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# Efficacy of High Intensity Focused Ultrasound (HIFU) for Lifting and Tightening Lax Facial & Neck Skin

Sharmila Nayak

# Efficacy of High Intensity Focused Ultrasound (HIFU) for Lifting and Tightening Lax Facial & Neck Skin

Sharmila Nayak | India

## INTRODUCTION

To meet increasing public demand about facial wrinkles and laxity due to aging, various noninvasive skin tightening & lifting treatment options are utilized including chemical peeling, fractional laser, radiofrequency & high intensity focused ultrasound; however, the ideal treatment option has yet to be identified[1,2,3,4]. Recently, High Intensity Focused Ultrasound (HIFU) was used as novel treatment for therapeutic and cosmetic purposes[5,6]. Focused ultrasound is highly convergent and uses different frequencies of acoustic energy than medical ultrasound devices. The high-frequency focused ultrasound beam is allowed to target the subcutaneous tissues such as the superficial musculoaponeurotic system (SMAS) passing harmlessly through the upper layers of skin. This HIFU beam generate instant microthermal lesions where collagen around the focal point will reach over 65°C and be denatured & contract within milliseconds leading to additional de novo collagen synthesis and remodeling[7, 9, 10]. HIFU has been demonstrated to be safe and effective in numerous clinical trials as a noninvasive aesthetic treatment and has been cleared by the United States Food and Drug Administration (FDA) to noninvasively lift tissues in the eyebrow, neck, and submentum, and improve lines and wrinkles of the décollete[10].

In proposed study, efficacy evaluation of the Ultraformer III (HIFU) treatment was done on the basis of clinical improvement, adverse effects and patient satisfaction, these parameters were evaluated using clinical photographs and by a Subject Global Aesthetic Improvement Scale (SGAIS) and Physician Global Aesthetic Improvement Scale (PGAIS) scores at 3 months after treatment, in 20 patients older than 25 years of age.

## MATERIALS & METHODS

20 healthy subjects consisting of 15 women & 5 men between 25 to 60 years of age with skin laxity and facial wrinkles were enrolled into the study. Each subject was given informed consent & express their willingness to comply with all study requirement. All patients were of Fitzpatrick skin types IV and V. They were treated with HIFU device (Ultraformer III, Classys, South Korea) to the entire face, except for the nose and eyes, by using the following elliptical transducers, 4.5 mm focal depth (4 MHz), 3 mm focal depth (7 MHz) and 1.5 mm focal depth (7 MHz). The pitch (distance between the two high intensity focused ultrasound) was kept constant at 1.5 mm for all the focal lengths and it delivers a shot in less than 35 milliseconds. Before initiating treatment, prior assessment of subjects' skin tissue quality was done based on parameters such as age & gender, BMI & volume of subcutaneous soft tissue in the region to be treated. On the basis of assessment, a customized protocol was developed for the subjects. Mild thick layer of ultrasound gel was applied before starting the treatment on the skin. Treatment for each area was were given in three passes (horizontally, vertically and diagonal) to form a grid pattern which will give a proper lifting and will minimizes the skipped area. The whole face was treated with three different focal depths depending on areas where shoots were given (4.5 mm, 4 MHz; 3 mm, 7 MHz and 1.5 mm, 7 MHz). On the whole face 60% of area was covered by 4.5 mm transducer, 30% area by 3.0 mm transducer and 10% by 1.5 mm transducer.

Standardized two-dimensional photographs of each subject in frontal and 45° angle views, along with profiles from each side, were obtained using fixed camera and lighting conditions before, and 3 months after the treatment. All the subjects were evaluated based on a blinded qualitative assessment compared 90-days post treatment photos with baseline photos and quantitative improvement in skin tissue lift. The Subject Global Aesthetic Improvement Scale (SGAIS), Physician Global Aesthetic Improvement Scale (PGAIS) & Patient Satisfaction Questionnaires (PSQ) were also completed on 90 days post-treatment. Efficacy evaluation criteria's- the primary evaluation criteria is the overall improvement in skin lifting & tightening using blinded qualitative assessment of before & after treatment photographs. Secondary efficacy evaluation was done using PGAIS & SGAIS scale based on PSQ.

Using subject's 2D photographs taken on each follow-up visit quantitative assessment of brow & lower face tissue lift were done. Baseline & post-treatment photos were matched to ensure proper alignment. For lower face, an improved lift measurement

was defined as a submental lift ≥1.0mm. For the upper face, a lift measurement was considered improved if the eyebrow was raised ≥0.5mm.

## RESULTS

### Demographic information

This study included 20 Indian patients (15 women and 5 men), aged 25 to 60 years (mean, 42.5 years) and All 20 subjects returned for the 90-day follow-up (100%). The number of shots delivered with the HIFU tightening device was 500±50.

### Efficacy evaluation results

Among the 20 evaluated subjects, photos of 5 patients were excluded from blinded photography assessment, efficacy results were positive for 15 patients (75%).


**Fig-1** Frontal view of a representative subject at baseline and post-treatment Day 90

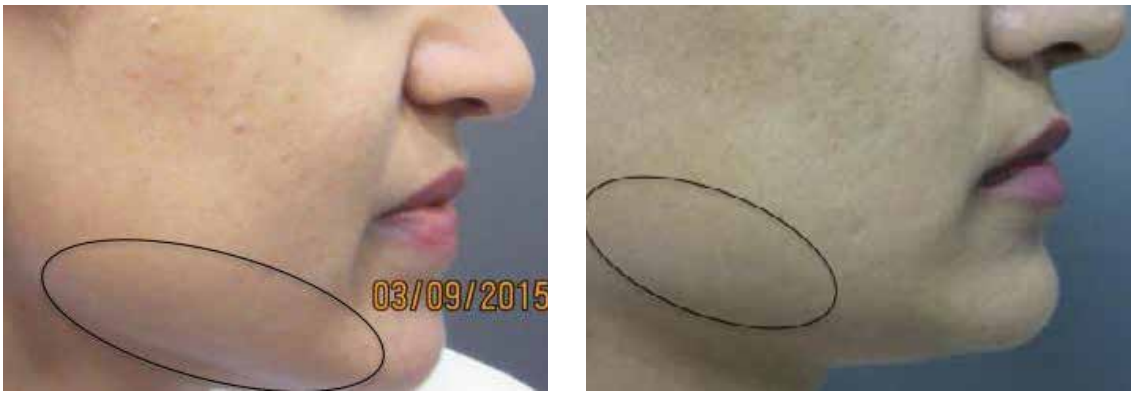


**Fig-2** Lateral view of a representative subject at baseline and post-treatment Day 90

Substantial improvement after 90 days post treatment can be seen in frontal & lateral views of the treated subjects in Fig-1 & 2 respectively. Results of the PGAIS reflects that 100 percent of the subjects were having aesthetic improvement after 90 days treatment, while SGAIS results indicated that 85 percent of subjects perceived aesthetic improvement after 90 days. Detailed PGAIS and SGAIS data are provided in Table 1.

| **Physician Scores** | **90 Days (N=20)** |
|---|---|
| Very much improved | 4 (20%) |
| Much improved | 10 (50%) |
| Improved | 6 (30%) |
| No change | 0 (0%) |
| Worse | 0 (0%) |
| All improved | 20 (100%) |
| | |
| **Subject Scores** | **90 Days (N=20)** |
| Very Much improved | 10 (50%) |
| Much improved | 3 (15%) |
| Improved | 2 (10%) |
| No change | 2 (10%) |
| Worse | 0 |
| All improved | 17 (85%) |

**Table-1** Global aesthetic improvement scale scores

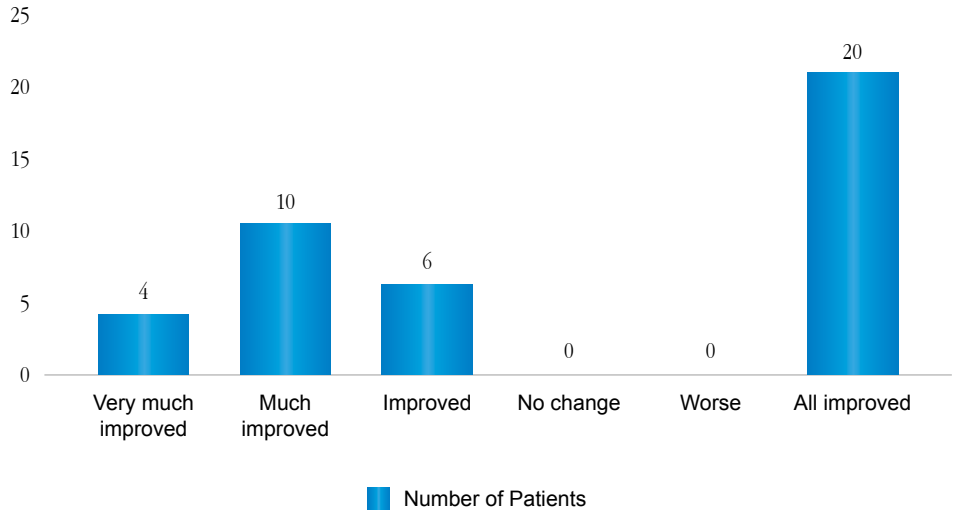


**Fig-3** Physician aesthetic improvement scale score (PGAIS)

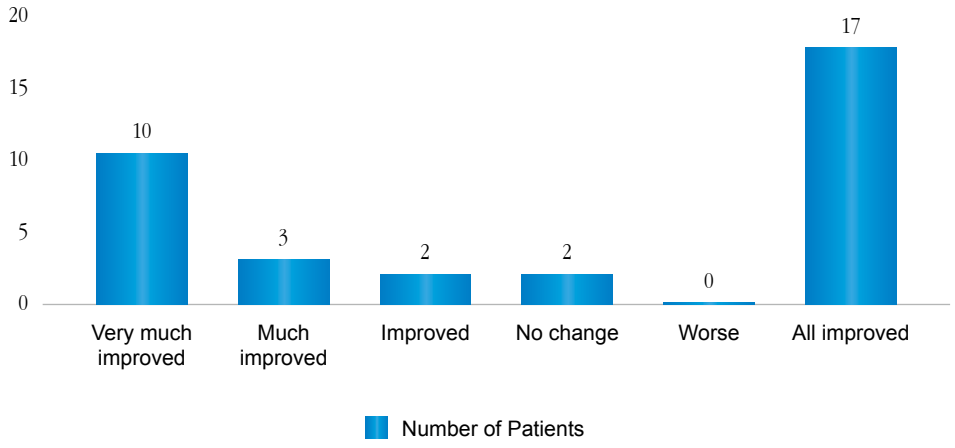


**Fig-4** Subject aesthetic improvement scale score (SGAIS)

## PATIENTS' SATISFACTION SCORE

Based on analysis of patient satisfaction questionnaires, 17 (85%) patients were found to have less sagging, 10 (50%) with less lines & wrinkles & 8 (40%) with smoother skin texture 8 (40%) (Fig-5).

We also assessed the efficacy and adverse effects 3 months after the treatment. Among 17 patients who replied, 5 patients answered that partial effects were still present in some areas.

| Parameter | 90 Days (N=20) |
|---|---|
| **Patient Satisfaction** | |
| Very Satisfied | 15 (75%) |
| Satisfied | 2 (10%) |
| Dissatisfied | 3 (15%) |
| Very Dissatisfied | 0 (0%) |
| Very Satisfied +Happy | 17 (85%) |
| | |
| **Improvement Noticed** | |
| Lines / Wrinkles | 10 (50%) |
| Less Sagging | 17 (85%) |
| More Even Skin Tone | 2 (10%) |
| Smoother Skin Texture | 8 (40%) |
| Other | 2 (10%) |
| No Improvement | 3 (15%) |
| **Would Continue & recommend treatment** | |
| Yes | 17 (85%) |
| No | 3 (15%) |

**Table-2** Patient satisfaction Questionnaires

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# Efficacy and Safety of Non-invasive Body Tightening with High Intensity Focused Ultrasound (HIFU)

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# Efficacy and Safety of Non-invasive Body Tightening with High Intensity Focused Ultrasound (HIFU)

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## ABSTRACT

**Background:** Noninvasive skin- tightening devices have become increasingly popular in response to increasing demand for improvements in skin laxity and tightening with minimal risk and recovery time.

Objective: We evaluated the efficacy and safety of HIFU for skin tightening in the face and body.

**Methods:** A total of 32 Korean subjects enrolled in this prospective clinical trial. The subjects were treated with HIFU to both cheeks, lower abdomen, and thigh. Skin elas-ticity was measured before and after treatment using a Cutometer (CT575, Courage and Khazaka®, Cologne, Germany). Three blinded, experienced dermatologists evalu-ated paired pre- and post- treatment (week 4 and 12) photographs according to the Global Aesthetic Improvement Scale (GAIS). Participants also completed self- assessments using GAIS. Subjects rated their pain on a numeric rating scale (NRS) im-mediately, 7 days, 4 weeks, and 12 weeks after treatment.

**Results:** Skin elasticity measured via a Cutometer was significantly improved 12 weeks after treatment at all treated sites (P<.05). Both IGAIS and SGAIS showed significant improvements 12 weeks after treatment. Immediately after treatment the mean NRS score was 3.00±1.586, but no pain was reported at 4 and 12 weeks post- treatment. No serious adverse effects were observed during the follow- up period.

**Conclusion:** HIFU safely and effectively improves skin elasticity and clinical contour-ing of the face and body.

KEYWORDS: body tightening, high-intensity focused ultrasound

## 1. INTRODUCTION

The most common features of aging skin are laxity and loss of elasticity. As the skin ages, elastic fiber, collagen, and connective tissue in the dermis are reduced. Skin moisture and subcutaneous fat also decrease. There are many procedures to improve skin laxity, such as laser therapy, radiofrequency, botulinum toxin, fat autografts, and surgical lifting. Of these procedures, botulinum toxin and fat autografts are used for facial rejuvenation but are difficult to apply for improving body laxity. Radiofrequency and infrared laser devices which expose the dermis to controlled heat and stimulate neocollagenesis in dermis have inferior efficacy so that surgery still remains the treatment of choice in moderate to severe tissue laxity.[1] Although surgical face lifting is the most effective treatment to improve skin laxity, it is also a procedure that involves risks such as scarring, infection, nerve damage, inherent risks of anesthesia, swelling, and bruising.[2]

HIFU technology was originally used as a non- invasive modality for selectively destroying tumor cells of internal organs by thermal coagulative necrosis for many decades.[3] HIFU was recently introduced as a new treatment modality for skin tightening and rejuvenation. The mechanism of HIFU is transcutaneous heat delivery to the deep dermis, subdermal connective tissue, and fibromuscular layer in precise microcoagulation zones at consistent programmed depths without damage to the epidermis. This microcoagulation is thought to cause gradual tightening of the skin through collagen contraction and remodeling.[4] HIFU first received approval for eyebrow lifting, but dermatologists are using the technology for many off-label applications, such as facial rejuvenation, skin whitening, and

lipolysis.HIFU has been used safely and effectively to treat facial and neck skin in a variety of skin types, but some studies have examined its use for the body, including our pilot study.[5–7] In this study, we sought to determine the clinical efficacy and safety of HIFU with novel transducers in both face and body regions.

## 2. SUBJECTS AND METHODS

Korean patients with skin laxity on the face, abdomen, and thigh were recruited for study entry. The study was approved by the Institutional Review Board of Chung-Ang University Hospital. Informed consent was obtained from all patients. Exclusion criteria were prior cosmetic or surgical treatments (eg, laser, RF, surgical lifting, filler injections), skin infection or inflammation, pregnancy, skin diseases that may alter wound healing, open wounds, and scarring over the treatment area.

For pre-treatment preparation, we applied topical anesthetic cream to all treated areas including both cheeks, the lower abdomen, and the posterior thigh. The sizes of the involved areas were 5.0 × 5.0 $cm^2$ on each cheek and 7.5 × 7.5 $cm^2$ on each lower abdomen and thigh (Figure 1). We used a HIFU device (ULTRAFORMER III (SHURINK) CLASSYS INC., Seoul, Korea) with five different transducers: one basic transducer for facial skin tightening (MF1: 7-MHz, 1.5-mm focal depth), and four newly developed transducers for body skin tightening (MF3: 2-MHz, 3.0-mm focal depth, MF4: 2-MHz, 4.5-mm focal depth, MF6: 2-MHz, 6.0-mm focal depth and MF9: 2-MHz, 9.0-mm focal depth). Ultrasound gel was applied to the treated area and the transducer of HIFU was pressed perpendicularly, uniformly, and firmly to the skin surface (Figure 2). Treatment exposure was initiated with a line of individual ultrasound pulses. The pulse duration for each individual exposure ranged from 25 to 40 milliseconds. The 25-mm-long exposure lines of ultrasound pulses were manually delivered adjacent and parallel to one another approximately 3–5 mm apart. We treated subjects with several types of transducers appropriate to the thicknesses of facial and body skin. Three transducers (MF1, 3, and 4) were applied to the face and all five transducers (MF1, 3, 4, 6, and 9) were applied to the body. The energy per ultrasound pulse ranged from 1.0 to 1.5 J. When patients reported feeling pain, we reduced exposures to 0.1–0.3 J per time, and did not increase exposures up to 1.5 J. The treatment lines included a total of 120 shots for the cheek, distributing a total 537.6 J, and 450 shots for the abdomen and thigh, distributing a total 900 J. The time required for complete HIFU treatment of the face and body was over 40 minutes.

All patients were followed up at 4 and 12 weeks after treatment, at which times we obtained clinical photographs using consistent patient positioning, camera settings (Canon EOS 600D, high-resolution setting, 5760 × 3840 pixels, Canon Inc., Tokyo, Japan), and room lighting. Baseline and post-treatment photographs were randomly displayed, and independently evaluated by three dermatologists who were masked to the study protocol. Investigator Global Aesthetic Improvement Scale (IGAIS) scores were determined using side-by-side comparisons of 4-and 12-week post-treatment photographs to baseline. The subjects also evaluated the tightening effects using the Subject Global Aesthetic Improvement Scale (SGAIS)

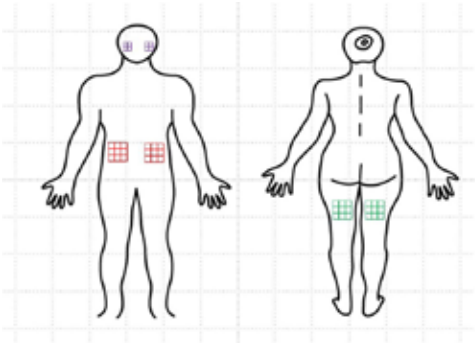

**Figure 1** Face and body treatment areas

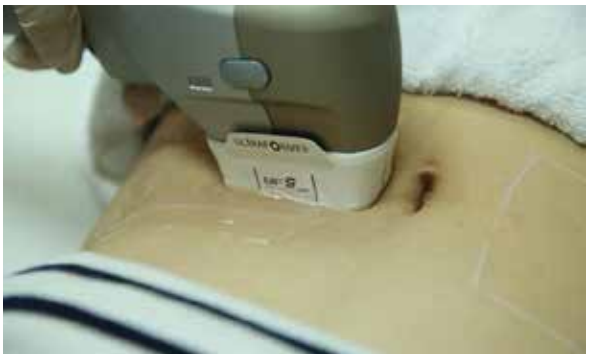

**Figure 2** The ULTRAFORMER III (SHURINK) HIFU device MF9 (2 MHz, 9.0 mm) tip applied on the abdomen (obtained from Classys Inc., with permission)

at 4 and 12 weeks post-treatment. We used the Cutometer (Courage+Khazaka Electronic GmbH, Cologne, Germany) to measure skin elasticity and objectively evaluate skin tightening. Among the cutometer-specific R values (R0–R9), the R7 value is the ratio of elastic recovery to the total deformation.

### 2.1 Statistical analyses

Statistical analyses were performed using SPSS version 21.0 for Windows (SPSS Inc., Chicago, IL, USA) and R version 3.2.3 (2015-12-10). We used Hochberg step-up methods to adjust values for multiple comparisons. and represents biological elasticity. Adverse effects were assessed at each visit after treatment. A numeric rating scale (NRS) was used to score pain immediately, 7 days, 4 weeks, and 12 weeks after the application of HIFU. Statistical comparisons before and after treatments were performed using paired t tests. Data are presented as mean±standard deviation. P values <.05 were considered statistically significant.

## 3. RESULTS

### 3.1 Efficacy

This study included 32 Korean patients (29 females and 3 males), aged 21–59 (mean±SD: 44.47±9.73) with Fitzpatrick skin types III and IV. All patients completed the 3-month study. The mean R7 value according to the Cutometer was significantly increased at 4 and 12 weeks post-treatment compared to baseline in all treated areas (Figure 3). The change of the mean R7 value at the thigh was 0.054±0.032, which represented the greatest change among the treated areas. IGAIS scores also showed good results (Table 1). Of the three treated areas, the cheek demonstrated the greatest improvements after treatment. At 4 weeks post-treatment, the improvement rates of subjects who were assessed as either improved (IGAIS score 1) or much improved (IGAIS score 2) were 96.9%, 84.4%, and 78.1% on the cheek, abdomen, and thigh respectively. At 12 weeks post-treatment, the improvement rate of the cheek area was reduced to 90.6%, but the body areas did not change significantly. Most subjects were satisfied with the results of treatment (Table 2). At 4 weeks post-treatment, all subjects rated SGAIS scores as greater than 1 on the cheek and thigh. The improvement rate assessed for the abdomen as greater than SGAIS 1 was 93.8%. At 12 weeks post-treatment, the improvement rates of cheek and thigh were reduced from 100% to 96.9%. However, the improvement rate of the abdomen increased to 96.8%.

### 3.2 Safety

The mean pain scores immediately and at 7 days after treatment were 3.00±1.586 and 0.031±0.177, respectively. The degree of pain decreased substantially within the first week post treatment. All patients were able to complete the treatment. No subjects

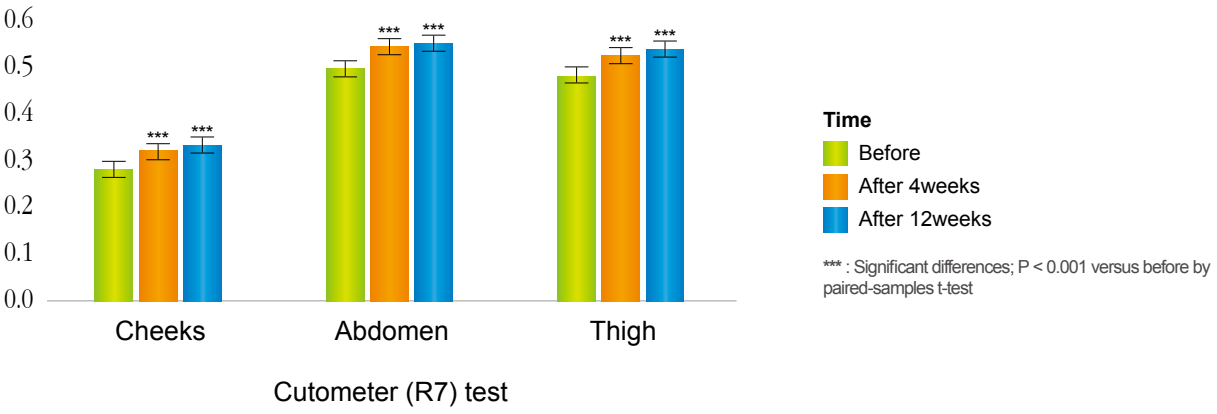


**Figure 3** Mean pre-and post-treatment R7 values of skin elasticity measured using Cutometers

| | | IGAIS | | | |
|---|---|---|---|---|---|
| | | **0** | **1** | **2** | **3** |
| Cheek | | | | | |
| Post-treatment(4W) | n | 1 | 29 | 2 | 0 |
| | % | 3.1 | 90.6 | 6.3 | 0 |
| Post-treatment(12W) | n | 3 | 29 | 0 | 0 |
| | % | 9.4 | 90.6 | 0 | 0 |
| Abdomen | | | | | |
| Post-treatment(4W) | n | 5 | 27 | 0 | 0 |
| | % | 15.6 | 84.4 | 0 | 0 |
| Post-treatment(12W) | n | 5 | 26 | 1 | 0 |
| | % | 15.6 | 81.3 | 3.1 | 0 |
| Thigh | | | | | |
| Post-treatment(4W) | n | 7 | 25 | 0 | 0 |
| | % | 21.9 | 78.1 | 0 | 0 |
| Post-treatment(12W) | n | 7 | 25 | 0 | 0 |
| | % | 21.9 | 78.1 | 0 | 0 |

0=No change, 1=Mild improvement, 2=Moderate improvement, 3=Significant improvement.

**Table 1** Investigator Global Aesthetic Improvement cale(IGAIS)

| | | SGAIS | | | |
|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 3 |
| Cheek | | | | | |
| Post-treatment(4W) | n | 0 | 13 | 13 | 6 |
| | % | 0 | 40.6 | 40.6 | 18.8 |
| Post-treatment(12W) | n | 1 | 10 | 10 | 8 |
| | % | 3.1 | 31.3 | 40.6 | 25 |
| Abdomen | | | | | |
| Post-treatment(4W) | n | 2 | 15 | 11 | 4 |
| | % | 6.3 | 46.9 | 34.4 | 12.5 |
| Post-treatment(12W) | n | 1 | 13 | 13 | 5 |
| | % | 3.1 | 40.6 | 40.6 | 15.6 |
| Thigh | | | | | |
| Post-treatment(4W) | n | 0 | 14 | 13 | 5 |
| | % | 0 | 43.8 | 40.6 | 15.6 |
| Post-treatment(12W) | n | 1 | 13 | 11 | 7 |
| | % | 3.1 | 40.6 | 34.4 | 21.9 |

0=No change, 1=Mild improvement, 2=Moderate improvement, 3=Significant improvement.

**Table 2** Subject Global Aesthetic Improvement Scale (SGAIS)

experienced persistent pain over the treatment areas at 3 months follow-up. Erythema was seen in up to 9.38% of the treatment sessions immediately post-treatment, but mostly subsided within 5 days (Figure 4). No patients showed surface injury or thermal damage on the treatment site. Ecchymosis was seen in up to 6.25% of treatment sessions immediately post-treatment. By 3 days post-treatment, all cases of ecchymosis had resolved. We observed no serious or delayed adverse effects during the follow-up period.

## 4. DISCUSSION

There are many noninvasive options of body sculpting, such as radiofrequency ablation, cryolipolysis, injection lipolysis, external low-level lasers, laser ablation, nonthermal ultrasound, and HIFU. Each of these treatments has no admission for treatment without anesthesia or analgesia and typically fewer complications than liposuction. However, with the exception of HIFU, patients have to visit the hospital several times for multiple treatments to achieve meaningful. Injection lipolysis and cryolipolysis have significant potential for AEs, which is largely unregulated and may cause significant pain, hematoma, allergic reactions, necrosis, scarring, panniculitis, and rapid release of lipids into the bloodstream.

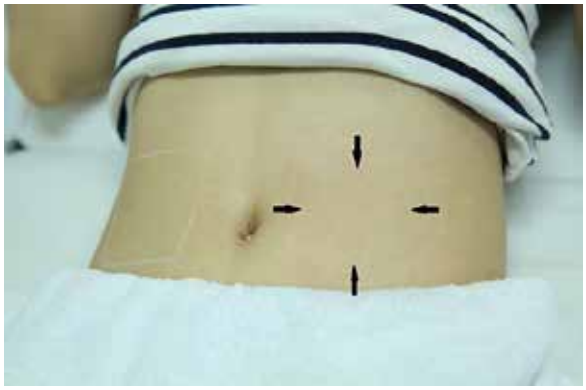

**Figure 4** Post-procedural mild erythema on the HIFU application site immediately after the treatment (black arrows). Erythema was resolved within 5 days

In contrast, previous clinical studies supported thermal HIFU for body sculpting have had no serious AEs including alterations in lipid profiles or other laboratory parameters[5-8]. Therefore, many clinicians are keeping an eye on the HIFU technique as purpose of body sculpting. Studies of HIFU facilitate the understanding of mechanisms of action for body sculpting. When used for body sculpting, HIFU delivers focused, high intensity ultrasonic energy to deep subcutaneous tissue, producing heat capable of effectively ablating adipocytes and thermally modifying collagen within the tissue matrix. In addition to local adipocyte necrosis, evidence of collagen remodeling from the thermal effects of HIFU has been observed.[9] Application of HIFU at a frequency of 1 MHz to adipose tissue leaves collagen fibers intact, but at frequencies of 2–3 MHz, diffuse contraction of collagen fibers occurs. Histological analyses performed after the procedure confirm that HIFU disrupts or denatures collagen fibers, resulting in new collagen formation accompanied by a general tightening of the septal fibers and skin[9]. Based on these results, newly developed transducers for application to body sites at a variety of focal depths (3.0–9.0 mm) are deemed to be suitable for body tightening. Also, we found no thermal damage on the skin surface of the HIFU treatment site. Kwon et al. has reported the temperature changes of the porcine model during HIFU procedure, which showed targeted subcutaneous fat to be around 70°C, while the skin surface temperature only went up to 33.1–35.6°C.[10] Therefore, we hypothesized that newly developed transducers could effectively and safely deliver HIFU energy deeper into the skin and eventually show body sculpting effects due not only to skin tightening but also to the reduction of subcutaneous fats. In this study, we used the Cutometer to evaluate the skin tightening effects of HIFU. Objective measurements of skin elasticity after laser, radiofrequency, and HIFU treatments are desirable. The use of uniform photographic documentation has improved, but there are often still inconsistencies in patient position and lighting. Physician-based grading systems are characterized by inherent elements of subjectivity. The purely objective quantification of results would be of great benefit for the evaluation of skin tightening procedures.

There are several reports describing the quantification of facial rejuvenation results using Cutometers. These include Shin et al., who used Cutometers to assess

the effectiveness of photographic rejuvenation with intense pulsed light (IPL).[11] Similarly, Naouri et al. assessed improvements in skin tightness after applying CO2 fractional lasers.[12] Ahn et al. demonstrated a stronger relationship between aging and skin elasticity parameters (R2, R7) than between aging and skin viscoelasticity parameters using Cutometers (R6),[13] while Kruger et al. made similar observations by conducting cutometric tests in a group of 120 females treating various parts of the body (cheek, neck, neckline, forearm, and back of the hand). They recommended the application of parameters R2 and R7 to evaluate the process of skin aging.[14] Thus, this study determined the R7 value from nine parameters of Cutometer.

In this study, we observed significant improvements in two body regions (abdomen and thighs) as well as the cheek when targeted for HIFU treatment. Adverse effects were limited to transient pain in most patients and occasional erythema or ecchymosis in some patients. HIFU can be safely and effectively used to improve the clinical appearance of the abdomen and thighs. Therefore, HIFU could meet current demands for significant, noninvasive skin lifting and tightening. Tightening and lifting of facial and body skin laxity can be achieved by inducing collagen fiber contraction and stimulating de novo collagenesis. By using newly developed transducers with different energy outputs and focal depths, HIFU treatment can be tailored to meet the unique physical characteristics of each patient.

## CONFLICTS OF INTEREST

Not declared.

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# High Speed Low-pain Micro Focused Ultrasound Tightening of the Lower Face and Neck

Adrian Lim, MD

# High Speed Low-pain Micro Focused Ultrasound Tightening of the Lower Face and Neck

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## INTRODUCTION

There is strong demand for non-surgical tightening procedures, especially to the jowl and neck areas, for a more youthful mandibular and neck contour (jawline). Popular procedures such as filler and botulinum toxin injections mainly target the face leaving the jowl and neck areas increasingly lagging with time. Non-surgical jowl and neck lifting procedures include skin resurfacing and various skin heating devices such as infrared, radiofrequency and micro-focused ultrasound (MFU).[1-4] Ablative resurfacing can tighten the skin but is largely limited by the recovery time and potential complications such as pigmentary alteration and scarring. On the other hand, non-invasive skin tightening devices are limited by subtle and inconsistent results, long treatment times and significant procedural discomfort.[5] In 2016, the Australian Therapeutic Goods and Services (TGA) approved a new high-speed, low-pain MFU device (Ultraformer 3) for skin tightening. This study is an evaluation of the safety, efficacy and patient satisfaction rate of Ultraformer 3 on lower face and neck laxity.

### Mechanism of action of Ultraformer 3

MFU can visibly tighten skin laxity in excess of 80% of cases.[6-8] MFU targets the SMAS (facelifting plane) for more natural and durable skin tightening. The delivery of the MFU is not associated with any epidermal injury and therefore does not require any recovery or down time. The focused and precise energy delivery is associated with significantly less side-effects such as burns, blisters, diffuse heating with collateral damage to adjacent epidermis or adipose tissue.

The Ultraformer 3 has a patented ultrasound focussing and delivery method that precisely targets tissue at adjustable depths of 4.5mm, 3mm and 1.5mm depending on the transducer cartridge selected, with corresponding frequencies of 4MHz, 7Mhz and 7 MHz respectively. In accordance to ultrasound physics, the higher frequency transducer cartridge corresponds to a more superficial focal depth. The Ultraformer 3 uses a proprietary mechanism enabling targeting a depth of 1.5mm without exceeding 7Mhz compared to conventional non-Ultraformer technology. The thermal injury zone (TIZ) is spaced between 1-2mm apart and the energy can be varied from 0.1J to 1.5J. The pulse duration for the 4.5mm cartridge range from 22ms (0.1J) to 33ms (1.5J) and the pulse duration for the 3mm cartridge range from 43ms (0.1J) to 65ms (1.5J). The relatively low pulse duration combined with adjustable energy allows precise and focussed energy delivery without excessive collateral damage beyond the TIZ. The patented technology also enables faster treatment times with less procedural discomfort.

The objective of this study is to prospectively evaluate the efficacy and safety of of the latest MFU (Ultraformer 3) for mandibular and neck contouring in patients with age-related laxity. We also undertook a patient satisfaction survey on the Ultraformer 3 procedure.

## METHODS

All 20 enrolled patients satisfied the inclusion/ exclusion criteria of: age 40 years or more, no previous skin tightening treatment in last 12 months, no neck or lower face botulinum injections for the last 6months and during the follow up period. Standardised face and neck photography was taken at baseline, immediately post-procedure and at subsequent follow-up at 6 weeks or more post-procedure. Patient satisfaction was assessed by a standardised survey performed at subsequent post-treatment follow-up visit (4 – 20 weeks). Procedural efficacy was rated by 2 blinded dermatologists examining baseline and post-procedural photos. The skin tightening treatment was administered by 2 trained registered nurses using the Ultraformer 3 (Classys, Korea). All patients were pre-treated with 60 minutes of compound anaesthetic to the lower face and neck and intra-operative chilled air cooling (Cryojet) and the additional options of using inhaled nitrous oxide if required. The treatment areas were: (A) lower face and (B) upper neck: submental and submandibular regions (avoiding thyroid). The method of treatment is as follows: (A) lower face: 2 passes – 2 columns down and 2 columns across – first pass is parallel to the jawline and second pass is perpendicular (90 degrees) to the jawline, and (B) upper neck: 2 passes parallel to the mandibular jawline (bilateral) and submental region.

## RESULTS

The patient demographics were: 19 females and 1 male, age range: 49 to 69 years-old (mean 58.7 years-old). Almost all patients commented on some degree of skin contraction and improvement in facial and neck contours immediately post procedure. At follow-up (4 – 20 weeks), 75% of patients continue to report a high degree of satisfaction. 95% of patients found the procedure tolerable requiring only topical anaesthesia and chilled air (Cryojet) for pain control during treatment. None required oral or injectable anaesthesia and only one third of patients requested additional inhaled nitrous oxide. 85% of patients would consider having the Ultraformer 3 again in the future and 75% would recommend the procedure to a friend. The patient satisfaction survey is summarized in table 1. Two blinded dermatologists were asked to study a series of subject images consisting of baseline images, immediately post-procedure images and one or more follow-up images ranging from 4- to 20- weeks post-procedure (figures 1-4). The blinded dermatologists were then asked to pick out the 'best' (most improved) image, which correlated with the follow-up images in 71.4% of cases (5 out of 7 patients). The blinded dermatologists (D1 and D2) were also asked to pick out the 'worse' image, which correlated with the pre-procedure baseline images in 72.5% of cases. The blinded dermatologists' survey is summarised in table 2.There were no long term adverse events noted. Mild to moderate transient erythema is commonly seen post-procedure lasting approximately 30 minutes. One patient on fish oil developed mild bruising that resolved fully after a few days. There were 2 transient but notable post-treatment effects: one patient had transient

| Strongly Disagree (-2) | Disagree (-1) | Uncertain (0) | Agree (1) | Strongly Agree (2) | Weighted Mean (-2 to 2) | Median Score |
|---|---|---|---|---|---|---|
| Q1. I am satisfied with the outcome of the procedure | | | | | | |
| 0 respondents | 1 respondent | 4 respondents | 7 respondents | 8 respondents | 1.1 | Strongly Agree |
| Q2. I would consider having the procedure again in the future | | | | | | |
| 0 respondents | 0 respondents | 3 respondents | 7 respondents | 10 respondents | 1.35 | Strongly Agree |
| Q3. I would recommend this procedure to a friend | | | | | | |
| 0 respondents | 0 respondents | 5 respondents | 6 respondents | 9 respondents | 1.2 | Strongly Agree |
| 4. I find the comfort level of the procedure to be | | | | | | |
| 'very uncomfortable'<br>1 respondent | 'uncomfortable but bearable'<br>7 respondent | 'slightly uncomfortable'<br>7 respondent | 'comfortable'<br>4 respondent | 'very comfortable'<br>1 respondent | -0.15 | Slightly uncomfortable but bearable |
| Q5. I find the duration of treatment | | | | | | |
| 'much longer than expected'<br>0 respondent | 'longer than expected'<br>1 respondent | 'about right'<br>14 respondent | 'shorter than expected'<br>3 respondent | 'much shorter than expected'<br>2 respondent | 0.3 | About right |

**Table 1** Ultraformer patient satisfaction survey.

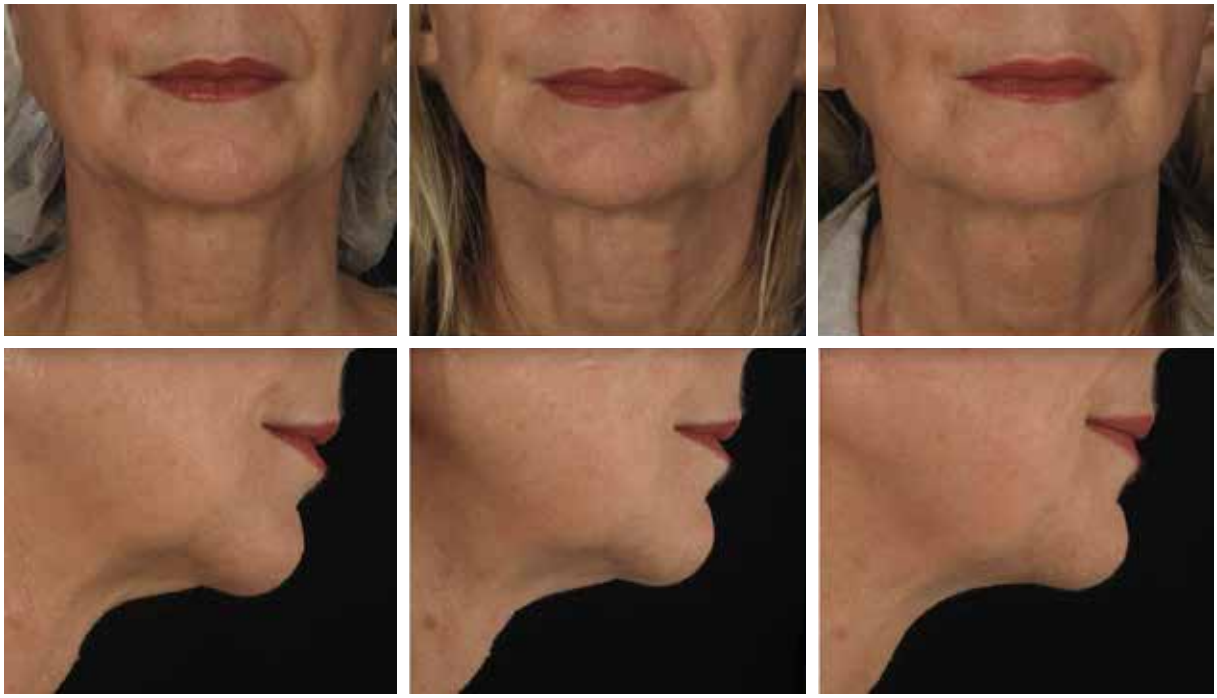

**Figure 1** 59 year-old female at baseline, 1-month, 2-months post-procedure (left to right).

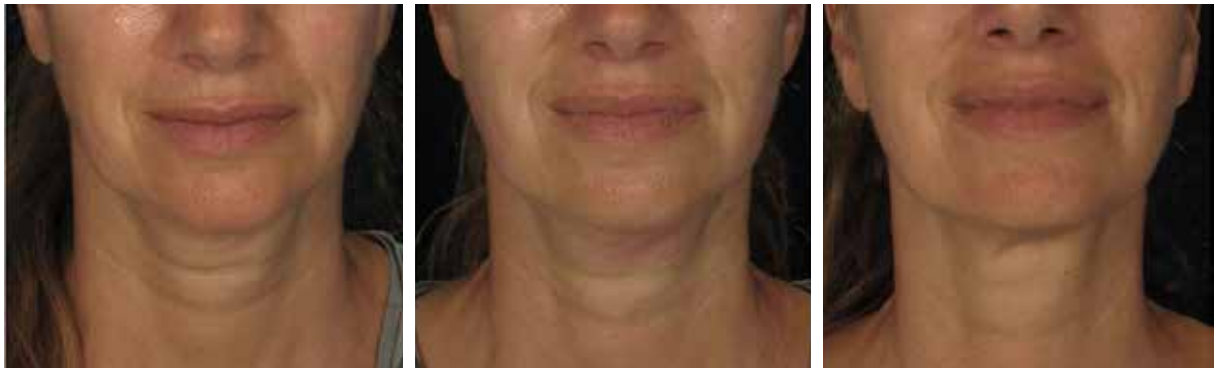

**Figure 2** 50 year-old female at baseline, immediately post, and 3-months post procedure (left to right).

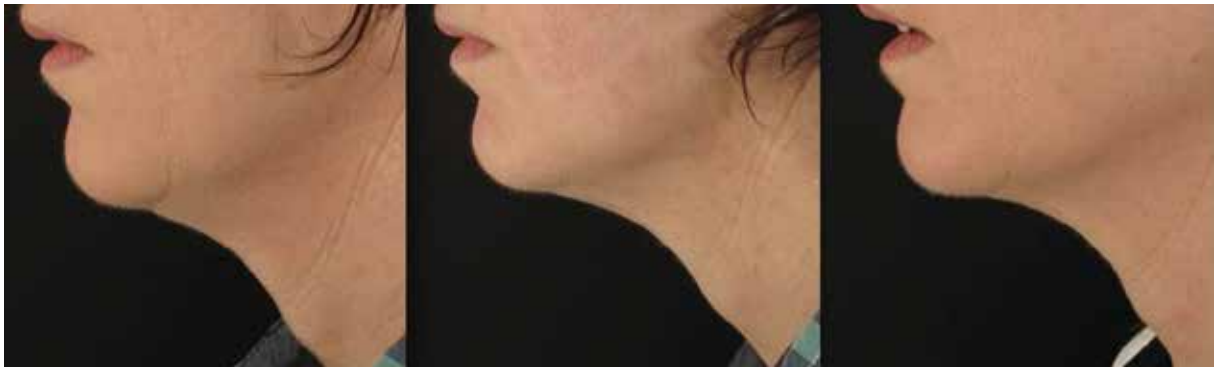

**Figure 3** 50-year old female at baseline, immediately post, and 3-months post-procedure (left to right).

| Case | Post (Week) | D1 * 'worse' | D2 * 'worse' | D1 ** 'best' | D2 ** 'best' |
|---|---|---|---|---|---|
| 1 | 0, 6, 20 | 0 | 0 | 1 | 0 |
| 2 | 0, 10 | 1 | 1 | 1 | 1 |
| 3 | 0, 4 | 0 | 1 | 0 | 1 |
| 4 | 0, 4 | 1 | 1 | 0 | 1 |
| 5 | 0, 6 | 1 | 0 | 1 | 0 |
| 6 | 0, 4, 8 | 1 | 0 | 1 | 1 |
| 19 | 0, 8 | 1 | 1 | 1 | 1 |
| 7 | 0 | 0 | 1 | | |
| 8 | 0 | 1 | 1 | | |
| 9 | 0 | 1 | 1 | | |
| 10 | 0 | 1 | 1 | | |
| 11 | 0 | 0 | 0 | | |
| 12 | 0 | 0 | 0 | | |
| 13 | 0 | 1 | 1 | | |
| 14 | 0 | 1 | 1 | | |
| 15 | 0 | 1 | 1 | | |
| 16 | 0 | 0 | 1 | | |
| 17 | 0 | 1 | 1 | | |
| 18 | 0 | 1 | 1 | | |
| 20 | 0 | 1 | 1 | | |
| | | 14/20 * | 15/20 * | 5/7 ** | 5/7 ** |

* correctly identifies the baseline ('worse') picture. D1, D2 mean = 72.5%
** correctly identifies the best ('lasest') picture. D1, D2 mean = 71.4%

**Table 2** Blinded physician (dermatologists D1 and D2) survey.

mild linear erythematous plaques for 24 hours after treatment and another patient had subtle asymmetry of smile for a few days after treatment, which fully resolved after one week.

## DISCUSSION

MFU has been used for skin tightening in facial and non-facial sites.[5,6,9,10] Upper face tightening for brow and eyelid laxity are easier to objectively measure using fixed landmarks such as pupils and eyebrows and have been subjected to studies with various skin tightening procedures including MFU.[6] The jowl and neck areas are more difficult to consistently measure in the absence of an objective grading scale or readily identifiable landmark and studies have to rely on photographic changes and subjective patient self-assessment. We elected to study jowl and neck tightening because this is an area that is not easily treatable by other non-invasive techniques such as cosmetic injectables and non-MFU skin tightening procedures. The aging jowl and neck is therefore of great concern to all cosmetic patients, with progressive lagging in these areas with the passage of time, relative to the mid to upper face, resulting in strong patient demand in our practice for jowl and neck tightening procedures.

The limitations of skin tightening devices include

inconsistent results, need for multiple treatments, procedural discomfort, durability of results and costs.[5] Patient satisfaction rate for skin tightening procedures range from 31% for monopolar radiofrequency to 80% for MFU.[8,11] In our study, 75% of patients are satisfied with the treatment outcome and this high patient satisfaction rate in part translates to a desire for repeat procedures (85%) and referring the procedure to others (75%). Procedural tolerability is another important patient consideration for return visits. In this regard, Ultraformer 3 is notably different from non-Ultraformer MFU in that it is well tolerated - 95% reported the experience as either 'very comfortable', 'comfortable' or 'slightly uncomfortable but bearable'. The average treatment time is less than 20 minutes and 70% of patients rated the treatment time to be 'about right' while another 25% rated the treatment time to be 'shorter' or 'much shorter' than expected. Pre-Ultraformer devices tend to be associated with a significant discomfort requiring oral anxiolytics and oral / intramuscular narcotic analgesics and is clearly a significant barrier to the uptake of pre-Ultraformer MFU treatments.[4]

The safety of MFU is well established with a very low reported incidence of adverse events. Overheating of the skin with inappropriately high energy settings can result in blisters and reticulate scars but the associated pain will usually prevent this from happening and indeed there are no reports of MFU related scarring.[4] In our study, there were 2 transient post-treatment effects that deserve further comment: firstly, transient mild linear erythematous plaques can occur but these generally last for less than 24 hours although there has been report of these lasting for days with subsequent full resolution with topical steroids. When linear plaques become noticeable during treatment, a decrease in fluence is recommended. Another patient had transient thermal neuropraxia from inadvertent MFU targeting of the left marginal mandibular nerve resulting in subtle transient lip weakness. The temporal nerve and marginal mandibular nerve are vulnerable to MFU effects at the temple and lateral chin respectively, and are 'caution areas' during MFU therapy. Transient sensory thermal neuropraxia presenting as tingling and numbness can also uncommonly occur.

Blinded physician assessment of the before-and-after photos show a noticeable change post-procedure (1- to 4.5- months, mean: 8.6 weeks). Although there is an initial non-response rate of up to 27.5%, based on on blinded 2-dimensional photo-ratings, these 'non-responders' may subsequently show a noticeable tightening response at alater time-point (figure 4), consistent with delayed collagen remodelling effects.

The durability of results has not been well studied and there is no data on the effects of regular MFU treatment on skin ageing. Although MFU is generally considered a single session treatment, others have anecdotally observed better patient results with up to 3 treatment sessions at 4-6 month intervals, followed by annual maintenance sessions (personal communication, Korea). We hypothesize that regular maintenance MFU treatments may slow down skin laxity and aging and we will examine this with longitudinal data on the effect of regular MFU on skin laxity over time. Our commercial experience with Ultraformer 3 has been very favourable. There is a market gap for a non-surgical lower face and neck tightening procedure that delivers consistent results without being too uncomfortable or protracted. Patients are often very receptive to procedural recommendation for jowls and facial sagging and will be prepared to have repeat treatments and recommend the procedure to others if the procedure meets their expectation in efficacy and tolerability. From the practitioner's perspective, the Ultraformer 3 is easy to handle and drive and can be performed by doctors, nurses, dermal therapists and other trained allied health practitioners. Ultraformer 3 can be delegated to suitably trained staff because of its dependable, non-laser technology coupled with a low incidence of adverse events. The device affordability and low running cost makes it an attractive business and commercial proposition, which adds value for the patient. The limitations of this study are a relatively small sample size, a relatively short follow-up period of less than 6-months and potential investigator bias from using an industry-sponsored device (Cryomed Australia).

## CONCLUSION

MFU therapy with the Ultraformer 3 is a safe, effective high-speed, low-pain procedure that meets a clear

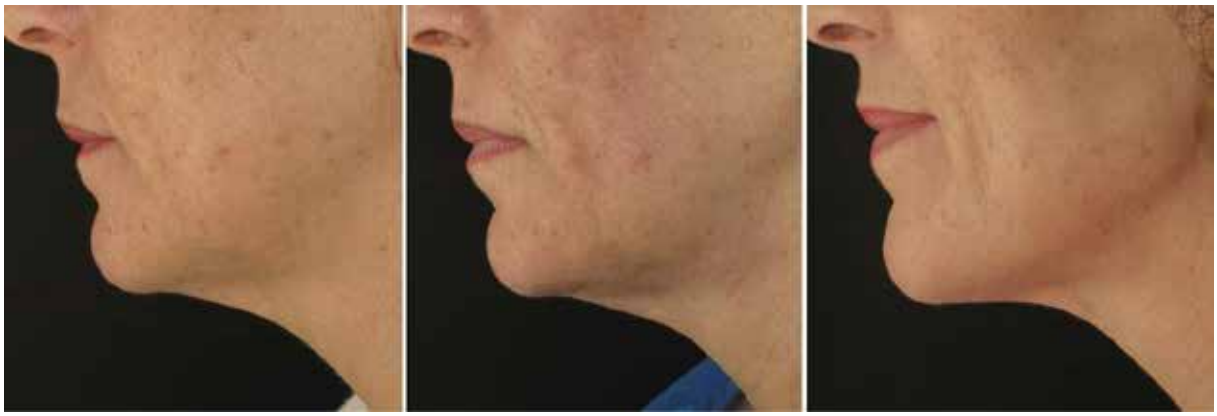

**Figure 4.** 50 year-old female at baseline, immediately post- and 1-month post-procedure (left to right) highlighting gradual neck and jawline tightening even though there was no observable change immediately post-procedure (centre image).

need amongst patients seeking skin tightening. The procedure induces noticeable skin tightening post-procedure with a 75% patient satisfaction rate that is independently and objectively verifiable. Patients tolerated the procedure well with only topical anaesthesia and chilled air cooling. The favourable procedural experience and results convert to an 85% reported desire for repeat procedures and 75% referral rate to others.

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# Face Lifting and Body Modeling without a Scalpel

Radosław Rzepnikowski

# Face Lifting and Body Modeling without a Scalpel

Radoslaw Rzepnikowski, MD | Poland

Ultraformer III is an innovative device used in the field of aesthetic medicine for facelift and body modeling and face without scalpel. Thanks to HIFU technology, the skin of the body is firmly nourished and rejuvenated. HIGH means High Intensity Focused Ultrasound is a technology that uses a focused ultrasonic wave that is responsible for heating the tissues of the skin, muscles and fat, which in turn leads to their shrinking and micro-stimulation stimulating the formation of new collagen.

The Ultraformer III machine, which allows for a non-operative lifting, is a milestone in the treatment of skin pruritis, especially in the most sensitive areas such as breast, buttocks, abdomen, thighs and shoulders . The ultrasound method is safe, noninvasive, clinically tested and above all effective. It gives spectacular results that satisfy every patient. After just one treatment the skin becomes more elastic and taut.

The non-invasive Ultraformer III machine is an incredible American equipment for skin lifting without the use of a scalpel. This is the latest aesthetic medicine solution utilizing a highly concentrated ultrasound beam to penetrate deeply into the tissues, allowing for the non-operative facelift of the body and face. One of its many advantages is the ability to perform surgery on any part of the body.

During the modeling process, a special head emitting ultrasonic waves is applied to the selected area of the patient's body that penetrates into the tissue. The heated tissues shrink, resulting in tension and increased skin tension. Skin smoothes, tightens, firms - giving spectacular effects like lifting. Ultraformer helps effectively eliminate slack, unsightly skin from places such as the abdomen, thighs, shoulders, neckline, neck.

The Ultraformer III has transducers of varying penetration depths ranging from 1.5 to 9 mm and therefore adapt to any skin type and age. Accurate power regulation makes the treatment perfectly suited to the conditions and needs of the patient.

# ULTRAFORMER III

# SMAS Face Lift with HIFU technology (High Intensity Focused Ultrasound) for the ULTRAFORMER Unit

Klaus FRITZ

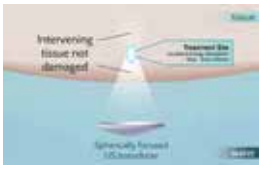
# SMAS Face Lift with HIFU Technology (High Intensity Focused Ultrasound) for the ULTRAFORMER Unit

Klaus Fritz, MD | Germany

Speech at IECTC (International Educational Course-Training for Cosmetologists)
Dermatology
President German Academy of Dermatology (DDA)
Past President ESLD (European Society of Laserdermatology)
Lecturer and Consultant at University Osnabrueck(D)
AssociatUniv.-Professor at University of Medicine and Pharmacy Carol Davila (Ro)

## BACKGROUND

As human gets older, skin and it's under structural tissues constantly get ageing process. Typically, number of fibroblast on the skin decreases and collagen synthesis also decreases and functions and numbers of many skin appendages are also dropped.
In the past, ablative laser or chemical peeling was used for face lifting. Recently, HIFU was introduced as a new treatment modality for skin tightening and rejuvenation.
HIFU (High Intensity Focused Ultrasound)
The deposition of acoustic energy can cause different bio-effects, such as transiently increasing cell and vessel permeability, tissue heating and irreversible tissue destruction.




Achieving Non-invasive lifting procedure, temperature is critical factor. Microfocused ultrasound heats tissue to >60°C, to denature collagen and cause contraction of the collagen structure without damage surrounding area.

## INTRODUCTION

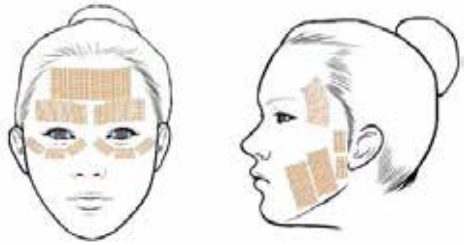
Face and scalp are composed of several layers and these can be specifically composed into five standard layers: Skin, Subcutaneous layer, Musculoaponeurotic layer (SMAS: Superficial Muscular Aponeurotic System), Loose areolar tissue (spaces and retaining ligaments), fixed periosteum and deep fascia.
For the face lifting effect, target tissue is dermis, connective tissue in fat layer and SMAS (at a depth of 4.5mm beneath the skin. The HIFU (High Intensity Focused Ultrasound) is irradiated fractionally at a depth of 3.0 or 4.5mm). The SMAS at a depth of 4.5mm is coagulated by the focused beams of light (fascia, SMAS, fibrous tissue). Skin regeneration and lifting effect by newly formed collagen and elastin.
Focused ultrasound heat up 65~70 (only focal area) and coagulate the tissue at the target lifting-4.5mm, 3.0mm and 1.5mm depth.

## METHOD

The best indications for face contouring are Forehead wrinkles, eyebrow, check, Jowl line, wrinkle lifting, skin tone improvement, V-line forming, double chin and neck wrinkle.
Focused ultrasound heat up 65~70°C (only focal area) and coagulate the tissue at the target lifting-4.5mm, 3.0mm, 2.0mm and 1.5mm depth standard treatment segments are as below. SIDE EFFECTS
The skin might appear flushed at first and the redness should disappear within a few hours factors affecting treatment response.

## CONCLUSION

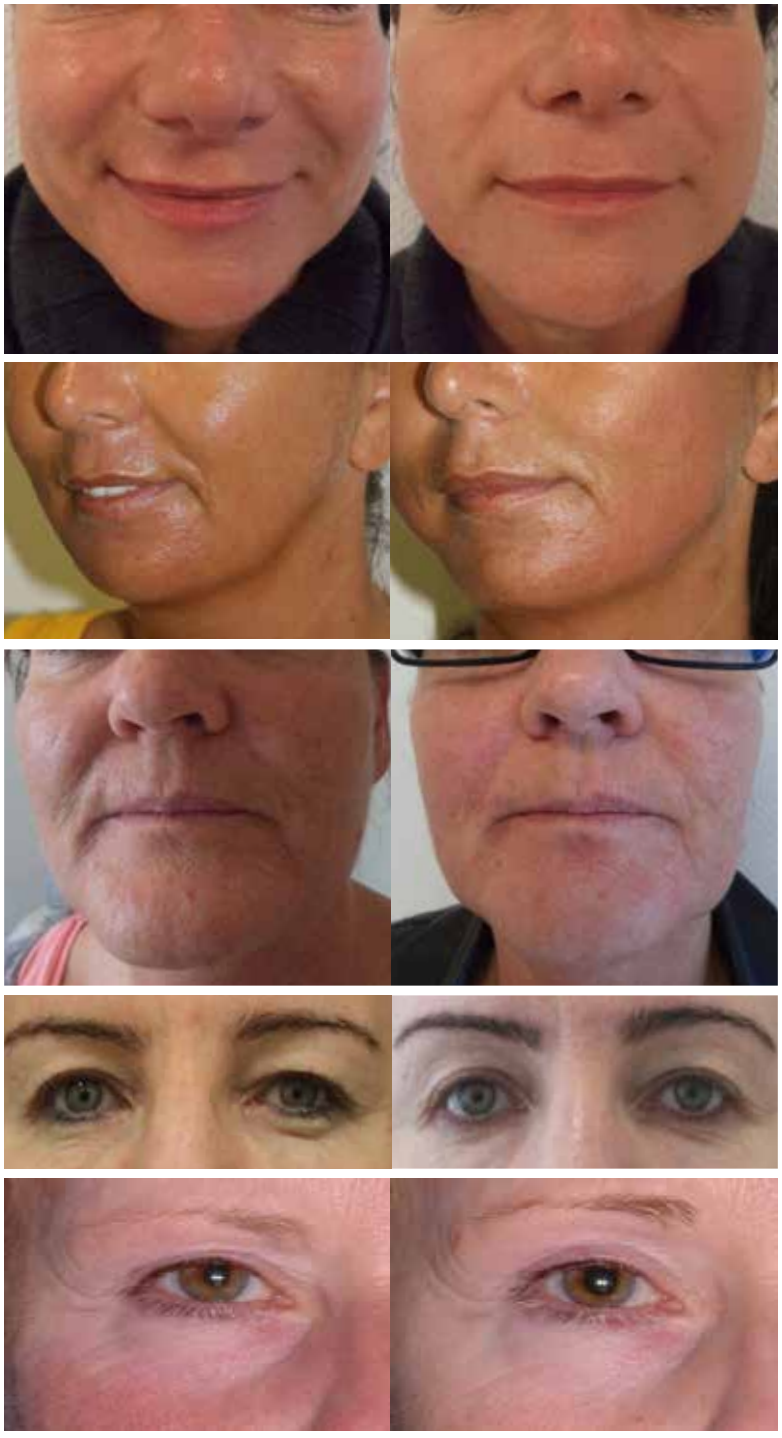
There will always be patients who are candidates for surgery but just don't want to go under the knife. HIFU treatment will not provide them drastic results like face lifting surgery. However, it is the only non-invasive procedure which reaches the same layers of skin as are addressed in a surgical facelift. There are some factors affecting HIFU treatment response; skin laxity- amount



| | Treatment Cartridge |
|---|---|
| Forehead | 1.5mm |
| Around eyes | 1.5mm |
| Cheek | 3.0mm/4.5mm |
| Lateral neck | 3.0mm/4.5mm |
| Submentum | 3.0mm/4.5mm |

of excess, loose skin on the face or neck, Volume: Degree and distribution of fat on the face, Skin quality: extent of lines, wrinkles, crepiness and sun damage. And Age and the lifestyle/health (smoker or nonsmoker, underlying heath issues) can be the factors as well.

HIFU treatment creates new collagen at multiple depths within the skin for a more multi-dimensional approach. Patients will likely need more than one treatment to get the results and will keep them coming back every 1~2 years for continued maintenance.



# The Most Exciting International Evolution in the Non-surgical Facelift

Serena Lim, MD

# The Most Exciting International Evolution in the Non-surgical Facelift

Serena Lim, MD | Australia

Hailed as the ‘next evolution’ in aesthetic science, the Ultraformer has taken the anti-ageing world by storm by performing the same procedure as cosmetic surgeons – but without cutting or disrupting the skin.

Necks, eyelids, chins, jawlines, brows and areas of the body that are wrinkling or sagging, such as armpits, stomachs, thighs, will lift under the ultrasound technology of the Ultraformer. And the bonus is that it can be performed over 30 minutes in a lunchtime break with no down-time, minimal side-effects and is almost completely painfree.

"Turkey necks, droopy eyelids, lowered brow lines, surface pores, even flabby arms and thighs: these are all areas the Ultraformer treats with immediate and ongoing results,” says Dr. Serene Lim. "Plastic surgeons in Europe are raving about this treatment due to the results in face and body contouring and tightening."

After years of research and working in the industry, Dr. Serene has long steered away from treatments in facial rejuvenation that have possible side-effects. So Ultraformer ticks all the boxes and is an affordable and less-frequent alternative to many procedures on the market.

"It is very precise, so the fat layer of the skin can be spared and fat necrosis avoided. All other modalities in facial rejuvenation treat the surface of the skin to the deep layers, so there is potential for more wrinkle formation when fat is destroyed, and pain when the nerve-rich dermis is affected. That won’t happen with the Ultraformer, and it is almost pain-free," she says.

The treatment takes about 30 minutes and is completely safe. It works through the ultrasound, which has been used in medicine for more than 70 years, contracting and shortening muscle fibres, which causes the lifting effect, stimulating collagen for a plumping youthful appearance or reducing fat for stubborn fatty deposits like under the chin.

"I am always after a natural face and one that can be achieved with minimal side-effects (some people may experience short term redness and/or tenderness). Ultraformer ticks all the boxes for me.

It’s a really exciting treatment in the facial rejuvenation area and my clients are more than happy with the results we are achieving," says Dr Serene.

The Ultraformer is the only treatment on the international market that works on the muscle fascia (SMAS) deep below the skin, which is the area surgeons tighten for face and neck lifts. Rather than using a needle or knife, the Ultraformer harnesses ultrasound technology to radiate energy to this layer to tighten and lift.


# ULTRAFORMER Achieves Effective Non-surgical Face Lifting, Tightening and Whitening

Klaus Fritz | Franco Lauro | Beom-Joon Kim

# ULTRAFORMER Achieves Effective Non-surgical Face Lifting, Tightening, and Whitening

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Seou l, Korea


Ever since its recent entrance in the aesthetic market, the Ultraformer device from Classys, Inc. globally continues to impress physicians and their patients with excellent face and neck lifting treatment outcomes. This innovative device offers cosmetic patients a variable non-invasive option to more traditional surgical lifting and tightening treatment approaches.

"In my opinion, the Ultraformer device is going to have a significant impact in the aesthetic industry," said Klaus Fritz, M.D., director of the Dermatology and Laser Centers in Landau, Germany, lecturer at the University of Osnabrueck, Germany, and former president of the European Society of Laser Dermatology. "The treatment outcomes one can achieve for face lifting and skin tightening with this device are remarkable:'

Based on mature, time-tested High Intensity Focused Ultrasound (HIFU) technology, Ultraformer effectively treats the superficial and deeper dermis, as well as the superficial muscular aponeurotic system (SMAS) with a triple layer lifting effect. Heating the targeted area to between 65 and 75°C, the highly focused acoustic energy creates thermal coagulation zones at 1.5mm, 3.0mm and 4.5mm depths, optimally penetrating the skin with geometric precision, while completely sparing the epidermis.

"HIFU affects all three layers of the superficial and mid-dermis as well as the SMAS, a method that may be more effective than one-pass protocols for skin tightening," said Beom Joon Kim, M.D., ph.D,. a professor in the department of dermatology, at the College of Medicine, Chung-Ang University, Seoul, Korea.

Certified by the Korean FDA for eyebrow lifting and CE marked, Ultraformer can also achieve excellent aesthetic outcomes in molar augmentating jowl lifting, nasolabial fold reduction and periorbital wrinkle reduction, as well as overall skin tightening and rejuvenation in targeted areas. "In my experience, the speed and simplicity of the treatment, coupled with the excellent cosmetic results one can achieve, distinguish the Ultraformer device from any other laser treatments employed for the same indications;'

Dr.Fritz stated.

Collagen is the primary protein in the dermis, along with subcutaneous fat and the SMAS. It is a family of structural proteins responsible for the strength and resilience of the skin and other tissues. HIFU energy heats the collagen fibers leading to denaturation. This in turn results in a thickening and shortening of the collagen fibers, greater tissue tension due to the rubber elastic properties of collagen, and ultimately, tissue tightening.

Soon after an Ultraformer treatment session, patients will appreciate a firmer feel to the skin, along with a smoothening of fine lines. While this immediate plumping effect is temporary, it signals the initiation of the neocollagenesis process."Following the initial effects, a wound healing response is initiated in the skin, resulting in the formation of new collagen fibers, which provides tightening of the skin in a longer term.

Photo courtesy by Dr. Franco Lauro

BeforeTx Post 2 months

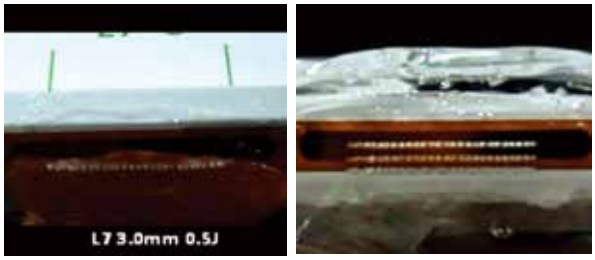
BeforeTx Post 2 months

After four weeks of treatment, patients' facial contours and fine wrinkles show significant improvement. Additional skin firming and tightening has shown over the next two to three months after treatment," Dr. Kim reported. This non-invasive procedure is associated with no downtime, allowing patients to return to daily activities immediately after the treatment, and dramatic results can be achieved as well with improvements seen in facial skin tightening and fine wrinkles up to six months after. Maintenance treatments could then be performed at three or six month intervals, depending on the degree of lifting and tightening that needs to be addressed in the individual patient at baseline.

"In my experience, the Ultraformer is the best device I have ever used for soft tissue and skin tightening;' said Franco Lauro, M.D., a plastic surgeon in private practice in Bologna, Italy. Treatments are extremely quick, with a typical face and neck tightening procedure lasting approximately 20 minutes, allowing patients to quickly return to their daily routine."

According to Dr. Lauro, there is no downtime associated with the Ultrafomer procedure and to date, he has not seen any complications from treatment underscoring the device's safety. "Using the Ultraformer, I can easily and safely treat every part of the body, and all Fitzpatrick skin types without hesitation, he added, "we can even combine treatment with other complementary aesthetic procedures in the same session."

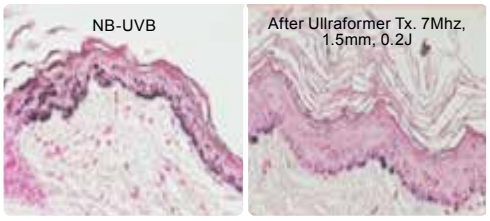
Featuring dual handpiece, the Ultraformer device offers a fluence of 0.1 to 1 J, and is equipped with three different cartridges ideal for the triple layer HIFU treatment approach, namely L7-3: 7 Mhz(3 mm), L4-4.5: 4 Mhz(4.Smm), and L?-1.5:7 Mhz(l.5 mm). Beyond its benefits in skin tightening, as well as face and neck lifting, the Ultraformer device has also shown its effectiveness in lightening skin, further demonstrating its versatility in cosmetic treatments. Dr. Kim, who is also a professor at the R&D Center of the Chung-Ang University Hospital-appointed by The Ministry of Education of the Republic of Korea for the Vrain Korea 21 Plus project team in the arena of dermatological science (2013-2020) - has explored the Ultraformer's effectiveness for this indication.



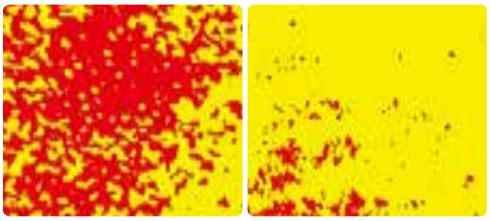

[ MeatTest ] [ Plastic Test ]

"I have performed NB-UVB examinations for the treatment of pigmentation in brown guinea pigs. From our research, my team and I have observed significant changes in skin pigmentation and can confirm the Ultraformer's efficacy in lightening the skin of animal models. We emitted both 0.1 J and 0.2J of the device's L7-1.5 settings in the study. Using these parameters, the lightening effect was observed three weeks following a protocol of four treatments per week for a month period." Dr. Kim® reported.

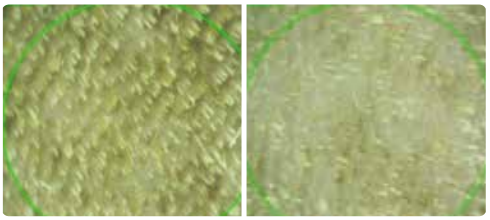
Numbers of melanin have been reduced after Ultraformer treatmeant by 7Mhz 1.5mm depth at 0.2J. The results were observed by Fontana Masson Stain, Image Pro Analysis and Folliscope as following pricture of [1 ] [2] [3].




[1] Fontana Masson Stain



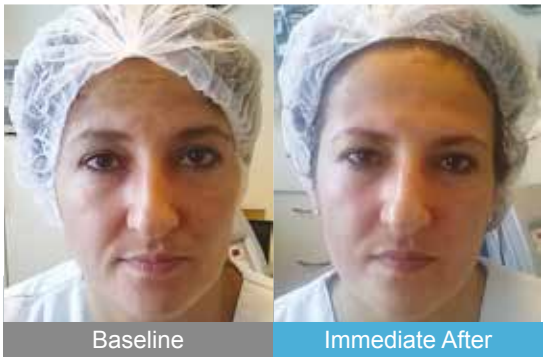
[2] Image Pro Analysis

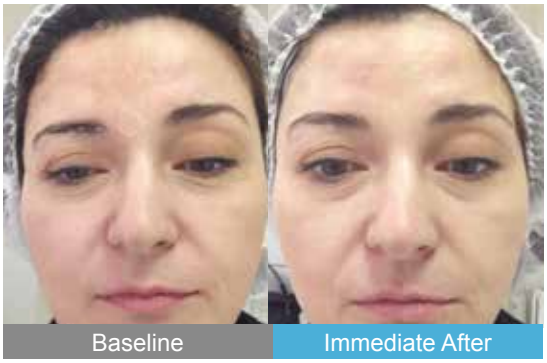


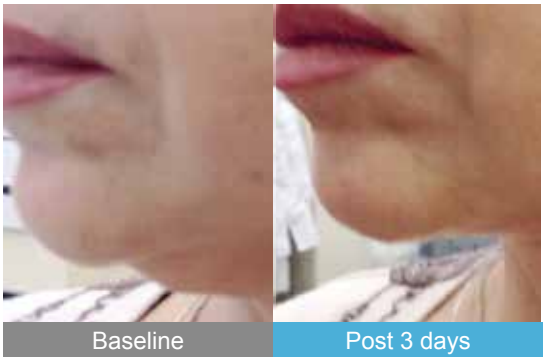
[3] Folliscope

® Dr. Beam June Kim, professor at R&D Center ofthe Chung-Ang University Appointed by The Ministry of Education ofthe Republic of Korea for the Brain Korea 21 Plus project team 1n the arena ofdermatology science (2013-2020)

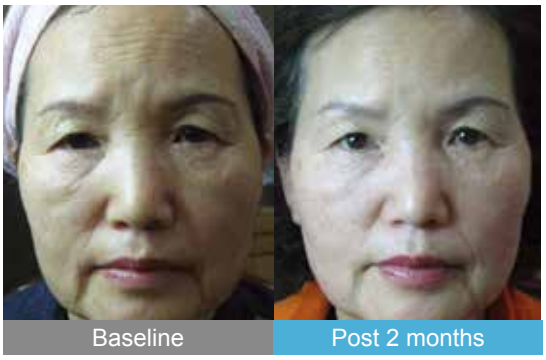
## Face & Neck lifting immediate and post few days

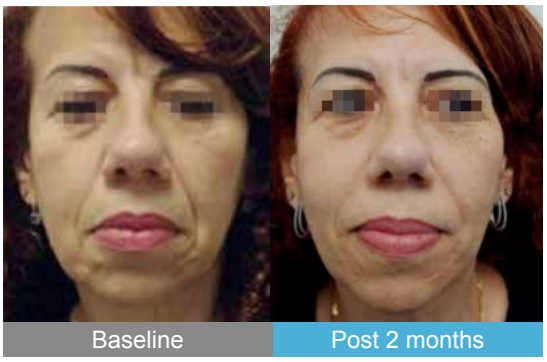



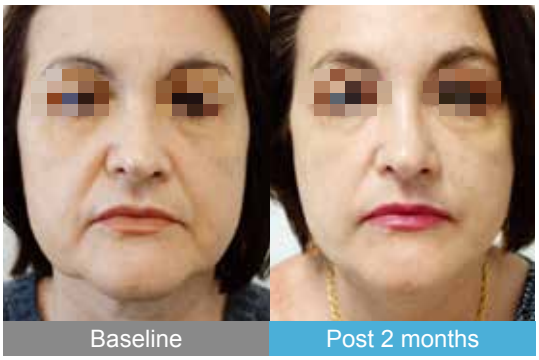



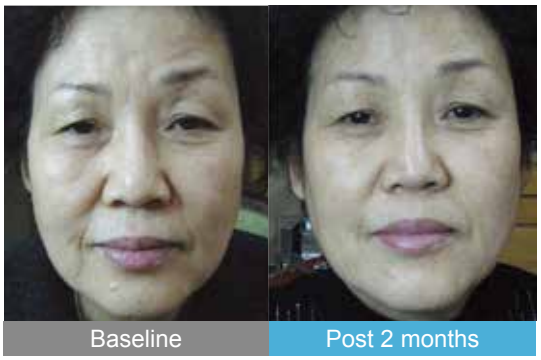



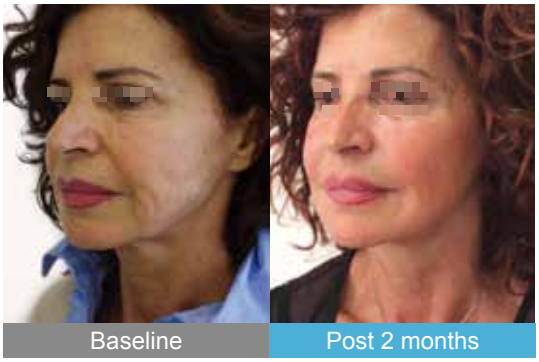

## Results post 2 month

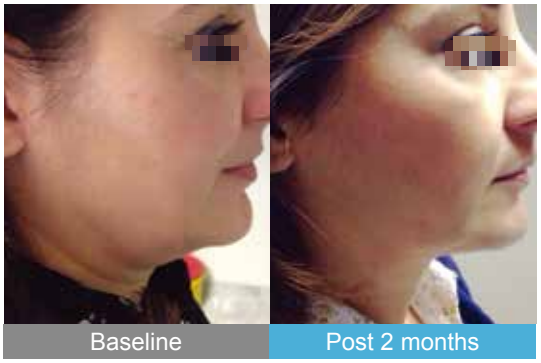



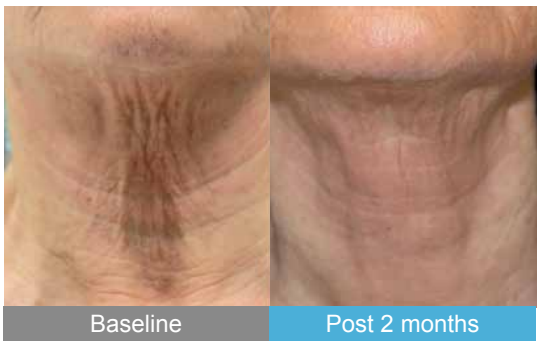



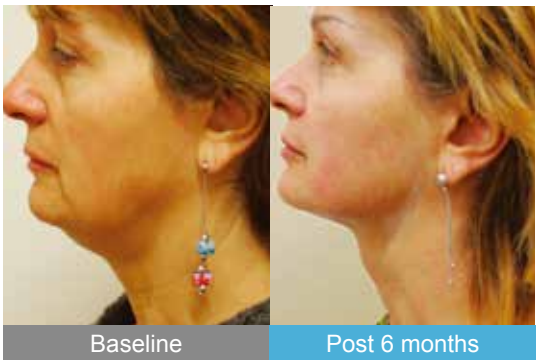








**Results post 6 month and 12 month**




# Evaluation of Micro Focused Ultrasound for Lifting and Tightening the Face

In Ho Lee | Seung Min Nam | Eun Soo Park | Yong Bae Kim

ORIGINAL ARTICLE http://dx.doi.org/10.14730/aaps.2015.21.2.65
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# Evaluation of Micro-focused Ultrasound for Lifting and Tightening the Face

In Ho Lee et al. | South Korea

Background Micro-focused ultrasound (MFU) has developed as an effective, noninvasive, skin-tightening method. However, certain factors have limited its replacement of invasive surgical procedures, including a relative lack of efficacy, persistence, and reliability. The purpose of this study was to evaluate the efficacy and safety of MFU for noninvasive skin tightening and to determine how long the skin tightening can be maintained.

Methods Between October 2013 and November 2014, 41 patients with sagging and laxity of the facial skin were treated with MFU. The treatment was performed following the manufacturer's recommended protocol that called for 300 treatment lines. We evaluated the patients using an automatic skin diagnosis system at pretreatment, and 2 and 4 months after treatment.

Results Of the 41 patients treated using MFU, 3 patients were lost to follow-up for nonstudy-related reasons. In our study, 38 patients (1 male and 37 female) were evaluated and ranged in age from 37 to 52 years. The median skin grade scores were 5 at pretreatment, 3 at 2 months posttreatment and 3 at 4 months posttreatment. After comparing pretreatment and 2 months posttreatment, pretreatment and 4 months posttreatment, and both 2 and 4 months posttreatment, there were statistically significant differences (P<0.01).

Conclusions This study suggests that the aging face, with wrinkling and sagging, can be improved using MFU, while minimizing injury to the epidermis and dermis.

Keywords Micro-focused Ultrasound, Aging face, Lifting

## INTRODUCTION

The signs of aged facial skin are not only fine lines and surface irregularities, but also sagging and wrinkling [1]. Noninvasive skin tightening is superior to invasive or surgical skin tightening in terms of rapid return to work, short recovery time, and low risk of adverse events. Because of these advantages, patients who desire a skin-tightening procedure prefer noninvasive skin tightening to invasive or surgical skin tightening [1,2].

To meet the demand of patients for noninvasive skin tightening, numerous devices have been developed. Laser and radiofrequency devices have been developed to resolve skin wrinkling and sagging [1-8]. Recently, micro-focused ultrasound (MFU) was developed as an effective noninvasive skin-tightening method. MFU is able to heat tissue greater than 60°C and produce a small thermal coagulation zone (<1 mm3) to reach the mid- to deep reticular layers of the dermis and subdermis while minimizing overlying papillary dermal and epidermal injury [9-11]. The delivery of MFU to a targeted zone in the superficial musculoaponerotic system (SMAS) provokes immediate contracture of denatured collagen and the initiation of neocollagenesis and collagen remodeling [10,12]. This action of MFU provokes noninvasive skin tightening and lifting of sagging facial skin. Certain factors have limited its replacement of invasive surgical procedures, including a relative lack of efficacy, persistence, and reliability. The purpose of this study was to evaluate the efficacy and safety of MFU for noninvasive skin tightening and to determine how long the skin tightening can be maintained.

## METHODS

Between October 2013 and November 2014, 41 patients with sagging and laxity of the facial skin were treated

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with MFU using 4-MHz, 4.5 mm and 7-MHz, 3.0 mm depth transducers (Ultraformer®, Classys Inc., Seoul, Korea). Treatment was performed following the manufacturer's recommended protocol that called for 300 treatment lines. Patients with active systemic or local infections, local skin diseases that might alter wound healing, history of psychiatric illness, and soft tissue augmentation material were excluded from this study.

**Pretreatment preparation**

Five percent lidocaine, as a topical anesthetic ointment (EMLA, AstraZeneca, Sdertlje, Sweden), was applied to the face for 45 minutes before the procedure. The ointment was washed off with mild soap and water immediately before the procedure.

**Ultrasound exposure protocol**

The ultrasound gel was applied to the skin. The transducer was placed firmly on the targeted skin surface and pressed uniformly for compling to the skin. Treatment exposure was initiated (4-MHz, 4.5 mm depth transducers; 0.9 J/mm$^2$ and 7-MHz, 3.0 mm depth transducers; 0.8 J/mm$^2$), with a line of individual ultrasound pulses being delivered within approximately 2 seconds. Then, the transducer slid to the next location and was repositioned 3 to 5 mm laterally such that it was adjacent and parallel to the previous treatment line. Complete treatment of the face required 15 to 20 minutes.

**Posttreatment care**

The ultrasound gel was washed off. Patients experienced mild redness and swelling that could persist for several days. Patients were instructed to visit our hospital promptly if they encountered any other adverse effects.

**Table 1.** Patients Characteristics

| Characteristic | Value |
|---|---|
| Sex (Female, Male) | 37, 1 |
| Mean Age (range) | 46 (37-52) |

**Outcome evaluation**

We evaluated the patients using an automatic skin diagnosis system(A-One Lite®, BOMTECH Electronics Co., Seoul, Korea) at pretreatment, and 2 and 4 months after treatment. The automatic skin diagnosis system evaluated skin laxity using a scanner. The sagging and laxity of the skin were graded from 1 to 6 using the system. A high skin grade score means that the sagging and laxity of the skin are severe. The clinician examined the skin for evidence of edema, erythema, hypopigmentation, and hyperpigmentation after treatment.

**Statistical analysis**

Statistical analyses were performed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). The Friedman test was used to compare the grade scores of patients at pretreatment, and 2 and 4 months after treatment. A P value less than 0.05 was considered statistically significant.

## RESULTS

All patients were treated using MFU and three patients were lost to follow-up for non-study related reasons. In our study, 38 patients (1 male and 37 female) were evaluated and ranged in age from 37 to 52 years (Table 1).

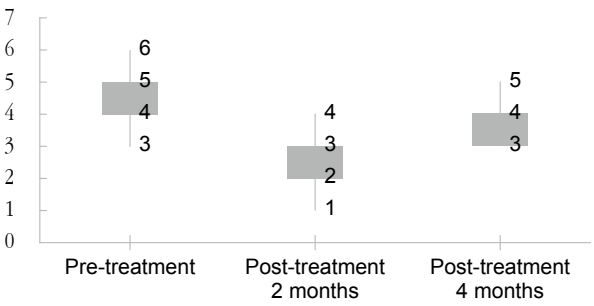


**Fig. 1**. Comparisons of skin grade scores at pretreatment and 2 months posttreatment, pretreatment and 4 months posttreatment 4 months, and 2 and 4 months posttreatment.

**Table 2.** The skin grade score

| Time | Pre-treatment (Median) | Post-treatment 2 months (Median) | Post-treatment 4 months (Median) | P-value*,†,‡ |
|---|---|---|---|---|
| Skin grade score | 5*,‡ (4-5) | 3*,† (2-3) | 3†,‡ (3-4) | < 0.01 |

*,†,‡P-value by Wilcoxon signed rank test.

Thirty-five patients immediately presented with slight erythema and edema after treatment, and three patients immediately presented with moderate erythema and edema after treatment. In all affected patients, both erythema and edema completely resolved by 2 days after treatment. Two patients presented with red linear striations of the checkafter treatment with the 3 mm transducer. They were treated using focal cooling without sequelae such as pigmentation and textural abnormalities. Hypopigmentation, hyperpigmentation, ulceration, and erosion were not present in any patients. There were no adverse events, such as nerve or muscle dysfunction, severe pain, bruising, and bleeding. The median skin grade scores were 5 (4-5) at pretreatment, 3 (2-3) at 2 months posttreatment, and 3 (3-4) at 4 months posttreatment (Fig. 1 and Table 2). After comparing pretreatment and 2 months posttreatment, pretreatment and 4 months posttreatment, and both 2

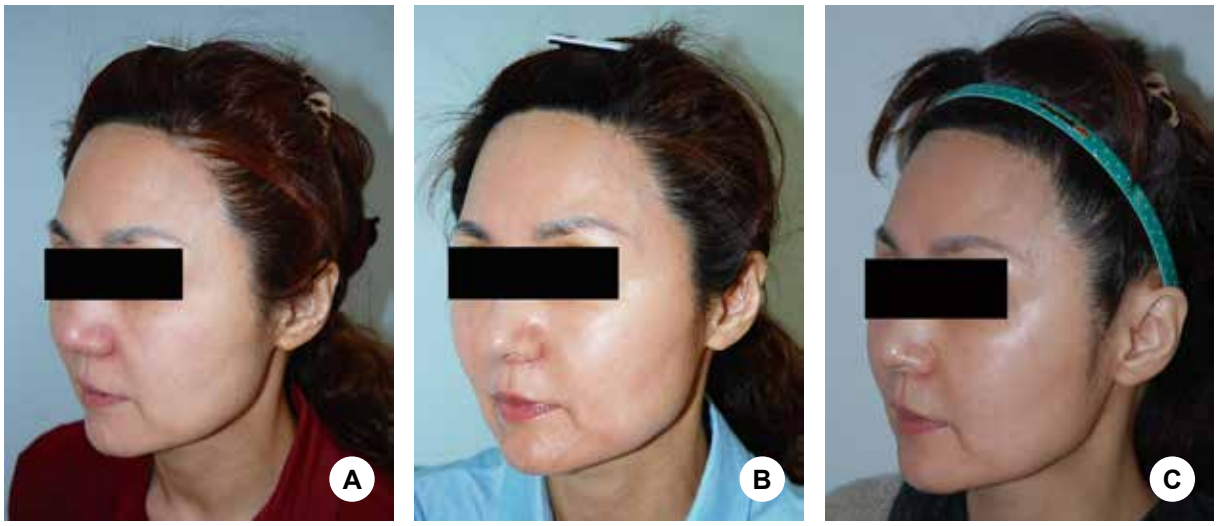


**Fig. 2.** A 46-year-old female patient with moderate skin sagging and wrinkling. At pretreatment, she was examined by the automatic skin diagnosis system and was given a skin grade score of 5 (A). At 2 months posttreatment, the skin grade score was 2 (B). At 4 months posttreatment, the skin grade score was 4 (C).


**Fig. 3.** A 38-year-old female patient with moderate skin sagging and wrinkling. At pretreatment, she was examined by the automatic skin diagnosis system and was given a skin grade score of 4 (A). At 2 months posttreatment, the skin grade score was 2 (B). At 4 months posttreatment, the skin grade score was 3 (C).

and 4 months posttreatment, there was a statistically significant difference in skin grade score (P<0.01) (Fig. 2 and 3).

## DISCUSSION

The SMAS consists of viscous, elastic fibers and extracellular matrix [10,13,14]. It is associated with specific facial muscles, such as the platysma, orbicularis oculi, and levator labii superioris. Collagen within SMAS decreases 6% every decade [10]. This decrease in collagen contributes to a prominent nasolabial fold, and hooding of the brow and jowl [10,15,16]. To minimize posttreatment adverse events, clinicians have developed various nonablative skin-tightening procedures to induce collagen shrinkage and remodeling [3,6,17]. Furthermore, ultrasound is able to penetrate into the subdermis layer and SMAS, and induce thermal coagulation to avoid undesired posttreatment adverse events compared with carbon-dioxide laser resurfacing [17-19].

Ultrasound energy has characteristics that are suitable for skin lifting and tightening. First, it is believed that ultrasound energy can be transmitted into the deeper subcutaneous layer of the face or even the SMAS, and is the most effective method for skin lifting and tightening [13,14,20-23]. Second, both the epidermis and dermis can be protected from ultrasound energy during its transmission, reducing the risk of advertent cutaneous layers [1].

Ultrasound used in medicine is classified into two types. One is high-intensity focused ultrasound (HIFU) and the other is MFU. HIFU uses high energy and is mainly used for nonsurgical ablation of tumors. HIFU can also be used to ablate adipose tissue for body contouring [10]. MFU uses much lower energy to treat the superficial layer of the skin [9] and is able to elevate the local temperature higher than 60°C to cause collagen contracture [24]. When energy is targeted to discrete areas within dermal and subdermal tissues, MFU induces discrete thermal coagulation zones while sparing adjacent nontarget tissues [9,11,12,25]. In addition, the heat induces the denaturation and contraction of collagen fibers in the subcutaneous fat layer [26].

According to the results of our study, skin tightening at 2 and 4 months posttreatment was improved compared to pretreatment. However, skin tightening at 2 months posttreatment was better than at 4 months posttreatment, suggesting the efficacy of MFU gradually decreases treatment. Based on our results, we recommend that retreatment should be performed after 3 months for greater efficacy.

Our study had limitations. First, our study did not include patients who had severe skin sagging and wrinkling. We recommended the surgical face-lift procedure for these patients. Second, the posttreatment results were evaluated with an automatic skin diagnosis system, but the reliability of the system has not been established. Therefore, discrepancies may occur between the automatic skin diagnosis system and realistic skin conditions. Third, our study did not include any histologic evaluations. Fourth, the MFU device that we used in our study is not capable of clearly imaging the targeted facial anatomy. We cannot ensure proper acoustic coupling between the transducer and skin before the application of MFU energy. Despite these limitations, the results were evaluated objectively.

## CONCLUSION

This study suggests that the aging face, with wrinkling and sagging, can be improved using MFU, while minimizing injury to the epidermis and dermis. In addition, retreatment is recommended after 3 months to maintain the efficacy of the results.

## PATIENT CONSENT

Patients provided written consent for the use of their images.

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# Tightening Effects of High Intensity Focused Ultrasound on Body Skin and Subdermal Tissue: A Pilot Study

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DOI: 10.1111/jdv.13713 JEADV

# Tightening Effects of High Intensity Focused Ultrasound on Body Skin and Subdermal Tissue: A Pilot Study

S.Y. Choi et al. | South Korea

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## ABSTRACT

Background High Intensity Focused Ultrasound (HIFU) has been introduced as a new treatment modality for skin tightening through application mainly to the face and neck.

Objectives This pilot study assessed the efficacy and safety of HIFU for body tightening in Asian females.

Methods Six Asian female adults were enrolled in this pilot study. All subjects were treated with HIFU to the both cheek, upper arm, lower abdomen, thigh and calf using the following probes: 7 MHz, 1.5 mm focal depth; 2 MHz, 3.0 mm focal depth; 2 MHz, 4.5 mm focal depth; 2 MHz, 6.0 mm focal depth and 2 MHz, 9.0 mm focal depth. Three blinded independent dermatologists assessed results using the Investigator Global Aesthetic Improvement Scale (GAIS) using paired pre- and post-treatment (week 4) standardized photographs. Also, we evaluated skin elasticity at all treated sites using a cutometer. Participants used the subject GAIS to assess their clinical improvement after treatment and rated their pain using a visual analogue scale (VAS) immediately, 1 and 4 weeks after treatment.

Results The three blinded evaluators judged all treated sites as showing clinical improvement 4 weeks after treatment. Skin elasticity measured via cutometer was significantly improved 4 weeks after treatment at all treated sites ($P < 0.05$). All patients scored themselves subjectively as more than 'improved' on the GAIS. Immediately after treatment the mean VAS score was 5.17  2.48, but no pain was reported at weeks 1 and 4. No permanent adverse effects were observed during the follow-up period.

Conclusion For body tightening, we applied HIFU using transducers with a lower frequency and deep focal depth to effectively deliver ultrasound energy to skin tissues. HIFU appears to be a safe and effective treatment modality for dermal and subdermal tightening.

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## CONFLICTS OF INTEREST

None declared.

## FUNDING SOURCES

None declared.

## INTRODUCTION

As skin tissue ages, its elasticity decreases and redundant facial, neck and body laxity are commonly seen. Various treatment modalities including surgical, laser and radiofrequency approaches have been used to improve skin laxity. Surgical lifting procedures for skin laxity are effective, but can leave visible surgical scars and are associated with risk and lengthy recovery times. Recently, patients seeking skin tightening are requesting safe and effective non-invasive alternatives associated with low risks and minimal downtime.

High Intensity Focused Ultrasound (HIFU) has been investigated as a tool for the treatment of solid benign and malignant tumours for the past several decades.[1] HIFU can produce small, micro-thermal lesions at precise depths in the dermis up to the fibromuscular layer, causing thermally induced contraction of collagen and tissue coagulation with subsequent collagenesis, while sparing the epidermis.[2–4] Recently, HIFU has been introduced as a new treatment modality for skin tightening and rejuvenation, primarily for the face and neck.[5] This pilot study was performed to assess the efficacy and safety of HIFU treatment for skin tightening treatment of body skin laxity in Asian females.

## PATIENTS AND METHODS

### Patients

This pilot study was approved by the Institutional Review Board of Chung-Ang University Hospital and followed the guidelines of the 1975 Declaration of Helsinki.

Based on the suggestion of a statistical committee, we referred to a previous study[6] to determine the number of subjects required for the current study. Six female adults were enrolled in the study.

**HIFU device**

The HIFU device used in this study was the ULTRAFORMER III, SHURINK (CLASSYS INC., Seoul, Korea). In this study, we used five different types of transducers. One of the transducers was a basic transducer for facial skin tightening (T1: 7 MHz, 1.5 mm focal depth). Four other transducers utilizing a lower frequency and deeper focal depths were newly developed for body skin tightening (T2: 2 MHz, 3.0 mm focal depth, T3:2 MHz, 4.5 mm focal depth, T4: 2 MHz, 6.0 mm focal depth and T5: 2 MHz, 9.0 mm focal depth). Each transducer delivered a series of ultrasound pulses along 25-mm long exposure lines. The pulse duration for each individual exposure ranged from 25 to 40 milliseconds.

**Treatment procedures**

Before treatment, we checked the patients, the thickness of skin components and all patients underwent treatment in five different areas including the both cheek, upper arm, lower abdomen, thigh and calf after topical anaesthetic cream. The sizes of the treated areas were 5.0 x 5.0 $cm^2$ on each cheek and 7.5 x 7.5 $cm^2$ on the lower abdomen as well as each upper arm, thigh and calf (Fig. 1).

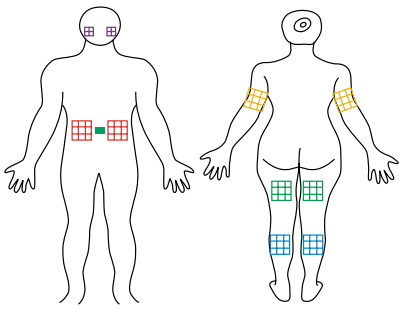

**Figure 1** Face and body treatment areas.

Ultrasound gel was applied to the treated skin and the transducer was pressed perpendicularly, uniformly and firmly to the skin surface. Treatment exposure was initiated with a line of individual ultrasound pulses being delivered over approximately 2s. Next, the probe was moved approximately 3 to 5 mm laterally so as to be parallel and adjacent to the line previously treated and the ultrasonic exposure was repeated.

Each side of the face was treated with three types of transducers (T1, T2 and T3), distributing a total of 552.5 J. Each side of the body was treated with five types of transducers (T1, T2, T3, T4 and T5), distributing a total of 817.2 J. We operated the powers with 1.0–1.5 J at each transducer. When patient feel pain, we reduced 0.1–0.3 J per time, but not increased up to 1.5 J. Complete HIFU treatment of the face and body occurred over 50–60 min. We prefer to use the shallow depth tips to deep depth tips. Because patient's pains are usually proportional to depth of tips.

**Efficacy and pain evaluation**

We evaluated the skin tightening effect of HIFU using photography and a cutometer. The investigator gathered digital photographs using identical cameras and camera settings (Canon EOS 600D, high-resolution setting, 5760 x 3840 pixels, Canon Inc., Tokyo, Japan) before and 4 weeks after the treatment. Three blinded independent dermatologists evaluated paired before and after photographs in a randomized fashion using the Investigator Global Aesthetic Improvement Scale (IGAIS). Subjects assessed the tightening effects using the Subject Global Aesthetic Improvement Scale (SGAIS) 4 weeks after treatment.

The Cutometer (Courage+Khazaka Electronic GmbH, Cologne, Germany) was used to measure skin elasticity. Among the cutometer-specific R values (R0–R9), we used the R7 value, which is defined as the ratio of elastic recovery to the total deformation and represents the biological elasticity. Pain was evaluated by visual analogue scale (VAS) immediately after week 0 and on weeks 1 and 4 after the application of HIFU. VAS is a simple and reproducible tool for the assessment of pain severity which consisted of 11 levels (0–10 points).

**Statistical analysis**

Statistical analyses were performed using SPSS version 18.0 for Windows (SPSS Inc., Chicago, IL). We used Hochberg step-up methods to adjust the values for multiple comparisons. Statistical comparisons between

before and after treatments were performed using paired t tests. Data are presented as means  standard deviation. Ps < 0.05 were considered statistically significant.

## RESULTS

Six Asian female subjects (Fitzpatrick skin types III–V) with skin laxity were enrolled in this study. Their ages ranged from 43 to 54 years (mean ± SD: 48.17 ± 4.45 years) and showed similar skin depth. All subjects completed the HIFU treatments and follow-up for 4 weeks. The mean value of skin elasticity measured by cutometer was significantly increased at 4 weeks after treatment compared to baseline in all treated sites on the face and body (Fig. 2). The change in the mean value of skin elasticity measured by cutometer was greatest in the lower abdomen (Fig. 3). Three blinded independent dermatologists judged all patients as showing clinical improvement 4 weeks after treatment. In terms of cheek outcomes, 5 (83.3%) of 6 subjects were assessed as improved (IGAIS score 1), and 1 (16.7%) of 6 subjects as much improved (IGAIS score 2).

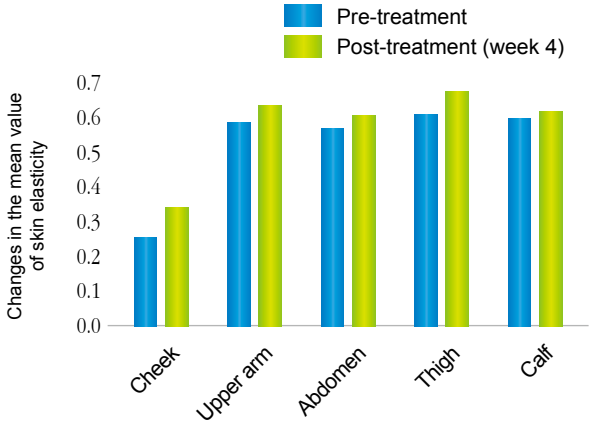


**Figure 2** Changes in the mean value of skin elasticity measured via cutometer (R7, mean  SD).

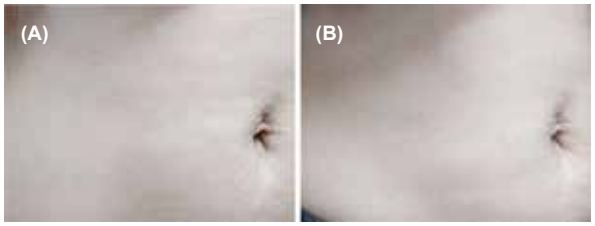


**Figure 3** The change in the skin elasticity in the lower abdomen (a) 0 week and (b) after 4 weeks.

In terms of body outcomes, including the upper arm, lower abdomen, thigh and calf, 6 (100%) of 6 subjects were assessed as improved (IGAIS score 1).

All subjects scored the SGAIS as more than score 1 in all treated sites. The mean SGIAS score in the calf was the highest. In the calf, 2 (33.3%) of 6 subjects were assessed as improved (SGAIS score 1), 2 (33.3%) of 6 subjects as much improved (SGAIS score 2) and 2 of (33.3%) 6 subjects as very much improved (SGAIS score 3).

We evaluated pain using the VAS immediately after treatment (week 0) and at weeks 1 and 4. Immediately after treatment, the mean VAS score was 5.17 ± 2.48 (range: 3–8). Three (50%) of six subjects rated their pain as mild, and 3 of (50%) 6 subjects rated their pain as moderate. One and 4 weeks after treatment, all subjects reported a VAS score of 0 (no pain).

One subject experienced edema on the right upper arm and one subject had muscle pain on the right calf after HIFU treatment. Both edema and muscle pain were mild and transient, and resolved within 1 week without any treatment. There were no serious or delayed adverse effects during the follow-up period.

## DISCUSSION

Recently, minimally invasive or non-invasive procedures have been gradually replacing surgical intervention in cosmetic dermatology. For the treatment of skin laxity, non-invasive, nonablative thermal therapeutic devices can immediately denature collagen fibres and contract collagen fibres in the dermis and subcutaneous tissues and induce delayed neocollagenesis and elastogenesis.[7,8] Radiofrequency, infrared light sources and HIFU have shown clinical effects for skin tightening and rejuvenation on the face and neck. However, there have been fewer clinical trials or reports of skin and subdermal tightening effects of non-ablative thermal devices in sites on the body, compared to the face and neck.

In this pilot study, we sought to assess the efficacy and safety of HIFU treatments using transducers that were newly developed to be suitable for use on the body skin and subdermal tissue for the purpose of skin tightening in body laxity in Asian people. A previous clinical report on the effects of HIFU on tightening of

the periorbitum and body sites, which enrolled a total of 82 patients including 8 Asians, has been published. However, this previous clinical study used conventional HIFU transducers (10 MHz, 1.5 mm focal depth; 7 MHz, 3.0 mm focal depth and 4 MHz, 4.5 mm focal depth). We applied newly developed transducers to body sites with a lower frequency (2 MHz) and deeper focal depths (3.0–9.0 mm) compared with conventional transducers. Therefore, we expected that newly developed transducers could effectively deliver HIFU energy deeper into the skin and subdermal tissues of the body and show tightening effects and safety. Of course, it may effect to subcutaneous areas with 9.0 mm transducer. But it can reduce subcutaneous fats and lead to skin rejuvenation. Also, other reports said that if practitioner consider skin depths and regulate transducers well, 1.1–1.6 mm transducers are safe to use.[9]

Although we applied topical anaesthetic cream on treated sites, most subjects complained of a mild to moderate degree of pain during treatment in proportion to depth or power of transducers. Their pain subsided without the use of analgesics, but the injection of small amounts of local anaesthesia into the subcutaneous tissue should be considered for pain reduction.

In conclusion, HIFU treatment using transducers with a lower frequency and greater focal depth could be an effective and safe treatment modality for skin and subdermal tightening of the body. The limitations of this pilot study were the small number of subjects and the short-term follow-up period. Based on the results of this pilot study, well-designed controlled clinical studies with greater subject enrolment and long-term follow-up will be necessary to establish optimal treatment parameters.

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