The Medical Face Lift: A Noninvasive, Nonsurgical Approach to Tissue Tightening in Facial Skin Using Nonablative Radiofrequency

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BACKGROUND. Traditional surgical rhytidectomy is aimed at correcting facial skin that is sagging, which is caused by excessive skin laxity as a result of photoaging. Operating room facilities, general anesthesia, and a skilled surgeon are needed. The patient has recuperation time, which may be prolonged if complications arise. Incision lines are where they could be easily camouflaged or where they blend with natural lines. Nevertheless, healing of surgical wounds and concurrent scars are seen in all patients.

OBJECTIVE. To evaluate the function of a novel technology that tightens tissue, using energy in the radiofrequency segment of the electromagnetic spectrum to produce internal heat within the skin.

METHODS. Fifteen patients had one treatment session under topical anesthesia and without sedation. Ages ranged from 41 to 68 years. The total treatment time lasted 40 minutes or less. A new radiofrequency unit with concurrent delivery of a cryogen spray to spare the epidermis from burning was used. Pain was used as a clinical indicator of maximum tolerable energy delivered. No postoperative care was needed.

RESULTS. All patients experienced minimal discomfort and were able to return to their normal activities right away. One patient did not respond to this treatment. For all of the others, visible results appeared approximately 12 weeks after the treatment session. In one patient, however, the results started at only 1 week after treatment. Four independent physicians outside of the study reviewed standardized photographs to evaluate results. The patients were followed for 6 to 14 months.

CONCLUSION. Fourteen of 15 patients obtained cosmetic improvement from facial skin tightening induced by a novel nonlaser, nonablative, noninvasive source. Nonablative radiofrequency is a safe and effective method to achieve tissue tightening of the face to correct excessive sagging from photoaging. Patients had visible results as early as 1 week and generally within 3 months after the procedure without wounding or scarring.

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A NEW technology that uses radiofrequency as the source of energy for nonablative tissue tightening has been developed by Thermage Inc. (Hayward, CA). A prototype of this machine, which also generates a spray of cryogen before, during, and immediately after the energy pulse, was used for this study. The cryogen spray is delivered from a nozzle housed within the treatment electrode and against the back of the electroplate, which touches the skin of the patient (Figure 1). This is a form of parallel cooling to preserve the surface of the skin from burning. The principle of simultaneous heat and cold delivery is currently in use by nonablative lasers used for dermal remodeling. In contrast with these devices, which are light based, the radiofrequency unit uses electricity in the safest, radiofrequency portion of the spectrum, at 6 MHz to generate heat in tissues. A nonablative laser delivers heat to the dermis by contiguous spread, with a decreasing gradient of heat. In contradistinction, this new radiofrequency system generates heat by the tissue resistance to the flow of electrons (impedance) while creating a uniform, intense, and sustained volumetric heating in the dermis. In addition, a laser is subject to optical laws, which means that most of its light is reflected, diffracted, or scattered, leaving only a fraction of that energy available to reach the intended dermal target.

Radiofrequency is not new to skin surgery. Available units are used to produce electrocoagulation and electrodesiccation. This machine differs from the previously available ones in that a concurrent spray of cryogen spares the epidermis from damage. In addition, the application of heat is uniform due to a new capacitor membrane at the treatment tip, which delivers a uniform, intense, and sustained level of heat to the dermis and beyond.

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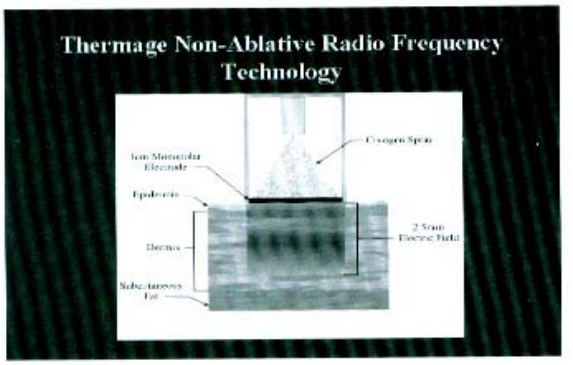

Figure 1. Diagrammatic illustration showing the treatment tip housing a nozzle, which sprays cryogen within the treatment tip.

Heat can change the shape of collagen fibrils while altering their periodicity and more importantly their length and diameter, leading to a shrinkage of collagen. Thermal injury inflicted on tissue is responsible for skin tightening after skin laser resurfacing.[1] A zone of heated yet viable collagen is found in the base of the laser wound under the debris from coagulated tissue. Heated fibroblasts are implicated in new collagen formation and subsequent tissue remodeling, which is cosmetically beneficial. Nevertheless, in laser resurfacing, ablation of tissue is necessary for reliably heating collagen to this degree. This implies a healing time before cosmetic results are apparent. Any unforeseen complications may result in less than optimal healing and less than optimal cosmetic results.

The nonablative radiofrequency system used in this study was devised to eliminate posttreatment morbidity as there is no tissue ablation.

Methods

Fifteen volunteer patients, who were part of a larger study involving different anatomic areas, were analyzed retrospectively and are the subject of this report. They were all women between the ages of 41 and 68. All had one treatment session only. One of them had a subsequent treatment session in different areas of the skin of the face. Informed consents were obtained, and appropriate institution review board protocol approval from two separate committees was secured. Routine medical history and physical examination were done for each patient. Excluded were patients with an ongoing treatment with topical or oral retinoids, healing problems, pacemakers, and skin disease with possible Köebner phenomenae. Skin types ranging from II to V in the Fitzpatrick's classification were included. No special skin preparation was undertaken except for washing the face with soap and water and application of a thick layer of ELA*Max* 4% (Ferndale Laboratories, Inc., Ferndale, MI) 1 hour before the procedure as a topical anesthetic.

Five patients were treated with a 0.25-cm bipolar electrode. Eight were treated with a "window frame" bipolar electrode, whereas a 1-cm monopolar electrode was used for treatment in two patients. Treatment settings were at a nominal setting of 11 for the two patients with a 1-cm electrode tip, equivalent to 52 J/cm^2. The average current was 0.447 amps. Energy settings of 0.201 to 0.395 amps were used for the other electrodes (average, 0.218; 110 amps).

The preauricular skin, treated in an area of approximately 2.5 × 4.5 cm, was treated in all 15 patients. The patients were asked to grade their pain level in a scale of 0 to 4, with 1 being mild and 4 being intolerable. The power settings in the machine were dropped if a level of 4 was reached. This was rarely seen in this group of patients because the energies selected were conservatively low.

Postoperatively, the patients were asked to remain in the premises for 1 hour for evaluation of possible complications, that is, thermal burns. No routine postoperative care was required.

Standardized photography with a high-resolution digital camera (Epson Photo PC 3000Z; Epson America, Inc., Long Beach, CA) was taken before the procedure, immediately postoperatively at 1 week after, and monthly thereafter for at least 4 months and for as long as 14 months.

Four dermatologic surgeons independent to the study were asked to evaluate the results by examination of the photographs. The following areas were graded: nasolabial fold softening, mandibular line improvement, cheek contour improvement, and, where present, marionette line softening. A grading of one of the following four degrees of improvement was given for each graded area on each patient: 0% to 25%, 25% to 50%, 50% to 75%, or 75% to 100%.

Results

All but one patient showed results. The nasolabial fold was moderately softened in some patient, whereas in others this change was remarkable. For nasolabial softening, 50% were considered to have at least a 50% improvement (Figure 2).

Cheek contour improvement refers to the increased tone to cheek skin, appearing less flabby. This change was graded 50% or more for 60% of patients (Figure 3).

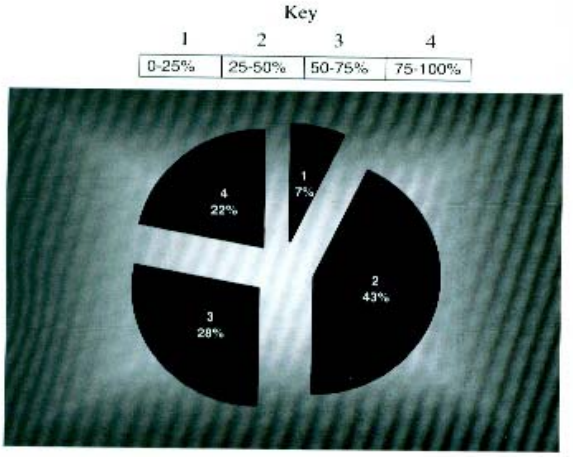

Figure 2. Nasolabial fold improvement.

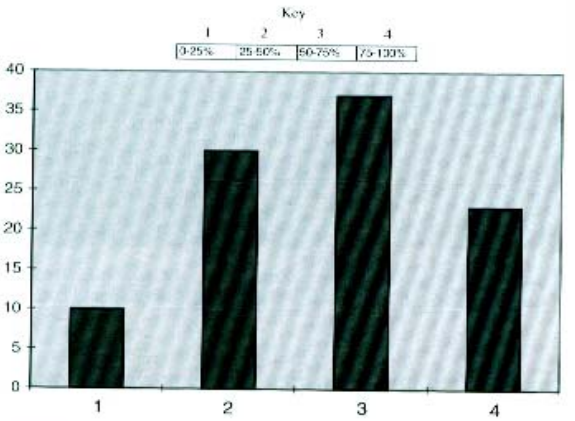

Figure 3. Cheek contour improvement.

Mandibular line improvement was the least visible change. It was defined as a sharpening of the mandibular edge; 50% or better was obtained in only 27% of patients (Figure 4).

Marionette lines, where present, improved 50% or more in 65% of patients (Figure 5).

One patient developed a 0.25 × 0.25-cm superficial burn on the skin of the temple. This was treated with two sessions of microdermabrasion, which resulted in virtual fading of the scar by the 3rd month postoperatively. No other side effects were encountered.

During the treatment, the patients experienced an intensely hot sensation lasting less than 2 seconds and immediately followed by one of intense cold that very

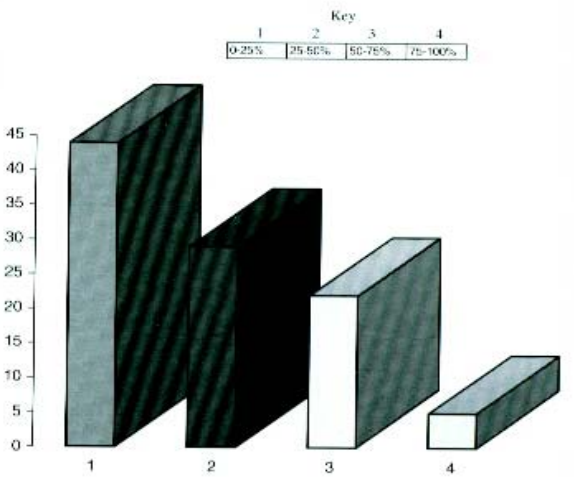

Figure 4. Mandibular line improvement.

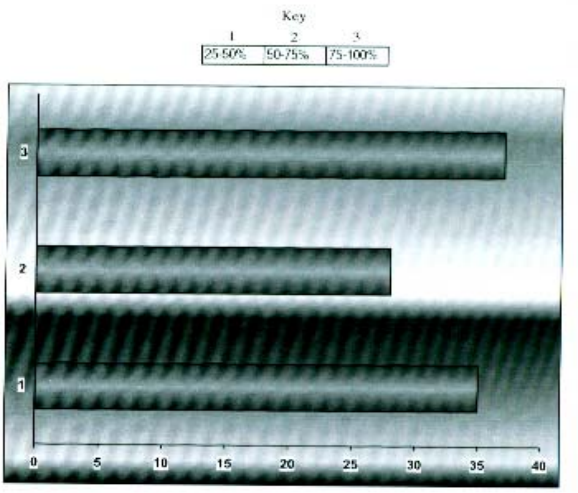

Figure 5. Marionette line improvement.

much neutralized the other. They all tolerated the procedure well with the help of the topical anesthetic. None developed postoperative soreness, edema, or ecchymoses; in fact, for all but one patient, there was no visible evidence of the procedure having been done at all in the immediate postoperative period. No down time existed for patients.

The improvement was gradual (Figures 6–10) to the point of not being detected by the patients themselves. Many said to us that they heard positive comments from people but without pointing out what the

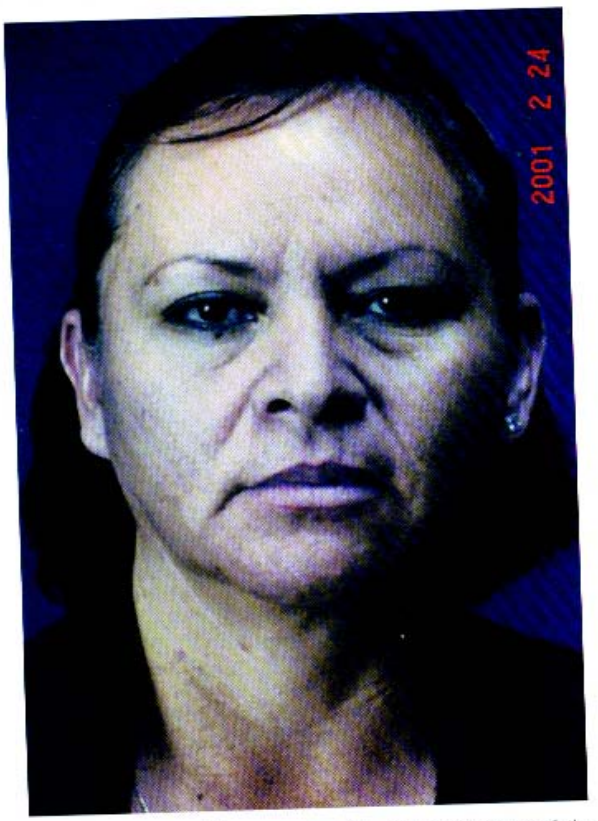

Figure 6. A 42-year-old woman showing gradual softening of the nasolabial folds and marionette lines (preoperative).

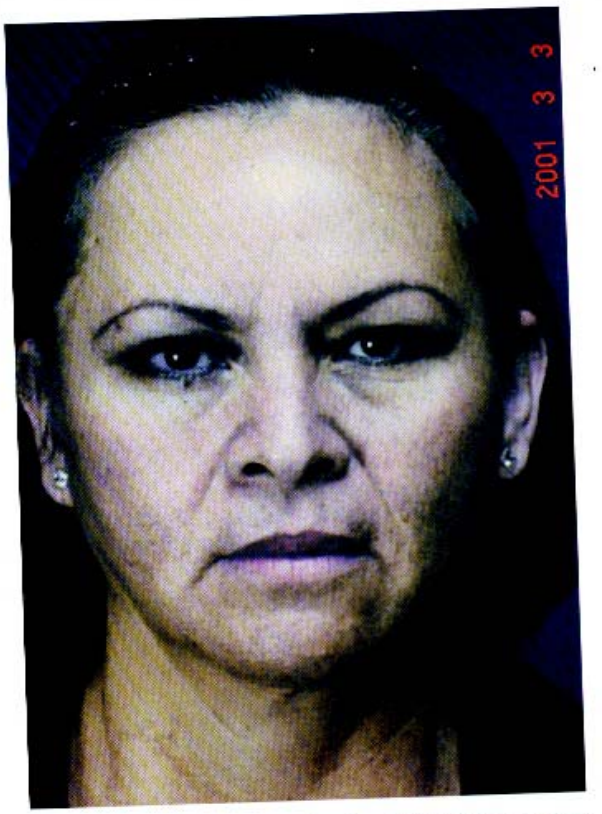

Figure 7. A 42-year-old woman showing gradual softening of the nasolabial folds and marionette lines (1 week, no change).

improvement was. The changes were evident upon comparison of preoperative and postoperative photographs. They appeared as early as 1 week postoperatively (Figures 11–13).

The patient that did not respond was overweight and had very heavy cheeks in comparison to the other patients in this group who were thin or medium built.

Discussion

Gradual changes, no down time, and minimal risk characterize this new procedure. The cosmetic improvement that follows a surgical rhytidectomy is undoubtedly more dramatic and more rapidly seen, and in this respect, this procedure can not be compared with it; however, it represents the possibility of similar cosmetic improvement for patients who are afraid of a major surgery, those who are still too young for it, and those who are poor surgical candidates. The changes seen in these patients were previously obtainable only through a surgical face lift. We believe this new technology produced tissue tightening through intense sustained uniform heat into the superficial, mid dermis, and deep dermis and possibly into the deeper subcutaneous tissue.

Of interest is that these patients were all treated in the preauricular areas. Since the time that we treated this group, the authors have tried treating the entire skin surface of the cheeks but failed to obtain comparable results. We also tried treating directly over the nasolabial folds with similarly disappointing results. We believe that treating at the preauricular areas rather than the entire surface of the skin of the cheeks or over the skin of the nasolabial folds makes a significant difference. The level of energy used or the type of electrode tip did not seem to make a difference for the cases that failed. The treated areas did.

One of the author's (J.R.E.) theory, is that in these patients the preauricular area served as an anchoring

Figure 8. A 42-year-old woman showing gradual softening of the nasolabial folds and marionette lines (1 month).

Figure 9. A 42-year-old woman showing gradual softening of the nasolabial folds and marionette lines (2 months).

point to stretch the skin distally to it. Finding the ideal anchoring point becomes very important in designing the ideal treatment algorithm for a given patient. There are many individual differences in skin redundancy and bone contour in patients, and for each, the ideal anchoring point should be determined in order to maximize the results.

In general, the anchoring point resides in areas of least movable skin and should extend to the edge of the freely movable areas. For example, for correction of the nasolabial folds, the anchoring points start at the hairline of the side burn and extend anteriorly for a few centimeters to cover the area of the rammus of the mandible. One can easily detect where the skin starts being freely movable using our fingertips with a gentle lateral movement over the skin in question. Again, there are some minor variations in people; thus, each treatment should be tailored to the individual patient. Treatment over the poorly movable skin of the preauricular area, close to the hairline, will anchor the skin, whereas treatment at the edge of this area, at the border with the freely movable skin, will probably be the most important in producing the stretch of the skin and the softening of the target fold distally. One could further refine the areas that will best anchor the upper half of the nasolabial point, that is, the area between the levels of the outer canthus to the tragus. Although the ideal anchoring point for the lower half of the nasolabial fold is in front of the tragus and earlobe, when one is trying to correct the jowls, the anchoring point is on the lower border of the zygomatic arch extending posteriorly to meet a vertical line at the level of the outer canthus. The principle of anchoring points becomes extremely valuable when using nonablative radiofrequency for skin tightening.

Skin tightening is probably the result of changes induced by heat in fibroblasts and collagen. These changes appeared mostly at 3 and 4 months after the

Figure 10. A 42-year-old woman showing gradual softening of the nasolabial folds and marionette lines (4 months).

Figure 11. A 36-year-old woman shown preoperatively.

procedure. They were progressive and improved with time perhaps because the heat exerted a stimulatory effect on fibroblasts. Histologic study at 1 week (personal, unpublished observation) revealed no evidence of an acute inflammatory infiltrate or tissue necrosis but instead a perivascular mononuclear cell infiltrate and an increase in the density of the superficial and deep dermis. This may be the result of primary collagen tightening and not a wound-mediated contraction of tissue through the normal process of tissue repair. This probably indicates that this is not a wound-mediated phenomenon. The fact that there is no swelling, bruising, tenderness, or pain after the procedure speaks for the absence of a significant dermal thermal wound. Histologic evaluation of skin immediately after application of high fluences with a 1-cm electrode tip failed to show any evidence of tissue necrosis or incipient inflammation (personal unpublished observation). Heated fibroblasts may be stimulated fibroblasts to produce collagen. Ross et al.[2] have suggested this possibility to explain tissue tightening after ablative laser procedures. These fibroblasts are present at the edge of the necrotic area; they are still viable and perhaps are responsible for the increased collagen production seen afterward.

In all but two patients, electrode tips with a shallow effect (papillary and mid reticular dermis) were used. In the other two, who happened to be two with the most pronounced skin laxity, the 1-cm electrode tip was used. The latter has a deeper effect, deep reticular dermis, and subcutaneous tissue. The size of the surface area of the electrode determines its penetration capability in terms of heat in tissue.

Subsequent to this retrospective review, similar cosmetic improvement has been obtained in many other patients treated prospectively in the anchoring points as described previously here. Further observations in these new patients have shown that both the superficial acting tip and the deep acting one are capable of producing the desired cosmetic effects.

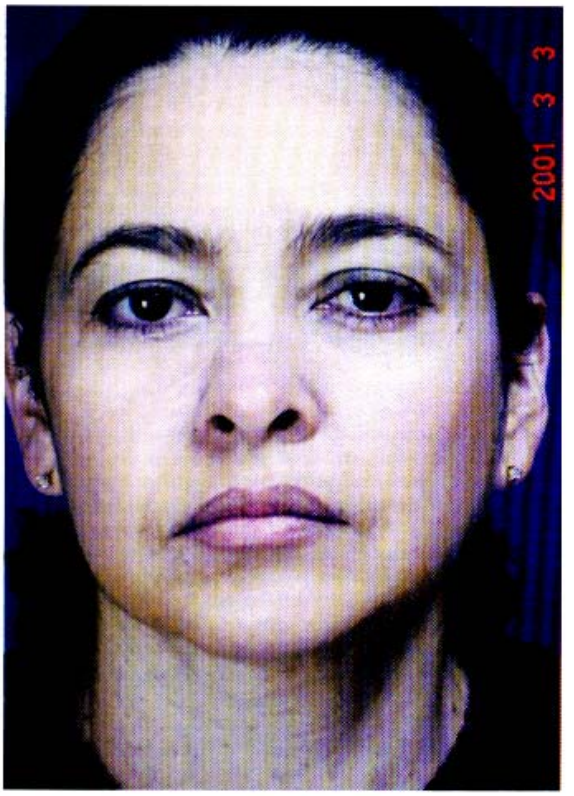

Figure 12. Softening of nasolabial fold 1 week postoperative.

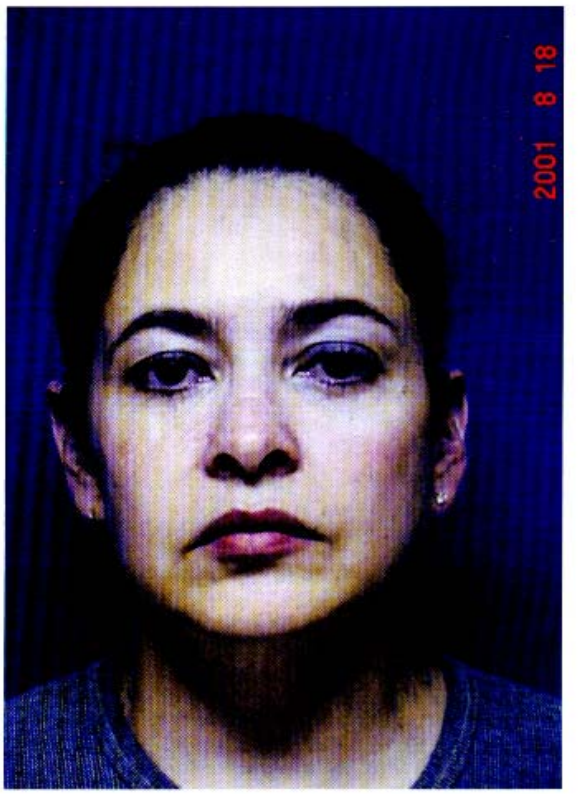

Figure 13. Softening of nasolabial fold continues (shown here at 6 months postoperative).

Refinements in possible combination of the two types of electrode tips may follow.

There may be an anatomical basis for the anchoring points, namely the insertion of the superficial musculoaponeurotic system,[3] although dermal tissue contraction probably plays quite a significant role in achieving the results.

For all of these patients, the energy levels used were small to medium. Significant cosmetic improvement was seen even with very low energy levels (settings of 11 in the 1-cm tip cases: 52 J; impedance: 216–268 ohms). Furthermore, the number of applications was six on average, per side. That means that only six squares of 1 cm each in a continuous grid-like pattern ware treated on the preauricular skin; this is an area of 2×3 cm, but perhaps by serendipity, we were exactly over useful anchoring points for the skin of the cheeks. It must be said, in passing, that these were the first patients in whom we used this technology on facial skin. That explains the low energy used and the limited number of applications per case to maintain a favorable safety profile. Later on, aggressive applications of much higher energies per application in the hope of enhancing results have yielded mixed results. Very high energies may indeed lead to a burn and ultimate scarring. Nevertheless, the degree of clinical response may not correlate at all and only represents an unnecessary risk for the patient, aside from the pain produced. These areas are the subject of current research, and the final criteria are still pending.

Although low to medium energy settings may stimulate fibroblasts with the heat produced, very high energies may melt down the contractile proteins precluding the possibility of contraction, except perhaps by tissue necrosis and subsequent scarring. Currently, one of the authors (J.R.E.) is using multiple passes (2 or 3) at a setting of 12.5 to 13.5 with the ThermaCool III beta machine (79 to 95 J per pass; impedance approximately 200 to 275) and obtaining encouraging results. Multiple passes at low levels are better tolerated by patients and may indeed prove more effective than a single pass at high levels.

Photographic evidence of improvement is now being seen at 1 to 2 months after treatment with this new approach. Heat may accumulate in tissue with each pass and total more than that of a single pass. The operator must finish one pass and start the next one from the first square on. This will avoid overlapping squares too soon.

In summary, nonablative radiofrequency appears to be safe and effective in producing cosmetically acceptable tissue tightening of the cheeks with improvement of the nasolabial fold, cheek contour, marionette lines, and possibly the jaw line as well. Further refinements in the technology as well as the techniques for its use will likely lead to further benefit of this novel therapy.

Commentary

Rapid changes in technology have become a constant in the life of dermatologic surgeons. We are all faced with the difficult task of evaluating new devices and attempting to determine whether they will live up to their promise. Far too often dermatologic surgeons purchase expensive new technology that is obsolete within 1 or 2 years.

Another dilemma is how we present this technology to our patients. If we embrace a new device early before there is extensive clinical experience, we run the risk of misleading, or worse, injuring our patients.

The quest for a method of nonsurgical skin tightening is the Holy Grail for dermatologic surgeons who are not interested in performing face lifts. Ablative laser resurfacing originally was touted for this use and did result in some skin tightening, but at the cost of hypopigmentation and occasionally scars. More recently, Sulamanidze has demonstrated that barbed APTOS threads can be used to resuspend and lift facial tissues.

The concept of a medical face lift is very appealing, particularly if it can be accomplished in a simple manner with minimal morbidity. Using nonablative radiofrequency devices for skin tightening is very intriguing. Ruiz-Esparza's concept of focal treatment in the preauricular area is innovative and practical. Although experience with these devices is minimal, they will become very popular if they fulfill their initial promise.

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