Combined Infrared Light and Bipolar Radiofrequency for Skin Tightening in Asians

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Background and Objective: As the demand for non-invasive procedures for skin tightening is increasing, combined optical and radiofrequency (RF) devices have recently emerged. The purpose of this study is to evaluate the safety and efficacy of a device that combined broadband infrared (IR) light (700–2000 nm) and bipolar RF (electro-optical synergy [ELOS]) for non-ablative treatment of facial laxity.

Design/Materials and Methods: Nineteen Chinese volunteers of skin types III–V, with facial laxity and periorbital rhytides, received three treatments at 3-week intervals with combined IR (700–2000 nm, 10 W/cm^2) and RF energies (70–120 J/cm^3). Standardized photographs were taken by the Canfield Visia CR system at baseline and serially for 3 months after the last treatment. Two masked assessors evaluated the photographs to assess the improvement in skin laxity. Patient satisfaction scores were also obtained.

Results: At 3 months after the last treatment, 89.5% of the subjects reported moderate to significant subjective improvement in skin laxity of cheek, jowl, periorbital area and upper neck, with a high overall satisfaction rating. Masked observers' assessments were less remarkable. Mild improvement in skin laxity was observed over mid and lower face. There was no serious complication.

Conclusion: The combination of broadband infrared light and bipolar radiofrequency produces mild improvement of facial laxity in Asians with no serious adverse sequelae. A high patients' satisfaction is achieved. However, further studies are necessary to demonstrate the long-term effects of the procedure and to optimize treatment parameters. Lasers Surg. Med. 39:471–475, 2007.

Key words: laser; non-ablative; non-invasive; radiofrequency; skin rejuvenation; skin tightening

INTRODUCTION

Although a dramatic improvement can be achieved with surgical lifting procedures, there is lengthy postoperative recovery and considerable inherent risk. As such, non-ablative skin tightening, which carries a lower risk of adverse effects, has gained popularity. Whereas non-ablative skin rejuvenation uses lasers or light sources to generate heat in the superficial dermis up to a depth of 1 mm, deep tissue heating using monopolar radiofrequency (RF) (ThermaCool, Thermage, Hayward, CA), infrared (IR) light sources (Titan, Cutera, Brisbane, CA), and combined diode laser and bipolar RF (Polaris WR, Syneron Medical Ltd., Yokneam, Israel) may affect the dermis up to a depth of 2–4 mm. The aim of deep tissue heating is to create collagen damage so as to induce new collagen formation. With effective cooling, the epidermis is protected, and therefore the fact that Asian patients have darker skin types is not a major issue. Further, Asian patients tend to have a square facial configuration in comparison to the triangular configuration in Caucasians. This is observed to the extent that aging induces more sagging of the cheek, formation of jowls, and prominent nasolabial folds [1,2].

Monopolar RF is the first non-invasive procedure that had been shown to be effective in skin tightening in multiple studies [3–9]. It is thought that volumetric heating of the dermis causes immediate tissue tightening by breaking hydrogen bonds in the collagen triple helix, causing contraction. Electron microscopic evaluation of skin biopsies immediately after treatment supports a morphological change in individual collagen fibril with contracted, partially denatured collagen in the mid to deep dermis [10]. This is then followed by continual improvement over the course of 4–6 months from a delayed wound healing process and new collagen formation. Nevertheless, significant pain during the procedure and cost of the disposable tip are important downsides of this technology. Besides, results are quite variable and factors to predict the effectiveness of this procedure are not yet well determined.

Recently, an IR light source with integrated contact cooling has been shown to be effective for the treatment of skin laxity. It has been postulated that by inducing thermal injury in a gradual manner, collagen can be heated up at

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a lower temperature over a more prolonged period of time. Therefore, much less pain is experienced without significant reduction of clinical efficacy. Ruiz-Esparaz examined the use of this device among 25 patients, indicating it to be effective in skin tightening with minimal discomfort [11].Another prospective study in Asian skin also confirmed its effectiveness in achieving mild to moderate gradual clinical improvement in the treatment of facial and neck skin laxity [12].

A new device which combines broadband IR (700–2000 nm) and bipolar RF has been developed in an attempt to address both skin laxity and rhytides. The purpose of this study is to evaluate the safety and efficacy of this device in the treatment of facial laxity in Asians.

MATERIALS AND METHODS

Nineteen Chinese volunteer patients of skin phototypes III–V, with skin laxity and periorbital rhytides were included in this prospective study. Patients received three treatments at 3-week intervals with combined IR (700–2000 nm, 10 W/cm^2) and RF (70–120 J/cm^3) energies of the ReFirme ST Applicator (Syneron Medical Ltd.). Patients were treated on the full face including the periorbital area, and the upper neck.

Exclusion criteria included scarring or infection of the area to be treated, history of face-lift, browlift or blepharoplasty, pregnancy, photosensitivity, presence of a deep suntan in the area to be treated, use of isoretinoin within 6 months prior to study, diabetes, use of pacemakers or internal defibrillators, known anticoagulative or thromboembolic condition, and concurrent treatments with other cosmetic modality. The protocol was approved by the Western Institutional Review Board, and all participants signed an informed consent form. Subjects were free to discontinue their participation at any time during the study.

Patients were first examined in the upright position to determine the ideal plan for placement of pulses. One side of the face was divided into treatment sections (Fig. 1). Water-based transparent gel was applied before treatment to hydrate the skin surface and to assure proper conductivity. The system handpiece was applied to the skin using gentle but firm pressure to ensure adequate coupling along with generation of light and RF pulses. The whole treatment section was covered with 50% overlap until clinical endpoint of tightening and edema was observed. The RF fluence could be increased or decreased by 10 J/cm^3 increments to achieve endpoints or to reduce signs of epidermal injury (e.g. visible blisters, frosting of the epidermis, or Nikolsky's sign), respectively. Each section was treated separately and the procedure was repeated on the other side of the face in a similar fashion. RF energy was lowered by 10% for treatment of the forehead and periorbital regions. At the end of treatment, the treated sites were observed for edema, erythema and blistering. No anesthesia was used.

Photographic imaging using a Canfield Visia CR System (Canfield, NJ) was used to assess all of the patients prior to each treatment session, and 1 and 3 months after the last treatment. The photographs were taken using standard

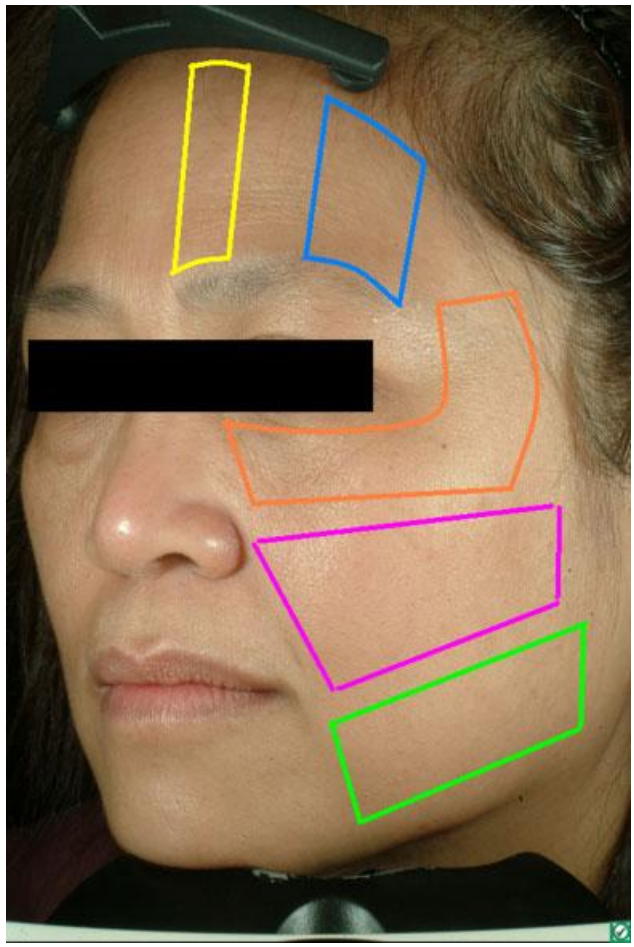

Fig. 1. Preoperative view showing placement of treatment sections. [Figure can be viewed in color online via www.interscience.wiley.com.]

light, cross-polarization, parallel polarization and UV light. The imagines were stored in the Canfield Mirror software and assessed by two masked assessors. Photographs were randomly displaced so that assessors were unaware of or unbiased to pre- or post-treatment image. Improvement in facial laxity was rated using the following scale: −1 (worsening), 0 (no change from baseline), 1 (mild improvement), 2 (moderate improvement), and 3 (significant improvement). Clinical scores were obtained for five specific locations: cheek, jowl, periorbital area, nasolabial fold, and upper neck. At each follow-up visit, the subjects filled in a subjective evaluation questionnaire based on the same scale. Patients also kept a daily diary of adverse events after each treatment.

Wilcoxon signed-rank tests were used to analyze the results. Statistical significance was defined as $P \leq 0.05$. Statistical analyses were performed using SPSS Version 11.0 (SPSS, Inc., Chicago, IL).

RESULTS

Nineteen female patients completed this prospective study. Patients were between the ages of 27 and 61 years

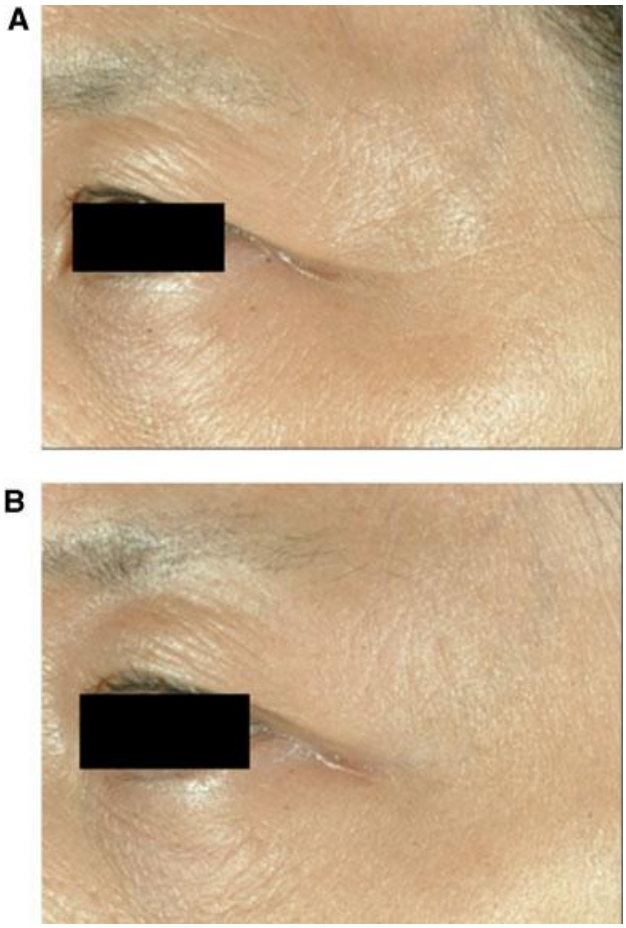

Fig. 2. Periocular rhytides before (**A**) and 3 months after the third RF-IR treatment (**B**). Objective clinical improvement score = mild improvement. [Figure can be viewed in color online via www.interscience.wiley.com.]

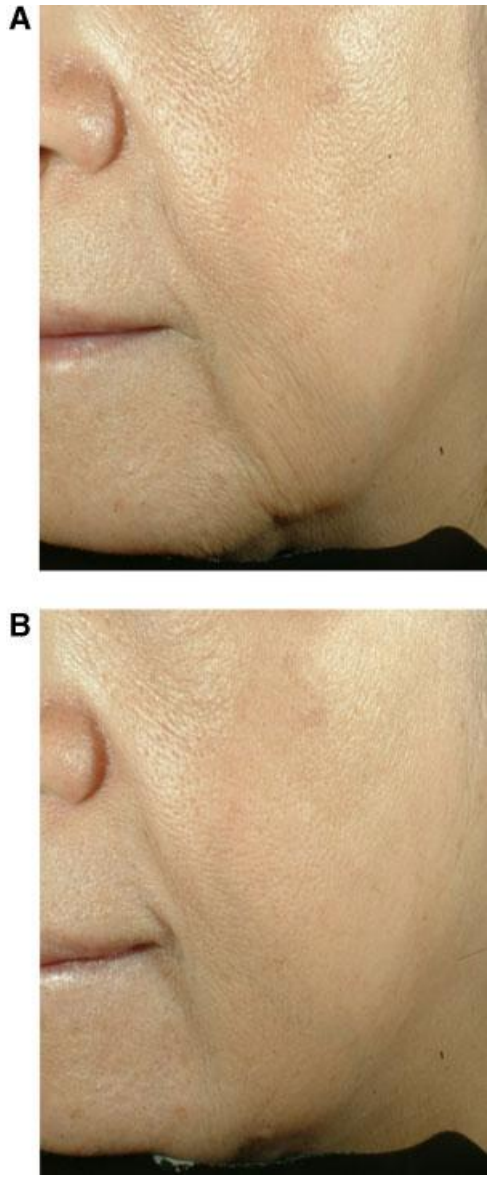

Fig. 3. Nasolabial folds and jowls before (**A**) and 3 months after the third RF-IR treatment (**B**). Objective clinical improvement score = moderate improvement. [Figure can be viewed in color online via www.interscience.wiley.com.]

(mean 44.5). Their baseline Fitzpatrick wrinkle classes were 26.3% class I ($n = 5$), 42.1% class II ($n = 8$), and 31.6% class III ($n = 6$).

At 3 months, mild to moderate improvement was observed in 47.3%, 36.8%, 26.3%, 26.3%, and 26.3% of patients in cheek, jowl, periorbital area, nasolabial fold, and upper neck, respectively (Figs. 2–4). Statistically significant improvement in skin laxity was shown in the cheek, jowl and nasolabial fold. Less improvement was noted in the periorbital area and upper neck (Table 1).

Patient assessments were more favorable than those done by masked assessors. At 3-month follow-up visit, 89.5% of patients reported moderate to significant improvement in laxity of cheek, jowl, periorbital area and upper neck; and 78.9% in nasolabial fold (Table 2). Subjective improvement in skin laxity was noticeable after the first treatment session in all patients. No significant difference in subjective wrinkle improvement was observed after the first, second and third treatment. All patients noted immediate post-treatment tightening of skin that persisted for up to 48 hours and settled approximately 2 weeks later. Firmness persisted at the 3-month follow-up visit.

The treatment was generally well tolerated, with 1 patient (5.3%) reporting no discomfort, 15 (78.9%) patients experiencing mild pain, and 3 patients (15.8%) experiencing moderate pain. The forehead and periorbital areas were more pain sensitive. Transient post-treatment erythema was universal to the procedure, and 3 patients (15.8%) experienced edema that resolved within 24 hours. Isolated small superficial crusting over the forehead were observed in 7.0% (4 episodes of 57 treatment sessions = 7.0% in total), all of which resolved without

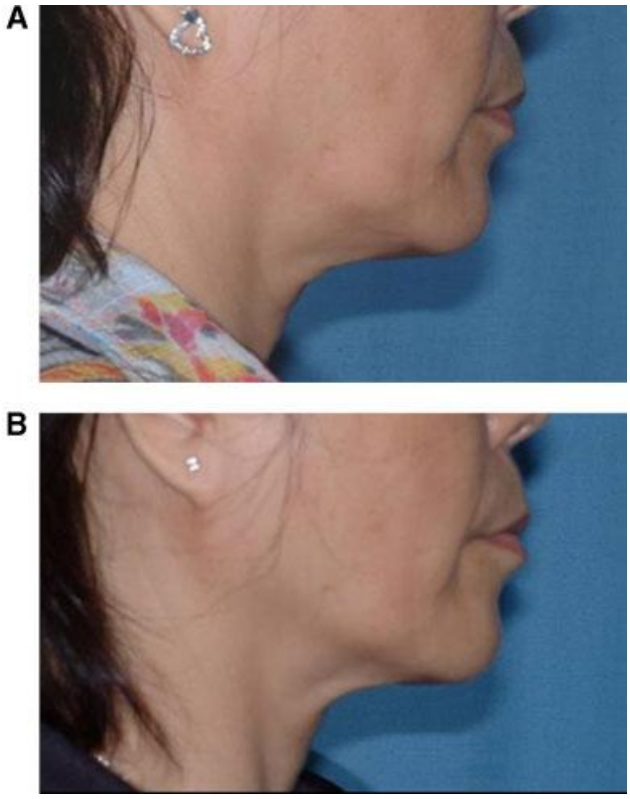

Fig. 4. Upper neck before (**A**) and 3 months after the third RF-IR treatment (**B**). Objective clinical improvement score = moderate improvement. [Figure can be viewed in color online via www.interscience.wiley.com.]

scarring within 3–5 days. No post-inflammatory hyperpigmentation (PIH) or scarring was seen in any patient.

DISCUSSION

The application of non-ablative lasers and intense pulsed light (IPL) sources has gained much popularity among Asian patients and is well-reported in the literature as being effective in improving dyschromia and fine wrinkles, but it has been recognized that these non-ablative modalities are much less effective in the treatment of deeper wrinkles and severe skin laxity, such as sagging jowls. Monopolar RF and IR light sources have been developed for deep dermal heating and deep tissue tightening. The mechanism for wrinkle reduction and skin tightening 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 carbon dioxide (CO_2) laser.

This is the first study to evaluate the safety and efficacy of the broadband IR-RF combination in the treatment of facial wrinkles and skin laxity in Asians. Two previous studies have evaluated the effectiveness of combined diode laser and bipolar RF in the treatment of facial rhytides, skin laxity and skin texture [13,14]. The present study suggests that the IR light source used in this device provides clinical improvement in skin laxity and rhytides at lower optical energy (10 J/cm^2) than the optical energies used in 900 nm Polaris WR studies of Doshi and Alster (32–40 J/cm^2) and Sadick and Trellers (30–50 J/cm^2), thus increasing patient safety. This can be explained by the fact that IR light energy is absorbed by water, and perhaps by collagen, causing a direct thermal effect on the dermal ground substance. Diode laser energy (900 nm), in contrast, is absorbed by hemoglobin, triggering cutaneous vessels and adnexal structures to produce cellular mediators and growth factors that may stimulate a wound healing response, which would also give rise to indirect heating of the dermis. Electro-optical synergy (ELOS) technology is employed in both devices. The proposed rationale behind ELOS is as follows: (1) a synergistic effect occurs between the two forms of energy when the various optical and bipolar RF parameters are set optimally and (2) lower levels of both energies can be used, potentially reducing the risk of side effects associated with either optical or RF treatment alone [15].

There are controversies regarding the use of bipolar RF for skin tightening. Recently an animal study evaluating the effect of epidermal cooling in lowering the level of

TABLE 1. Objective Clinical Improvement Scores at 3 Months After the Last Treatment

Improvement	Cheek	Jowl	Periorbital area	Nasolabial fold	Upper neck
No	52.6% (10)	63.2% (12)	73.7% (14)	73.7% (14)	73.7% (14)
Mild	36.8% (7)	31.6% (6)	26.3% (5)	21.1% (4)	21.1% (4)
Moderate	10.5% (2)	5.3% (1)	0.0% (0)	5.3% (1)	5.3% (1)
Significant	0.0% (0)	0.00% (0)	0.0% (0)	0.0% (0)	0.0% (0)
P-value	0.005*	0.025*	0.082	0. 046*	0.102

*Statistically significant.

TABLE 2. Patient Subjective Improvement in Skin Laxity at 3 Months After the Last Treatment

Improvement	Cheek	Jowl	Periorbital area	Nasolabial fold	Upper neck
No	0.0% (0)	0.0% (0)	5.3% (1)	0.0% (0)	10.5% (2)
Mild	10.5% (2)	10.5% (2)	5.3% (1)	21.1% (4)	0.0% (0)
Moderate	36.8% (7)	36.8% (7)	47.4% (9)	36.8% (7)	47.4% (9)
Significant	52.6% (10)	52.6% (10)	42.1% (8)	42.1% (8)	42.1% (8)

maximal change in collagen fibers was published [16]. In contrast to monopolar RF with pre-, during and post-cooling, the cooling time in bipolar RF is often not adequate to achieve such an effect. Besides, the merits of ELOS system remain to be clarified, and comparative studies are needed to determine whether this is indeed more effective and safer than light or RF sources used alone. Besides, further studies to determine the optimal treatment parameters and technique are necessary.

As with other modalities of non-ablative treatment of wrinkles and skin laxity which impart subtle results, accurate and consistent objective evaluation of the efficacy is difficult. Leffel demonstrated in a review of the literature on non-ablative skin rejuvenation that consistent data on the efficacy of wrinkle reduction could not be provided [17]. To overcome this problem, the Canfield Visia CR system was employed in the current study to provide comparable and standardized photographs for evaluation. The system consists of a configurable head support that ensures proper and consistent registration of the position of the patient's head. The photographs were taken using standardized lighting. While this is effective in the assessment of facial laxity such as that of the jowl, improvement in the neck can be difficult to assess. Further, external factors on skin hydration (e.g. the use of emollients, changes of air humidity, lifestyle factors) may have significant impact on wrinkle depth. This may further explain the discrepancy between the objective and subjective evaluation. More recently, the Leal laxity classification system has been employed to assess the efficacy of monopolar RF device [9]. Although this classification allows better assessment of the degree of skin laxity, inter- and intra-observer variation still exists.

Superficial crusting is the main side effect with this procedure. A similar complication was also reported with the use of IR light source for skin tightening in Asians [12]. This may be attributed to the fact that IR light reflects from prominent bony areas, for example, the forehead. The incidence of this may be reduced by ensuring proper contact of the treatment tip to the skin during exposure.

The mid and lower face was more responsive to treatment than the periorbital area and upper neck. A limited capacity for dermal remodeling due to the relatively thin skin in these areas, as well as the effects of gravity, could be possible explanations for the decreased response seen in the neck region.

CONCLUSION

The combination of broadband infrared light and bipolar radiofrequency produces mild improvement of facial laxity in Asians with no serious adverse sequelae. A high patients' satisfaction is achieved. However, further studies are necessary to demonstrate the long-term effects of the procedure and to optimize treatment parameters.

REFERENCES

1. Chan HH, Kono T. Laser treatment on ethnic skin. In: Dover JS, Goldberg D, editors. Laser and lights, Vol. 2. Philadelphia, USA: Elsevier Saunders; 2005. pp 89–101.
2. Chan HHL. Effective and safe use of lasers, light sources, and radiofrequency devices in the clinical management of Asian patients with selected dermatoses. Lasers Surg Med 2005;37: 179–185.
3. Fitzpatrick RE, Geronemus RG, Goldberg DJ, Kaminer M, Kilmer S, Ruiz-Esparza J. Multi-center study of noninvasive radiofrequency for periorbital tissue tightening. Lasers Surg Med 2003;33:232–342.
4. Ruiz-Esparza J, Barba-Gomez JM. The medical face lift; a noninvasive, nonsurgical approach to tissue tightening in facial skin using non-ablative radiofrequency. Dermatol Surg 2003;29:325–332.
5. Alster TS, Tanzi E. Improvement of neck and cheek laxity with a nonablative radiofrequency device: A lifting experience. Dermatol Surg 2004;30:503–507.
6. Hsu TS, Kaminer MS. The use of nonablative radiofrequency technology to tighten the lower face and neck. Semin Cutan Med Surg 2003;22:115–123.
7. Kushikata N, Negishi K, Takeuchi K, Wakamatsu S. Non-ablative skin tightening with radiofrequency in Asian skin. Lasers Surg Med 2005;36:92–97.
8. Biesman B, Carruthers J, Baker S, Leal H. Monopolar treatment of human eyelids: A prospective evaluation. Lasers Surg Med 2006;S18:94.
9. Bogle M, Ubelhoer N, Weiss RA, Mayoral F, Kaminer MS. Evaluation of the multiple pass, low fluence algorithm for radiofrequency tightening of the lower face. Lasers Surg Med 2007;39:210–217.
10. Zelickson B, Kist D, Bernstein E, Brown DB, Ksenzenko S, Burns J, Kilmer S, Mehregan D, Pope K. Histological and ultrastructural evaluation of the effects of a radiofrequency based nonablative dermal remodeling device: A pilot study. Arch Dermatol 2004;140:204–209.
11. Ruiz-Esparza J. Painless, nonablative, immediate skin contraction induced by low-fluence irradiation with new infrared device: A report of 25 patients. Dermatol Surg 2006; 32(25):601–610.
12. Chua SH, Ang P, Khoo LS, Goh CL. Nonablative infrared skin tightening in type IV to V Asian skin: A prospective clinical study. Dermatol Surg 2007;33(2):146–151.
13. Doshi SN, Alster TS. Combination radiofrequency and diode laser for treatment of facial rhytides and skin laxity. J Cosmet Laser Ther 2005;7:11–15.
14. Sadick NS, Trelles MA. Nonablative wrinkle treatment of face and neck using a combined diode laser and radiofrequency technology. Dermatol Surg 2005;31:1695–1699.
15. Sadick NS, Makino Y. Selective electro-thermolysis in aesthetic medicine: A review. Lasers Surg Med 2004;34: 91–97.
16. Felipe I, Redondo P. Animal model to explain fat atrophy using nonablative radiofrequency. Dermatol Surg 2007;33: 141–145.
17. Leffell DJ. Clinical efficacy of devices for non-ablative photorejuvenation. Arch Dermatol 2002;138:1503–1508.