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Thermage: the nonablative radiofrequency for rejuvenation

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Abstract Thermage is a noninvasive nonablative device that uses monopolar radiofrequency energy to bulk heat underlying skin while protecting the epidermis to produce skin tightening. It is used for the treatment of rhytids on the face including the periorbital region and lower face, and more recently, for off-face applications. Studies have shown that it can impart mild tightening of periorbital mid, and lower facial laxity. Other radiofrequency devices have also shown objective improvements in cellulite of the buttocks and thigh regions. Thermage is an efficacious and safe nonsurgical alternative for treating mild skin laxity. © 2008 Elsevier Inc. All rights reserved.

Introduction

Photodamage is manifest in a number of ways on the aging face. Fine lines and dynamic rhytids are earlier manifestations that give way, as the process continues, to deeper, more static rhytids especially around the eyes, forehead, glabella, and in the lower jaw around the lower mouth. In more sebaceous areas of the face, enlargement of pores also occur. As the support system wanes, deeper nasolabial folds develop. Laxity of the jowls occurs later and tends to be more severe in individuals endowed with additional subcutaneous facial adipose tissue. Dyschromia, as a result of telangiectasias, erythema and solar lentigines, also reflects photodamage to skin.

The challenge faced by any one photorejuvenation method is to improve the appearance of any or all of the above in a safe manner. Although older ablative methods of photorejuvenation predictably produced improvement in photodamage, the demands of today's cosmetic patient with busy work and social schedules require techniques where downtime and potential for adverse outcomes are limited. Noninvasive procedures with little downtime and favorable side-effect profiles are thus advantageous.

Thermacool TC (Thermage, Hayward, Calif) is a noninvasive nonablative radiofrequency (RF) device that delivers monopolar RF energy in the form of an electrical current that generates heat through the inherent electrical resistance of dermal and subcutaneous tissue. The generated heat produces subtle damage to collagen, and in combination with the following inflammatory cascade induced by heating, a tightening effect is realized. Through this controlled volumetric heating of the dermis, the device is especially efficacious for the treatment of moderate laxity of the lower face. The optimal candidate is a patient most commonly in the mid-thirties to mid-sixties with some sagging of the jowls but lacks the need for a surgical lifting procedure. Other applications where the tightening effect is beneficial is in the treatment of the periorbital and supraorbital/forehead areas where a degree of brow and forehead lifting can be achieved. Buttocks and thighs are newer applications that show varying degrees of efficacy depending on patient baseline characteristics. The device initially received Food and Drug Administration clearance for treatment of periorbital rhytids and subsequently for treatment of rhytids of the lower face. The Food and Drug Administration granted regulatory clearance in January 2006 for the use of the device in off-face noninvasive treatment of wrinkles that allowed for use of the device on nonfacial skin including abdomens, thighs, and buttocks.

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Device properties

Volumetric heating is the principle on which the tightening effect of RF treatment is based. Tissue resistance to the flow of electrical current within an electric field causes the generation of heat. The 3-dimensional unit of epidermis and dermis is heated uniformly while contact and air cooling is used to protect the epidermis, producing a subtle degree of damage to collagen fibrils. An immediate tightening effect is observed because of shortening of collagen bundles, and a later effect arising from the inflammatory cascade set in place by deep heating/deep wounding leads to new collagen synthesis. The details of this mechanism and the molecular players involved are not yet understood. It has been observed that clinical reduction in the surface area of the cosmetic unit treated is responsible for the appearance of tightened skin.^{1,2}

The device consists of 3 main components: a generator, a handheld tip, and a cryogen unit. The generator changes the electric field polarity at the tissue interface at a frequency of up to 6 million times a second. Tissue resistance to the movement of electrons produces heat by the process of resistive heating. The handheld tip, containing a cooling apparatus, is applied to the skin and protects the epidermis with pre-, parallel, and postcooling. Sensors in the handpiece monitor temperature and pressure. The instrument has a capacitive-coupled electrode design that disperses energy uniformly across the surface area of the treatment tip membrane, thus creating a uniform electric field or zone of heating in tissue at controlled depths. The depth of heating with RF devices depend on treatment tip size and geometry.³⁻⁷ It is estimated that the device heats tissue to 65°C to 75°C, the critical temperature at which collagen denaturation occurs.⁸ Use of a cooling tip allows the device to provide deep volumetric heating of tissue without damaging the epidermis. Achieving the correct balance between sufficient deep heat generation adequate for collagen denaturation and effective epidermal cooling to avoid epidermal injury are both essential for this modality to work. More recently, a variety of tip sizes have been introduced that can be chosen depending on the anatomical area being treated.

Energy output of the device is calculated using the following formula:

$$\text{Energy}(J) = I^2 \times z \times t$$

where I is current, z is impedance, and t is time in seconds. Briefly, heat (J) is created by the impedance (z) to the movement of electrons relative to the amount of current (I) and time (t) that current is delivered to tissue.^{1,6}

Treatment protocol

All patients should have carefully taken preoperative and postoperative photographs. Ideally, standardized photo-

graphy in the same room with the same lighting and in the same positions should be obtained. Investment in a high-quality standardized photography system is useful for this application so that an appropriate evaluation of improvement can be demonstrated. We have found it useful to have patient photographs taken from the front, from both sides, and at a 3-quarter turn. These photographs are invaluable in assessing long-term responses to therapy; by taking photographs at each follow-up visit, we have been able to document continued improvement for up to 3 months after the initial RF treatment. Most of our patients have their face and neck treated in a single session. During our initial phases of clinical experience, we used relatively higher energies and fewer passes than we are currently using. Our shift to a lower-energy and higher-pass protocol was done to increase efficacy, tolerability, and safety. We currently treat facial and neck laxity as follows. Coupling fluid is applied generously to the areas to be treated. If the philtrum and upper lip is to be treated, the teeth are protected by wet gauze placed between the teeth and the upper lip. Eye protection is not required. After calibrating the impedance, our first 2 passes on the face are done at an energy of 150 to 202 J. We routinely use the 3-cm² medium tip. After 2 passes over the entire face at this energy, we make 3 or more additional passes in areas of concern to the patient with an energy of 133 J. Treatment of the neck is done with the 3 cm² tip at a setting of 133 J. Additional caution is taken when treating the neck; only 3 to 4 passes of this area is usually done using the lower energy only. During treatment, we are constantly evaluating the patient for signs of tightening and edema. We have found that this is an important clinical end point and must be seen for the treatment to be efficacious. The number of passes at the lower energy of 133 J is determined in large part by our impression of clinical response. Until the practitioner is comfortable with the treatments, it is advisable to take advantage of the temporary grid system that is supplied by the company. The grid is applied to the skin before treatment and directs the placement of the handheld tip with each successive pressure point. Pressure with the tip needs to be applied evenly or an error message is displayed and the tip cannot fire until the machine is reset. This is a built-in safety feature that ensures contact of the cooling tip with the skin preventing overheating of the epidermis. Pressure points should be adjacent but not overlapping each other. When more than a single pass is done, an entire region should be treated with the first pass before a successive pass is completed, allowing for tissue cooling between passes, thus minimizing epidermal injury. Keen intraoperative observation and patient feedback are crucial because they allow the physician to determine if there is adequate analgesia or if any adverse reactions are occurring, such as vesiculation or other signs of epidermal injury. Intraoperative edema is considered an expected outcome and correlates with clinical efficacy.

Histologic and ultrastructural changes

Zelickson et al² histologically evaluated abdominal human skin in 2 patients up to 8 weeks after treatment, using energies from 104 to 181 J. Examination of an immediate post-treatment biopsy revealed only a mild perivascular and perifollicular infiltrate that was not seen on either the 3- or 8-week follow-up biopsy. Electron microscopic evaluation of the post-treatment biopsies at 0, 3, and 8 weeks post-treatment demonstrated increased diameter of collagen fibrils and decreased distinction of the borders between the fibrils up to a depth of 5 mm in the skin. Increased diameter is indicative of shortening of the collagen fibrils. In addition, Northern blot analysis revealed an increase in collagen type I messenger RNA expression. The increase in collagen expression after treatment supports the notion that the thermal injury created by the RF device may stimulate a wound healing response.

Appropriate candidates

From our studies, as well as those of others, we have found that the device is of negligible benefit to obese patients and patients with extreme skin redundancy. It can be used safely on patients who have had prior cosmetic procedures, including rhytidectomy, laser surgery, fillers (excepting possibly silicone; see below), and botulinum toxin. Recently, safety has been demonstrated with treatments over tissue previously injected with medium-term soft tissue fillers.⁹ For those patients who have RF treatment and subsequently decide to have either a rhytidectomy or a blepharoplasty, it is best to wait at least 3 months because the tightening effects continue for months following treatment with the device. Use of the device in patients with pacemakers is contraindicated. In addition, care should also be taken to obtain a history of any metal implants, braces, or hardware; treatment should be avoided overlying these areas. The device can be used safely for patients of all skin types. In addition, as no damage to the hair follicle occurs with treatment, the risk of hair loss following treatment is not a potential problem.

Applications

Periorbital rhytids

An RF device was Food and Drug Administration-cleared in November 2002 for the treatment of periorbital rhytids. Subsequently, the device was cleared for treatment of facial laxity. Fitzpatrick et al⁶ treated 86 patients with periorbital rhytids and followed them up for 6 months in a blinded, multicenter prospective study. Patients received treatment in the lateral canthal and forehead areas. A single

pass was performed using energies ranging from 52 to 220 J, depending on location and skin thickness. Treatment efficacy was evaluated by comparison of photographs taken pre-treatment and at 2, 4, and 6 months post-treatment by blinded reviewers. Eighty-three percent of patients demonstrated an improvement from their baseline to their 6-month follow-up visit, with most gaining improvement by 1 Fitzpatrick point. In addition, eyebrow lift was assessed by using Adobe PhotoShop (San Jose, Calif), version 6.0, to measure the distance between a reference line (which was defined as a horizontal line drawn through the apex of the medial canthi) and the superior margin of the brow. For each side of the face, measurements from the horizontal reference line to the superior margin of the brow were taken at 1.5, 2, 2.5, and 3 cm lateral to the medial canthus. Six percent of patients gained an eyebrow lift, with an average of 1.49 mm of elevation on the right and 1.3 mm of elevation on the left. Similar findings were reported by Nahm et al.¹⁰

Middle and lower face

In a recent study, our group treated 24 patients with laxity of the neck, nasolabial folds, marionette lines, and jawline with the RF device using energies ranging from 106 to 144 J.¹¹ Two passes were performed on the forehead, 3 on the cheeks, and 1 on the neck. Each patient received 1 to 3 treatments spaced 4 weeks apart. Of the 24 patients, 17 demonstrated visible improvement at the 1-month follow-up evaluation. Most of the patients who showed improvement at the 1-month follow-up visit had an even greater improvement at the 3-month follow-up evaluation (Fig. 1). Similar to our findings, Alster and Tanzi⁴ reported improvement in mild to moderate cheek laxity and nasolabial fold prominence in 30 patients treated with RF using energies ranging from 103 to 131 J. Similar findings were reported by several other authors.^{5,12-15}

Buttocks and thighs

Although no studies have been published on the use of the Thermacool TC system for the treatment of cellulite and/or subcutaneous tissues of the buttocks and thighs, several studies on other RF devices used as monotherapy or in combination with other light devices have recently been published. Del Pino et al¹⁶ treated 26 female patients with visible cellulite on the buttocks or thighs with the Accent RF System (Alma Lasers, Inc, Caesarea, Israel), a unipolar RF device. Two treatments of 3 passes at 91 J/cm² were performed with adjustments of fluences, depending on patient tolerance of heat or to a temperature between 39 and 41°C on each treatment zone. Before and after ultrasound, measurements of the distance between Camper's fascia and the stratum corneum and stratum corneum to the muscle 15 days after the second treatment demonstrated that 68% of patients achieving a 20% volumetric contraction.



Fig. 1 Single Thermacool TC treatment of mid and lower facial laxity using the 1 cm² tip with 3 passes at an energy of 106 mJ. Note significant improvement over baseline in mid and lower facial laxity continuing to at least 6 months of follow-up.

Alster and Tanzi¹⁷ reported their results treating 20 patients in a split-side study of combined bipolar RF, infrared light, and mechanical suction-based massage device on the cellulite of thighs and buttocks. Subjects were treated in 8 biweekly sessions with 20-W RF, 20-W infrared (700-1500 nm) light, and 200 mbar vacuum (750-mm Hg negative pressure) on one side of the buttocks and thighs (other side untreated). Circumferential leg measurements and clinical improvement scores of photographs showed that circumferential thigh measurements were reduced by 0.8 cm on the treatment side, and 90% (18/20) of patients had 50% clinical improvement.

Anesthesia

Pain during the procedure varies significantly from patient to patient, from none to barely tolerable. Patients most often describe the pain as a brief burning sensation that rapidly dissipates. In the study by Fitzpatrick et al,⁶ most of the subjects reported their pain experience as mild to moderate. With appropriate preparation and use of the lower-energy and higher-pass protocol, however, most patients find the procedure tolerable. In the past, all our patients were anesthetized with topical anesthesia for 1 hour before the procedure. A study by Wahlgren and Quiding¹⁸ showed that, in patients who had a eutectic mixture of lidocaine and prilocaine (EMLA) applied under occlusion to the legs, successful anesthesia was achieved to an average depth of 2.9 mm. Although some patients can tolerate the discomfort associated with the procedure using only topical anesthetics, our experience has shown that an adjunctive means of pain control is typically required. This necessity is not surprising because the RF device can achieve ultrastructural changes down to 5 mm and likely has the potential to produce pain down to that level as well. In the past, we routinely offered oral analgesia but have recently found that, with the newer lower-energy protocol along with the addition of forced air-cooling, almost all patients report a minimal amount of discomfort and do not feel the need for oral analgesia. We have also found the use of forced air-cooling to

be helpful with other rejuvenating laser treatments, such as fractional photothermolysis, and have reported this elsewhere in more detail.¹⁹ Those patients in the periorbital study by Fitzpatrick et al⁶ who received nerve blocks reported having experienced no pain during the procedure. Although efficacious with regard to analgesia, we have 2 concerns regarding the use of nerve blocks or infiltrative anesthesia. The first is that the edema that results from tissue infiltration could potentially decrease efficacy owing to the relatively limited depth of penetration. The second concern is that we use excessive pain as an important feedback and possible indication that we should alter our treatment—either decrease energy or move to another area. For this reason, we do not advocate nerve blocks for this procedure.

Side effects

Most patients experience only temporary and mild erythema and edema after the procedure. One patient developed transient crusting, which rapidly resolved, and another developed a transient depression, which spontaneously resolved in 3 weeks. A variety of other, mostly mild, side effects have also been reported. During early trials with the device, erosions, vesiculation, and subsequent crusting were seen, but this has become much less common with further development of the device (Thermage, Hayward, Calif, personal communication). We and others have found that some patients describe tenderness along the jawline and neck that can last up to a few weeks after the procedure. Other patients have experienced a temporary dysesthesia in the treatment areas. The relationship between either dysesthesia or tenderness and treatment energy has not been determined. It is tempting, however, to speculate that the lower-energy, higher-pass protocol will be less likely to produce these unwanted effects. Other side effects that have rarely occurred include temporary anesthesia of the earlobe after treatment of the posterior neck. Another patient developed transient trigeminal neuralgia. At our center, we

noted the postoperative development of biopsy-proven granulomas in a patient who had a history of silicone injections in her nasolabial folds.²⁰ The granulomas developed in the areas in which she had received silicone injections and resolved over a 1-year period of treatment with steroid injections. Before the advent of the lower-energy and higher-pass protocol, there were more frequent occurrences of 2 side effects that required closer follow-up evaluation. The first of these is the development of mildly indurated subcutaneous nodules. These occurred primarily on the neck but were occasionally also seen on the jawline and perioral regions. These resolved spontaneously over a period of several weeks. The lesions have not been histologically characterized but may represent an inflammatory panniculitis-like reaction. Owing to the apparent increased sensitivity of the neck, we now use only the lower-energy setting of approximately 83 J and will often perform fewer passes than on the face. Since we have adopted the lower-energy treatment protocol, these nodules have rarely been seen. The other side effect that seems to correlate with the higher-energy treatment protocol is fat atrophy. The loss of fat causes localized unevenness, which appears relatively late during the postoperative period. Although the natural history is for self-correction over a period of 1 to 2 years, it is possible (and often advisable) to treat any remaining contour irregularities with injectable fillers or fat transfer.

A recent study retrospectively examined the safety of Thermacool TC in 600 consecutive patient treatments on the lower face.²¹ Treatments were done with the 1 cm² standard tip at 81-124 J/cm², 1 cm² "fast" tip at 62-109 J/cm², 1.5 big fast tip at 75-130 J/cm², and a 3 cm² bigger tip at equivalent fluences as availability allowed. The most common immediate and expected clinical effects were erythema and edema lasting less than 24 hours, although 6 patients reported edema lasting for up to 1 week. There were no permanent side effects. In total, 2.7% of treatments resulted in temporary side effects, the most significant of which was a slight depression on the cheek in 1 patient, which completely resolved within 3.5 months. Other side effects included localized areas of acneiform subcutaneous erythematous papules in 4 cases and a linear superficial crust in one case with the original tip, all of which resolved within 1 week. One patient reported small erythematous subcutaneous nodules resolving in 17 days. Tenderness of the neck lasting from 2 to 3 weeks was also reported in 3 cases. Likewise, the authors conclude that, as treatment algorithms evolved over the 4 years of this study, the algorithm of multiple passes at lower fluence was associated with better clinical outcome and greater patient acceptance.

Other applications/future directions

Recent applications where RF has shown promise has been in the treatment of rosacea,²² acne scarring,^{23,24}

hypertrophic scars, and keloids,²⁵ and studies have demonstrated efficacy and safety in darker skin types.²⁶

Studies are currently under way at many facilities to establish the potential usefulness of the Thermacool TC device to treat laxity of the arms, legs, abdomen, and buttocks. Early anecdotal reports suggest that treatment of the superior half of the buttocks can provide a lift to the inferior portion. In addition, early results of treatment of the extremities have demonstrated a decrease in the circumference of the treated arm or leg. At least 4 patients in our facility demonstrated marked improvement in abdominal laxity after a single treatment with the device. They both denied having experienced any weight fluctuations, change in an exercise regimen, or other pertinent behavioral modifications.

Novel combination therapy with other light-based modalities are being investigated currently to examine whether RF can be synergistically used with other devices to enhance treatment efficacy.²⁷⁻³⁰

Conclusions

Radiofrequency technology provides a viable, noninvasive treatment alternative for mild tissue laxity of the periorbital region, nasolabial folds, jowls, and marionette lines, as well as the possibility of tightening on the abdomen, buttocks, and thighs. In addition, it may improve the appearance of acne scars and improve acne.^{23,24}

Although RF does not improve laxity to the same degree as surgery, it does have the advantage of avoiding surgery-associated recovery time and potential complications. Favorable aspects of using RF for dermatologic purposes include minimal chance of side effects and rapid treatment times. A number of studies are currently under way to develop additional dermatologically relevant treatment applications for RF. More rigorous randomized and blinded studies are needed to validate our observations.

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