Evaluation of the Multiple Pass, Low Fluence Algorithm for Radiofrequency Tightening of the Lower Face

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Background and Objective: Non-ablative monopolar radiofrequency technology delivers heat to the deep dermis and subdermal layers of the skin to improve facial laxity. The purpose of this study is to evaluate the multiple pass, low fluence treatment algorithm for lower face laxity.

Study Design/Materials and Methods: Sixty-six subjects with moderate facial laxity were treated with a maximum of 5 passes over the lower face and neck. Treated areas were evaluated using the Leal Laxity Classification System and by independent photographic assessment. Measurements of skin stiffness and energy absorption were taken with the BTC2000 device.

Results: The average treatment level was 62.0 (83 J/cm²) with 556 pulses per treatment. At the 6 month follow-up visit, 92% of patients had a measurable improvement in overall appearance. Independent photographic review revealed improvement in 84% of subjects at 6 months. Objective measures utilizing the BTC2000 device demonstrated improvement that diminished with time.

Conclusion: The low-fluence, multiple pass technique is an effective algorithm for radiofrequency skin tightening.


Key words: Thermage; tightening; skin contraction; ThermaCool; rhytids; noninvasive; nonablative; rejuvenation; aging; laxity

INTRODUCTION

Monopolar radiofrequency devices can deliver uniform heating at controlled depths to the deep dermis and subdermal layers of the skin, causing immediate collagen contraction and subsequent remodeling over the course of months. It is thought that volumetric heating of the dermis causes direct tissue tightening by breaking hydrogen bonds in the collagen triple helix, causing contraction. Electron microscopic evaluation of skin immediately post-treatment supports a morphological change in individual collagen fibrils with contracted, partially denatured collagen in the mid to deep dermis [1]. Studies have also found selective contraction of fibrous septae in the subcutaneous fat, which is thought to be responsible for the inward, Z-dimension tightening [2]. This gives the patient immediate, visible improvement the day of the procedure with continued improvement over the course of 4 to 6 months from a delayed wound healing response.

Prior studies with the original 1-cm tips have shown good results in skin tightening over the forehead, cheeks, peri-orbital area, jowls, and neck with treatment energies ranging from 58 to 144 J/cm² [3–6]. In the first multicenter trial to evaluate non-ablative, monopolar radiofrequency for skin tightening, Fitzpatrick et al. [3] found a baseline to 6-month improvement in 83% of subjects, treating at energies of 58–140 J/cm² and an average 68 repetitions (REPS) per treatment. Alster et al. [4] evaluated the 1 cm tips in the treatment of cheek, jawline, and neck laxity. They found a 35 to 40% subjective improvement of nasolabial and mesolabial folds and a 30 to 35% improvement in submandibular and neck laxity. Average treatment fluences were 130 J/cm² on the cheek and 110 J/cm² on the neck [4]. Moy et al. [6] published their findings on the improvements in eyebrow position and cheek laxity in 10 patients using a system of objective measurements. They analyzed jowl surface area changes after split-face treatment with the 1.0 cm tip at fluences from 97 to 143 J/cm² [6]. The treated jowl decreased in surface area by 22.6% and the untreated jowl did not change [6]. Early studies hypothesized that higher treatment energy levels may correlate with an improved clinical response [4,5]. The average number of REPS was not considered a major variable for success, and for patients treating multiple areas (cheeks, jawline, and neck), the total was approximately 100 REPS [5]. The present study was undertaken to evaluate whether performing treatments at lower energies with multiple passes and more pulses could achieve equal or better results to the previously used techniques.

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MATERIALS AND METHODS

Patient Selection

The study was open to male or female volunteers, at least 35 years of age, with moderate facial skin laxity and skin types I–IV. Detailed exclusion criteria can be found in Table 1.

The Radiofrequency Device

The ThermaCool radiofrequency skin tightening device (Thermage Corporation, Haywood, CA) consists of a radiofrequency generator, processing computer, cooling component, hand piece, and single use treatment tip. The radiofrequency generator produces a 6 MHz alternating current that creates an electric field through the skin. The electric field shifts polarity 6 million times per second, causing a change in orientation of charged particles within the electric field. Tissue resistance to this particle movement generates heat.

Contact cooling from cryogen spray on the inner surface of the treatment tip occurs before, during and after each energy pulse to protect the epidermis and create a reverse energy gradient where temperatures are highest in the deep dermis and coolest near the epidermis. A computer within the device receives and displays real-time data from a microprocessor in the treatment tip on pressure, current flow, and skin temperature. Internal monitors will not permit a complete radiofrequency pulse if any parameters fall outside preprogrammed limits. Thus, feedback from the treatment tip to the computer in the radiofrequency generator regulates the amount of energy applied to the tissue.

The current study was performed using the 1.5-cm² fast tips. Since the study was completed, two additional tips are available: a 3 cm² tip which is able to treat a larger surface area with each pulse, and a smaller 0.25 cm² tip which is useful for the treatment of small areas such as eyelids.

The Leal Laxity Classification System

The Leal laxity classification system is a quantitative method of measuring facial skin laxity. This scale divides the face into 4 regions: upper face (pupillary line and above), middle face (pupillary line to oral commissure), lower face (oral commissure to jawline), and upper neck (jawline to start of thyroid cartilage). Each region then receives two analyses: (1) type of laxity and (2) degree of laxity.

Laxity type was determined by a “pinch test” and classified as either A, B, or AB, defined as follows: Type A has superficial laxity limited to the skin, Type B has structural laxity involving subcutaneous tissue, and Type AB has combined cutaneous and structural laxity. Patients limited to type A skin laxity were excluded from the study. Treatment success was defined as movement from Type B to Type A or Type AB to Type A or B.

The degree of skin laxity was quantified on a 6-point scale with 0 being absence of facial laxity and 5 being extreme skin laxity. Patients with no skin laxity (0) or prominent (4) to extreme (5) skin laxity were excluded from the study. Treatment success was defined as any movement toward zero on the laxity scale.

BTC2000 Measurements

BTC2000 measurements were gathered from 20 patients at one study center (Chestnut Hill, MA) at baseline, 2 months, 4 months, and 6 months post-treatment. The BTC2000 device is a biomechanical tissue characterization system used to measure the impact of the radiofrequency procedure on skin stiffness and energy absorption. Skin stiffness (mmHg/mm) is a measure of the mechanical property of the skin and is calculated as the slope of the linear part of the stress-strain pressure deformation curve. Energy absorption (mmHg*mm or mbar*mm) reflects the total area beneath the pressure or stress-strain curve. It depicts overall tissue compliance or the amount of energy it takes to deform the skin.

Measurements with the BTC2000 were kept standard for each subject by using an individualized template created by tracing facial landmarks onto a transparency sheet. Measurements recording upper and lower limits of a negative pressure vacuum (mmHg) were taken at four points on each cheek for stress/strain calculations.

<table>
<thead>
<tr>
<th>TABLE 1. Exclusion Criteria</th>
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<tbody>
<tr>
<td>Dermabrasion, chemical peeling, or laser resurfacing within 1 year</td>
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<tr>
<td>Microdermabrasion within 3 months</td>
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<tr>
<td>Fat augmentation within 18 months</td>
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<tr>
<td>Collagen, botulinum toxin, oral retinoids within 6 months</td>
</tr>
<tr>
<td>Prior radiofrequency treatment within 1 year</td>
</tr>
<tr>
<td>Topical retinoids or related creams within 2 weeks</td>
</tr>
<tr>
<td>Topical steroids within the treatment area within 2 months</td>
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<tr>
<td>Oral steroids within 1 year</td>
</tr>
<tr>
<td>History of photosensitivity, collagen vascular disorder, diabetes, congestive heart disease</td>
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<tr>
<td>History of skin cancer, facial implants or radiation therapy in the treatment area</td>
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<tr>
<td>Active local or systemic infection or immunocompromised status</td>
</tr>
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<td>Pregnant or lactating women</td>
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<td>Pacemaker or internal defibrillator</td>
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</table>
Protocol

A total of 66 patients were treated at three clinical sites (Chestnut Hill, MA, N = 21; Miami, FL, N = 22; Hunt Valley, MD, N = 23). Baseline data for each subject included photographs, clinical evaluation of skin laxity using the Leal classification system, and BTC2000 measurements for skin stiffness and energy absorption.

The use of topical anesthesia and/or additional oral or intramuscular analgesics was optional and at the discretion of each clinical site. Investigators were not allowed to use nerve blocks, tumescent anesthesia, or sedation to the extent that all sensation was blunted or the subject was unable to participate in the treatment process. Prior to treatment, topical anesthesia was thoroughly removed (if utilized), a treatment grid was applied using dye transfer paper, a return pad was attached to the patient and hooked up to the radiofrequency device, and coupling fluid was applied to the treatment areas. Volunteers were treated with two passes with the 1.5 cm tip to the full treatment area: cheeks, upper neck, perioral area, chin, and submentum. The forehead, orbit, nose, and lips were not treated (Fig. 1). The investigator was then asked to use the remaining three passes at his/her discretion on areas needing greater skin tightening. Pulses were not stacked or overlapped.

Patient feedback to the operator was used as the basis for choosing the appropriate energy for a particular treatment segment in a given individual. Subjects were asked throughout the treatment about their level of pain on a scale of 0 (none) to 4 (intolerable). The goal was to calibrate temperature settings to keep the discomfort level below a 2 or 3.

Thirty to sixty minutes post-procedure, photographs were taken using standardized techniques, and patients were carefully inspected for areas of persistent erythema, edema, blanching, blistering, ulceration, scabbing, purpura, hyper- or hypo-pigmentation, textural changes, or other side effects.

Follow-ups were conducted at 1, 2, 4, and 6 months. Photographs, clinical evaluation using the Leal facial laxity scale, and BTC2000 measurements were conducted at each visit. In addition, investigators were asked to rate the amount of improvement compared to baseline photographs according to the following scale: No improvement—0%, Minimal improvement <25%, Good improvement 25%–50%, Very good improvement 50%–75%, or Excellent improvement >75%.

Assessment of Skin Laxity by Independent Photo Reviewers

Four independent clinicians were involved in the evaluation of subject photo sets using the Leal facial laxity classification system. A photo set is defined as a collection of photos from a single subject taken at baseline, 4 months post-treatment, and 6 months post-treatment. Reviewers were asked to rate the degree of skin laxity of six specific segments of the face at each time point within the set. Reviewers were blinded as to which photographs were baseline and post-treatment. The six facial segments included the right and left middle face, right and left lower face, and right and left upper neck (Fig. 1). Segments were ranked according to the degree of skin laxity on the Leal 6-point scale described above, with 0 being absence of facial laxity and 5 being extreme skin laxity.

Subject Satisfaction

At the 4 and 6-month follow-ups, subjects were shown their baseline and previous follow-up photographs and asked whether or not they were satisfied with their treatment outcome.

RESULTS

Subject Demographics

Subjects were 40–75 years of age with an average age of 53 years. The majority of patients were female (94%) and non-smokers (92%). Four different Fitzpatrick skin types were treated with the most frequent type being Type III (42%), followed by Type II (26%), and an almost equal number of Type I (17%) and Type IV (15%).

Treatment

The repetitions (REPS) of energy delivery ranged from 220 to 720 pulses per treatment with an average of 480 REPS for all three investigational sites and an average treatment time of 70 minutes. The subjects treated at the Chestnut Hill site had the highest average REPS per Subject (M = 556), followed by those treated at the Hunt Valley site (M = 461) and the Miami site (M = 427). There was little variation in the total number of REPS delivered to each Subject at any one investigational site.
Treatment levels for all sites ranged from 60.5 to 65 with the average being 62 (83 J/cm²). The Hunt Valley site had the highest average treatment level (63), while Chestnut Hill and Miami both averaged 62.

Reported side effects included mild superficial crusting resolving without sequel (N = 2), mild erythema resolving by the first follow-up visit (N = 2), focal linear depressions observed during treatment resolving within 1-hour (N = 1), and mild edema (N = 1). Two patients reported numbness along the jawline at the 1 month visit resolving by the 2 and 4 month visits. There were no permanent side effects.

Physical Assessment of Skin Laxity
At baseline, 48% (N = 30) of patients were rated as having deep laxity involving the subcutaneous tissue (Type B) and 52% (N = 33) were rated as having a combination of both cutaneous and structural laxity (Type AB). Patients with superficial skin laxity (Type A) at baseline were excluded from study participation.

At 4 months follow-up, 15% (N = 9) showed improvement in the type of skin laxity by moving from a Type B to a Type A or from a Type AB to a Type A or B. At 6 months, the percentage with improvement in type of skin laxity more than doubled to 39% (N = 24).

Investigator Improvement Assessment
At 4 months follow-up, 95% (N = 60) demonstrated improvement in facial skin laxity. (Fig. 2A–D). The majority (46%) had good (26–50%) improvement, and 19% had very good (51–75%) improvement. Five percent had no evidence of improvement compared to baseline (Fig. 3).

Fig. 2. A: Patient with skin tightening of the neckline and jowls 4 months after treatment. B: Patient with continued improvement, particularly in the nasolabial folds. C: Patient with noted improvement in skin tightening demonstrated by diminution of the jowl as well as improvement and effacement of the marionette lines. D: Patient with excellent skin tightening in the jowls, cheeks, and nasolabial folds peaking 4 months post-treatment.
Fig. 2. (Continued)

Fig. 3. Amount improvement at 4 and 6 months post treatment.
At 6 months follow-up, 92% demonstrated improvement in facial skin laxity. Thirty-three percent (n = 20) had good (26–50%) improvement and 28% (n = 17) had very good (51–75%) improvement. At 6 months, 8% (N = 5) showed no improvement compared to baseline (Fig. 3).

**BTC2000 Analysis**

The primary variable of stiffness showed a significant increase of 26 mm Hg/mm at 2 months (P = 0.002), but the increase had dropped to an average of 4 mm Hg/mm at 4 months (P = 0.559), and at 6 months was near baseline (P = 0.433). The corresponding primary variable of energy absorption showed an average decrease of 10.8 mm Hg*mm at 2 months (P = 0.007), and increases of 0.2 and 3.6 mm Hg*mm at 4 and 6 months (P = 0.940 and 0.102 respectively).

When results are viewed with respect to percentages of patients improved, 81% of patients were improved with respect to stiffness at 2 months, 71% were improved at 4 months, and 35% were improved at 6 months. For energy absorption, 81% were improved at 2 months, 47% were improved at 4 months, and 25% were improved at 6 months.

**Assessment of Skin Laxity by Independent Photo Reviewers**

Improvements in laxity classification, defined as movement toward zero on the 6-point Leal assessment scale, occurred in 75% of the photo sets at 4 months and 84% of the photo sets at 6 months. Forty-two percent of the six facial regions showed improvement at 4 months post-treatment and 54% of facial regions showed improvement by at least a half point at 4 months post-treatment and 54% of facial regions showed improvement by at least a half point at 4 months post-treatment and 54% of facial regions showed improvement by at least a half point at 4 months post-treatment and 54% of facial regions showed improvement by at least a half point at 4 months post-treatment and 54% of facial regions showed improvement by at least a half point at 4 months post-treatment.

Looking at the three facial regions independently, the lower face was improved most often at 4 months (48%), compared to the middle face (46%) and upper neck (32%). The middle face was improved most often at 6 months (65%), compared to the lower face (58%) and upper neck (41%). Differences between right and left sides of the face were not significant. Percent of photo sets showing improvement by region is outlined in Table 2.

A summary of the treatment results can be found in Table 3.

**TABLE 2. Percentage Showing Improvement by Region**

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage improved at 4 months</th>
<th>Percentage improved at 6 months</th>
</tr>
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<tbody>
<tr>
<td>Middle face</td>
<td>46%</td>
<td>65%</td>
</tr>
<tr>
<td>Lower face</td>
<td>48%</td>
<td>58%</td>
</tr>
<tr>
<td>Upper neck</td>
<td>32%</td>
<td>41%</td>
</tr>
<tr>
<td>Overall</td>
<td>95%</td>
<td>92%</td>
</tr>
</tbody>
</table>

**Subject Satisfaction**

At the 4 and 6-month follow-ups, subjects were shown their baseline and previous follow-up photographs and asked whether or not they were satisfied with their treatment outcome. Seventy-eight percent of patients were satisfied at the 4-month post-treatment visit, and 70% of patients were satisfied at the 6-month post-treatment visit. All three sites showed an average 8% decrease in the number of satisfied patients from 4 to 6 months post-treatment.

**DISCUSSION**

Prior studies evaluating the use of the original 1.0 cm tip have demonstrated improvement in facial laxity with non-ablative monopolar radiofrequency treatments. Most of these studies judged improvement via subjective evaluation without objective data due to the inherent difficulties of scientifically quantifying improvements in cosmetic appearance. In this study, we sought to develop an objective means of determining improvement in skin tightening and to increase the power of the subjective evaluation. This was accomplished with a novel biomechanical tissue characterization system measuring stress/strain properties and the impact of the radiofrequency procedure on both skin stiffness and the amount of energy required to deform the skin. In addition, skin laxity was defined and quantified using the Leal laxity classification system and independent photographic assessment. All centers used a treatment algorithm of moderate energies, multiple passes, and treating to a visible endpoint.

In terms of physical assessment of skin laxity using the Leal laxity classification system, substantially more subjects at the Hunt Valley site demonstrated improvement in their skin laxity by moving from Type B to Type A laxity or Type AB to Type A or B laxity. This group of subjects had predominantly Type AB laxity at baseline, versus the other two sites which had predominately Type B laxity. Without a control group, this could be a reflection of differences in investigator interpretation of the Leal scale. It may also indicate that patients with combined cutaneous and subcutaneous structural laxity have a better treatment prognosis than those with purely subcutaneous laxity. This would make sense considering the two mechanisms at play in radiofrequency skin tightening: (1) contraction of collagen fibrils in the dermis and (2) contraction of fibrous septae in the subcutaneous fat. Patients with combined laxity could be expected to have improvements through both mechanisms, while patients with only subcutaneous laxity could be expected to gain most of their benefit through contractions in the fibrous septae.

Evaluation of extent of improvement confirmed that 92% of patients undergoing radiofrequency skin tightening with the 1.5 cm tip using the multiple pass, low fluence algorithm will show some improvement in facial skin laxity 6 months post-treatment. This means that less than 10% of patients are unresponsive to treatment. In the group of responders, nearly one-third had a very good response, defined as a 51–75% improvement in skin laxity. Another third had a good response, defined as a 26–50%
improvement in skin laxity. Thus, approximately two-
thirds of patients can be expected to have a good or very
good response to radiofrequency skin tightening with the
multiple pass, low fluence algorithm.

When one looks at this same data in terms of the number
of repetitions (REPS) of energy delivered, we find that
subjects treated with a higher number of REPS per
treatment appear more likely to achieve a very good
response to radiofrequency skin tightening. The average
number of REPS for all three investigational sites was 480.
The site with the highest average REPS per subject (580)
had the largest proportion of subjects achieving a very good
response at 6 months follow-up. The site with the lowest
average REPS per subject (427) had the lowest proportion
of subjects achieving a very good response and the highest
percentage of subjects achieving a minimal (<25%)
response or none at all. In fact, all eight subjects who were
judged to have had no response at 6 months post-treatment
came from the site using the lowest number of REPS
per subject. While this may represent differences in
investigator assessment bias, the data trends toward more
improvement with more pulses per treatment.

Measurements of skin tightening using the BTC2000
device revealed that patients have a peak overall improve-
ment in skin stiffness and energy absorption 2 months post-
procedure with rates decreasing at 4 and 6 months. Eighty-
one percent of patients had improved skin stiffness at
2 months follow-up, while 35% were improved at 6 months
follow-up. For energy absorption, 81% were improved at 2
months, while 25% were improved at 6 months. This data is
in contrast to clinical and independent photographic
assessment which demonstrated continued improvement
in skin tightening from 4 to 6 months. This brings into
question the utility of the BTC2000 device as an objective
means of measuring clinical effect. In comparison to other
published studies, some have seen continued improvement
in skin laxity over time [6], while others have shown a
peak in tightening at 3 months with diminishing results at
6 months [4].

Further studies are needed to clarify this issue.

Photographic assessment of individual regions by inde-
pendent review showed that the middle face was most often
improved at long-term (6 months) follow-up, with 65% of
photo sets having visible tightening in the area. The upper
neck was least often improved, with 41% of photo sets
having some degree of visible tightening in the area.

The middle and lower face regions may respond more
readily to radiofrequency treatments because the cheeks
and jowl typically have a higher proportion of subcutaneous
fat in comparison with the thin skin of the neck.

In comparison to prior studies evaluating the 1 cm tip at
higher energies and fewer REPS, the low-fluence, multiple
pass algorithm appears to have improved efficacy and
increased consistency in tissue tightening with each
treatment. The Alster study noted some degree of improve-
mnt in 93% of subjects after radiofrequency treatment of
the cheeks and 85% of patients after treatment of the upper
neck at 6 months follow-up [4]. While the percentage of
patients with measurable improvement is comparable to
the present study, the degree of improvement is less. With
the low-fluence, multiple pass technique, one-third of
patients achieved significantly more improvement at a
lower average setting per treatment when compared to the
Alster study [4]. Similar trends are seen in comparison
to the Moy study measuring improvements in cheek laxity
[6]. Thus, the low-fluence, multiple pass algorithm for
monopolar radiofrequency skin tightening appears to be a
superior treatment protocol when compared to those using
high fluences and fewer pulses per treatment.

Interestingly, despite a measurable improvement in skin
laxity in 92% of subjects, only 70% of patients stated they
were satisfied with their outcome 6 months after treatment.
While patients are naturally happier with better results,
there may be a perceived dissatisfaction on the patient’s
part with subtle but significant changes in skin tightening.
It is essential to evaluate and understand in the initial
consultation what the patient would like to achieve, and to
counsel them prior to the procedure what they might expect
in terms of treatment success.

CONCLUSIONS
To achieve maximal results with minimal side effects,
radiofrequency treatments should employ multiple passes
at low to moderate temperature settings until a desired
endpoint of visual tightening is seen. Data trends toward
increased tightening and more predictable results with
an increased number of pulses done at energy settings
individualized to a patient’s comfort level and tolerability.
Patients appear to have a peak overall improvement in skin
stiffness and energy absorption 2 months post-procedure
with rates decreasing at 4 and 6 months.

REFERENCES
1. Zelickson B, Kist D, Bernstein E, Brown DB, Ksenzenko S,
Burns J, Kilmer S, Mehregan D, Pope K. Histological and

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**TABLE 3. Outcome Summary**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Evaluation</th>
<th>Percentage improved at 4 months</th>
<th>Percentage improved at 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall appearance of treated areas</td>
<td>Investigator</td>
<td>95%</td>
<td>92%</td>
</tr>
<tr>
<td>Skin laxity type</td>
<td>Investigator</td>
<td>15%</td>
<td>39%</td>
</tr>
<tr>
<td>Skin laxity classification</td>
<td>Independent review</td>
<td>75%</td>
<td>84%</td>
</tr>
<tr>
<td>BTC measurement-stiffness</td>
<td>Investigator</td>
<td>71%</td>
<td>35%</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>Subject</td>
<td>78%</td>
<td>70%</td>
</tr>
</tbody>
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