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14. ABSTRACT Studies have been performed aimed at an improved biomechanical understanding of blast injury with the goal of creating new technologies for the mitigation of auditory injury from blast. Fiber-optic pressure sensors were used to measure and correlate external auditory canal (EAC) and intracranial pressure profiles during blast events. A compact programmable bench top simulator system was used to recreate recorded blast pressure profiles and deliver simulated blast wave forms at high intensity to human temporal bones. Intra-cochlear pressures were measured during harmonic and impulse stimuli using off-the-shelf fiber-optic pressure probes. Intra-cochlear pressures and ossicular displacements were recorded simultaneously and compared with those predicted by an existing auditory injury model. Stapedial displacements as measured both by scanning and single –axis LDV were found to exceed predicted values for extremely high pressure sand long durations characteristic of blast events. An electromechanical transducer was used to counteract ossicular movement resulting from harmonic and impulse stimuli, demonstrating feasibility of active mitigation of auditory injury from blast exposure. Future activities will be directed to improved auditory hazard models and development of active systems protective against blast injury.

15. SUBJECT TERMS-
Blast injury ,acoustic trauma , auditory injury, ossicular velocity, auditory hazard model ,hearing protection

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1 Blast Overpressure (BOP) experiments:

1.1 Objectives: Whole-head blast overpressure measurement

An important objective of this research effort is to evaluate the potential for auditory injury from blast exposure in the context of related injury (e.g. TBI) and within the environment of the head with and without protective equipment. For this reason, it is critical that blast pressures in the free-field be related to the pressures in the EAC. In this set of experiments, it was desired that pressures be measured in the EAC both unprotected and, with earplugs, both medial and lateral to the plug in whole heads exposed to the shock wave in various orientations and over a range of pressures. It was also desired that specimens be tested at pressures likely to cause TM rupture so as to assess the distribution of injury with pressure.

1.1.1 Facilities

The NMCSD shock tube was unavailable while modifications were made to the tube to reduce the noise level in the vivarium. A rugged polycarbonate enclosure was built to surround the tube exit, containing and diffusing blast wave energy before its entry into the facility. The following is a preliminary report of results taken during the first round of whole-head experiments with the newly modified shock tube.

1.1.2 Experimental Design

Specimen preparation

Mastoid The mastoids were all drilled out using the standard technique but the facial recess was not drilled. Thinning of the posterior EAC wall was performed.

Posterior EAC wall Drilled through using a 1mm diamond bur to enter into the EAC to be used as the channel for the EAC probe.

EAC / TM Cleaned and examined to ensure patency of transcanal hole and intact TM.

EAC probe Placement made through the mastoid bowl and transcanal wall into the EAC and then secured with Jeltrate. Placement confirmed under indirect visualization using a rigid scope. The postauricular incision was then sutured closed with the wire further secured to scalp with suture, taking care not to directly suture through the wire.

External probe 1 For the first day the probe was secured to the scalp and located on the forehead. On the 2nd and 3rd day it was placed through the top portion of the posterior scalp incision with only the pressure probe tip externalized. It was secured with jeltrate and the incision was closed over the jeltrate with suture. The 2nd probe for Ear 2 was placed midway through the experiment just adjacent to the first. A 16 gauge catheter was passed through the skin and then the probe was passed through the catheter and secured using suture.

Head placement Head was secured with a Mayfield and the lateral head/ear was placed at the threshold of the Blast Over-Pressure (BOP) tube.

BOP outputs Outputs were done on day 3 specifically at PSI levels 2/3/4/5/7/10/12/15/20 for with and without ear plugs. Day 2 was at less consistent ranges but within the same range. Day 1 did not include testing with ear plugs.

Examination of TMs for rupture was performed after each BOP using a rigid endoscope. This also allowed re-verification of EAC pressure probe placement. On Day 3 endoscopic examination was not performed.

Data description Data from Day 2 (first day of ear plug testing) is reported for two ears using earplugs. Probe placement for the third ear was too lateral and would have caused the ear plug to come in contact with the probe itself.

Ear 1 Testing began with the EAC and external probe. BOPping began at 4 PSI because we were concerned that it will be difficult to achieve consistent peak pressures lower than this. Testing was performed as low as 2 PSI but at 1 PSI a significant BOP was not possible. Near the end of the Ear Plug testing for Ear 1 the external probe became unreliable and ultimately after the 20 PSI BOP the probe failed. Of note, the ratio of EAC/External probe PSI measurements remained fairly constant around a 1:3 ratio for the "earplug" set.

Ear 2 Same set up and plan as Ear 1. The first of 3 sets seems anomalous because pressures measured by the external probe were less than in the EAC with the ear plug present up to 5 PSI. The external probe at higher levels was reading lower as well. To resolve the anomaly we repeated the ear plug test with a second external probe adjacent to the first external probe to verify its values. The first external probe remained in the exact same spot for the second set. The external probe gave reliable results in the second set. We did see in both the first and second sets that the EAC probe read higher than the external (s) up to 5 PSI and then gave lower measurements; this is unexplained. The ratios of the EAC / external 1 also were < 1 at this point and in the mid range became similar to EAR 1. Note also the ratio of External 1: External 2 remained relatively constant between $1.00 - 1.19$ suggesting consistent external ear readings. With successive test runs, the research team took pains to ensure that the specimen was EXACTLY in the same place with each successive BOP. For all 3 sets of Ear 2 data and the "no ear plug" set of Ear 1, output was observed to drop with the change from 200 to 400 gauge film in the shock tube rupture membrane.

Lessons learned

Tympanic membrane rupture Data were highly variable, with one rupture at 7 PSI, another at 20 PSI and some never or up near 40+ PSI. Moving the specimen after successive BOPs caused greater error in replacing the specimen in front of the tube. Some of the inconsistency may be due to variable thawed states, e.g. specimens in the morning tended to be more frozen then afternoon specimens.

Specimen placement The ear / head was placed at the threshold of the tube and close to central each time. Consistent specimen placement was critical to data repeatability. Even a $\frac{1}{2}$ inch off created up to a 2 PSI difference in measured pressure at the same PSI in BOP output. By Ear 2 the team was able to keep the specimen in the same spot by marking the specimen and measuring between successive BOPs. In future experiments great care will be taken to ensure consistent specimen placement and minimal movement between BOPs

Film gauge The 200 gauge film was limiting output once we got to the 10-12 PSI BOP output levels. Above this level the film would prematurely rupture. Also, Ear 2 and the second set for Ear 1 showed a significant drop when the film was changed, as measured by the probes. For the next set of experiments, it is recommended that the film be consistent throughout the test run. For pressures above 12 PSI 400 gauge film is preferred, and can also be used at lower PSI ranges.

Output range tested A good curve from $1 - 20$ PSI was desired; however, a reliable BOP at 1 PSI was difficult to achieve. Also, the external probes were inconsistent or broke at 20 or higher PSI. Lastly, results were inconsistent below 5 PSI. Suggestion: test output levels 2-5, 7, 10, 12, 15 but perhaps consider eliminating levels 2-4.

EAC (internal) probe placement Overall very good / consistent results were achieved, and the probes, which were secured with jeltrate in the mastoid bowl, were reliable. Good technique was developed for placement just lateral to the TM and ensuring just the tip was in the EAC.

External probe Reliability and consistency of the external probe is the biggest issue observed. On day 1 placement was midline on the forehead just above the brow. Day 2 and 3 it was placed more laterally, which gave better results. The external probe was placed in parallel to the EAC probe so the tips were in similar planes. Despite closer placement the probe is still a good 4-5 cm above the EAC, bringing into question whether the pressure it sees is comparable to pressure in the external auditory meatus. If the external probe is needed as a control, great care in placement is needed to make better comparisons between specimens. Additionally, it is very difficult to consistently secure the probe. On Ear 2 a 16-gauge catheter was inserted through the skin with the probe tip just poking out. It protected the probe better; however, there were still problems with reliability and consistency at high PSIs. One thought is to place the probe either through the conchal bowl from posterior to anterior, or it could be placed along the cheek along the zygoma (anterior to posterior) so the tip is just anterior to the tragus. Suggestion: need a more consistent setup for the external probes which protects it as well, such as a 16-gauge catheter. A mounted Dytran probe could be used as a control as long as each specimen is consistently in the same place.

Probe integrity The FISO fiber optic sensors break when used as the external probes or don't read data consistently at high pressures. We have learned how to better protect the sensors, but they remain vulnerable, especially when exposed to the blast wind. Long-term, we need to evaluate what types of sensors are most appropriate for the various locations, perhaps restricting the FISOs to those locations where nothing else will fit.

Ear plug placement Ear plug placement was straightforward and plugs stayed in place. We found that the more medial the EAC probe the better we ensured (theoretically) that the ear plug and the probe did not come in contact. There is significant ear-to-ear variability in how the ear plugs fit and how well they attenuate.

Number needed to test There is great variability in the peak pressure at TM rupture. Since the EAC is not usable for evaluation of earplug attenuation after rupture, any fine-grained study of earplug effectiveness should perhaps be completed on the entire population of whole-head specimens available at NMCSD before even trying to complete the study of pressure to rupture. When those data are acquired, it seems likely from early experience that 14 ears will not suffice to define the distribution to high confidence.

1.1.3 Whole-Head EAC data from NMCSD, April 2012

EAR 1					
	Film	Output			Ratio
File	Gauge	(psi)	EAC	External	(EAC/Ext)
Ear Plug					
1	100	4	2.5	6.54	0.382262997
2		2	1.2	4.28	0.280373832
5		3	1.56	5.4	0.288888889
6	200	3	1.51	5.31	0.284369115
8		5	1.48	5.3	0.279245283
9		7	1.55	5.21	0.297504798
10		10	2.75	8.54	0.322014052
11	400	10	3.18	9.44	0.336864407
12		12	3.2	8.75	0.365714286
14		15	3.46	7.83	0.441890166
15		20	1.93	5.46	0.353479853
		20	4.72	14.78	0.319350474
No Ear Plug					
	200	2	1.17		
		3	1.84		
		4	3.69		
		5	7.53		
		7	8.44		
		10	9.9		
	400	12	3.61		
		15	9.14		
		20	18.9		

Note: The external pressure probe was broken after the 20 PSI BOP in the first Ear plug set and not available for the second part

Probe placement: EAC: through posterior canal just lateral to TM

External 1: lateral head just superoanterior to same auricle

External 2: lateral head just superior to External 1

Note: all probes were placed parallel to one another

EAR 2							
	Film	Output		External	External	Ratio	Ratio
File	Gauge	(psi)	EAC	1	2	(EAC/Ext1)	Ext1/Ext2
Ear Plug							
50	200	2	1.53	1.2		1.275	
2		3	2.05	1.71		1.198830409	
3		4	2.18	1.88		1.159574468	
4		5	3.49	4.31		0.80974478	
5		7	5.25	4.02		1.305970149	
7		10	6.87	14.02		0.490014265	
8		12	6.85	5.68		1.205985915	
9	400	12	2.9	4		0.725	
10		15	4.21	4.73		0.890063425	
11		20	9.28	6.7		1.385074627	
	Note 1						
Ear Plug							
12	200	2	1.057	0.9		1.174444444	
13		2	1.03	0.835	0.925	1.233532934	1.107784431
14		3	1.43	1.31	1.38	1.091603053	1.053435115
15		4	1.78	1.54	1.65	1.155844156	1.071428571
17		5	2.5	3.23	3.5	0.773993808	1.083591331
18		7	3.44	6.49	7.78	0.530046225	1.198767334
19		10	4.98	11.16	12.93	0.446236559	1.158602151
20		12	5.25	13.61		0.385745775	
21		12	4.88	9.51		0.513144059	
22		12	5.03	13.33		0.377344336	
23	400	15	3.22	4.64	4.65	0.693965517	1.002155172
24		20	7.81				
25		20	7.76				
No Ear Plug							
26	200	2	1.6	1.07	1.17	1.495327103	1.093457944
27		3	2.36	1.78	1.96	1.325842697	1.101123596
28		4	7.51	4.71	4.97	1.59447983	1.055201699
29		4	3.01	2.39	2.6	1.259414226	1.087866109
30		5	7.6	4.78	5.92	1.589958159	1.238493724
31		5	9.07	5.91	6.62	1.534686971	1.120135364
32		7	11.67	7.75		1.505806452	0
33		10	16.07	12		1.339166667	0
34		10	17.36	13.89		1.249820014	0
35		12	15.9	13.6		1.169117647	0
36	400	12	4.48	3.86	3.87	1.160621762	1.002590674
37		10	3.77	3.18	3.94	1.185534591	1.238993711
38		15	6.05	5.29	5.43	1.143667297	1.026465028

Note 1: Only 1 External probe used
Note 2: 2 External probes adjacent to one another to verify external probe 1 data using same head
Note: External probe malfunction where data not present

1.1.4 Facilities for future tests

The research team has evaluated two other shock tube facilities and found them suitable for these experiments: one in Littleton, CO and one in Albuquerque, NM. Another shock tube facility in San Antonio, TX has been identified and will also be considered when determining the location for the next full experimental set.

1.1.5 Conclusions:

Preliminary data from whole-head pressure measurements show that the placement of the specimen with respect to the shock tube is critical to data consistency; also the location and protection of the pressure probes needs to be made very robust and standardized across experiments. TM rupture was highly variable with peak pressure, and may be difficult to assess consistently with this experimental setup.

2 Intracochlear pressure measurement

Previously, researchers have measured intracochlear pressures in cadaveric temporal bones for harmonic stimuli at sound pressure levels typical of normal hearing. These experiments used custom made fiber optic pressure sensors, which involve great time and difficulty in fabrication, and require a facility equipped to handle hazardous chemicals (e.g. hydrofluoric acid). In addition, the signal-conditioning circuitry was custom-designed for use with these sensors. An experimental method for measurement of cochlear pressures using off-the-shelf sensors and circuitry was desired.

In earlier experiments [5], intracochlear pressures were measured at high input sound pressure levels, while ossicular velocities were measured at lower input levels; these measures were then normalized to one another. More recently, [4] intra-cochlear pressures and ossicular velocities were measured simultaneously; as noted above, this approach required the use of custom fiber optic pressure sensors for their higher sensitivity. To our knowledge, the current set of experiments is the first occasion where commercially available, off-the-shelf pressure sensors have been used to measure differential intracochlear pressures simultaneously with LDV measurements of ossicular velocity. The use of readily available commercial sensors with a very large dynamic range opens the possibility for measurements and characterization of ossicular dynamics across the sound pressures characteristic of normal hearing and the extreme pressure levels seen in blast events. These experiments also act as proof of concept for application of 260 micrometer diameter sensors for direct intracochlear pressure measurements, simultaneously with LDV measurement of ossicular velocity, without the need for separate input pressure intensity levels. Experiments are planned in which these techniques will be extended to sound pressure levels at and above 170 dB SPL using a blast simulator so as to characterize ossicular dynamics and intracochlear pressures during blast exposure.

2.1 Experimental methods:

2.1.1 Population / sample studied:

Six human cadaveric temporal bones were used for this study, three of which were expended to develop the technique.

2.1.2 Specimen Preparation:

Procurement and handling of cadaveric heads and temporal bones were conducted in accordance with Naval Medical Center San Diego, United States Army Medical Research and Material Command, and University of California San Diego custodial and ethical regulations. The temporal bones were harvested from fresh cadavers. The porous acousticus and cochlear acqueducts were occluded with bone wax and stored in normal saline solution the day before experiments. The temporal bsones were prepared by a mastoidectomy and extended facial recess, exposing the malleus head (M), incus body (I), incus long process (ILP), stapes superstructure (S) and round window membrane (RWM). The extended facial recess involves sacrificing facial nerve and widening facial recess to completely view of oval and round window. The promontory was thinned at oval and round window to get access to the scala vestibuli and scala tympani for placement of sensors.

2.1.3 Method(s):

Specimen Preparation Human temporal bones were prepared by a mastoidectomy and an extended facial recess affording a full view of the stapes and round window (RW). Cochleostomies were drilled in the scala vestibuli and scala tympani with a 500 µm diamond burr until the wall of the otic capsule was blue-lined; the final aperture was then created with a hand pick to make a hole of 300 um. Sensors were placed in the scala vestibuli and scala tympani and sealed with alginate cement. Acoustic stimuli were applied and data (stapes or RW velocity and intracochlear pressures) were acquired using a custom Matlab program controlling a Hammerfall sound card. The calibrated tones were presented from 50 Hz to 18.1 kHz with 2 frequencies per octave and ranging from 90-130 dB SPL.

2.1.4 Fiber Optic Pressure Sensors

Commercially available fiber optic sensors of 260 µm diameter with associated signal conditioners (FISO FOP M-260, FISO, Inc. 195-500 St-Jean-Baptiste Quebec City, QC G2E 5R9, Canada) were used for these experiments. These were 260 micrometer diameter sensors with frequency response up to 200 kHz and sufficient sensitivity to record at sound pressure levels typical of normal hearing. Figure 1 shows the sensor diagram reproduced from its data sheet (`http://www.fiso.com/section.php?p=21`). Note particularly the pressure sensitive membrane. The pressure sensors were pre-calibrated by FISO, and the calibration factor was entered before each experiment.

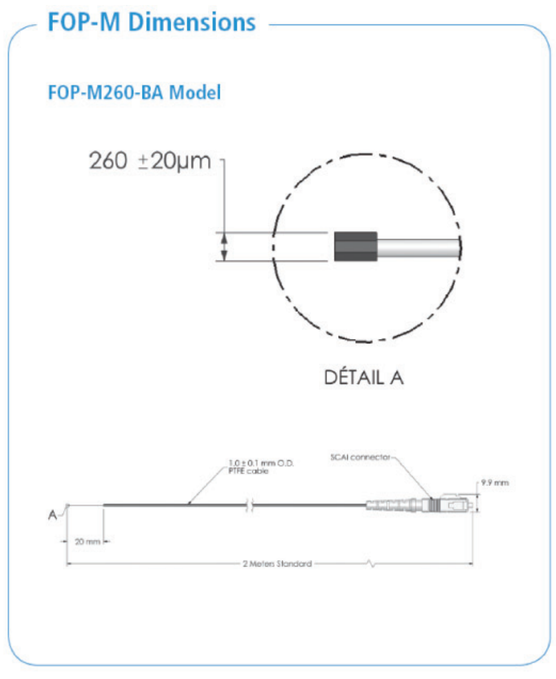


Figure 1: FISO FOP M 260 Fiber Optic Sensor (Reproduced from FOPM M260 sensor datasheet from FISO).

2.1.5 Cochleostomy and Sensor Placement

The temporal bones were verified to behave normally by recording the stapes velocity at known SPL before and after cochleostomy. These were verified against the range of normal temporal bone velocities as shown by Rosowski et al., 2007 [[6]. Cochleostomies were drilled in the scala vestibuli and scala tympani. The cochleostomies were drilled with a 500 um diamond burr until the wall of the otic capsule was blue-lined. The final aperture was created with a hand pick to make a hole of 300 um, and the sensors were placed in the scala vestibuli and scala tympani. The sensors were tightly sealed with alginate dental impression material (Jeltrate, L.D. Caulk Co.). To prevent entry of air into the cochlea, the process of cochleostomy drilling and sensor placement was performed while the temporal bone was immersed in saline solution. This was possible in part because the alginate is strongly hydrophilic, and sets up readily under water. Figures 2,3, and 4 show the temporal bone preparation for pressure sensor placement in cochleostomies and stimuli presentation in the EAC. The temporal bone preparation and sensor placement was similar to that described in Nakajima et al., 2009.

2.1.6 Stimuli Presentation and Data Collection

Stimuli generation and data collection were performed using a custom written matlab program (Mathworks, 3 Apple Hill Drive Natick, MA 01760-2098 USA). The matlab program controlled the stimulus presentation and

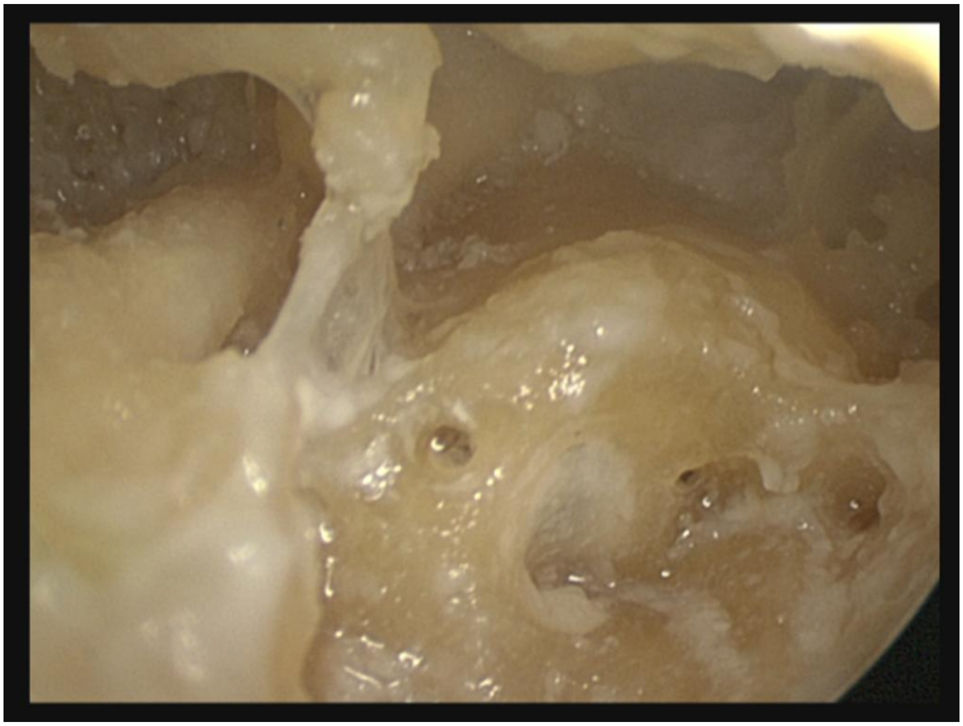


Figure 2: Cochleostomies in scala vestibuli (L) and scala tympani (R)

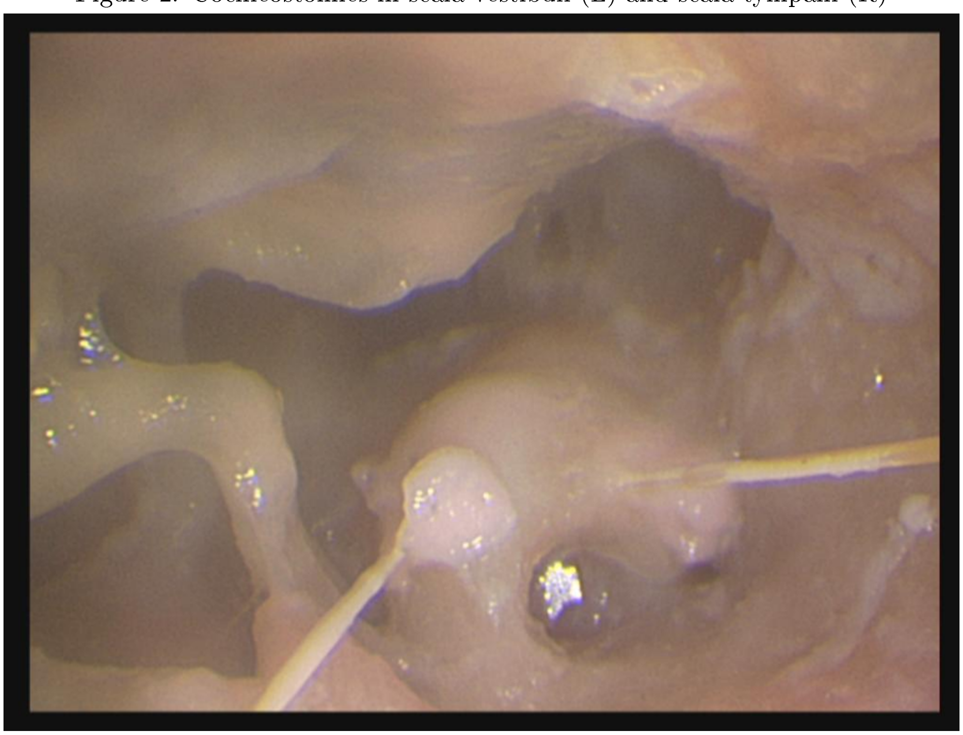


Figure 3: Placement of pressure sensors and mirror in round window

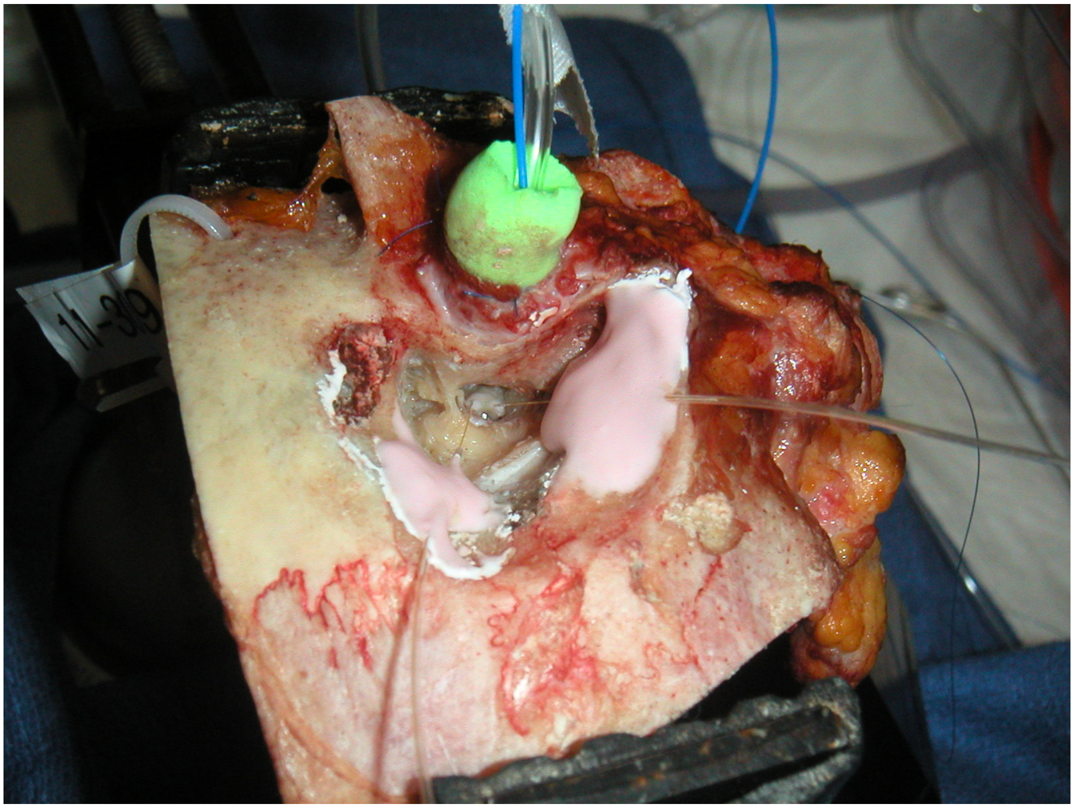


Figure 4: Temporal bone setup

data collection through a Hammerfall sound card (RME, Am Pfanderling 60 85778 Haimhausen Germany). The tones were presented from 50 Hz to 18.1 kHz with 2 frequencies per octave. Each tone was presnted 20 times and averaged to increase the signal-to-noise ratio. A polyethylene tube was connected from a TDT CF1 speaker (TDT, Alachua, FL 32615 USA) speakers to EAC [4] through a foam ear plug. A calibrated FOM-BA (dia=800 microns, FISO, 500 St-Jean-Baptiste, suite 195 Quebec, QC, G2E 5R9 CANADA) sensor was also placed in the EAC through a foam plug locating the sensor approximately 1 mm from the TM. The stimulus itself, pressure sensor data from EAC, scala tympani, scala vestibuli and ossicular velocity either at stapes or RW were recorded. The ossicular velocities were recorded with a single axis LDV (model CLV-2534-3, Polytec, 16400 Bake Parkway Irvine, CA, USA) from stapes or RW one at a time.

2.2 Results: Intracochlear Pressure Measurements

2.2.1 Velocity Transfer Functions

The stapes and RW velocities were recorded before and after the cochleostomy. Figures 7,8,9, and 10 show the stapes and RW velocity transfer functions measured after cochleostomy and placement of pressure sensors. These transfer functions were calculated by dividing velocity by sound pressure level at TM in terms of Pascals (Pa). The shaded area shows the acceptance criteria for a temporal bone to be considered normal according to Rosowski et al., 2007[6]. Note that the normal stapes velocity transfer function is shown as a shaded area for reference in plots of both stapes and RW velocity, though it is not strictly applicable to the latter. There was no significant difference observed in transfer functions before and after cochleostomy. The stapes velocity transfer functions show a drop in velocity around 1 kHz relative to the normal band; this may be an artifact of preservation and handling for the experimental lot of temporal bones. In future experiments, stapes transfer function will be carefully examined to determine which factor(s) in specimen history, handling and preparation may affect frequency-dependent response. Taking the 1000 Hz anomaly into account, these temporal bones are substantially normal in response, and suitable for evaluating the

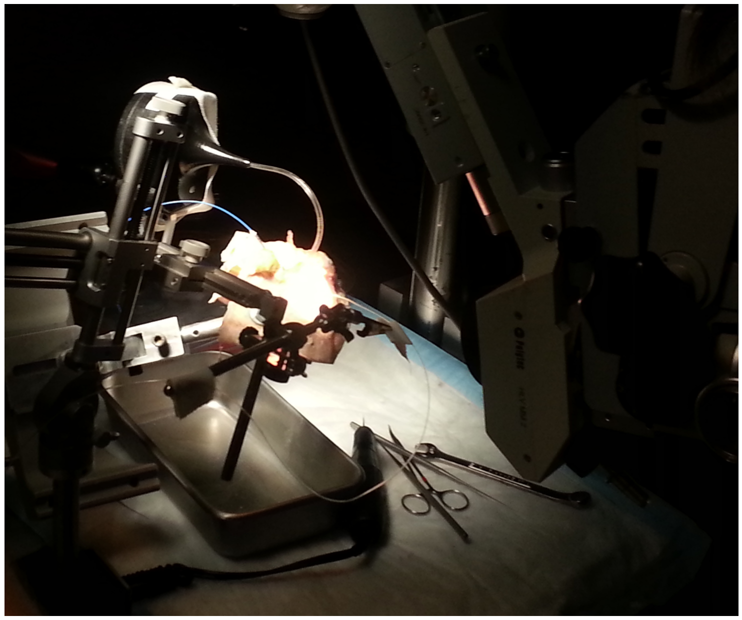


Figure 5: Temporal bone as mounted with LDV and manipulator. Note micrometer stage used to advance pressure probe into scala.

Figure 6: Blast simulator with tube to EAC

pressure-measurement technique.

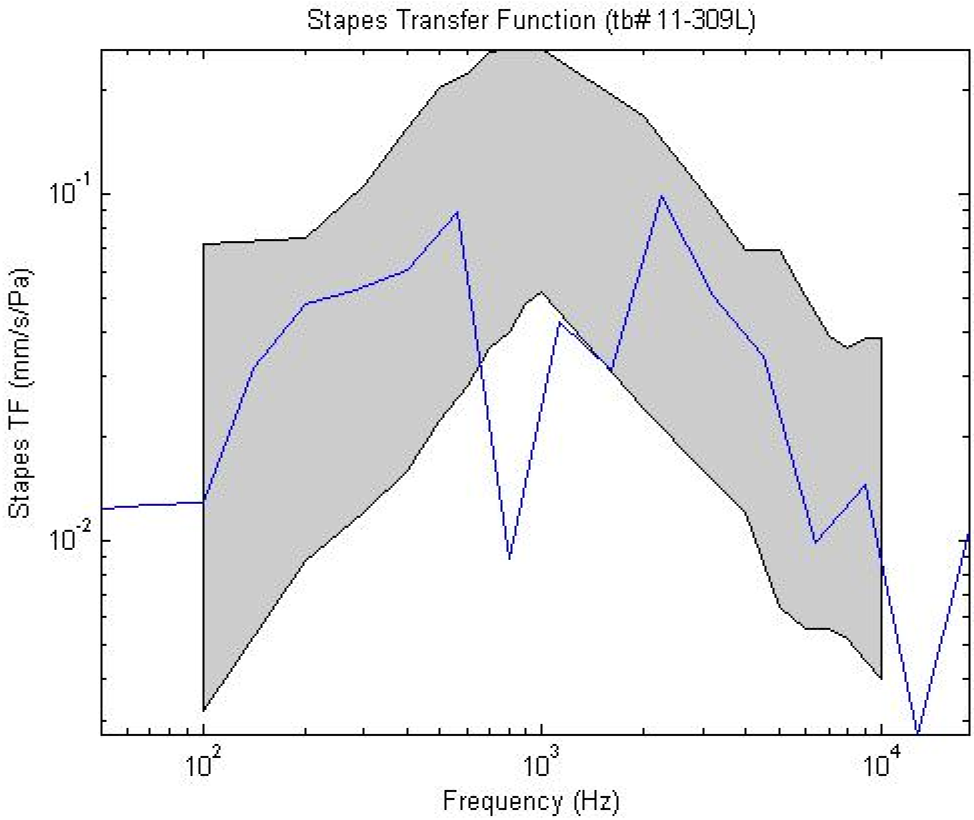


Figure 7: TB1 Stapes Velocity

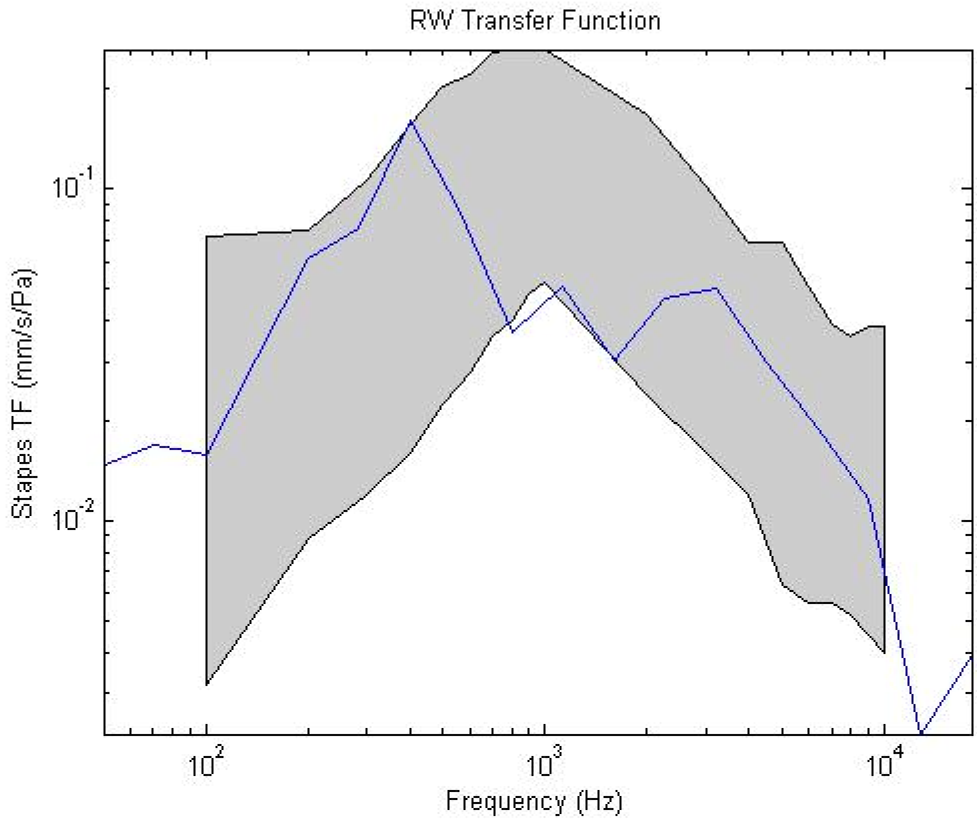


Figure 8: TB1 RW Velocity

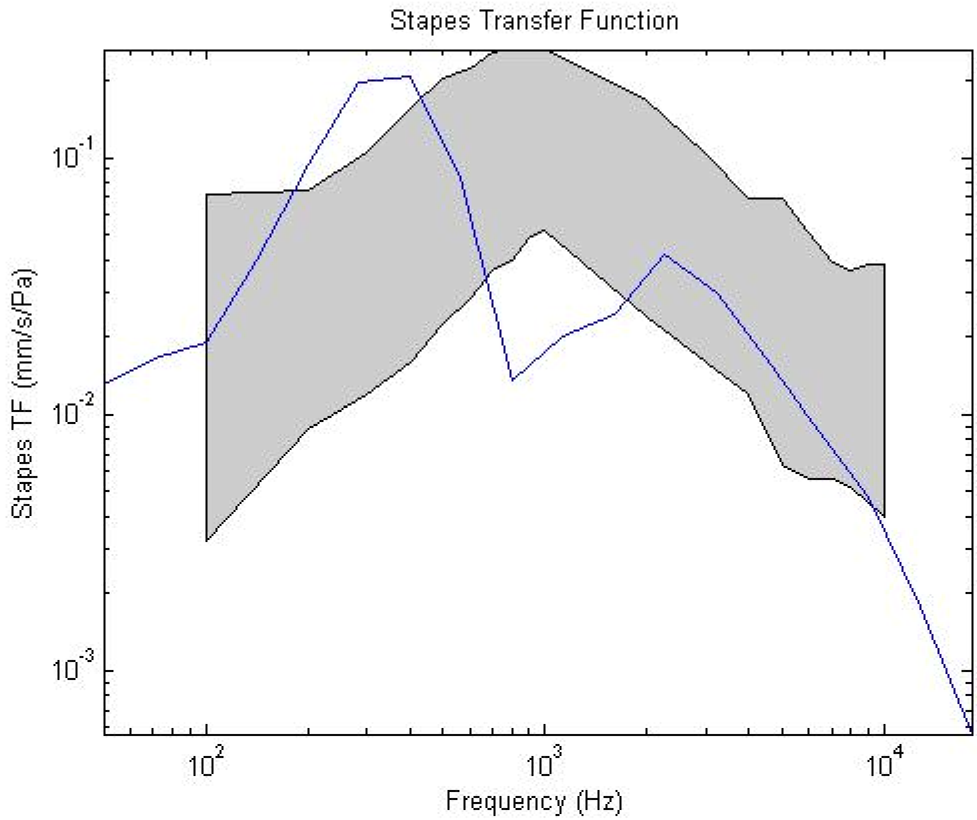


Figure 9: TB2 Stapes Velocity

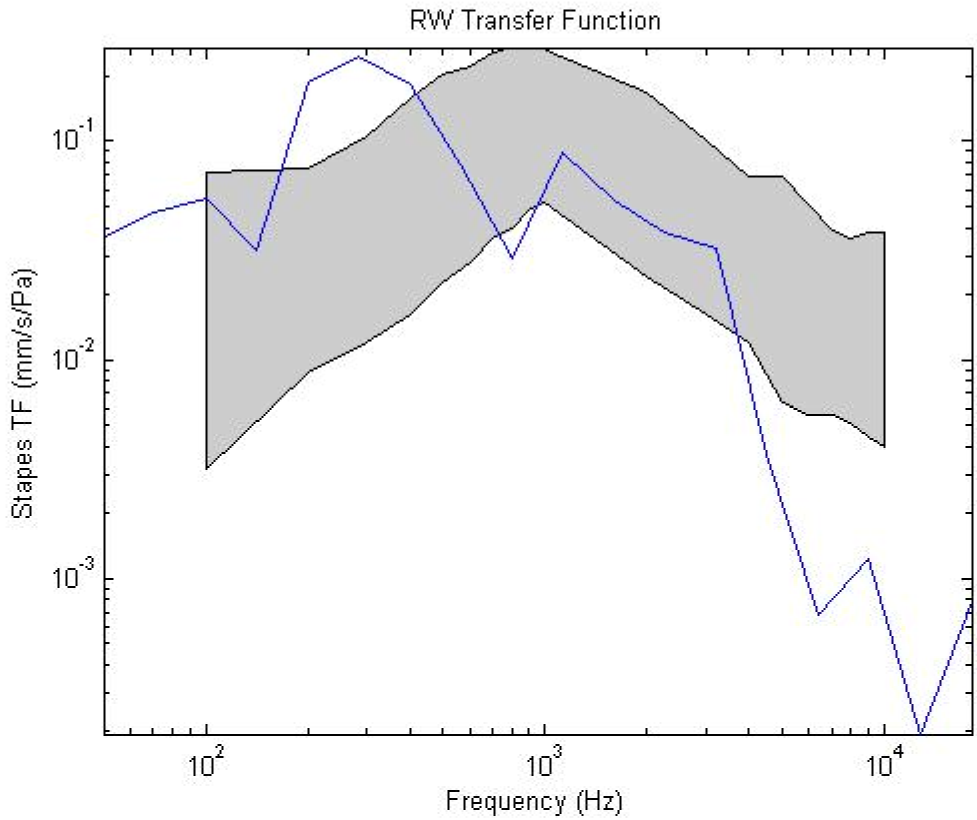


Figure 10: TB2 RW Velocity

2.2.2 Intracochlear Pressure Transfer Functions and Phase

Transfer functions for intracochlear pressure measurements were calculated by taking the ratio of intracochlear pressure to pressure measured at the TM The scala vestibuli transfer function Psv/Pec, also referred to as "middle ear gain" was taken, as well as the scala tympani transfer function Pst/Pec. Phase difference was also calculated between intracochlear pressures and TM pressures. Figures 14 and 13 show the transfer functions and phase recorded for both temporal bones. These plots are similar to Figure 2 from Nakajima et al., 2009 [4]. Pressure measurements, transfer functions and phase were all recorded at single input voltage level (1 V) to the TDT CF1 speaker. This produced sound pressure levels from 90-130 dB SPL at the TM pressure sensor. The data recorded here are broadly similar to the data shown in Nakajima et al., 2009 [4]. In both temporal bones, Psv/Pec and Pst/Pec declines more rapidly above 1 kHz than reported in Nakajima et al., 2009. Placement of the pressure probe may affect the transfer function; future experiments will examine this closely. For both temporal bones, phase of the middle ear pressure gain showed a 360 deg. change over an approximately 12000 Hz span. This is consistent with a middle ear group delay of 83 microseconds, as reported in Nakajima et al., 2009.

First temporal bone lot: Of the first four temporal bones tested, two were used to develop the technique, and did not yield usable data. The remaining two temporal bones of the first lot were found to correspond reasonably well with published data, though some discrepancies were observed. As noted above, in both temporal bones pressure transfer functions declined more rapidly above 1 kHz than reported in Nakajima et al., 2009, and a middle ear group delay of 83 microseconds was observed. See Figure 14.

Second temporal bone lot: After evaluation of data from the first lot of temporal bones, a matched pair of temporal bones were tested using an improved technique. A micrometer stage was used to position the pressure probe (see Figure 5) and advance it carefully into the cochleostomy. This setup was used for both scala tympani and scala vestibuli. Data from the second lot of temporal bones is more consistent between bones, and is in better agreement with published data (see Figure 16). It is believed that the improvement in data quality is largely the result of better sensor placement.

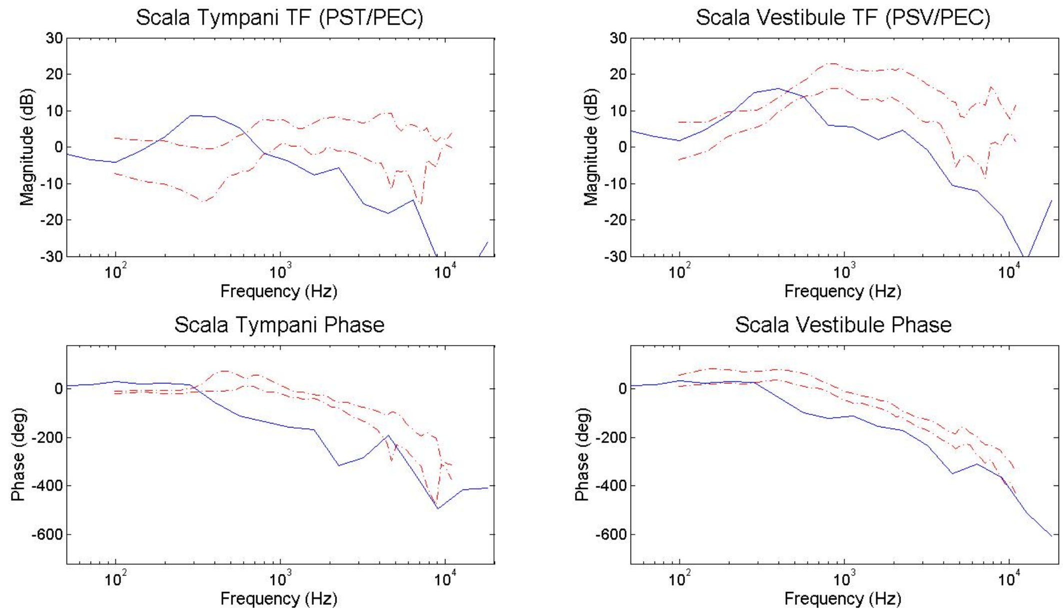


Figure 13: TB2 Intracochlear Pressure Transfer Function along with Phase

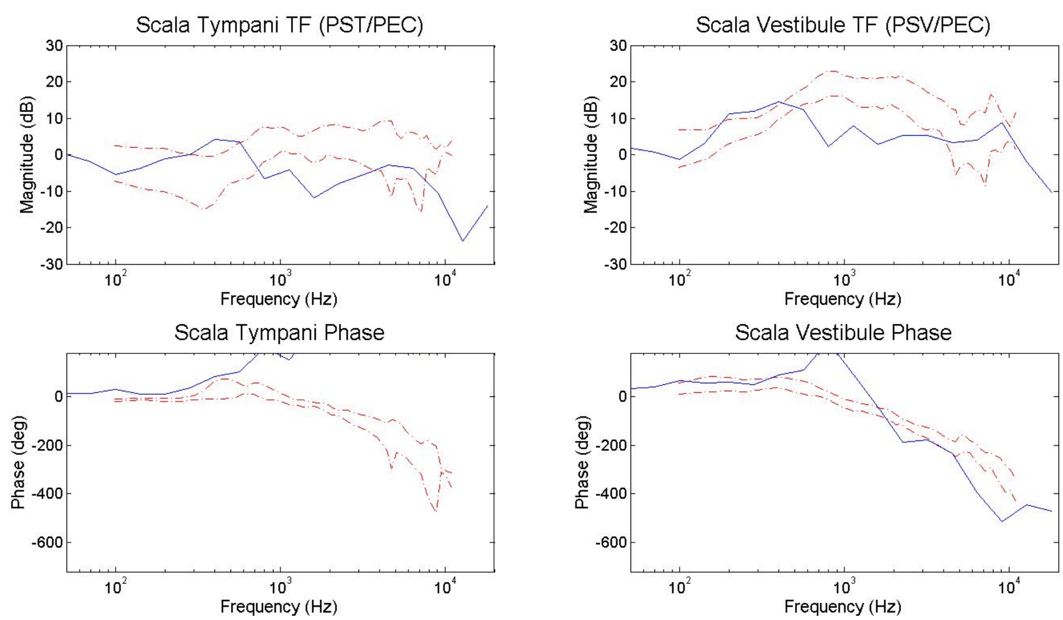


Figure 14: TB1 Intracochlear Pressure Transfer Functions along with Phase

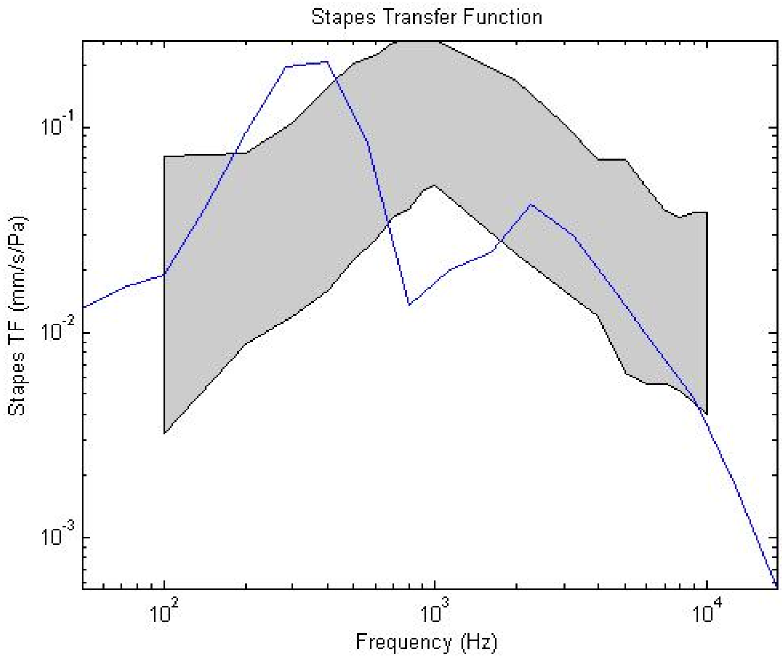


Figure 11: Stapes velocity transfer function, temporal bone UCSD11-309L

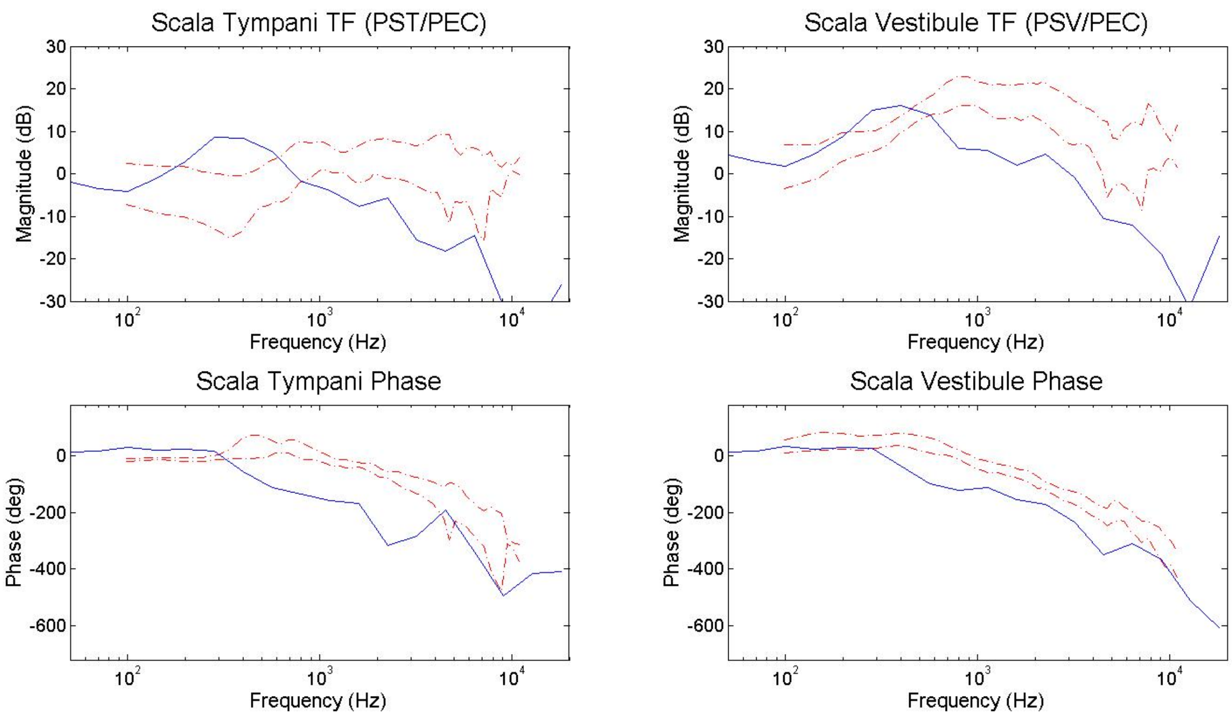


Figure 12: Pressure transfer functions, temporal bone UCSD11-309L

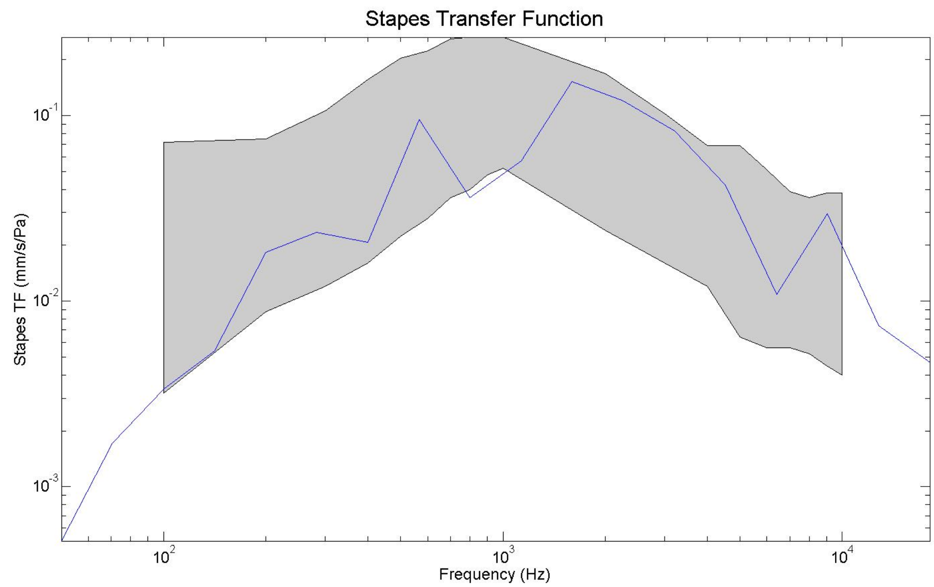


Figure 15: Stapes velocity transfer function, temporal bone LMD0072

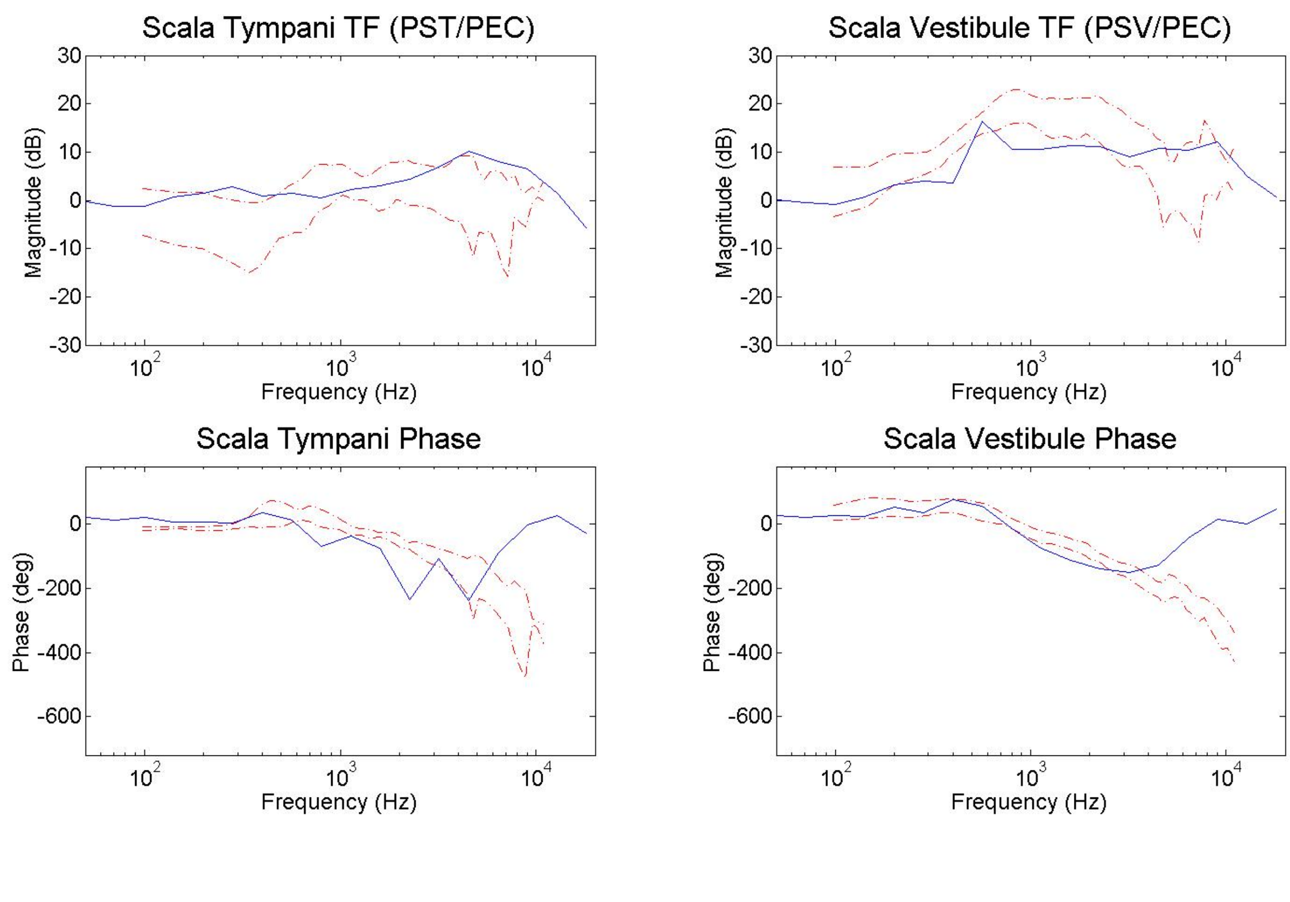


Figure 16: Pressure transfer functions, temporal bone LMD0072

2.2.3 Findings:

2.2.4 Conclusions / Recommendations:

The 260 µm sensors were successfully placed with cochleostomies, demonstrating the feasibility of using off-the-shelf sensors. Data quality is dependent on placement technique. However, it does appear to be possible to capture the essential points of a successful sensor placement. One of the research team (Pfannenstiel) described the placement in a document which was then supplied to another member (Lupo). Using that guidance, Dr. Lupo was able to successfully place sensors on the first try. Use of a micrometer stage to accurately gauge the depth of placement appears to be a critical element in repeatable sensor placement.

2.2.5 Implications:

The use of off-the-shelf pressure sensors with a large dynamic range has promise for the exploration of auditory dynamics at very high sound pressure levels using a blast simulator so as to characterize ossicular dynamics and intracochlear pressures during blast exposure. A poster presentation describing this research was presented at the Military Health System Research Symposium (MHSRS) 2012[1].

3 Measured vs. Predicted Stapedial Velocities and Displacements

3.1 Single Axis LDV Stapes Velocity Measurement Method

A single-axis LDV was used to measure stapes velocities in response to high intensities and low frequencies. These measurements were taken as complementary to the scanning LDV data collected at NMCSD. They were intended to confirm observations of high stapedial displacement at low frequencies and to test the hypothesis that the high displacements were caused primarily by the low frequency component.. The measurements were taken from low frequency pure tones matching the primary component of the blast impulse wave, 22 Hz. The measurements were conducted for high sound pressure levels, equivalent to 172 dB SPL at some pure tone frequencies.

3.2 Comparison of Scanning LDV Data with Single Axis LDV Data

The stapes velocities from the single axis LDV were compared with scanning LDV plotted for different tones and the blast impulse wave. As observed earlier with the scanning LDV, stapedial displacements exceeding 10 micrometers were observed, disproportionately at lower frequencies. This lends support to the hypothesis that the annular ligament displays some viscoelastic behavior, especially at very high pressures. A poster describing results of LDV measurements of ossicular displacements was presented at the ARO Midwinter Meeting Feb. 25-29 2012[3].

3.3 Blast Simulator Condensing Cone Performance

Pressure measurements were conducted to estimate condensing cone performance in improving the sound pressure levels. The pressures were measured with FISO FOP-M260 sensors placed at the base and at the apex of the condensing cone. The ratio of apex to base pressure (effective gain) by frequency is shown in Fig. 18. Gain varied with frequency, with maximum gain around 1300 Hz. The length of the cone is slightly less than 1meter, or approximately 1/14 wavelength at 22 Hz and 4 wavelengths at 1300 Hz. The conical shape does yield 4 dB gain at the lowest frequencies, but does not concentrate sound pressures to the degree desired. Future work will be directed to improving blast simulation with an optimized waveform, possibly in a hyperbolically converging cross-section.

4 Active Mitigation of Auditory Injury from Blast Exposure

In previous work it was shown that ossicular response to high intensity tones differs from response to simulated blast waveforms at similar peak intensities. Measured stapedial displacement in previous experiments exceeded the predictions of an auditory damage model for long duration, high intensity events. The aim

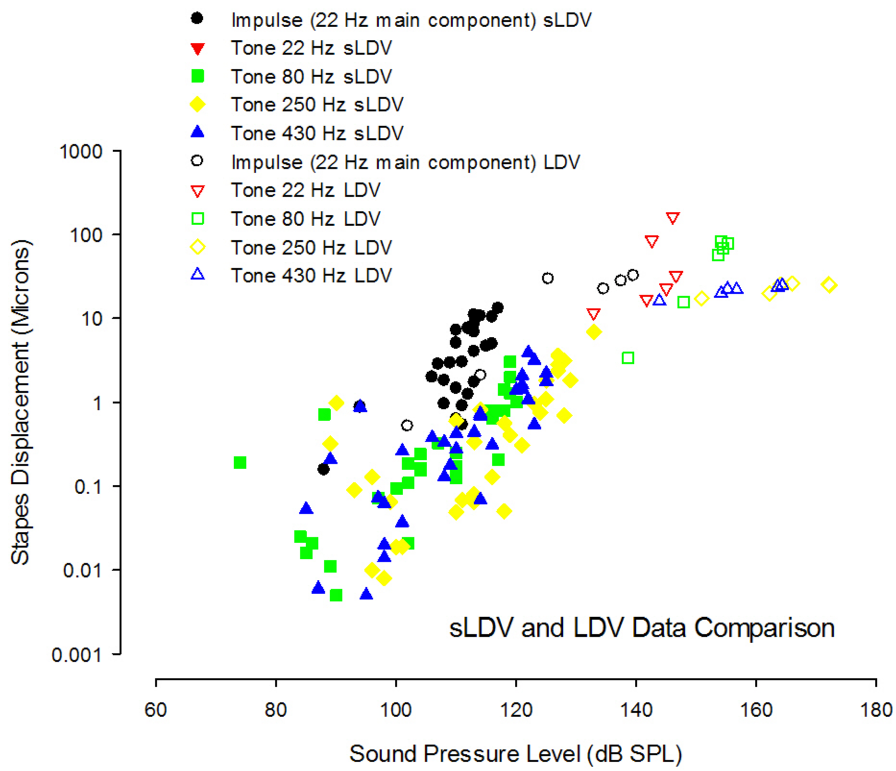


Figure 17: Stapes velocities

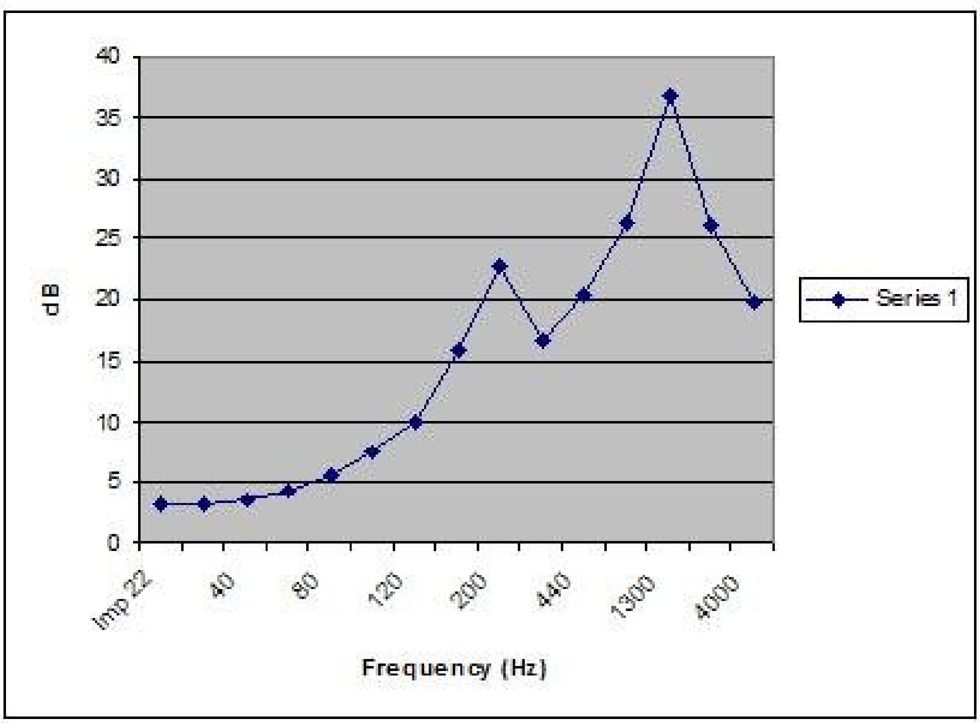


Figure 18: Condensing cone performance

of the current effort is to assess the possibility of damping or reducing ossicular displacements from blast events, with earlier results suggesting the approaches to be explored. High-intensity harmonic (tone) stimuli and simulated blast events were applied to temporal bones using the acoustic blast simulator, and ossicular velocity was measured with acoustic stimulus alone, and with mechanical stimulus applied to the incus body and to the Incus Long Process (ILP). Different mitigation techniques were explored to assess their promise in hearing protection.

4.1 Experimental methods:

A compact, programmable blast simulator was used to produce acoustic stimuli simulating high-intensity noise and waveforms characteristic of blast. For this set of experiments, the 300W amplifier used previously was replaced with a 1000W amplifier, permitting acoustic intensities as high as 180 dB SPL. For baseline measurements, ossicular velocity was measured while the blast simulator delivered harmonic or impulse stimuli to the external auditory canal (EAC) of a human temporal bone (Fig. 19). After baseline measurements were taken, a Middle Ear Transducer (MET) was placed in the temporal bone so as to contact the incus. In one set of experiments, the transducer made contact with the body of the incus (Fig. 20). In another set, the transducer was clipped to the long process of the incus using an aWengen prosthesis (Fig. 21). In one experiment, the applied stimulus was a simple harmonic tone from a signal generator which was applied simultaneously to the acoustic driver and the transducer, while the phase of the acoustic driver was varied in increments (Fig. 22).

4.1.1 Ossicular velocity measurement without MET:

Human cadaveric temporal bones were prepared by a mastoidectomy and extended facial recess, exposing the malleus head (M), incus body (I), incus long process (ILP), stapes superstructure (S) and round window membrane (RWM). The temporal bones were fixed firmly to a stereotaxic table fixed on the surgical table. This approach allows the temporal bone to be adjusted in 3 axes of movement. An aural speculum was mated to the end of a condensing cone which concentrated the acoustic energy from the subwoofer and amplifier. The speculum was placed in the ear canal and isolated from the laser Doppler vibrometer (LDV) head with foam. TDT System 3 hardware connected to a PC was used to present stimulus and record LDV velocity as well as sound pressure level at ear drum using B&K microphones. Mirrors using glass microspheres were placed on the ILP to enhance the reflected LDV signal. Stimuli were presented from 110 to 170 dB SPL at 10 dB steps and presented 10 times with averaging to increase the signal to noise ratio. Tones at 22, 40, 60, 80, 100, 125, 150, 200, 250, 431, 613 and 1300 Hz were presented for displacement measurements. These measurements were also taken for blast impulse.

4.1.2 Ossicular velocity measurement with MET (either powered or not powered):

A bone bracket was used to anchor Otologics' MET to the cortical surface of the temporal bone. The MET was adjusted to assure optimum loading by means of the Transducer Loading Assistant (TLA). Measurements for tones and blast impulse were first performed without powering the MET transducer. The measurements were then repeated while the MET was driven with a DC signal at 0.5 V or a signal of opposite phase to the acoustic signal (tone or blast impulse).

4.1.3 Ossicular velocity measurement with MET clip on ILP (either powered or not powered):

A MET transducer with an attached aWengen clip was fixed firmly to a micromanipulator. The MET was then loaded carefully to the ILP. Tone or impulse signals of opposite phase than the acoustic stimulus were presented to MET and velocities measured. First tones or impulse were presented through the TDT system on two different channels (EAC and MET transducer) as shown in figure 21. The signal to the MET transducer was delay===ed to change the relative phase between acoustic and MET signals. Then a simple frequency generator was driven with a 250 Hz tone to MET and the blast simulator. The phase between signals was varied by adjusting the speaker phase through the amplifier. Phase was varied between 0 to 180 deg in 45 deg. increments while velocities were recorded. This approach is shown in Fig. 30.

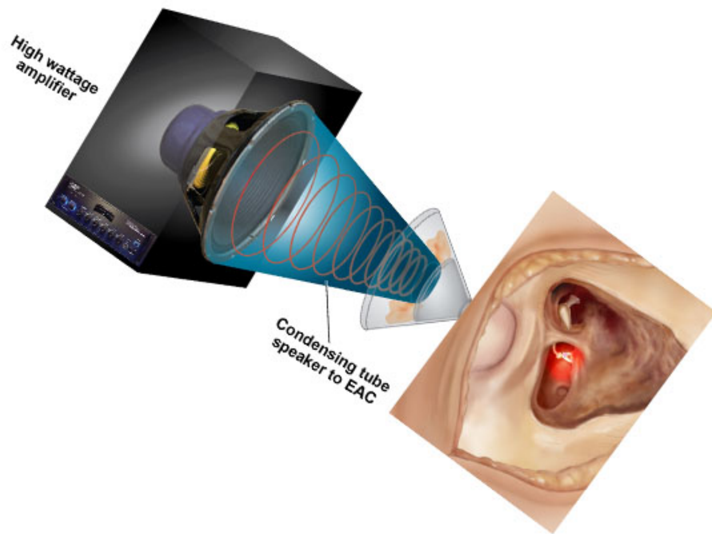


Figure 19: Ossicular velocity measurement without MET on Incus

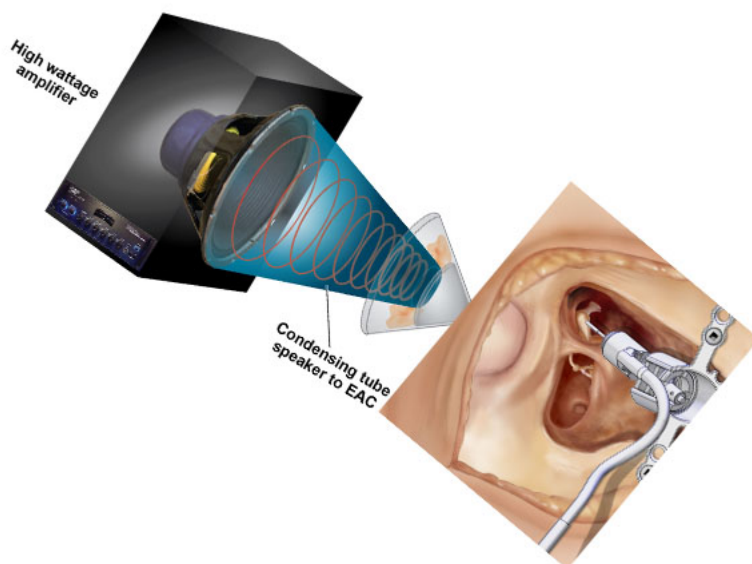


Figure 20: Ossicular velocity with MET on Incus (MET is in non energized or DC powered or opposite phase signal powered

4.1.4 Measurement of Ossicular Velocity with delayed signal to MET with Tones:

An aWengen clip is connected to the MET and attached carefully to ILP without changing the measurement angle or location of microsphere used for measurement. Figure 9 shows the data collected with pure tone stimulus in acoustic only and acoustic with MET clip on ILP powered with different phase than acoustic stimulus. The MET signal dominated at lower levels and acoustic dominated at higher levels. As MET with CLIP powered with same level at all instants and it is dominating at lower levels (the lower 5 levels in panel B) and are constant as seen in panel B. Then the higher levels are dominated by acoustic stimulus and did not significantly change with or without MET clip on ILP powered with different phase signal.

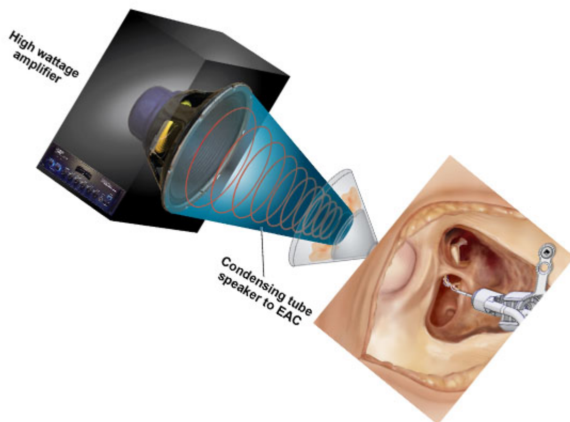


Figure 21: Ossicular velocity with MET on ILP using aWengen CLIP (MET is energized with opposite phase signal powered)

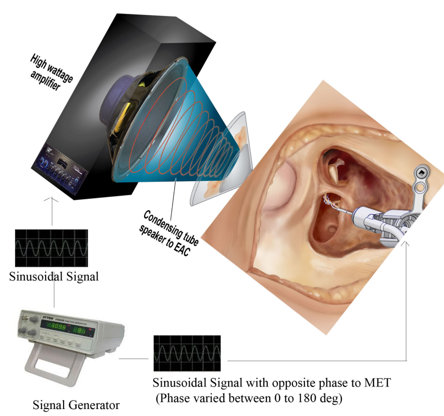


Figure 22: Ossicular velocity measurement with varying phase signal between ear canal and MET to cancel the velocity

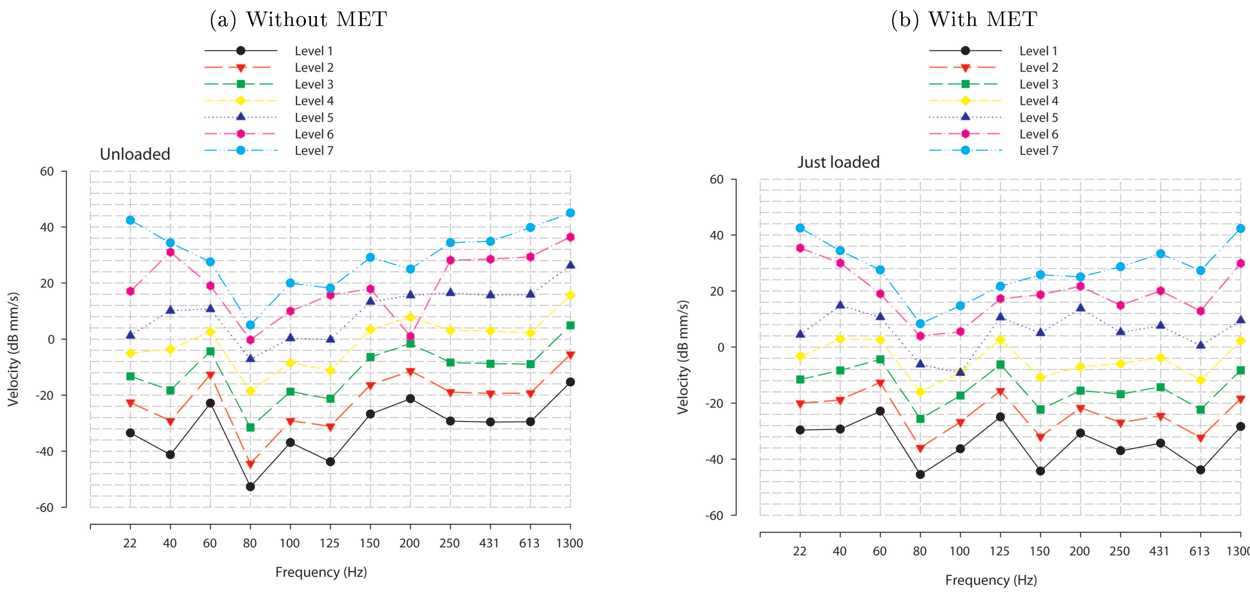
4.2 Results: Measurement of Ossicular Velocity with Active Mitigation:

4.2.1 Results: Measurement of Ossicular Velocity from Harmonic Stimuli:

Results: Measurement of Ossicular Velocity without and with MET (not powered) on Incus body to tones: The current blast simulator produced sound pressure levels up to or more than 170 dB SPL with pure tones. Tones were presented at ~110-170 dB SPL ranges and ILP velocity recorded with the LDV. Then the signals converted to frequency spectrum and velocity amplitude values noted down. Figure

23 shows the ILP velocity for different frequencies across different levels. Panel 23a shows the values with the transducer unloaded and Panel 23b shows values with the transducer loaded to the incus body but not energized. There is no difference greater than 2-5 dB observed between the unloaded and loaded condition across tones. This shows that the normal transmissive acoustic pathway is not significantly hindered by contact of the MET with the incus body.

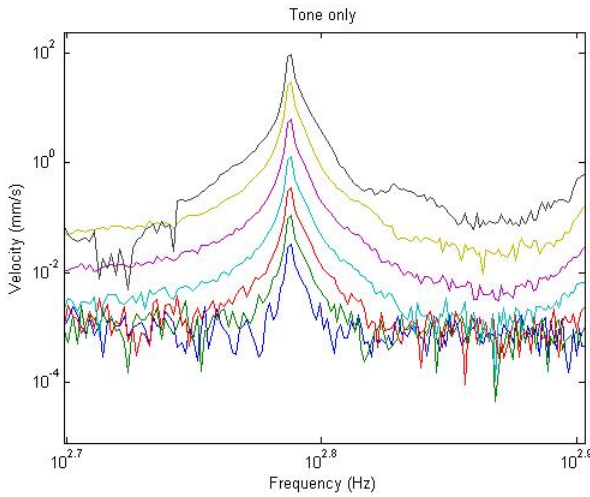
Figure 23: Measurement of Ossicular Velocity without and with MET (not powered) on Incus body to tones:



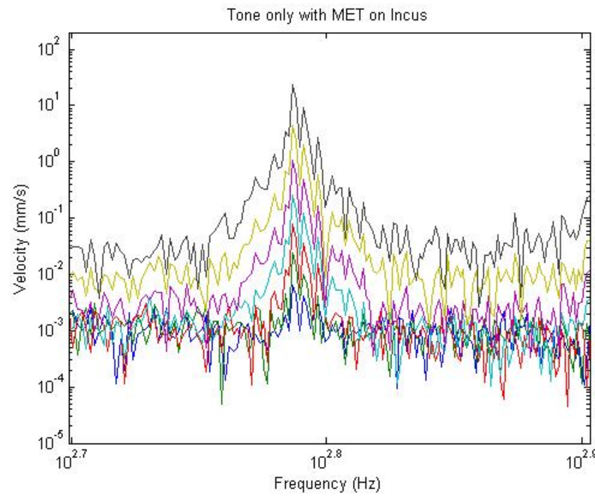
Measurement of Ossicular Velocity with DC powered MET on Incus body to Tones: ILP velocity was measured with harmonic stimulus of 613 Hz while the MET transducer was simultaneously DC powered at either positive 500 mVrms or negative 500 mVrms. Figure24 shows ILP velocity at different intensity levels. Again, panel B shows either 2-5 dB loss of velocity due to loading of MET on Incus body but not powered. Panels 24c and 24d show velocities when the MET was DC powered. There is no significant difference of more than 2-5 dB observed between four experimental conditions shown here such as: a) Unloaded; b) loaded; c) positive DC powered and d) negative DC powered. The small movement of the transducer against the body of the incus does not appear to exert a stiffening effect sufficient to suppress ossicular movement significantly in response to acoustic stimulus.

Figure 24: Measurement of Ossicular Velocity with DC powered MET on Incus body to Tones:

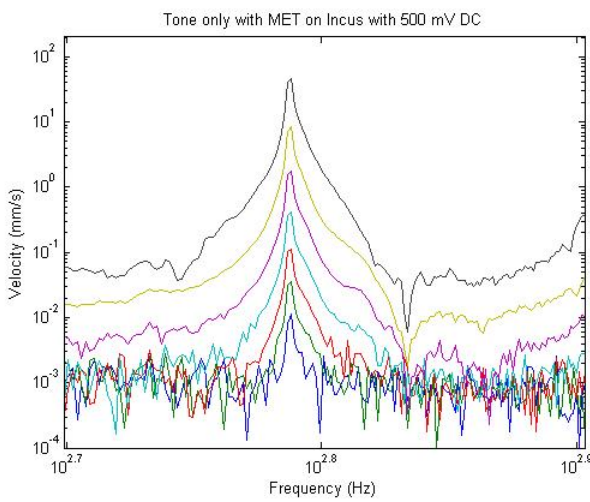
(a) No contact



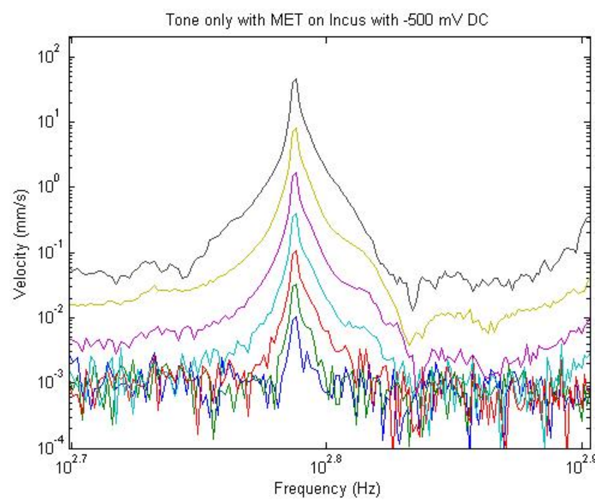
(b) With contact, transducer not powered



(c) Transducer driven at +500mV DC



(d) Transducer driven at -500mV DC

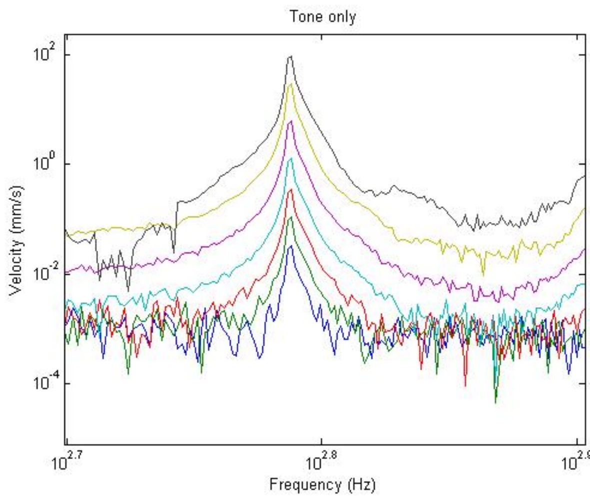


Measurement of Ossicular Velocity with delayed signal (different phase than acoustic stimulus) to MET with a CLIP on ILP with Tones: An aWengen clip was connected to the MET and attached carefully to the ILP without changing the measurement angle or location of the microspheres used to enhance the LDV signal. Figure 25 shows the data collected with pure tone stimuli, acoustic only and acoustic with a superposed mechanical signal applied by the MET clip on the ILP. The MET was powered with a signal of different phase from the acoustic stimulus. The MET signal dominated at lower levels and acoustic dominated at higher levels. The MET with clip was powered at the same level for all runs, and dominates response at lower levels (the lower 5 levels in panel 25b). The higher levels were dominated by acoustic stimuli, indicating that response to the mechanical stimulus was not as great as the acoustic response at these levels. Ossicular response did not significantly change with or without the MET clip on the ILP powered with a signal of different phase.

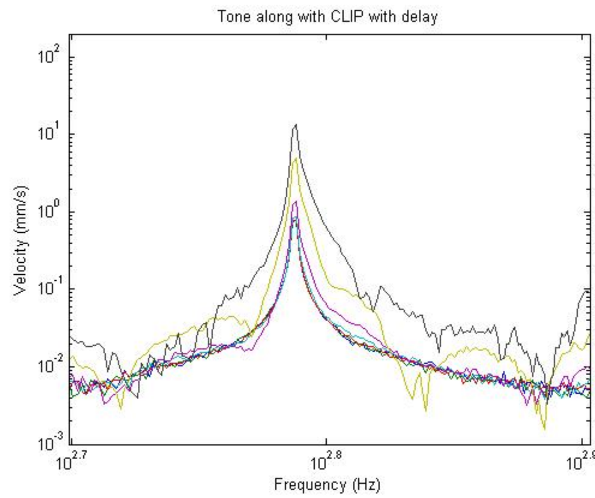
Measurement of Ossicular Velocity with varying phase between MET with a CLIP on ILP and ear canal signals with Tones: In this experiment, a pure tone was delivered to the blast simulator and to the transducer simultaneously, with the ability to vary the acoustic phase continuously between 0 and 180

Figure 25: Measurement of Ossicular Velocity with delayed signal to MET with a CLIP on ILP with Tones:

(a) Acoustic tone stimulus only



(b) Acoustic tone stimulus with transducer clip at incus long process; mechanical signal delayed



deg. Acoustic phase was varied in 45 deg. increments while ILP velocity was measured. As seen in figure 26, the resulting ossicular velicity varied between 3.0 and 1.5 mm/sec., indicating that the signals reinforced one another at 0 deg., and canceled at 180 deg. This suggests that, with sufficient fidelity, mechanical stimulation of the ossicles can be used to cancel acoustic response.

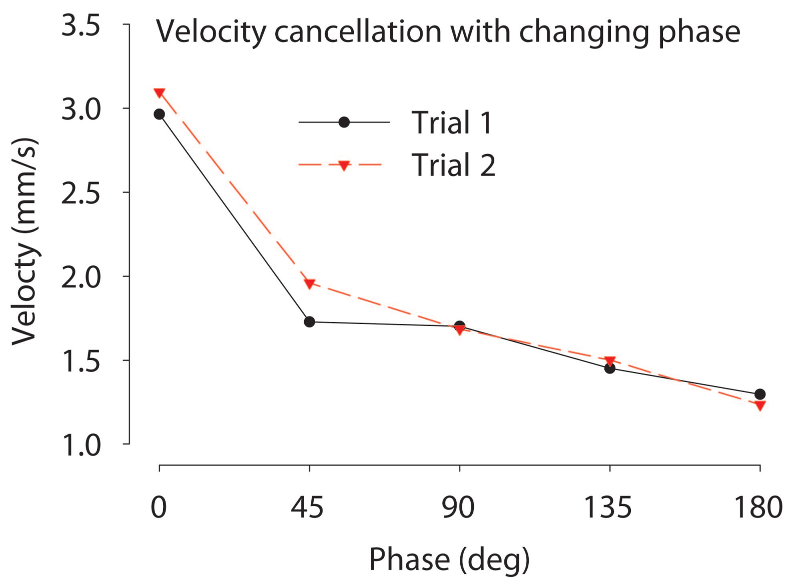


Figure 26: Decrease in velocity amplitude with varying phase

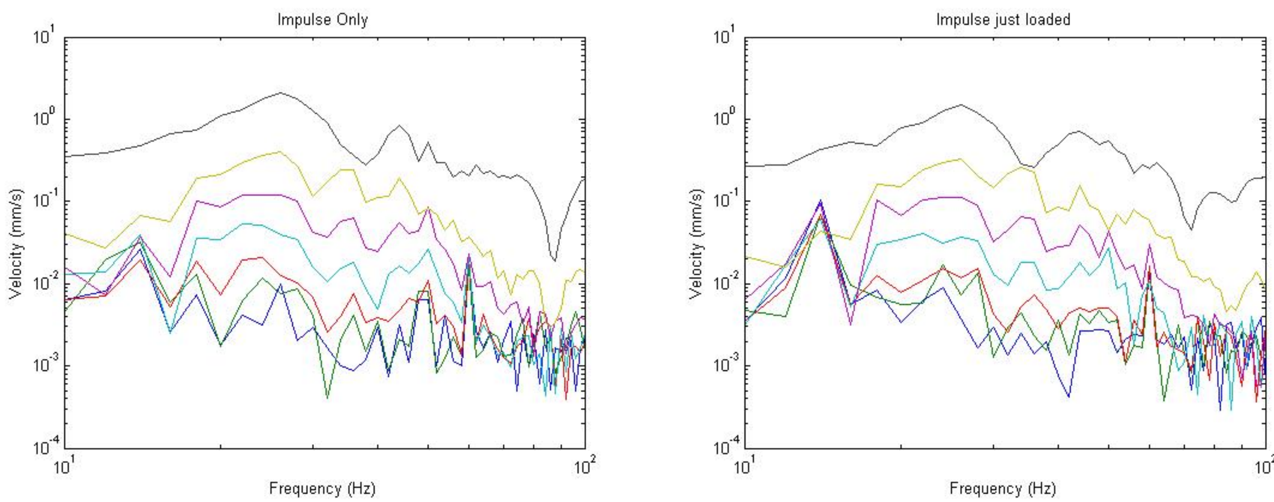
Harmonic cancellation using incus body contact and variable phase A transducer was clipped to the incus long process while harmonic stimuli of various frequencies and intensity were transmitted both to the blast simulator as acoustic source and through a TDT digital audio processor at various time delays. At 1300 Hz, the mechanical input from the transducer was able to reduce the stapedial response to acoustic input by 6 dB (Fig. 27). At 12000 Hz, the phase-dependent effect of the transducer is clear (Fig. 28). Even at antiphase the transducer does not cancel the acoustic response at 12 kHz, but reduces it nearly to baseline. This frequency was chosen among those for investigation because one full cycle corresponds closely to the middle ear's typical 83 microsecond group delay. It is possible that nonlinearity in the middle ear's transmission characteristic reduces the effectiveness of cancellation; this will be the subject of future study.

4.2.2 Results: Measurement of Ossicular Velocity from Impulse:

Measurement of Ossicular Velocity without and with MET (not powered) on Incus body to simulated blast Impulse: Impulse responses were measured with the transducer unloaded and loaded, as shown in the frequency domain in figure 29. There in no significant loss in ILP velocity due to loading of MET on Incus body. Also, figure 29 shows that the energy of impulse is mostly located around 20-30 Hz, as was previously observed in the blast pressure waveform recorded at a shock tube.

Figure 29: Measurement of Ossicular Velocity without and with MET (not powered) on Incus body to simulated blast Impulse:

(a) Unloaded (b) Just loaded



Ossicular Velocity with acoustic Impulse stimulus and MET on Incus body with opposite phase signal : Acoustic stimuli at various levels were applied simultaneously with an opposite phase or reversed impulse signal from the MET. The frequency spectrum of velocity measurements is shown in Figure 30. Note that at higher intensity levels the acoustic signal dominates response, as the transducer is unable to deliver a counteracting stimulus of this magnitude. Conversely, at lower stimulus levels, response to the transducer dominates. At levels where the acoustic and mechanical signals are of comparable intensity, there is no significant change in ILP velocity due to an opposite phase signal applied to the incus body when compared with the response to an acoustic stimulus alone.

Measurement of Ossicular Velocity with opposite phase and either delayed or not delayed signal to MET with a CLIP on ILP with Impulse: An impulse stimulus was presented with the MET clip attached to the ILP. Figures 31 and 32 show the velocity data under different conditions of presentation level and (mechanical) time delay. Results are shown in both time domain and frequency domain. For clarity, the time domain signals are shown only at single level of presentation. These show acoustic alone, MET alone and acoustic and MET combined with different time delays at a single level of presentation. The MET signal interferes with the acoustic signal as seen in panel 31c. A time delay of 10 msec (panel 31d) and 15 msec (panel 31e)was then introduced to assess the effect of delay on cancellation. Although the interference can be seen to shift, it does not appreciably reduce the intensity of the peak ossicular response, indicating that the mechanical signal must be much more faithful to the acoustic response in order to achieve cancellation. These results are shown in the time domain in figure 32. As was seen with the MET applied to the incus

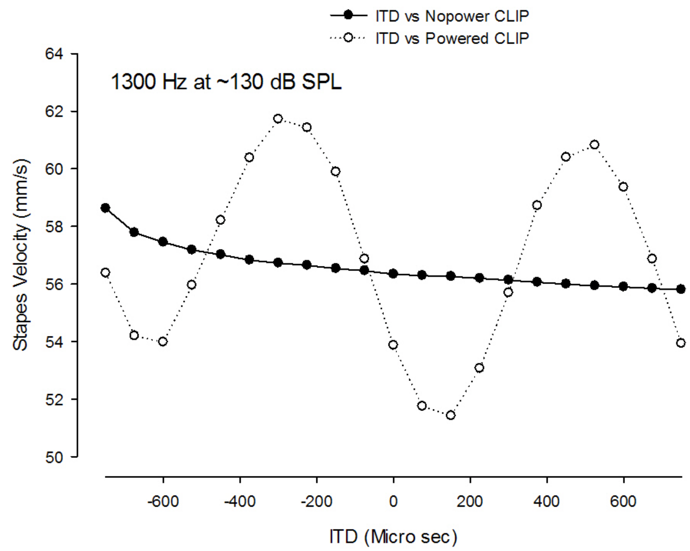


Figure 27: Harmonic stimulus cancellation, 1300 Hz

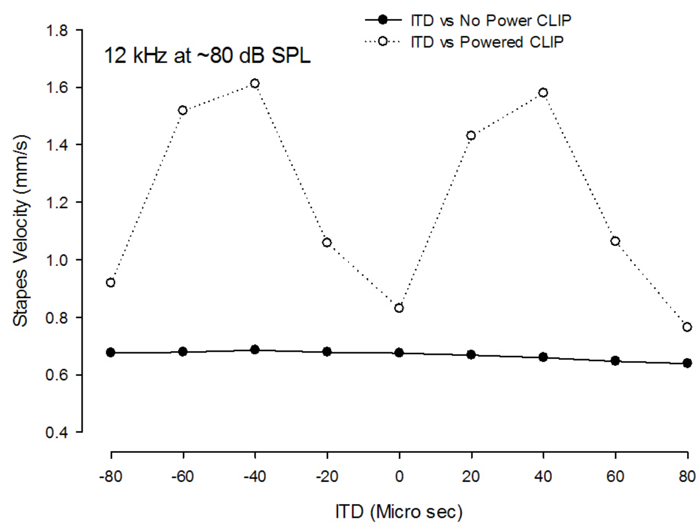
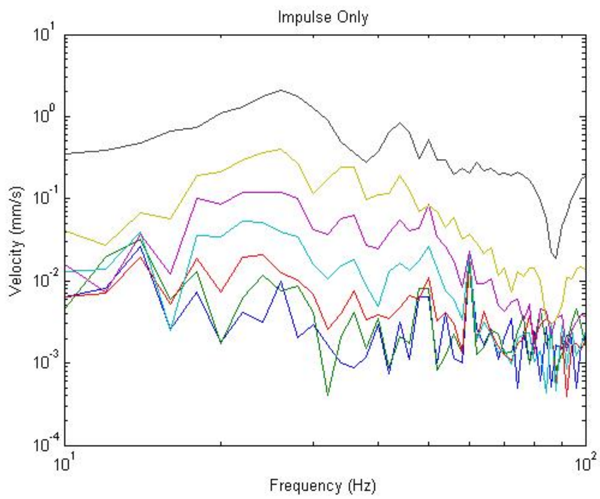


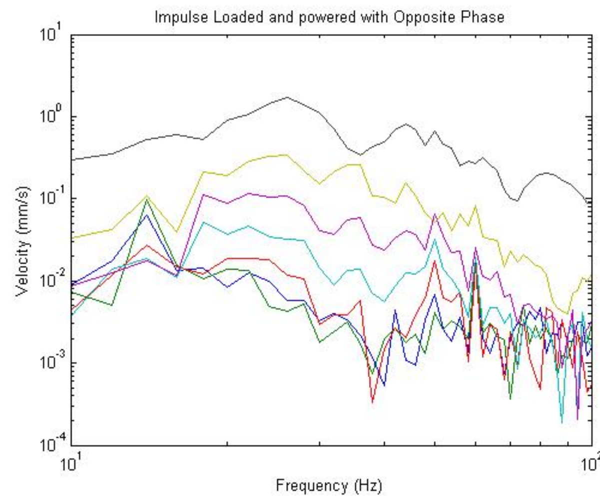
Figure 28: Harmonic stimulus cancellation, 12000 Hz

Figure 30: Measurement of Ossicular Velocity with opposite phase signal to MET on Incus body with Impulse stimulus:

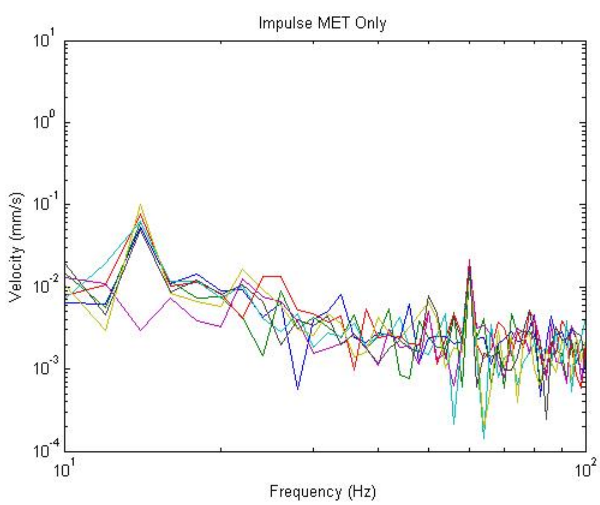
(a) Acoustic impulse only



(b) Acoustic impulse with transducer driven at opposite phase



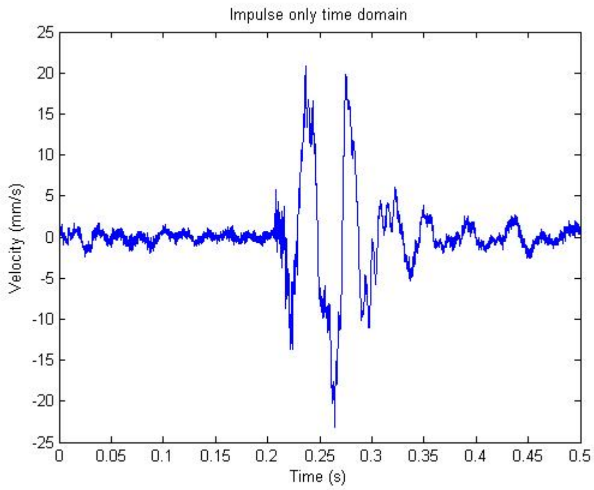
(c) No acoustic input; transducer driven with impulse at opposite phase



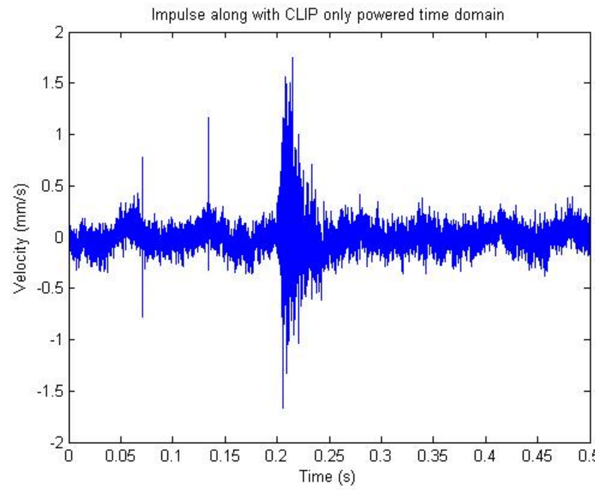
body, the MET signal dominated at lower levels, while at higher levels the acoustic signal was dominant. In future experiments, digital filtering will be explored as a means to improving cancellation for the impulse waveform.

Figure 31: Measurement of Ossicular Velocity with opposite phase and either delayed or not delayed signal to MET with a CLIP on ILP with Impulse: Time Domain

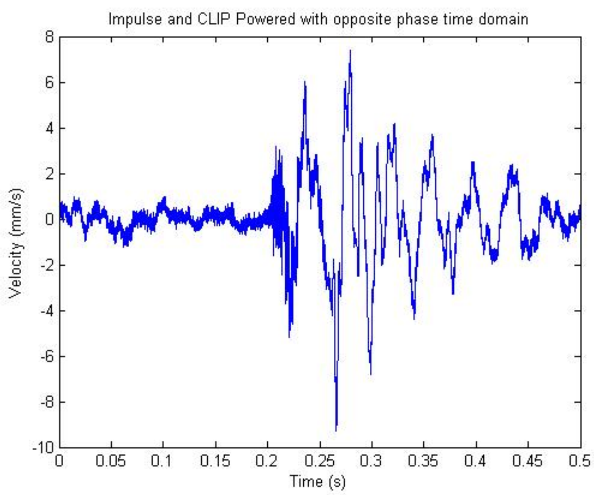
(a) Acoustic impulse only



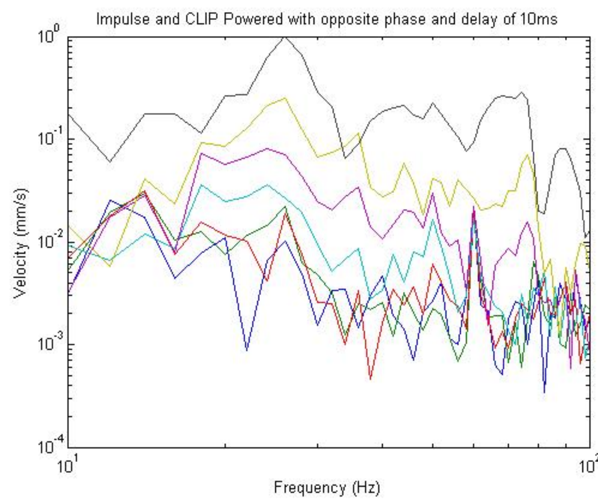
(b) Acoustic impulse stimulus with transducer clip at incus long process



(c) Acoustic impulse stimulus with transducer clip at incus long process



(d) Acoustic impulse stimulus with transducer clip at incus long process; mechanical signal delayed 10 ms



(e) Acoustic impulse stimulus with transducer clip at incus long process; mechanical signal delayed 15 ms

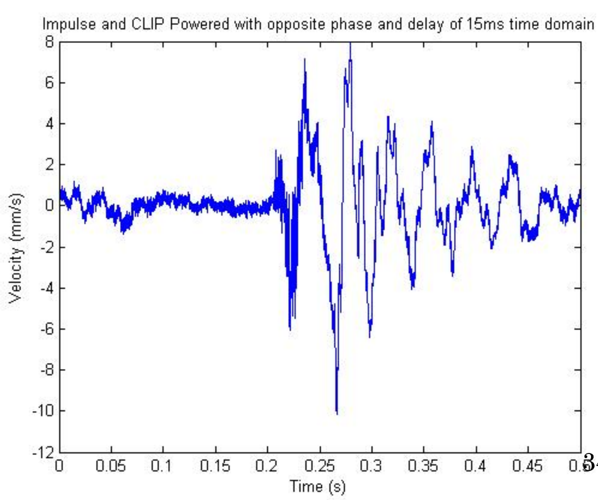
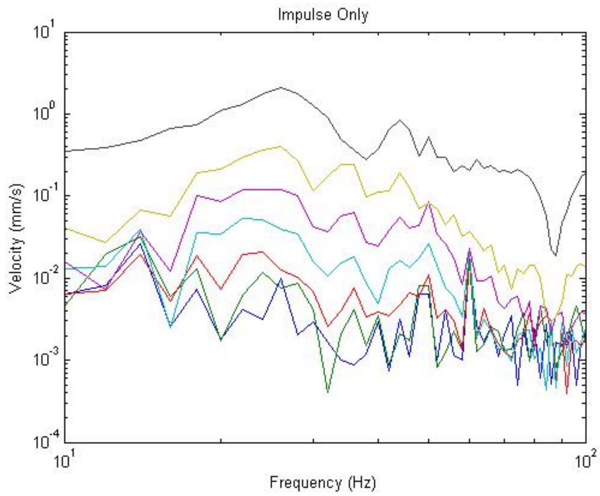
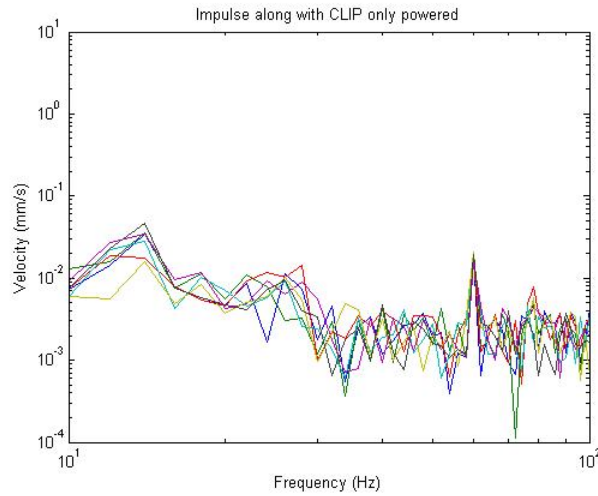


Figure 32: Measurement of Ossicular Velocity with opposite phase and either delayed or not delayed signal to MET with a CLIP on ILP with Impulse: Frequency Domain

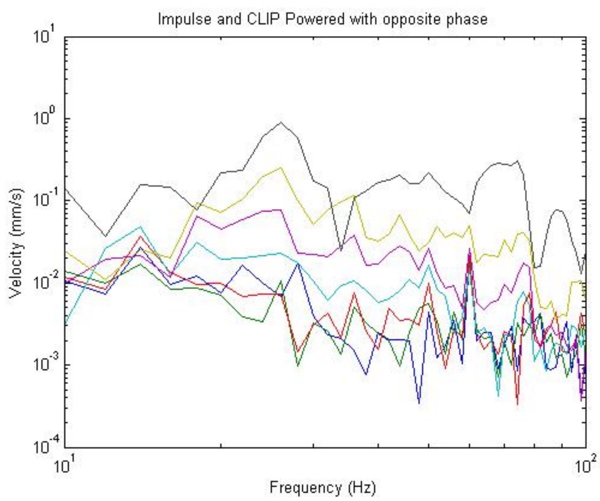
(a) Acoustic impulse only



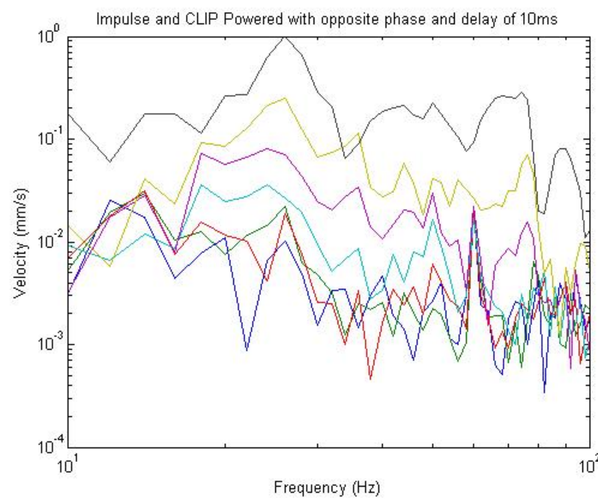
(b) Acoustic impulse stimulus with transducer clip at incus long process



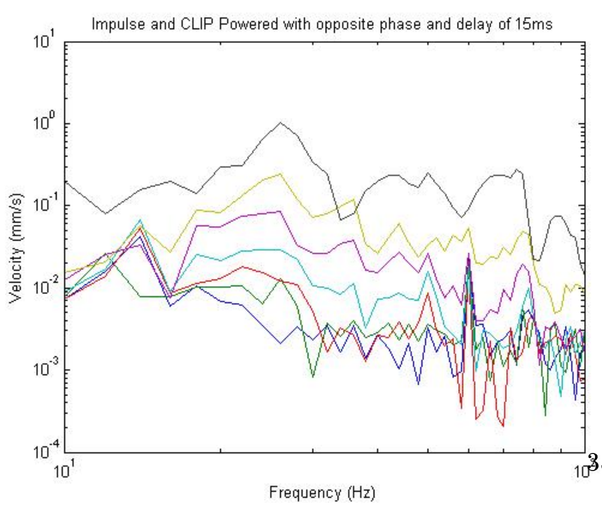
(c) Acoustic impulse stimulus with transducer clip at incus long process



(d) Acoustic impulse stimulus with transducer clip at incus long process; mechanical signal delayed 10 ms



(e) Acoustic impulse stimulus with transducer clip at incus long process; mechanical signal delayed 15 ms



4.3 Conclusions and Discussion:

The acoustic blast simulator produced stimuli as high as 180 dB SPL, approaching real-world conditions likely to result in TM rupture. At intensities between 150 dB SPL and 180 dB SPL, response to the acoustic signal was greater than the equivalent vibration producible by the transducer under these test conditions; for this reason, acoustic response dominated at high intensities. At intensities of 150 dB SPL and below, the transducer was able to deliver vibration sufficient to dominate the acoustic signal.

When the transducer was DC powered at 500 mV, its displacement was insufficient to stiffen the ossicular chain appreciably. This transducer was designed to deliver displacements within the normal range of audition, and its small excursion is unlikely to make it useful as a stiffening mechanism without some redesign.

When the transducer was excited with a signal of phase opposite to the acoustic stimulus and applied to the incus body, its effect was negligible. When the same approach was used with the transducer clipped to the incus long process, the effect of superposing the mechanical and acoustic stimuli was clear. This was demonstrated by the shifting pattern of interference as varying time delays were introduced to the mechanical signal. However, the fidelity of the mechanical signal to the acoustic signal was not great, and the two signals, while interfering, did not cancel. In future experiments, it is planned to detect the acoustic signal within the EAC and reproduce it in counter-phase for the mechanical signal. It is expected that this will result in better cancellation.

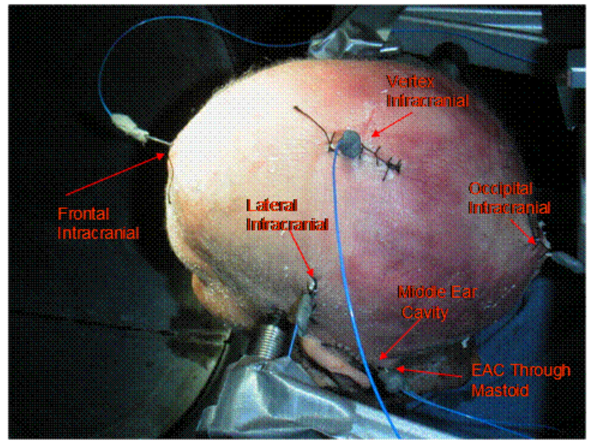
When the acoustic and mechanical signal were simple harmonic stimuli at the same frequency, it was possible, by varying the phase of the acoustic stimulus, to change the ossicular response by a factor greater than two. This shows that mechanical stimulation of the ossicular chain can counteract the large velocities and displacements resulting from blast impulse and high noise levels. Future experiments will be directed to exploring practical means of exploiting this effect for hearing protection.

A poster presentation describing this research was presented at the Military Health System Research Symposium (MHSRS) 2012[2].

5 Planned Future Work

5.1 Correlate intracranial and EAC pressures

The correlation of intracranial to EAC pressures in whole cadaver heads is important to establishing a relationship between the threshold of traumatic brain injury and the threshold of hearing damage. Data thus far have been taken from whole heads in two rounds of experiments. No data set is sufficiently large to relate intracranial and EAC pressures at a statistically significant level. Experiments involving whole cadaver heads are time- and labor-intensive, difficult to replicate, and require careful adherence to ethical protocols for use of human specimens. At the same time, the data derived from these tests are critical to understanding the physics of wave propagation and mechanics of shock wave-induced trauma. Accordingly, it is desirable that these experiments result in validation of a more easily replicated physical model, such as a headform with realistic acoustic properties. Tasks to completion will be conducted in two steps:

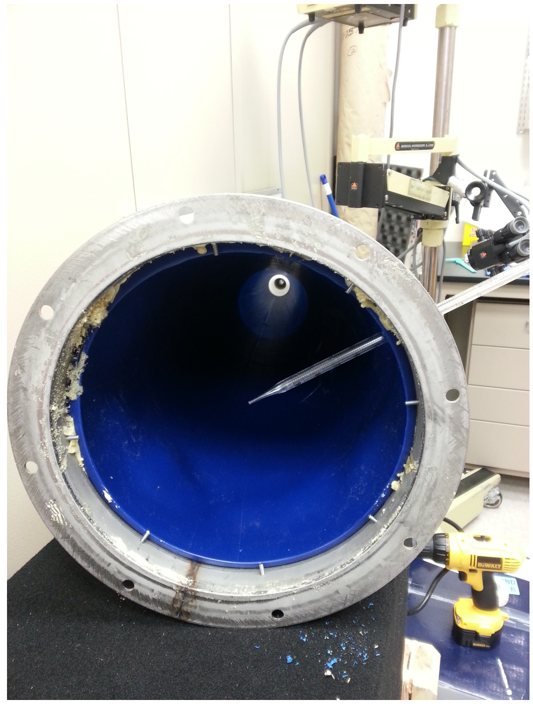


Completion of the cadaver head data set Eight cadaver heads will be prepared for testing, with the objective that at least six will yield consistent, realistic data. These will be instrumented so as to capture the peak pressure as the shock wave enters and exits the skull. Pressures will be chosen to approach those at which TM rupture becomes likely. The first data set will be taken with intact heads, and will consist of concurrent measurement of intracranial and EAC pressures up to the threshold of TM rupture. For the second data set, brain tissue will be replaced with a material of similar density and wave propagation speed, e.g. ballistic gel. This data set will consist of intracranial pressures suitable for comparison to the first data set. The second data set will also be run with and without personal protective equipment (helmets). These two data sets will serve as the foundation for validation of the acoustically realistic headform.

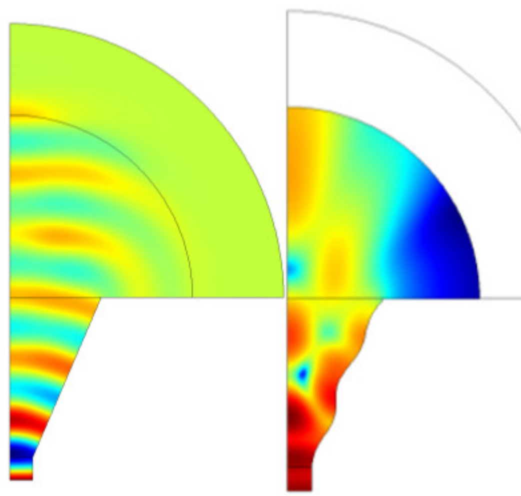
Replication in acoustically realistic headforms An engineering headform will be adapted to simulate the acoustic properties of bone and soft tissue. Techniques now exist for 3-D printing of complex geometries such as the human skull – and, indeed, are used to produce faithful replicas of subject anatomy in advance of difficult surgeries (ref: Walter Reed study). Two headforms will be fabricated, with materials chosen for acoustic properties (density and wave propagation speed) similar to bone, brain and soft tissue. These will be instrumented and tested under the same conditions as the cadaver heads, and results compared to determine if the engineering headform may be considered validated as a physical model for future studies.

5.2 Optimize waveguide in blast simulator

The blast simulator has been a very useful tool in replicating blast pressure waveforms and delivering them to temporal bones. The stapedial displacements at very long duration pulses have been greater than predicted by existing models, indicating that further work with the simulator may shed light upon auditory response to blast. To do this, we need greater pressure gain at low frequencies. An appropriate modification of the simulator condensing waveguide will help achieve extremely high SPLs at the frequencies of interest. Tasks to completion include:



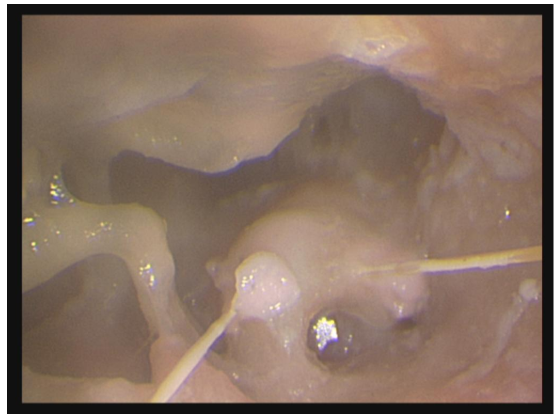
Optimize the acoustic waveguide for simulation of blast An acoustic model will be developed using a numerical simulation engine such as COMSOL. The change in cross-section over tract length will be optimized so as to produce an effective pressure gain highest in the very low frequencies of interest.



Demonstrate blast-regime SPLs with simulator The simulator with optimized waveguide will be used to reproduce recorded shock tube waveforms at comparable intensities – that is, in the 1 - 10 psi range where TM rupture occurs. With this upper bound established, the simulator will become a useful tool for the exploration of auditory mechanics during blast events.

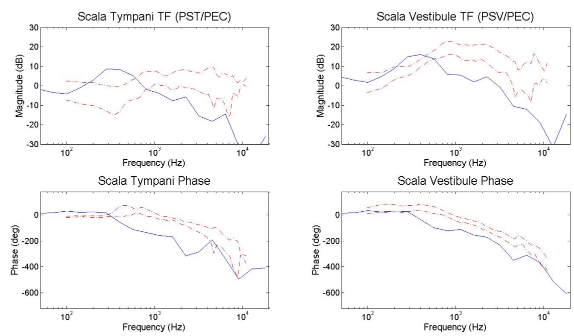
Publish simulator specifications If the simulator with optimized waveguide does reproduce blast waveforms with sufficient fidelity to be generally useful, its specifications and geometry will be published for the use of other researchers.

5.3 Map intracochlear pressures to bone and air conduction

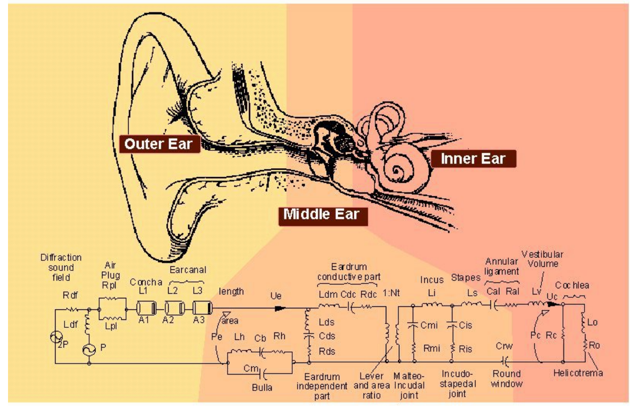


Differential intracochlear pressure is a good correlate to sensation for both air- and bone-conduction, and is a correspondingly good correlate to hearing damage. Results thus far show promise that consistent measurement of cochlear pressures may be achieved with well-defined procedure for preparation of temporal bones, using off-the-shelf sensors and signal conditioning electronics. This will be an extremely useful tool in validating the predictions of an end-to-end model of acoustic trauma. Tasks to completion include:

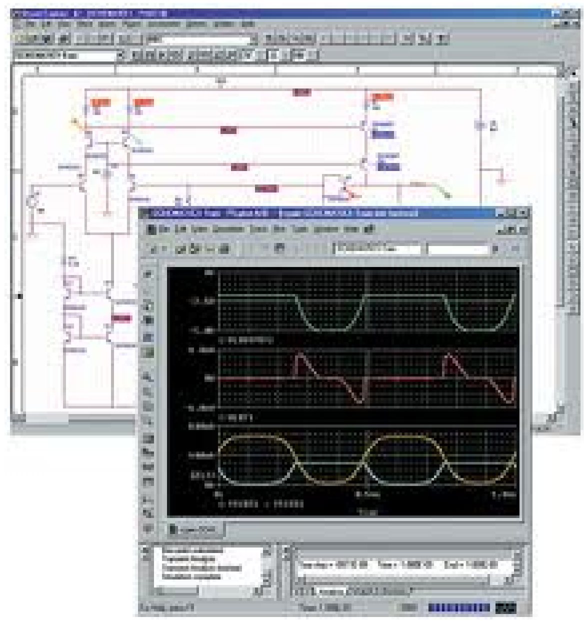
Develop intracochlear pressure data set for air- and bone-conduction A statistically robust data set will be developed using a sample of temporal bones. Results will be compared with those published for known EAC stimulus levels to confirm specimen quality and experimental technique. With the validity of the technique established, experiments will be performed using bone vibrators to correlate intracochlear pressures under AC and BC stimulation.



5.3.1 Build lumped model with acoustic pressure, velocity and intracochlear pressure



The model used thus far to predict stapedial displacement and compare it to experimental results is the AHAAH model. The model has been used as a "black box" – that is, without influence over the internal parameters and routines used to model auditory response to a given stimulus. This was possible because an executable version of AHAAH is published and available to researchers seeking to compare results. Results thus far suggest that AHAAH under-predicts stapedial displacement in response to high-intensity, long-duration pulses. To determine whether an improvement might be made to the model, it will be necessary to show that a modification to the constitutive equations governing stapedial response – specifically to the nonlinear spring rate and damping of the annular ligament – can improve the model's correspondence with measured results. This will be accomplished in two stages:

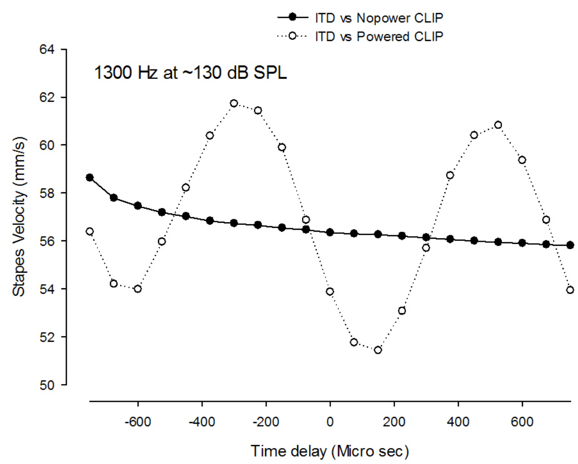


Replicate AHAAH results in circuit simulator A general-purpose circuit simulator, e.g. **pSPICE** or **ngspice**, will be used to replicate the AHAAH model. Building a circuit model with the connectivity and element parameters published for AHAAH is straightforward. Model confirmation will be accomplished by comparison of the model's and AHAAH'S responses. It should be noted that AHAAH includes a simulation of the stapedial reflex to predict "warned" response to impulse; this will not be included in the circuit model.

Modify model elements and replicate observed results The circuit model will be used to predict stapedial response to high-intensity, long-duration impulse. The parameters corresponding to the damping and nonlinear spring rate of the annular ligament will be fitted to the experimental data to optimize correspondence with results. The physical significance of the optimized parameters (e.g. micromechanisms of stiffening or viscoelastic phenomena such as relaxation) will be compared with published studies of auditory physiology to develop a reasonable physical explanation for the observed results.

5.4 Demonstrate active mitigation of impulse using breadboard

To date, active mitigation experiments have been conducted using static displacement to stiffen the ossicular chain, and simple phase-reversal combined with adjustable time or phase delay to attempt active cancellation. Active mitigation of incident harmonic noise was shown to be feasible, with greater than 6 dB of cancellation demonstrated. However, the displacement (stroke) available from the MET was insufficient to significantly stiffen the ossicular chain; this approach will require a transducer with longer travel. Direct cancellation of the impinging wave was also attempted. When a signal was introduced to cancel a simulated blast impulse, the impulse waveform and cancellation signal were not well enough matched to achieve good cancellation. This is believed to be partly due to the very close phase matching required, compounded by the mechanical nonlinearity of the ear. For this phase, a step will be taken to achieve improved active cancellation.



Build and test cancellation breadboard This circuit will be constructed with simple analog components to provide a feedback loop with fine phase control and some filtering capability to compensate for ossicular nonlinearity. A transducer will be attached to the incus long process (ILP) with an aWengen clip as in earlier experiments. Harmonic acoustic stimuli from 90 dBSPL to 140 dBSPL will be introduced to the EAC while the phase of the cancellation signal is changed in small increments to determine the optimum delay; this is expected to be around 80 microseconds. FFT decomposition of stapes velocity will be used to tune the filter. With the cancellation circuit optimized, experiments will be conducted to determine the degree of cancellation achievable for a simulated blast waveform at high intensity. The system will be demonstrated in a suitable cadaveric specimen, with estimates of the degree of protection conferred.

References

[1] James Easter, Xianxi Ge, Gregory Capra, Kanthaiah Koka, James Eric Lupo, and Travis Pfannenstiel. Measurement of differential intracochlear pressure using off-the-shelf pressure sensors. *Military Health System Research Symposium*, 2012.

[2] Kanthaiah Koka, James Eric Lupo, Travis Pfannenstiel, and James Easter. Active mitigation of auditory blast injury: A temporal bone model. *Military Health System Research Symposium*, 2012.

[3] Kanthaiah Koka, Travis Pfannenstiel, Xianxi Ge, Jianzhong Liu, Ronald Jackson, Gregory Capra, Vikrant Palan, Mario Pineda, Ben Balough, and James Easter. Blast wave impact on auditory pathway: A cadaveric temporal bone study. *Association for Research in Otolaryngology Midwinter Meeting*, 2012.

[4] Hideko Heidi Nakajima, Wei Dong, Elizabeth S Olson, Saumil N Merchant, Michael E Ravicz, and John J Rosowski. Differential intracochlear sound pressure measurements in normal human temporal bones. *Journal of the Association for Research in Otolaryngology : JARO*, 10(1):23–36, March 2009.

[5] S. Puria, W. T. Peake, and J. J. Rosowski. Sound-pressure measurements in the cochlear vestibule of human-cadaver ears. *J Acoust Soc Am*, 101(5 Pt 1):2754–2770, May 1997.

[6] J J Rosowski, W Chien, M E Ravicz, and S N Merchant. Testing a method for quantifying the output of implantable middle ear hearing devices. *Audiology & neuro-otology*, 12(4):265–76, January 2007.