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Effect of cochlear implantation on middle ear function: a three-month prospective study

Short Running Head: Effect of CI on middle ear function

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None declared.

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Abstract

Objectives: To determine if cochlear implantation has a delayed effect on the middle ear conductive hearing mechanism by measuring laser doppler vibrometry (LDV) of the tympanic membrane (TM) in both implanted and contralateral control ears, pre-operatively and three months post-operatively; then comparing the relative change in LDV outcome measures between implanted and control ears.

Study Design: Prospective cohort study

Methods: Eleven pre-operative adult unilateral cochlear implant recipients in previously un-operated ears with normal anatomy and aerated temporal bones were included in this study. The magnitude and phase angle of umbo velocity transfer function in response to air conduction (AC) stimulus, and the magnitude of umbo velocity in response to bone conduction (BC) stimulus were measured in the implant ear and the contralateral control ear, pre-operatively and three months post-operatively and compared.

Results: No significant changes in the magnitude or phase angle of TM velocity in response to either AC or BC stimulus were observed in the implanted ear relative to the contralateral control ear, three months following cochlear implantation.

Conclusion: From the result of LDV measurements, it can be said that cochlear implantation has no significant delayed effect on the middle ear conductive mechanism.

Key Words: Cochlear implant; Laser doppler vibrometry; Conductive hearing loss.

Level of Evidence: Level 4

Introduction

Hearing preservation in cochlear implantation (CI) with electrical acoustic stimulation to the implanted ear improves speech perception, particularly in noise.^{1,2,3} However up to 50% of implanted ears can lose residual hearing postoperatively.⁴ Residual hearing can be lost immediately after CI if the cochleostomy or inserted electrode array damages the cochlea and induces oxidative stress and apoptosis within the organ of Corti; or it can be delayed if fibrosis accumulates in or around the cochlea over time.⁵ Choi and Oghalai⁶ modeled the effect of cochlear implantation on cochlear biomechanics and concluded that damping of the scala tympani by the array or post-operative scarring predominantly affects tuning in the apex of the cochlea, and therefore low frequency hearing. Rowe et al.⁷ observed a delayed, progressive increase in auditory brainstem response (ABR) thresholds at 2 kHz but not at higher frequencies over a 12-week period after the guinea pig round window was pierced then sealed with muscle. This hearing loss was speculated to result from progressive fibrosis at the round window affecting cochlear mechanics, consistent with Choi and Oghalai's⁶ model. A subsequent animal model study by Rowe et al.⁸ revealed that delayed low frequency hearing loss following insertion of an electrode array through the round window was associated with fibrosis at the round window, and in particular the stapes which lies close to the electrode. A corollary of these considerations is that sound conduction to or within the inner could become more impeded as fibrosis and scar tissue affecting the ossicular chain and/or scala tympani matures.

Laser doppler vibrometry (LDV) is the most sensitive tool available to determine change in middle ear mechanics.^{9,10} The aim of this study was to determine if cochlear implantation has any delayed effect on the conduction of sound across the middle ear by assessing any change in LDV of the TM three months following implantation.

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Materials and Methods

Ethical approval

This study was approved by the Royal Victorian Eye and Ear Hospital Human Research and Ethics Committee (reference number: 14/1191H; principle investigator: Joseph Wasson).

Patient selection and surgery

The study was performed prospectively from 23rd October 2014 to 3rd July 2015. Study participants were adults with normal anatomy and an aerated temporal bone (determined by pre-operative computer tomography and magnetic resonance imaging), preparing to undergo cochlear implantation. Patients under 18 years of age and those with ipsilateral middle ear disease or effusion, or previous ipsilateral major ear surgery were excluded. Pre-operative cochlear implant patients were mailed an invitation to participate, a patient information sheet, a consent form, and an appointment time that could be cancelled or ignored. All recruits underwent pre-operative LDV no more than two weeks before CI. Patients gave signed informed consent, then had their otological history reviewed to ascertain whether they previously had major ear surgery or chronic otitis media. Any cerumen was removed from both ears and examined to ensure that the external ear was healthy and TM intact with no evidence of middle ear effusion. Tympanometry was performed on both the preoperative and contralateral ears to check for normal middle ear function (type A tympanogram) or mild eustachian tube dysfunction (type C1 tympanogram). Patients with significant eustachian tube dysfunction (type C2

typanogram) or middle ear effusion (type B tympanogram) in either ear were excluded. LDV and tympanometry were repeated in both ears as close as conveniently possible to three months after implantation.

Nineteen patients agreed to participate in the study. Eight of these patients were subsequently excluded because they had type B or C2 tympanograms and a consequent poor LDV signal (five patients) or because they failed to attend their post-operative appointment (three patients). The remaining 11 patients were recruited to the study, of which eight patients had no previous history of ear surgery, however three patients had previously undergone uncomplicated contralateral CI. During the course of this study all eleven patients underwent routine CI surgery via a postauricular incision, mastoidectomy and posterior tympanotomy, performed by the two senior authors of this paper. Seven patients received a Contour Advance Nucleus CI512 implant (Cochlear Ltd) via a cochleostomy. The other four patients, who all possessed residual hearing, received a straight Nucleus CI422 implant (Cochlear Ltd) via the round window. All electrodes were fully inserted and sealed with periosteum at the cochleostomy (CI512) or round window (CI422).

Laser Doppler Vibrometry equipment arrangement

Figure 1 provides an overview of the LDV recording arrangement. Acoustic stimuli were generated and LDV measurements captured with Matlab R2014a software (Mathworks) running on a Macbook Pro laptop (Apple). Sound was generated with an SBX-FI HD USB audiophile sound card (Creative Technology) and amplifier (Sense Audio). Air conduction (AC) sound was delivered from the amplifier to the patient via an ER-2 earphone (Etymotic Research) connected to a glass-backed sound

coupler (Polytec PI) and ear speculum. An ER-7C probe microphone system (Etymotic Research) was also attached to the sound coupler with a nylon tube positioned deep within the ear speculum, such that the microphone tip came within 5 mm of the TM. Information from the microphone was relayed back to Matlab via the USB sound card. The earphone was substituted with a B71 bone transducer (Radioear) on a headband for bone conduction (BC) sound stimulation.

The helium-neon laser beam of a CLV-2534 LDV (Polytec), mounted on an OpMi-1 microscope (Zeiss), was focused through the glass backed sound coupler and speculum onto the TM via a joystick-controlled aiming prism. Reflected light data was captured by Matlab via the USB sound card.

Laser doppler vibrometry measurement

LDV was used to measure TM vibration in response to AC and BC sound stimuli in both the implant and contralateral ears. With the speculum and attached sound coupler positioned within the ear canal, the system was calibrated by playing a white noise stimulus to measure the in-situ frequency response, then generating a finite impulse response (FIR) filter to apply to subsequent stimuli such that the frequency response became flat between 160 Hz and 16 kHz. A 1 kHz tone was then played to check loudness. The test stimulus was a multi sinewave tone consisting of 21 logarithmically spaced frequencies between 160 Hz and 16 kHz of 80 dB sound pressure level (SPL) loudness, presented simultaneously over three seconds.

The BC stimulus was calibrated less conventionally. Instead of targeting a stimulus of known sound intensity, we attempted to devise a stimulus that would provide an

approximately flat frequency response for umbo velocity. To achieve this, a white noise stimulus was applied to one otologically normal ear and the frequency response of the umbo velocity measured. A FIR filter was then applied to all subsequent stimuli in an attempt to provide a flat frequency response at the umbo. The same filter was used for all participants. Like the AC stimulus, the BC stimulus was a multi sinewave tone consisting of 21 logarithmically spaced frequencies between 160 Hz and 16 kHz of 80 dB SPL loudness, presented simultaneously over three seconds. The stimulus intensity was configured so that umbo velocity in the otologically normal ear from which the calibration was derived was 5 $\mu\text{m/s}$ at each frequency. Because the bone conduction probe had limited loudness, a velocity of 5 $\mu\text{m/s}$ was only achieved within 5 dB between 500 Hz and 4000 Hz, with reduced velocities at lower and higher frequencies.

The AC sound stimulus was delivered to the ear via the earphone, sound coupler and speculum. The BC sound stimulus was delivered via the bone conductor, held to the forehead of the participants with a static force of 5 N provided by a steal headband. The bone conductor was placed at the midline of the forehead, rather than the ipsilateral mastoid, because all implanted ears underwent cortical mastoidectomy, and therefore morphological changes in the mastoid bone between pre- and post-operative measurements could have altered the BC stimulus. The TM LDV to AC and BC sound stimulus was measured first in the implant ear, then the contralateral ear.

LDV compares the frequency of emitted light with the frequency of light reflected from the target surface. The reflected light frequency is modulated by the vibrational velocity of the sound-stimulated TM. An accurate comparison of

reflected and emitted light depends on the amplitude of reflected light, signified by a percentage signal strength gauge on the LDV velocity decoder. The lower the amplitude of reflected light (or signal strength) at the velocity decoder, the noisier the velocity estimate. The laser was focused within the light reflex at a point closest to the umbo. This position maximized reflection, being orthogonal the direction of light travel, and enabled TM vibrational velocity to be recorded close to the ossicular chain conductive mechanism. The first author aimed the laser during all measurements. A research assistant monitored and provided verbal feedback on signal strength to help the first author optimize light reflection. Reflected light was detected and decoded by the vibrometer after each stimulus to produce a voltage output proportional to umbo velocity. Measurements were repeated if the signal was indistinguishable from the noise floor in the frequency domain as judged by the research assistant, who monitored the Fast Fourier Transformation (FFT) analyser throughout LDV measurement. The noise floor was considered to be the parts of the Fast Fourier Transformation (FFT) analyser spectrum between stimuli. For the numerical analysis, this was taken as the average of 10 FFT bins each side adjacent to the stimulus frequency starting 5 bins away.

Each set of measurements was repeated four times to check for consistency. These four measures were averaged for analysis. For AC measurements, data points with a magnitude squared coherence between the microphone and laser signals below 0.5 were excluded. For BC measurements, data points with a signal to noise ratio below 10 dB were excluded.

Outcome measures for the AC stimulus were the umbo velocity transfer function in dB (the ratio of umbo velocity to sound pressure at each stimulus frequency) and the difference in response phase angle in degrees between umbo velocity and sound pressure. For the BC stimulus, it was only possible to measure the change in umbo velocity in dB at each stimulus frequency. Pure tone audiometry was not chosen as an outcome measure because seven of 11 patients lacked residual hearing and LDV is the most sensitive tool available for detecting conductive changes at the umbo.

Outcome measure comparison and statistical testing

Pre-operative LDV outcome measures for AC and BC stimuli were subtracted from their post-operative equivalents to derive a value and direction for change. Change values for the implant and control ears were compared and tested for significance using a paired two-sample t-test with Bonferroni correction at each stimulated frequency. All statistical analyses were performed with Matlab R2014a software (Mathworks).

Results

Patient details are summarised in Table 1.

There was no significant change in the absolute magnitude of umbo velocity transfer function in response to AC stimulus after CI when mean pre- and post-operative LDV measurements were compared (Figure 2). Umbo velocity decreased by up to 4 dB at frequencies below 1 kHz after CI. A similar trend was observed in the contralateral ear, and there was no significant difference between ears (Figures 2 and 3). When the mean relative change in the magnitude of umbo velocity transfer function for implanted and contralateral ears was compared (Figure 3), the umbo velocity of implanted ears following CI tended to be higher than that of contralateral ears between 1.3 and 4 kHz, but differences between ears were not significant at any frequency.

The mean change in phase angle of the umbo velocity transfer function of implanted and contralateral ears between pre- and post-operative measurements is graphically presented in Figure 4. There is a trend towards a gain in the phase angle of implanted ears relative to contralateral ears between 400 Hz and 4 kHz, with a maximum gain of 27 degrees at 1.6 kHz, but this difference was not statistically significant.

Figure 5 illustrates the mean relative change in the magnitude of umbo velocity in implanted and contralateral ears in response to the BC stimulus. There is a trend towards an increased magnitude of umbo velocity in the implanted ear relative to

the contralateral ear between 800 Hz and 4 kHz, but differences were not statistically significant at any frequency.

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Discussion

To the best of our knowledge, this study is the first to perform LDV on the TM in the months following CI. There were subtle changes in LDV outcome measures in the implanted ear, which might support a stiffening of the stapes footplate at the oval window and an increase in mass of the ossicular chain, but no significant differences existed between the implanted and control ears.

For AC stimuli, Rosowski et al.^{9,10} showed that factors which stiffen the conductive mechanism cause a decrease in the magnitude of umbo velocity transfer function and an increase in phase angle at frequencies of 1 kHz and below, relative to normal, on LDV. These observations were greatest in lateral ossicular pathology such as malleal fixation, which significantly stiffens the tympano-ossicular system, whereas patients with otosclerotic fixed stapes only experience a small increase in tympano-ossicular stiffness due to the flexibility of the incudomalleolar and incudostapedial joints.^{9,10} For pathologies which loosen the tympano-ossicular system, such as partial or total ossicular interruption, the opposite was observed, with an increase in the magnitude of umbo velocity transfer function at frequencies of 1 kHz and below; and a decrease in phase angles relative to normal.^{9,10}

In this study, there was a small gain in umbo transfer function phase angle at low frequencies on AC stimulus relative to the contralateral ear (Figure 4) and a small decrease in the magnitude of the umbo transfer function at frequencies below 1 kHz following CI (Figure 3). Such observations suggest the impedance of the stapes increases at the oval window following CI.^{9,10} However, there was an inexplicable,

similar decrease in the magnitude of the umbo transfer function in the contralateral ear, despite no surgical intervention or change in middle ear pressure between measurements (figure 3; table 1). Furthermore, the gains in phase angle and the magnitude of the umbo transfer function in implanted ears were not significantly different from those of control ears.

Recent animal CI hearing preservation experiments by Rowe et al.^{7,8} were able to replicate delayed low frequency hearing loss following CI in the guinea pig. Muscle and periosteal round window sealants were associated with thickening of the round window and fixation of the stapes through fibrosis and ossification, and so the delayed hearing loss was likely to be conductive in nature.⁸ Clinically, ossicular fixation with conductive hearing loss caused by bone dust collecting on the ossicular chain has been reported following endolymphatic sac decompression surgery.¹¹ Therefore, CI surgery could theoretically increase impedance at the stapes footplate by fibrosis, ossification or bone dust ankylosis, resulting in a delayed conductive hearing loss due to stapes fixation. While some trends in these data point in that direction, the effect was too small to be considered significant.

Only two studies have previously investigated the acute impact of cochlear implantation on middle ear sound conduction in live human recipients using LDV.^{12,13} Huber et al.¹² reported a cohort of 18 patients who underwent intraoperative LDV measurements of the stapes and round window in response to an acoustic stimulus before and after CI. No significant difference in volume displacement amplitude or phase angle of either the stapes or round window was reported after CI.¹² Similarly, Donnelly et al.¹³ reported a series of seven patients who underwent intraoperative

pre- and post-CI LDV displacement measurements of the incudostapedial joint, with a variable effect of electrode insertion on stapes displacement observed.¹³ These intraoperative experiments did not account for any subsequent delayed ossicular chain ankylosis or cochlear fibrosis that may occur following CI.

During BC stimulation, temporal bone^{14,15} and live human ear¹⁶ LDV experiments have shown that ossicles including the umbo move in phase with equal magnitude as the surrounding temporal bone at low frequencies. Only above frequencies of 1.5 – 2 kHz does the phase of the ossicles begin to lag that of the temporal bone.^{14,15} If the mass of the ossicles is increased, its resonance frequency is reduced, causing the ossicular chain to become vibrationally decoupled from the temporal bone at lower frequencies, yielding a greater umbo velocity.¹⁴ To the best of our knowledge, this study is the first to examine LDV of the TM in response to BC stimulus following CI in live human cochlear implant recipients. There was a small but statistically insignificant increase in the magnitude of umbo velocity at lower frequencies in the months following CI, relative to the contralateral ear (Figure 5). These trends suggest that a subtle increase in mass of the ossicular chain may have occurred three months following CI, possibly from bone dust settlement on the ossicles.

There is evidence to suggest that LDV measurements at the umbo may not be sensitive enough to detect a change in cochlear mechanics caused by intracochlear scarring associated with the electrode array. A cadaveric study of 10 human temporal bones by Gan et al.¹⁷ compared LDV measurement of the TM, incudostapedial joint and stapes footplate in response to an acoustic stimulus before and after draining the cochlea of perilymph. Perilymphatic drainage caused an

increased in the magnitude of the incudostapedial joint and stapes footplate displacement transfer function at higher frequencies, consistent with reduced cochlea impedance, however measurements at the umbo remained unchanged due to the compliant joints within the ossicular chain.¹⁷ Therefore, this study was unable to investigate any fibrosis and change to sound conduction within the cochlea, as the flexibility of ossicular joints effectively buffers any subtle changes in inner ear impedance caused by pathology. Other temporal bone studies have shown that stapes fixation can reduce the sound induced velocity of the stapes by 50 dB, yet umbo velocity is reduced less than 10 dB due to the flexibility of the ossicular chain.¹⁸ Such compliance of the ossicular chain may explain why the results in this study demonstrated trends to suggest a possible delayed stiffening of the stapes and increase in ossicular chain mass, but did not reach significance.

This study has several limitations. Firstly, the participant number was only sufficient to detect relatively large effects. Secondly, three patients already had a cochlear implant in the contralateral ear, which may have affected their LDV measurements for this ear. Ideally, healthy un-operated ears would have been better as controls. Thirdly, although patients with type C2 and B tympanograms were excluded from this study, two patients with a type C1 tympanogram were included, and small negative pressures have been shown to dampen TM velocities at lower frequencies.¹⁰ Finally, while LDV may be the most sensitive tool available for detecting change in middle ear biomechanics, it can underestimate changes in the impedance of the stapes,¹⁸ which may result from cochlear implantation.

Conclusion

In this study, subtle changes in LDV measurements were observed three months following CI, but no trends reached significance and any difference observed between implanted and control ears is likely to be clinically irrelevant. Therefore, from the result of LDV measurements, it can be said that cochlear implantation has no significant delayed effect on the middle ear conductive mechanism.

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ossicular chain. *Hear Res* 2005; 204: 60-77.

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List of Figures

Figure 1: Arrangement of laser doppler vibrometry experimental equipment.
1 = laptop; 2 = sound card; 3 = vibrometer; 4 = microscope-mounted laser; 5 = microphone; 6 = amplifier; 7 = bone conductor; 8 = ear phone; 9 = microphone nylon tube probe; 10 = sound coupler; 11 = ear speculum; 12 = laser doppler vibrometry recording; AC = Air Conduction; BC = Bone Conduction.

Figure 2: Mean absolute magnitude of the umbo velocity transfer function of for implanted contralateral ears pre- and post-operatively. Standard error of the mean bars are shown for pre-operative implant ear values. Pre CI = implanted ear pre-operatively; Pre Control = contralateral control ear pre-operatively; Post CI = implanted ear post-operatively; Post Control = contralateral control ear post-operatively

Figure 3: Mean relative change in the magnitude of umbo velocity transfer function for implanted and contralateral ears. Standard error of the mean bars are shown. CI ear = implanted ear; Control Ear = contralateral ear.

Figure 4: Mean relative change in phase angle of the umbo velocity transfer function of implanted and contralateral ears between pre- and post-operative LDV measurements. Phase angles were unwrapped for comparison. Standard error of the mean bars are shown. CI ear = implanted ear; Control Ear = contralateral ear.

Figure 5: Mean relative change in magnitude of the umbo velocity of implanted and contralateral ears in response to a bone conduction stimulus. Standard error of the mean bars are shown. CI ear = implanted ear; Contra Ear = contralateral ear.

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Table 1: Demographics and tympanometry results. CI = cochlear implant;
t ymp = tympanometry; I = implant ear; C = contralateral ear; LDV =
laser doppler vibrometry; m = months; d = days.

Patient	Age	Sex	Past Otological History	CI device	Pre op t ymp (I/C)	Post op t ymp (I/C)	Post op LDV (months)
1	67	M	None	CI422	A/A	A/A	5m 7d
2	75	M	None	CI422	A/A	A/A	3m 9d
3	55	F	None	CI422	A/A	A/A	3m 11d
4	79	M	Contralateral CI	CI422	A/A	A/C1	3m 16d
5	35	M	Contralateral CI	CI512	A/A	A/A	3m 10d
6	54	M	None	CI512	A/A	A/A	2m 28d
7	51	M	None	CI512	A/A	A/A	3m 3d
8	77	M	None	CI512	A/A	A/A	4m 13d
9	33	F	Contralateral CI	CI512	A/A	A/A	2m 25d
10	69	F	None	CI512	C1/A	A/A	3m 1d
11	38	F	None	CI512	A/A	A/A	2m 10d

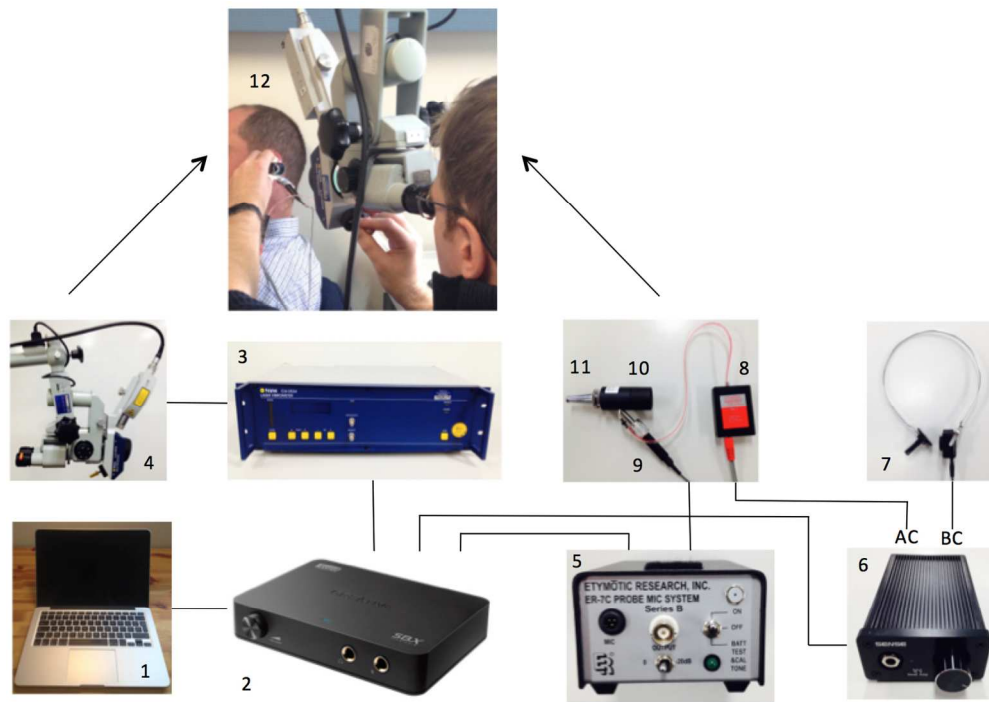


Figure 1: Arrangement of laser doppler vibrometry experimental equipment. 1 = laptop; 2 = sound card; 3 = vibrometer; 4 = microscope-mounted laser; 5 = microphone; 6 = amplifier; 7 = bone conductor; 8 = ear phone; 9 = microphone nylon tube probe; 10 = sound coupler; 11 = ear speculum; 12 = laser doppler vibrometry recording; AC = Air Conduction; BC = Bone Conduction.

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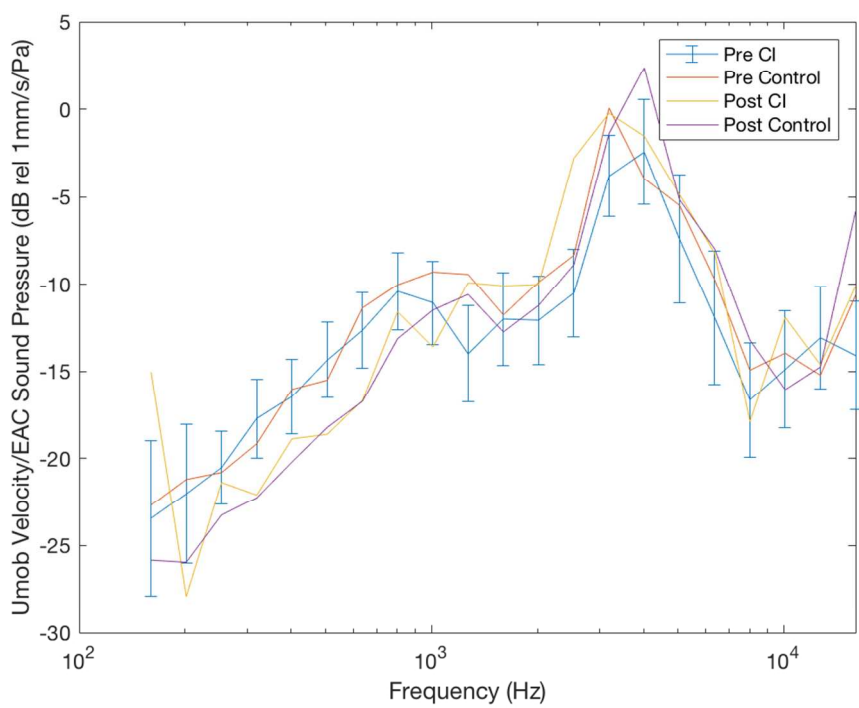


Figure 2: Mean absolute magnitude of the umbo velocity transfer function of for implanted contralateral ears pre- and post-operatively. Standard error of the mean bars are shown for pre-operative implant ear values. Pre CI = implanted ear pre-operatively; Pre Control = contralateral control ear pre-operatively; Post CI = implanted ear post-operatively; Post Control = contralateral control ear post-operatively.

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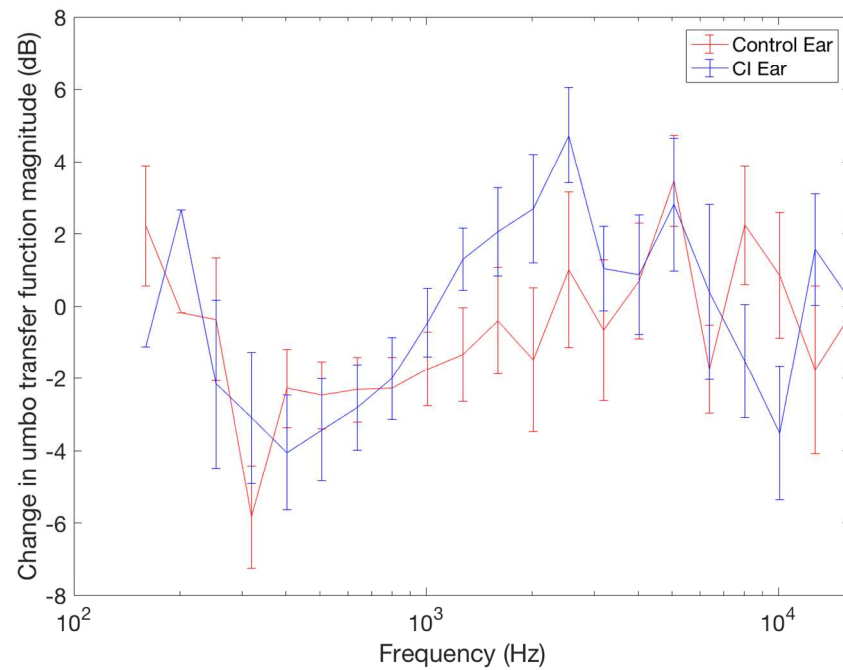


Figure 3: Mean relative change in the magnitude of umbo velocity transfer function for implanted and contralateral ears. Standard error of the mean bars are shown. CI ear = implanted ear; Control Ear = contralateral ear.

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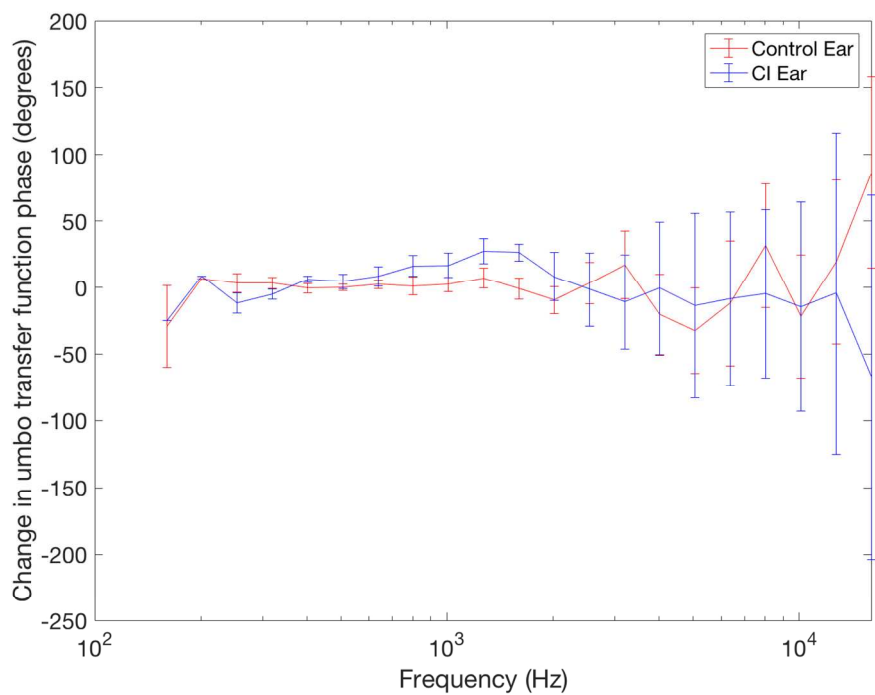


Figure 4: Mean relative change in phase angle of the umbo velocity transfer function of implanted and contralateral ears between pre- and post-operative LDV measurements. Phase angles were unwrapped for comparison. Standard error of the mean bars are shown. CI ear = implanted ear; Control Ear = contralateral ear.

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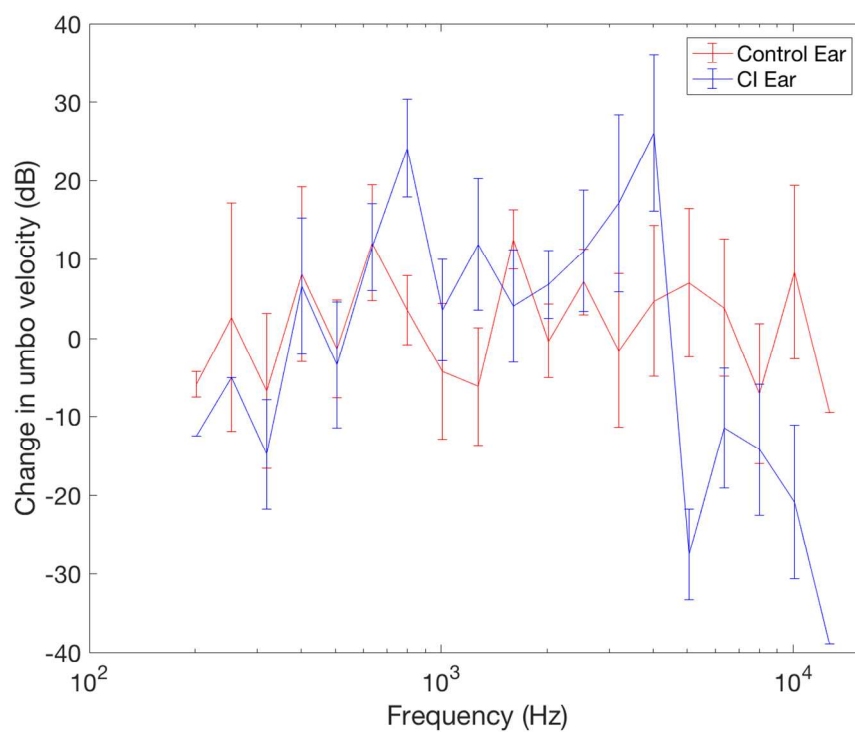


Figure 5: Mean relative change in magnitude of the umbo velocity of implanted and contralateral ears in response to a bone conduction stimulus. Standard error of the mean bars are shown. CI ear = implanted ear; Contra Ear = contralateral ear.

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