Improvement of Neck and Cheek Laxity With a Nonablative Radiofrequency Device: A Lifting Experience

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OBJECTIVE. **Laxity of cheek and neck skin is a common cosmetic complaint of patients as they age. Improvement of skin laxity can be difficult to achieve without invasive surgical lifting procedures. The object of this study was to evaluate the safety and efficacy of a novel nonablative radiofrequency device in the treatment of cheek and neck laxity.**

METHODS. **Fifty patients (skin phototypes I to IV) with mild-to-moderate cheek laxity (n = 30) or neck laxity (n = 20) received one treatment with a radiofrequency device (ThermaCool; Thermage Corp., Hayward, CA). Topical anesthetic cream was applied under occlusion for 60 minutes before treatment of the skin extending laterally and inferiorly from the nasolabial folds to the preauricular regions and mandibular ridge for treatment of the cheeks and from the mandible to mid neck for treatment of the neck. Clinical improvement of treatment areas was independently determined by three masked assessors' evaluations of comparative photographs at baseline, immediately after treatment, at 1 week, and at 1, 3, and 6 months after treatment using a quartile grading scale (0 = less than 25%, 1 = 25% to 50%, 2 = 51% to 75%, 3 = more than 75% improvement). Patient satisfaction surveys were also obtained at each follow-up visit.**

RESULTS. **Significant improvement in cheek and neck skin laxity was observed in the majority of patients. Patient satisfaction scores paralleled the clinical improvements observed. Side effects were mild and limited to transient erythema, edema, and rare dysesthesia. No scarring or pigmentary alteration was seen.**

CONCLUSIONS. **Noninvasive radiofrequency bulk dermal heating of skin can achieve safe and effective tissue tightening of the cheeks and neck. Although tightening continued to be evident 6 months after a single treatment, the longevity of clinical results has yet to be determined.**

T. S. ALSTER, MD, AND E. TANZI, MD HAVE INDICATED NO SIGNIFICANT INTEREST WITH COMMERCIAL SUPPORTERS.

REJUVENATION OF photodamaged facial skin has become an increasingly popular practice as a result of the aging "baby boomer" population concomitant with a greater societal acceptance of cosmetic procedures. Although dramatic clinical improvement can be achieved with surgical lifting procedures, there is considerable associated postoperative recovery and monetary expense. As such, noninvasive procedures with little postoperative recovery and a low side-effect profile are in considerable demand. Although ablative laser skin resurfacing is a well-accepted treatment modality for facial rejuvenation because of its ability to improve predictably the appearance of photoinduced rhytides,[1–5] patients may be hesitant to pursue this treatment option because of the extended postoperative recovery period and inherent risks of the procedure. Nonablative laser and light sources such as the 1320-nm Nd:YAG,[6,7] 1450-nm diode,[8] 1540-nm Erbium:glass[9,10] lasers and the intense pulsed light source[11,12] have demonstrated efficacy in the noninvasive treatment of facial rhytides. However, disadvantages of nonablative laser and light-based treatment include the necessity for multiple treatments, delayed clinical softening of rhytides, and results that do not match those typically seen after ablative laser skin resurfacing. Therefore, the development of a truly noninvasive, deep tissue-tightening technique continues to interest cosmetic surgeons and the public alike.

Recently, a novel device (ThermaCool TC; Thermage Inc., Hayward, CA) was developed to deliver radiofrequency energy in a nonablative fashion. This unique radiofrequency system is based on an entirely different treatment principle than the photothermal reaction created by most dermatologic lasers. Unlike a laser, which uses light energy to generate heat in targeted chromophores based on the theory of selective photothermolysis,[13] radiofrequency technology produces an electric current that generates heat through resistance in the dermis and subcutaneous tissue. The depth and degree of thermal injury are dependent on the geometry and size of the treatment tip and the conductive properties of the tissue being treated, respectively. The thermal effect is determined by the formula: energy (J) = $I^2 \times R \times T$ (I = current, R = impedance of the tissue, and T = time of application).

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Tissues with higher impedance, such as subcutaneous fat, generate greater heat, thus resulting in a deep tissue thermal effect.[14,15] Although radiofrequency has been used for many years in dermatologic surgery for electrodesiccation and electrocauterization, the ThermaCool radiofrequency device uses a unique capacitor membrane at the treatment tip that allows uniform, volumetric application of heat. Simultaneous delivery of cryogen within the treatment tip effects deep tissue heating with concomitant protection of the epidermis.

Initial studies[15–18] suggest that this novel radiofrequency device shows promise for the treatment of skin tightening; however, data on the long-term effects of the procedure are limited. The object of this study was to evaluate the safety and efficacy of a novel nonablative radiofrequency device in the treatment of cheek and neck laxity.

Methods

Fifty consecutive patients (mean age of 53.3 years; skin phototypes I to IV) with mild-to-moderate cheek (n = 30) or neck (n = 20) laxity were included in the study after informed consent was obtained. Patients with a history of ablative laser skin resurfacing, dermabrasion, phenol peel, nonablative laser procedure, or temporary filler (e.g., collagen, fat, hyaluronic acid) injections within 2 years of study initiation were excluded from the study. A history of pacemaker insertion or of injectable silicone or other permanent fillers in the facial areas also served as exclusion criteria.

Topical anesthetic cream (ELA Max-5; Ferndale Laboratories, Inc., Ferndale, MI) was applied to the treatment area under occlusion for 60 minutes and then completely removed with water-soaked gauze before the radiofrequency procedure. Pretreatment also included oral administration of diazepam (5 to 10 mg). Each patient received a single nonablative radiofrequency treatment. Treatment sites were outlined with a 1.0-cm^2 ink grid, which extended laterally and inferiorly from the nasolabial folds to the preauricular regions and mandibular ridge for the treatment of the cheeks and from the mandible to mid neck for the treatment of the neck. The ThermaCool system was used at fluences ranging 97 to 144 J/cm^2 (level of 13.5 to 16; average of 130 J/cm^2) on the cheeks and 74 to 134 J/cm^2 (level of 12 to 15.5; average of 110 J/cm^2) on the neck. Treatment was delivered in a single, nonoverlapping pass over the treatment area through an applied conductive fluid. Immediately after treatment, the conductive fluid was completely removed with saline-soaked gauze, and cool compresses were applied for 15 minutes.

Photographic documentation using identical camera settings, lighting, and patient positioning was obtained at baseline and immediately after treatment, at 1 week, and at 1, 3, and 6 months after treatment. The degree of clinical improvement of treatment areas was independently determined by three masked assessors' evaluations of randomly assigned comparative before and after treatment photographs using a quartile grading scale (0 = less than 25%, 1 = 25% to 50%, 2 = 51% to 75%, 3 = more than 75% improvement). At the end of the study, the subjects documented their degree of satisfaction on a scale of 1 (lowest) to 10 (highest) for the treated area. Side effects of the radiofrequency treatment were documented at each follow-up evaluation.

Results

Clinical improvement of nasolabial and mesolabial folds after radiofrequency treatment of the cheeks was observed in 28 of 30 patients, with mean clinical scores of 1.40, 1.09, 1.62, 1.56, and 1.53 immediately after treatment, at 1 week, and at 1, 3, and 6 months after treatment, respectively (Figure 1).

Clinical improvement of submandibular and upper neck skin laxity after radiofrequency treatment of the neck was observed in 17 of 20 patients, with mean clinical scores of 1.13, 0.08, 1.24, 1.31, and 1.27 immediately after treatment, at 1 week, and at 1, 3, and 6 months after treatment, respectively. At each postoperative visit, higher average clinical scores were seen in the patients treated on the cheeks (Figures 2A–C and 3A–C). The five subjects who demonstrated no clinical improvement were all older than 62 years of age.

The treatment was generally well tolerated, with patients describing the procedure as moderately uncomfortable. Mild posttreatment erythema was seen in all patients studied and persisted for 2 to 12 hours (average of 2.3 hours) after the procedure. Twenty eight of 50 subjects (56%) described a sore or achy

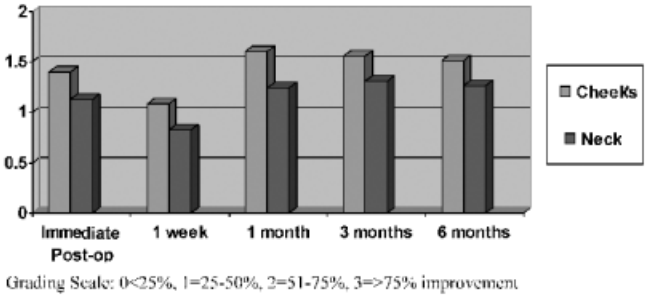

Figure 1. Mean clinical improvement scores. Grading scale: 0 = less than 25%, 1 = 25% to 50%, 2 = 51% to 75%, 3 = more than 75% improvement.

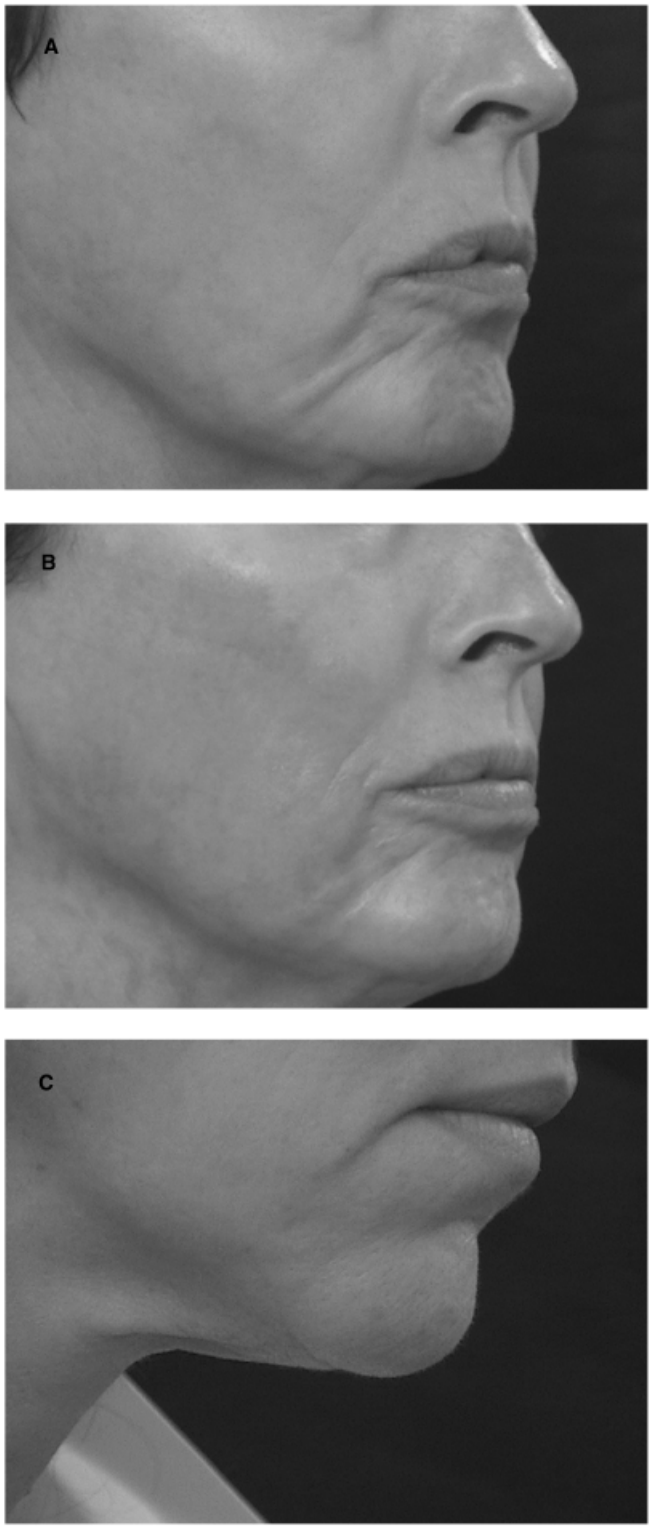

Figure 2. Cheek and Mandibular laxity pretreatment (A). Mild erythema and edema seen immediately after radiofrequency treatment (B). Clinical tightening noted 6 months after single radiofrequency treatment (C).

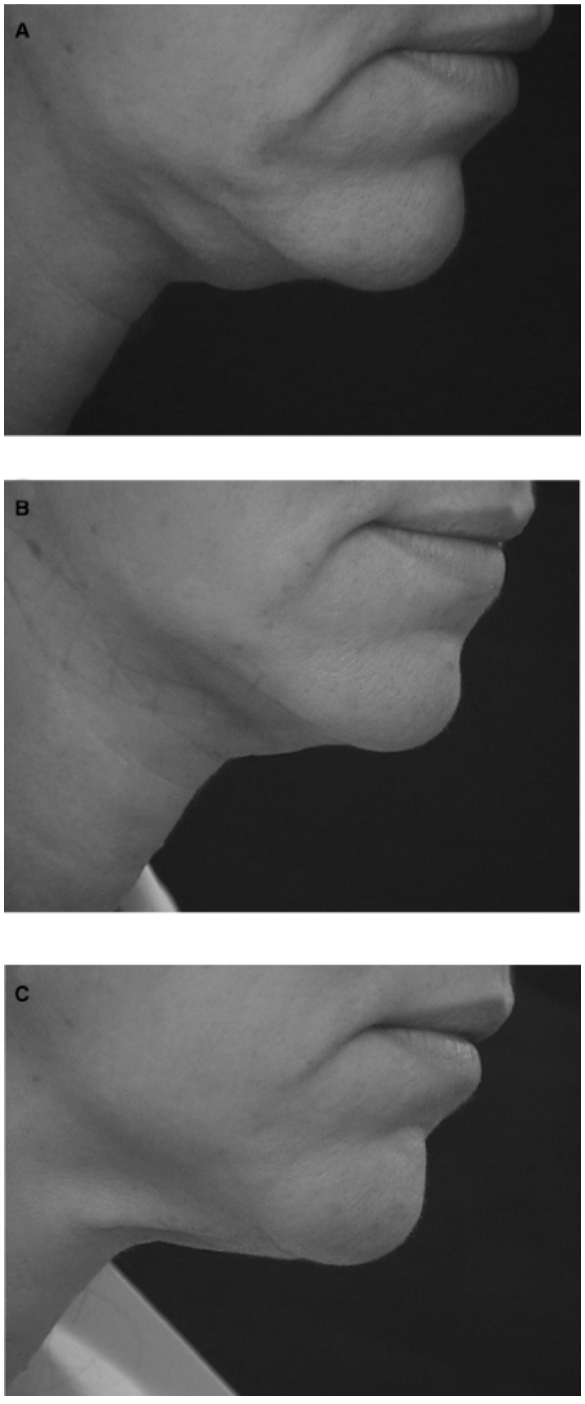

Figure 3. Neck laxity before treatment (A). Erythema and noticeable tightening noted immediately after radiofrequency treatment (B). Prolonged tightening seen 6 months after single radiofrequency treatment (C).

sensation in the treated areas after the radiofrequency procedure; this was controlled with oral nonsteroidal anti-inflammatory medications. Erythematous papules that resolved spontaneously within 24 hours were observed in three patients (6%). One patient developed dysesthesia along the mandible after treatment on the cheeks that resolved without adverse sequelae 5 days after radiofrequency treatment. No pigmentary alteration, blistering, or scarring was observed in any

patient throughout the study period. Patient satisfaction surveys revealed average satisfaction scores of 6.3 and 5.4 in patients that received radiofrequency treatment on the cheeks and neck, respectively.

Discussion

The data reported herein demonstrate that the novel radiofrequency device offers a safe and effective noninvasive technique to tighten lower face and upper neck skin laxity without surgery. The results of this study are consistent with previous reports[15–18] using this novel radiofrequency device for deep tissue tightening. In a multicenter study of 86 patients, 80% demonstrated modest clinical improvement of periorbital skin laxity and measurable brow elevation.[16] Ruiz-Esparza and Gomez[17] reported clinically evident skin tightening in 14 of 15 patients treated with a single radiofrequency treatment on the lower third of the face. Consistent with our study's data, the nasolabial and mesolabial folds were more responsive to treatment than the mandibular ridge and jowls. The relatively thin neck skin and its limited capacity for dermal remodeling as well as the effects of gravity could be possible explanations for the decreased response seen in the neck region compared with the lower face. In an evaluation of 36 patients with photodamage or rhytides, Iyer et al.[18] showed that approximately 70% of patients noticed significant improvement in skin laxity 3 months after a single radiofrequency treatment with greater improvement noted after multiple treatments; however, the patient sample size (n = 12) receiving multiple treatments was too small to draw definitive conclusions.

Hsu and Kaminer[15] treated the lower face and neck in 16 patients with a single radiofrequency procedure. Although only one third of the patients reported satisfactory results, several interesting trends were noted. Younger patients demonstrated greater improvement; the average age of the unsatisfactory group was 58 compared with 51 in the group with an improved clinical outcome. The authors attribute this finding to the fact that heat-labile collagen bonds are progressively replaced by irreducible multivalent cross-links as the skin ages, thus rendering older skin less amenable to heat-induced tissue tightening. Our observation that the five patients who were not responsive to treatment were the oldest patients in the study (more than 62 years of age) is consistent with their findings. Hsu and Kaminer also correlated higher treatment energy levels with an improved clinical response. Indeed, this may explain the greater clinical response demonstrated in our study in which average treatment energies were 130 and 110 J/cm^2 on the cheeks and neck, respectively (as compared with 113.8 and 99.7 J/cm^2 used in the aforementioned study).

The mechanism of action after radiofrequency treatment is hypothesized to be that of immediate collagen contraction, followed by secondary collagen synthesis and remodeling, a process similar to that induced by ablative laser skin resurfacing with the CO_2 laser.[15,17–21] Thus, immediate clinical improvement may be noted in some patients; however, it may take several months to realize the end clinical results after radiofrequency treatment. The higher clinical improvement scores noted in our study immediately after treatment (compared with those obtained 1 week after treatment) were attributed to tissue swelling in the skin areas rather than to true tissue tightening.

Conclusion

As demand grows for minimally invasive techniques to treat the signs of aging and photodamaged skin, cosmetic surgeons are challenged to develop procedures that provide clinical improvement while minimizing side effects. Although the skin-tightening effects after a single radiofrequency procedure are modest, the noninvasive nature of the procedure, coupled with an excellent side effect profile, makes this an attractive alternative to surgical lifting procedures in those patients with mild-to-moderate skin laxity. In the future, further investigation is warranted to enhance our understanding and optimize treatment parameters of this novel radiofrequency device.

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Commentary

Drs. Alster and Tanzi have produced a valuable article describing their experience with nonablative radiofrequency to improve skin laxity of cheeks and neck. It is indeed a lifting experience for those of us who saw the impossibility of producing skin tightening in a totally noninvasive manner until very recently, when this new technology became available. For dermatologists had, for a very long time, figured out many different ways to improve the surface of the skin with office-based procedures, but improving skin laxity was always in the territory of invasive surgery. Overcorrection, sutures, scars, convalescence, time lost from work, and "unnatural operated-on look" were always to be considered for patients contemplating surgery, and then, what about patients who were not yet surgical candidates but already presented incipient skin sagging? Most were turned down from having surgery because the risk–benefit ratio was not appropriate for them. No more. We now have a new tool in our armamentarium, and we are only at the beginning. In time, we should figure out the ideal treatment parameters, interval, and number of treatments, etc. Articles such as this add significantly to our collective experience with this new device and get us so much closer to realizing our goals. Congratulations Drs. Alster and Tanzi.

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