

Non-invasive Reduction of Accessory Breast Fat Using Multilayer High-Intensity Focused Ultrasound: A Quantitative Ultrasound-Based Study

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Abbreviations

BMI, body mass index; GAIS, Global Aesthetic Improvement Scale; HIFU, high-intensity focused ultrasound; US, ultrasound

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Objectives—Accessory breast tissue often presents as localized axillary subcutaneous fullness, presenting as a palpable soft-tissue bulge composed of adipose or glandular elements, causing mechanical discomfort and esthetic concern. While surgical excision remains effective, it may result in scarring, postoperative pain, and risks of seroma/hematoma or contour irregularity, leading to growing interest in noninvasive approaches. The objective of the study is to investigate the effect of noninvasive high-intensity focused ultrasound (HIFU) on subcutaneous fat thickness in axillary accessory breast tissue.

Methods—This prospective study enrolled 30 women with BMI ≥ 27 kg/m² and accessory breast fat. All participants underwent a single HIFU session using multiple focal depths of 4.5, 6.0, and 9.0 mm at operating frequencies of 4 and 2 MHz, with energy settings of 1.5–2.0 J per shot. Fat thickness was measured by ultrasound at baseline and 8 weeks. Secondary outcomes included investigator-rated Global Aesthetic Improvement Scale (GAIS) and patient satisfaction scores.

Results—Among the 28 participants who completed the 8-week follow-up, mean subcutaneous fat thickness decreased from 19.2 ± 3.4 mm at baseline to 15.8 ± 3.1 mm at 8 weeks. The mean paired reduction was 3.4 ± 1.6 mm (17.7%), which was statistically significant (95% CI, 2.8–4.0 mm; $p = 1.1 \times 10^{-11}$). All participants showed GAIS improvement with high satisfaction. No serious adverse events were observed; mild and transient effects included transient thermal discomfort and localized erythema resolving within several hours to 2 days, and no cases of skin burn were identified.

Conclusion—Non-invasive HIFU produced a measurable reduction of accessory breast fat with favorable esthetic outcomes and an acceptable safety profile.

Key Words—accessory breast tissue; high-intensity focused ultrasound; noninvasive fat reduction; subcutaneous fat thickness; ultrasound assessment

Accessory breast tissue, also referred to as ectopic breast tissue, is a relatively common congenital condition resulting from incomplete regression of the embryonic mammary ridge and most frequently presenting in the axillary region as axillary accessory breast tissue composed of adipose and/or glandular elements. Although often asymptomatic, axillary accessory breast tissue may be associated with esthetic concern and mechanical discomfort, particularly in women with elevated body

mass index (BMI).^{1–4} The condition may consist of variable proportions of adipose tissue, glandular tissue, or a combination of both, leading to heterogeneous clinical presentation and treatment considerations.⁵ Surgical excision, often combined with liposuction, remains the standard treatment for prominent or symptomatic accessory breast tissue and reliably achieves volume reduction.^{1,5} However, surgical approaches are associated with inherent drawbacks, including scarring, postoperative downtime, and the risk of contour irregularity or fibrosis, which may be unacceptable to patients seeking minimally invasive options.^{3,4} As a result, interest has grown in noninvasive modalities for patients with predominantly adipose accessory breast tissue who desire contour improvement without surgery. Noninvasive body-contouring technologies, including radiofrequency (RF), cryolipolysis, laser-based devices, and injectable lipolytic agents, have demonstrated efficacy for localized fat reduction in various anatomical regions.^{6–9} Nevertheless, the axillary region presents unique challenges due to its anatomical variability, relatively thin and heterogeneous adipose layer, and proximity to neurovascular structures. These factors may limit the applicability or precision of some noninvasive modalities, particularly those relying on diffuse thermal distribution, applicator-based geometry, or chemically induced inflammatory responses.^{10,11} High-intensity focused ultrasound (HIFU) is a noninvasive modality that delivers acoustic energy converging at predefined focal depths, enabling localized thermal injury within subcutaneous adipose tissue while sparing overlying skin structures.^{12–14} In prior body-contouring studies of the abdomen and flanks, HIFU creates discrete thermal coagulation zones within the subcutaneous fat layer, leading to adipocyte disruption and localized tissue injury. The treated adipose tissue is subsequently cleared through an inflammatory–resorptive process characterized by macrophage-mediated removal of cellular debris and gradual remodeling over several weeks, which is reflected clinically as progressive reduction in fat thickness rather than immediate volume loss.^{15–17} At the cellular level, fat reduction after focused ultrasound (US) is mediated by spatially confined adipocyte injury that can involve heat-driven protein denaturation and coagulative necrosis within the focal zone, with relative preservation of the

overlying dermis when energy deposition is depth-matched. Histopathologic studies have shown well-demarcated adipocyte disruption followed by a sterile wound-healing response, including recruitment of inflammatory cells and progressive macrophage phagocytosis of released lipid droplets and cellular debris over approximately 2–12 weeks.^{18,19} In addition to thermal effects, acoustic pressure fluctuations may contribute to mechanical stress and microcavitation in the interstitial compartment depending on device parameters, further promoting adipocyte membrane disruption within the targeted layer while limiting damage to adjacent structures.^{11,15}

HIFU has been extensively investigated for noninvasive fat reduction in the abdomen, flanks, and submental region, with multiple studies demonstrating US-measured fat reduction and favorable safety profiles. However, despite its established use in body contouring, clinical data on the application of HIFU for axillary accessory breast fat reduction remain limited.

Given the anatomical heterogeneity of the axillary accessory breast region and the depth-selective capabilities of focused US, HIFU represents a theoretically suitable noninvasive option. In the present study, HIFU treatment was performed using a HIFU system (ULTRAFORMER MPT [SHRINK UNIVERSE]; Classys Inc., Seoul, Korea), which enables multilayer, depth-selective energy delivery through interchangeable transducers. In this study, a 4.5-mm cartridge operating at 4 MHz and 6.0-mm and 9.0-mm cartridges operating at 2 MHz were used, with treatment energies ranging from 1.5 to 2.0 J per shot. Objective imaging-based assessment is particularly important in this context, as visual contour changes may be subtle and influenced by patient posture and arm position. In this study, quantitative assessment of subcutaneous fat thickness was performed using a high-resolution diagnostic US system (HS1; Minolta, Japan) equipped with a 15-MHz linear-array transducer to ensure precise visualization of superficial adipose tissue layers.

The objective of this study was to evaluate the effect of noninvasive HIFU on subcutaneous fat thickness in the axillary accessory breast region in women with a BMI of 27 kg per square meter or higher, using US-based measurements, investigator-rated esthetic assessments, patient-reported satisfaction, and safety outcomes.

Methods

Study Design and Participants

The objective of this prospective single-center clinical study was to evaluate the effect of non-invasive HIFU on accessory breast subcutaneous fat reduction in women with elevated BMI.

A total of 30 female participants with a BMI ≥ 27 kg/m² were enrolled. All participants presented with identifiable axillary accessory breast fullness that was considered adipose-predominant on clinical examination and baseline ultrasound assessment. Written informed consent was obtained from all subjects prior to participation.

Exclusion criteria included pregnancy or lactation, active skin disease or infection at the treatment site, prior surgical or energy-based treatment to the axillary region within 6 months, known bleeding disorders, use of anticoagulant medication, accessory breast tissue with predominantly glandular features on ultrasound, and any systemic condition deemed by the investigators to interfere with study participation or outcome assessment.

Participants were instructed to maintain their usual diet and physical activity throughout the study period. Body weight and BMI were monitored at baseline and at the 8-week follow-up visit, and no clinically meaningful changes in BMI were observed during the study period. Of the 30 enrolled participants, 28 completed the 8-week follow-up and were included in the final analysis. The 8-week post-treatment time point was selected based on prior clinical and histologic studies of HIFU for body contouring, which have demonstrated that adipocyte injury is followed by inflammatory clearance and measurable reduction in subcutaneous fat thickness over approximately 6–12 weeks. An 8-week interval was therefore considered sufficient to capture structural remodeling while minimizing confounding effects from long-term lifestyle or weight changes.

Ultrasound-Based Measurement

US imaging was performed to quantitatively assess subcutaneous fat thickness in the accessory breast region at baseline (pre-treatment) and at 8 weeks post-treatment. At baseline, ultrasound was also used to confirm that the treated area was predominantly composed of subcutaneous adipose tissue and to

exclude cases in which discrete glandular tissue appeared to predominate within the axillary accessory breast region. Imaging was conducted using a high-resolution diagnostic US system (HS1; Minolta, Japan) equipped with a 15-MHz linear-array transducer. The high-frequency probe was selected to ensure adequate axial resolution for accurate visualization and measurement of superficial subcutaneous adipose tissue in the axillary region. US machine settings, including gain and imaging depth, were standardized across all examinations, and minimal probe compression was applied to avoid artificial reduction in fat thickness.

US examinations were conducted with participants in a standardized supine position, with the ipsilateral arm abducted to ensure consistent exposure of the axillary region. Subcutaneous fat thickness was defined as the vertical distance between the dermal-subdermal interface and the underlying muscular fascia.

Measurements were obtained at the central portion of the accessory breast fat pad in both axillary regions. For each participant, ultrasound measurements were performed at the same locations at baseline and follow-up. At each time point, the mean of the bilateral axillary measurements was calculated and used for analysis. For each subject, US measurements were performed at the same locations at baseline and follow-up, and mean values were used for analysis. All US assessments were performed by the same experienced operator to minimize inter-observer variability.

Technical Characteristics

The HIFU system used in this study delivers focused acoustic energy to predefined tissue depths through interchangeable transducer cartridges with fixed focal lengths and operating frequencies. Energy output is adjustable from 0.1 to 2.0 J in 0.1 J increments, enabling controlled thermal dosing. Focused US energy generates localized thermal coagulation zones at the target depth while minimizing energy exposure to the epidermis and adjacent tissues.

The system is equipped with 10 interchangeable cartridges designed for both facial and body applications, allowing depth-specific energy delivery according to tissue thickness.

For adipose tissue targeting in body-contouring procedures, F-type cartridges are primarily used. These cartridges emit focused US energy in a linear

pattern, generating a series of discrete thermal coagulation points along a predefined treatment line at a fixed focal depth. Each emission creates a confined focal thermal zone within the targeted layer, enabling controlled and depth-selective deposition of energy across the subcutaneous adipose compartment while minimizing dispersion to superficial structures. F-type cartridges are available at focal depths of 1.5, 2.0, 3.0, and 4.5 mm for facial applications and 6.0, 9.0, and 13.0 mm for body treatments, permitting tailored selection based on adipose thickness.

In contrast, booster-type cartridges deliver energy in a circular emission pattern and are primarily intended for superficial tissue tightening rather than depth-selective adipose reduction. These cartridges are available at focal depths of 1.5, 3.0, and 4.5 mm.

Cartridge penetration depth is further influenced by operating frequency. Deeper body cartridges function at lower frequencies (2 MHz), which enhance acoustic penetration into thicker subcutaneous tissue, whereas superficial cartridges operate at higher frequencies (up to 4 MHz), providing greater precision within more superficial tissue planes.

US energy may be delivered as discrete focal emissions or in a micro-pulsed manner, enabling more uniform thermal distribution across the target depth. In body applications, focused US induces localized thermal effects within subcutaneous adipose tissue, resulting in gradual adipocyte disruption and subsequent tissue remodeling, while preserving the overlying skin surface.

Treatment Protocols

All participants underwent a single-session HIFU treatment targeting accessory breast fat in the axillary region. Treatments were delivered using F-type cartridges with focal depths of 4.5 mm (4 MHz), 6.0 mm (2 MHz), and 9.0 mm (2 MHz) to target the superficial, intermediate, and deeper portions of the axillary subcutaneous adipose layer (Figure 1). The 4.5-mm cartridge was included to target the superficial component of the axillary subcutaneous fat layer, which could not be adequately addressed by the deeper body cartridges alone.

A standardized multilayer protocol was used in all participants. For each axilla, approximately 300 shots were delivered, with approximately 100 shots at each depth. Treatment was performed in sequential passes from deep to intermediate to superficial layers (9.0 mm

→ 6.0 mm → 4.5 mm). Energy was allocated by depth within a predefined range: 1.9–2.0 J/dot for the 9.0-mm pass, 1.7–1.8 J/dot for the 6.0-mm pass, and 0.9–1.0 J/dot for the 4.5-mm pass. Shot spacing was standardized at 1.5 mm, with treatment lines placed 5 mm apart, resulting in a total of approximately 600 shots for bilateral treatment. The total treatment time for bilateral axillary application was approximately 10 minutes.

The treatment area per axilla was approximately 6–10 cm², determined based on individual anatomical variation. Optional topical lidocaine cream was applied prior to treatment for pain management at the discretion of the patient and investigator. A continuous layer of US coupling gel was applied throughout the procedure to facilitate acoustic transmission and to support epidermal surface protection during energy delivery.

Outcome Measures

The primary outcome measure was the change in US-measured subcutaneous fat thickness in the accessory breast region from baseline to 8 weeks post-treatment. The unit of analysis was the participant, and the participant-level value was defined as the mean of the bilateral axillary measurements at each time point.

Secondary outcome measures included investigator-rated Global Aesthetic Improvement Scale (GAIS) scores and patient-reported satisfaction assessed at the 8-week follow-up visit. GAIS evaluations were based on standardized baseline and 8-week clinical photographs and were performed by two independent physicians who were blinded to the treatment parameters and not involved in the treatment procedures. Clinical photographs were obtained under standardized conditions with consistent participant positioning, arm position, camera distance, and lighting to allow comparable visualization of axillary contour across visits. GAIS scores were categorized as very much improved, much improved, improved, no change, or worse. Inter-rater agreement between the two evaluators was assessed using weighted Cohen's kappa to determine consistency of the GAIS ratings.

Patient satisfaction was assessed using a 5-point Likert scale ranging from very dissatisfied to very satisfied at the 8-week follow-up visit.

Safety outcomes were evaluated by monitoring treatment-related adverse events (AEs) throughout the study period. Adverse events were assessed immediately after treatment and again at the 8-week follow-up visit through direct patient questioning and

clinical examination. All AEs were documented and classified according to severity and duration.

Statistical Analysis

Statistical analyses were performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean $\pm$ standard deviation (SD), and categorical variables are presented as number (percentage). The primary endpoint was the change in ultrasound-measured subcutaneous fat thickness from baseline to 8 weeks after treatment. The unit of analysis was the participant, and for each participant the mean of the bilateral axillary measurements at each time point was used for analysis. Because measurements were obtained at both time points in the same participants, the paired pre- and post-treatment comparison was analyzed using a two-sided paired *t*-test. The mean paired difference, 95% confidence interval (CI), and exact *p* value were calculated. A two-sided *p* value < 0.05 was considered statistically significant. Efficacy analyses were performed in

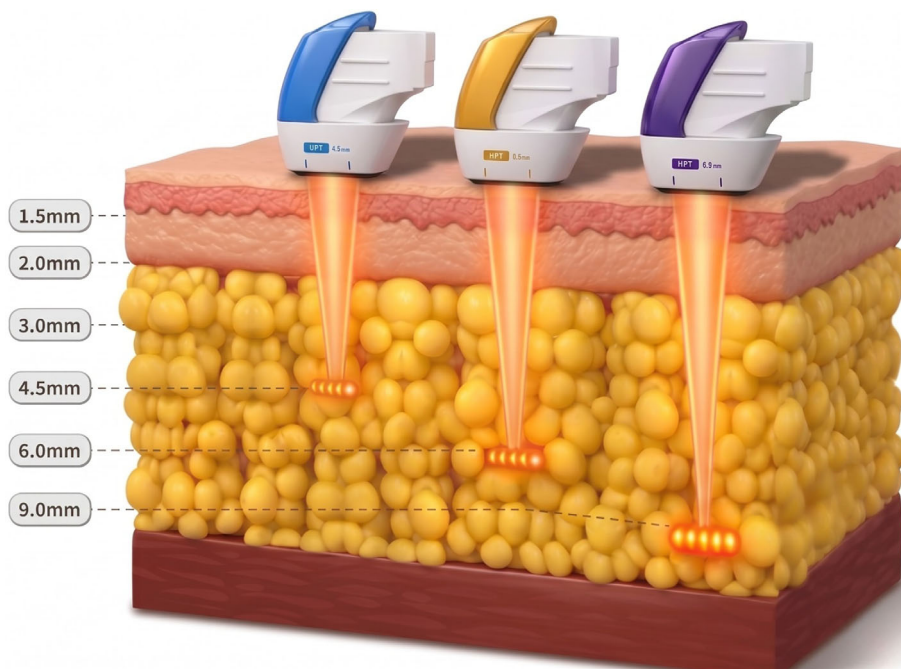
participants with available ultrasound measurements at both baseline and the 8-week follow-up (complete-case analysis, $n = 28$). No imputation was performed for missing efficacy data. Safety analyses were also performed in the 28 participants who completed the 8-week follow-up. For GAIS, agreement between the two blinded evaluators was assessed using weighted Cohen's kappa with corresponding 95% CI. A formal a priori sample-size calculation was performed for the primary endpoint. Assuming a clinically meaningful mean paired reduction of 2.0 mm, a standard deviation of paired differences of 3.0 mm, 80% power, and a two-sided alpha of 0.05, 20 evaluable participants were required. Allowing for an anticipated dropout rate of approximately 30%, the target enrollment was set at 30 participants.

Results

Participant Characteristics

All participants underwent the planned HIFU treatment. Two participants were lost to follow-up, and

Figure 1. Schematic illustration of high-intensity focused ultrasound (HIFU) treatment depths using F-type cartridges. Cartridges with focal depths of 4.5, 6.0, and 9.0 mm were sequentially applied to target different layers of subcutaneous adipose tissue in the axillary accessory breast region. The illustration demonstrates depth-selective energy delivery beneath the dermis to accommodate individual variation in adipose tissue thickness.



28 participants completed the 8-week US assessment. The mean age was 36.4 ± 7.2 years (range, 24–49 years), and the mean BMI was 29.1 ± 1.8 kg/m². Mean BMI did not change significantly during the 8-week follow-up period (baseline: 29.1 ± 1.8 kg/m²; 8 weeks: 29.0 ± 1.7 kg/m²).

Ultrasound-Based Changes in Subcutaneous Fat Thickness

US measurements demonstrated a measurable reduction in subcutaneous fat thickness in the accessory breast region at 8 weeks following HIFU treatment compared with baseline.

The mean subcutaneous fat thickness decreased from 19.2 ± 3.4 mm at baseline to 15.8 ± 3.1 mm at 8 weeks post-treatment. The mean paired reduction was 3.4 ± 1.6 mm, corresponding to a 17.7% relative decrease from baseline. This change was statistically significant (95% CI, 2.8–4.0 mm; paired t-test, $p = 1.1 \times 10^{-1}$).

Most participants demonstrated a reduction in subcutaneous fat thickness at 8 weeks compared with baseline. Representative clinical photographs illustrating visible contour improvement in the accessory breast region following HIFU treatment are shown in Figures 2 and 3. In an exploratory analysis, participants were

stratified into age tertiles to assess potential age-related differences in response (Tertile 1: 24–30 years, $n = 9$; Tertile 2: 31–38 years, $n = 10$; Tertile 3: 39–49 years, $n = 9$). Mean US-measured fat thickness reduction at 8 weeks was 2.9 ± 1.2 mm in Tertile 1, 3.2 ± 1.0 mm in Tertile 2, and 2.8 ± 1.1 mm in Tertile 3. Baseline BMI across age tertiles was 29.4 ± 1.7 , 28.8 ± 1.9 , and 29.1 ± 1.8 kg/m², respectively.

Investigator-Rated Global Aesthetic Improvement Scale (GAIS)

At the 8-week follow-up visit, investigator-rated GAIS scores indicated overall esthetic improvement in the treated participants. Nineteen out of 28 participants (67.9%) were rated as “improved,” and 9 participants (32.1%) were rated as “much improved.” No participants were rated as “no change” or “worse” following treatment. Inter-rater agreement between the two blinded evaluators was substantial (weighted Cohen’s $\kappa = 0.79$; 95% CI, 0.63–0.95).

Patient Satisfaction

At 8 weeks post-treatment, the mean satisfaction score was 4.2 ± 0.8 , with 11 participants (39.3%)

Figure 2. Clinical photographs of a 25-year-old female participant with accessory breast tissue (BMI 27.8 kg/m²). (A) Baseline and (B) 8 weeks after a single HIFU treatment session. Post-treatment images demonstrate a visible reduction in axillary fullness and improved contour of the accessory breast region compared with baseline.

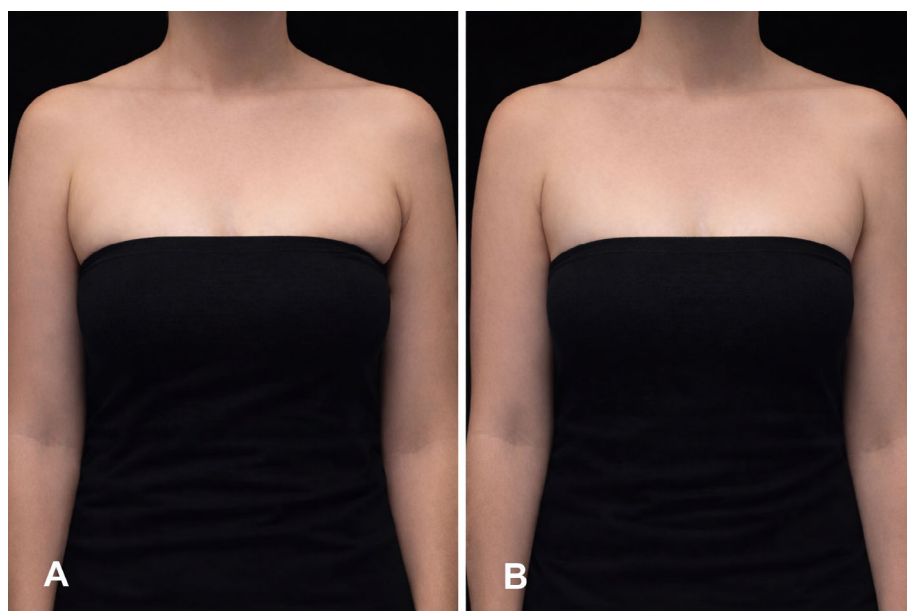
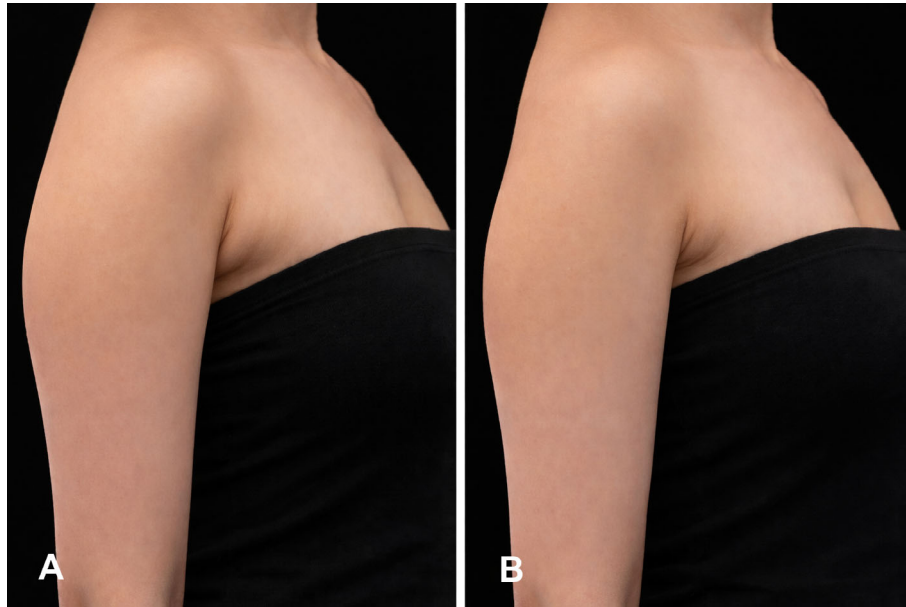


Figure 3. Clinical photographs of a 35-year-old female participant with accessory breast tissue (BMI 30.2 kg/m²). (A) Baseline and (B) 8 weeks following HIFU treatment. Post-treatment photographs demonstrate a clearly visible reduction in axillary soft-tissue volume, with decreased protrusion of the accessory breast and a flatter lateral chest wall profile compared with baseline.



reporting a score of 5 (very satisfied), 11 participants (39.3%) reporting a score of 4 (satisfied), and 6 participants (21.4%) reporting a score of 3 (neutral). No participants reported scores of 1 or 2 (dissatisfied or very dissatisfied).

Safety and Adverse Events

HIFU treatment was well tolerated in all participants. No serious AEs were observed during the study period. Mild and transient AEs included transient thermal discomfort during energy delivery in 11 participants (39.3%) and localized erythema immediately after treatment in 8 participants (28.6%). All reactions resolved spontaneously within several hours to 2 days without medical intervention. Despite the relatively thin and heterogeneous adipose layer in the axillary region, no cases of epidermal burn, blistering, ulceration, persistent pain, nodules, infection, or sensory disturbance were observed.

Discussion

Interpretation of Subcutaneous Fat Changes

In the present study, high-frequency US measurements demonstrated a reduction of 3.4 mm in

subcutaneous fat thickness, corresponding to a relative decrease of 17.7% at 8 weeks following a single HIFU session. Because fat thickness was assessed directly at the central portion of the accessory breast using US, the observed change represents a structural alteration within the subcutaneous adipose layer rather than an indirect estimation of contour change. Given a baseline mean thickness of 19.2 mm in this anatomically confined region, an absolute reduction of 3.4 mm corresponds to a relative decrease of 17.7%, representing a clinically meaningful change in a small, contour-sensitive area such as the axilla.

Importantly, HIFU treatment in this study was delivered across multiple focal depths (4.5, 6.0, and 9.0 mm), covering the full thickness range of axillary subcutaneous adipose tissue. This layer-adaptive approach was designed to engage adipose tissue throughout its vertical extent rather than concentrating energy at a single fixed plane. The US-detected reduction at follow-up therefore reflects the cumulative effect of adipocyte injury and subsequent remodeling across multiple adipose layers.

Preclinical evidence supports this interpretation. Focused US has been shown to generate spatially confined thermal injury within the subcutaneous

adipose layer when the focal zone is appropriately aligned with fat tissue, resulting in adipocyte disruption with preservation of overlying skin structures.¹⁸ Histologic analyses further demonstrate that such focal adipose injury leads to localized coagulative necrosis followed by gradual resorption over time.¹⁹ These findings provide biological context for the progressive fat thickness reduction captured by US in the present study. Notably, the observed time course in our study (8-week reduction rather than immediate volume loss) is consistent with histologic timelines reported in human and animal studies, where inflammatory cell recruitment is followed by macrophage-mediated phagocytosis of lipid droplets and cellular debris over several weeks, culminating in measurable thinning of the subcutaneous adipose layer.

At the cellular and tissue level, HIFU-mediated fat reduction is driven by focal energy deposition within a depth-defined treatment zone. HIFU concentrates acoustic energy within a small focal volume, producing a rapid and localized temperature elevation that may exceed the threshold for protein denaturation within the targeted adipose layer, thereby inducing confined coagulative necrosis with irreversible adipocyte injury while minimizing thermal exposure to the overlying epidermis when the focal depth is appropriately selected.^{12,14} Damaged adipocytes release lipid droplets and chemotactic signals that trigger a localized sterile inflammatory response. Macrophages and other inflammatory cells infiltrate the treated adipose compartment, engulf extracellular lipid and cellular debris, and facilitate gradual clearance through lymphatic transport and physiologic hepatic lipid metabolism, which aligns with the progressive remodeling pattern observed clinically. In parallel, focal injury may also influence the adipose extracellular matrix and fibrous septa, contributing to remodeling of the treated compartment and translating modest millimeter-scale thinning into perceivable contour change. Depending on device output characteristics (pulse structure and acoustic pressure), mechanical stress and microcavitation phenomena may additionally contribute to adipocyte membrane disruption within the focal zone; however, the dominant mechanism in high-intensity body contouring protocols is generally described as focal thermal injury with subsequent inflammatory-resorptive remodeling.^{11,15}

Computational modeling studies reinforce the relevance of depth-matched targeting. Mortazavi and

Mokhtari-Dizaji demonstrated that acoustic energy delivered by HIFU rapidly attenuates outside the predefined focal depth, and that effective adipocyte injury depends on alignment between focal depth and adipose layer geometry.²⁰ This is particularly relevant in the axillary accessory breast region, where fat thickness can vary across a small surface area; multi-depth delivery may therefore increase the probability that focal zones intersect the adipose layer across individuals, promoting more uniform adipocyte injury and consistent US-measured thinning.

From a clinical perspective, the magnitude of fat thickness reduction observed in this study is comparable to reductions reported in established HIFU body-contouring trials, which typically range from 2 to 4 mm after a single treatment session when assessed by US or caliper-based measurements.^{13,14,21} The present findings extend these observations by demonstrating that US-based assessment combined with multi-depth HIFU treatment can yield reproducible structural changes even in anatomically variable adipose regions. Nevertheless, structural reproducibility across anatomical variation does not necessarily preclude the possibility that biological factors such as age-related tissue changes may influence treatment response.

Age-related alterations in connective tissue architecture become more pronounced beginning in the fourth and fifth decades of life, including progressive reductions in dermal collagen content, decreased skin elasticity, and changes in adipose septal structure and extracellular matrix composition.^{6,11} Such changes may modify tissue biomechanics and remodeling kinetics following focal adipocyte injury. In the axillary accessory breast region, where contour appearance is influenced by both fat volume and skin support, age-dependent differences in connective tissue properties could theoretically affect the visible or durable outcome of treatment even if millimeter-scale fat thinning is comparable.

In the present study, exploratory tertile-based comparisons within the 24–49-year age range demonstrated similar US-measured reductions across subgroups. However, because the subgroup sizes were small and the analysis was exploratory, no firm conclusion regarding age-related differences can be drawn from the present data. Given that age-related alterations in connective tissue architecture and skin

support may influence tissue biomechanics and remodeling kinetics, further studies including older age groups and longer follow-up intervals are needed to determine whether age-related biological differences affect long-term contour remodeling or aesthetic durability after HIFU treatment.

Clinical Outcomes and Safety

Beyond objective US measurements, investigator-rated GAIS scores and patient-reported satisfaction indicated meaningful esthetic improvement following treatment. In previous clinical studies, esthetic improvement after noninvasive fat reduction has been shown to correlate imperfectly with absolute fat volume reduction, underscoring the importance of incorporating both clinician- and patient-reported outcomes. In a multicenter controlled trial, Coleman et al reported that nonthermal focused US produced statistically significant improvements in global esthetic assessments despite relatively modest reductions in measured fat thickness, emphasizing the relevance of contour smoothness and localized shape changes rather than absolute volume loss alone.¹⁵ Similarly, Solish et al observed that patient satisfaction remained high across varying energy levels of HIFU treatment, even when quantitative fat reduction differed between treatment arms.¹³

In the context of axillary accessory breast tissue, esthetic perception may be particularly sensitive to small changes in contour, given the visibility of the region during arm adduction and clothing wear. The concordance observed in this study between US-based reduction, GAIS improvement, and high patient satisfaction scores suggests that modest structural changes within the subcutaneous compartment can translate into perceptible esthetic benefit.

The safety profile observed in this study aligns with previously reported HIFU data across both pre-clinical and clinical settings. Early safety studies in human volunteers demonstrated that focused US could ablate subcutaneous adipose tissue without inducing skin burns, nerve injury, or systemic AEs.¹² Subsequent randomized sham-controlled trials confirmed that HIFU-related adverse effects are typically limited to transient procedural discomfort and short-lived erythema, resolving without intervention.¹⁴ In contrast to injectable lipolytic agents, which are associated with predictable inflammatory responses and

risks of nodularity or prolonged tenderness,^{10,22} HIFU avoids direct tissue penetration and chemical-induced inflammation.

When compared with other noninvasive modalities, such as RF or cryolipolysis, HIFU offers depth-selective energy delivery that may be advantageous in anatomically sensitive regions. Reviews of noninvasive body contouring devices have highlighted that RF-based systems rely on broader thermal diffusion, which may limit precision in regions with heterogeneous fat distribution.^{6,9} The absence of serious AEs in the present study supports the tolerability of focused US in the axillary region, where vascular and neural structures are relatively concentrated.

Comparison with Surgical Management

Surgical excision, often combined with liposuction, remains the standard treatment for symptomatic or prominent accessory breast tissue. Case series and surgical reviews consistently report reliable volume reduction with these approaches but also emphasize the trade-offs of invasiveness, scarring, and postoperative recovery.¹⁻⁴ In addition, reported procedure-related complications may include hematoma or seroma, infection, sensory disturbance, hypertrophic scarring, and contour irregularity, particularly when managing anatomically constrained axillary tissue. Hwang et al demonstrated that minimal-incision excision combined with liposuction can achieve satisfactory esthetic outcomes; however, even minimally invasive surgical approaches entail inherent risks of fibrosis, contour irregularity, and patient reluctance toward operative intervention.³ More recent case series continue to support surgical management as definitive therapy, particularly for glandular-dominant accessory breast tissue.⁵

In contrast, the present study does not propose HIFU as a replacement for surgical excision but rather as a noninvasive option for selected patients with predominantly adipose accessory breast tissue who seek contour improvement without surgery. In this context, HIFU may serve as an alternative for patients with mild to moderate fullness or as a preparatory or adjunctive modality in staged treatment strategies.

Comparison with Other Noninvasive Modalities

In body contouring applications, noninvasive fat reduction modalities differ primarily in how energy is

distributed within the tissue and how adipocytes respond at the structural level, a distinction that has been emphasized in foundational reviews of noninvasive body contouring technologies.¹¹ These mechanistic differences directly influence treatment depth control, predictability of fat reduction, and potential region-specific limitations when applied to anatomically constrained areas such as the axillary accessory breast.

RF-based systems induce adipose tissue remodeling through volumetric dielectric heating, resulting in relatively diffuse thermal elevation across the dermal and subcutaneous layers.^{23–25} In body applications, this bulk heating effect can achieve circumferential reduction and skin tightening over broad surface areas through diffuse hyperthermic injury to adipocytes and surrounding connective tissue; however, energy distribution is governed by tissue impedance rather than fixed focal geometry.²⁶ As a result, the depth of maximal adipocyte injury may vary depending on local fat thickness and tissue composition, which can be a practical limitation in the axillary accessory breast where adipose thickness can be shallow and heterogeneous over a confined area. In anatomically adjacent regions such as the upper arm, US-measured fat thickness reduction following noninvasive RF-based protocols has generally been reported in the low millimeter range (approximately 1–3 mm after a single treatment cycle), although many RF studies emphasize circumference reduction rather than direct US thickness endpoints.

Injectable lipolytic agents, such as deoxycholic acid (ATX-101), achieve fat reduction through chemically mediated adipocyte lysis followed by an inflammatory clearance process.^{10,22} In axillary-adjacent contour concerns, including anterior periaxillary fat and bra-line adiposity, deoxycholic acid has been reported as a feasible treatment option. However, for axillary accessory breast fullness, the need for repeated sessions and the predictable post-injection inflammatory response (eg, swelling and tenderness) may be less desirable in a motion-prone area where discomfort can be functionally limiting. In US-based upper-arm studies using diluted deoxycholic acid administered over multiple sessions (typically 3 treatment sessions), baseline fat thickness values have generally ranged from approximately 18–24 mm, with cumulative mean subcutaneous fat thickness reduction

of approximately 4.7–7.5 mm reported at 20 weeks. These reductions, however, were achieved after repeated treatment sessions, and US-based thickness data specifically targeting axillary accessory breast tissue remain limited.

Cryolipolysis induces adipocyte apoptosis through controlled cooling and has demonstrated measurable fat layer reduction in multiple body sites.^{7,8} In the axillary accessory breast region, achieving stable applicator coupling and consistent tissue draw may be challenging because the target is often a small, irregularly contoured pad adjacent to the axillary crease. Although direct US-based data for accessory axillary breast fat are scarce, in upper-arm cryolipolysis studies—an anatomically comparable region in terms of contour constraint and superficial adipose thickness—baseline fat thickness values have typically ranged from approximately 20–25 mm, with mean reductions of approximately 2.0 mm at 8 weeks and up to 3.2 mm at 12 weeks after a single treatment cycle.^{8,27} Similarly, external 1,060-nm diode laser systems have demonstrated US-measured reductions of approximately 2–4 mm after a single session in body contouring studies of localized adiposity; however, these approaches can be constrained by applicator geometry and surface coupling, which may limit adaptability in anatomically variable regions.

In comparison, the present study demonstrated a mean US-measured reduction of 3.4 mm (17.7%) following a single HIFU session at 8 weeks in the axillary accessory breast region. Additional treatment sessions may reasonably be expected to produce further millimeter-scale reduction, as cumulative effects have been reported with repeated energy-based interventions in other body-contouring applications. However, in the axillary accessory breast region, incremental reduction should be carefully balanced against potential risks, including contour irregularity, accentuation of skin laxity, asymmetry, and considerations related to the proximity of neurovascular structures. Accordingly, optimization of treatment intensity and session number should be individualized based on tissue thickness, skin support, and anatomical variability. Beyond the observed millimeter-scale reduction, a practical advantage of HIFU for this application is the ability to deliver energy at predefined focal depths across multiple planes (4.5, 6.0, and 9.0 mm) using line-based coverage, which

can help address heterogeneous fat thickness without relying on tissue suction, broad thermal diffusion, or injection-plane distribution. When contextualized against available US-based millimeter endpoints from anatomically adjacent regions, the magnitude of reduction observed with multilayer, depth-selective HIFU falls within or slightly above the range reported for several established noninvasive modalities after a single treatment session. However, direct head-to-head US thickness data specifically targeting accessory axillary breast tissue are limited across modalities, underscoring the need for standardized, region-specific comparative studies using uniform imaging endpoints.

Limitations and Future Directions

Several limitations should be acknowledged. The study involved a small cohort and a single treatment session with short-term follow-up. The study population consisted of women with elevated BMI and adipose-predominant accessory breast tissue, and the applicability of this approach to patients with normal BMI or congenital accessory breast tissue remains to be established. Histologic confirmation of adipocyte injury was not performed, and longer-term outcomes remain to be determined. Future studies incorporating repeated treatment sessions, extended follow-up, and comparative designs with surgical or injectable modalities would further clarify the role of HIFU in the management of accessory breast tissue. Additionally, imaging-based volumetric assessments and correlation with surgical specimens could provide deeper insight into tissue-level remodeling processes induced by focused US.

Conclusion

In this study, a single session of noninvasive HIFU produced a measurable reduction in subcutaneous fat thickness in the axillary accessory breast region at 8 weeks, with an absolute reduction of 3.4 mm (17.7%) from baseline as assessed by US imaging. Multilayer treatment using focal depths of 4.5, 6.0, and 9.0 mm enabled layer-adaptive targeting and was accompanied by improvements in investigator-rated GAIS scores and high patient satisfaction. Treatment was well tolerated, with no serious AEs and only mild,

transient local reactions. While surgical excision remains definitive for glandular or severe accessory breast tissue, these findings support HIFU as a noninvasive option for selected patients with predominantly adipose accessory breast fullness seeking contour improvement, and further studies with larger cohorts and longer follow-up are warranted to clarify durability and optimal patient selection.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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