Nonablative Infrared Skin Tightening in Type IV to V Asian Skin: A Prospective Clinical Study

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BACKGROUND Nonablative skin tightening devices have been developed to treat facial and neck skin laxity without damage to the epidermis. There are at present two main approaches: the pioneer method by monopolar radiofrequency and the second by infrared light.

OBJECTIVE This study aims to determine the clinical efficacy and safety of nonablative infrared light in the treatment of facial and neck skin laxity in Type IV to V Asian skin.

METHODS This is a prospective noncomparative open study. Adult patients with facial and neck skin laxity were recruited for the study. Three treatment sessions spaced 4 weeks apart were performed. Photographic documentation was performed serially during the study period. Final clinical assessment was performed 6 months after the last treatment. Response parameters included patient self-assessment as well as doctor's assessment.

RESULTS Twenty-one patients were evaluated. All patients were of Fitzpatrick skin types IV and V. Patient assessments of response at 6 months after treatment were as follows: 19% reported mild improvement, 38% reported moderate improvement, and 43% reported good improvement. Doctor's assessments of photographs before and 6 months after treatment showed observable lifting of sagging skin folds in 86% of patients. Of these, 28% were assessed as significant-mild, 38% as significant-moderate, and 19% as significant-excellent. The treatments were associated with minimal pain and edema. The main side effect was isolated superficial blistering in 7 episodes of 63 treatments performed, which resolved without scarring in all patients.

CONCLUSION Direct application of infrared light with epidermal cooling is effective in achieving mild to moderate gradual clinical improvement in the treatment of facial and neck skin laxity. The procedure is associated with minimal downtime and is safe for use in darker skin, Types IV and V.

The Titan device used in this study was loaned by Cutera, Inc.

Nonablative treatment of skin laxity has recently been made possible by devices that create uniform heating of the dermis and the underlying tissue. Heating of the collagen to critical temperatures causes the collagen to contract; this process provides the initial results of tighter looking skin soon after the procedure is performed. Subsequent to the initial effect, the skin starts a wound healing response resulting in the formation of new collagen, which provides longer-term tightening of the skin. As a result of these two processes, the skin is tightened, laxity is reduced, and facial contours are renewed.

There are different approaches to heating up the dermis to effect clinical skin tightening. The first is by radiofrequency energy and the second by infrared light. Both these approaches are nonablative and do not require any surgical incision to be made to the skin.

In this study, we evaluate the clinical efficacy and safety of direct application of nonablative infrared light to facial and neck skin to treat facial and neck laxity. Secondary benefits such as improvement in fine lines, reduction in pore size, and improvement in skin texture are also evaluated.

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ISSN: 1076-0512 • Dermatol Surg 2007;33:146–151 • DOI: 10.1111/j.1524-4725.2006.33032.x

Materials and Methods

This is a prospective noncomparative open study. Twenty-one patients with facial and/or neck skin laxity were enrolled into the study. All patients were of Fitzpatrick skin types IV and V. There were 20 women and 1 man. Patient ages ranged from 43 to 60 years (mean, 52 years). The study protocol conformed to the hospital's ethical guidelines and complied with the 1975 Declaration of Helsinki, and all patients gave informed consent. Inclusion criteria included patients with clinical facial or neck skin laxity who were of legal age (>21 years) to give informed consent. Exclusion criteria were previous surgery to correct facial skin laxity, recent or previous treatment with radiofrequency skin-tightening devices, pregnancy, isotretinoin use over the past 12 months, photosensitizing drugs such as tetracyclines, aspirin, anticoagulants, active wound infections, vitiligo, and history of keloids.

Patients were treated with an infrared nonablative heating device (Titan, Cutera, Inc., Brisbane, CA). The integrated handpiece of the device incorporates contact epidermal cooling before, during, and after the heating phase of each treatment exposure.

Topical anesthesia using topical anesthetic cream (EMLA, AstraZeneca, London, UK) under occlusion for 1 hour of pretreatment was given to minimize patient discomfort. Treatment areas were then thoroughly cleansed of the topical anesthesia and makeup. A layer of refrigerated ultrasound gel, 1 mm thick, was applied to the entire treatment area. For the cheeks and jowls, the treatment area comprised the entire cheek from 10 mm below the lower border of the lower eyelid to the edge of the mandible. For the anterior neck, the treatment area was from the midneck up to the edge of the mandible.

Three passes of adjacent nonoverlapping exposures were made over the treatment areas. The following treatment parameters were used: 32 to 40 J/cm^2 over the soft tissue of cheeks and submental area and reduced fluence of 28 to 32 J/cm^2 over bony areas and forehead. Each exposure consisted of sequential precooling, heating, and postcooling whose timings were preprogrammed. The entire treatment areas were treated before the next pass was administered, and duration between each pass was approximately 15 to 20 minutes. Attention was paid to ensure proper contact of the treatment window measuring 1.5×1 cm throughout the treatment exposure of precooling, heating, and postcooling. No routine posttreatment was necessary. Patients were advised to avoid unnecessary sun exposure and tanning during the peritreatment period. A total of three repeated treatments were carried out at monthly intervals.

Before each treatment, patients were questioned on the effects from the previous treatment. Patients were asked to assess the degree of skin tightening subjectively, and possible side effects were recorded. Photographic documentation was performed before each treatment and 3 and 6 months after the last treatment.

Final assessment was performed 6 months after the last treatment. Response parameters included patient self-assessment of skin tightening as well as doctor's assessment. Patient's self-assessment was obtained by recording the subjective degree of skin tightening after treatment compared with before treatment. Patient assessment included feeling of increase in skin firmness and tone as well as observable lifting of sagging skin. Improvement was recorded by patients as none, mild, moderate, and good.

Doctor's assessment was based on the evaluation of pre- and posttreatment photographs by three independent dermatologists who were not part of the study. Photographic assessment of skin tightening focused on assessing observable lifting of skin folds such as the nasolabial folds and marionette lines, renewing of contours along the jaw, and lifting of submental sagging skin. Improvement was assessed by doctors as none, significant-mild, significant-moderate, and significant-excellent.

Secondary response parameters such as effects on skin texture, pore size, and fine lines as reported by patients were also recorded. These parameters were assessed by direct questioning of the patients after each treatment in the form of structured questionnaire in which patients were asked to rate each parameter as being worse, no change, or improved after treatment as compared with before treatment.

Results

All 21 patients completed the treatments and follow-ups; none dropped out of the study because they were unable to tolerate the treatment or side effects. During all treatments, patients felt only minimal or no pain. No patient felt severe pain requiring additional pain relief with analgesia or sedation.

Patient assessments of response at 3 months after treatment were as follows: 5% reported no improvement, 38% reported mild improvement, 33% reported moderate improvement, and 24% reported good improvement. At the final 6-month posttreatment, patients' reports were as follows: 0% reported no improvement, 19% reported mild improvement, 38% reported moderate improvement, and 43% reported good improvement (Figure 1). Seventy-five percent of patient reported that they were quite satisfied to very satisfied with the treatment results, 20% of patients were just a little satisfied, and 5% of patients were not satisfied.

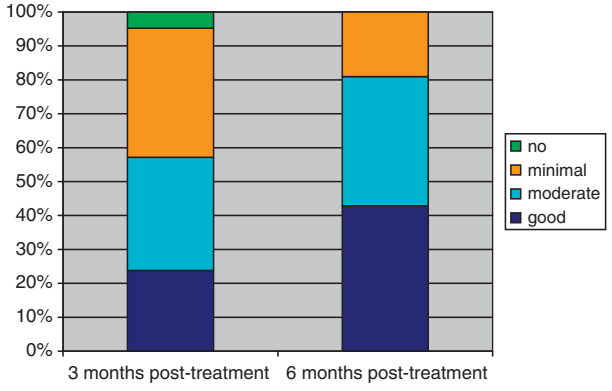

Figure 1. Patient self-assessment of skin tightening.

Doctor's assessment of photographs before and 6 months after treatment showed observable lifting of sagging skin folds in 86% of patients. Of these, 29% were assessed as significant-mild, 38% as significant-moderate, and 19% as significant-excellent (Figures 2–5). Secondary benefits reported by patients at 6-month posttreatment included improvement in skin texture (60%), reduction in pore size (50%), and reduction in fine wrinkles (40%).

Complications

Of the 63 treatments that were performed, there were 7 minor episodes of superficial blistering. These blistering episodes occurred in the early phase of the study when higher fluences (36–40 J/cm^2) in the treatment parameter range were used. None occurred when lower fluences (28–34 J/cm^2) were used in subsequent treatments. All these resolved with temporary postinflammatory hyperpigmentation. At the final 6-month posttreatment review, no scarring or residual dyspigmentation was present. No significant pain or edema was noted during or immediately after the treatment.

Discussion

Nonablative treatment of skin laxity has recently been made possible by devices that are able to deliver uniform heat deep into the dermis while preserving epidermal integrity by effective surface cooling. This heating process causes initial collagen contraction which may be noticed soon after the procedure as immediate skin tightening.[1] Although the initial tightening may be impressive to patients, it is often temporary. More importantly, the heating initiates progressive collagen remodeling over the next several weeks and months resulting in gradual skin tightening and reduction of skin laxity.[1]

There are currently two approaches to the delivery of heat. The first is by radiofrequency energy. Monopolar radiofrequency devices were the first to be reported in scientific literature to be able to produce clinical skin tightening without causing epidermal

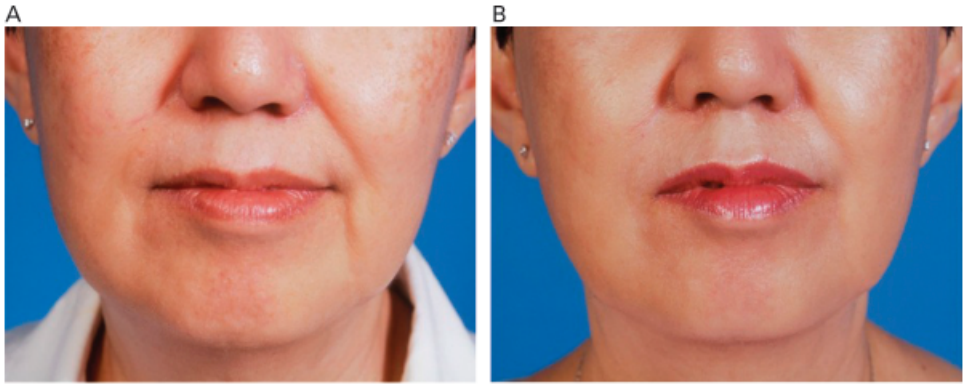

Figure 2. Before (A) and after (B) pictures showing significant improvement in mid and lower facial laxity 6 months after three infrared treatments.

damage.[2] To date, there have been several articles demonstrating the efficacy of monopolar radiofrequency skin-tightening devices.[2–5] Initial protocols using single-pass high-energy settings were associated with higher incidences of side effects such as erythema, edema, blistering, and subcutaneous fat necrosis. Subsequent reports suggest that using multiple passes with lower-energy settings are probably safer, more tolerable, and efficacious.[5,6] Multiple treatments also tended to give better results than a single treatment.[7,8] In darker Asian skin, monopolar radiofrequency has been shown to be effective as well in treating facial skin laxity.[9]

An alternative approach to delivering uniform heat deep into the dermis is via direct application of nonablative infrared heat as evaluated by this study. The device used in this study emits a broadband light spectrum between 1,100 and 1,800 nm. Epidermal protection is effected by integrated contact cooling before, during, and after the heating phase of each exposure. Following lessons learned from radiofrequency skin tightening, multiple passes using moderate fluence were employed in this study to maximize safety and efficacy. Three treatments performed monthly were done again to maximize clinical outcomes and to demonstrate efficacy if present. The results of this study demonstrated that infrared light is able to treat skin laxity of the face and neck. Results are, however, gradual and subtle with photographic assessments showing significant improvements in 86% of patients. Results at 6 months appear superior to that at 3 months according to patient assessment data consistent with the

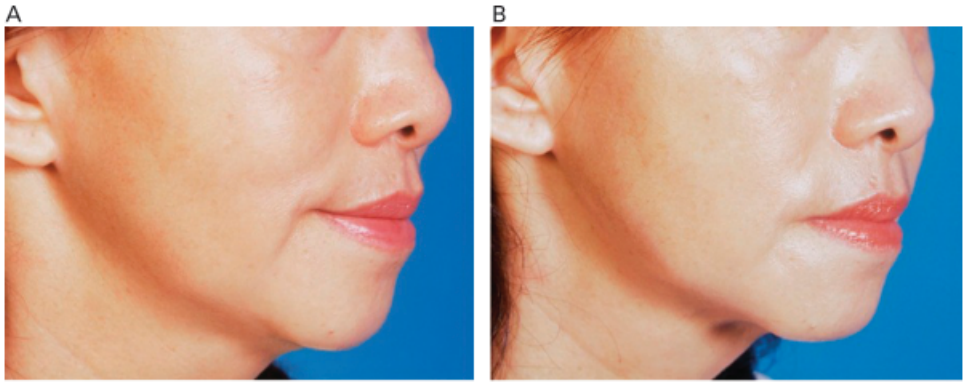

Figure 3. Before (A) and after (B) pictures showing significant improvement in mid, lower facial and upper neck laxity 6 months after three infrared treatments. The clinical improvements are clearly evident despite mild variation in the lighting/exposure between the two pictures.

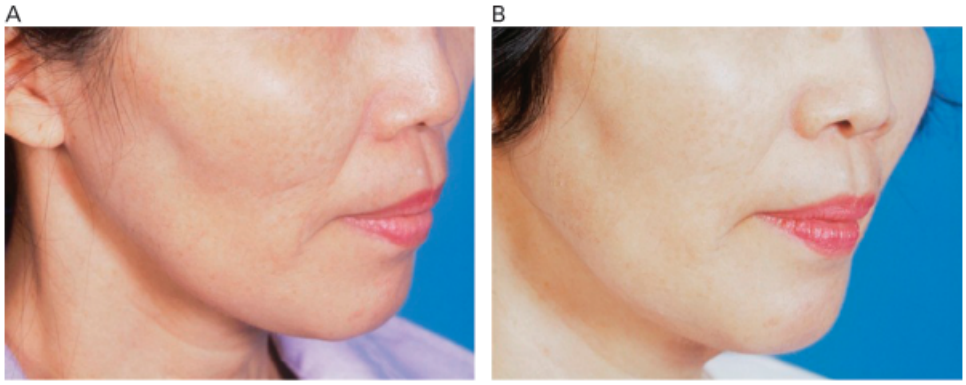

Figure 4. Before (A) and after (B) pictures showing significant improvement in mid and lower facial laxity 6 months after three infrared treatments.

progressive collagen remodeling that occurs as part of the healing process. The close age range of our patients (20/21 were between the ages of 50 and 60) did not allow us to analyze clinical response relative to age groups; it is, however, likely that younger patients with less advanced skin laxity and who are not obese will demonstrate better clinical response.

The relative merits of radiofrequency and infrared approaches remain to be clarified. Taking previous reports in the literature into consideration, the infrared approach appears to be less painful and is associated with minimal/no local edema; although new and revised monopolar radiofrequency technologies utilize lower energy and are also associated with less pain. Superficial blistering is a problem when high fluences are used, and a lower fluence (28–34 J/cm^2) is recommended when treating Asian facial skin. The incidence of blistering can also be reduced by ensuring proper contact of the treatment window to the skin during exposures and by ensuring an interval of at least 5 minutes between each treatment pass.

Our study also demonstrated that subjective improvements in skin texture and pore size were reported by patients although these improvements were not validated by objective measurements. As such, we hesitate to recommend this treatment for these complaints until objective and sustainable results can be demonstrated by further studies.

In conclusion, our study demonstrates that the nonablative infrared light with integrated epidermal cooling is effective in the treatment of facial and

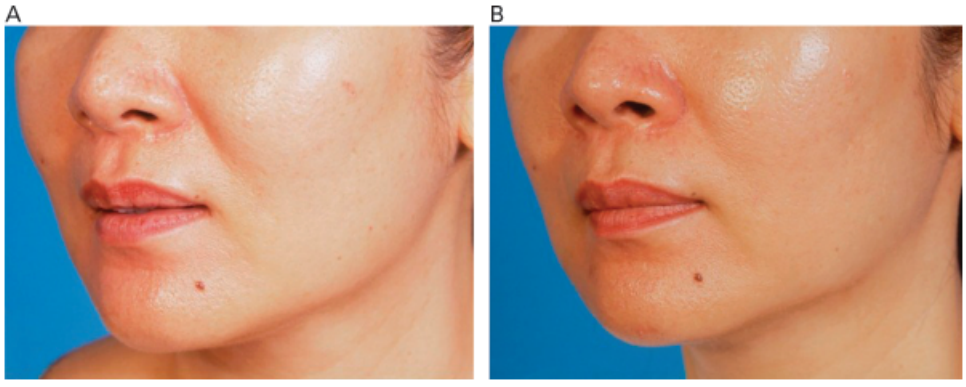

Figure 5. Before (A) and after (B) pictures showing significant improvement in the nasolabial folds 6 months after three infrared treatments. The clinical improvements are clearly evident despite mild variation in the lighting/exposure between the two pictures.

neck skin laxity. Results are, however, gradual and variable with observable clinical improvement achievable in 86% of patients. The infrared approach is a viable alternative to the pioneer radiofrequency approach in the nonablative treatment of facial skin laxity. The findings of our study will be useful for physicians using this new modality in treating patients with darker skin types in their community.

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