

experienced burns, skin breakdown, or scarring. At 4-month follow-up, patients in the 2-treatment group received higher scores in all categories of photographic analysis; the difference in improvement in the nasolabial folds was statistically significant ($P=.04$). In self-assessment ratings, individuals receiving 2 treatments reported more improvement than subjects in the single-treatment group 4 months after treatment ($P=.03$). In both treatment groups, physician photographic assessment demonstrated continued improvement in all subsites between the 1-month and 4-month assessments ($P<.05$). Although the overall change noted by both patients and physicians was modest in most patients, 75% of subjects ($n=15$) stated they would consider paying for additional treatments.

Conclusions: Two RF treatments yielded significantly better improvement than a single treatment in the nasolabial folds. Significant improvement in laxity after treatment was seen between the 1- and 4-month follow-up visits in both single- and 2-treatment groups. Although overall improvements were modest in both groups, patient satisfaction was relatively high.

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FACIAL RHYTIDS RELATED TO skin laxity and photodamage have been traditionally treated with surgical intervention or ablative skin resurfacing. Over the past several years, facial cosmetic surgeons have sought to match the rejuvenative effects of these invasive techniques while minimizing recovery time and the risks of postoperative infection, dyschromia, and scarring. Nonablative skin resurfacing technologies share a common method of inducing thermal dermal injury while preserving epidermal integrity. Immediate heat-induced changes in collagen structure and long-term dermal collagen remodeling are believed to induce tissue tightening. While several noninvasive laser and light-based systems have been clinically evaluated and

approved for use by the US Food and Drug Administration (FDA) for the treatment of facial rhytids, the clinical results have not approached those of traditional resurfacing techniques.^{1,2} In addition, multiple treatment sessions over several months are typically required.

In contrast to light-based nonablative resurfacing, radiofrequency (RF) treatment applies RF energy to the skin with concomitant cryogen cooling of the epidermis. Tissue resistance to RF energy generates heat, which causes a controlled thermal dermal injury. A capacitor membrane at the treatment tip allows controlled and uniform application of heat; the geometry and size of the treatment tip affects the depth of injury. Ultrastructural and Northern blot analysis of treated skin has demonstrated epidermal preservation,

thermal changes in collagen fibrils, and increased type I collagen messenger RNA steady-state expression.³ Although less uniform, dermal changes paralleled those seen in skin after ablative carbon dioxide laser resurfacing.^{4,5}

Clinical results using the ThermoCool TC RF system (Thermage Inc, Hayward, Calif) to treat tissue laxity in the periorbital areas, forehead, and middle and lower face have been encouraging.⁶⁻¹² The device has received FDA approval for the noninvasive treatment of facial wrinkles and rhytids in the periorbital area and has been approved by the Canadian Health Protection Branch for non-surgical brow-lift and nonsurgical tightening of periorbital and facial tissue, including rhytids. While initial results have generally been modest, treatments have been well tolerated with minimum adverse effects and negligible recovery time. Treatment with higher energy levels has correlated with improved results.^{9,12} Greater improvement of laxity has also been noted in patients receiving multiple RF treatments, although this has not been studied in a controlled fashion.¹⁰ The purpose of the present study was to compare the effectiveness of 1 RF treatment with 2 treatments on middle and lower face laxity.

METHODS

The study protocol was approved by the Abbott Northwestern Hospital institutional review board. Twenty patients with mild to moderate laxity of the middle and lower face, selected from the investigators' clinical practice, were randomly assigned to receive either a single RF treatment or 2 treatments spaced 1 month apart. Exclusion criteria included prior cosmetic facial surgery or placement of tissue fillers, scarring in the treatment region, and/or allergy to topical anesthetics. Demographics, medical history, and Fitzpatrick skin type were recorded. In exchange for participation in the study, patients received treatment(s) at a uniform discounted rate (1/3 off the price of a single treatment).

Patient treatment areas were marked with a 1-cm² grid pattern. In the middle face, the treatment zone extended laterally from the nasolabial folds to the preauricular area and mandibular angle; the lower face treatment area extended inferomedially from the mandible to the middle neck. Topical anesthetic (5% lidocaine) was applied for at least 30 minutes prior to treatment then completely removed. After application of conductive fluid, each 1×1-cm grid square was treated in a single pass without overlap using the 1-cm tip. Treatment energy levels were titrated to patient tolerance and ranged from 85 to 135 J/cm².

Acute clinical response was recorded after each session to assess skin changes, including edema, erythema, and blistering. Immediately after treatment, subjects rated pain experienced during treatment on a 0 to 4 scale (0, no pain; 4, severe pain). Standardized photographs (5 views) were taken at baseline and at 1 and 4 months after the last treatment. At the 1- and 4-month posttreatment follow-up visits, subjects completed a self-assessment questionnaire and rated improvement in facial laxity on a scale from 0 (worsened laxity) to 4 (marked improvement). Subjects also rated their likelihood of pursuing additional treatments at full price.

Using a percentage scale, 4 blinded physicians experienced in cutaneous laser therapy and cosmetic surgery independently rated improvement in nasolabial folds, marionette lines, jowls, laxity under the chin, and overall appearance. Mean improvement in each category for the single- and 2-treatment groups were compared using an independent sample *t* test. Mean

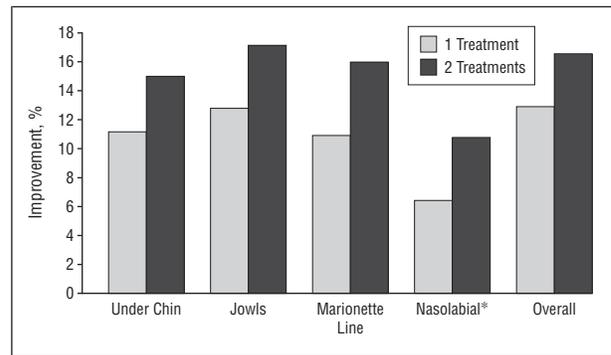


Figure 1. At 4-month follow-up, patients in the 2-treatment group received higher scores than those in the single-treatment group in all categories of photographic analysis. The asterisk indicates a significant difference.

self-assessment scores with respect to subjects' estimates of improvement and willingness to have additional treatments were also compared with independent sample *t* tests.

RESULTS

Study patients included 19 women and 1 man ranging in age from 40 to 63 years (mean age, 51 years). Thirteen subjects had Fitzpatrick skin type II, 6 had type III, and 1 had type IV. Eleven patients received a single RF treatment, and 9 patients underwent 2 treatments.

All subjects experienced mild edema and mild to moderate erythema as an acute clinical response; no patients experienced burns, skin breakdown, or scarring. Mean pain rating on a scale from 0 to 4 was 2.81 after the first treatment and 2.5 after the second session; 2 patients rated the pain as severe. After her first treatment, 1 patient assigned to the 2-treatment group experienced exacerbation of symptoms from a preexisting temporomandibular joint condition. Her symptoms resolved fully within 2 months. Although a clear correlation between her treatment and symptoms could not be established, a second session was not scheduled.

At 4-month follow-up, patients in the 2-treatment group received higher scores in all categories of photographic analysis (**Figure 1**). However, only the difference in improvement in the nasolabial folds was statistically significant ($P=.04$). Differences in jowl ($P=.09$) and marionette line ($P=.05$) improvement were of borderline significance. On self-assessment, individuals who received 2 treatments reported more improvement than those in the single-treatment group 4 months after treatment ($P<.05$) (**Figure 2**). In both the single- and 2-treatment groups, physician photographic assessment demonstrated continued improvement in all subsites from 1 month to 4 months ($P<.05$).

The overall change noted by both patients and physicians was modest in most patients (**Figure 3** and **Figure 4**). Two patients in the single-treatment group and 1 patient in the 2-treatment group were judged to have minimal response to treatment (less than 10% overall improvement). There was no clear correlation between response to treatment and patient age or skin type. Despite the less than dramatic results overall, 75% of subjects ($n=15$) responded that they would consider paying

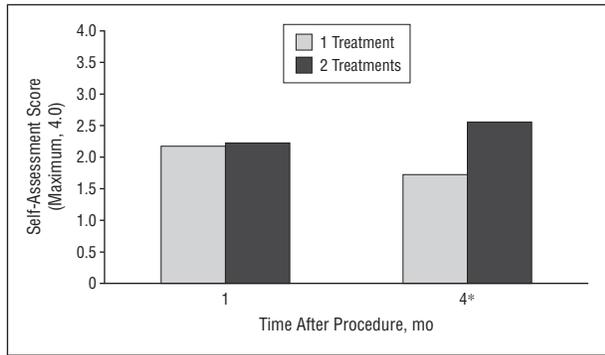


Figure 2. Patient self-assessment of improvement in middle and lower face laxity. The asterisk indicates a significant difference.

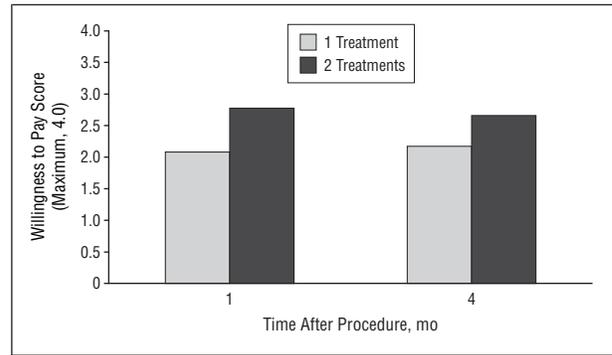


Figure 5. Patient willingness to pay for additional treatments.



Figure 3. Pretreatment (A) and 4 months posttreatment (B) in subject receiving a single treatment.



Figure 4. Pretreatment (A) and 4 months posttreatment (B) in subject receiving 2 treatments.

for additional treatments, and more than 50% (11/20) would strongly consider doing so (**Figure 5**).

COMMENT

The promising results of nonablative RF tissue tightening were first reported in the periorbital areas. A multicenter study of 86 patients demonstrated measurable brow elevation and modest clinical improvement in

periorbital rhytids in 80% of subjects⁶; a separate study showed improvement of lower eyelid laxity in 9 of 9 patients.⁷ More recently, however, nonuniform clinical effects and the potential for asymmetric brow elevation have been described.⁸ Concerns regarding the potential for subtle variations in tissue tightening may make the ThermoCool TC device more ideally suited to areas where minor asymmetries are less likely to produce clinically observable results (eg, the middle and lower face).

Several reports have demonstrated the efficacy of RF treatments for middle and lower face laxity.⁹⁻¹² In an evaluation of 40 patients with middle and/or lower face laxity and rhytids, photodamage, or acne scarring, Iyer et al¹⁰ reported that 12 patients who received more than 1 treatment noticed further improvement after successive treatments. However, the lack of uniformity of site or number of additional treatments did not allow for definitive conclusions. Our data support the observation that multiple treatments can produce significantly better results. The more dramatic clinical response in the nasolabial folds seen in the present study has also been noted by other researchers.^{11,12}

The proposed mechanism of RF tissue tightening through immediate thermally induced collagen reorganization followed by remodeling is supported by clinical observation and ultrastructural analysis.^{3,10,11} The present study also demonstrated continued clinical improvement over time. Blinded photographic analysis consistently demonstrated significant clinical improvement between 1- and 4-month follow-up visits. This observation extended to all treated subsites in both single- and 2-treatment groups and underscores the importance of long-term follow-up when reporting treatment results.

Although most patients treated with the ThermoCool TC System have had minimal adverse effects and consistently modest to moderate improvement in skin laxity, reports of patient satisfaction have varied widely.^{7-9,12} The high rate of satisfaction in the present study despite modest improvement and substantial patient expense (2/3 of regular fee) may reflect thorough pretreatment patient education and realistic expectations of clinical results. Our patients attended informational sessions on the mechanism of action of the RF device as well as observed clinical results. They were shown before and after treatment photographs of patients treated with RF who had achieved typi-

cal results. Prior to actual enrollment, the treating physician again addressed risks, benefits, treatment discomfort, and anticipated results in detail.

Despite improved clinical effects in our 2-treatment group, the results fall significantly short of improvements regularly attained through invasive techniques. However, continued refinement of techniques, including the use of multiple treatments, multiple passes, and adjusted energy levels, may carry results to a level that will satisfy patients and physicians alike. Excellent patient tolerance, consistent results, and the low incidence of complications justify further study in RF tissue tightening.

The data reported in the present study support several conclusions. First, using a single-pass technique, 2 treatments of the middle and lower face with the ThermaCool TC System produce better results than a single treatment. Second, clinical findings indicate that facial laxity continues to undergo significant improvement between 1 and 4 months after the procedure. Finally, although most results with ThermaCool TC are mild to moderate improvement, the procedure is well tolerated and has an extremely low adverse effect profile and minimal to no down time. Patient satisfaction is critically linked to thorough pretreatment education and accurate expectations.

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