



ULTRAFORMER III

MMFU I Micro & Macro Focused Ultrasound

Reform Your Youth

www.ultraformer.com

 **CLASSYS**
Technology for better life



Lift Tighten Contour

The Ultraformer III is an optimum, non-invasive ultrasound device that lifts and tightens the face for a youthful complexion and tightens the body for slimmer contours. With precision per shot pulse, HIFU-powered transducers are designed to either remodel collagen to remove facial wrinkles and sagging skin or tighten body tissues to reflect your full potential.

ULTRAFORMER III

Uplift your face, diminish those wrinkles, and shape your body



Multi-functional & Multi-depth
Cartridges



Micro & Macro Focused
Technology



Application
Face & Body



Non-invasive Procedure
Safety



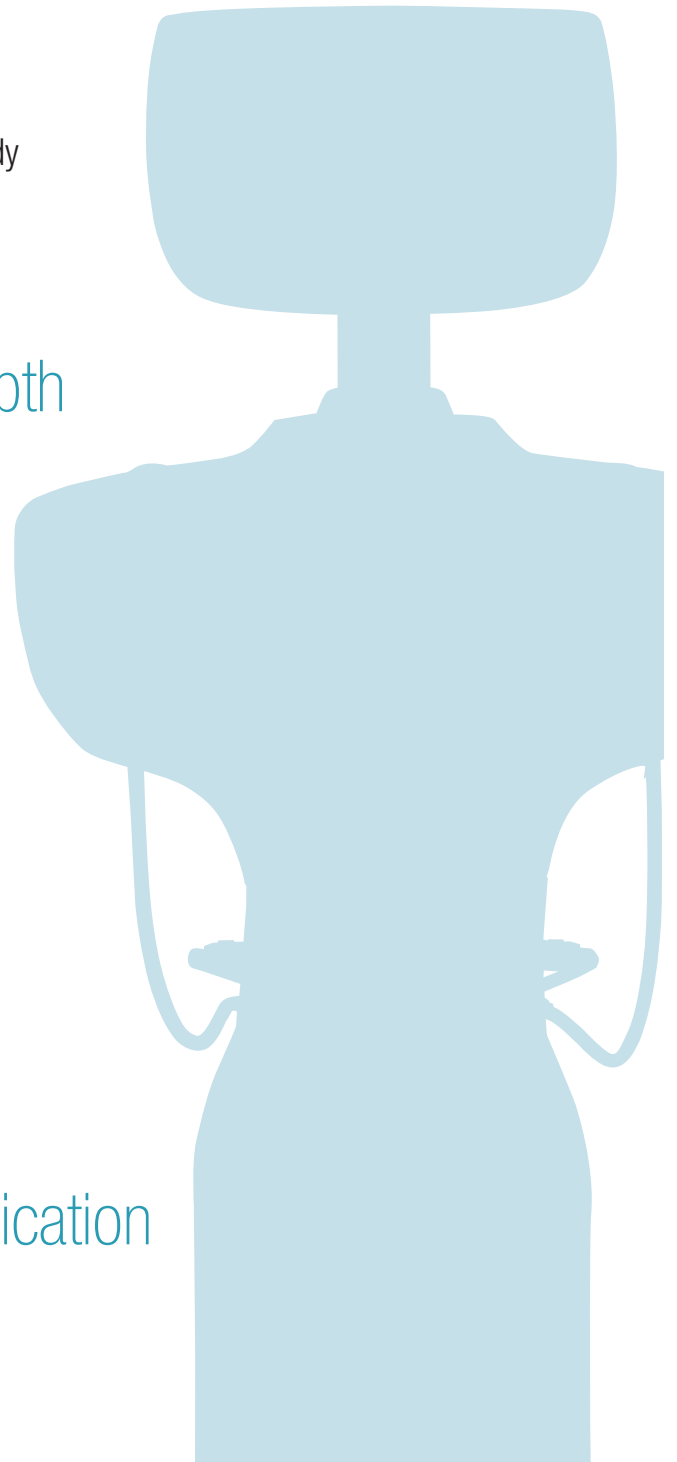
Effective & Less Pain
Treatment



Faster & Precise Shot Application
Transducers



High Peak Power
Dual Engine



Benefits for Patients

- Applicable for all skin types and tones
- 15-20 minute treatments with NO downtime
- No pre or post treatment skin care requirements
- Quick and long-lasting results

Benefits for Practice

- Safe and effective alternative to Botox, invasive surgery
- Customized treatment based on patient assessment
- Complements other aesthetic treatments offered
- Highly profitable and quick turnover on investment



Technology & Mechanism

HIFU transducers deliver an equal distribution of ultrasound waves into multiple layers of skin and body tissues without direct contact to the epidermis. Fitted with multiple cartridges that generate thermal energy, the Ultraformer III maintains stabilized temperatures of 65~75°C to induce coagulation for collagen renewal in the face and tightens body tissues for contouring waistlines, the thighs, and other parts of the body.

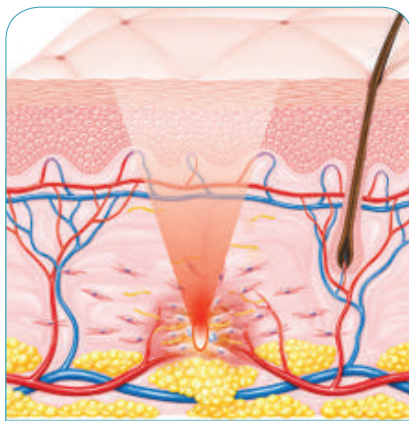
Neocollagenesis

Collagen renewal in the face triggered by HIFU involves heating the dermal and superficial muscular aponeurotic system (SMAS) layers that undergo separate phases of blood coagulation, wound contractions, and tighter shelving of new collagen to reduce wrinkles and sagging skin.

01

Inflammation Phase

Post treatment, the target area undergoes blood coagulation and hemostasis to control blood flow, which then induces a uniform migration of surrounding skin cells.

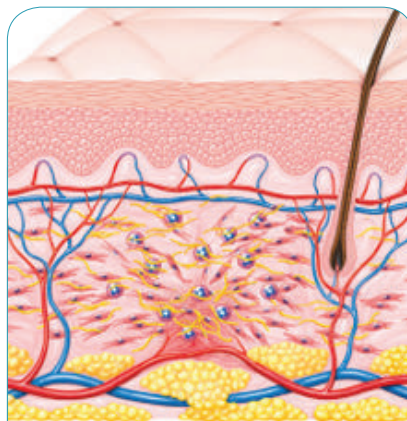


- Hemostasis
- Skin Coagulation
- Cell Migration

02

Proliferative Phase

48 hours after receiving treatment, fibroblasts produce new connective tissue known as granulation tissue to form on the wound, triggering a tighter build-up of new collagen.

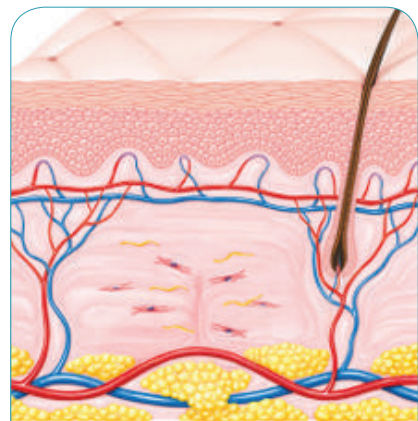


- Granulation Tissue
- Wound Contraction
- Collagen Synthesis

03

Remodeling Phase

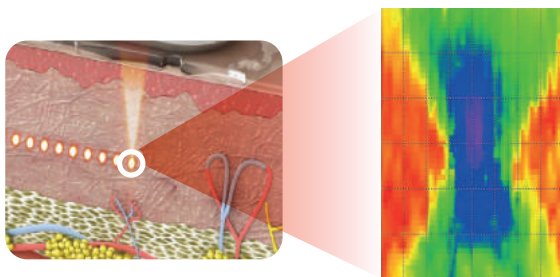
Over the course of 3 weeks to 6 months following treatment, the dermal layers of skin triggers renewal of cross-linked collagen fibers for a tighter and wrinkle-free complexion.



- Collagen Renewal
- Strength Increase
- Skin Lifting & Tightening

Micro Focused

Cartridges with highly concentrated ultrasound beams deliver power with accuracy and precision to the specified focal region.



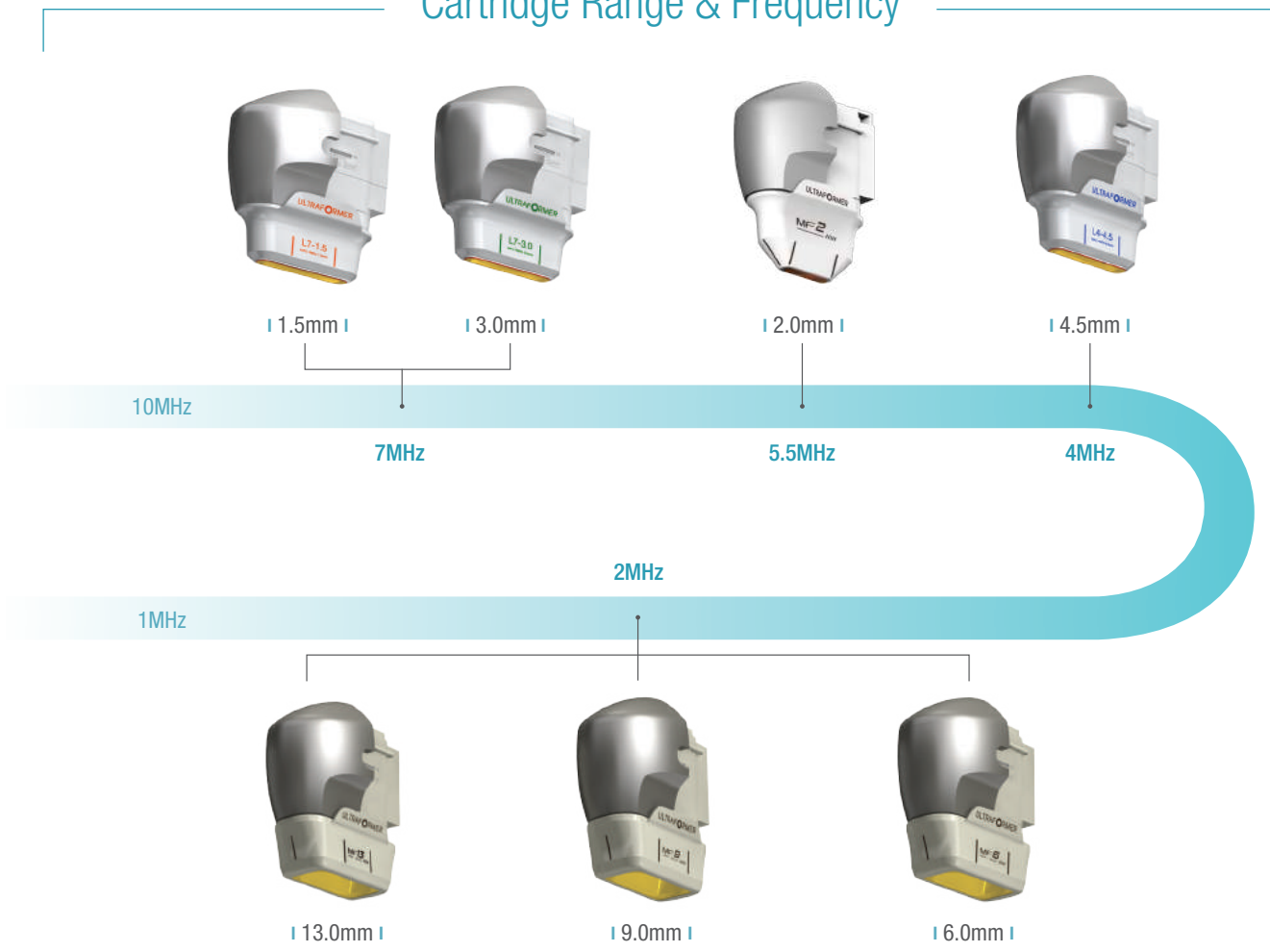
Macro Focused

Cartridges with lower frequencies allow deeper penetration to the focal region with a larger energy density.



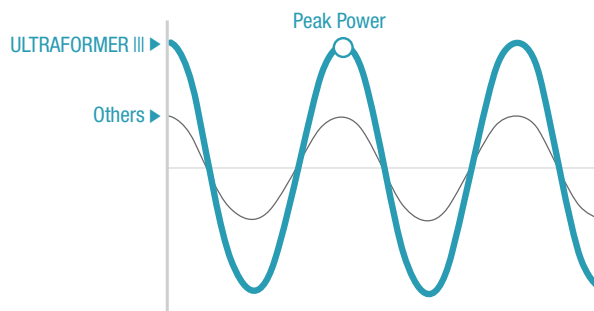
Technology

Cartridge Range & Frequency



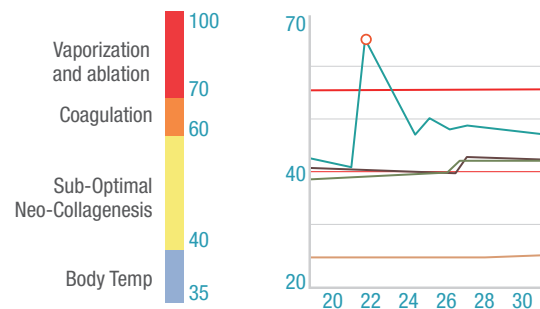
Dual Engine High Peak Power

High peak power delivers energy effectively to target layers of skin without diffusing heat to surrounding tissues, yielding less pain and a low rate of side effects combined with effective clinical results.



MMFU Thermal Energy

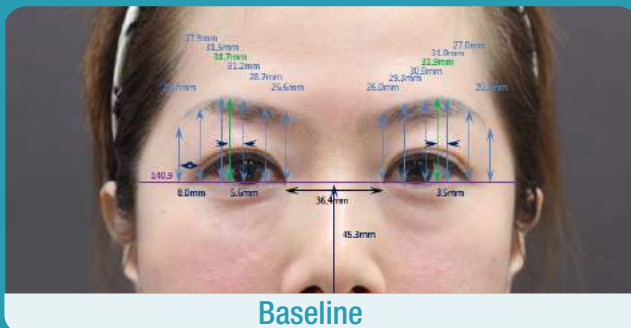
Generating approximately 65.4°C into target layers induces natural coagulation and wound-healing processes to stimulate collagen renewal underneath the epidermis.



Brow Lifting Efficacy

Clinical Study Abstract

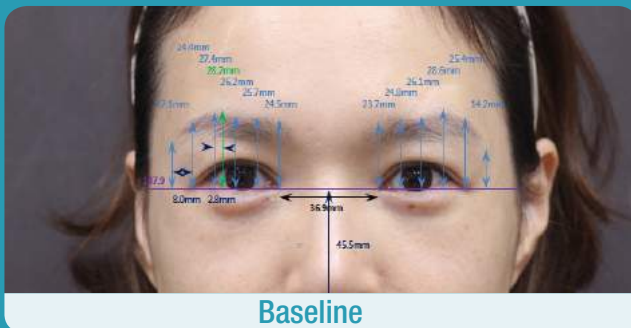
Over the course of 12 weeks, 30 patients participated in a clinical study to assess the efficacy of brow lift procedures using the Ultraformer III. Clinical photos were recorded at the start of each session to document improvement in results.



Baseline



Post Procedure



Baseline



Post Procedure

Measurement of AEH Improvement

1.56 mm

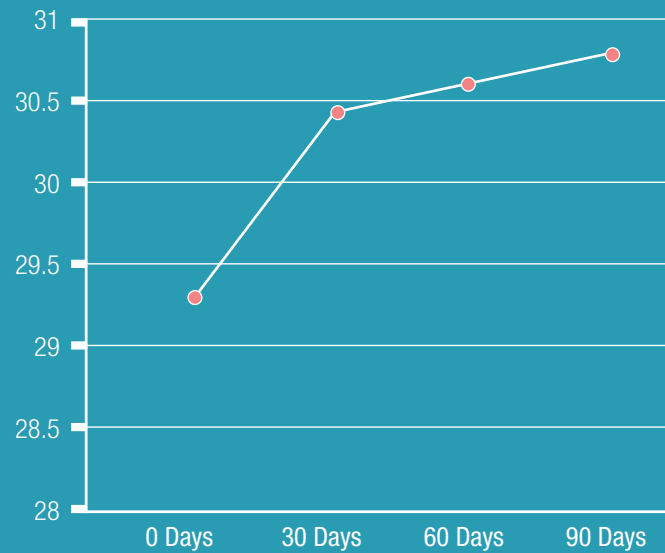
Patients evaluated in the course of 90 days achieved an average lifting effect of 1.56mm.

90%

90% of 30 subjects receiving brow lifts under clinical evaluation reported significant lifting and tightening just above the eyebrows 90 days post procedure.

30 days

The highest rate of clinical improvement was commonly recorded in the first 30 days following the first session of treatment.



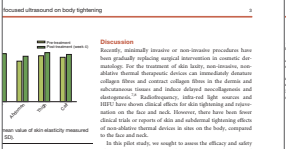
Proven Efficacy Through Clinical Studies

Tightening effects of high-intensity focused ultrasound on body skin and subdermal tissue

[J Eur Acad Dermatol Venereol. 2016 Sep;30(9):1599-602.]

Research Abstract

Procedures with the Ultraformer III to increase skin elasticity in the face and tighten areas of the body through the non-invasive method of HIFU under multiple depth cartridges were evaluated to determine the efficacy of the device as a practical alternative to invasive procedures and surgery. The study was based on the standards of the Global Aesthetic Improvement Scale (GAIS) and elasticity changes to skin were measured via a cutometer.

<p>DOI: 10.1111/jdv.13110</p> <p>SHORT REPORT</p> <p>Tightening effects of high-intensity focused ultrasound on body skin and subdermal tissue: a pilot study</p> <p>S.Y. Choi, Y.A. No, S.Y. Kim, B.J. Kim, T.M. Kim</p> <p>Abstract High-intensity focused ultrasound (HIFU) has been introduced as a new treatment modality for skin tightening and regeneration in the face and neck.</p> <p>Objective This pilot study assessed the efficacy and safety of HIFU for body tightening in Asian females.</p> <p>Methods The Asian female study was conducted in the pilot study. All subjects were treated with HIFU in the both cheek, upper arm, lower abdomen, thigh and calf using the following protocol: 7 MHz, 1.5 mm focal depth; 2 MHz, 2.5 mm focal depth; 2 MHz, 4.5 mm focal depth; 2 MHz, 6.5 mm focal depth; 2 MHz, 8.5 mm focal depth. These focused ultrasound treatments were assessed using the Investigator Global Aesthetic Improvement Scale (GAIS) with patient pain and post-treatment issues as secondary endpoints. 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 reported pain using a visual analogue scale (VAS) immediately, 1 week and 4 weeks after treatment.</p> <p>Results The mean global aesthetic (subject) of treated sites at 4 weeks after treatment was significantly improved (4 weeks after treatment of treated sites P < 0.05). All patients scored themselves subjectively as more than improved on the GAIS. Immediately after treatment the mean VAS scores were 1.7, 1.8, 2.0, 2.0, 2.0, but no pain was reported at 1 week. No permanent adverse effects were observed during the follow-up period.</p> <p>Conclusions For body tightening, we applied HIFU using transducers with a lower frequency and deep focal depth to effectively deliver ultrasound energy to skin tissue. HIFU appears to be a safe and effective treatment modality for cosmetic and aesthetic tightening.</p> <p>Received 28 October 2015; Accepted 15 March 2016</p> <p>Conflicts of interest None declared.</p> <p>Funding sources None declared.</p> <p>Introduction As skin ages, it is difficult to decrease and maintain facial, neck and body fat as commonly seen. Various treatment modalities including medical, laser and radiofrequency approaches have been used to improve skin laxity. Surgical skin tightening procedures for skin laxity are effective, but can have serious side effects 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 risk and minimal downtime.</p> <p>High-intensity focused ultrasound (HIFU) has been investigated as a tool for the treatment of skin tightening and regeneration for the past several decades. HIFU can produce steady energy-focused lesions at precise depths in the tissues up to 10</p>	<p>31 and 70%. distributing a total of 101.2 J. We reported the pain, we reduced to 1.1 ± 0.3 for 1 week, but also increased to 1.5 J.</p> <p>Grouping HIFU treatment of the face and body consisted of 50–60 sites. We prefer to use the shallow depth tips to deep depth tips. Because patient's pain was usually proportional to depth of tips.</p> <p>Efficacy and pain evaluation We evaluated the skin tightening effect of HIFU using photographs and a cutometer. The investigator gathered digital photographs using standard camera and camera settings (Canon EOS 400D, high resolution setting, 700 × 300 pixels, Canon lens, Takahashi lens) before and 4 weeks after the treatment. Three blinded independent dermatologists evaluated pre-treatment and after photographs in a randomized fashion using the Investigator Global Aesthetic Improvement Scale (GAIS). Subjects assessed the tightening effects using the Subject Global Aesthetic Improvement Scale (SGAIS) 4 weeks after treatment.</p> <p>The Cutometer The Cutometer (Colson, GOMES, GOMES, GOMES) was used to measure skin elasticity. Among the cutometer-specific values (R1–R3), we used the R2 value, which is defined as the ratio of elastic recovery to the total distance and represents the biological elasticity.</p> <p>Pain was evaluated by visual analogue scale (VAS) immediately after each tip and at weeks 1 and 4 after the application of HIFU. VAS was a simple and reproducible tool for the assessment of pain severity which consisted of 11 levels (0–10 points).</p> <p>Statistical analysis Statistical analysis was performed using SPSS version 16.0 for Windows (SPSS Inc., Chicago, IL, USA) and Fisher's exact test was used to compare between before and after treatments were performed using paired t-test. These were presented as mean ± standard deviation. P < 0.05 was considered statistically significant.</p> <p>Results The Asian female subjects (European skin type III–IV) with skin laxity were enrolled in this study. They were 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.</p> <p>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 greater for the abdomen (Fig. 3).</p>	<p>Increased ultrasound on body tightening</p>  <p>Discussion Recently, minimally invasive or non-invasive procedures have been generally replacing surgical alternatives as cosmetic methodology for the treatment of skin laxity, non-invasive, non-ablative thermal treatment devices can increase dermal collagen fibers and contract collagen fibers in the dermis and subdermal tissues and induce dermal remodeling and skin tightening.^{1,2} Radiofrequency, laser and light sources and HIFU have shown clinical effects of skin tightening and contraction on the face and neck. However, there have been fewer clinical reports of skin and subdermal tightening effects of non-ablative thermal devices in sites on the body, compared to the face and neck.</p> <p>In this pilot study, we sought to assess the efficacy and safety of HIFU treatments using transducers that were specially developed to be suitable for use on the body skin and subdermal tissue for the purpose of skin tightening in body parts in Asian people. A previous clinical report on the effects of HIFU on tightening of the prefrontal and head area, which included a total of 42 patients including 4 Asians, has been published. However, this previous clinical study used conventional HIFU transducers (10 MHz, 1.5 mm focal depth; 7 MHz, 10 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 (1.5–8.5 mm) compared with conventional transducers. Therefore, we expect that newly developed transducers could effectively deliver HIFU energy deeper into the skin and subdermal tissues of the body and deliver tightening effects and skin tightening. Also, other reports said that practitioners should also apply and applied transducers with 1.1–1.4 mm transducers in all to use.³</p> <p>Although we applied aesthetic courses on treated sites, most subjects complained of a mild to moderate degree of pain during treatment in proportion to depth of pain of treatment. Their pain subsided within the use of analgesics, but the intensity of mild intensity of heat transducers into the subcutaneous tissue should be considered for pain reduction.</p> <p>By conducting 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 limitation of this pilot study was 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 numbers and long-term follow-up will be necessary to establish optimal treatment parameters.</p> <p>References 1. Lanza RL, Hsu RA, Burke PJ, et al. Invasive focused ultrasound volume reduction of the face and neck: a pilot study. <i>J Cosmet Dermatol</i> 2014; 14: 100–107.</p>	<p>Choi et al.</p> <p>1 Chikamoto M. Evaluation of skin tightening after laser assisted lipolysis. <i>Lasers Surg Med</i> 2010; 42: 648–650.</p> <p>2 Choi SY, Kim S, Kim BJ, et al. Evaluation of skin tightening in the face and neck using high-intensity focused ultrasound. <i>Dermatol Surg</i> 2015; 41: 100–107.</p> <p>3 Hsu RA, Lanza RL, Hsu RA, et al. Invasive focused ultrasound volume reduction of the face and neck: a pilot study. <i>J Cosmet Dermatol</i> 2014; 14: 100–107.</p> <p>4 Hsu RA, Lanza RL, Hsu RA, et al. Invasive focused ultrasound volume reduction of the face and neck: a pilot study. <i>J Cosmet Dermatol</i> 2014; 14: 100–107.</p> <p>5 Hsu RA, Lanza RL, Hsu RA, et al. Invasive focused ultrasound volume reduction of the face and neck: a pilot study. <i>J Cosmet Dermatol</i> 2014; 14: 100–107.</p>
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“The HIFU device used in this study was the Ultraformer III (CLASSYS INC.)” Business Cha

“Pain was evaluated by visual analogue scale (VAS) ... 1 and 4 weeks after treatment, all subjects reported a VAS score of 0 (no pain)”

“Most subjects were satisfied with the results of treatment (Table 2). At 4 weeks post-treatment, all subjects rated SGAS scores as greater than 1 on the cheek and thigh. The improvement rate assessed for the abdomen as greater than SGAS 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%.”

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.

Proven Efficacy Through Clinical Studies

Efficacy and safety of non-invasive body tightening with high-intensity focused ultrasound (HIFU)

[Skin Research and Technology 2017; 1-5]

Research Abstract

Clinical researchers have conducted treatment procedures on subjects with the Ultraformer III to determine whether high-intensity focused ultrasound (HIFU) is an effective, non-invasive alternative to incision-based procedures or surgeries for improving skin elasticity and contours of the face and body. Over the course of 12 weeks following treatment, researchers evaluated the device for its efficacy and safety based on the standards of the Global Aesthetic Improvement Scale (GAIS) and changes to skin elasticity measured over time via a cutometer.

The collage includes the following elements:

- Title Page:** Shows the journal title 'WILEY' and the article title 'Efficacy and safety of non-invasive body tightening with high-intensity focused ultrasound (HIFU)'. It lists authors: E. J. Ko^{1,2}, J. Y. Hong¹, T. R. Kwon¹, J. E. Choi¹, Y. J. Jung^{1,3}, S. Y. Choi^{1,4}, K. H. Yoo¹, S. Y. Kim¹, and B. J. Kim¹.
- Abstract:** Summarizes the study's purpose, methods, and findings. It states that HIFU was used to improve skin elasticity and body contours, with significant improvements observed at 12 weeks post-treatment.
- Introduction:** Discusses the need for non-invasive body tightening and the role of HIFU technology.
- Clinical Photographs:** Shows a patient's face and body before and after treatment, highlighting improvements in skin elasticity and body contours.
- Tables:** Includes the Investigator Global Aesthetic Improvement Scale (GAIS) and a table showing the change in mean SGAS score at 12 weeks post-treatment.

“GAIS scores also showed good results (Table 1).”

“Most subjects were satisfied with the results of treatment (Table 2)”

SGAIS Improvement Rate

96.9%

Cheek & Thigh

96.8%

Abdomen

12 Weeks Post Procedure

Conclusion

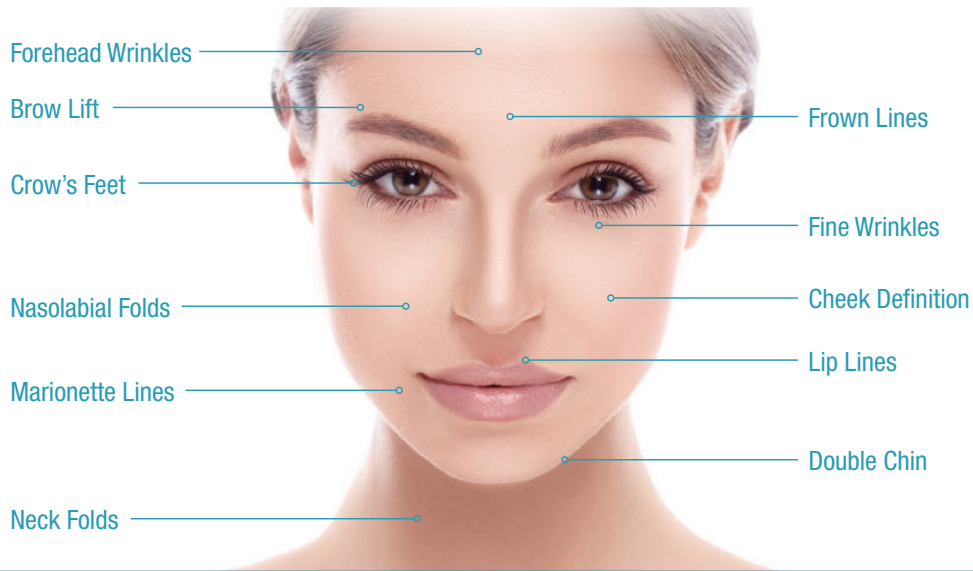
In this study, we observed significant improvements in two body regions (abdomen and thighs) as well as the cheek when targeted for HIFU treatment. By using newly developed transducers with different energy outputs and focal depths, HIFU treatment can be tailored to meet the unique physical characteristics of each patient.

This is a smaller version of the research paper abstract, highlighting the title, authors, and key findings. It includes the title 'Efficacy and safety of non-invasive body tightening with high-intensity focused ultrasound (HIFU)', the authors' names, and a brief summary of the study's purpose and results.

Applications

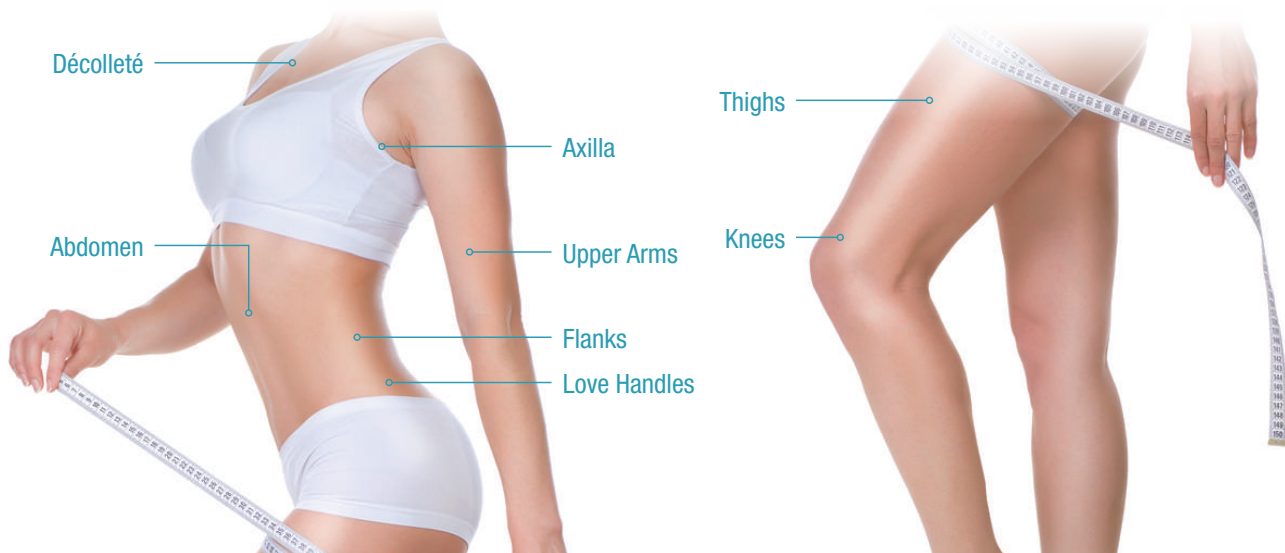
Face

Micro focused depth cartridges at 1.5mm, 2.0mm, 3.0mm, and 4.5mm directly transfer an equal distribution of ultrasound energy into the dermal and superficial muscular aponeurotic system (SMAS) layers of the face to stimulate collagen renewal.



Body

Macro focused depth cartridges at 6.0mm, 9.0mm, and 13.0mm directly transfer an equal distribution of ultrasound energy into the subcutaneous tissue, inducing contractions to dispose of stubborn fat cells naturally through the body as waste.



FAQ

What are the advantages of the Ultraformer III?

The Ultraformer III utilizes cartridges focused on multiple depths of skin for lifting and tightening the face as well as tightening body tissues for contouring purposes. The patient can receive customized treatments on the face and body with the stable delivery of ultrasound energy, fast application, and precise accuracy of MMFU-powered transducers.

How is fat naturally removed from the body by the Ultraformer III?

Macro-focused depth cartridges damage fat cell membranes consisting of triglycerides and are then transported through the vascular and lymphatic systems to the liver. This process is made possible through the body's natural metabolism as the liver makes no distinction between fat disposed of by the Ultraformer III and fat originating from food consumption.

Are there any side effects?

Although competitive results for facial lifting and tightening and body contouring will likely show over the next 3 months post treatment, patients may still experience slight redness for a few hours as well as swelling or tingling in either treatment area for up to a few weeks. There may also be bruising and numbness on treated areas but should resolve 2-4 weeks following procedure.

Is there any pain during treatment?

The Ultraformer III delivers comfortable procedures with its uniquely-designed transducer system developed only by CLASSYS. Many patients and practitioners report that the Ultraformer III, in comparison with other devices, delivers minimal pain with slight discomfort to the face or body, though sensations quickly subside immediately following treatment.

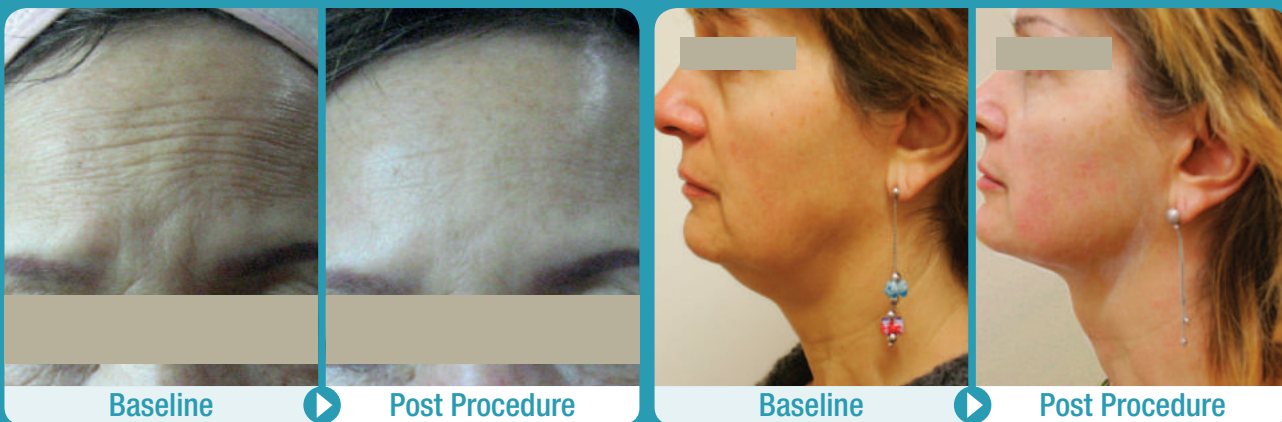
Am I a candidate for the ULTRAFORMER III?

Patients with diverse skin conditions such as fine lines, wrinkles, and hyperpigmentation on the face, or stubborn belly fat and love handles desiring a more curvaceous body figure, serve as ideal candidates for the Ultraformer III. Practitioners can also accommodate both face and body profiles with a variety of multi-depth cartridges that cater to a larger demographic of candidates.



Face | Lifting & Tightening

Participants shown in the following clinical photos received one ULTRAFORMER III treatment on the target areas presented. Evidence of clinical photos obtained from baseline and post procedure measurements indicates results in progress.



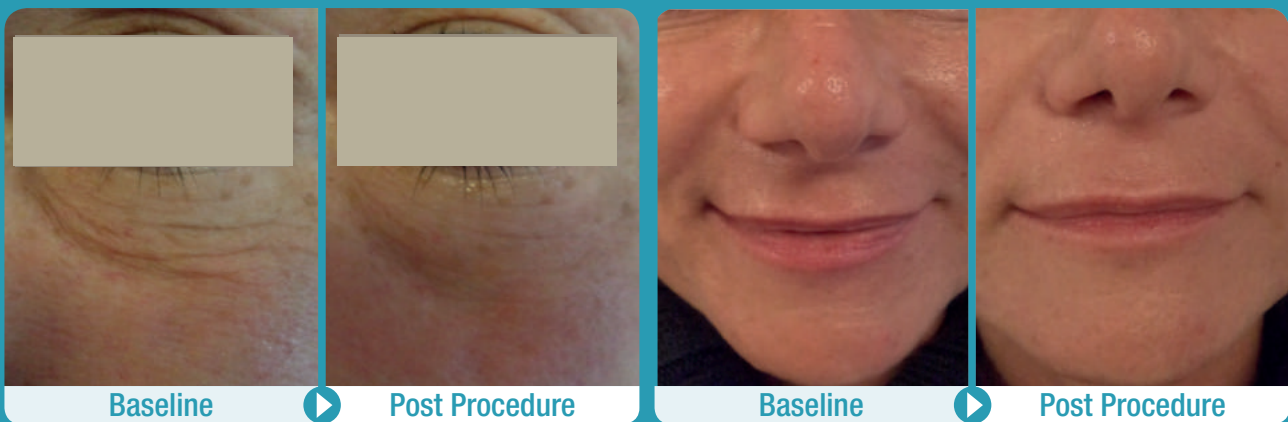
※ Individual results may vary. Unretouched photographs.

“
*I noticed a much brighter complexion after receiving my first Ultraformer III treatment.
I'm now confident to say goodbye to those fine lines and wrinkles.*
”

- Sarah Newman, 50 -

“
*I was amazed at how the Ultraformer III could treat the narrow contours of my face.
Not only that, I can go straight to work right after treatment!*
”

- Nicole Sutherland, 36 -



Body | Tightening & Contouring

Participants shown in the following clinical photos received one ULTRAFORMER III treatment on the target areas presented. Evidence of clinical photos obtained from baseline and post procedure measurements indicates results in progress.



※ Individual results may vary. Unretouched photographs.

The Classsys Advantage

Providing Tools for Your Success

When partnering with a company with a global technology standard, a matching standard of support is a necessary tool to help with maximizing your success. Active on all mainstream networks in our day and age, Classsys provides a top tier support service that caters to your practice.

Web & Social Media

A committed team dedicated to support web and mainstream social media, to grow our online presence in the face of new trends.



Education & Training

Providing practitioners with a comprehensive package of tools, knowledge, and training for the proper and professional use of our technologies.



Strategic Marketing

A live database of dynamic content and material, suitable for both B2B and B2C end-users operating in globally diverse markets.



Medical Professional Testimonials



 **Dr. Benjamin Ascher,
MD, Plastic Surgeon**

"I was deeply impressed by the skin-lifting results after experiencing the Ultraformer III for the first time. It shows significant scientific improvements of HIFU technology to develop great results. I believe Classsys will be one of the leading global companies to come based on their outstanding technology."



 **Dr. Klaus Fritz,
MD, Plastic Surgeon**

"Ultraformer III brings immediate tightening effects with different cartridges for the face. Surgery was the normal option for skin lifting procedures but now we can achieve equal results using the Ultraformer III non-invasively. My patients are always surprised about their remarkable clinical outcomes."



 **Dr. Jean Louis Sebagh,
MD, Plastic Surgeon**

"I've been using the Ultraformer III for more than a year now and I am very satisfied with its clinical results. I believe the Ultraformer III is a game changer for skin lifting. Injections and surgery were options for skin lifting prior to HIFU, but now the Ultraformer III non-surgical treatment reflects better."



 **Dr. Franco Lauro,
MD, Plastic Surgeon**


"Ultraformer III's skin tightening effects are amazing. Laser technology has limitations in terms of clinical results and side effects. The Ultraformer III presents excellent skin tightening using HIFU that delivers energy, especially to the SMAS layer. The energy takes apart old collagen and induces formation of new collagen effectively."



 **Dr. Michael H. Gold,
MD, Dermatologist**

"For those who have never tried the Ultraformer III with HIFU technology, I'd like to say that this is a great tightening procedure device. We like to use it for tightening from the eyes down to the neck. Patients reflect great results and they are highly satisfied."



 **Dr. Nobuhiro Suetake,
MD, Plastic Surgeon**

"The Ultraformer III is a very effective and satisfactory device that makes it possible to offer my patients a very complete treatment. I have experience with other HIFU devices, however, before the Ultraformer III, I was not satisfied with other devices due to high pain levels and unsatisfactory clinical results."



 **Dr. Jong-seo Kim,
MD, Plastic Surgeon**

"I am very impressed with the Ultraformer III in which there is a high rate of patient satisfaction. HIFU devices have replaced the trend of RF devices recently because these devices like the Ultraformer are more effective and is less painful. It helps with blood circulation and remodels collagen effectively."



 **Dr. Katia Paskova,
MD, Dermatologist**

"The effect of the Ultraformer III is instantaneous. This is because we work on the tissues and various layers of the skin. With age, skincare products and cosmetics is just not enough. The Ultraformer is suitable for patients who do not want surgical facelift procedures."



 **Dr. Marcin Ambroziak,
MD, Dermatologist**

"I have been using the Ultraformer III for more than 6 months now. This is a very versatile device because there are cartridges ranging from 1.5mm up to 9.0mm. So, we can use the device not only to treat sagging skin on the face, but we are able to treat other areas of the body as well."



The Classsys Advantage

Since opening our doors in 2007, Classsys Inc. was founded with the sole purpose to create technology that provides intuitive solutions for our consumers to reflect their potential. This has resulted in providing medical & aesthetic solutions that have reached consumers around the globe, with a diverse range of applications for lifting, tightening, fat reduction, and body contouring procedures. Comfort coupled with beneficial, fast-proven results is the source of our motivation and the reason we strive to innovate solutions for our consumers in the medical & aesthetics industry.



ultraformer.com



T. +82-2-517-2114 | classsys.com | ultraformer.com | info@classsys.com

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UF3B062017