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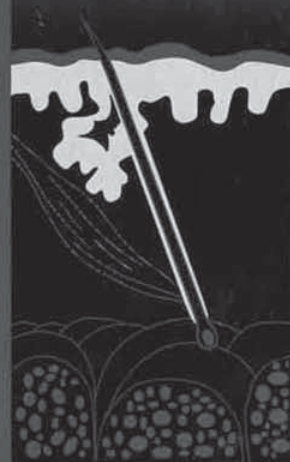
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The Use of Nonablative Radiofrequency Technology to Tighten the Lower Face and Neck

Te-Shao Hsu, MD, and Michael S. Kaminer, MD*

The ThermoCool TC system is a radiofrequency device capable of delivering higher energy fluences to a greater volume of tissue than nonablative lasers, with no epidermal injury. It has been successful in treating periorbital rhytides and lifting eyebrows. Given these positive findings for treatment of the upper face, the device has been recently applied to rejuvenate and tighten the skin on the lower face and upper neck. This study shows the efficacy and patient satisfaction with this application. Data were compiled over a 6-month period from patients treated with the ThermoCool TC system on the lower face. Up to 3 areas were treated: cheeks, jawline, and upper neck. Treatment parameters and adverse events were recorded and digital photographs taken. Telephone interviews were then conducted after the treatment to assess patient satisfaction. Sixteen patients underwent treatment of the lower face during this period. Eleven of the patients had all three areas (cheeks, jawline, and neck) treated. Two patients had only the cheeks and jawline treated, and 3 patients underwent treatment of the cheeks only. The average level was 14.6 for the cheeks with the average energy of 113.8 joules per pulse. The average treatment level of the jawline was 14.0, with the average energy of 107.0 joules per pulse. The average level was 13.8 for the neck, at the average energy of 99.7 joules per pulse. All patients experienced mild erythema and edema of the treatment areas as expected, and all resolved within 48 hours post-treatment. Fifteen of the 16 patients were available for interview. Ten patients found the results unsatisfactory while five patients were satisfied. Four of 11 (36%) patients who had all 3 areas treated reported satisfactory results, compared to 1 of 4 (25%) of patients who had only 1 or 2 areas treated. The satisfactory group consistently was higher in both dial setting and energy per pulse. Furthermore, the average age of the unsatisfactory group was 58, compared to 51 of the satisfactory group. Photographic analysis of pre- and post-treatment digital images did not yield statistically significant results. Our study adds the growing body of information on this new device. Radiofrequency causes movement of charged particles within the tissue, and the resultant molecular motion generates heat. The heat in turn causes collagen shrinkage and new collagen deposition. Based on our findings, younger patients tend to respond better. This

is not surprising, since heat-labile collagen bonds are progressively replaced by irreducible multivalent cross-links as the tissue ages. Second, higher dial settings and corresponding higher energy per pulse correlated with better response. Third, those who had the entire surface area of the face and neck treated tend to do better than those with partial treatment. The data from the study give us critical clues in refining this exciting new technology for cosmetic uses and beyond.

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Noninvasive cosmetic procedures with minimal patient recovery and low complication rates are often preferred over invasive procedures. Several nonablative lasers have been developed for this purpose, but they typically require numerous treatments over 6 months to achieve modest cosmetic benefit, primarily because of the time required for secondary collagen response to thermal injury. An alternative is a device based on radiofrequency (RF) capable of delivering higher energy fluences to a greater volume of tissue than non-ablative lasers, with no epidermal injury.

The ThermoCool TC System (Thermage, Hayward, CA) is one such device. Treatments can be performed in an outpatient setting with little or no recovery time needed. In November 2002, the US Food and Drug Administration (FDA) granted clearance to the ThermoCool TC System for the noninvasive treatment of periorbital rhytides.¹ The new cosmetic use clearance is based on clinical data from a multicenter study showing that a

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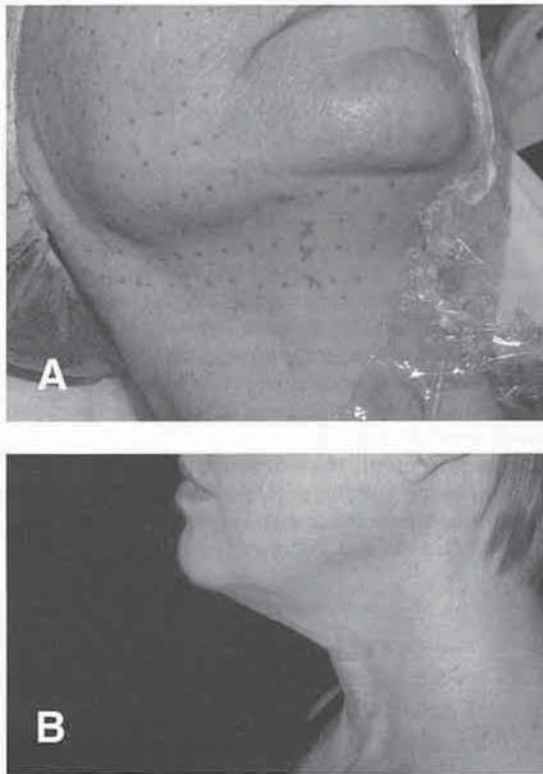


Fig 1. (A) Hand-drawn grid pattern. (B) Treatment of the neck extends to the submental area. The second side remains under plastic occlusion until ready for treatment to maximize the anesthetic effect.

single nonablative treatment with the device can safely improve the appearance of periorbital skin. Performed in an outpatient setting with a topical anesthetic, the procedure typically lasted about 25 minutes, and patients were able to resume routine activities immediately after treatment. About 80% of patients showed a significant improvement in

an objective assessment of their wrinkle severity, with progressive improvements noted up to 6 months after a single treatment.² The US regulatory clearance was preceded earlier by Canadian Health Protection Branch approval for noninvasive brow lift and tightening of periorbital facial tissue.

This device has several key components: radio-frequency generator, handpiece, treatment tip, and cooling module. The generator produces a 6-megahertz alternating current RF signal directed to targeted tissue. The RF generator is regulated by an internal computer that processes feedback information from the hand-piece and treatment tip, including temperature, application force, and impedance. A return pad extends from the generator module to the patient's back to allow a path of travel for the RF signal. The hand-piece contains a computer logic board that gathers information about tip temperature, and treatment force against the skin and then relays the information to the generator computer. The treatment tip delivers the RF energy to the skin with simultaneous surface cooling. The contact membrane continually monitors the tip temperature through the use of built-in thermistors. A coupling fluid is used to ensure thermal and electrical contact with the skin. The cooling module controls the pressure of cryogen coolant that is metered by a valve within the hand-piece and delivered to the back-side of the tip. Surface cooling is maintained throughout treatment cycle (pre-, during, and post-treatment) as cryogen is sprayed onto the cooling membrane in the treatment tip.

This device delivers volumetric and uniform heating to the deep dermis via a unique form of RF energy. Each treatment cycle consists of 3 phases.

Table 1. Patients With Treatment to Cheeks, Jawline, and Neck

Patient No.	Sex	Age	Dial Setting for Cheek	Dial Setting for Jawline	Dial Setting for Neck	Average Dial Setting	Improvement (self assessment)	Follow-up (months)
2	F	73	14.5	13.5	14	14	2	8
6	F	52	14.5	13.5	13.5	13.8	5	7
7	F	52	15	15	15	15	8	6
8	F	42	14	14	13.5	13.8	2	4
9	F	69	14.5	13.5	13.5	13.8	0	4
10	F	54	14.5	13	13	13.5	0	2
12	F	45	14.5	13.5	13.5	13.8	0	2
13	F	48	15	13.5	13.5	14	5	2
14	F	65	14.5	14	14	14.2	0	2
15	F	57	15	15	14.5	14.8	0	2
16	F	60	15	15	14.5	14.8	10	1

Table 2. Patients With Treatment to Cheeks and Jawline Only

Patient No.	Sex	Age	Dial Setting for Cheek	Dial Setting for Jawline	Average Dial Setting	Improvement (self assessment)	Follow-up (months)
3	F	44	14.5	13	13.8	Lost to F/U	—
4	F	51	14.5	13	13.8	2	7

Over the course of the 6.3- to 6.5-second cycle, the skin is exposed to an initial phase of cryogen pre-cooling, followed by simultaneous heating and cooling, then post-cooling. The depth and volume of the thermal injury directly correlate to the geometry of the RF treatment tip, a component that can be selected by the clinician to target a depth of thermal injury desired. Unlike lasers, which target specific chromophores on the principle of selective photothermolysis, RF generates heat based on tissue's natural resistance to the movement of electrons within an RF field. This phenomenon is governed by Ohm's Law: Impedance Z (ohms) to the movement of electrons creates heat relative to current I (amps) and time t (seconds).

$$\text{Energy (Joules)} = I^2 \times Z \times t$$

However, unlike standard RF energy that concentrates energy at points and edges, the ThermoCool TC System (Thermage) uniformly heats skin at controllable depths. Through the use of groundbreaking technology of capacitive coupling utilizing a dielectric material, a uniform electric field is created that distributes energy into a large volume of tissue, not small flat planes of heat.

The feasibility of this novel RF device coupled with a concurrent epidermal cooling system was studied using a three-dimensional mathematical model of the temperature distribution within human skin.³ The results show that this treatment tip design induces volumetric heating deep within the dermis while still protecting the superficial skin layers from thermal injury. This allows for much greater temperature rise below the surface than in the epidermis. Penetration depth of RF energy varies with the surface area of the treatment tip, while heat generation depends on the

electrical impedance of the tissue. Therefore, heating profiles depend on the tissue electrical properties, size of the treatment tip, and amount of surface cooling. This allows for tailoring the treatment to meet specific goals.

The first human clinical study conducted with this device tested a wide range of dose effects and included assessments of skin contraction, gross pathology, and histological changes.⁴ Once the energy is delivered to the tissue, a dual effect is observed. Primary collagen contraction, similar to that seen with ablative carbon dioxide laser (CO2) resurfacing, is postulated as a short-term mechanism of action. Secondary collagen synthesis in response to thermal injury is predicted over a longer time period. Accordingly, some patients see an immediate response, although the majority sees improvement at 4 to 8 weeks, which may increase for 6 months or more after a single treatment. Fibroplasia and signs of increased collagen formation were most frequently observed in the papillary dermis and less frequently seen in the reticular dermis.⁴

Given the success with periorbital rhytides, we have begun treating the lower face and the upper neck to induce skin tightening. We present the data compiled over a 6-month period, focusing on patient satisfaction after the treatment.

MATERIALS AND METHODS

Between May 17, 2002 and December 6, 2002, 16 patients were treated with ThermoCool TC (Thermage) on the lower face. None of the patients had laser or intense-pulsed light treatment to the face within 1 year. All patients used topical lidocaine 5% cream (Ela-Max 5; Ferndale Labora-

Table 3. Patients With Treatment to Cheeks Only

Patient #	Sex	Age	Dial Setting for Cheek	Improvement (self assessment)	Follow-up (months)
1	F	62	13	3	7
5	F	42	15	8	7
11	M	58	15	0	2

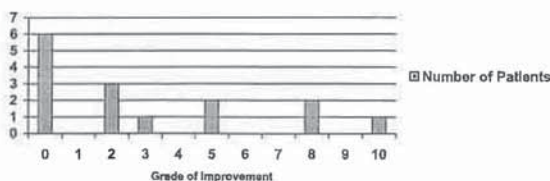


Fig 2. Grading of outcome by patients.



Fig 3. (A-E) Pre-treatment photographs.



(F-J) Post-treatment photographs.



Fig 3. (K, L) Comparison of pre-and post-treatment jawline.

tories, Ferndale, MI) for approximately 1 hour prior to treatment to reduce discomfort. Up to 3 areas were treated: cheeks, jawline, and upper neck. Treatment of the cheeks started at the preauricular area, crossing below the malar eminence, and stopping at the nasolabial folds. The jawline included the areas stretching from the posterior angle of the mandible along the jowls to the lateral chin, staying lateral to the marionette lines. The upper neck treatment included the area from the inferior border of the mandible down to the level of the thyroid cartilage but avoiding skin over midline cartilaginous structures. The midline submental soft tissue region was included in the treatment of the neck.

A hand-drawn grid pattern was made on the patient's skin with a red fine tip pen (Fig 1). The grid pattern produced squares approximately 1.2 x 1.2 cm in size for placement of the treatment tip. Treatment levels were adjusted to patient tolerance. All were treated with the 1-cm tip. Telephone interviews were conducted between January 13, 2003 and January 15, 2003. Patients were asked to rate the outcome on a 0 to 10 scale, 0 being no improvement, 10 being maximum improvement. Photographic analysis by blinded physicians was also performed.

RESULTS

The average age of the 16 patients was 54.3, ranging from 42 to 73 years old. Fifteen were women, 1 was a man. Eleven of the patients had all 3 areas (cheeks, jawline, and neck) treated. Two patients had only the cheeks and jawline treated, and 3 patients underwent treatment of the cheeks only. Tables 1-3 summarize the results of the 3 groups.

Treatment level of all 3 areas ranged from 13 to 15 on the dial setting. The average level was 14.6

for the cheeks with the average energy of 113.8 joules per pulse. The average treatment level of the jawline was 14.0, with the average energy of 107.0 joules per pulse. The average level was 13.8 for the neck, at the average energy of 99.7 joules per pulse. Of the 10 patients who underwent treatment for all 3 areas, they received on average total of 99.4 pulses. In comparison, those who had cheeks and jawline treated and those who had cheeks treated only received on average total of 110.5 and 57.0 pulses, respectively. All patients experienced mild erythema and edema of the treatment areas as expected, and all resolved within 48 hours post-treatment. One patient also reported mild urticarial reaction at several treatment spots, which also resolved completely with topical fluocinolone. No other adverse reactions were noted.

Fifteen of 16 subjects were available for the telephone interview. Figure 2 summarizes their responses when asked to grade the outcome of the treatment. We may separate the subjects into 2 groups. The mild to no improvement (unsatisfactory) group include those who graded the treatment 0 to 4, and the moderate to excellent improvement (satisfactory) group included those who graded 5 to 10. Ten patients, or two thirds of the patients, fall into the first group. Five patients, or one third of the pool, fall into the satisfactory group (Figs 3A-L and 4A-J).

More detailed analysis reveals many interesting comparisons between the 2 groups. Four of 11 (36%) of the patients who had all 3 areas treated reported satisfactory results, compared to 1 of 4 (25%) of patients who had only 1 or 2 areas treated. When limiting the comparison to the 11 patients with all 3 areas treated, we find the unsatisfactory group had an average of 99 pulses per treatment, comparable to 100 pulses per treatment in the satisfactory group. However, comparisons of the dial settings and energy between the 2 groups show a consistent difference (Figs 5 and 6). Even when sorted into separate anatomic areas of treatment, the satisfactory group consistently was higher in both dial setting and energy per pulse. Furthermore, the average age of the unsatisfactory group was 58, compared to 51 of the satisfactory group. Given the small sample size, the differences were not statistically significant.

Photographic analysis of pre- and post-treatment digital images did not yield statistically

significant results. Although some patients demonstrated significant improvement seen in photographs (Figs 3K and L), others were very difficult to interpret reliably. The inherent difficulty in documenting changes of the lower face, as well as this anatomic location's extreme sensitivity to changes in lighting and patient positioning, reveal the challenges faced in developing a quantifiable method of analyzing the lower face.

DISCUSSION

The dermis is composed primarily of type I collagen. It is made up of 3 polypeptide chains, which are stabilized in a triple-helix arrangement by intramolecular cross-links. These molecules are in turn aggregated into a parallel pattern to form collagen fibrils. This fibrillar arrangement is maintained by intermolecular cross-links and provides the tissue with tensile properties. The intramolecular cross-links are reducible covalent aldehyde bonds, which are progressively replaced by irreducible multivalent cross-links as the tissue ages.⁵

When collagen is heated, the heat-labile intramolecular cross-links are broken, and the protein undergoes a transition from a highly organized structure to a random, gel-like state. Collagen shrinkage occurs through the cumulative effect of the unwinding of the triple helix and the residual tension of the heat-stable intermolecular cross-links. This heat-induced denaturation typically occurs at approximately 65°C. The precise heat-induced behavior is dependent on both the maximum temperature reached and the exposure time, in addition to any mechanical stress applied to the tissue during heating, age, pH of the environment, the concentration and orientation of the collagen fibers, and the hydration level of the tissue. New collagen deposition is also observed, although the mechanism is less well defined. Numerous studies have documented that thermally modified tissues undergo a remodeling process characterized by fibroplasia and increased collagen deposition.⁵

Clinically, 2 types of energy systems have been used to thermally modify collagen: laser energy and radiofrequency energy. Laser energy is transformed into heat energy through an interaction dependent on the wavelength of the laser and the

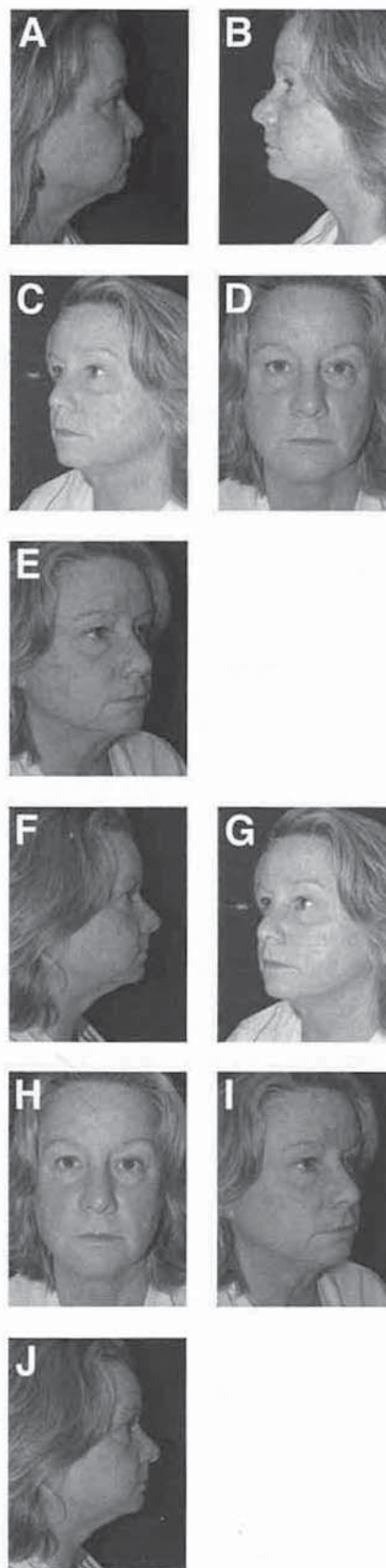


Fig 4. (A-E) Pre-treatment photographs. (F-J) Post-treatment photographs.

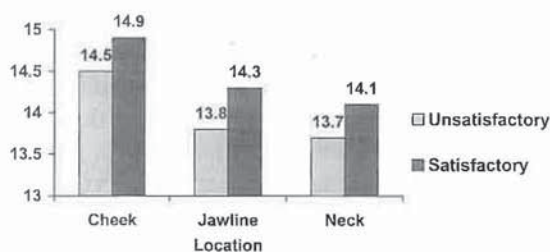


Fig 5. Average dial settings.

properties of the tissue. Radiofrequency energy is a form of electromagnetic energy. When applied to tissues, rapidly oscillating electromagnetic fields cause movement of charged particles within the tissue, and the resultant molecular motion generates heat. Similar to laser energy, the thermal effect of radiofrequency energy in tissues is determined by the level of energy, duration of treatment, and nature of the tissues. In addition, the electrode type, size, and shape all have an effect.

The first radiofrequency device aimed at skin tightening was initially studied using a standard guinea pig model.⁶ The results show that heating the dermal layer of the skin is associated with collagen denaturation and subsequent thickening and shortening of the collagen fibrils. An immediate collagen denaturation is characteristically followed by a period of increased fibroblast activity and neo-collagen formation over a several months. The results also indicate a correlation between power settings and degree of skin contraction measured immediately after treatment. Histological changes associated with new collagen formation in the dermis were observed in the treatment areas where significant skin contraction was observed.

A multicenter trial on human subjects eventually led to FDA approval of the ThermoCool TC (Thermage) device. Eighty-six patients with periorbital skin laxity and brow ptosis underwent a single treatment. At 6-months post-treatment, 80% of patients showed at least a 1.0 improvement in Fitzpatrick Wrinkle Classification Score and measurable brow elevation. Satisfaction data was available for 14 periorbital patients at their 6-month visit. Of the 14 patients, 12 reported that they were satisfied or very satisfied with the treatment. Patients frequently commented that the treated area felt tighter and that family members and friends noticed a difference in their appear-

ance. Other investigators support the conclusion with similar findings.⁷ Once again, changes in appearance were corroborated histologically with finding of thickened epidermis and increased density of the dermis post-treatment.

Our study adds to the growing body of information on this new device. Whereas the studies to date have focused on objective data such as measurements and histologic changes, we have instead focused on the patients' subjective opinions regarding the treatment, due to inherent difficulties in quantitatively demonstrating facial skin tightening through photographic analysis. For as yet unknown reasons, the positive changes that patients and physicians see in three dimensions do not translate well into two-dimensional photographic evidence. In the 2 series of photographs shown here, even though both patients are very satisfied with the outcomes, one patient's improvement are clearly visibly through photographs (Fig 3K and L), showing a tighter jawline, while the other patient's improvements are not evident in these photographs. Furthermore, we feel that patient satisfaction is critically important in any elective cosmetic procedure. It is a measurement as valid as any objective data, yet the inability to document these changes photographically stresses the need for the development of a reproducible quantitative mechanism to measure the improvement in lower face contours.

We found that only one third of the patients saw either moderate or excellent results, while two thirds saw little or no improvement. At first glance, these results are disappointing. However, a closer inspection reveals fascinating differences between those who had satisfactory outcomes and those who did not. A question we hoped to answer is: can we predict or control how well a patient would respond to this treatment? The data from the study gives us critical clues. Based on our findings, younger patients tend to respond better. This is not surprising, since heat-labile collagen

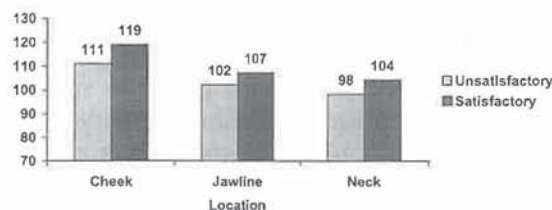


Fig 6. Energy per pulse (J).

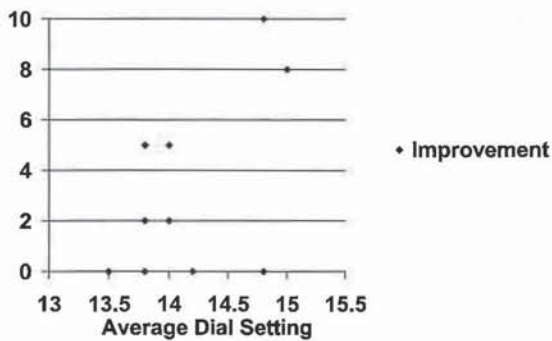


Fig 7. Improvement versus dial setting.

bonds are progressively replaced by irreducible multivalent cross-links as the tissue ages. Therefore, at the same energy setting, younger skin should respond more dramatically. Second, higher dial settings and corresponding higher energy per pulse correlated with better response. A graphic analysis shows a direct relationship between improvement and dial setting (Fig 7). Similar results were already seen in the guinea pig skin model discussed previously.⁶ However, the physician should take care to balance the better results delivered by higher energy with patient tolerance and possible burn to the skin. Third, those who had the entire surface area of the face and neck treated tend to do better than those with partial treatment. Based on this finding, we propose that all 3 areas be included in all treatments of the lower face, a technique we refer to as "Tri-zonal Radiofrequency Tightening (TZRT)."

While other investigators have used more involved and invasive anesthesia, such as nerve blocks, oral sedatives, or conscious sedation, we have found that patient discomfort is adequately controlled with topical anesthesia alone. We apply 5% lidocaine cream (Ela-Max 5; Ferndale Laboratories) to all treatment areas at least 1 hour prior to the procedure. The application should be thick (almost an entire 30-g tube used for each lower face treatment), and covered with plastic film for occlusion. Based on our experience, patients often fail to perform this properly at home, so we now routinely ask the patient to arrive 1 hour prior to scheduled treatment to allow our nursing staff to apply the cream. With proper application, patients rarely complain of excessive discomfort, and we can safely avoid risks inherent to the more aggressive forms of anesthesia.

We note that for several patients, the interviews were conducted at only 1 to 2 months after the procedure (Tables 1-3). Given that based on previous experiences the improvement in skin may continue up to 6 months, we feel that the general patient satisfaction may be even higher at a later time point. The small sample size of this study may also have skewed the findings. We also note that the average total number of pulses for treatment of 2 areas is higher than that for treatment of three areas. We feel that this may be caused by the specific facial anatomy of the 2 patients that had 2 areas treated. This may also be corrected with larger sample size.

Anecdotal evidence from this study suggests that patient expectations are critically linked to patient satisfaction. Those looking for modest improvement tended to be happier with their results, while those looking for more extensive changes tended to be less enthusiastic. Proper patient counseling is therefore essential to the success of the procedure.

In addition, it can take up to 6 months to see improvement after ThermoCool TC (Thermage) treatment of the lower face. Some of our patients were followed for only 1 to 2 months after treatment, so it is expected that they will continue to experience some degree of improvement. However, since it can take months to see improvement after treatment, it is possible (and by our observation likely) that some patients do not appreciate the extent of their improvement due to its gradual onset. They almost become used to their new post-treatment facial features, and view them as part of what they had pretreatment. This is but one of several compelling reasons for the need to develop a quantifiable system to measure improvement of the lower face.

Other studies are now underway to further refine the use of this device. Results from a multicenter study completed in April 2003 will compare single vs. multiple treatments. In addition to tightening of facial and neck skin, other clinical applications are currently being tested: stretch marks and cellulite, breast lift, acne, and acne scarring. Already, the Mexico experience has shown 80% to 90% efficacy in active acne cases, with an FDA monitored Active Acne Study in progress. Transmission electron microscopy studies have already characterized morphological changes in individual collagen fibrils and con-

firmed partial denatured collagen in mid and deep dermis after treatment. Further studies of mechanism of action within subcutaneous structures including superficial musculoaponeurotic system (SMAS), ligaments, fascia, muscle, and fat are underway.

The last several decades have seen advancements in ablative lasers and other ablative modalities to rejuvenate the skin, including CO₂ laser, Erbium:Yttrium aluminum garnet laser, chemical peels, and dermabrasion. Despite the excellent results delivered by experienced surgeons, the invasive nature of these devices carry inherent risks and discomfort to the patient. More than ever, patients now seek noninvasive procedures that deliver results. Much of the focus has been on nonablative lasers and intense pulsed light devices, but recent studies have revealed radiofrequency as a nonablative modality with yet untapped potential for cosmetic uses and beyond. Besides its ease of use and excellent safety profile, the RF device has a distinct advantage over other nonablative devices—the potential to achieve controlled, uniform heating at greater depths than those reported with light-based technologies.

Table 4. ThermoCool TC Treatment of the Lower Face

Predictors of Improvement

Younger age

Higher treatment fluence

Larger treated surface area (TZRT technique)

Table 5. ThermoCool TC Treatment of the Lower Face

Issues for Further Investigation

Role of multiple passes

Utility of multiple treatments

Optimal patient selection

Quantifiable methods for assessing improvement

With further studies, this device may become a primary tool in skin rejuvenation in the near future.

This data is an early step in defining the parameters and potential for use of the ThermoCool TC (Thermage) for treatment of the lower face and neck. The Tri-Zonal Radiofrequency Tightening (TZRT) technique, energy settings, and number of pulses per site require further investigation (Table 4). In addition, quantifiable methods for analysis of improvement will aid in further understanding the effects of RF on the lower face. However, it is clear from this early study that some patients experience what they see as significant improvement in facial contours with a single RF treatment. Our challenges are to better understand how to apply the technology and its mechanism of action, and equally importantly how to choose the best candidates for treatment (Table 5). It is likely a combination of 1) refinements in treatment technique and 2) improvement in patient selection that will enable us to increase the percentage of patients who experience significant results with this treatment.

REFERENCES

1. Thermage company website www.Thermage.com.
2. Fitzpatrick R, Geronemus R, Goldberg D, et al: First multicenter study of a new non-ablative radiofrequency device to tighten periorbital tissue. Presented at the American Society for Laser Medicine and Surgery. April 2003, Anaheim, CA.
3. Tunnell JW, Pham L, Stern RA, et al: Mathematical model of non-ablative RF heating of skin. *Lasers Surg Med* 14:318, 2002 (suppl)
4. Kilmer SL: A New Nonablative Radiofrequency Device: Preliminary Results. *Controversies and Conversations in Cutaneous Laser Surgery*. Chicago, IL, American Medical Association Press, 2002, pp 95-100
5. Arnoczky SP, Aksan A: Thermal modification of connective tissues: basic science considerations and clinical implications. *J Am Acad Orthop Surg* 8:305-313, 2000
6. Ross EV, Egbert B, Knowlton E, et al: A New Non-Ablative Radiofrequency Technology for Skin-Tightening Application. *American Academy of Dermatology Annual Meeting*, 2000.
7. Ruiz-Esparza J, Barba-Gomez JM: Volumetric Heating of Skin using Radiofrequency: Preliminary Findings. *Controversies and Conversations in Cutaneous Laser Surgery*. Chicago, IL, American Medical Association Press, 2002, pp 101-110