

# High-Intensity-Focused Ultrasound: Changing the Face of Body Sculpting

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## ABSTRACT

Noninvasive procedures that utilize high-intensity-focused ultrasound (HIFU) for the percutaneous ablation of targeted tissues is increasingly being used for the management of an array of oncological and nononcological conditions and has been investigated for new uses such as noninvasive subcutaneous adipose tissue ablation. Once adipocytes have been ablated with HIFU, macrophages are attracted to the area to engulf and transport the lipids and cellular debris. This removal results in an overall reduction in local adipose tissue volume. The HIFU is an attractive alternative to more invasive procedures for body contouring that may appeal to patients resistant to surgical options. It does not require general anesthesia and can be performed as an outpatient procedure thus substantially cutting treatment cost, recovery time, and decreasing the risk of side effects, complications, and patient discomfort. This procedure allows the surgeon to manipulate the device placed remotely on the body surface to precisely target tissues to be ablated beneath the dermis. A single session of HIFU treatment on abdominal subcutaneous adipose tissue has been demonstrated to achieve mean reduction in waist circumference of up to 4.7 cm. The procedure has been found to be safe and well tolerated. The commonly reported adverse events such as prolonged tenderness, ecchymosis, hard lumps, edema, and pain are all nonserious in nature and resolve spontaneously over time. In addition, the majority of patients surveyed have expressed their satisfaction with the outcome of the procedure. Conclusion: HIFU is a powerful means for selective tissue destruction.

**Keywords:** ablation, body contouring, HIFU, noninvasive, ultrasound

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Traditional body sculpting approaches involving invasive surgery while being effective in improving body contours are hampered by the associated morbidity due to the invasive procedure and the risk of deleterious side effects. With advances in technology-assisted modern medicine, the focus in recent years has been on the development of noninvasive body sculpting methods. These appeal to a wider audience than more invasive alternatives as they offer the advantages of reduced scarring, shorter procedure time, and markedly reduced recovery time and post-treatment complication. Several minimally invasive body sculpting techniques involving the use of ultrasound, lasers, infrared light, radio frequency systems, either alone or in combination, and coupled with mechanical manipulation of the skin have demonstrated benefit in studies involving small patient cohorts. However, the majority of these minimally invasive procedures require multiple sessions while providing only short-lived benefits.<sup>1-5</sup>

High-intensity-focused ultrasound (HIFU) is a promising, clinically relevant, thermal ablation technique that allows minimally invasive treatments while not necessitating the insertion of a probe into the target tissue, the hallmark of a true noninvasive procedure. Instead the source device in HIFU is placed on the surface of the body. The high-powered beam of ultrasound generated does not harm the tissues it traverses, but focuses at a predetermined focal point to

enable selective destruction of targeted subcutaneous adipose tissue leaving surrounding tissues intact. This ensures trackless ablation of target tissues without the insertion of an applicator into the target area thus allowing for increased patient comfort and acceptability compared to traditional liposuction procedures. This noninvasive ablation procedure offers several advantages in that it allows the movement of the source device to target different tissue, while procedures that require probes to be inserted are only able to target tissues in its immediate vicinity. Furthermore, the wound-healing response attracts fibroblasts into the area, which together with heat denaturation of collagen that has occurred during the HIFU procedure, induces the formation of new collagen and tightening of septal fibers potentially resulting in a skin tightening effect.<sup>6</sup>

## CLINICAL APPLICATION OF HIGH-INTENSITY-FOCUSED ULTRASOUND (HIFU)

External HIFU, a treatment method that enables noninvasive tissue heating and ablation is gaining rapid clinical acceptance in a number of applications.<sup>6,7</sup> To date, the clinical applications for HIFU have been explored in diverse areas such as neurosurgery, ophthalmology, urology, gynecology, and oncology. The HIFU has been applied for the management of Parkinson's diseases and other neurological conditions with some degree of success.<sup>8-11</sup> In ophthalmol-

ogy, HIFU has successfully been used to treat glaucoma, traumatic capsular tears, intraocular tumors, retinal detachment, and vitreous hemorrhage in an experimental setting.<sup>12-16</sup>

The effectiveness of HIFU as a noninvasive surgical tool has been demonstrated in the treatment of tumors in the liver, kidney, breast, bone, uterus, and pancreas and in the palliative management of chronic pain of malignant origin. In addition, HIFU has been demonstrated to have benefits in managing conduction defects and congenital anomalies in the heart and for surgical hemostasis.<sup>17</sup>

In particular, HIFU has been found to be an effective minimally invasive, outpatient method for managing prostate cancer patients with a low clinical stage disease (cT1 to T2), with PSA less than 20 ng/ml and small prostate volumes of less than 40 ml. The HIFU also provides an option for managing patients who have failed radiation therapy; or have local recurrences after radical prostatectomy; and for the reduction of a large tumor mass for palliative reduction of associated pain, bleeding, and obstruction. The HIFU provides the surgeon with the control and precision required to accurately target and destroy prostate tissue while leaving adjacent tissues relatively unaffected. Prostate cancer patients managed with HIFU have reported negative biopsy rates of 87.2% at 1 year; however, long-term efficacy and safety of the procedure in managing prostate cancer patients has yet to be established.<sup>18-20</sup>

The novel HIFU device has been developed to achieve targeted reduction of adipose tissue by precisely focusing ultrasound energy to cause ablation of adipocytes without damage to the epidermis, dermis, or underlying tissues and organs. A custom designed ultrasound transducer delivers energy across the skin surface at a relatively low intensity, and brings this energy to a focus in the subcutaneous adipose tissue causing cell necrosis via a controlled thermal effect.

There are two primary mechanisms that help to achieve the percutaneous destruction of adipocytes with HIFU. Firstly, the device focuses the HIFU at a the desired point within the subcutaneous adipose tissue whereby it increases the temperature at this focal point to above 56C causing instant coagulative necrosis and cell death at the targeted area, while the temperatures outside the focal region remain below cytotoxic levels. The entry and exit path and tissue surrounding the focal area thus remain intact as the energy across the skin surface and in the surrounding areas is at a relatively low intensity.<sup>6</sup>

Following the HIFU procedure, a wound-healing response ensues that is primarily spearheaded by migration of macrophages into the area, which rapidly phagocytize the remnant lipids and cellular debris to clear the area. The majority of the disrupted adipose tissue is cleared away within 8 to 12 weeks post-treatment, while 95% of reabsorption is completed by 18 weeks, resulting in an overall reduction in adipose tissue volume in the treated areas. Importantly, no clinically relevant elevation in fatty acid, total cholesterol, very low density lipoprotein, low density lipoprotein, high density lipoprotein,

or triglyceride levels have been noted following the HIFU procedure.<sup>21</sup>

Secondly, in HIFU, besides thermal energy, mechanical energy may also be delivered through the process of cavitation. Cavitation involves the creation, oscillation, growth, and collapse of bubbles, which generates mechanical energy that results in tissue destruction. This has been confirmed by digital images of bubble cloud formation in gel phantom laboratory model systems. In addition, histological analysis of adipocytes in the boundaries of the treated areas has revealed findings confirming that the adipocytes have sustained mechanical injury, while there is no evidence of thermally induced cell destruction. Importantly, utilization of nonthermal-focused ultrasound technology does not result in cellular damage in adjacent blood vessels, nerves, connective tissues, or epidermal and dermal tissues.<sup>22</sup>

The major caveat of the HIFU technique is that it can target only a localized area with each exposure. Typically, the focal zone is ellipsoidal in shape with diameters of approximately 1.5x0.15 cm. Acoustic energy delivery and its conversion into heat and regular treatment monitoring are also important components of treatment planning decisions that need to be ascertained.<sup>6,23</sup>

## HIGH-INTENSITY-FOCUSED ULTRASOUND (HIFU) IN BODY SCULPTING

Fatemi reported his experience using a new HIFU device on 85 patients to remove excess adipose tissue from the anterior abdomen and flank areas. The patient cohort, with an average age of 43.8 years, were treated with a single HIFU session and achieved a decrease in waist circumference by an average of 4.6 cm after 3 months. The HIFU device was calibrated to deliver a total energy of 104 to 148 J/cm and two passes with the HIFU device were made over the area to be treated in each patient. The treatment time for patients ranged between 1 and 1.5 h and a mean energy level of 134.8 J/cm<sup>2</sup> was used at a focal depth of 1.1 to 1.6 cm for the procedures. Importantly, the procedure negated the need for general anesthesia, thus patients required little or no recovery time. Post hoc analysis of impact of different energy levels on the change in waist circumferences showed that there was no increased benefit with using higher energy levels. The procedure was well tolerated by the majority of patients. Adverse events such as prolonged tenderness, ecchymosis, hard lumps, edema, and pain, all of which resolved spontaneously, were experienced by 11.8% of treated patients. Fatemi and Kane have expressed their satisfaction with their experience with HIFU and conclude it is an effective and safe method for noninvasive body sculpting.<sup>24</sup>

In another study, a single treatment with the HIFU device obtained significant reduction in waist circumference. In the study, 282 patients were treated with a single session of HIFU in the anterior abdomen and flank areas using a mean energy dose of 137 J/cm<sup>2</sup>, at two different passes and two different focal depths. The HIFU device was calibrated to deliver a total energy ranging around 140 J/cm<sup>2</sup> or higher at a focal depth of

1.1–1.8 cm, and at least two passes with the HIFU device were made over the area to be treated to deliver the appropriate amount of energy. At 3 months following the procedure, the patients had experienced a mean 4.7 cm reduction in waist circumference. Side effects such as prolonged posttreatment tenderness, edema, hard lumps, ecchymosis, and pain during the treatment were reported by 13.5% of patients. However, all reported adverse events were nonserious and temporary in nature. The treatment-related pain resolved once treatment was completed, while the hard lumps, tenderness, and ecchymosis resolved over 4 weeks and the edema in 12 weeks.<sup>25</sup>

Use of noninvasive HIFU for localized body contouring provides an option for patients seeking esthetic improvements, reducing the potential for complications encountered with traditional invasive techniques, such as ultrasound-assisted lipoplasty and suction-assisted lipoplasty, thus contributing to improvement of patient satisfaction.<sup>26</sup> A survey of 50 patients who had undergone HIFU, conducted during the 4-month posttreatment follow-up visit, revealed that 70% of patients were satisfied with the reduction in waist circumference they had achieved with HIFU at 3 months and continued to be satisfied with the treatment outcome at 4 months.<sup>25</sup>

The safety and efficacy of a transcutaneous-focused ultrasound device that uses noninvasive, nonthermal, focused ultrasound for body contouring was assessed in a prospective study conducted on 30 healthy patients. Following three treatments at 1-month intervals, patients reported a mean reduction in fat thickness by 2.28 cm and a reduction in mean circumference by 3.95 cm, with no major adverse effects associated with the treatment.<sup>27</sup> In another study, Teitelbaum and colleagues reported a mean reduction in treatment area circumference by approximately 2 cm and 2.9 mm in skin fat thickness in 164 healthy adult subjects who were evaluated over a 12-week period following a single treatment of the abdomen, thighs, or flank region with the Contour I device. The treatment was found to be safe and well tolerated.<sup>28</sup>

Currently the LipoSonix device is not FDA approved in the US.

## IN CONCLUSION

The innovative use of HIFU therapy for the destruction of unwanted subcutaneous adipose tissue is a noninvasive alternative for localized body contouring that offers several benefits over traditional invasive procedures. It can be performed as an outpatient procedure and does not necessitate general anesthesia, resulting in reduced cost, recovery time, and risk of complications. Technological advances leading to further improvement in imaging and energy delivery techniques will likely lead to the expanded range and applicability of HIFU in the future. Further randomized, controlled trials are required to provide a greater understanding of this novel procedure.

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