Virginia Tech
Focused Ultrasound Lab

Histotripsy for Precise, Non-invasive, and Non-thermal Ablation of Keloid Scars

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What are Keloids?

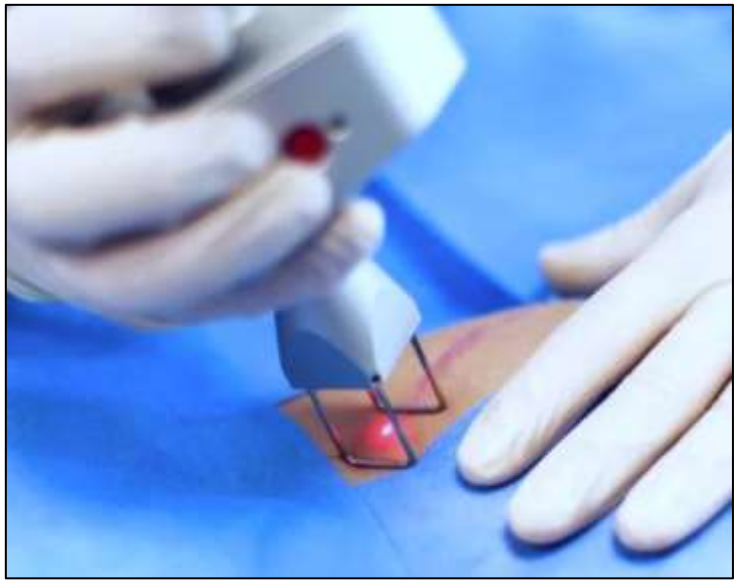
Keloids are pathological scars that form in response to skin trauma and aberrant wound healing processes[1-4]

Keloids grow over several years, rarely regress over time, and cause cosmetic/physical disfigurement

1American Academy of Dermatology Association; 2Boston Children's Hospital; 3McGinty S, Siddiqui WJ. Keloid. 2022 Stat, Pearls Publishing;
4Huang, S. et al, 2020. Quantitative assessment of treatment efficacy in keloids using high frequency ultrasound and shear wave elastography: a preliminary study. Scientific Reports

Keloid Treatment

Current treatment options for keloids include corticosteroid injections, surgical excision, and thermal ablation[1-4]

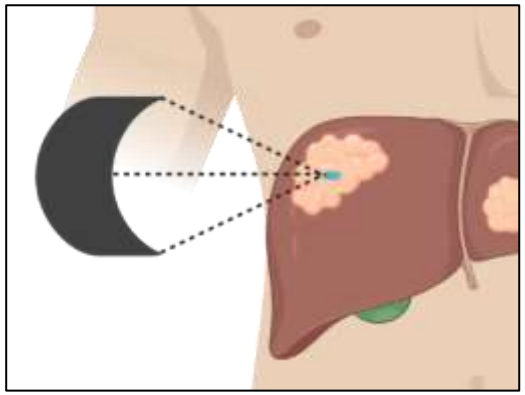


These treatments are associated with inconsistent results and very high recurrence rates post excision

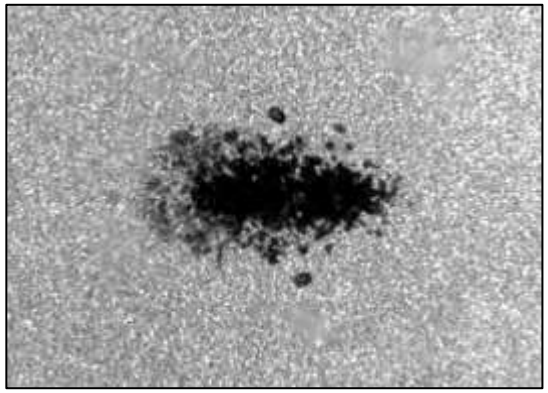
1American Academy of Dermatology Association; 2Boston Children's Hospital; 3McGinty S, Siddiqui WJ. Keloid. 2022 StatPearls Publishing;
4Huang, S. et al, 2020. Quantitative assessment of treatment efficacy in keloids using high frequency ultrasound and shear wave elastography: a preliminary study. Scientific Reports
Image adapted from VIP laser clinic medspa, STL Dermatology & Cosmetic surgery, VIP laser clinic med spa websites

What is Histotripsy?

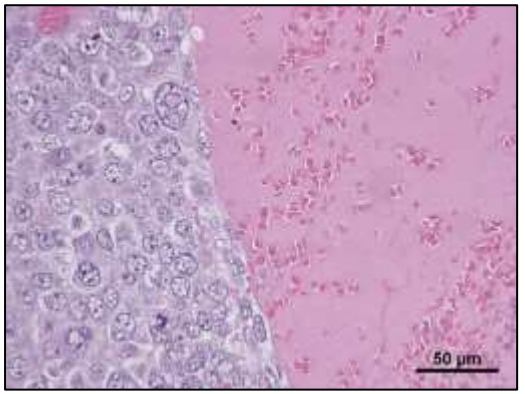
Non-invasive



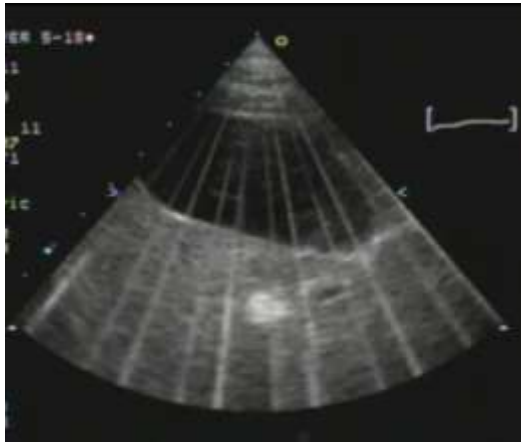
Cavitation



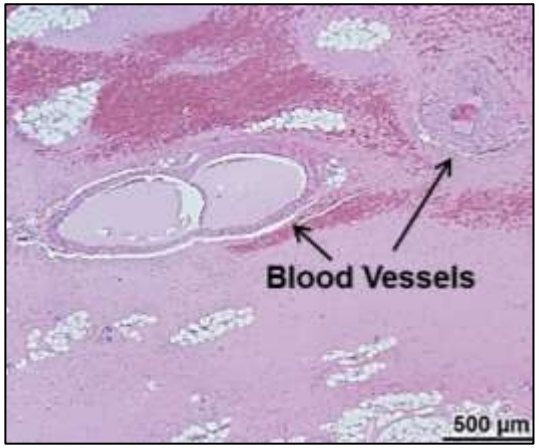
Precise Tumor Ablation



Real-time Image Guidance



Tissue Selective



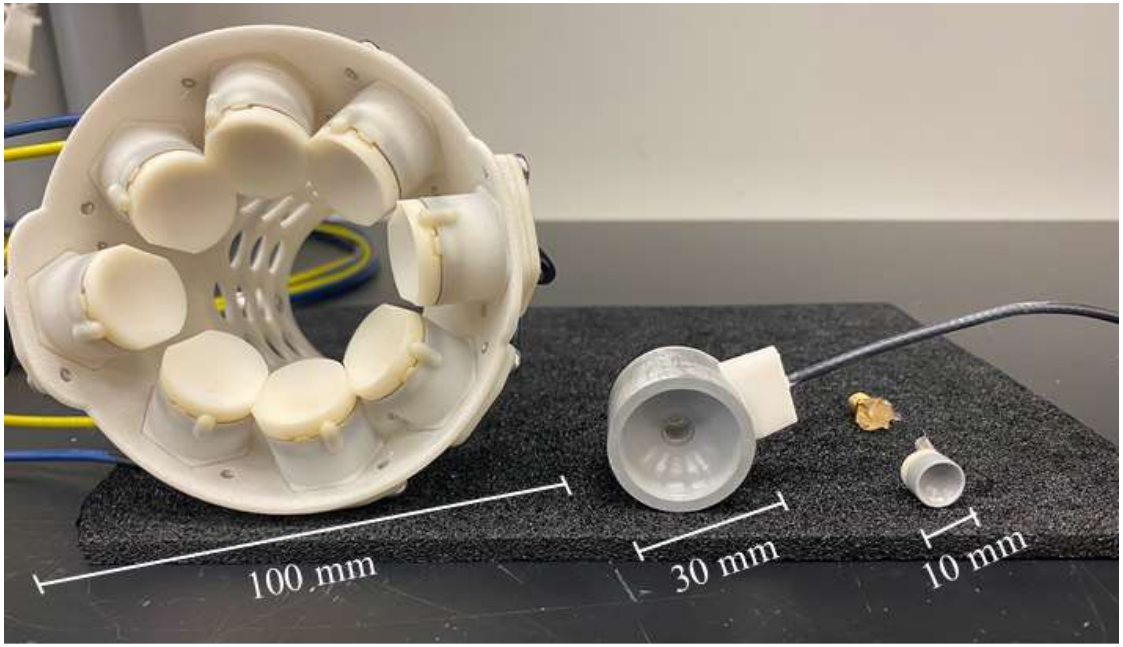
Histotripsy is the first completely non-invasive, non-thermal, and non-ionizing tumor ablation method

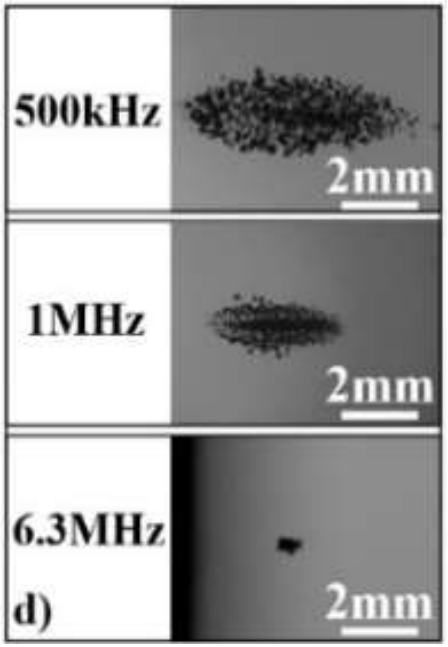
Histotripsy Clinical Status

HistoSonics received FDA approval for their Edison histotripsy device in October 2023

High Precision Histotripsy

Recent work by our group has developed miniaturized histotripsy devices for high precision ablation





In this study, we investigate histotripsy for the precise ablation of keloid scars for the first time

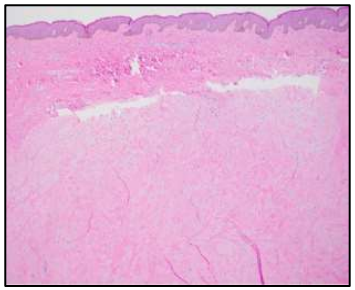
Inclusion Criteria

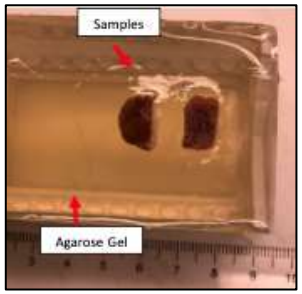
Keloid samples were collected from Carilion Clinic Dermatology Clinic after resection under an approved IRB

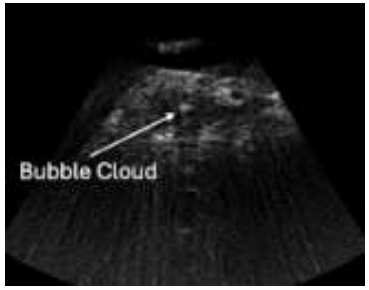
<u>Eligible patients</u>

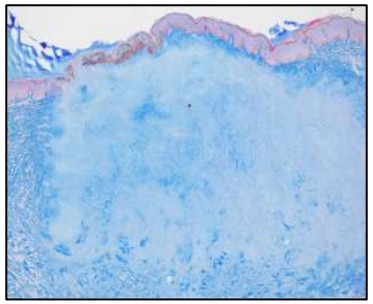
- *Well formed keloids (present >12 months)*
- *No recent keloid treatments*
- *No medical conditions affecting keloid consistency*

Experimental Workflow







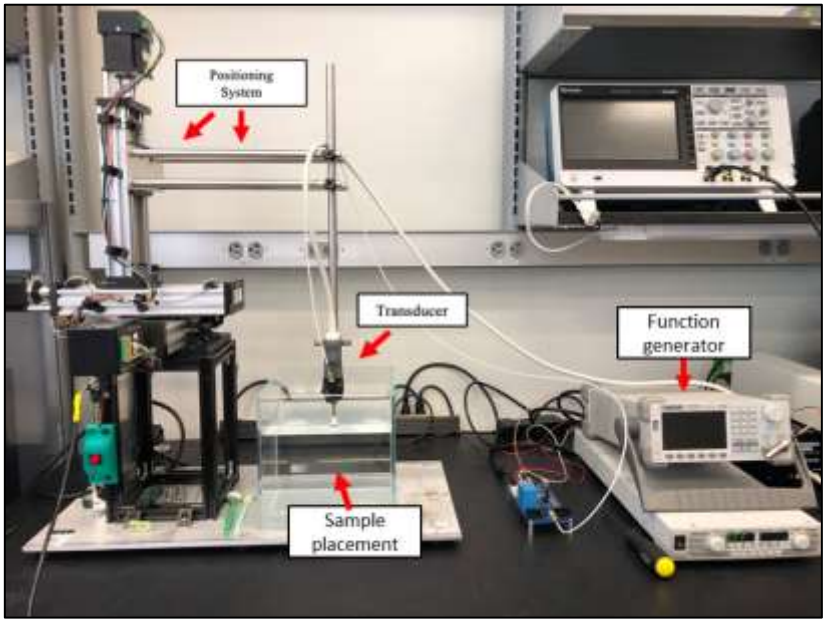


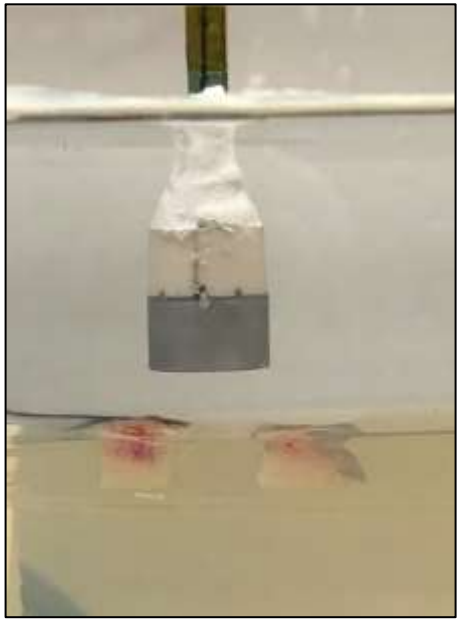
Keloid excision → Pre-histotripsy pathology analysis → Sample preparation → **Ex-vivo** histotripsy treatment (ideally within 24 hr) → Post-histotripsy pathology analysis (ablation scoring)

Transducer Frequency: 6.3 MHz
Pulsing Parameters:
1kHzPRF,
multicycle pulses
Dosage: 2,000-6,000 pulses/point
Treatment Volume:
Varied depending on keloid

Experimental Set-up

Feasibility of histotripsy for precise keloid scar debulking was evaluated *ex vivo* using excised human keloids

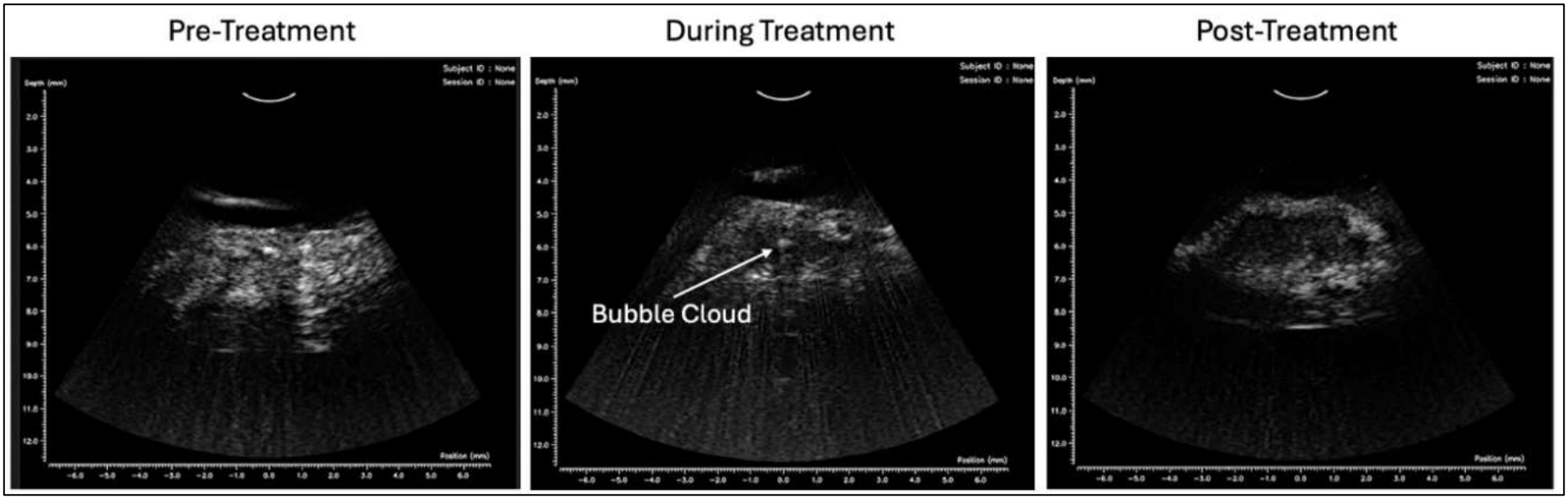




Histotripsy was applied (100-10,000 pulses/point) using a 6.3 MHz transducer guided by 30 MHz ultrasound imaging

Example Results: Treatment

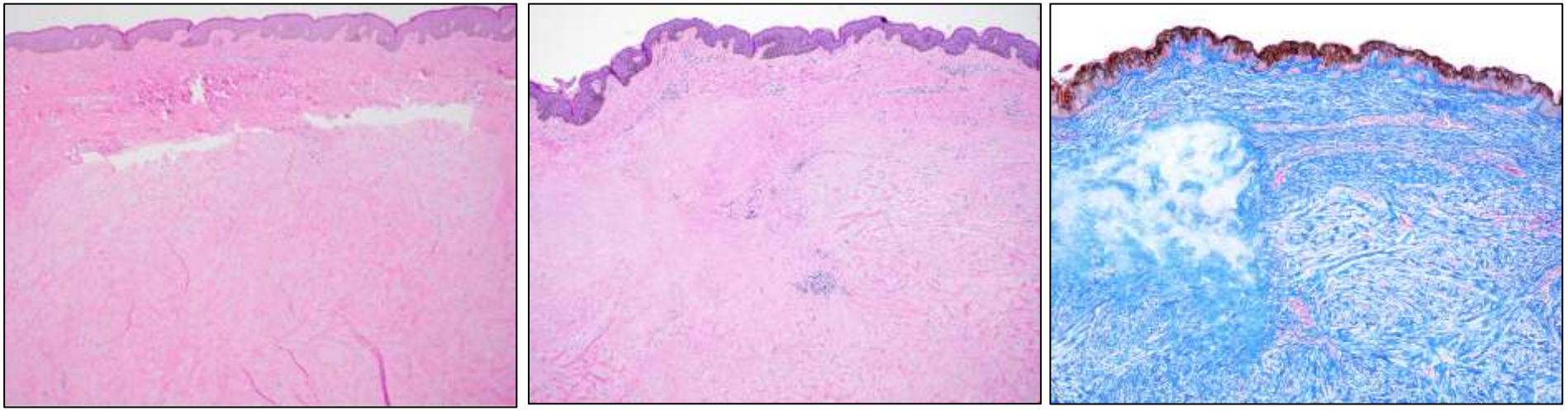
Precise histotripsy bubble clouds were generated inside of all treated keloid samples to date



Hypoechoic regions were identified in the samples post treatment, indicating effective histotripsy ablation

Example Results: Histology

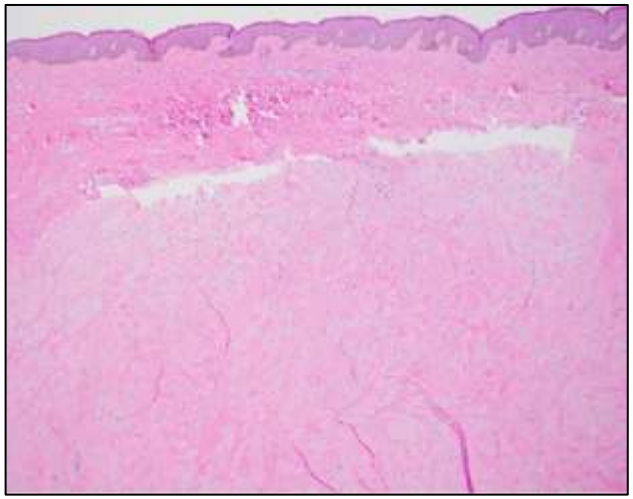
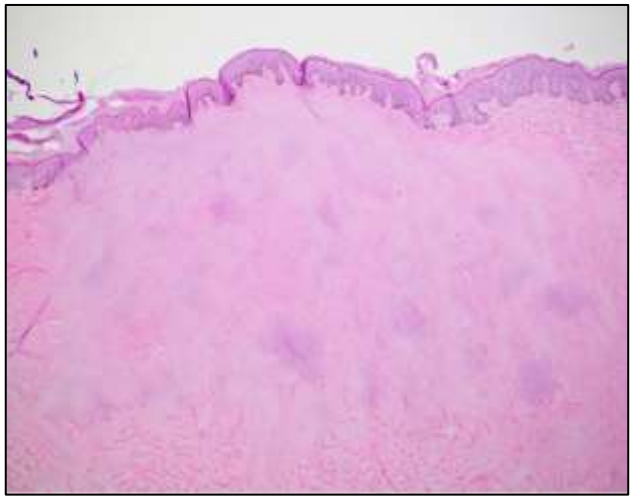
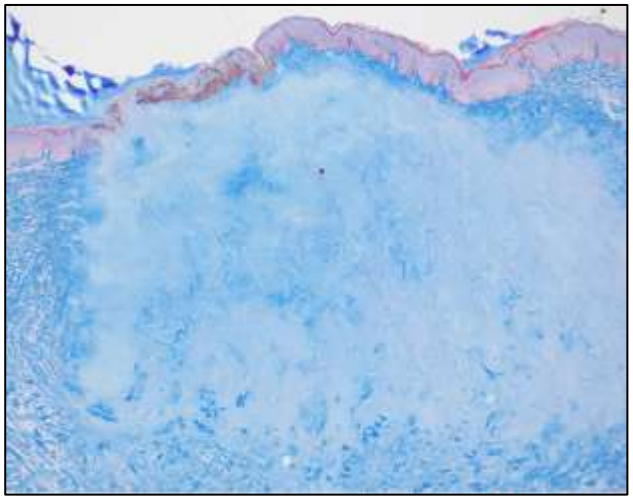
H&E and Trichrome images show precise and complete ablation up to the skin surface



Histological analysis showed histotripsy "liquified" the keloid into an acellular tissue homogenate

Example Results: Histology

H&E and Trichrome images show precise and complete ablation up to the skin surface

Histological analysis showed histotripsy "liquified" the keloid into an acellular tissue homogenate

Summary of Results

Histotripsy is capable of generating effective and precise keloid ablation in preliminary studies

- Robust bubble clouds were generated in all keloid samples
- Complete debulking of the targeted keloid volume was produced
- Precise ablation under the skin surface demonstrated using high frequency histotripsy systems

Project status

- 4 patients enrolled and treated to date
- A total of 25 samples are targeted to complete our full study

Overall, results suggest histotripsy is a promising modality for noninvasive debulking of keloid scars

Focused Ultrasound Lab

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