Effectiveness of HIFU Therapy for Nonsurgical Facial and Body Contouring: A Systematic Review of Prospective and Experimental Studies

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Background: Liposuction, the most common body sculpting surgical procedure known today is associated with the risk of numerous complications. A safer and more noninvasive approach involves the use of high-intensity focused ultrasonography (HIFU) lasers, which work by selectively damaging fat tissue through apoptosis or necrosis induction of fat cells. The authors' systematic review was designed to identify the effectiveness of HIFU for nonsurgical facial and body contouring.

Methods: An exhaustive literature search was conducted of the PubMed/MEDLINE, Cochrane Central, Scopus, and EBSCO electronic databases for the period from November of 2005 to July of 2020. The full text of selected articles was reviewed for possible study inclusion, and articles fulfilling the inclusion criteria were recruited. Characteristics of the included studies were noted, and outcomes were assessed. Assessment of quality and risk of bias was performed for all the studies using the RevMan tool and the methodological index for nonrandomized studies.

Results: The initial search revealed a total of 4584 citations, of which only 11 were included in the present review: nine used HIFU for recontouring of the abdomen and only two used HIFU over the face and neck. Studies evaluated either the efficacy of HIFU or the safety of its use. The average total energy ranged from 140 to 248 J/cm^2 for the abdominal region and 0.3 to 1.2 J/cm^2 for the face and neck. The focal depth ranged from 1.1 to 1.8 cm. All the studies showed promising results with the use of HIFU.

Conclusion: HIFU therapy is safe, effective, and minimally invasive, with predictable results when used for body and facial recontouring. *(Plast. Reconstr. Surg.* 151: 533, 2023.)

Today's superscrutinizing high-definition cameras, the pressure of self-representation on various social media platforms, and the pursuit of perfect body and face since the very genesis of mankind have increased the demand for body sculpting and contouring. With "image" being the currency and language of the contemporary world, numerous medical procedures have been developed for body contouring or sculpting. They have gained popularity not necessarily in a quest to abide to the societal beauty standards but also because these are perceived as tools for enhancement of one's self-confidence.

Body sculpting consists of procedures and methodologies to optimize the smoothness, definition, or silhouette of the human physique, particularly the torso, by means of diet and exercise or medical interventions.[1] For many years, the

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most common medical procedure has been liposuction. This surgical procedure basically entails the removal of focal or large volumes of subcutaneous fat. Although it effectively removes large amounts of excessive and unwanted fat, liposuction, like any other surgical procedure, comes with some complications, such as significant recovery time, postsurgical pain, infection, scarring, deep vein thrombosis, and anesthesia-related adverse effects. In addition to these complications, high procedural costs and extensive recovery time make liposuction a not-so-appealing option for nonobese patients with only focal adiposity.[2]

To overcome these shortcomings, several noninvasive methods are being adopted. Advancements in liposuction techniques have been made which, though popular, remain questionable on the grounds of safety and efficacy.[3–5] Several methods have been developed using technologies such as cryolipolysis, radiofrequency ablation, low-level external laser therapy, injection lipolysis, low-intensity and low-frequency nonthermal ultrasonography, and high-intensity focused ultrasonography (HIFU) lasers, which work on the principle of selectively damaging fat tissue through apoptosis or necrosis induction of fat cells.[6,7]

HIFU is a noninvasive body contouring technique wherein the local temperature is raised above 56°C within the targeted subcutaneous layer. Coagulative necrosis and cell death is induced in the unwanted adipose tissue, and the intervening papillary dermal and epidermal layers of skin remain unaffected. When heat is applied at the discrete thermal coagulation points, collagen fibers in the facial planes, such as the superficial muscular aponeurotic system, platysma, and the deep reticular dermis, are denatured and contract further, stimulating de novo collagen.[1]

Nonthermal effects can also be exerted, leading to fat cell lysis without any effects to the surrounding tissues. Shemer and colleagues, using these very principles, reported noninvasive size reduction of lipoma by means of HIFU treatment. It was revealed in a study conducted recently that the fibrous layer contracts because of thermal denaturation after HIFU treatment.[8–10] After the HIFU treatment, a healing response is induced by the necrosed cells wherein macrophages and other cells are attracted. The macrophages then engulf and transport lipids and cellular debris away from the treated area. A majority of the destroyed adipocytes are resorbed within 12 weeks after treatment, and 95% are resorbed after 18 weeks. It is the reabsorption that then results in an overall reduction in local fat volume. There is no significant increase in plasma lipids because of these changes. The wound healing cascade further attracts the inflammatory cells, followed by fibroblast induction. In addition to this collagen denaturation by heat, new collagen formation also results, which is followed by tightening of septal fibers and skin. Possible adverse effects are sensations of prickling, tingling, warmth, heat, discomfort, or pain during treatment; and temporary erythema, ecchymosis, discomfort, paresthesia, and edema after treatment.[11]

Despite HIFU being a topic of great clinical significance in the present aesthetic-driven age, a comprehensive literature search revealed the absence of exploration of the HIFU treatment modality through a systematic review, which would help conceptualize and consolidate the data available on this modality, which is of great significance in the domain of plastic surgery. This systematic review deployed standard experimental and prospective study designs to elucidate the effectiveness, efficacy, safety, and tolerability of HIFU for nonsurgical facial and body contouring by assessing the total energy, focal depth, and site at which the procedure was performed.

MATERIALS AND METHODS

The focused research question was addressed by the implementation of a systematic review. It was designed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-E 2012 checklist,[12] matching global standards of reporting a systematic review. It was registered in the International Prospective Register of Systematic Reviews portal.

Search Strategy

An electronic literature search using the PubMed/MEDLINE, Cochrane Central, Scopus, and EBSCO online databases was conducted from November of 2005 to July of 2020. Free-text words and Medical Subject Headings (MeSH) terms were used, consisting of "extracorporeal shockwave therapy," "extracorporeal," "ultrasound," "high intensity ultrasound," "high intensity focused ultrasound," "face sculpting," and "body contouring": ((((("extracorporeal shockwave therapy"[MeSH Terms] OR (("extracorporeal"[All Fields] AND "shockwave"[All Fields]) AND "therapy"[All Fields])) OR "extracorporeal shockwave therapy"[All Fields]) OR ((((("high"[All Fields]

AND "intensity"[All Fields]) AND "focused"[All Fields]) AND "ultrasound"[All Fields]) AND "therapy"[All Fields])) OR "high intensity focused ultrasound therapy"[All Fields]) OR (("face"[MeSH Terms] OR "face"[All Fields]) AND (("body contouring"[MeSH Terms] OR ("body"[All Fields] AND "contouring"[All Fields])) OR "body contouring"[All Fields])).

The title screening was conducted for the articles identified followed by the abstract and keyword screening for the relevant articles. The articles that were shortlisted for possible inclusion were subjected to full-text screening. The full texts were read, and the final inclusion of studies was carried out according to inclusion and exclusion criteria.

Only full-text articles in the English language were considered. An attempt was made to discern any unpublished studies and to contact the authors of published studies for additional information. References of the included studies were also searched to identify any relevant study for possible inclusion in the review. All the screenings were performed by two independent reviewers. In cases when consensus was not reached, a third reviewer was approached for final determination for inclusion of the study.

Inclusion Criteria

The inclusion criteria were in tandem with the standardized participants, intervention, comparator control, main outcome, strategy, and study design amplified and described in Table 1.

Exclusion Criteria

Case reports, abstracts, technical reports, laboratory/in vitro studies, opinions, and review studies were excluded.

Risk of Bias and Quality Assessment in Individual Studies

Basic Screening of Articles

Each study was checked through a critical evaluation procedure for its internal and external validity. Only articles with good and fair internal and external validity were considered. In addition, the template for intervention description and replication checklist[13] and guide along with the Standard Protocol Items: Recommendations for Interventional Trials statement[14] and the Consolidated Standards of Reporting Trials 2010 guidelines[15] were followed to critically appraise each article, depending on its experimental design nature.

Specific and Targeted Assessment of Risk of Bias

The Cochrane RevMan 5 software (Version 5.4)[16] was deployed to assess the risk of bias in randomized controlled trial study designs. The standard seven-point parameters in this tool included checking for random sequence generation, allocation concealment, blinding of participants, blinding of outcome, attrition bias, reporting bias, and other biases. For nonrandomized/uncontrolled trials, the methodological index for nonrandomized studies (MINORS) scale[17] and ROBINS-I tool[18] were used to assess the risk of bias.

Assessment of Heterogeneity

Heterogeneity was discerned by computing I^2 values, which yielded a considerably high level of heterogeneity in the collated data ($I = 0.92$). In lieu of this inconsistency, a meta-analysis was not carried out further.

RESULTS

The study screening process in accordance with the Preferred Reporting Items for Systematic

Table 1. PICOS Strategy for Evaluating the Scientific Evidence

Letter	Meaning	Definition
P	Participants/population	Inclusion: Healthy adults who have HIFU therapy irrespective of the sample size of the study Exclusion: Adolescents (younger than 18 yr) and older people (older than 70 yr); patients having active local infections or skin diseases that might alter wound healing, keloidal scars, and acne; those with significant ptotic skin or subcutaneous fat or history of undergoing any recent ablated or nonablative skin procedures/operations were also excluded
I	Intervention(s)	HIFU therapy for nonsurgical facial and body contouring
C	Comparator(s)/control	None
O	Main outcome(s)	To assess the effectiveness of HIFU therapy to reduce subcutaneous fat through targeted skin tightening and improvement in the general appearance of the face and body
S	Study design	This systematic review considered only those studies that had an experimental study design (randomized controlled trials/nonrandomized trials/quasi-trials/single-arm interventions)

PICOS, participants, intervention, comparator control, main outcome, strategy, and study design.

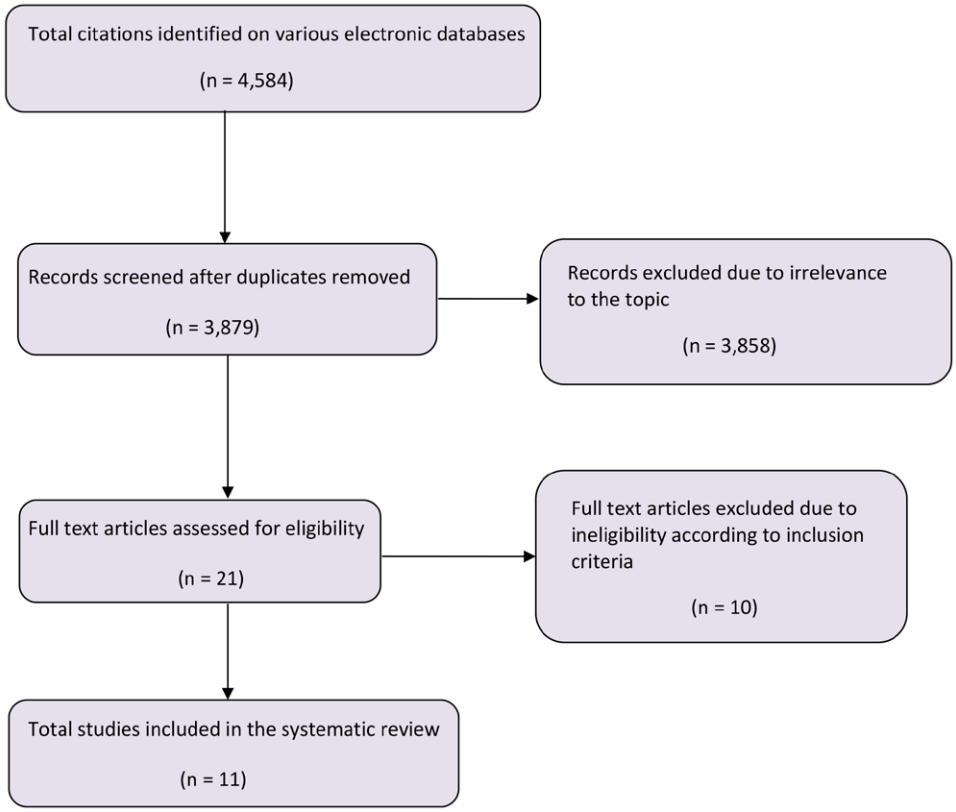

Fig. 1. Study selection process.

Reviews and Meta-Analyses flowchart is presented in Figure 1. Following an exhaustive literature search of the aforementioned electronic databases, a total of 4584 citations were obtained. After removing the duplicates, 3879 citations underwent initial review for possible inclusion in the study. Of these, 21 citations were selected for full-text review, which led to further exclusion of 10 articles. The characteristics of these included studies[1,2,11,19–26] are exhibited in Table 2. After exclusion, 11 studies[8,27–35] were found to be eligible for inclusion in the systematic review. Table 3 highlights the excluded studies and the reason for their exclusion.

Characteristics of Included Studies

Of the 11 studies recruited in this systematic review, in nine studies, the site for HIFU was the abdomen and only two studies used HIFU over the face and neck. Six studies were controlled trials and the remaining five studies were single-arm studies. Studies evaluated either the efficacy of HIFU or the safety of its use. Two studies evaluated both parameters. The average total energy ranged from 140 to 248 J/cm^2 for the abdominal region and 0.3 to 1.2 J/cm^2 for the face and neck. The focal depth ranged from 1.1 to 1.8 cm among the included studies. The characteristics of the included studies are presented in Table 1.[1,2,11,19–26]

Patient Satisfaction

Six of 11 studies evaluated patient satisfaction following treatment apart from the efficacy and safety of the treatment. Both studies on the facial region evaluated patient satisfaction.[24,26] Shome et al.[24] used a subjective assessment scale at 6 months and Aşiran Serdar et al.[26] performed assessment at 3 months after treatment for each area. The patients scored their satisfaction on a scale of 1 to 4, ranging from not satisfied to very satisfied.

Of the other nine studies focusing on the abdominal region, only four evaluated patient satisfaction following treatment. Solish et al.[21] and Robinson et al.[22] used the Global Aesthetic Improvement Scale to evaluate subject-assessed clinical improvement. Apart from the Global Aesthetic Improvement Scale, Robinson et al.[22] also used the Likert scale to evaluate satisfaction. Shek et al.[23] did not report the method of evaluating patient satisfaction. Jewell et al.[1] performed a

Table 2. Characteristics of the Individual Included Studies

Reference	Sample Size	Mean Age (yr)	Site	Parameters	Follow-Up	Outcome
Fatemi, 2009[11]	282	41.3 yr	Abdomen	Total energy: 140 J/cm² Focal depth: 1.1–1.8 cm	3 mo	Waist circumference decreased by an average of 4.7 cm
Gadsden et al., 2011[19]	G1: 33 G2: 50 G3: 43	36 yr	Abdomen	Total energy: G1: 166–210 J/cm² G2: 118–248 J/cm² G3: 141 J/cm² Focal depth: 1.1–1.8 cm	Not specific	No significant changes in laboratory tests and physical assessment; histology studies revealed normal healing
Jewell et al., 2011[1]	G1: 63 G2: 59 G3: 58	42.1 yr	Abdomen	Total energy: G1: 177 J/cm² G2: 141 J/cm² G3: 0 J/cm²	12 wk	Statistically significant reduction in waist circumference in both the study groups compared to controlled group
Jewell et al., 2012[20]	G1: 63 G2: 59 G3: 58	41.1–42.8 yr	Abdomen	Total energy: G1: 177 J/cm² G2: 141 J/cm² G3: 0 J/cm² Focal depth: 1.3 cm	24 wk	No significant changes in laboratory tests and physical assessment
Solish et al., 2012[21]	G1: 14 G2: 16 G3: 15	42–44 yr	Abdomen	Total energy: G1: 141 J/cm² G2: 156 J/cm² G3: 177 J/cm²	12 wk	Waist circumference decreased by an average of 2.51 cm
Robinson et al., 2014[22]	G1: 29 G2: 29 G3: 30 G4: 14 G5: 14	45.2 yr	Abdomen	Total energy: 150–180 J/cm² GR: 1 pass each site, then second pass and so on SR: all passes at one site then going to next site G1: GR, 30 J/cm² (5 passes) G2: GR, 30 J/cm² (6 passes) G3: SR, 30 J/cm² (5 passes) G4: GR, 60 J/cm² (3 passes) G5: SR, 60 J/cm² (3 passes)	12 wk	Waist circumference decreased by an average of 2.3 ± 2.9 cm
Shek et al., 2014[23]	12	39.5 yr	Abdomen	Total energy: 150 J/cm² Focal depth: 1.3 cm	12 wk	Waist circumference decreased by an average of 2.1 cm
Guth et al., 2018[2]	G1: 12 G2: 12	18–59 yr	Infra-abdomen	G1: Received HIFU, parameters not specified G2: Did not receive HIFU	30 min	Infraumbilical circumference showed a significant decrease of 0.6%; laboratory parameters did not present any appreciable changes
Shome et al., 2019[24]	50	25–55 yr	Face and neck	Total energy: Forehead: 0.3–0.35 J Malar: 0.35 J Temple: 0.35 J Cheeks: 1.2 J Submental area: 0.45 J	6 mo	Statistically significant improvements were reported objectively and subjectively
Hong et al., 2019[25]	20	35.80 ± 10.36 yr	Abdomen	Total energy: First session: 150 J/cm² Second session: 135 J/cm² Focal depth: 1.3 cm	16 wk	Waist circumference decreased by an average of 3.43 cm; no significant changes in physical assessment
Aşiran Serdar et al., 2019[26]	75	37–75 yr	Face and neck	Two different transducers were used *First:* Total energy: 1.2 J/cm² Focal depth: 4.5 mm *Second:* Total Energy: 0.3 J/cm² Focal depth: 3 mm	3 mo	The rate of improvement in each area was more than 80% according to the physicians' assessment, whereas patient satisfaction degree in each area was over 78%

G1, group 1; G2, group 2; G3, group 3; GR, grid repeat; SR, site repeat.

Table 3. List of Excluded Studies

Reference	Reason for Exclusion
Ascher, 2010[27] Coleman et al., 2017[8] Fonseca et al.,2018[28]	High-intensity microfocused ultrasound therapy was not used in the study
Katz et al., 2019[29]	High-intensity focused electromagnetic field device was used in the study
Moreno-Moraga et al., 2007[30]	High-intensity microfocused ultrasound therapy was not used in the study
Shek et al., 2009[31]	
Shek et al., 2016[32]	Nonthermal focused ultrasound and radiofrequency device was used in the study
Teitelbaum et al., 2007[33]	High-intensity microfocused ultrasound therapy was not used in the study
Tonucci et al., 2014[34]	Low-intensity ultrasound device was used
Wilkerson et al., 2018[35]	High-intensity microfocused ultrasound therapy was not used in the study

patient satisfaction survey with components such as rating their perceived improvement with the flatness of the abdomen, likeliness to pursue additional treatment, and general satisfaction with the results. Overall satisfaction was calculated as the mean of the three item scores.

Safety and Complications

A few studies carried out laboratory tests and/or histopathologic examination of the excised HIFU-treated tissue to evaluate the safety of the HIFU treatment. They found that HIFU is a safe treatment modality for body contouring.

Fatemi[11] used HIFU in patients before abdominoplasty. Following abdominoplasty, the tissue was examined histopathologically to identify cellular and collagen reaction after HIFU. Histopathologic examination showed that adipocytes will collapse membrane but no visibly damaged cells. It also revealed that the wound healing response was seen in the tissues 2 weeks following treatment. Gadsden et al.[19] also carried out histology examination of the excised tissues following HIFU and abdominoplasty. They found that the lesions were of consistent size and character, located at the predetermined focal depth, and did not extend into the skin or fascia. There was no evidence of calcification, fat necrosis, or infection. The resolution of lesions produced by HIFU treatment was consistent with normal healing processes.

Gadsden et al.[19] carried out laboratory tests for the patients, including clinical chemistry and

Table 4. Complications Observed in the Included Studies

Reference	Complications
Fatemi, 2009[11]	38 (13.5%) reported one or more adverse events, including prolonged tenderness after treatment ($n = 10$), edema ($n = 6$), hard lumps ($n = 3$), significant ecchymosis ($n = 28$), and significant pain during treatment ($n = 5$); however, all the events were temporary
Gadsden et al., 2011[19]	A total of 703 adverse events were reported by 152 HIFU-treated patients; all events were temporary, and all resolved spontaneously; three reported serious adverse event occurrences (anemia, appendicitis, and pulmonary thromboembolism) were determined by the investigator to be unrelated to treatment with the HIFU device
Jewell et al., 2011[1]	The most common treatment-emergent adverse events were pain, bruising, and edema; all pain resolved within 7–10 days; bruising and edema resolved within 12–14 days and 13–16 days, respectively, and were almost exclusively mild to moderate in intensity; there were no unanticipated adverse events or unanticipated adverse device events; two serious adverse events (ie, pneumonia and breast cancer) were reported, but neither was considered by the investigator to be related to treatment
Jewell et al., 2012[20]	The most common adverse events deemed related to treatment were procedural pain, postprocedure pain, ecchymosis, and swelling; all pain resolved within 7–10 days after the procedure; bruising and edema resolved within 12–14 days and 13–16 days, respectively
Solish et al., 2012[21]	A majority of patients reported moderate pain, mild or transient abdominal bruising or redness; there were no serious adverse events or unanticipated adverse device effects
Robinson et al., 2014[22]	During the course of the study, there were no unanticipated adverse device effects and one serious adverse event that was unrelated to treatment; most treatment-emergent observed expected effects were seen at the 4-wk follow-up visit, and included tenderness (23–50% of subjects), edema (8–31%), ecchymosis (0–19%), erythema (0–6%), numbness (0–8%), and hard lumps (0–8%); all observed effects had resolved by the 12-wk follow-up visit without intervention, aside from three cases of prolonged tenderness
Shek et al., 2014[23]	The most common adverse effects were pain and bruising that resolved; no unexpected or serious adverse effects were noted
Shome et al., 2019[24]	Nerve and muscle dysfunction, facial fat deformity, scarring, and bleeding were observed
Hong et al., 2019[25]	Bruising was observed in six patients, but all cases were resolved within 1 wk after treatment; no serious or delayed adverse effects were reported during the follow-up period
Aşiran Serdar et al., 2019[26]	Nineteen patients (25.3%) reported pain, five patients (6.7%) had transient erythema, and two patients (2.7%) had both transient erythema and pain; all adverse effects were resolved after the procedure; only one patient (1.3%) had the complaint of numbness in the right mandibular region that resolved spontaneously within 10 days

hematology parameters, serum lipids, liver function tests (LFTs), and C-reactive protein or leptin levels. None of these tests showed any clinically significant posttreatment changes from baseline. Similarly, Hong et al.[25] carried out blood tests such as complete blood count, LFTs, and serum lipid profile during the study period and found that all the parameters remained stable

Guth et al.[2] carried out lipid profile along with other tests including complete blood count, kidney function tests, LFTs, pancreatic function, levels of C-reactive protein, and erythrocyte sedimentation rate. They compared them with the patients in the control group and found that there was no statistical difference between them. Similarly, Jewell et al.[1] carried out clinical laboratory tests, which did not reveal any abnormalities with regard to lipid profiles, markers of inflammation, coagulation, liver or renal function, hematologic assessments, or blood chemistry. In 2012, Jewell et al.[20] published their sham-controlled study that evaluated the safety of HIFU treatment. The HIFU device exhibited an adverse event profile similar to that of sham treatment. There were no significant changes from baseline in laboratory values.

No study has observed any unanticipated adverse events during or after the course of treatment. Minor complications were identified in all the studies that resolved either on their own or with the help of medications. The details of complications observed in each study are exhibited in Table 4.

Quality Appraisal, Critical Evaluation, and Risk-of-Bias Assessment

Quality assessment and risk of bias was performed for all the studies using the RevMan tool and MINORS, which is depicted in Figures 2 and 3 and Tables 5 and 6, respectively. Figure 2 shows the risk-of-bias assessment of individual studies and Figure 3 shows the summary of risk-of-bias assessment in seven different domains.

MINORS scoring revealed that the studies deploying other experimental designs apart from randomized controlled trials, barring one, had low risk of bias. The ROBINS-I methodology further consolidated the fact that all the 10 studies had low to moderate risk of bias.

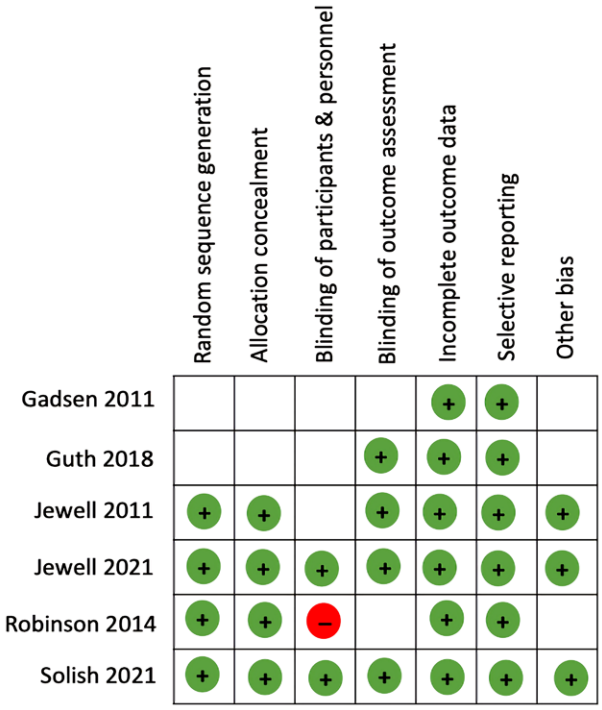

Fig. 2. Risk-of-bias assessment of included randomized controlled trials.

DISCUSSION

Aging is a process that has a dynamic continuum. It is a characteristic and highly individualistic phenomenon that is natural, yet can be controlled, shaped, and tweaked by contemporary cosmetic procedures.[36,37] Changes that occur naturally follow a certain predictable pattern, across various cross cultural groups and ethnicities.[38] A wide range of technologies are available to perform aesthetic body sculpting which, even though noninvasive, require multiple treatments and can only achieve relatively superficial or temporary effects. These results are apparent and manifest as face and body image. HIFU is a noninvasive body sculpting technology in which unwanted adipose cells are disrupted. The two mechanisms that result in ablating the adipose tissue are mechanical effects to disrupt the cell membranes and heat in the focal spot of HIFU that destroys additional fat cells at temperatures above 58°C. The result is coagulative necrosis and almost immediate cell death within the targeted area, whereas the surrounding tissue remains mostly unaffected. This is the first systematic review focusing on the HIFU treatment and its implications, by deploying the standard prospective and experimental study designs.

To date, several heterogeneous studies have been carried out to evaluate efficiency, efficacy, effectiveness, tolerability, and safety of HIFU treatment. The HIFU treatment carried out by Fatemi reported a decrease in the waist circumference by

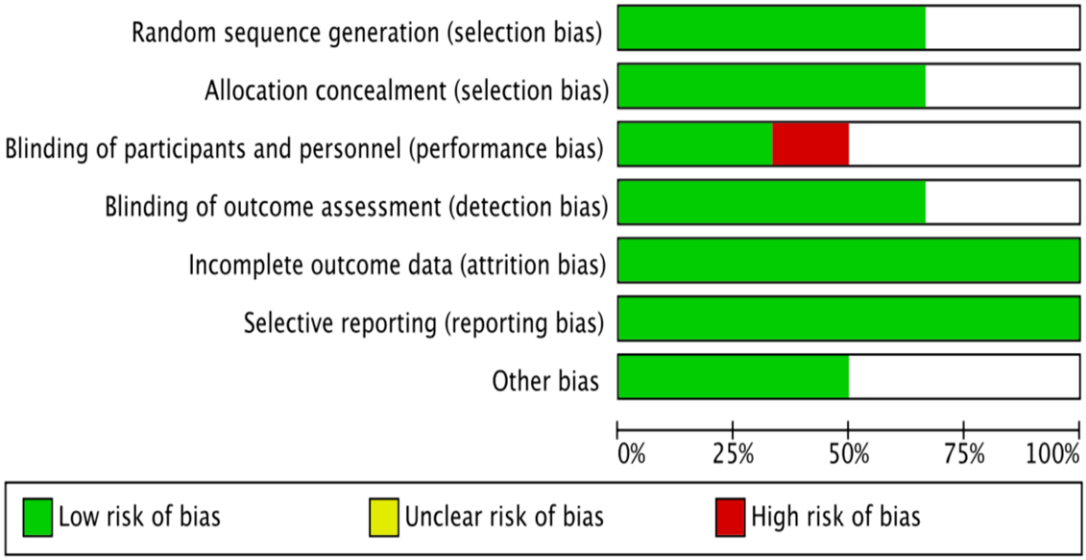

Fig. 3. Summary of risk-of-bias assessment in seven different domains.

an average of 4.7 cm after one treatment with two different focal depths after 3 months. These findings were obtained from 282 patients who underwent a single treatment targeted at the anterior abdomen and flanks using energy of 140 J/cm^2 or higher, at a focal depth of 1.1 to 1.8 cm. There were a few patients who did not achieve their desired results because of changes in their weight or when the applied energy levels were too little.[11]

A significant decrease of 0.6% was noted in infraumbilical circumference of subjects receiving HIFU single treatment by Guth et al.[2] Hong et al. found a reduction of 3.43 cm in mean waist circumference and local fat thickness and a significant reduction of the Waist-to-Hip Ratio.[25] When Jewell et al. recruited adults with subcutaneous abdominal fat greater than or equal to 2.5 cm thick, they noted a reduction of 2.44 cm for 59 J/cm^2 and 2.06 cm for 47 J/cm^2.[1,20] In the study by Baxter, among adults aged 18 to 65 years, body mass index less than or equal to 30 mg/kg^2 and subcutaneous adipose tissue (SAT) thickness greater than or equal to 2.5 cm in the abdomen and flank were observed.[39]

Several studies were conducted for evaluating the effectiveness and tolerability of HIFU. One such study by Robinson et al. used high and low fluence settings with grid-repeat and site-repeat techniques. It concluded that 30 J/cm^2 and 60 J/cm^2 per pass HIFU treatments delivered in a grid-repeat or site-repeat manner produce statistically significant abdominal SAT reduction of greater than 2 cm in the populations.[22] In a similar study, Shek et al. evaluated its effectiveness for sculpting of the abdomen wherein the 12 participating subjects who had adipose thickness greater than or equal to 2.5 cm received one treatment. A mean fluence of 161 J/cm^2 and 1.3 cm of focal depth was used. A reduction of waist circumference by 2.1 cm at 12 weeks after treatment was noted, and the mean pain score was 5.7 on a scale of 0 to 10. It was concluded in this study that there is minimal downtime associated with HIFU for body shaping, it has a significantly lower risk of infection, and there no need for tumescent or general anesthesia as opposed to liposuction.[23] The treatment setting preferences of an HIFU device for the most effective treatment were studied by Solish et al. wherein HIFU was applied to the anterior abdomen in three passes of decreasing depth (1.6, 1.3, and 1.1 cm). The least discomfort was experienced by patients at the 47-J/cm^2 energy level, whereas the 52-J/cm^2 treatment had the shortest treatment time, and the quickest onset was noted with 59-J/cm^2 treatment. Therefore, a high energy level necessarily did not equate to better results.[21]

Very few studies evaluated the efficacy and safety of HIFU for reconstruction and recontouring of facial architecture. The study by Shome et al. assessed both these in 50 Indian adult patients opting for correction of midface and lower face sagging. At 6 months, a mean improvement objectively by 2.5 grades and subjectively by 2.8 grades was seen. The majority of the patients had swelling, which persisted for 2 to 14 days. Most commonly, patients reported a slight amount of pain and discomfort during the procedure,

Table 5. Individual MINORS Score

	Clearly Stated Aim	Inclusion of Consecutive Patients	Prospective Data Collection	Endpoints Appropriate to Study Aim	Unbiased Assessment of Study Bend Points	Follow-Up Period Appropriate to Study Aim	<5% Lost to Follow-Up	Prospective Calculation of Sample Size	Adequate Control Group	Contemporary Groups	Baseline Equivalence of Groups	Adequate Statistical Analysis	
Fatemi, 2009[11]	2	1	2	2	1	2	0	0	NA	NA	NA	NA	10/16
Gadsden et al., 2011[19]	2	1	2	2	2	2	0	0	0	2	2	0	15/24
Jewell et al., 2011[1]	2	1	2	2	2	2	0	0	2	0	2	2	17/24
Jewell et al., 2012[20]	2	1	2	2	2	2	0	0	2	0	2	2	17/24
Solish et al., 2012[21]	2	2	2	2	2	2	0	2	0	2	2	2	20/24
Robinson et al., 2014[22]	2	1	2	2	1	2	2	0	0	2	2	2	18/24
Shek et al., 2014[24]	2	1	2	2	1	2	0	0	NA	NA	NA	NA	10/16
Guth et al., 2018[2]	2	2	2	2	1	2	0	0	2	0	2	2	17/24
Shome et al., 2019[24]	2	2	2	2	2	2	0	0	NA	NA	NA	NA	12/16
Hong et al., 2019[25]	2	1	2	2	1	2	0	0	NA	NA	NA	NA	10/16
Aşiran Serdar et al., 2019[26]	2	2	2	2	2	2	0	0	NA	NA	NA	NA	12/16

Table 6. Risk-of-Bias Assessment Using MINORS Criteria[a]

Reference	Revisits Primary Outcome	Score 1	Score 2	MINORS Quality Score	Score 3	Risk of Bias
Fatemi, 2009[11]	Yes	A	B	10/16	B	Low
Gadsden et al., 2011[19]	Yes	A	B	15/24	C	High
Jewell et al., 2011[1]	Yes	A	B	17/24	B	Low
Jewell et al., 2012[20]	Yes	A	B	17/24	B	Low
Solish et al., 2012[21]	Yes	A	C	20/24	B	Low
Robinson et al., 2014[22]	Yes	A	B	18/24	B	Low
Shek et al., 2014[23]	Yes	A	C	10/16	B	Low
Guth et al., 2018[2]	Yes	A	C	17/24	B	Low
Shome et al., 2019[24]	Yes	A	C	15/16	B	Low
Hong et al., 2019[25]	Yes	A	C	10/16	B	Low
Aşiran Serdar et al. 2019[26]	Yes	A	C	15/16	B	Low

[a]Best evidence synthesis.

which diminished significantly with the use of local anaesthesia. Adverse effects such as transient erythema, edema, and occasional bruising have been reported previously. Postoperative hyperpigmentation, striated linear skin patterns, or wheals are some of the uncommon adverse effects.[24] Aşiran Serdar et al. studied the effectiveness of HIFU for facial and neck rejuvenation among 75 subjects. Marked improvement of nasolabial folds, jawline, neck, and submental area was noted. Transient erythema and numbness in the mandibular region were reported as adverse events that were temporary and resolved spontaneously within 10 days.[26]

Gadsden et al. treated 152 healthy patients with total HIFU energy doses of 47 to 331 J/cm^2. The safety of each treatment regimen was confirmed before the energy levels were raised. Abdominoplasty was performed after 14 weeks, after which histopathologic analyses of excised tissues were performed. It was found that predictable thermal necrosis composed of adipocytes and collagen within the midlamellar matrix was produced. Precise necrotic zones were surrounded by normal tissue with intact blood and lymphatic vessels. The controlled rise in temperature to nearly 70°C at the HIFU focal zone disrupted and destroyed the fat cells, and collagen fibers thickened and contracted. Thermal HIFU reliably ablated SAT without injuring the overlying epidermis, dermis, deep fascial plane, or vascular structures and healed normally, with only a slight increase in the number of local macrophages. Consistent with other reports of ultrasonic lipoplasty, dysesthesias were noted at the higher energy levels that resolved spontaneously. Satisfactory improvement in abdominal contour without residual symptoms was reported. It was observed that low energy levels (47 to 59 J/cm^2) were well tolerated, with acceptable improvements in the reduction of areas of localized abdominal fat deposits; however, higher energy levels resulted in a greater incidence of adverse events.[19]

The complications such as pain, edema, bruising, ecchymosis, hard lumps, and numbness reported by various studies were temporary and resolved within 15 days after the procedure.[1,11,19–23,25,26] When adverse effects were assessed by Baxter et al., no cases of burns or other skin complications were noted. Inflammatory markers, liver, and renal function also showed no significant changes.[39] In contrast to these, Shome et al. reported some unusual complications of nerve and muscle dysfunction, in addition to bleeding and scarring.[24]

In the current era of cosmetic operations, HIFU being a minimally invasive procedure presents to be a boon. The high cost, though justified because of the technical expertise and advancements it mandates, acts as a deterrent to its extensive use. This systematic review follows the Cochrane style, thus limiting the studies included to standard experimental studies. The exclusion of case reports, case series, and other nonexperimental types of study may have led to the omission of some prevailing clinically relevant data. However, the stringent methodology that has been followed during this study ensures that the results obtained have a lower risk of bias. Because of the scarcity of experimental studies, heterogeneity of the data has been reported, which made conduction of a meta-analysis not feasible. The results thus may be interpreted with mild to moderate caution.

CONCLUSIONS

The HIFU treatment modality offers a game-changing vista in the treatment of plastic surgery and aesthetic recontouring and reshaping of the body. Social desirability traits and the urge for a

pleasant appearance have led it to gain steady popularity. With predictable results through a minimally invasive approach and a semipermanent effect, HIFU has made headway into the commercial and conventional means of treatment offered by specialists and demanded by patients.

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