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ORIGINAL ARTICLE BODY CONTOURING

Evidence-Based Efficacy of High-Intensity Focused Ultrasound (HIFU) in Aesthetic Body Contouring

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Abstract Being profitable procedures with little disposable costs, a number of noninvasive technologies have gained much popularity in recent years and are permeating the aesthetic marketplace. High-intensity focused ultrasound (HIFU) when focused at a targeted depth of 1.1 to 1.6 cm within subcutaneous tissue raises local tissue temperature at the focal point resulting in almost immediate cell death without damage to the surrounding tissues. Despite having gained popularity, little information is available regarding HIFU use for the treatment of localized fat and aesthetic body sculpturing. The current literature review is intended to investigate evidence-based efficacy of HIFU in aesthetic body contouring.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Nonsurgical cosmetic · High-intensity focused ultrasound · Minimally invasive procedure

Introduction

With modern lifestyle, aesthetic body sculpting has become much in demand [1]. Nowadays, a wide range of surgical invasive and noninvasive technologies are available to manage localized adiposity that constitutes a major source of dissatisfaction and decrease of self-esteem to many women and men [1, 2]. Presented as alternatives to surgery for body contouring and skin tightening with presumed decreased costs, risks and downtime, a number of noninvasive technologies have gained much popularity in recent years and are permeating the aesthetic marketplace [3–7]. There are currently four leading noninvasive techniques for reducing localized subcutaneous adipose tissue: low-level laser therapy (LLLT), cryolipolysis, radio frequency (RF) and high-intensity focused ultrasound (HIFU) [8]. These technologies deliver an external form of energy intended to cause necrosis or apoptosis of adipocytes [7, 9]. Being profitable procedures with little disposable costs, they are also attractive to many aesthetic medicine physicians as well as to plastic surgeons [7].

Nonlinear propagation of ultrasonic waves in tissues results in considerable mechanical stress and vibrates composite molecules to produce frictional heat [1, 10, 11, 13]. It increases tissue temperature above the upper limit of protein denaturation with resultant coagulative necrosis. Moreover, alternating compression and expansion of sound waves results in mechanical acoustic cavitation with subsequent cellular membrane rupture and leakage of triglyceride [1, 4, 12–14]. Ultrasound energy probably activates also a pro-inflammatory mechanism consisting of pyroptosis, cell swelling, and lysis. Pyroptosis is a cell death pathway mediated by activation of caspase-1, a protease that also activates the inflammatory cytokines IL-1β, and IL-18 [1].

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Several HIFU devices are currently available on the market for the treatment of localized fat, among which are Ultra 4D (Sculpt Pro Aesthetics, Manchester, UK), LIPOcel^{TM} (Jeisys Medical, Korea), Liposonix (Beijing VCA Laser Technology, Beijing China), and Artec EVA® (Artec Group, Luxembourg), just to name a few.

Ultrasound devices use different ranges of frequency: low frequency (40–60 kHz), medium frequency (300–500 kHz), and high frequency (0.75–3 MHz) [1]. At high frequencies, ultrasound energy is highly convergent. When focused at a targeted depth of 1.1 to 1.6 cm within subcutaneous tissue, HIFU energy raises local tissue temperature at the focal point resulting in almost immediate cell death without damage to the surrounding tissues [2, 4, 5, 11]. Macrophages are then recruited to the damaged area; cellular debris and extracellular lipids are subsequently engulfed and transported away from the zone of injury [4]. Most disrupted adipose tissue is resorbed within 8 to 12 weeks after treatment, and 95% is resorbed after 18 weeks [2]. The process of adipolysis is not associated with a systemic inflammatory response or significant alterations in serum lipid profiles, liver or renal functions, or hematologic changes [2, 11, 15]. At a frequency of 2–3 MHz, ultrasound waves result also in diffuse contraction of collagen fibers [16]. Being non-ionizing, ultrasound treatments can theoretically be applied repeatedly to achieve the desired effect [13].

Introduced in 1942 as a therapeutic modality, HIFU has been used for noninvasive ablation of benign and malignant solid organ tumors and to treat conditions such as kidney stones and glaucoma, avoiding the need for more aggressive surgical procedures. Only recently ultrasound energy has been applied for selective destruction of adipose tissue and contracting cutaneous collagen fibers [1, 3, 4, 13, 14, 17]. Teitelbaum et al. [18] were the first to describe circumference reduction after focused ultrasound treatment of the abdomen, thighs, and flanks. They reported a reduction of 2 cm in waist circumference (WC) and approximately 2.9 mm in skin fat thickness.

Despite having gained popularity, little information is available regarding HIFU use for the treatment of localized fat and aesthetic body sculpturing [1, 11, 19]. Moreover, quantitative analysis of adipose tissue response after HIFU treatment is still poorly understood [20]. Reported results have been also modest and mostly suboptimal. The current medical literature review is intended to investigate evidence-based efficacy of HIFU in aesthetic body contouring.

Material and Methods

A PubMed and Scopus literature search was conducted for "High-intensity focused ultrasound" separately and in combination with "body contouring", "fat reduction" and "lipolysis". Clinical and experimental studies and case reports evaluating efficacy and safety of HIFU as an aesthetic noninvasive technique were included. Reviews and studies about combination therapies or studies comparing various HIFU therapeutic strategies to other noninvasive technologies were excluded.

Results

"High-intensity focused ultrasound" "search" revealed 7221 publications in Scopus and 4011 in PubMed. When the combined searches were conducted, only 14 clinical (Table 1) and 6 experimental (Table 2) studies matching the inclusion criteria were retrieved. Of the clinical studies, one was a retrospective chart review to evaluate WC reduction [21] and one was a case report to evaluate skin-tightening effect of HIFU [22]. All others were prospective studies. Three manuscripts were about multiple conducted studies conducted by authors [15, 23, 24], one of which included an ex vivo thermal evaluation of HIFU on porcine abdominal adipose tissue [23]. Two were post-market studies [15, 25] and two were split-body studies, one comparing different HIFU protocols and the second assessing histologic changes in post-treatment excised abdominal flap [1, 26]. Two reports were from the same first author about the same multicenter clinical comparative study with a sham group published in two different journals [27, 28]. Eight clinical and two experimental studies were industry-funded, or one or more of their authors were consultants or clinical investigators to the industry.

The prospective study comparing two HIFU treatment protocols of Fonseca et al. demonstrated a reduction in fat layer thickness in both treatment groups measured by ultrasonography; however, despite their claim of improved body contouring they have failed to show any significant improvement in WC. Jewel et al. reported the only comparative sham-controlled multicenter randomized single-blinded clinical trial that was identified [28]. A total of 180 adult patients with subcutaneous abdominal fat greater than or equal to 2.5 cm thick were randomized in 3 groups. Fifty-nine patients received three passes of HIFU treatment of the anterior abdomen and flanks at total energy levels of 141 J/cm^2, 63 patients had total energy levels of 177 J/cm^2, and 58 patients constituted the sham control group with no energy applied. Statistically significant reduction in circumference versus sham was achieved for the high-energy

Table 1 Clinical studies: levels of evidence according to the American Society of Plastic Surgeons levels of evidence rating scale for therapeutic studies [49]

Author year	Design and follow-up	#	Anatom. location	Outcome	Level of evidence
Hong et al. 2020 [11]	Prospective; HIFU treatment at different energy levels; waist circumference, US, caliper, CT; FU 16 wk; not comparing treatment vs. no treatment	20	Abdomen, flanks	Waist circumference reduction 3.43 cm; the treatment effect is cumulative; fat thickness reduction by caliper; subcutaneous fat area showed no significant reduction by CT; 4 patients gained weight	IV
*Fonseca et al. 2018 [1]	Prospective; comparing 2 groups; G1 (6 patients: 6 sessions, 3 passes, once a week); G2 (23 patients: 10 sessions, 2 passes, twice a week); skinfold caliper, measuring tape, US, photographs, serology tests, satisfaction questionnaire; 1 patient had split-body treatment with histology; FU 15 d after last session	31	Rt lower abdomen. Lt was control	Improvement in body contouring and reduction of thickness of the fat layer observed by ultrasonography in both groups: G1 ($P < 0.001$) and G2 ($P < 0.0001$); no measurements given, no significant circumference difference	II
Lim et al. 2018 [35]	Long-term clinical outcome of HIFU lipolysis; GA: 26 completed 1–3 m FU, GB: 24 completed 12 m FU; 36 patients available for final analysis; not comparing treatment vs. no treatment	50	Abdomen, thighs	GA: circumference reduction at 3 months: abdomen 1.80 cm, thighs at 1 m 1,79–2.09 cm; single session of HIFU treatment maintained its effect up to 1 year	IV
Ko et al. 2017 [22]	2 case reports: evaluate efficacy and safety of HIFU for skin tightening; skin elasticity measured by Cutometer; 3 blinded dermatologists evaluated paired pre- and post-treatment (week 4 and 12) photographs; patients' self-assessment; FU 12 wk	32	Face, lower abdomen, thighs	Skin elasticity significantly improved; cheek demonstrated the greatest improvements after treatment; no serious adverse effects	IV
*Guth et al. 2017 [23]	Animal study and prospective none comparative pilot clinical study; immediate effect and safety of HIFU single treatment for male localized fat; caliper, circumference measurements, blood tests; FU 30 min	24	Swine skin abdomen	Ex vivo T measurement at the local area of application of HIFU in swine tissue	IV
				No significant difference in skinfold and abdominal circumference of supraumbilical and umbilical areas; 0.6% decrease in infraumbilical circumference; 25% increase in number of segmented neutrophils	
Otto et al. 2016 [30]	Open-label, none comparative single-arm exploratory study; photographs, caliper, measurement, US; FU 3 m	21	Abdomen	87.5% of pre-treatment photographs correctly rated by two independent blinded reviewers; reduction in abdominal circumference 3.3 cm observed at 3 m	IV
Robinson et al. 2014 [15]	2 randomized post-market multicenter studies; 1 HIFU treatment with 1 of 5 treatment protocols; FU 12 wk; not comparing treatment vs. no treatment	118	Abdomen, flanks	All subjects had significant mean circumferential reduction of 2.3 6 cm from baseline at 12 weeks, with no significant differences among the 5 treatment groups	II
Sheket al. 2014 [4]	Prospective; effectiveness of a HIFU device for sculpting the abdomen; waist circumference, photographs, questionnaire; FU 12 wk	12	Abdomen	Seven out of 12 subjects were satisfied; average circumferential decrease was 2.1 cm at 12 wk; average pain score associated with the procedure was 5.7 at a scale of 0–10	IV
*Shalom et al. 2013 [26]	Single-blind pilot split-body study; patients scheduled to undergo abdominoplasty within 4 weeks after receiving HIFU lipolysis on one side; blood tests, and urine analysis performed 1, 3, 7, 14, and 28 days after treatment. Excised tissue sent for histologic review	6	Abdomen	No major adverse events and laboratory analysis; fat necrosis with infiltration of lymphocytes and macrophages without adjacent tissue damage on histology	III
*Jewel et al. 2012 [27]	Prospective; randomized, sham-controlled, single-blind trial of the safety and tolerability of an HIFU device; US, blood samples, verbal pain assessment scale; efficacy assessed at 12 wk, and safety at 24 wk	180		Most common adverse events were post-procedure pain, ecchymosis, and swelling; during 24 wk of FU, there were no meaningful changes or trends from baseline in lipid panel findings, liver function, renal function, or inflammatory markers	II

Table 1 continued

Author year	Design and follow-up	#	Anatom. location	Outcome	Level of evidence
*Solish N, et al. 2012 [25]	Prospective; randomized, single-blind post-marketing surveillance study of various HIFU settings; waist circumference; patient rating, safety, and pain assessment; not comparing treatment vs. no treatment	45	Abdomen flanks	Waist circumference decreased by 2.51 cm; 69% to 86% of patients and 73% to 79% of investigators rated appearance as improved	II
*Gadsden et al. 2011 [24]	3 prospective clinical studies; treated with HIFU, including patients for elective abdominoplasty performed up to 14 weeks following HIFU procedure; histology of excised specimens, Safety evaluations: chemistry and hematology profiles, physical examinations, adverse events; not comparing treatment vs. no treatment	152	Abdomen	17 had abdominoplasty; histopathology: well-demarcated disruption of adipocytes, phagocytosis of released lipids and cellular debris after 14 to 28 d; HIFU effects were limited to targeted layers; healing 95% complete after 8–14 wk	IV
*Jewel et al. 2011 [28]	Multicenter, randomized, sham-controlled, single-blind trial; participants assigned randomly to receive 3 passes of different doses of HIFU; waist circumference, satisfaction survey, blood samples; FU 12 wk	180	Abdomen, flanks	Statistical significance waist reduction (small change) versus sham was achieved for the high energy treatment group; patient satisfaction also favored each active treatment versus sham;	II
*Fatemi et al. 2010 [21]	Retrospective chart review; 1 treatment session, serology in 10 patients, survey in 50 randomly selected; FU 3 m; not comparing treatment vs. no treatment	85	Abdomen, flanks	Waist circumference decreased by 4.6 cm; 11.8% adverse events, 70% satisfied	IV

*Authors are paid consultants or clinical investigators, or study funded by industry

treatment group (− 2.52 cm vs − 1.21 cm; p 0.002) but not for the lower energy group. Interestingly in this study, a reduction of − 1.21 cm in circumference was observed in the sham group. The net improvement that can be attributable to the high-energy treatment would thus be only − 1.31 cm.

Experimental studies were mostly descriptive intended primarily to demonstrate thermal damage induced by HIFU and the physiologic response with timeline histologic evaluation. Major focus of most clinical studies was more on HIFU safety rather than effectiveness in body contouring. Safety end points included lipids and liver function profiles, evaluation of potential complications, as well as assessment of pain and patients' comfort. The primary efficacy end point was circumference measurement. Secondary end points included skinfold caliper measurements of fat thickness, ultrasound analysis of fat layer thickness, digital photographs, patients' satisfaction, and self and investigator outcome evaluation; in few studies where excised tissue was available following surgery, histology evaluation was also made.

HIFU clinical application was mainly for abdomen and flank contouring. Reported mean WC reduction was around 2–5 cm [2, 11, 15, 19, 25, 29]. In some studies, however, quantitative measurements were not indicated; reduction in WC was reported as statistically significant or as a percentage change from the initial measurement [23, 27]. Information about subcutaneous fat layer measurement was available in only two reports [1, 11]. Fonseca et al. [21] described a significant reduction in fat layer thickness without providing quantitative measurements. Hong et al. [11] demonstrated 5 mm reduction in fat thickness measured with calipers, while Otto et al. [30] did not report any results despite measuring skin and fat layer thickness at all study visits using an ultrasound scanner. No clear information about fat layer thickness reduction was available as well from other studies despite routine pinch caliper measurements.

Discussion

Standard HIFU at high-frequency acoustic energy (2 MHz) treatment protocol for localized fat excess starts by demarcating the treatment area using a template with treatment dots marked usually in a 2.8 cm × 2.8 cm grid pattern [1, 4, 25, 28]. HIFU energy is delivered to an adjusted predetermined depth dictated by thickness of the adipose tissue. It rapidly raises adipose temperature to above 55C°. Various total energy delivery protocols have been described; the final result depends on the total fluence delivered regardless of the number of passes, provided there is no excessive overlap of treatment locations [4, 21, 24]. Thermal tissue damage occurs at the focal point and the volume of the focal region (thermal zone) undergoing lipolysis is estimated to be 1 cm^3 [1, 24]. Thermal

Table 2 Experimental studies: levels of evidence based on rating scale of Ackley et al. [50]

Author year	Design and follow-up	#	Outcome	Level of evidence
Gupta et al. 2018 [45]	Numerical investigation of the thermal response of tissue-mimicking biological phantom(s) subjected to high-intensity focused ultrasound (HIFU); simulations performed on the 3D physical domain for two-layered as well as multilayered medium of water and liver tissue	N/A	Temperature at the focal region increases with an increase in the transducer frequency; presence of fat and muscle layers in multilayered tissue phantoms result into a clear shift in the focal spot of pressure waves	VI
Lee et al. 2017 [12]	Immediate tissue reactions induced by focused HIFU via two-dimensional ultrasound images and histologic evaluation of cadaveric skin from the abdomen and thigh	N/A	Round-to-oval ablative thermal injury zones (TIZs) occur in subcutaneous fat layers; tumescent infiltration-like setting induces larger HIFU-induced TIZs	VI
*Kwon et al. 2016 [46]	To develop evaluation methods for HIFU for nonsurgical, permanent fat reduction in the anterior abdomen using a porcine model; photography, ultrasound, gross and microscopic pathology, and serum lipid and liver function level analysis, carbon tracer test	7,6,1	HIFU treatment effectively reduces abdominal fat; it accurately treats the target subcutaneous fat layer	VI
Pyo et al. 2016 [20]	Porcine fat tissue was used to verify thermo-mechanical responses as well as to emulate HIFU-assisted lipolysis. After acoustic treatments, all samples were cross-sectioned and photographed for quantitative evaluations. Treated porcine tissue was assessed histologically	N/A	Shorter focal length could cover a wider range of adipose tissue during HIFU treatments; histology analysis confirmed that the HIFU-treated regions underwent irreversible denaturation due to temperature reaching the melting point of the adipose tissue (30 $\sim$ 32)	VI
Weiss et al. 2012 [47]	To demonstrate in the porcine model that selective heating of fat is possible with a noncontact, operator-independent device; 4 treatments of a total of 30 min each; T of epidermis adipose tissue measured by thermocouple; US, biopsy needle before treatment, after the first treatment, after 2nd, 4th treatment and 3 m after last treatment	3	Gross and microscopic histologic marked reduction in adipocytes, with incremental fat diminution after each treatment; 70% reduction of abdominal fat layer; histologic evaluation: epidermis, dermis, and adnexal structures unaffected, while adipocytes are significantly affected; average adipose layer thickness reduction by ultrasound 6.9 mm	VI
*Jewel et al. 2011 [48]	Series of preclinical studies performed in a validated porcine model; in vivo HIFU treatment of abdominal subcutaneous adipose tissue; thermocouple temperature data, full-body necropsy, local pathology and histology studies, clinical hematology, urinalysis, and blood chemistry parameters	7,8,2,3,8	Tissue T approaching 70 °C, restricted to focal area; no clinically significant changes in serum liver function, free fatty acids, or cholesterol; no evidence of fat emboli or accumulation; preserved vasculature and nerve fibers within HIFU focal area; normal healing response migration of macrophages into damaged tissue and removal of disrupted cellular debris and lipids	VI

*Authors are paid consultants or clinical investigators, or study funded by industry

HIFU effect does not result in a uniform layer of damage; it rather results in pinpoint dots of injury like a quilt.

While the efficacy of HIFU in producing targeted tissue damage has been largely demonstrated and confirmed by histologic studies and is not in question, its efficacy in body contouring remains in doubt. Change from baseline circumference is the reported primary effectiveness end point of all HIFU clinical studies. Waist circumference (WC) and waist-to-hip ratio (WHR) are widely accepted anthropometric parameters for assessing and classifying abdominal obesity. However, with the lack of clear standardization, measuring these parameters can be highly inaccurate, as it requires specific manipulation [31, 32]. Training reduces only slightly circumference measurement errors that can be particularly high in overweight and obese patients due to difficulty in locating anatomical landmarks [31–33]. In defining central obesity, the lack of measurement accuracy results in misclassification of individuals by 6% when using WC measurements and 23% when using WHR determination [34].

Certain guidelines for circumference measurements have been proposed to reduce inaccuracy and margin of error. Measurements of WC, for example, should be performed in the morning after fasting for at least 8 h at well-described levels; individuals must remove their shoes and, with the arms to the sides, the measuring tape is placed

horizontally parallel to the floor with sufficient tension to avoid slipping off but without compressing the skin; measurements are also made twice to the nearest 1 mm at the end of a normal expiration; if the difference between the two recorded measurements is greater than 5 mm, a third measurement should be taken, and the mean of the two nearest values is recorded [31, 34].

Abdominal circumference measurements reported in the clinical studies of this review were not made uniformly by all researchers as recommended. Fonseca et al. [1] indicated using a flexible measuring tape at the mid-level between the lower rib margin and the iliac crest, while Guth et al. [23] made these measurements at the level of the umbilicus as well as 5 cm above and 5 cm below it 30 min before and after treatment and thereafter during follow-up visits. For their part, Hong et al. [11], and Solish et al. [25], asked their patients to fast for 3–4 h before presentation; in order to increase reproducibility and reliability, a single researcher made the measurements throughout the entire study period. Solish et al. [25] aligned markings with the plate of a wall-mounted measuring stick and made measurements with a calibrated, spring-loaded tape measure provided by the sponsor. Otto [30] and Jewell et al. [28] indicated that a validated technique regarding patient positioning, posture, height, dress, and breathing was applied to make WC measurement but did not indicate whether measurements were made by a single or many researchers. Otto described as well recording the distance of the anatomical areas at which measurements were made from a fixed point on the wall to ensure consistency at each follow-up visit. Moreover, to assure that the tension-controlled tape was placed horizontally, a laser system projecting a perpendicular beam was used. For Robinson et al. [15] two sets of measurements were made at the level of the largest waist circumference with the patients in the standing position and arms crossed and hands tucked under the axillae; patients were instructed to relax their abdominal muscles, exhale, and hold their exhalation throughout each measurement. Shek et al. [4], on the other hand, trained technicians to measure with standard patients' posture, position, and breathing; with a special tape designed to have consistent tension, WC measurement was made at two pre-determined sites by the primary investigator (at the iliac crest and point of maximum WC). To secure making follow-up measurements consistently, measured sites were recorded on a clear plastic sheet with reference to anatomical landmarks. Others, however, have omitted mentioning details about their measuring technique [35]. Reliable consistent measurements are obviously lacking. Due to shortcomings of clinical measurements with measuring tapes, techniques providing high-quality representation of the human body surface with optical three-dimensional (3D) scanners and noninvasive digital anthropometry would be more valuable in accurately assessing the effect of HIFU therapy and in evaluating patients outcome [36–38]. This new technology provides an objective and reproducible source for the detection of body shape changes [38]; its use in research and in clinical practice is on the rise particularly since bulky and costly 3D body scanners of the last decade have been replaced by inexpensive, accurate, and easy-to-use devices [38, 39].

Despite routine caliper measurements, a reduction in fat layer thickness as a secondary efficacy end point was reported in only two clinical studies. Fonseca et al. [1] documented a significant reduction ($P < 0.001$) in the thickness of the fat layer confirmed by ultrasound measurement analysis ($P < 0.001$) but they did not provide quantitative measurements. Fat thickness measured by Hong et al. [11] showed a 5 mm reduction which they have qualified as significant: 34.32 mm at baseline; 30.26 at week 8; and 29.32 mm at week 16. Though "Pinching force" variations may contribute significantly to measuring errors [40], it has been reported that body fat can be estimated with similar accuracy by either skinfold caliper or ultrasound imaging; nevertheless, actual subcutaneous fat thickness is best estimated by ultrasound considered to be more accurate, reproducible and sensitive [41, 42]. Interestingly in the study of Hong et al. [1], in contrast to their reported reduction of WC and fat thickness, CT imaging did not demonstrate any significant reduction in fat layer thickness. Moreover, their assumption that small changes in depth can make a big difference in circumference is not substantiated nor justified.

Though investigators and researchers usually instruct patients to maintain their diet and exercise regimens constant during the study period, weight change is another source of inaccuracy in determining changes in circumference and fat layer thickness. It may be impossible to regulate patients' lifestyle during a study period of 12 weeks [6]. Data from the multicenter, randomized, sham-controlled, single-blinded trial of 180 patients reported by Jewel et al. [27] documented a decrease in waist circumference at 12 weeks of 2.52 cm in the study group as well as a decrease in the sham control group of 1.21 cm. Once treated with a device or enrolled in a study protocol, patients' subconscious changes in diet, activity, and lifestyle seems to be almost inevitable [6].

Global Aesthetic Improvement Scale (GAIS) was also a standard tool for evaluating HIFU efficacy in most clinical studies with reported 68–86% improved or much improved waist or thigh profile at week 12. Though subjective scales are important for assessing the success of cosmetic procedures, patient self-rating scores and patient satisfaction surveys cannot constitute a highly satisfactory objective proof of efficacy. Patient expectations play an important role in their assessment of treatment results [43]. In the

study conducted by Jewell et al. [28], 68.4% of the subjects that received the higher-energy treatment rated the outcome in WC reduction at 12 weeks as improved or much improved, similar to 23.4% of the sham group subjects in whom the placebo effect may have subconsciously affected their judgment. Investigators' GAIS ratings are even a lesser proof of efficacy. Besides obvious bias, a 1 cm or greater change in WC that most body contouring surgeons if not all would consider as none significant, was rated improved or much improved by Solish et al. [25]. Current healthcare environment demands high-quality data to guide decision-making and patient education; the use of subjective scales and hoc questionnaires is simply no longer acceptable and practitioners should be cautious about studies utilizing generic questionnaires and highly subjective rating scales to measure outcomes of innovative treatment modalities [44].

Regardless of heterogeneity of the clinical studies reviewed and questionable outcome measurement tools, circumference and fat layer thickness reduction reported by all was at best modest [14]. Guth et al. [23] observed 0.6% infra-umbilical circumference reduction in subjects submitted to HIFU single treatment when compared with control subjects. Validity of estimating such modest outcome with inaccurate measuring tools possessing a substantial margin of error should be highly questionable. Establishing standard methods of assessment that can provide accurate and reproducible results is a major challenge for the evaluation of any noninvasive body contouring treatment [6]. Except with highly objective, accurate, and standardized measurement tools with a margin of errors significantly less than the improvements being evaluated, such measurements remain highly questionable and cannot be considered significant as claimed.

Conclusion

HIFU seems to be a safe treatment option for reducing subcutaneous adipose tissue with self-reported patient's satisfaction of 47 to 86% [14]. Treatment is generally well tolerated by the majority of patients with reported mild side effects and pain during treatment as well as temporary erythema and edema with mild ecchymosis after treatment [21]. However, while effective, available most optimistic clinical outcome, even from industry-sponsored studies, suggests that its effects on aesthetic body contouring are at best mild to moderate [14].

Unfortunately, interest in promoting HIFU favorable outcomes has outpaced the development of validated reliable tools to measure objectively treatment results. Published pre- and post-treatment photographs are not very convincing, despite some visual evidence of mild fat reduction and statistically significant reported reduction in circumference and subcutaneous fat layer thickness [1, 4, 11, 15, 21]. The technique may be an option for nonobese patients who seek a minimal reduction of focal fat accumulation [11] but certainly is not as advertised an alterative to surgical body contouring in patients for whom a more optimal outcome would be desirable. Whether offering patients a 45-min office treatment, with 7 to 10 days of mild discomfort and up to 16 days of edema and bruising, to achieve a decrease in WC of a little more than a centimeter is really worthwhile should be seriously considered [6]. It is not clear how this modest efficacy can fit into an aesthetic plastic surgery practice [6]. Facing the multitude of novel market-driven aesthetic procedures, discussions guided by reliable outcome and complications data are certainly needed for patient education as well as for informed decision-making. Irrespective of the fierce competition by none plastic surgeons, developing an evidence-based practice is now more than a necessity to maintain the integrity, the sustainability, and the development of our profession.

Compliance with Ethical Standards

Conflicts of interest The authors declare that they have no conflicts of interest.

Human and Animal Rights This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent For this type of study, informed consent is not required.

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