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NEW METHODS AND TECHNIQUES

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Facelift

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NON-SURGICAL RADIOFREQUENCY FACELIFT

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Abstract

There has been considerable interest in using non-ablative methods to rejuvenate the skin. The ThermoCool TC™ (Thermage™ Inc.) is a radiofrequency (RF) device that has been introduced to induce tightening of the address the problem of skin via a uniform volumetric heating into the deep dermis tightening, resulting in a 'non-surgical facelift'. Radiofrequency produces a uniform volumetric heating into the deep dermis. Twenty treatment areas in 17 patients were treated to evaluate the efficacy and safety of RF treatment to the brow and jowls. The technique was found to produce gradual tightening in most patients, and there were no adverse effects.

Background

There has been considerable interest in using non-ablative methods to rejuvenate the skin. Non-ablative treatment produces controlled thermal injury to the dermis while protecting the epidermis. Many laser and light sources have been used to smooth the skin by inducing collagen regrowth and remodeling (Table 1). While these modalities result in

increased collagen and smoothing of the skin, none produce the tightening seen with the CO₂ laser. All of these devices work by utilizing light to produce heat in the targeted area to increase and remodel collagen. They produce different levels of heat at different depths and in different tissues depending on their wavelength, spot size, and energy delivered.

The ThermoCool TC™ (Thermage™ Inc.) is a radiofrequency (RF) device that has been introduced to address the problem of skin laxity. Radiofrequency energy has been used to treat cardiac arrhythmias¹, benign prostatic hypertrophy², sleep apnea³, and for endovenous closure of the saphenous vein⁴. The ThermoCool TC™ delivers RF energy to the skin with contact cooling to protect the epidermis. It has FDA approval for the noninvasive treatment of periorbital rhytids and wrinkles. It is also approved for dermatological and general surgical procedures for electrocoagulation and hemostasis.

Unlike lasers and light sources, which produce heating in tissue according to the differential absorption of optical energy by the target (selective photothermolysis), the ThermoCool TC™ uses RF energy to deliver a uniform volumetric heating effect into the deep dermis and underlying tissue. Heat is generat-

Table 1

Devices Used For Non-Ablative Collagen Remodeling

- N-Lite (585 nm) (Pulsed Dye)
- Vbeam (595 nm) (Pulsed Dye)
- Medlite (1046 nm) (Nd:YAG)
- CoolTouch (1320 nm) (Nd:YAG)
- Smoothbeam (1450 nm) (Diode)
- Vasculite (515-1200 nm) (Pulsed Light)
- IPL Quantum (560-1200 nm) (Pulsed Light)

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ed by the tissue's natural resistance to the flow of current within an electric field, not photon absorption. The ThermoCool TC™ has a unique capacitive coupled electrode design that disperses energy uniformly across the surface area of the treatment tip membrane, creating a uniform electric field (zone of heating) in tissue at controlled depths. This electric field changes polarity 6 million times per second. The charged particles within the electric field change orientation at that same frequency, and the tissue's natural resistance to that movement generates heat. This is referred to as resistive heating. By utilizing a unique method of contact cooling prior to, during, and post application of the energy, a reverse thermal gradient is produced with the greatest heating in the deep dermis while the epidermis is protected from thermal injury (Fig. 1). The procedure tightens deep tissue while sparing the epidermis.

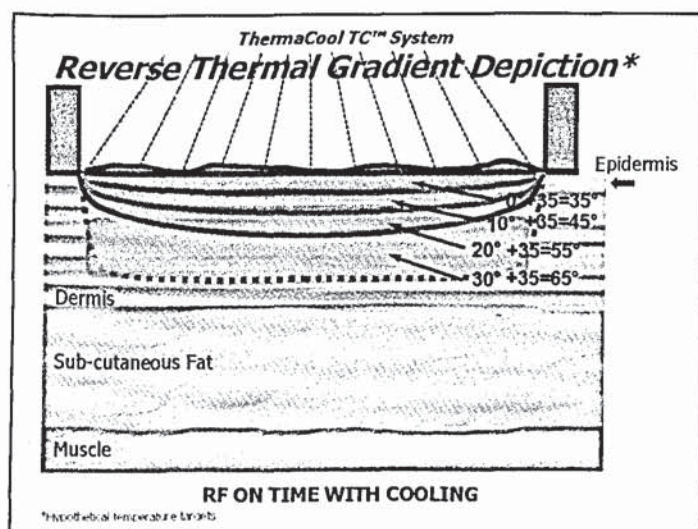


Figure 1.

The depth of heating using RF technology is dependent on the treatment tip, not wavelength. Depths of heating and cooling are controlled by treatment tip geometry and/or cooling parameter adjustments within the tip. In the future new treatment tips may enable different levels of the dermis and subcutaneous tissue to be targeted.

The complete mechanism of action of the tissue tightening is unclear. It has been hypothesized that the ThermoCool TC™ delivers enough heat into a large volume of tissue to cause immediate collagen

contraction followed by a significant wound healing response, resulting in gradual tissue tightening over time. The heat produced by the RF energy changes the molecular structure of the triple helix collagen molecule by heating it to a point where it breaks the hydrogen bonds, resulting in collagen contraction⁶. Unpublished Transmission Electron Microscopy (TEM) research performed immediately post-treatment reinforces this hypothesis. This research demonstrated an immediate morphological change in individual collagen fibrils and confirmed partial denatured (contracted) collagen in the mid and deep dermis.

Equipment

The ThermoCool TC™ System (Fig. 2) consists of a radiofrequency (RF) generator, cooling module,

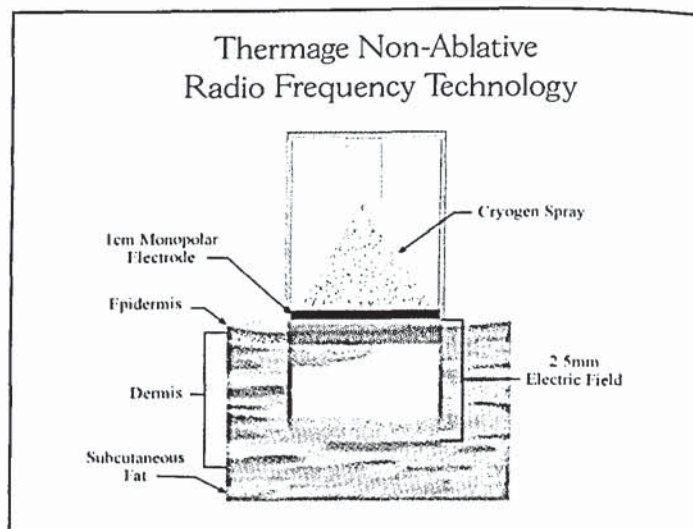


Figure 2.

hand piece, and a single-use capacitive coupled treatment tip. The RF generator produces a 6-megahertz alternating current RF signal. It has a Pentium-based computer that can receive, process, and display real-time information from sensors in the hand piece during each treatment cycle. This information includes RF "on" time, tissue temperature, tissue impedance, energy delivered, tip application pressure, and tissue response. Software monitors this information and will not permit or will abort treatment if any one of these falls out of preprogrammed parameters. The cooling module houses

the cryogen, which is used as a contact coolant to protect the epidermis from thermal injury. The hand piece contains a computer logic board and microprocessor that measures and transmits information to the RF generator module. Cryogen spray is delivered within the hand piece to cool the inner surface of the treatment tip membrane. A valve in the hand piece regulates the rate, frequency, and duration of the delivery of cryogen prior to, during, and post-treatment to protect the epidermis from overheating. The sterile disposable treatment tip is for single patient use. An internal clock permits only a predetermined number of treatment cycles and will make the tip inoperative after a certain period of time. Since the surface membrane of the treatment tip is critical for delivering a precise amount of RF energy to the skin while providing simultaneous heating and cooling and measuring important data, this internal electronic clock ensures that each patient is treated with a new, intact, well functioning tip. The surface membrane of the treatment tip is critical to capacitively couple the RF energy to the skin. The treatment tip is both a heating and cooling device, and the contact membrane continually monitors skin surface temperature through skin thermistors.

Procedure

A grid is applied to the area to be treated using dye transfer paper (Fig. 3), which ensures uniform treat-

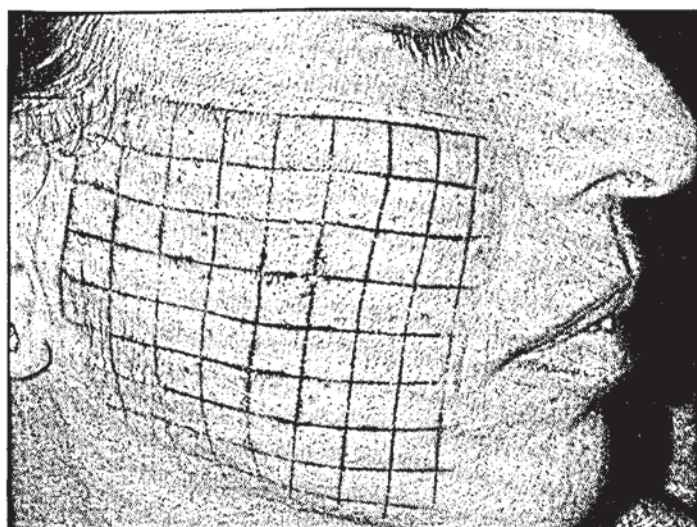


Figure 3.

ment of the entire skin surface area. The procedure can be performed using topical anesthesia; we use ELA-Max® 5 (lidocaine 5%; Ferndale Laboratories, Inc., Ferndale, Michigan) under occlusion (Fig. 4). It is left in place for one hour and is removed only in

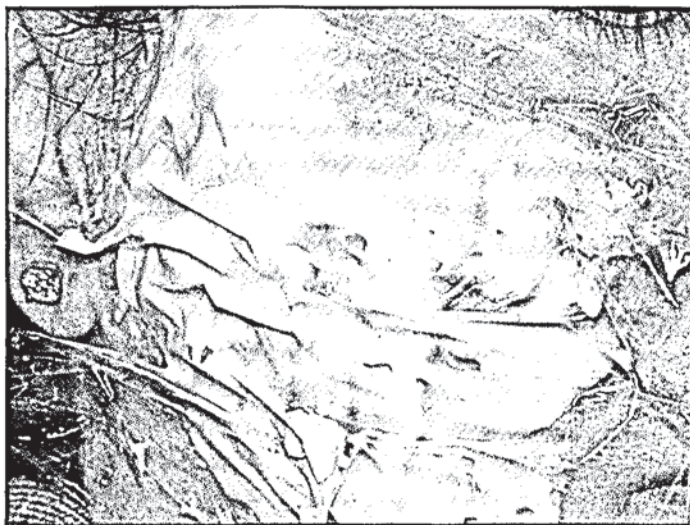


Figure 4.

the area to be treated immediately before treatment. Oral medicines, nerve blocks, and/or intravenous sedation have also been used. However, eliminating patient feedback to pain to determine safe treatment levels can increase the risk of injury. Tumescant anesthesia or local infiltration is not recommended because either may change the local impedance, which in turn may affect capacitive coupling of RF to skin, possibly resulting in either a burn or ineffective treatment.

Treatment algorithms are still being developed. Most physicians treat the entire skin surface area, believing that the cumulative tissue tightening will lead to optimal results. Some physicians treat only the 'anchoring points', believing that this is all that is necessary and actually is preferable. Others make several passes at lower energies and some do a second pass only on select areas (this is the technique we used in this study). Some physicians also plan to do multiple treatments. Whether one of these treatment plans proves to be better than the others remains to be seen.

Patient Study

We treated 17 female patients (20 treatment areas) with Fitzpatrick Skin Types II to IV ranging in age from 42 to 60. In our study one treatment session was performed and the entire area (i.e., the entire forehead for the brow lift and the entire cheek extending to just beyond the nasolabial fold and 1 cm below the jawline for treatment of the jowls, puppet lines, and nasolabial folds) was treated via a single pass. A second pass at the same energy was then made over the 'anchoring points'. The first 12 patients were treated only in the brow area; the next 8 were treated for reduction of nasolabial folds, puppet lines, and jowls. Three patients who had had their brow treated returned to have their jowls treated. One, who had had improvement in her brow, had a second treatment on the brow six months following her first treatment. Long-term evaluation to see if there is further improvement will be done. Initial treatment was performed at a setting of 16.0 (144 J/cm²). This was reduced if the pain was severe, and all patients were treated ultimately at settings of 14.5 (125 J/cm²) to 16.0 (144 J/cm²). The discomfort the patient feels builds to a crescendo as the heat builds up and then decreases after the RF energy is turned off and the cooling continues. It is important to maintain contact with the skin throughout the entire treatment cycle to insure that adequate post-RF cooling occurs. We used discomfort level in determining treatment levels. All patients were successfully treated utilizing only topical anesthesia. Patients were evaluated at monthly intervals and were followed for a minimum of four months.

Results

It has been stated that the improvement with the ThermoCool TC™ is gradual to the point of not being detected by the patients themselves⁷. This was the case with many of our patients. Since the improvement is gradual, occurring in many cases over a period of up to four months, the patient does not see an immediate dramatic difference. Since the changes are subtle, the patients often have difficulty appreciating the slow improvement. Once shown the pre-treatment photographs, however, most of

the patients in our study felt that they had benefited from the procedure and three of the original twelve patients requested treatment to an additional area. In some patients improvement was seen as early as six weeks with continued tightening over time, however in the majority there was no appreciable change at all for several months. 18 of the 20 patients treated (90%) saw improvement when pre- and four-month post-treatment photographs were compared (Figs. 5-12).



Figure 5: Pre-treatment.



Figure 6: Same patient as Fig. 5, four months post-treatment.



Figure 7: Pre-treatment.



Figure 8: Same patient as Fig. 7, four months post-treatment.

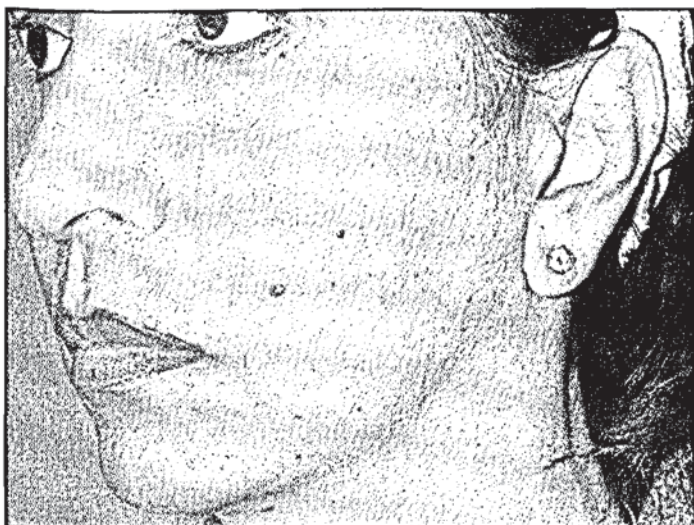


Figure 9: Pre-treatment.



Figure 10: Same patient as Fig. 9, four months post-treatment.

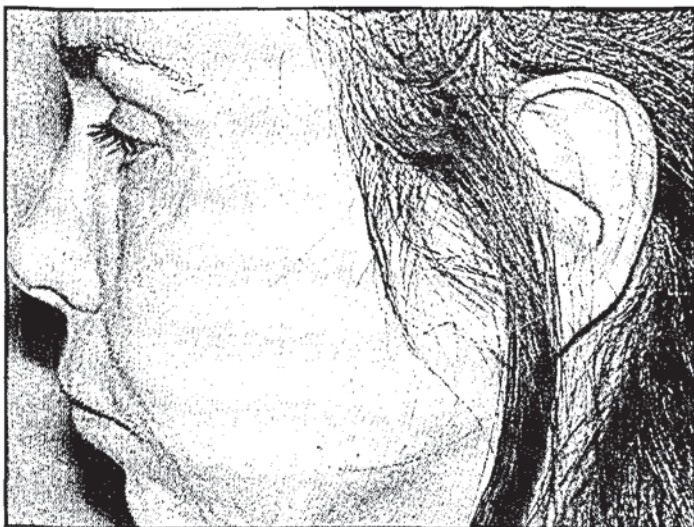


Figure 11: Pre-treatment.



Figure 12: Same patient as Fig. 11, four months post-treatment.

We had no complications. There was mild erythema, which lasted a few hours. There were no burns, blisters, pigment changes, or nodularity in any patient. We attribute this in part to the fact that we lowered the energy level if the patient had more than the expected discomfort. This feedback would not be present if a patient were treated with a nerve block, local anesthesia, or intravenous sedation. The procedure is safe and there was no "down time" following the procedure. There is continued improvement over a several month period.

Conclusion

The ThermoCool TC™ is an intriguing method of safely and efficiently delivering heat to the dermis to attempt to effect changes in the collagen resulting in collagen remodeling and tightening. Like all new applications of technology, it is still a work in progress. Treatment algorithms, the ability to predict which patients are most likely to have a positive response, and analysis of long term results are still evolving. While our study was to determine the efficacy of a single treatment session, some physicians are doing studies to determine if multiple treatments produce better results.

At present there is definite but subtle improvement in most patients. If the ThermoCool TC™ proves to be able to predictably produce skin tightening, it will be a major advance in non-surgical rejuvenation.

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