

# A Prospective, Split Face, Single-Blinded Study Looking at the Use of an Infrared Device with Contact Cooling in the Treatment of Skin Laxity in Asians

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**Background:** Although monopolar radiofrequency treatment is effective in the improvement of skin laxity, the pain and cost that are associated with this method suggest the need for alternative treatment options. Recently, an infrared device with contact cooling has been shown to be effective in the treatment of skin laxity, with ultrastructural changes observed that are similar to those that are observed following treatment with a monopolar radiofrequency device. However, no control was included in previous studies.

**Objective:** To conduct a prospective, split-face, single-blinded study to look at the efficacy and complications among Asians of treatment for skin tightening with an infrared device with contact cooling.

**Method:** Thirteen Chinese women were treated. An infrared device with contact cooling (Titan, Cutera, Brisbane, CA) was used to treat one side of the face and the untreated side served as the control. The treatment was performed twice with a 4-week interval between the treatments and the patients were followed up by subjective assessment using a structured questionnaire 1 and 3 months after the second (and last) treatment. In all cases, pre- and post-treatment clinical photographs were taken. Two independent observers assessed the photographs.

**Results:** Twenty-three percentage of patients reported mild improvement, 15% reported moderate improvement, and 54% reported significant improvement 3 months after their second (and last) treatment. In terms of objective assessment, 41% of patients were identified to have some degree of improvement of the treated side 3 months after their second treatment. Compared with the untreated side, the treated side improved significantly ( $P = 0.031$ ) at 1 and 3 months after the second treatment. Blistering occurred in one patient, which had resolved completely by the 3-month follow-up visit.

**Conclusion:** An infrared device with contact cooling can be used effectively and safely for the treatment of skin laxity, especially in smaller anatomical areas. *Lasers Surg. Med.* 40:146–152, 2008. © 2008 Wiley-Liss, Inc.

**Key words:** infrared; Asians; skin tightening

## INTRODUCTION

Skin laxity is a common complaint of patients who request skin rejuvenation. Although surgical procedures such as face-lifts remain the gold standard to improve skin laxity, the morbidity and downtime that are associated with such procedures lead most patients to consider these procedures as second-line treatment options. The development of skin cooling has revolutionized the role of laser, light source, and radiofrequency in skin rejuvenation. Whereas nonablative skin rejuvenation that involves lasers or light sources heats up the superficial dermis up to a depth of 1 mm, deep tissue heating that involves radiofrequency, laser, or infrared light sources aims to induce thermal injury in the dermis as deep as 2–4 mm [1]. The aim of deep tissue heating is to create collagen damage that leads to new collagen formation, which can achieve tissue tightening. Noninvasive skin tightening procedures can be particularly applicable to skin of color such as Asians as such procedures are skin-type independent. Furthermore, the aging process of Asians differs from that of Caucasian skin, with mid-face aging such as sagging of the malar fat pads a common manifestation [2], which makes skin tightening an important aspect in the management of skin aging in skin of color patients.

Of all of the methods that are currently used for skin tightening, monopolar radiofrequency (Thermacool, Thermage, Haywood, CA) has been most studied [3,4]. Previous electron microscopy data indicated that the mechanism of action involved reversible and irreversible collagen damage that led to temporary immediate skin tightening that lasted for a few weeks [5]. This was then followed by a healing process with collagen formation and long-term skin

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improvement. Although monopolar radiofrequency treatment is effective in the improvement of skin laxity, the pain and cost that are associated with this procedure suggest the need for alternative treatment options.

Recently, an infrared device with contact cooling has been shown to be effective in the treatment of skin laxity, with ultrastructural changes observed that are similar to those that are observed following treatment with a monopolar radiofrequency device [6]. A recent clinical study that examined the use of this infrared device in the treatment of 25 patients indicated that it was effective in tightening skin with minimal discomfort [7]. Another study that looked at the efficacy of this device in the treatment of Asian patients also confirmed its effectiveness [8]. However, no control was included in either of the studies. Our objective is to perform a prospective, split-face, single-blinded study to look at the efficacy and complications among Asians of treatment for skin tightening with this device.

## METHODS AND SUBJECTS

Chinese women were recruited into the study. They were of skin type III or IV and had not received any treatment with laser, light source, radiofrequency, Botulinum toxin, or filler injection in the 6 months prior to the study. Other exclusion criteria included the use of photosensitizing agents such as tetracycline or oral isotretinoin in the 6 months prior to the commencement of the study or a history of keloids.

All of the patients were treated on one side of their face with an infrared light source device (Titan, Cutera). The other side of their face was not treated and served as the control. All of the patients were offered the opportunity to have the untreated side of their face treated after the last follow-up visit of the study.

One hour before treatment, EMLA cream was applied to the half of the face that was receiving treatment. All of the treatments were performed by a single operator (HC). The forehead, cheek, and submental areas were treated with three passes of the infrared device (spot size 10 cm × 1.5 cm) with fluences that ranged from 36 to 46 J/cm<sup>2</sup>. The fluence that was used was determined by the degree of discomfort of the patients and the patient was not to experience more than a moderate degree of discomfort. The fluence that was used was decreased by 10–15% over bony areas such as the forehead.

## ASSESSMENT

All of the patients were assessed before their first treatment, at 1 and 3 months after their final treatment by the following.

**Questionnaire.** All of the patients were assessed for the degree of improvement in terms of pore size, wrinkle improvement, and overall degree of satisfaction with a structured questionnaire. For those who could not return for photographic assessment, a telephone interview was conducted.

**Clinical photographs.** Photographic imaging that used a Canfield Visia CR system (Canfield, NJ) was used

to assess all of the patients before each treatment session. The system consists of a configurable head support that ensures the proper and consistent registration of the position of the patient's head at center 0°, left 37°, and right 37°. The photographic images all had a 10.2-megapixel resolution. The photographs were taken using standard light, cross-polarization, parallel polarization, and UV light. The images were stored in the Canfield mirror software and assessed by two independent blinded assessors. The mirror software enables the images to be displayed in a side-by-side comparison format. The software also allows the images to be magnified for more accurate comparison. Assessors were masked about which side the patient received treatment, and the images were randomly displayed in a nonsequential fashion. The whole face was shown in the photographs, and the two photographs were compared side by side—by viewing the same and the opposing sides. After they had jointly assessed the photographs and reached mutual consensus, the assessors were asked to score the degree of skin laxity in the following categories:

- (a) Worsening.
- (b) No change.
- (c) Mild improvement.
- (d) Moderate improvement.
- (e) Significant improvement.

The Wilcoxon signed ranks test was used for statistical assessment to test the difference between the treated and un-treated sides of the face. A statistical difference of <0.05 was considered to be significant.

## RESULTS

Thirteen Chinese women (mean age 55, range from 47 to 68) were recruited into the study. According to the baseline Fitzpatrick wrinkle classification system, 7 out of 13 patients were in class I, 5 were in class II, and 1 was in class III. The degree of subjective improvement 1 and 3 months after the last treatment is listed in Figures 1–3. Overall, 3 out of 13 patients reported mild improvement, 2 reported moderate improvement, and 7 reported significant improvement 3 months after their last treatment. The objective assessments by blinded assessors are listed in Figures 4 and 5. Two patients did not return for photographic assessment 1 month after the last treatment and one did not return 3 months after the last treatment. Three months after their last treatment, 5 out of 12 patients were identified to have some degree of improvement of the treated side. Compared with the un-treated side, the treated side improved significantly ( $P=0.031$ ) at 1 and 3 months after the last treatment (Figs. 4, 5, 6A–D, 7A–D).

Blistering occurred in one patient, which had resolved completely by the 3-month follow-up visit.

## DISCUSSION

Regardless of skin type, skin laxity is one of the most common complaints among aging patients. Although

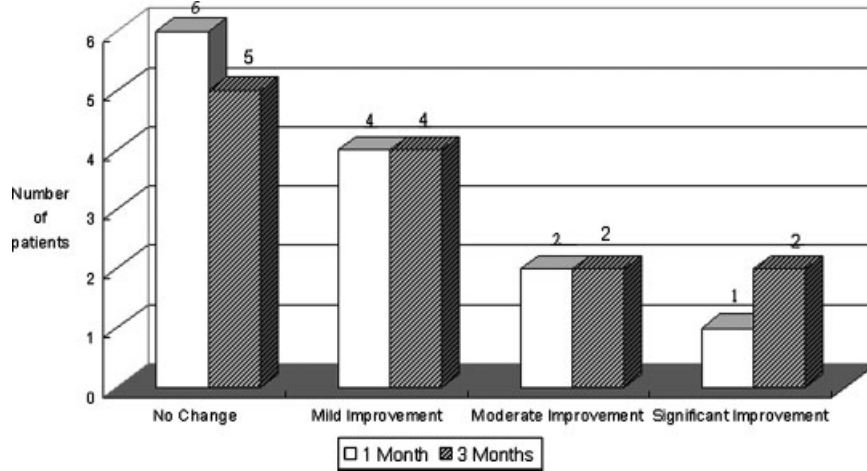


Fig. 1. Subjective assessment of pore size improvement.

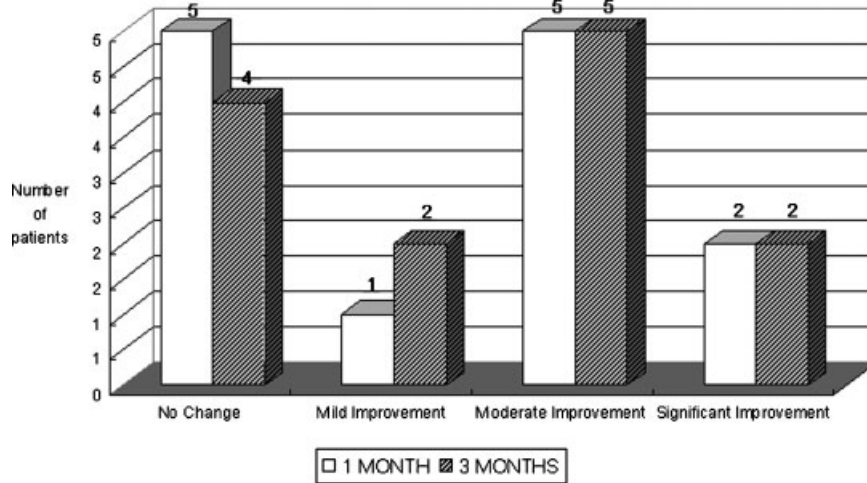


Fig. 2. Subjective assessment of wrinkle improvement.

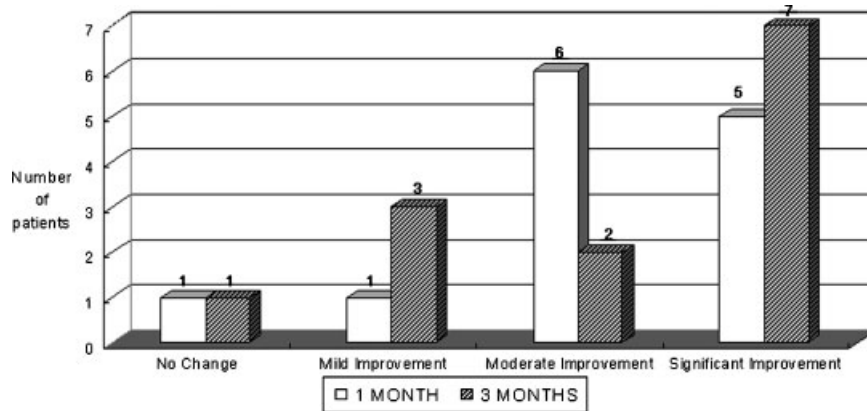
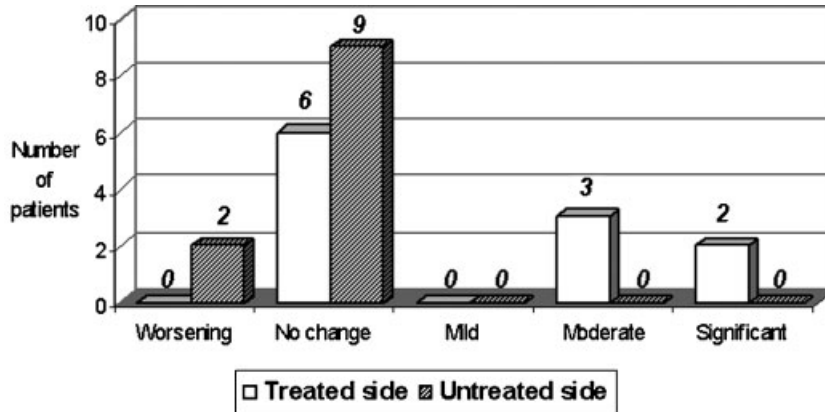


Fig. 3. Subjective assessment of overall improvement.



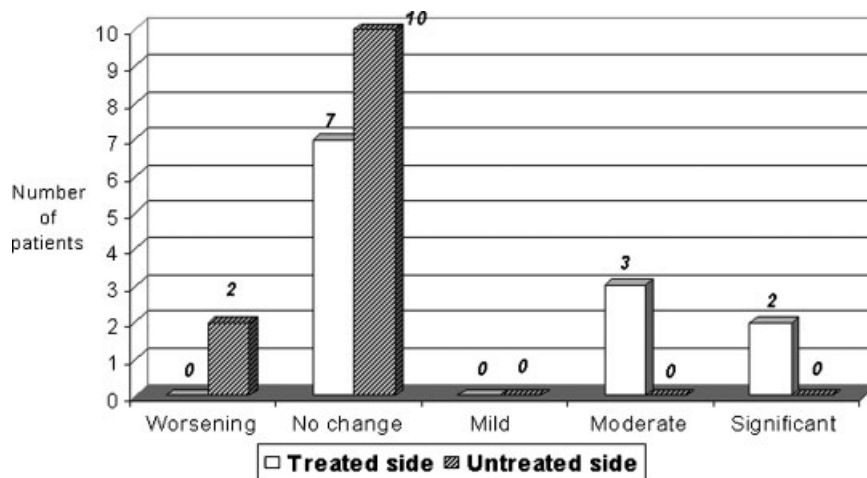
The treated side shows more improvement than the untreated side at 1 month after the second treatment ( $p = 0.031$ ).

Fig. 4. Degree of tightening between treated side and untreated side by blinded observer 1 month after last treatment.

invasive or ablative procedures such as face-lifts or laser resurfacing are effective in skin tightening, the downtime and potential adverse effects that are associated with such procedures are not well accepted. Monopolar radiofrequency is the first nonablative approach that has been shown to be effective in skin tightening. The initial approach, which involved the use of a single-pass, high fluence regimen, was associated with a greater degree of discomfort and complications including tissue irregularity and burns [3]. A new treatment protocol that uses a multipass, low fluence regimen has been developed with the aim to reduce the discomfort of patients and the risk of adverse effects. A recent study indicated that this new treatment protocol is effective [4]. However, there are several issues concerning the use of monopolar radio-

frequency for skin tightening. First, the procedure is effective in some but not all patients and factors to predict the effectiveness of this procedure have not yet been determined. Second, the discomfort that is associated with this procedure despite the use of low fluence and multiple passes is still significant. Finally, as the device has a disposable tip that can only be used for a single treatment session, the cost effectiveness of this procedure is another important concern.

More recently, an infrared light source device with contact cooling has been used successfully 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 a lower temperature over a longer period of time [7,9]. In doing so, the discomfort of patients can be reduced



The treated side shows more improvement than the untreated side at 3 months after the second treatment ( $p = 0.031$ ).

Fig. 5. Degree of tightening between treated side and untreated side by blinded observer 3 months after last treatment.

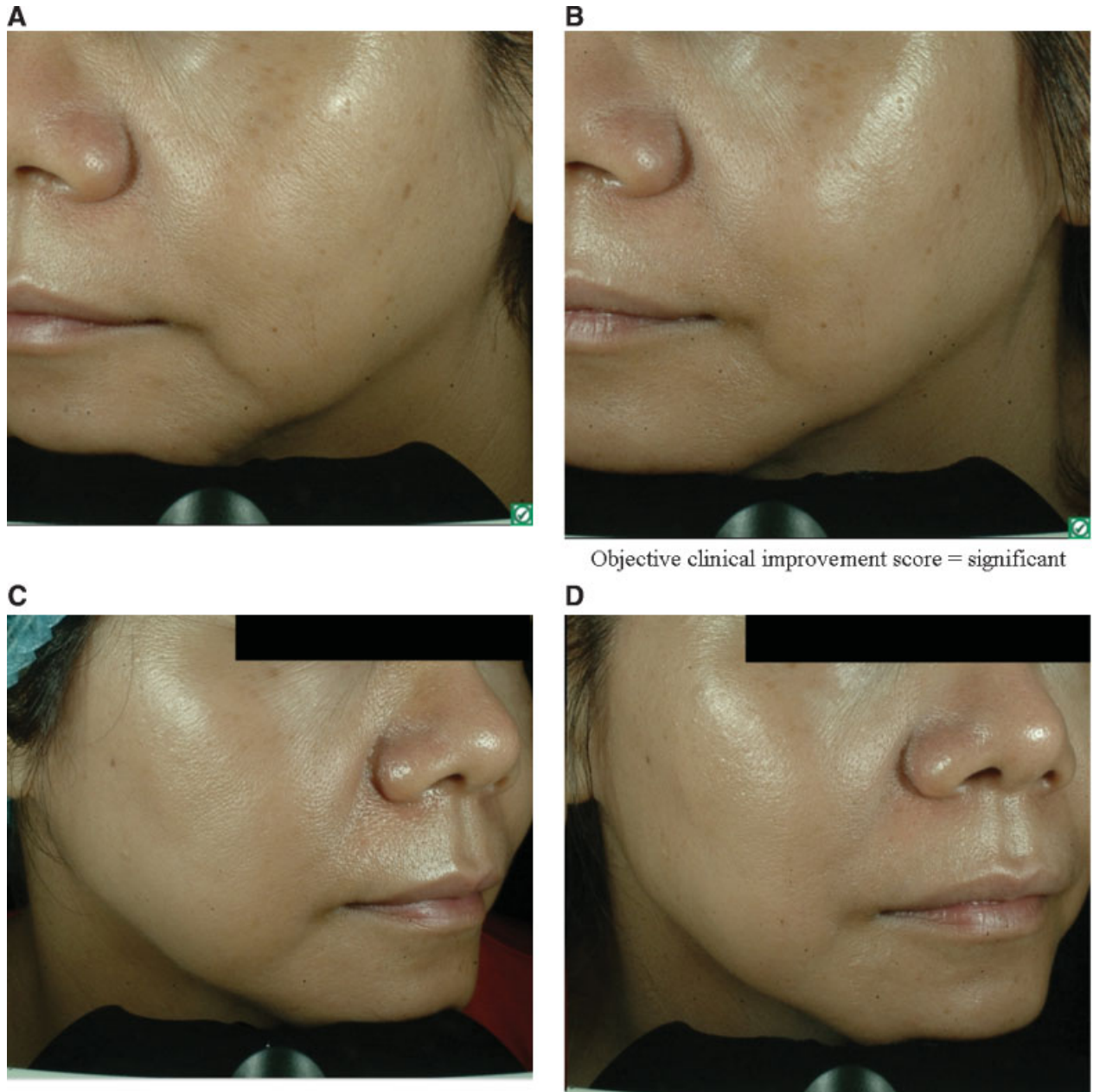


Fig. 6. **A:** Treated side at baseline. **B:** Three months after the last treatment. **C:** Control side at baseline. **D:** After 3 months.

without a significant reduction in clinical efficacy. Two clinical trials that look at the effectiveness of this device have been published so far. Ruiz-Esparaz examined 25 patients who were treated with an infrared device and suggested that skin tightening can be achieved in a painless manner using low fluence ( $20\text{--}30\text{ J/cm}^2$ ) [7]. Of the 25 patients who received a single treatment, 22 demonstrated photographic improvement. Although a blinded assessor graded the photographs, no control was performed. Besides the lack of a control, the methodology in this study also differs from ours, as our patients received

two treatment sessions with a 4-week interval between treatments and much higher fluences were used.

Another recent study that looked at the effect of skin tightening among Asian patients on whom this infrared light source device had been used treated patients with parameters that were similar to those that were used in our study [8]. However, three monthly treatments were performed rather than the two that were performed in our study. Interestingly, in terms of subjective assessment 3 months after the last treatment, the findings of the study were similar to ours, with 67% of patients reporting a

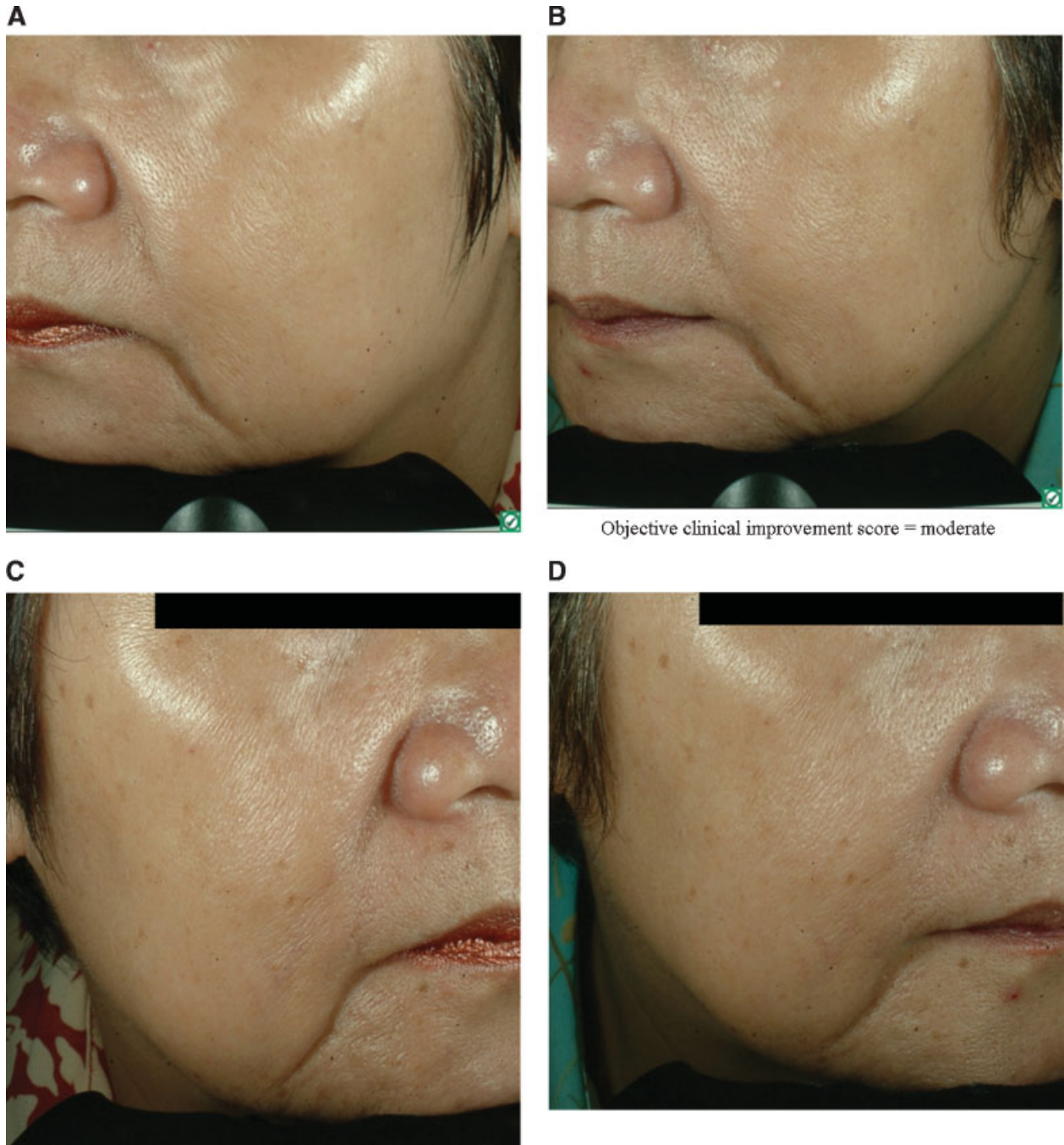


Fig. 7. **A:** Treated side at baseline. **B:** Three months after the last treatment. **C:** Control side at baseline. **D:** After 3 months.

moderate to significant degree of improvement as compared to the 69% reporting a moderate to significant degree of improvement in our study. However, in terms of objective assessment, there are significant differences, with 86% of patients showing some degree of skin tightening by photographic assessment in their study compared with only 41% in our group. Several factors may explain such differences. Although the additional treatment session (three monthly

treatments in the previous study compared with two in our current study) may lead to a greater degree of improvement, the lack of control in that study could also contribute to the different treatment outcomes. Nonetheless, our findings demonstrated a statistically significant degree of improvement in terms of skin tightening of the treated side of the face compared with the untreated side of the face, which is important as it further illustrated the role of an

infrared light source device as an alternative means to improve skin laxity.

One of the major issues in all skin tightening clinical studies is the lack of an accepted standard regarding the accurate assessment of the degree of skin tightening. We have used a photographic imaging system with a configurable head support so that all of the photographic assessments can be standardized. While this is effective in the assessment of facial skin laxity such as the jowl, improvement in the neck can be difficult to assess. Furthermore, accurate grading can be difficult. This may further explain the discrepancy between our findings and those of the previous study in which three treatments were given. More recently, the Leal laxity classification system has been used to assess the efficacy of the monopolar radiofrequency device [4]. Although this classification allows better assessment of the degree of skin laxity, interobserver and intraobserver variations still exist.

In terms of the limitations regarding the use of an infrared light source for skin tightening, our study confirmed the observation of others, that is, that blistering is the most common complication. This is likely due to the bulk tissue heating that occurred as a result of overlapping, although poor contact cooling may be a contributing factor. To improve the visibility of the operator, the design of the handpiece has recently been modified to reduce the risk of overlapping. Further study is necessary to confirm the safety profile of this new handpiece.

There are limitations regarding the use of this infrared device for skin tightening. With a relatively small spot size (10×15 mm as compared with 30×30 mm of the mono-polar radiofrequency device) and a long pulse width (5–10 seconds), the treatment time for a large anatomical area (such as the full face or abdomen) can be very time consuming. Also, our study and others indicate that the optimal treatment parameters (number of treatment sessions, interval time between treatments, and the appropriate fluences) remained to be determined. It has recently been suggested that different devices should be used for the treatment of skin laxity in different anatomical sites [1]. We agree with this, and in practice, for patients who complain of skin laxity that affects most parts of the face, monopolar radiofrequency is offered. For localized improvement, an infrared light source can be used for skin laxity. In an off-face area such as the abdomen, we use an infrared light source with a much larger spot size (Infrared Handpiece from Starlux, Palomar, Burlington, MA). Preliminary data that look at the use of a bipolar radiofrequency with an infrared light source (ReFirme ST device, Syneron Medical

Ltd., Yokneam, Israel) and focused ultrasound (Ulthera, LLC, Mesa, AZ) suggest that these methods may be effective for the treatment of skin laxity [10,11]. Further clinical trials are necessary to confirm their effectiveness.

In conclusion, an infrared device with contact cooling is safe and effective for the treatment of skin laxity, especially in smaller anatomical areas. Blistering is the main complication and can be overcome with a change in the handpiece design. Further studies are necessary to determine the optimal treatment parameters such as the number of treatment sessions and length of the interval between treatments.

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