Non-Invasive Cosmetic Procedures

Thomas Procedures in Facial Plastic Surgery

R. James Koch, MD
Director
Northern California Face and Laser Institute
Palo Alto, California, USA

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2 Enterprise Drive, Suite 509
Shelton, CT 06484
Tel: 203-402-0646
Fax: 203-402-0854
E-mail: info@pmph-usa.com

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Radiofrequency Tissue Tightening

R. James Koch, MD and Brain P. Kim, MD

Introduction

It is generally agreed that we have excellent modalities to resurface or peel the superficial layers of skin. This may be accomplished by the use of ablative lasers (such as pulsed carbon dioxide and erbium:YAG) or by other ablative modalities (such as chemical peels and dermabrasion). Nonablative skin or soft tissue tightening would certainly be desirable when there is no indication for superficial skin peeling. For example, if there was no actinic damage, pigment irregularities, or texture problems. In addition, leaving the epidermis and upper dermis intact would reduce the healing process. Furthermore, while we already have reliable surgical procedures, tissue repositioning without surgery would fit into the noninvasive realm.

The ThermaCool™ System (Thermage Inc., Hayward, CA) has been cleared by the Food and Drug Administration for the noninvasive treatment of wrinkles and rhytids. Currently, all other uses are investigational. In brief, it works by using radiofrequency (RF) energy to heat the skin. Concurrent cooling protects the epidermis during the treatment, and because of this one can safely deliver up to 144 joules/cm^2 of energy to a treatment site. Because of its capacitive coupling treatment tip, it heats a uniformly large volume of tissue. The clinical effects of this are tightening of the treated tissue yielding a noninvasive browlift, facelift, or necklift. The mechanism for these effects are two-fold: (1) immediate contraction of existing collagen fibrils, and (2) a delayed wound healing response which most likely entails neocollagen production by stimulated fibroblasts.

Radiofrequency is a form of alternating electric current (AC current). Most medical RF devices like electrosurgery units operate at 500 kilohertz or more. Electric fields are created between two electrodes which cause molecules to rotate or move. At the surface of the skin, the charge is changing polarity from positive to negative, alternately attracting and repelling electrons and charged ions. Polar molecules are induced to rotate back and forth, vibrating at 6 million times per second. It is the resistance to this movement that creates heat in the tissue.

The ThermaCool System consists of three principle components: the RF Generator, Cooling Module, and Handpiece Assembly (consisting of a handpiece and treatment tip) (**Figure 6-1**). The generator supplies RF power while continuously monitoring and displaying output current, output energy, treatment duration, and measured impedance. The return path for the electric current is through a return pad.

The generator also controls the cooling module, which circulates coolant through the handpiece assembly. Canisters of coolant are utilized in the cooling module. The handpiece assembly delivers RF energy while cooling tissue by conduction (**Figure 6-2**). It is comprised of the reusable handpiece and the sterile, single-use treatment tip. Inside the handpiece, there is a force sensor that ensures that the tip is in contact with the patient, and that not too much or too little contact force is applied. In addition to the treatment tips, there are kits, which contain

Figure 6-1. ThermaCool System consists of three principle components: the RF Generator, Cooling Module, and Handpiece Assembly (consisting of a handpiece and treatment tip).

coupling fluid, return pads, cryogen canisters, and skin marking paper.

Preoperative Considerations

Unlike most lasers, one is able to treat all skin types with this device. The depth of the heating achieved is tip-dependent, and not wavelength-dependent. Each tip contains an EPROM memory chip, which stores information on its size, model, and its heating and cooling parameters. There are four thermistors, one in each corner, to detect the temperature of the tip and ensure proper cooling is delivered to protect the epidermis. Different heating profiles will be introduced through the use of different tips. So as new treatment tips are introduced to change depth of treatment and associated control parameters, one merely puts on a new tip and all of these settings are uploaded to the RF generator from the tip's memory chip.

Similar to a monopolar electrocautery or "Bovie" unit, an electric circuit is created by the device and the patient becomes part of this circuit. The current flows out of the RF generator, through the handpiece cable, through the treatment tip, and into the skin. Then the current flows through the patient's body and is collected by a return pad on the patient's back. It then flows through the return cable and back to the generator.

There are three phases to the treatment cycle: precooling, simultaneous delivery of RF and cooling, and postcooling. After the tip comes into contact with the skin, coolant is sprayed on the back surface of the electrode. This draws heat out of the surface of the skin, and generates a thermal gradient. Then the RF energy and cooling are applied in parallel. At the end of RF delivery, the system initiates a postcool phase, which safely removes the heat. All of these phases are computer-controlled.

Technique

With regard to the actual procedure, our practice is to have the patient come in to the clinic 1 hour before the procedure. After jewelry is removed, topical

Figure 6-2. ThermaCool system handpiece assembly.

5% lidocaine cream (ELA-Max® 5, Ferndale Laboratories, Ferndale, Michigan) is applied to the area to be treated for 1 hour and occluded. There is some discomfort experienced at the site being treated, but this is brief and there is no discomfort following the procedure. This sensation has been described as a building heat intensity that then dissipates. Clinicians have dealt with this by supplementing topical analgesics with regional nerve blocks and/or oral or IV sedation. Our current practice is to offer oral sedatives and analgesics but then the patient loses the ability to drive home. Most of our patients do not want this, and like the idea of it being a true "lunchtime" procedure. Some clinicians will use the level of discomfort as a guideline for treatment energy levels, maintaining the patient at a "2 1/2" on a four point discomfort scale to balance efficacy, patient comfort, and safety.

After placement of the return pad, the skin marking paper is used to temporarily mark the treatment area. The coupling fluid is used liberally to facilitate contact between the skin site and treatment tip. Recommended treatment levels vary depending upon the area being treated (**Figure 6-3**). There is usually no change in the surface appearance of the treated skin, and any occurrences of local erythema and edema are usually resolved in 2 days.

Repeat treatment sessions are usually performed after 2-3 months, and the author usually plans a series of 2-3 of these. Some clinicians report promising results using multiple low energy passes in the same session. There may also be a place for maintenance treatments with prior treated patients getting annual treatments, for example.

Figure 6-3. ThermaCool System Console Panel where desired treatment levels are entered.

Results

The senior author (RJK) has performed seven Thermage-sponsored clinical trials to assist in the development of the device. These include the following studies: (1) the nonsurgical browlift, (2) facial treatment with moderate settings and multiple passes, (3) facial contouring with the medium depth tip, (4) the long-term wound healing effects of radiofrequency energy, (5) facial contouring with the deep tip, (6) the noninvasive tightening of arms, and (7) the noninvasive treatment of cellulite. We will focus on the first one.

In an initial study treating the periorbital and forehead areas of 86 patients, the ThermaCool showed significant efficacy after a single treatment session: 83% showed improvement in the crow's feet area using a standardized wrinkle score, and 50% rated their aesthetic change as good or very good (unpublished data from Thermage, Inc). A novel measurement system was developed for the quantification of brow position changes. Subsequently, we took part in a multi-institutional study to evaluate the effects of multiple treatment sessions on objective measures of efficacy.

One hundred twenty five patients were randomized in a 1:2 ratio into either a single treatment or a multiple treatment group. The multiple treatment group was treated monthly for up to four treatments. At the Stanford site, there were a total of 40 subjects, the protocol was approved by the Institutional Review Board, and it was performed under a clinical trial agreement with Thermage, Inc.

Similar to the single treatment study, patients were treated in the periorbital and forehead areas, and followed for 6 months after last treatment (which would be 9-month follow-up for the multiple treatment group). In addition, standardized wrinkle scoring was applied to blinded photographs by three independent reviewers at 2, 4, and 6 months.

The preliminary results from our site suggest that approximately 60% of patients have significant brow elevation after 1 treatment, and approximately 80% of patients have significant brow elevation after 4 treatments. Common patient comments include "my eyes appear more open" and "my forehead is

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Figure 6-4. Patient treated with the 1.5 cm^2 tip using multiple neck passes immediately following submental liposuction. (A) Baseline, (B) 9 months after treatment. Note improvement in neck contour.

smoother". Many patients have pre-existing brow position asymmetries, and interestingly the ThermaCool treatment tends to equalize many of these discrepancies.

In practice, there have been encouraging early results in its use for active acne and as a skin tightening adjunct to body liposuction. The author has seen very good results for shallow acne scars and in conjunction with neck liposuction (**Figure 6-4**).

Postoperative Care and Complications

Because it is a nonablative procedure, there is no need for antibiotics, wound dressings, or ointments. We have treated all Fitzpatrick Sun-Reactive Skin types without hyper- or hypopigmentation, and have not experienced any complications to date.

Figure 6-5. Patient treated with the 1.5 cm^2 tip using multiple facial passes during one treatment session. (A) Baseline, (B) 4 months after treatment. Note improvement in jawline.

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Conclusions

Our experience is that our very good Therma-Cool results have been comparable to that of the minimally invasive procedures; that is, endoscopic browlift for brow ptosis, and mini-facelift for moderate facial elastosis (**Figure 6-5**). For the neck, there is not yet a time-tested minimally invasive procedure, thus our current options for significant laxity is a traditional facelift (via neck component) versus ThermaCool.

Many patients do not want the cost, risk, and down time associated with surgical procedures, and this gives them an alternative. We have always attempted to reduce the telltale signs of surgery, but the patient-driven trend is avoidance of an "operated" look.

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