Histotripsy for the Treatment of Cauliflower Ear: A Feasibility Study in Porcine Ears

Avi Gandhi

Abstract

Chronic auricular hematoma (cauliflower ear) is a common deformity among contact-sport athletes that results from ear trauma and can lead to hearing impairment, recurrent infections, and cosmetic disfigurement. Current treatments for established cases typically require invasive surgical reconstruction and may yield suboptimal outcomes. This study evaluates histotripsy—a noninvasive, non-ionizing, and non-thermal focused ultrasound ablation technique—as a potential alternative treatment for chronic cauliflower ear. An ex vivo porcine auricular model with gelatin-based simulated hematomas was developed to determine whether cavitation generated by histotripsy could liquefy clot-like material to enable minimally invasive removal. Targeted single-cycle pulses were delivered under real-time ultrasound guidance using a high-frequency transducer. In pilot testing (n = 20), measurable mass reduction occurred only in fully embedded, clot-injected models, with a mean mass decrease of 0.03 ± 0.03 g. In the structured experimental phase (n = 8), the greatest and most interpretable ablation occurred in 15% gelatin models with intact skin covering, which demonstrated mass decreases (0.01–0.02 g). Even though no-skin models showed confounding water absorption, ablation was clearly seen. A two-way analysis of variance demonstrated a significant overall difference in mass change among experimental conditions ($F(2,5) = 180.97$, $p < .0001$), supporting the structural dependence of histotripsy efficacy. These findings provide preliminary evidence that histotripsy can noninvasively ablate cauliflower ear–like tissue while preserving overall auricular structure. This proof-of-concept supports further optimization and in vivo investigation to determine whether image-guided histotripsy could serve as a minimally invasive alternative to surgical reconstruction for chronic cauliflower ear.

Introduction

The auricle (external ear) is composed of elastic cartilage wrapped by perichondrium and skin, forming structures such as the helix, antihelix, scapha, and conchal bowl (cymba and cavum concha) (Hohman et al., 2024). The perichondrium nourishes the avascular cartilage, so trauma that separates it from the cartilage can starve the tissue and lead to ischemic cartilage necrosis (Hohman et al., 2024). Repeated blunt trauma—common in wrestling, martial arts, rugby, and other contact sports—can cause a subperichondrial auricular hematoma. Blood accumulating between the perichondrium and cartilage separates them and cuts off the cartilage's blood supply. Without prompt drainage, the cartilage becomes ischemic and necrotic, and fibrocartilage scar tissue replaces the normal architecture (Hohman et al., 2024; Putri et al., 2023).

Cauliflower ear is a common result of such injuries. For example, 55% of Olympic-level judokas and 84% of elite martial artists have auricular deformities (Nitsch et al., 2023). While often viewed as merely cosmetic, cauliflower ear can impair sound conduction (causing hearing loss) and predispose patients to chronic infection (Cleveland Clinic, 2024; Greywoode et al., 2010). Athletes have reported pain, difficulty wearing headgear, and social stigma from the condition (Cleveland Clinic, 2024).

Acute auricular hematomas must be drained within hours to prevent permanent cartilage damage (Greywoode et al., 2010). Standard care is prompt needle aspiration or surgical drainage of the hematoma, followed by a pressure dressing to prevent reaccumulation.

Antibiotics are often given to prevent perichondritis (infection of the perichondrium) (Greywoode et al., 2010). Timely intervention preserves the ear's shape, whereas delays beyond 7–10 days allow clots to organize and cartilage to deteriorate.

Once cauliflower ear becomes chronic (>2 weeks post-injury), simple drainage is ineffective, and surgery is usually required. Surgeons must excise fibrotic cartilage and attempt to reconstruct the ear's shape. Minor deformities can be corrected with local flaps and sutures, but severe cases require complex reconstructions—e.g., using 3D guides and autologous rib cartilage grafts to replace deformed sections (Putri et al., 2023). These procedures involve long recovery, frequent revisions, and risk of complications such as infection (Greywoode et al., 2010). Even with surgery, outcomes can be suboptimal if residual deformity remains or if the patient returns to contact sports and re-injures the ear.

Histotripsy is a noninvasive, non-ionizing ultrasound ablation technology that destroys tissue via mechanical stress rather than heat (Xu et al., 2021). Focused high-amplitude ultrasound pulses generate microscopic cavitation bubble clouds at the target. The rapid expansion and collapse of these bubbles produce intense localized stress that fractionates tissue into fine acellular debris (Vlaisavljevich et al., 2016; Xu et al., 2021). Essentially, histotripsy liquefies the targeted tissue, which the body can then resorb or that can be aspirated away. For example, histotripsy has been shown to break apart tumor cells and tissue cultures into subcellular fragments in gel models (Vlaisavljevich et al., 2016; Xu et al., 2021). **Figure 1** illustrates cavitation generated by two histotripsy techniques.

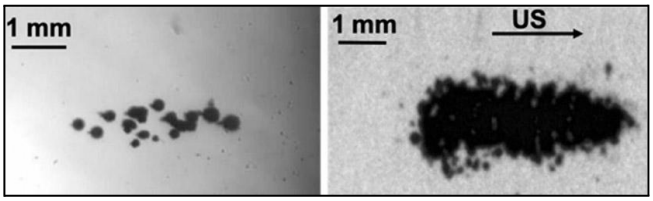

Figure 1: (Left) Cavitation generated by intrinsic threshold histotripsy and (Right) shock scattering histotripsy. Cavitation occurs from left to right (Vlaisavljevich et al., 2016). Permission was granted from the Vlaisavljevich Laboratory at Virginia Tech.

Clinically, histotripsy is emerging as a viable therapy. In 2023, the FDA approved a histotripsy system (HistoSonics' "Edison") for noninvasive liver tumor ablation, reporting >95% success and safety rates (ASCO Post Staff, 2023). These treatments are performed under real-time ultrasound imaging to visualize cavitation (ASCO Post Staff, 2023). Beyond liver tumors, histotripsy is being explored for kidney stone fragmentation (lithotripsy), blood clot lysis, uterine fibroid ablation, and the destruction of calcified plaques.

Given its capabilities, histotripsy could offer a novel treatment for chronic cauliflower ear. Auricular scar tissue is dense fibrocartilage (often with calcification) that is difficult to eliminate without surgery. Histotripsy can penetrate soft tissue and selectively liquefy a targeted zone without incisions. In theory, focusing histotripsy on cauliflower ear tissue would break apart the dense scarred cartilage into liquid debris that could be reabsorbed or aspirated. Histotripsy's ability to disrupt fibrous tissue suggests it could overcome the stiffness of cauliflower ear. Moreover, the ear's superficial location makes it an accessible target, provided an adequate ultrasound coupling medium is used on the skin.

An ex vivo porcine ear model was used for this study because pig auricular cartilage closely resembles human cartilage in structure and composition (rich in type II collagen beneath the perichondrium) (Ryu et al., 2017). The research question was: Can histotripsy effectively ablate scarred auricular (cauliflower ear) tissue in a porcine ear model such that the liquefied tissue can be aspirated? The hypothesis was that focused ultrasound cavitation would fragment

the fibrotic auricular tissue into acellular debris while preserving the ear's overall structure. If so, ultrasound imaging should show fluid-filled (liquefied) zones in treated areas, and histology should confirm loss of normal cartilage architecture in those regions (Vlaisavljevich et al., 2016).

The ultimate goal of this feasibility study is to evaluate a minimally invasive alternative to surgery for cauliflower ear. By ablating deep scar tissue without open incisions, histotripsy could reduce patient morbidity and downtime. If the results are promising, they will lay the groundwork for further animal studies and eventual clinical trials. In time, this approach could provide athletes and others with a new, noninvasive option to reverse cauliflower ear deformities.

Methods and Materials

Pilot Study Setup: Fresh porcine ears were used to develop an ex vivo model of auricular hematoma (cauliflower ear). Ears were obtained shortly after slaughter from a local slaughterhouse (Virginia Tech Meat Center or Firehouse Farms) and either used within hours or frozen for later use. Porcine auricular cartilage's nonlinear elastic properties closely match human ear cartilage (Zopf et al., 2015). Before the experiments, each ear was shaved to ensure unobstructed propagation of ultrasound.

As seen in **Figure 2**, each ear was sectioned into four regions (A, B, C, D) based on anatomical landmarks and further cut into smaller sectors. As seen in **Figure 3**, samples were either partially submerged in a degassed water tank or fully embedded in gelatin inside a custom tray mounted on a three-axis positioning system. A custom 32-element, 1 MHz histotripsy transducer (aperture 120.5 mm, focal length 75 mm, f-number 0.62) with a coaxial L18 linear ultrasound imaging probe was used for therapy and guidance. The focal alignment and cavitation activity were monitored via ultrasound imaging, following standard histotripsy guidance protocols (Xu et al., 2021). The pilot study was divided into three phases, progressively increasing acoustic coupling and tissue softness to find conditions that produce cavitation.

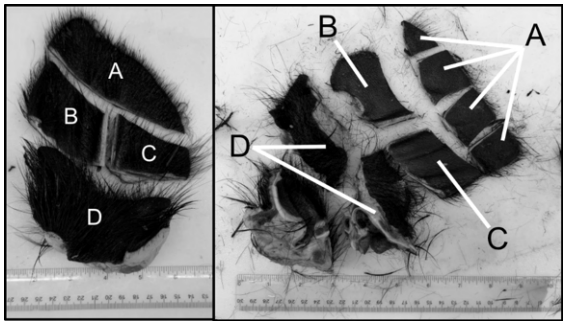

Figure 2: (Left) The sectioned four regions (A, B, C, D) of a porcine ear. (Right) The smaller sectors of those regions.

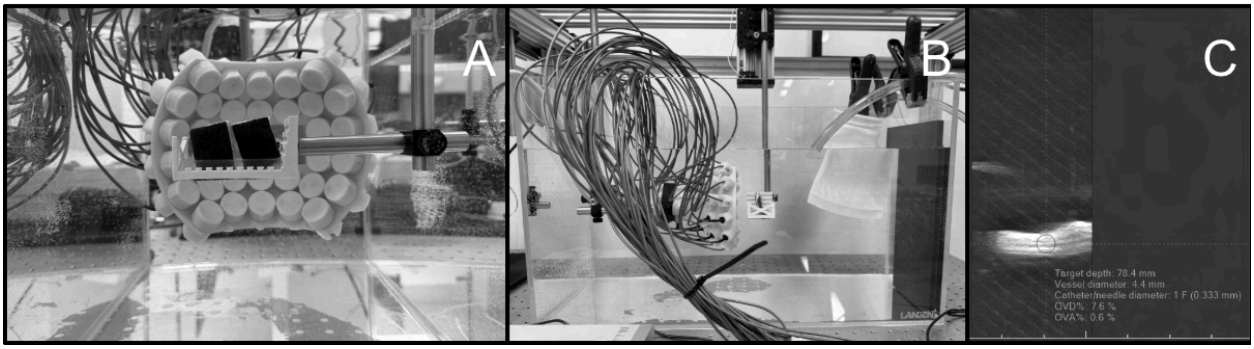

Figure 3: (A) Histotripsy treatment setup for the treatment of porcine ears from the front view. (B) Histotripsy treatment setup for the treatment of porcine ears from the side view. (C) Ear sample on B-mode ultrasound imaging.

Phase 1 (n=4): As seen in **Figure 4**, ears were half-embedded in gelatin (simulating partial coupling) with no clot mimic injected. Treatment used single-cycle pulses with small target volumes (1–8 mm^3), 500 Hz pulse repetition frequency (PRF), ~6,000–20,000 pulses per location, at 110 V drive voltage. No cavitation or mass change was observed in any sample.

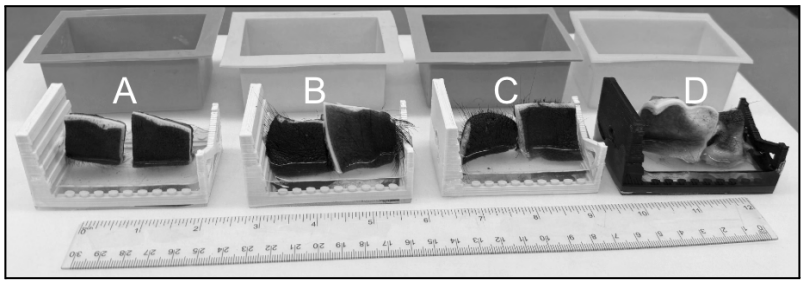

Figure 4: Displays the samples and trays used in Phase 1 of the pilot study.

Phase 2 (n=4): As seen in **Figure 5**, ears were fully embedded in gelatin (better coupling), with no clot injection. Treatment targeted a ~8 mm3 volume with a 500 Hz PRF, ~6,000–25,000 pulses per spot, at 120 V. Some prefocal cavitation and tissue disruption were noted in 3 of 4 samples, but no measurable mass loss occurred.

Phase 3 (n=12): As seen in **Figure 5**, ears were fully embedded in gelatin and had a "hematoma" model: a 3% red gelatin mixture was injected between the cartilage and skin (subperichondrial) and allowed to solidify. Treatment targeted volumes from ~4 mm^3 up to 320 mm^3 with 500–1000 Hz PRF, 1000–45,000 pulses per location, at 120 V. Most samples exhibited robust prefocal cavitation. Some had slight but measurable mass reductions (mean ≈ 0.03 ± 0.03 g) accompanied by internal tissue liquefaction, whereas others showed cavitation damage without significant mass change. These pilot results suggested that both good acoustic coupling and a clot-mimicking inclusion were needed to achieve tissue ablation.

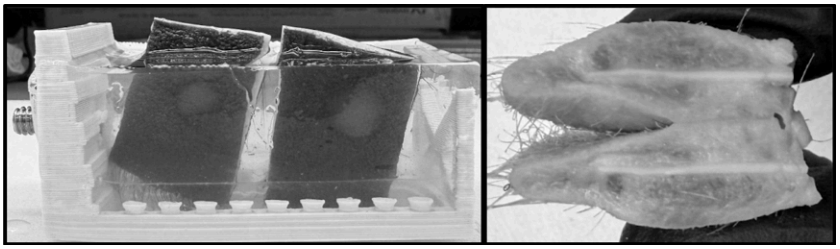

Figure 5: (Left) Displays the fully porcine gelatin embedding model used in Phase 2. (Right) Displays the porcine gelatin injected between the cartilage and skin used in Phase 3.

Transducer Adjustment: In the pilot study, extensive prefocal cavitation in the large 1 MHz transducer prevented full ablation of the target zone. To improve precision, a smaller 6.3 MHz hand-held transducer (aperture 10 mm, focal length 7 mm) with a co-aligned 30 MHz imaging probe was used. Higher-frequency transducers produce sub-millimeter focal zones, enabling more precise targeting in small or superficial tissues (Woodacre et al., 2018). As seen in **Figure 6**, the ears were positioned under this 6.3 MHz transducer in the water tank, thereby minimizing prefocal cavitation and improving focus.

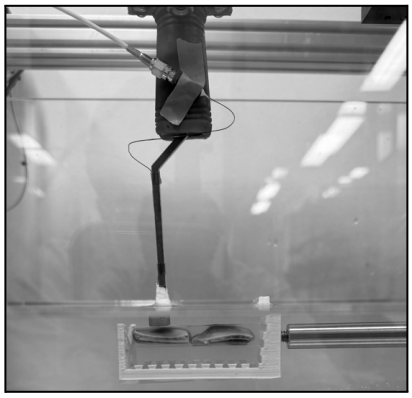

Figure 6: Displays the 6.3 MHz transducer used directly above a sample.

Blood Clot Trial: An attempt was made to simulate hematomas using actual blood clots by recalcifying fresh porcine blood in 1 mL molds (Khokhlova et al., 2016). However, most samples failed to form solid clots and remained liquid, so this approach was discontinued.

Porcine Gelatin Hematoma Model Experiment (n=8): A refined cauliflower ear model was created using gelatin to mimic hematomas. Fresh pig ears were half-embedded in a 7.5% porcine gelatin matrix (all gelatin prepared in 0.9% saline with red dye for visibility). Histotripsy was applied using the 6.3 MHz transducer under continuous ultrasound image guidance (Xu et al., 2021; Ponomarchuk et al., 2024). Three conditions were tested:

3% (No Skin) Group (n=3): Three porcine gelatin models using 3% porcine gelatin without pig skin covering were used to mimic acute hematomas. Hematoma models were treated with single-cycle volumetric pulses using 6 mm3 target zones, 2000 pulses per location, a 1000 Hz PRF, and 350 volts.

15% (No Skin) Group (n=3): Three porcine gelatin models using 15% porcine gelatin without pig skin covering were used to mimic chronic hematomas. Hematoma models were treated with single-cycle pulses, volumetrically, using 27 mm^3 target zones, pulses per location ranging from 500 to 1000, 1000 Hz PRF, and 350 volts.

15% (Skin) Group (n=2): Two porcine gelatin models using 15% porcine gelatin covered with pig skin covering were used to model chronic auricular hematomas. As seen in **Figure 7**, four porcine gelatin models using 15% porcine gelatin covered with pig skin were used to model chronic auricular hematomas. Ears models were treated with single-cycle volumetric pulses using 27 mm3 target zones, 500 pulses per location, a 1000 Hz PRF, and 350 volts.

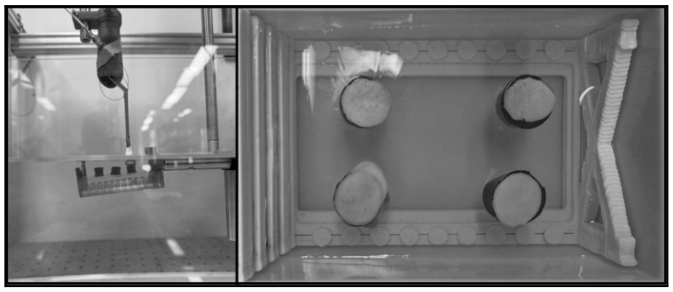

Figure 7: (Left) Porcine gelatin models in the water tank. (Right) Porcine gelatin models covered with pig skin.

Data Collection: Each treated region was weighed before and after histotripsy using an analytical balance, and the mass difference (post – pre) was calculated to quantify tissue removal. Any aspirated fluid volume was also recorded.

Statistical Analysis: Statistical tests were performed using JMP software with significance set at $\alpha = 0.05$. In the pilot study, a two-way ANOVA assessed the effects of gelatin embedding (half vs. full) and clot injection (no vs. yes) on mass change. In the gelatin model experiment, a two-way ANOVA evaluated the effects of clot stiffness (3% vs. 15% gelatin) and skin presence (no vs. yes) on mass change.

Safety and Compliance: All procedures were conducted under approved animal use protocols. The coupling water bath was deoxygenated (<10% O_2 saturation) to reduce ultrasound attenuation. Ultrasound exposures were delivered with short duty cycles (≤1% to avoid thermal effects) (Khokhlova et al., 2016), and output levels were verified with a hydrophone. Standard laboratory safety practices for ultrasound experimentation were followed throughout.

Results

Pilot Study: In the pilot study, cavitation and tissue disruption were achieved only under specific conditions. Phases 1 and 2 (with either partial or full gelatin embedding but no injected clot) showed no measurable mass change; Phase 1 had no cavitation at all, and Phase 2 showed some cavitation but with no effect on mass. In contrast, Phase 3 (with full embedding and a gelatin “hematoma”) successfully generated cavitation and slight tissue liquefaction, as seen in **Figure 8**. Most Phase 3 samples exhibited prefocal cavitation, and several had small mass decreases (on the order of 0.0–0.1 g), confirming that the presence of a clot mimic was crucial for effective ablation.

Figure 8: The liquefaction and damage done inside a porcine ear.

Gelatin Model Experiment:

3% Gelatin, No Skin: The 3% soft gelatin clots (acute hematoma analog) showed visible cavitation and ablation, but the sample masses often stayed the same or increased slightly due to water absorption from the tank. This made it difficult to quantify tissue removal by mass change alone.

15% Gelatin, No Skin: As seen in **Figure 9**, the 15% stiff gelatin clots (chronic analog without skin) exhibited clear cavitation damage, but like the 3% models, they tended to gain weight from water uptake during treatment, masking any true mass loss.

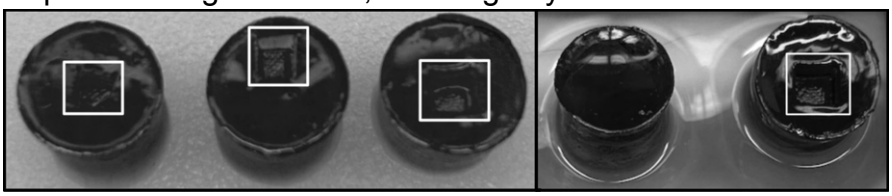

Figure 9: The treatment results of the 15% (No Skin) Group are displayed. (Left) These are the results of the treatment. (Right) This is a side-by-side comparison of an untreated sample and a treated sample. The white boxes outline the ablated regions.

15% Gelatin, With Skin: In the 15% gelatin models covered by skin, histotripsy produced obvious ablation zones and, importantly, a net decrease in mass. The two

skin-covered samples lost approximately 0.01–0.02 g each, and cavitated regions were evident on inspection. The presence of the skin barrier prevented fluid infiltration, allowing the detection of the actual removal of material. As seen in **Figure 10**, some minor damage to the overlying skin was observed directly above the treatment sites.

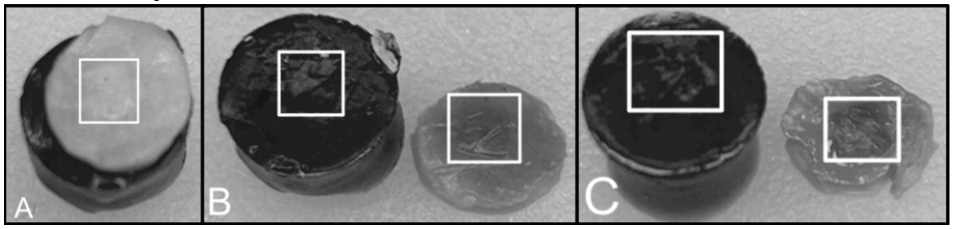

Figure 10: (A, B, C) The treatment results of the 15% (Skin) Group are displayed. The white boxes outline the ablated regions. The superficial and deep regions of the porcine skin layer suffered visible damage.

Statistical Outcomes:

Pilot Study: A two-factor ANOVA (embedding level × clot injection) showed a significant effect on mass change ($F(2,17)=4.09$, $p=0.036$, $R^2\approx0.33$). Essentially, only the fully embedded + injected condition (Phase 3) yielded any mass reduction (~0.03 g), whereas all other conditions had ~0 g change, making Phase 3 significantly different from Phases 1–2.

Gelatin Model Experiment: A two-way ANOVA (gelatin stiffness × skin presence) revealed a highly significant effect ($F(2,5)=180.97$, $p<0.0001$, $R^2\approx0.99$). The skin-covered 15% gelatin group was the only one with a decrease in mass, distinctly different from both no-skin groups (which actually had slight mass increases). This statistical result underscores that the combination of a stiff clot analog and an intact skin layer led to measurable tissue removal, unlike the other conditions.

Discussion

This study explored histotripsy as a method to liquefy auricular hematoma (cauliflower ear) tissue in a porcine model for potential minimally invasive treatment. The findings indicate that histotripsy can induce cavitation and partial tissue ablation in the auricle, but achieving complete liquefaction and aspirating the debris remains challenging.

In the pilot study, intact cartilage alone proved resistant to histotripsy at the tested settings, whereas introducing a gelatin “hematoma” made the tissue more vulnerable to cavitation. Only in Phase 3, which combined good acoustic coupling (full gelatin embedding) with a clot mimic, did mass reduction occur. This suggests that the rigidity of auricular cartilage can hinder cavitation, consistent with reports that stiffer, collagen-rich tissues have higher cavitation thresholds (Vlaisavljevich et al., 2013). The pilot also underscored the importance of acoustic coupling and target composition: without both, no measurable ablation occurred.

In the gelatin hematoma experiments, the key result was that the 15% gelatin with the skin model best demonstrated effective ablation. Both 3% and 15% no-skin models absorbed water during treatment, confounding the mass measurements even though cavitation clearly occurred. The skin-covered model, however, prevented waterlogging and showed a real decrease in mass, aligning with visible tissue destruction. This model closely simulates a clinical scenario (ablating a hematoma through intact skin) and was enabled by using the 6.3 MHz transducer to precisely focus on the thin auricular tissue (Woodacre et al., 2018). Still, even in this optimized setting, the liquefied tissue was not easily aspirated. The ablated volume might have been too small or insufficiently fluid to be drawn out, or perhaps the gelatin did not

perfectly mimic the drainage behavior of real clots (Khokhlova et al., 2016). It's also possible that the aspiration technique or timing needs refinement. Thus, while histotripsy clearly disrupted the fibrous tissue, translating that into complete removal remains a hurdle.

Limitations: This study used ex vivo pig ear models with gelatin clots, which may not capture all aspects of human cauliflower ear (e.g., true fibrocartilage structure or calcifications). The sample sizes were modest—particularly the n=2 in the critical skin-covered group—so the results should be confirmed with more samples. Another limitation was the reliance on mass change as the primary metric of ablation. Water absorption in unskinned samples masked the actual tissue loss; future studies should incorporate other measures (e.g, imaging of cavity volume or direct aspirate volume) less prone to this artifact. Finally, the inability to aspirate the liquefied tissue is a significant gap. For clinical translation, effective removal of the debris must be possible after tissue fractionation.

Continuation: The next step is to focus on the 15% gelatin + skin model with a larger cohort and consistent protocols. A study with a substantial sample size (e.g., ≥30 samples) using standardized histotripsy settings will allow robust statistical analysis—likely employing paired pre/post measurements and tests like a paired t-test to detect significant mass reductions. Additional outcomes such as the volume of aspirated material, ultrasound-visible cavity formation, and histological evaluation of treated tissue will provide a more complete assessment of efficacy.

Clinically, if ongoing studies validate that histotripsy can reliably liquefy and enable the removal of cauliflower ear tissue, the technique could be advanced toward patient trials. One can envision a scenario where an athlete with cauliflower ear undergoes an outpatient histotripsy session: the ear is coupled to an ultrasound probe and, under image guidance, cavitation is induced to break down the scar tissue, which is then aspirated through a small puncture. This would be a minimally invasive alternative to open surgery. Given the high prevalence of cauliflower ear in contact sports (Nitsch et al., 2023) and the drawbacks of surgical treatment (Putri et al., 2023), a noninvasive therapeutic option would represent a noteworthy advancement in sports medicine and otolaryngology.

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