

Testing a Novel Piezoelectric Middle-Ear Microphone in Sheep

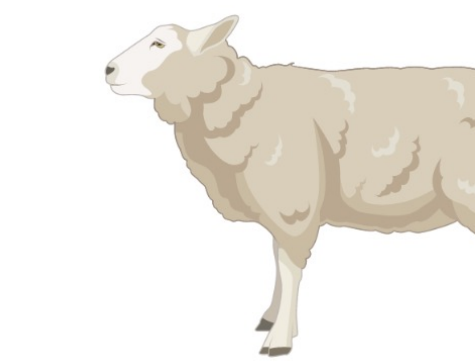
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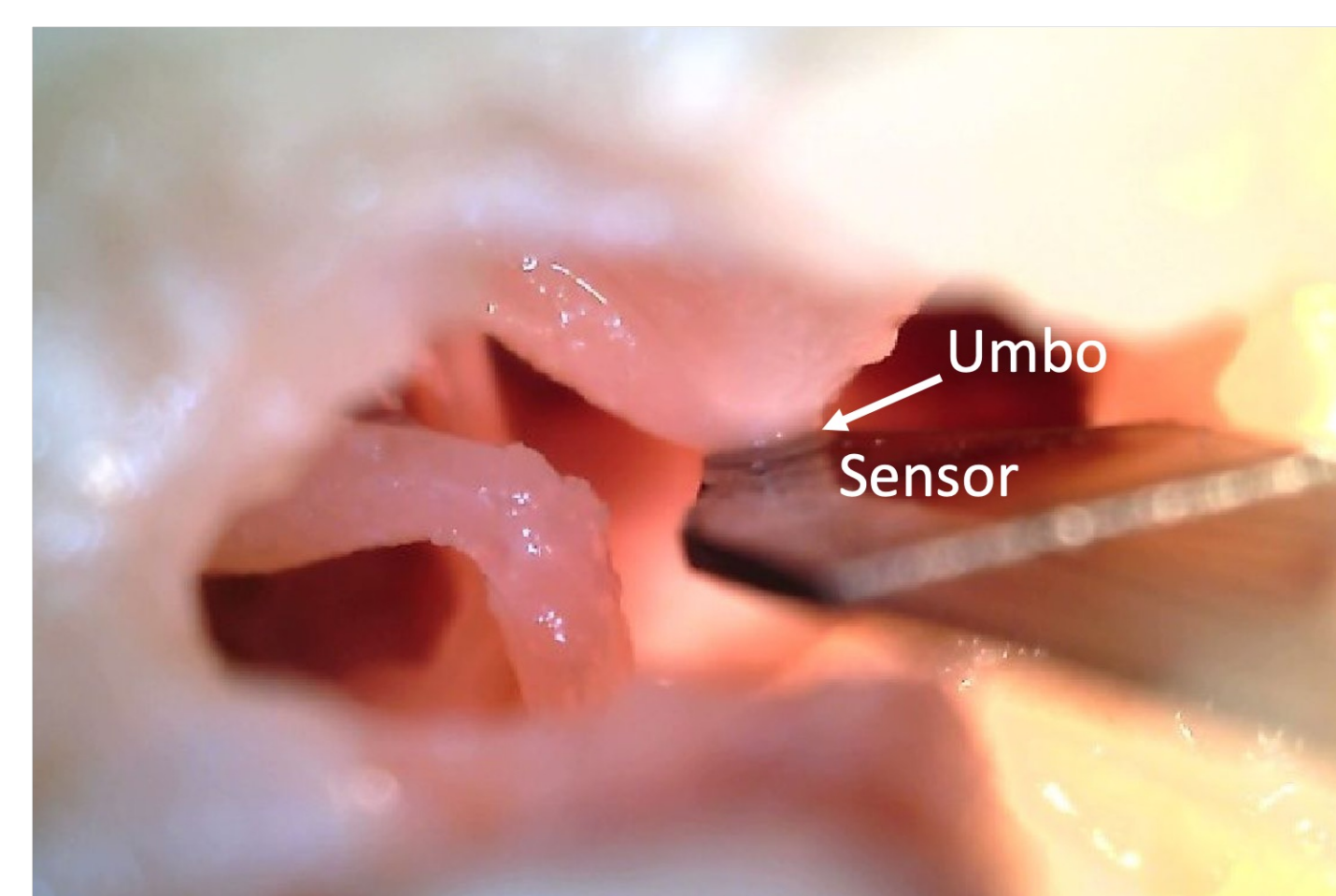
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Introduction

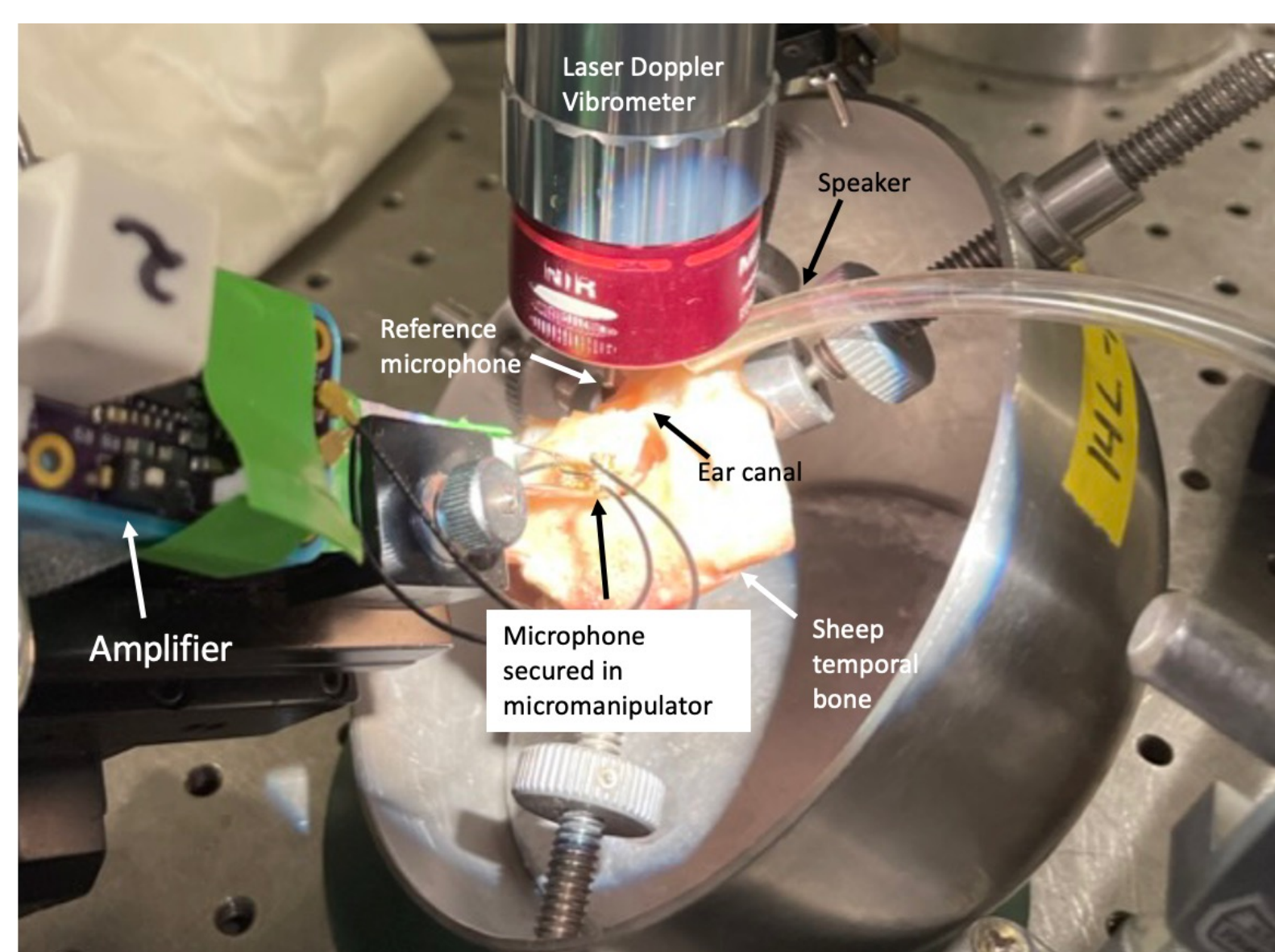
- ❖ We are working on an implantable middle-ear microphone for fully implantable hearing devices
- ❖ The microphone has a polyvinylidene fluoride (PVDF) sensor that contacts the umbo and has performed well in cadaveric human temporal bone tests
- ❖ Sheep are a suitable animal model to test the microphone *in vivo* due to similar middle ear anatomy to humans
- ❖ We developed a surgical approach for implantation of the microphone and tested microphone performance in cadaveric sheep temporal bones, in preparation for future live-sheep trials



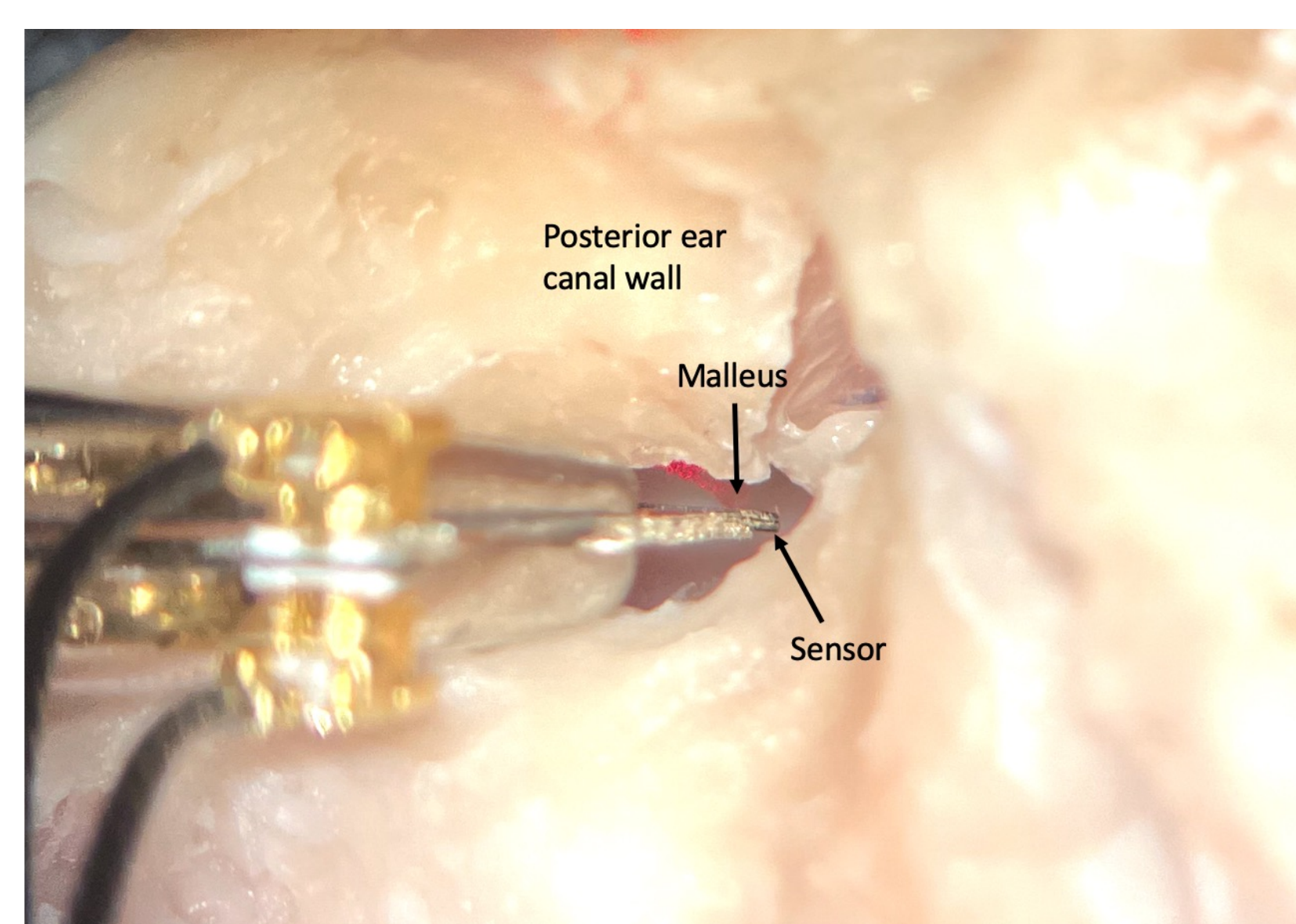
Sensor contacting umbo of human middle ear

Methods

- ❖ Temporal bones from five cadaveric fresh but previously frozen Hampshire sheep heads were surgically prepared with extended facial recess approach
- ❖ Middle-ear microphone was secured in a micromanipulator with the sensing region interfacing the convex portion of the manubrium close to the umbo
- ❖ Open-field single-tone stimuli from 1-20 kHz at 60-90 dB SPL were presented and measured with a reference microphone at the ear canal
- ❖ Middle-ear microphone output was measured via a custom-made amplifier and manubrium velocity was measured via laser Doppler vibrometer (LDV) through the ear canal



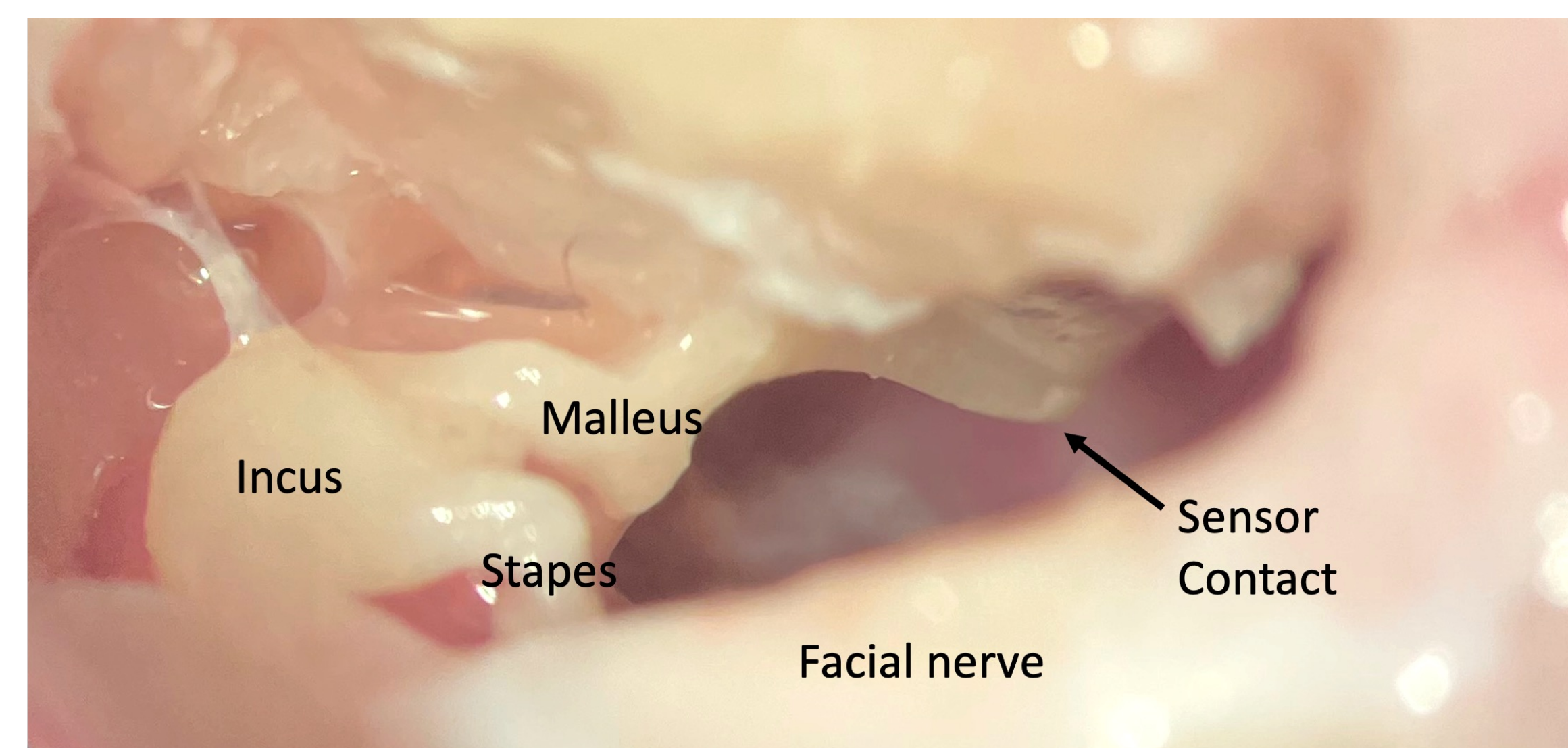
View of experimental setup in sound booth with sheep temporal bone, LDV, reference microphone, speaker, and microphone with amplifier



Microscopic view of sensor contacting manubrium of sheep malleus in left ear through facial recess surgical approach (tympenic membrane appears red due to LDV laser)

Results

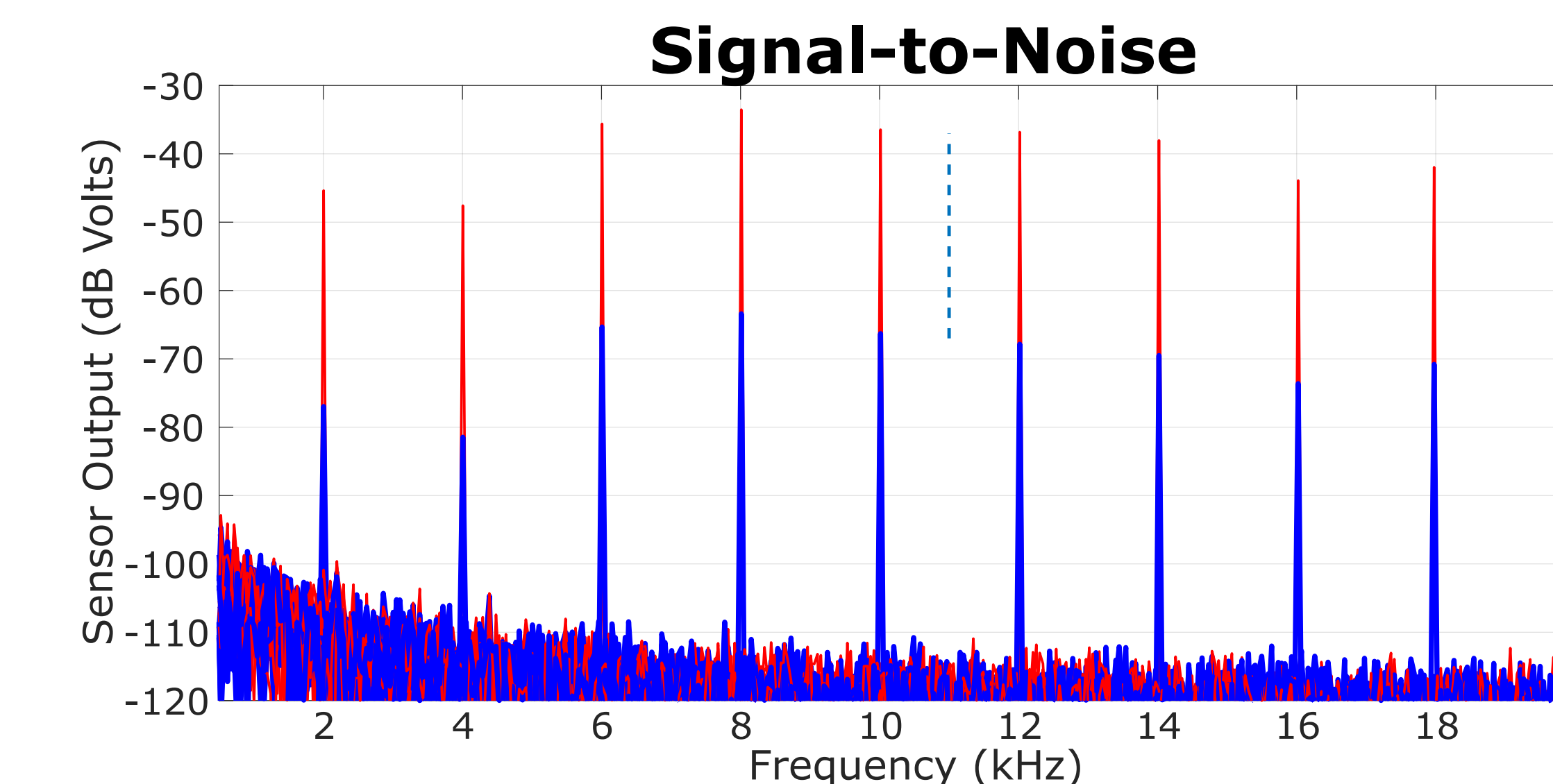
- ❖ The sheep malleus extends anteroinferiorly deep into middle ear cavity with a convex manubrium → sensor contacts convex portion of manubrium rather than umbo
- ❖ Sensor can be surgically placed with preservation of facial nerve
- ❖ The noise level was on average -110 dB Volts, and the microphone sensor output at 60 dB SPL sound stimulus was on average -70 dB Volts
- ❖ The microphone behaved linearly across the tested range of stimulus sound pressure



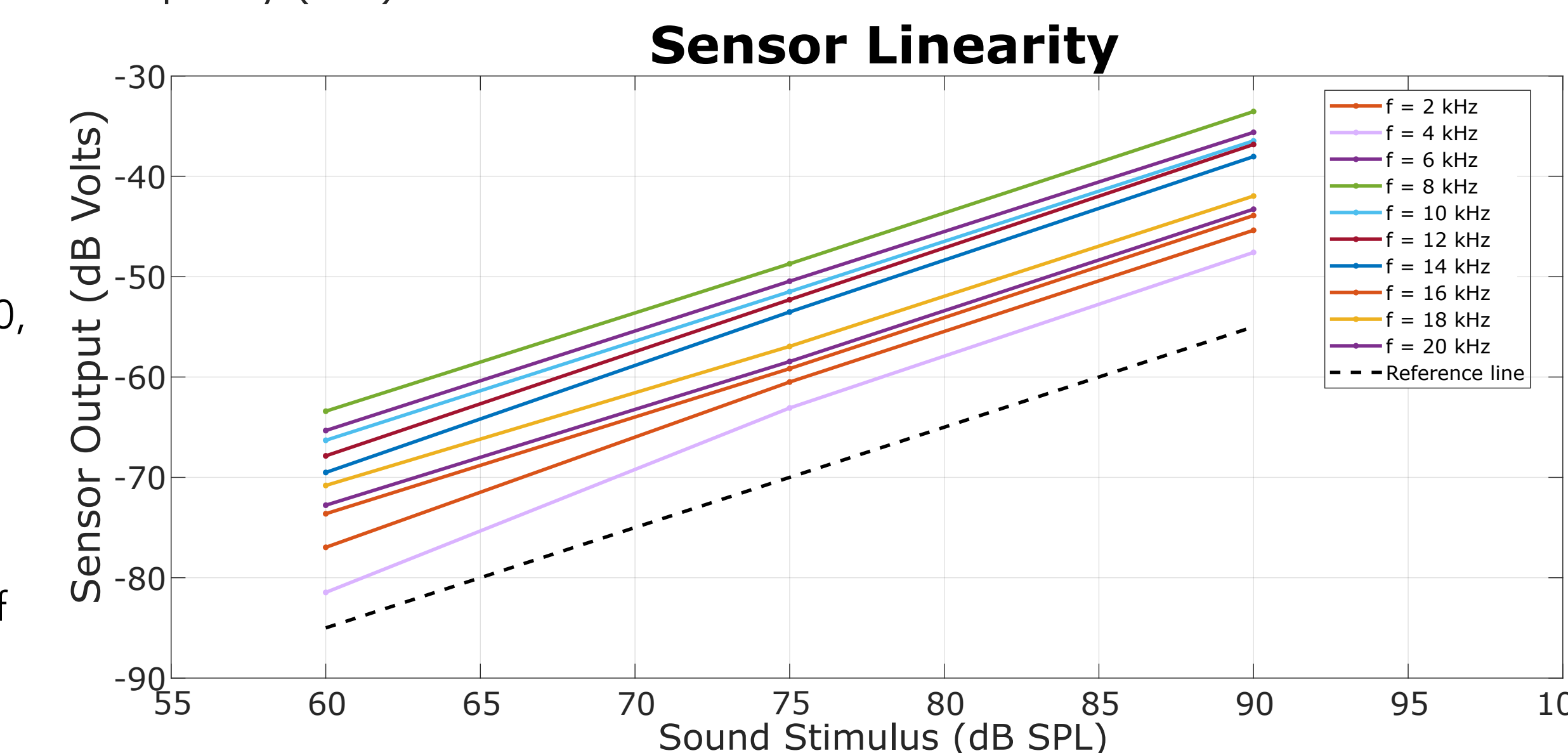
Left: Microscopic view of right sheep middle ear through extended facial recess surgical approach showing manubrium of malleus where sensor makes contact.

Right: Linearity plot showing sensor output in response to 60, 75, and 90 dB SPL sound stimulus at frequencies from 2-20 kHz. Black dotted reference line depicts the slope of a perfectly linear response.

Note: Data from 1 kHz not shown, as umbo displacement measured by LDV was nonlinear likely due to degradation of temporal bones at time of testing.

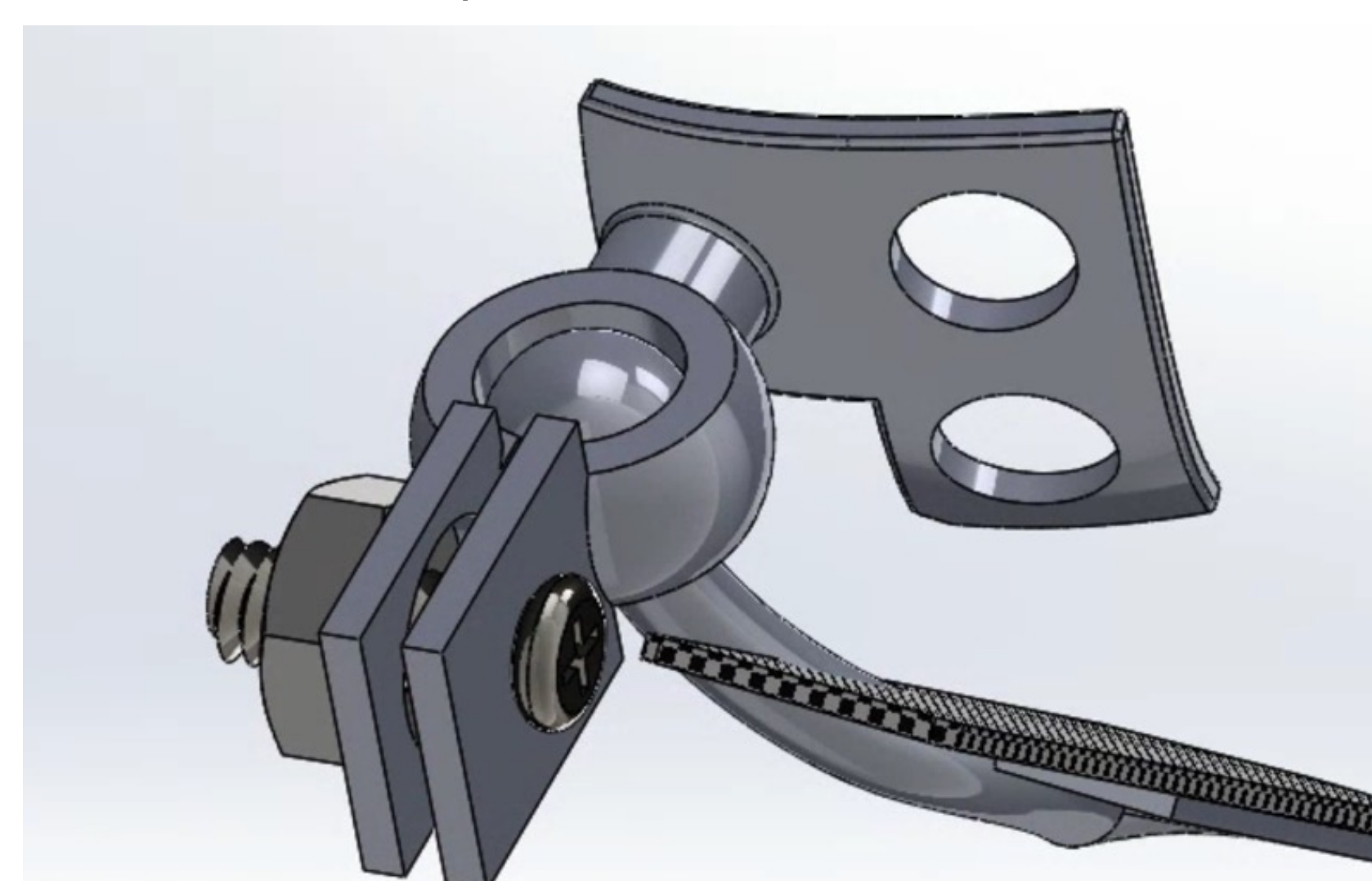


Left: Signal-to-noise plot showing sensor output in dB Volts in response to sound stimulus at 60 dB SPL (blue) and 90 dB SPL (red) at various presented frequencies from 2-20 kHz, with the noise level depicted at the bottom. Dotted reference line shows a difference in sensor output of exactly 30 dB (a perfectly linear response).

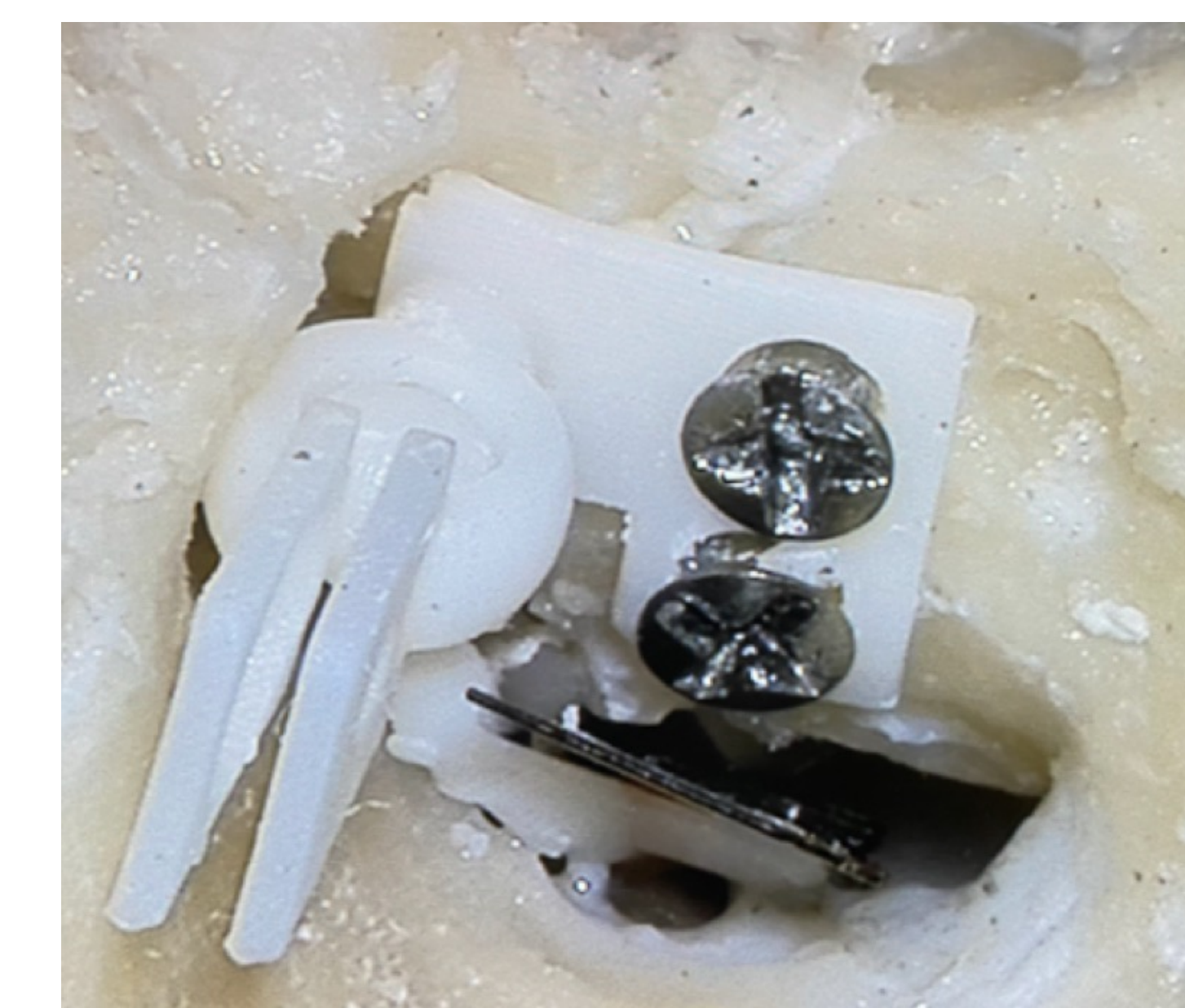


Fixation Device

- ❖ We are developing a fixation device to secure the microphone in place *in vivo*
- ❖ Using micro-CT scans of the post-surgical sheep temporal bones, we have been designing 3-D printed prototypes of the fixation device and iteratively improving the design
- ❖ The device has a plate that screws into the posterior ear canal, an arm containing the sensor that extends into the middle ear, and a ball-socket joint that is fixed once the sensor is in position



Prototype of fixation device showing plate, ball-socket joint fixed in place with screw, and arm with sensor (checked object) at the end



3D-printed fixation device prototype implanted in right sheep temporal bone

Conclusions

- ❖ The middle-ear microphone can be inserted with preservation of the facial nerve in Hampshire sheep
- ❖ In these previously frozen specimens, the microphone demonstrated **good signal-to-noise ratio** and **behaved linearly** across a dynamic range of input sound pressure
- ❖ These results suggest that Hampshire sheep will be suitable for **future *in vivo* large-animal survival trials** of our middle-ear microphone and potentially other types of middle-ear implants

References:
 Kaufmann CR, Tejani VD, Fredericks DC, Henslee AM, Sun DQ, Abbas PJ, Hansen MR (2020) Pilot Evaluation of Sheep as In Vivo Model for Cochlear Implantation. *Otol Neurotol.* 41(5):596-604.

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