

**CLASSYS ULTRAFORMER**  
**The True Efficacy and Value**

**ULTRAFORMER CLINICAL CASE BOOK**



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# ULTRAFORMER- Lifting & Tightening

By Sharmila Nayak | India

## Efficacy of High Intensity Focused Ultrasound (HIFU) for lifting & tightening lax facial & Neck skin

### 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<sup>1,2,3,4</sup>. Recently, High Intensity Focused Ultrasound (HIFU) was used as novel treatment for therapeutic and cosmetic purposes<sup>5,6</sup>. 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<sup>7,9,10</sup>. 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<sup>10</sup>.

In proposed study, efficacy evaluation of 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 month 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

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the focal lengths and it delivers a short 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 given in three passes (Horizontally, Vertically and diagonally) to form a grid pattern which will give a proper lifting and will minimize the skipped area. The whole face was treated with three different focal depths depending on areas where shots were given (4.5 mm, 4 MHz; 3 mm, 7 MHz and 1.5 mm, 7 MHz). On 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  $\geq 1.0$ mm. For the upper face, a lift measurement was considered improved if the eyebrow was raised  $\geq 0.5$ mm.

## 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  $500 \pm 50$ .

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## 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%). substantial improvement after 90 days post treatment can be seen in frontal & lateral views of the treated subjects in Fig-1 & 2 respectively.



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

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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

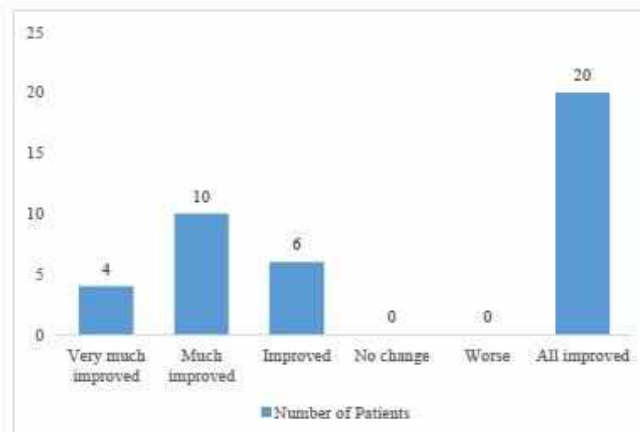


Fig-3- Physician aesthetic improvement scale score (PGAIS)

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**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)
<b>Patient Satisfaction</b>	
Very Satisfied	15 (75%)
Satisfied	2 (10%)
Dissatisfied	3 (15%)
Very Dissatisfied	0 (0%)
Very Satisfied +Happy	17 (85%)
<b>Improvement Noticed</b>	
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%)
<b>Would Continue &amp; recommend treatment</b>	
Yes	17 (85%)
No	3 (15%)

**Table-2- Patient satisfaction Questionnaires**

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## Conclusion

In present study facial lifting with Ultraformer-III in 20 patients older than 25 years of age was performed. Clinical improvement, Physician & Patients satisfaction after the 3 months treatment was observed. Based on these observed results, it is concluded that HIFU can be a safe, effective, and noninvasive option for facial lifting and improvement of wrinkles. HIFU demonstrated appreciable lifting and tightening of facial and neck tissue resulting in improved GAIS scores and a high degree of patient satisfaction.

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# ULTRAFORMER- Tightening Face & Neck

By Adrian Lim, MD | Australia

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## High-speed low-pain micro-focused ultrasound tightening of the lower face and neck

### 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).<sup>1-4</sup> 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.<sup>5</sup> 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.<sup>6-8</sup> 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 MIFU (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

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By Adrian Lim, MD | Australia

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 6 months 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.

	Strongly disagree (-2)	Disagree (-1)	Uncertain (0)	Agree (1)	Strongly agree (2)	Weighted mean (-2 to 2)	Median score
<b>Q1. I am satisfied with the outcome of the procedure</b>							
	0 respondent	1 respondent	4 respondents	7 respondents	8 respondents	1.1	Strongly agree
<b>Q2. I would consider having the procedure again in the future</b>							
	0 respondent	0 respondent	3 respondents	7 respondents	10 respondents	1.35	Strongly agree
<b>Q3. I would recommend this procedure to a friend</b>							
	0 respondent	0 respondent	5 respondents	6 respondents	9 respondents	1.2	Strongly agree
<b>Q4. I find the comfort level of the procedure to be:</b>							
	'very uncomfortable'	'uncomfortable but bearable'	'slightly uncomfortable'	'comfortable'	'very comfortable'	-0.15	Slightly uncomfortable but bearable
	1 respondent	7 respondents	7 respondents	4 respondents	1 respondent		
<b>Q5. I find the duration of treatment:</b>							
	'much longer than expected'	'longer than expected'	'about right'	'shorter than expected'	'much shorter than expected'	0.3	About right
	0 respondent	1 respondent	14 respondents	3 respondents	2 respondents		

Table 1. Ultraformer patient satisfaction survey.

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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.



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).

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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 ('latest') picture. D1, D2 mean = 71.4%

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

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

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notable post-treatment effects: one patient had transient 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.<sup>5,6,9,10</sup> 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 MIFU.<sup>6</sup> 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-MIFU 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.<sup>3</sup> Patient satisfaction rate for skin tightening procedures range from 31% for monopolar radiofrequency to 80% for MFU.<sup>8,11</sup> 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.<sup>4</sup>

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.<sup>4</sup> 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.

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By Adrian Lim, MD | Australia

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 a later time-point (figure 4), consistent with delayed collagen remodeling 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.



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).

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 need amongst patients seeking skin tightening. The procedure induces noticeable skin tightening post-procedure with a 75% patient satisfaction rate that is

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By Adrian Lim, MD | Australia

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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# ULTRAFORMER- Skin Tightening

By Radosław Rzepnikowski, MD | Poland

## Face lifting and body modeling without a scalpel

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.

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By Radosław Rzepnikowski, MD | Poland

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- SMAS Face Lift

By Klaus FRITZ, MD | Germany

Speech at IECTC (International Educational Course-Training for Cosmetologists)

## SMAS face lift with HIFU technology (high intensity focused ultrasound) for the Ultraformer unit

Dr. Klaus FRITZ, Prof.

Dermatology

President German Academy of Dermatology (DDA)

Past President ESLD (European Society of Laserdermatology)

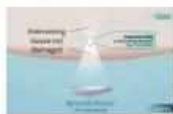
Lecturer and Consultant at University Osnabrueck(D)

AssociatUniv.-Professor at University of Medicine and Pharmacy Carol Davila (Ro)

### Background

As human gets older, skin and its 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  $>60^{\circ}\text{C}$ , 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 MusculoAponeurotic 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) ad coagulate the tissue at the target lifting- 4.5mm, 3.0mm and 1.5mm depth

# ULTRAFORMER- SMAS Face Lift

By Klaus FRITZ, MD | Germany

## Method

The best indications for face contouring are Forehead wrinkles, eyebrow, cheek, Jowl line, Winkle lifting, skin tone improvement, V-line forming, Double chin and neck wrinkle.

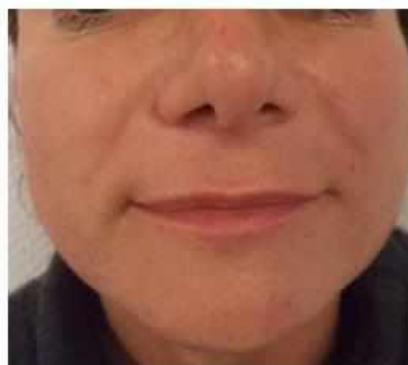
Focused ultrasound heat up 65~70°C (only focal area) and coagulate the tissue at the target lifting-4.5mm, 3.0mm, 2.0mm and 1.5mm depth

Standard treatment segments are as below.



	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

## The results



# ULTRAFORMER- SMAS Face Lift

By Klaus FRITZ, MD | Germany



## 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 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 health 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.

# ULTRAFORMER– Non surgical facelift

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By Serena, MD | Australia

## **The most exciting international evolution in the non-surgical facelift**

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.

# ULTRAFORMER- Non surgical facelift

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By Serena, MD | Australia

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- Face Tightening & Whitening

By Klaus Fritz, Franco Lauro, Beom-Joon Kim, MD | Germany, Italy, Rep. of Korea

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



**Klaus Fritz, M.D.**  
 Director  
 Dermatology and Laser Centers  
 Landau, Germany  
 Lecturer  
 University of Osnabrueck,  
 Germany



**Franco Lauro, M.D.**  
 Plastic Surgeon  
 Private Practice  
 Bologna, Italy



**Beom-Joon Kim, M.D., Ph.D.**  
 Department of Dermatology  
 College of Medicine  
 ChungAng University  
 Seoul, Korea

Ever since its recent entrance in the aesthetic market, the Ultraformer device from Cynos, 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 musculoaponeurotic 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 1.5 mm, 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 male augmenting jaw 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.



Before Tx  
 Photo courtesy of Dr. Franco Lauro



Post 2 months



Before Tx  
 Photo courtesy of Dr. Franco Lauro



Post 2 months



# ULTRAFORMER- Face Tightening & Whitening

By Klaus Fritz, Franco Lauro, Beom-Joon Kim, MD | Germany, Italy, Rep. of Korea



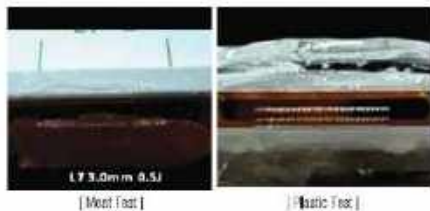
"Following the initial effects, a wound healing response is initiated in the skin, resulting in the formation of new collagen fibers, which provides tightening of the skin in a longer term. After four weeks of treatment, patients' facial contours and fine wrinkles show significant improvement. Additional 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 Ultraformer 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."

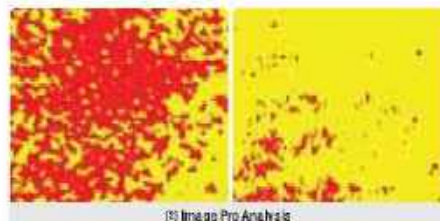
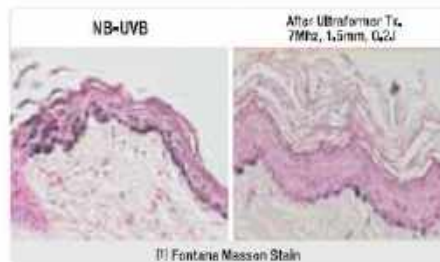
Featuring dual handpiece, the Ultraformer device offers a fluence of 0.1 to 1 J, and is equipped with three different cartridges ideal for the triple-layer HIFU treatment approach, namely L7-3: 7 MHz (3 mm), L4-4.5: 4 MHz (4.5mm), and L7-1.5: 7 MHz (1.5 mm).



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 Vra in Korea 21 Plus project team in the arena of dermatological science (2013-2020) – has explored the Ultraformer's effectiveness for this indication.

"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 0.2 J 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<sup>®</sup> reported.

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



<sup>®</sup> Dr. Beom-Joon Kim, professor at R&D Center of the Chung-Ang University, Appointed by The Ministry of Education of the Republic of Korea for the Vra in Korea 21 Plus project team in the arena of dermatology science (2013-2020)

# ULTRAFORMER- Face Tightening & Whitening

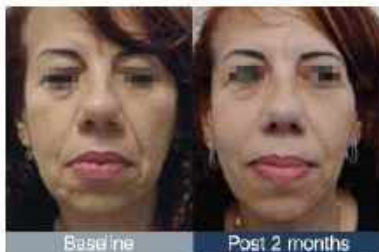
By Klaus Fritz, Franco Lauro, Beom-Joon Kim, MD | Germany, Italy, Rep. of Korea

## Ultraformer Facelifting Immediate Results

- Face & Neck lifting immediate and post few days



- Results post 2 month



# ULTRAFORMER- Face Tightening & Whitening

By Klaus Fritz, Franco Lauro, Beom-Joon Kim, MD | Germany, Italy, Rep. of Korea



• Results post 6 month and 12 month



# ULTRAFORMER- Wrinkles and skin laxity

By Hyunchul Park, Eunjin Kim, Jeongeun Kim, Youngsuck Ro, Wooyeon Ko | Rep. Of Korea

Ann Dermatol Vol. 27, No. 6, 2015

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ORIGINAL ARTICLE

## High-Intensity Focused Ultrasound for the Treatment of Wrinkles and Skin Laxity in Seven Different Facial Areas

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**Background:** High-intensity focused ultrasound (HIFU) treatment has recently emerged in response to the increasing demand for noninvasive procedures for skin lifting and tightening. **Objective:** This study was aimed at evaluating the clinical efficacy of and patient satisfaction with HIFU treatment for wrinkles and laxity in seven different areas of the face in Asian skin. **Methods:** Twenty Korean patients with facial wrinkle and laxity were analyzed after a single session of HIFU treatment. Two independent, blinded clinicians evaluated the clinical improvement in seven areas of the face by comparison of standardized photographs obtained before, and at 3 and 6 months after treatment. Assessment of subjective satisfaction and adverse effects of treatment were done by using questionnaires. **Results:** The physicians' evaluation and patients' satisfaction with the clinical effects of HIFU in each area were similar regardless of the number of treatment shots. The jawline, cheek, and perioral areas were the sites where HIFU was most effective, in decreasing order. The adverse effects included erythema and swelling in six cases, and purpura and bruising in two cases. However, the adverse effects were mild and transient. **Conclusion:** HIFU could be a safe, effective, and noninvasive procedure that can be used to improve facial wrinkles and skin laxity in Asian skin. It is particularly effective for clinical improvement in the jawline, cheek, and perioral areas. (*Ann*

*Dermatol* 27(6) 688~693, 2015)

### -Keywords-

High-intensity focused ultrasound, Laxity, Wrinkle

### INTRODUCTION

Recently, there has been increasing public concern about facial wrinkles and loss of elasticity due to aging. In response to this problem, various treatments, including chemical peeling, microdermabrasion, fractional laser, and radiofrequency, have been proposed for the treatment of facial wrinkles and laxity; however, the ideal treatment option has yet to be identified<sup>1-4</sup>. Recently, ultrasound was introduced as a new treatment for therapeutic and cosmetic purposes<sup>5,6</sup>. High-intensity focused ultrasound (HIFU) may be the best example of this technique. White et al.<sup>7</sup> reported the first dermatologic, aesthetic use of HIFU in 2008, and HIFU was approved by the Food and Drug Administration in 2009 for use in browlifting. Currently, it is being used for facial rejuvenation, lifting, tightening, and body contouring, which are considered "off-label" use<sup>8-10</sup>. The principle of HIFU is to induce cellular damage and volume reduction of the target area selectively by means of coagulation by generating instant microthermal lesions through the accumulation of high-frequency ultrasound beams at the specific tissue site without any damage to the epidermis and adjacent tissue<sup>11</sup>.

In this study, we evaluated the clinical improvement, adverse effects, and patient satisfaction through the evaluation of clinical photographs and by using a questionnaire at 3 and 6 months after Ulthera treatment, in patients older than 30 years who desired facial lifting and wrinkle improvement.

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# ULTRAFORMER- Wrinkles and skin laxity

By Hyunchul Park, Eunjin Kim, Jeongeun Kim, Youngsuck Ro, Wooyeon Ko | Rep. Of Korea

Efficacy and Patient Satisfaction of HIFU

## MATERIALS AND METHODS

The study protocol conformed to the guidelines of the 1975 Declaration of Helsinki and was approved by the Hanyang Medical Hospital Institutional Review Board and Ethics Committee (IRB No. 2013-01-024).

Twenty patients with facial wrinkles and skin laxity were enrolled in the study. All patients were of Fitzpatrick skin types III and IV. Informed consent was obtained from all patients, consisting of 18 women and 2 men. The patients' ages ranged from 37 to 75 years (mean, 52.3 years). They were treated with a HIFU tightening device (Ulthera system; Ulthera Inc., Mesa, AZ, USA) to the entire face, except for the nose and eyes, by using the following probes: 4 MHz, 4.5-mm focal depth; 7 MHz, 4.5-mm focal depth; and 7 MHz, 3.0-mm focal depth. We used hand pieces that delivered energy at 7.5 MHz and focal depths of 3.0 and 4.5 mm. Topical lidocaine/prilocaine cream (EMLA cream; Astra Pharmaceutical Products Inc., Westborough, MA, USA) was applied under an occlusive dressing for 60 minutes. In three patients, we used a nerve block of the supraorbital, supratrochlear, infraorbital, and mental nerves. After cleaning the face, a layer of ultrasound gel was applied to the skin. Each probe delivered a set of pulses in a linear array at 1-cm intervals. From 400 to 500 shots were delivered according to the size of the face. Standardized photographs of frontal and 45° angle views, along with profiles from each side, were obtained before, and 3 and 6 months after the treatment.

The clinical assessment was based on the evaluation of pretreatment and posttreatment photographs by two independent clinicians who were not directly involved in the treatments. They divided the face into seven areas (supraorbital, zygomatic, infraorbital, perioral, cheek, preauricular, and jawline, excluding the nose and periorbital areas). To assess the severity of facial wrinkles and skin laxity, we modified the eight-point photographic scale suggested by Chung et al.<sup>12</sup>. Each facial area was evaluated before treatment and after 3 and 6 months by using the following scale: 0, none; 1, mild; 2, mild/moderate; 3, moderate; and 4, severe. The overall clinical improvement was also assessed. In addition, we conducted a survey to assess patient satisfaction and adverse effects. Each patient scored their satisfaction in each area of their faces, and also scored their overall satisfaction with their improvement after treatment on a scale of 1 to 5, as follows: 1, not satisfied; 2, somewhat satisfied; 3, satisfied; 4, very satisfied; 5, extremely satisfied. On the basis of the Global Aesthetic Improvement Scale (GAIS), we subdivided the degree of improvement and satisfaction into five scales in the inverse order of GAIS. We adjusted the order of the scale to make

it easier to understand whether the treatment was effective or not. This questionnaire also included several questions about the patients' satisfaction after HIFU treatment, their assessment of adverse effects, and their opinions about whether they would like to undergo further HIFU treatment or whether they would recommend HIFU to others.

All experimental data were analyzed by using paired Student's *t*-tests with SPSS ver. 12.0 statistical software (SPSS Inc., Chicago, IL, USA). All *p*-values were two-tailed, and 0.05 was considered statistically significant.

## RESULTS

### Demographic information

This study included 20 Korean patients (18 women and 2 men), aged 37 to 75 years (mean, 52.3 ± 13.9 years). The number of shots delivered with the HIFU tightening device was 420 ± 59.1.

### Physicians' evaluation score

All patients showed clinical improvement after treatment compared with baseline. Representative photos are shown in Fig. 1 (the patients' consent was obtained). All seven areas showed clinical improvement at 3 and 6 months compared with baseline. The improvement was significant at 3 months after treatment, and efficacy was maintained throughout 6 months. The average wrinkle and skin laxity score decreased most in the jawline and periorbital areas (Table 1, Fig. 2).

### Patients' satisfaction score

On the surveys of patient satisfaction by areas, the scores at 3 and 6 months were 3 or higher. The jawline, perioral, and cheek areas showed the highest satisfaction scores. We observed that after 6 months, satisfaction decreased in all areas, except for the cheek area, which instead showed improvement (Table 2, Fig. 3).

Answers to the question "Which area do you think showed the most improvement after Ulthera treatment?" included the jawline, cheek, and perioral areas at 3 and 6 months after the treatment. However, in a survey after 6 months, satisfaction in the cheek and perioral areas had somewhat increased compared with that in the jawline (Fig. 4A). We also assessed the efficacy and adverse effects 12 months after the treatment by means of a telephone interview or through e-mail. Among 15 patients who replied, 4 patients answered that partial effects were still present in some areas.

### Adverse effects

When we asked about adverse effects, there were six pa-

# ULTRAFORMER- Wrinkles and skin laxity

By Hyun-chul Park, Eunjin Kim, Jeongeun Kim, Youngsuck Ro, Wooyeon Ko | Rep. Of Korea

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Fig. 1. Clinical photographs showing before (A, D), 3 months (B, E), and 6 months (C, F) after high-intensity focused ultrasound treatment.

Table 1. Physicians' evaluation score for the treatment areas

Variable	Baseline	After 3 months	After 6 months	p-value
Supraorbital	2.26 ± 0.93	1.47 ± 0.70	1.47 ± 0.69	< 0.001
Zygomatic	1.84 ± 0.60	1.21 ± 0.54	1.16 ± 0.50	< 0.001
Infraorbital	2.11 ± 0.88	1.53 ± 0.61	1.47 ± 0.61	< 0.001
Perioral	2.26 ± 0.65	1.37 ± 0.50	1.37 ± 0.50	< 0.001
Cheek	1.95 ± 0.71	1.21 ± 0.54	1.16 ± 0.50	< 0.001
Preauricular	1.74 ± 0.65	1.26 ± 0.45	1.26 ± 0.45	< 0.001
Jawline	2.47 ± 0.61	1.53 ± 0.51	1.47 ± 0.51	< 0.001
Overall	2.37 ± 0.68	1.47 ± 0.51	1.47 ± 0.51	< 0.001

Values are presented as mean ± standard deviation.

tients with erythema and swelling, and two patients with purpura and bruising. However, these resolved within 2 weeks without any permanent complications (Fig. 4B). No serious adverse events, including neuralgia, nerve palsy, severe edema (lymphatic damage), blistering, or fat atrophy were noted throughout the 6 months after treatment. In addition, no long-term adverse effects were reported in the 15 patients who replied after 12 months.

#### Willingness to continue and recommend high-intensity focused ultrasound treatment

When we asked if patients wanted to receive more treatments and would recommend the treatment to others, most of them answered positively. However, one patient did not want retreatment because of unsatisfactory effect-

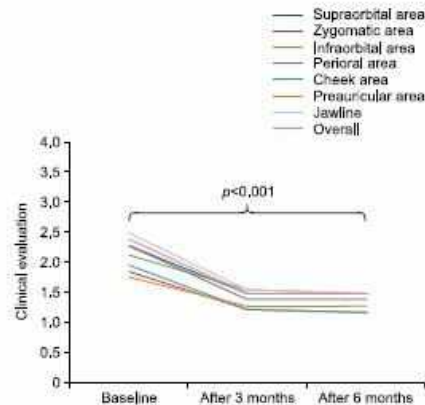


Fig. 2. Physicians' evaluation score for the treatment areas. 0: none, 1: mild, 2: mild/moderate, 3: moderate, 4: severe.

tiveness, and two patients said they would not recommend the treatment to others because of the cost (Fig. 4C).

#### DISCUSSION

Both intrinsic and extrinsic aging processes contribute to aesthetic changes. Advances in the understanding of skin biology have led to the development of a number of tech-

# ULTRAFORMER- Wrinkles and skin laxity

By Hyunchul Park, Eunjin Kim, Jeongeun Kim, Youngsuck Ro, Wooyeon Ko | Rep. Of Korea

**Table 2.** Patients' satisfaction score for the treatment areas

Variable	After 3 months	After 6 months	p-value
Supraorbital	3.70±0.73	3.50±0.89	0.1250
Zygomatic	3.75±0.64	3.60±0.82	0.2500
Infraorbital	3.50±0.89	3.35±0.93	0.2500
Perioral	4.00±0.79	3.90±0.91	0.5000
Cheek	3.80±0.77	3.80±1.06	1.0000
Preauricular	3.75±0.64	3.70±0.80	1.0000
Jawline	4.05±0.83	3.90±0.97	0.2500
Overall	3.80±0.83	3.65±0.81	0.3750

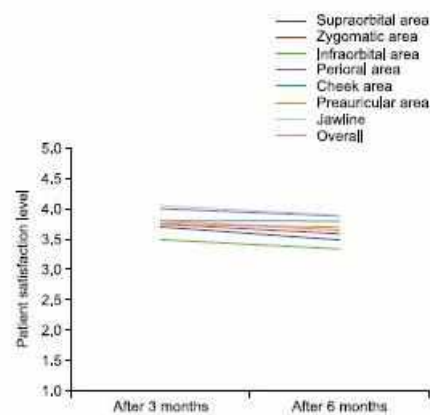
Values are presented as mean±standard deviation.

nologies for rejuvenating the skin. Current treatment modalities include ablative and non-ablative lasers, radiofrequency devices, and ultrasound devices<sup>1-4,10</sup>. Recently, HIFU treatment has received proper medical attention as a 'high-tech' way to improve wrinkles and skin laxity<sup>5-10</sup>. This technique combines direct ultrasound visualization of targeted tissue with the noninvasive delivery of focused ultrasound energy. Precise microcoagulation zones from the deep dermis to the superficial musculoaponeurotic system (SMAS) have been demonstrated. These zones cause gradual tightening of the skin through collagen contraction and remodeling<sup>11</sup>.

To date, few articles have demonstrated the efficacy of HIFU skin-tightening devices. In 2010, Alam et al.<sup>5</sup> reported that HIFU was a safe and effective modality for facial skin tightening. Another recent study showed that HIFU could also be used safely and effectively to improve the skin texture and contour of the upper arms, extensor knees, and medial thighs<sup>13</sup>. In addition, Suh et al.<sup>9</sup> reported clinical and histopathologic changes after HIFU treatment, and suggested that HIFU was a safe, effective, and noninvasive procedure that can be used to tighten the facial skin of Asian people. Unlike in previous studies, we divided the face into seven areas (supraorbital, zygomatic, infraorbital, perioral, cheek, preauricular, and jawline) and then evaluated each part after HIFU treatment.

In this study, regardless of the number of treatment shots, physicians' evaluations and patients' satisfaction with the clinical effects of HIFU seemed similar in all areas. Improvement was prominent after 3 months and showed a gradual decrease with time. The top 3 areas with the highest scores were slightly different in the physicians' evaluations and patients' satisfaction scores, which were the jawline, cheek, and perioral areas in decreasing order for physicians' evaluations, and the jawline, perioral, and cheek areas in decreasing order for patients' satisfaction. Additionally, there was no statistical difference in patient

**Efficiency and Patient Satisfaction of HIFU**



**Fig. 3.** Patients' satisfaction score for the treatment areas. 1: not satisfied; 2: somewhat satisfied; 3: satisfied; 4: very satisfied; 5: extremely satisfied.

satisfaction at 3 and 6 months ( $p < 0.375$ ). Therefore, subjective satisfaction was sustained for at least 6 months. Also, we observed continuous efficacy in the physicians' evaluation on the zygomatic, infraorbital, cheek, and jawline areas. This might be due to (i) more shots being administered on the zygomatic and cheek areas (200~300 shots) and (ii) the difference in the depth between the dermis and the subcutaneous layer in the infraorbital and jawline areas.

A remarkable finding was that the evaluation by the clinicians and the patients' satisfaction concerning the efficacy of HIFU in each facial area were similar at all time points. However, patients' satisfaction was higher relative to the evaluation by clinicians. This may be because HIFU not only resulted in facial lifting and improvement of wrinkles but also in improvements in skin tone, facial contour, and subjective symptoms such as tightness or tension on the skin.

This study has several limitations. First, only a small number of patients were included in this study because of cost issues. Second, this study did not include controls. However, despite these limitations, the present study demonstrated the clinical and adverse effects of a novel HIFU treatment in a real clinical situation.

In conclusion, we performed facial lifting with Ulthera in 20 patients older than 30 years, and observed clinical improvement and patient satisfaction after the treatment. We consider HIFU to be a safe, effective, and noninvasive option for facial lifting and improvement of wrinkles. Further

# ULTRAFORMER- Wrinkles and skin laxity

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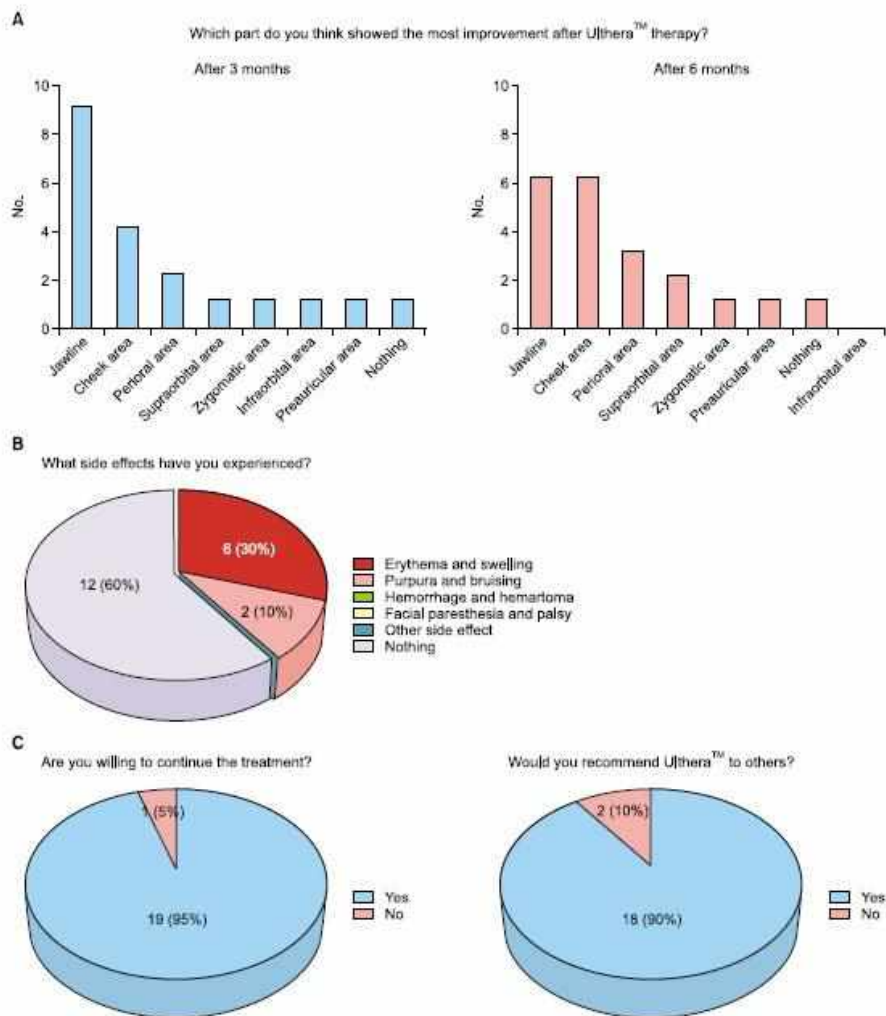


Fig. 4. Results of the questionnaire: the most improved area (A), the side effects (B), and the willingness (C) to continue and recommend Ulthera™.

evidence is needed from studies with more patients conducted at multiple institutions. Additionally, there is a need for studies on patient factors associated with different outcomes, appropriate treatment intervals, number of shots used, equipment settings, and the need for com-

bined therapy with other treatments, such as botulinum toxin. Histologic and molecular approaches are also needed to elucidate the mechanisms underlying changes in the collagen of the dermis to the SMAS layer due to micro-coagulation zones.



# ULTRAFORMER- Skin Tightening

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Efficacy and Patient Satisfaction of HIFU

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