A comparison of sound transmission of middle ear prostheses manufactured via SLM

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Abstract. Middle ear surgeries involve Total Ossicular Replacement Prosthesis (TORP) or Partial Ossicular Replacement Prosthesis, where all or some of the three ossicle bones are replaced. Current prostheses are dissimilar to the natural ossicles in geometry, size and only recover up to 75% sound transmission. Additive manufacturing offers complex, near-net shape geometries that allow for patient specific implants. A novel design is used to manufacture a TORP in Ti6Al4V(ELI) via Additive Manufacturing. The sound transmission level of the of the additively manufactured titanium prosthesis was measured by laser doppler vibrometry and compared to that of a Silver additively manufactured prosthesis. The sound transmission level of the additively manufactured prostheses are also compared to that of the international standards and literature using this method.

1 Introduction

The titanium alloyTi6Al4V extra-low interstitial (ELI) has good biocompatibility, and excellent corrosion and wear resistance as well as high strength-to-weight ratio (1-4). All these properties lend it well for use in various industries, especially in the medical field for prostheses and implants (5). Ti6Al4V is difficult to machine thus limiting the shape, geometry and complexity of parts that can be made using conventional manufacturing methods like casting and powder metallurgy. Additive Manufacturing (AM) is a process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive methodologies (6). Additive Manufacturing circumvents the challenges introduced by conventional manufacturing methods in that complex geometry, near-net shape and fully dense components are possible to make.
Hearing loss is a global problem, accounting for about 8-20% of the world population according to the World Health Organization (7). The affected population are often prevented from the working world, education and have a poor social life leading to their isolation and dependency. Conductive hearing loss, which is the discontinuation and fixation of the

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ossicular chain, accounts for approximately 55% of cases (7). It is mainly due to ear infections, congenital malformations as well as blunt and sharp traumas. Surgical reconstruction of the ossicular chain using total ossicular replacement prosthesis (TORP) or partial ossicular replacement prosthesis (PORP) are useful in conductive hearing loss rehabilitation. Available prostheses are made from different materials such as silastic, stainless steel, platinum, and titanium. There has been little improvement in terms of middle ear prostheses/ implantable middle ear hearing devices (IMEHD) in the past 50 years. Their format and design to simulate the middle ear anatomy has not changed or improved, only changes in different materials have given advances to the technology. Poor stability of the prostheses in the middle ear resulting in dislodgments or migration from the middle ear to the external ear canal are some of the challenges facing patients and surgeons alike (7). There is a need for prosthesis designs that better simulate the human ossicular chain anatomy in design, shape, weight, and movement with good stability. This should better sound recovery beyond what is currently possible with available middle ear prostheses. Additive Manufacturing offers the complexity and precision to make prostheses that are similar to the ossicular bones in shape, weight and size.
The study looks at the sound transmission level of novel design additively manufactured ossicle prostheses that are similar in geometry and size to human ossicles. The sound transmission is measured with a Laser Doppler Vibrometer in a middle-ear simulated setup.

2 Methods

2.1 Specimen

Ti6AL4V ELI grade powder was used to manufacture an ossicle prosthesis on a SLM 125 machine with optimised parameters. A silver (Ag) additively manufactured prosthesis ossicle that was readily available was also tested. Silver prostheses have been used in literature to study middle ear sound transmission as in the study by Ronnblom et al. [8]. Both prosthetics are shown in figure 1.

Fig. 1. Additively Manufactured ossicles in silver (left) and in titanium (right)

2.2 Test Setup

The vibration velocity of the stapes bone of the ossicles is indicative of the sound transmission from the ear canal to the oval window. Such transmission can be measured using laser doppler vibrometry. The method for the measurement of middle ear structures velocities

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to test the ex-vivo performances of Implantable Middle Ear Hearing Device (IMEHD) or prostheses using human temporal bones and laser doppler vibrometry is described by ASTM F2504-05. The setup is shown in Figure 2.

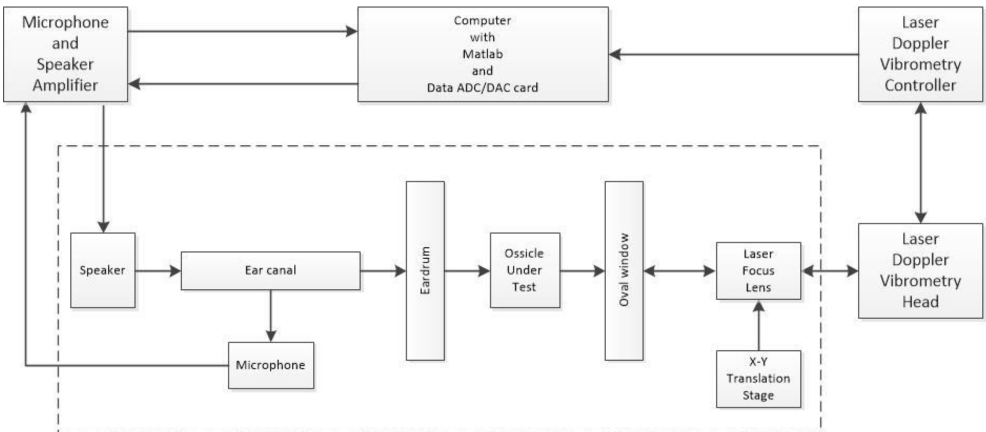

Fig. 2. Testing equipment setup ASTM F2504-05 (9)

For this study, the simulated inner ear setup is discussed in this section and depicted in figure 3. The microphone amplifier is based on the LM386 and amplifies the microphone signal by 200x. The output from the microphone is fed to a MATLAB controlled ADC card for digitization and further processing. The speaker amplifier is a class A amplifier and drives the speaker at a maximum of 5Vp-p. The amplifier is driven by a signal generated by a MATLAB controlled DAC card. The speaker is a general purpose 8Ω, 1W speaker mounted in vibration dampening foam in such a way as to allow the position of the speaker to be changed relative to the simulated ear canal. The simulated ear canal is made from a 10mm diameter, 20mm long ABS tube that is supported by vibration dampening foam and placed against the simulated ear drum. The open-end points towards the speaker. There is a 1mm hole in the tube at the end closest to the simulated ear drum to allow the probe microphone access to measure the acoustic pressure in the interior of the simulated ear canal. The microphone is an ICP Probe Microphone (Model 377B26) fitted with a 20mm probe tip with which it was calibrated. The microphone calibration certificate specifies the sensitivity to be 2.15mV/Pa. The microphone signal is conditioned by a Platinum Stock Products ICP sensor signal conditioner (Model 480C02). The output from the signal conditioner is fed to the microphone amplifier.

The simulated ear drum is a sandwiched assembly consisting of 5 layers. The first and fifth layer is made from 1mm thick rectangular polycarbonate sheets with a 10mm hole in the centre. The second and fourth layer consists of double-sided tape that holds the assembly together. The middle layer is made from stretched latex rubber and is the functional part of the simulated ear drum. The ossicle under test can be any prosthetic ossicle. The ossicle under test is suspended between the simulated ear drum and oval window by clamping it between the two stretched latex rubber films. The simulated oval window is a sandwiched assembly consisting of 5 layers. The first and fifth layer is made from 1mm thick rectangular polycarbonate sheets with a 3mm hole in the centre. The second and fourth layer consists of double-sided tape that holds the assembly together. The middle layer is made from stretched latex rubber and is the functional part of the simulated oval window. The simulated oval window is equipped with a Mitutoyo micrometre screw that renders it movable and facilitates precise clamping of the ossicle under test. The simulated oval window has a small (roughly $1mm^2$) piece of retroflective tape on the side facing the laser vibrometer focussing head that ensures a strong back reflection of laser light for the laser vibrometer to measure the velocity of the oval window.

The laser focussing head is held rigidly on a X-Y translation stage pointed towards the retroflective tape. The focal spot is visually evaluated and tuned to be a minimum size on the retroflective tape. The X-Y translation stage is used to adjust the horizontal and vertical position the laser spot on the retroflective tape. The first step in positioning is to get visual confirmation that the laser spot is on the retroflective tape and the second step in positioning is fine tuning the X-Y stage for maximum signal as indicated by the signal strength indicator on the laser vibrometer. The laser vibrometer is a Polytec differential measuring Fiber Vibrometer (OFV-552) with the one channel closed off to allow single ended measurement. The laser vibrometer controller is a Polytec OFV-5000 controller set up for a maximum sensitivity of 1mm/s/V. The maximum frequency of measurement is limited to frequencies below 20KHz. The vibrometer is further set up with a band pass filter between 100Hz and 5KHz to eliminate noise outside of the band of interest. The band of interest for the measurements lie between 400Hz and 4KHz.

All of the components enclosed by the dashed lines in the system block diagram (figure 2) are rigidly mounted on components made from 10mm thick aluminium plate. The components were ether machined or water jet cut to final size. All fastening of aluminium components were accomplished by using stainless steel Allen cap screws of various sizes. Various mechanical features were added to allow for adjustments to be made to the mechanics during experimentation. The entire mechanical assembly is mounted on a tripod for vibration isolation from the laboratory work bench on which other equipment is operated during experiments. The additively manufactured ossicle prostheses were positioned in place by a grip for the test measurements.

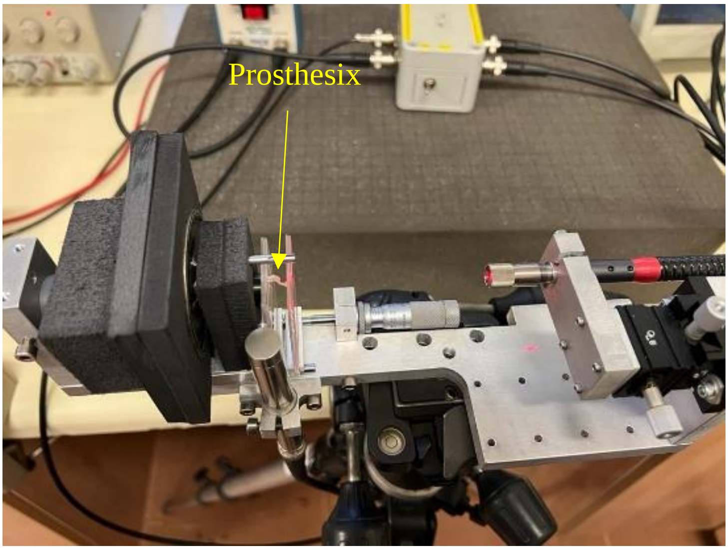

Fig. 3. The test setup

2.3 Analysis

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The DAQ system is initialised and setup to start the experiment. The sampling frequency is set at 1MHz; the excitation signal duration is set at 0.2s; the excitation signal amplitude is set at 15mV. The value is set so as to avoid clipping of the microphone signal at the most responsive frequency. The excitation frequency range is [400Hz, 4 kHz] at intervals of 100Hz; finally, the excitation signal is amplified by a factor of 200.

Upon receipt of the raw signal from the microphone and from the fiber vibrometer, the signals are pre-processed using a Fourier transform based method to remove noise and stray signals. Part of the stray signals is the 50-Hz signal embedded in the fiber vibrometer signal. To remove these signals, a Fourier transform is performed on the time-signal at each excitation. The frequency components at the excitation frequency are selected and retained by setting the components in the other positions to zero. Once this processed is done, an inverse Fourier transform is performed to regenerate the time signal at the excitation frequency. The signals are analysed using software that was written in MATLAB R2015a using built-in functions. Ten runs were done at each excitation frequency. The described analysis steps are shown in figure 4.

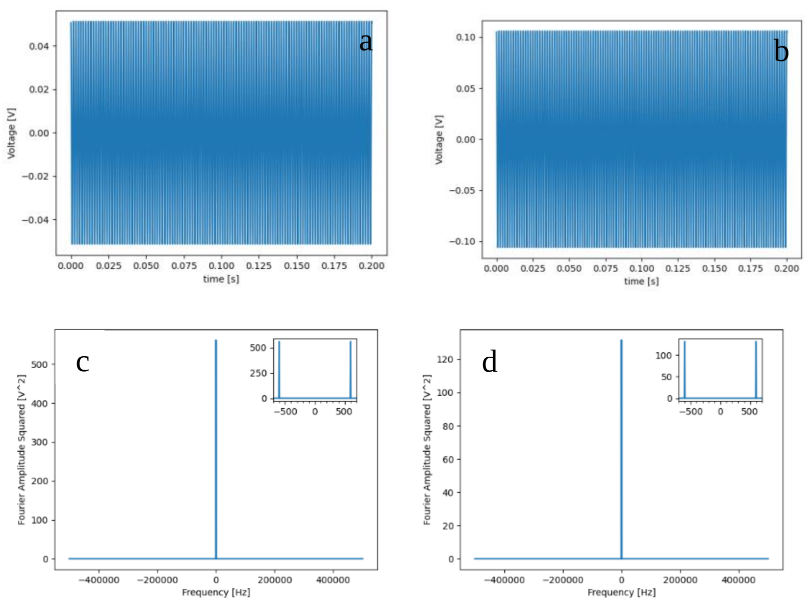

Fig.4. a) Filtered time signal of the microphone at 600 Hz for the Ag ossicle. (b) Filtered time signal of the vibrometer at 600 Hz for the Ag ossicle. (c) Squared Fourier components of the filtered microphone signal at 600 Hz. The subplot at the top right corner displays the frequency range between 0 – 700 Hz. (d) Squared Fourier compontes of the filtered vibrometer signal at 600 Hz. The subplot at the top right corner displays the frequency range between 0 – 700 Hz.

The stapes velocity induced by the sound is measured by Laser Doppler Vibrometry. The middle-ear transfer function, H_{TV} is computed.

$$H_{TV} = \frac{V_U}{P_T}$$
(1)

Where H_{TV} is the middle ear transfer function, V_U is the velocity of the stapes and P_T is the sound pressure at the tympanic membrane (ear drum)

3 Results

The sound transmission results of the titanium (245 mg) and silver (489 mg) additively manufactured ossicles are displayed in figure 5 and figure 6 below. Figure 5 shows the sound pressure level in decibels in the test frequency range. The titanium and silver ossicles showed a steady sound pressure level between 70 and 90 decibels through the test frequency range. The results show a similar trend between the ossicles, confirming the reliability of the simulated test measurement. It also shows that the effect of weight seems to be a non-factor to the sound response of the ossicle prostheses similar to the result in (8). The stapes velocity vibration as measured by laser doppler vibrometry at different frequencies is shown in figure 6. For both ossicles, there is an initial increase in stapes velocity as the frequency increases, this is to about 2800 Hz. There is a dip at 2900Hz and then the stapes velocity continues to increase with further increase in frequency to approximately 3300 Hz. For the rest of the test frequency range, the stapes velocity for both ossicle prostheses decreases with increasing frequency. The similarity in the trend of the prostheses again gives confidence to the repeatability and reliability of the simulated test measurements.

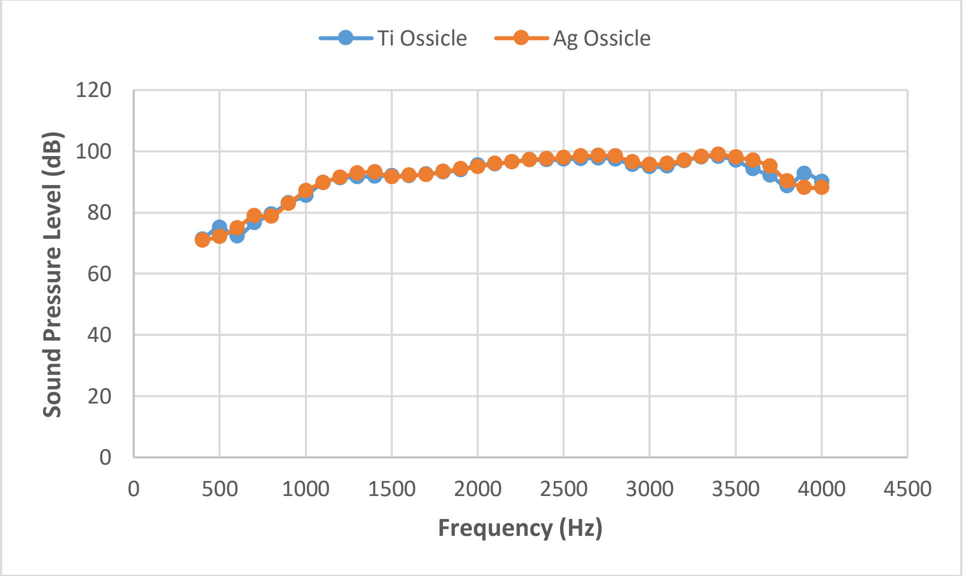

Fig. 5. The sound pressure level of the additively manufactured ossicles in the frequency range 400-4000 Hz

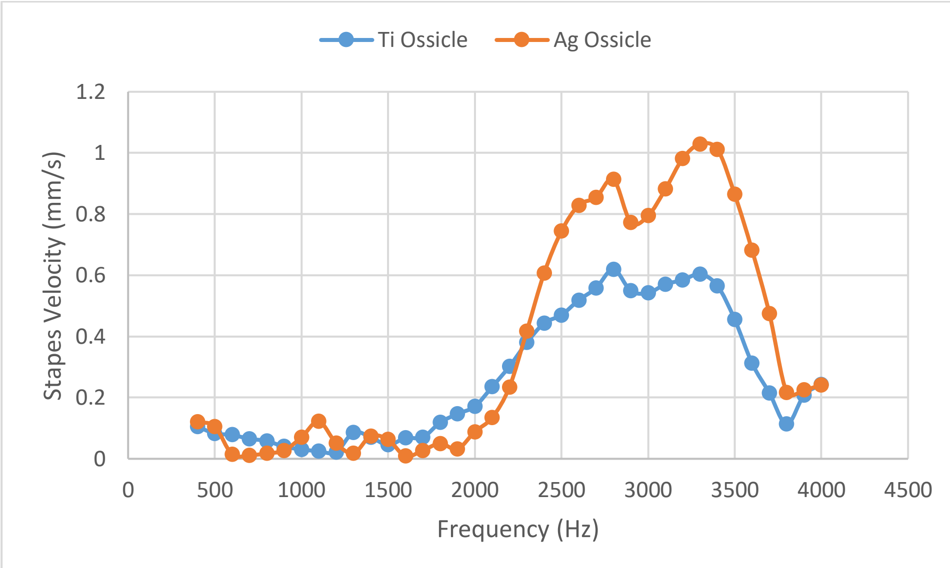

Fig. 6. The stapes velocity as a function of frequency of the titanium and silver additively manufactured ossicle prostheses.

Figure 7 gives the sound transfer function of the prostheses over the test frequency range. The silver ossicle prosthesis has better sound transfer than the titanium ossicle prosthesis in the frequency ranges of 400-500Hz, 1000-1200 Hz and 2300-4000Hz.

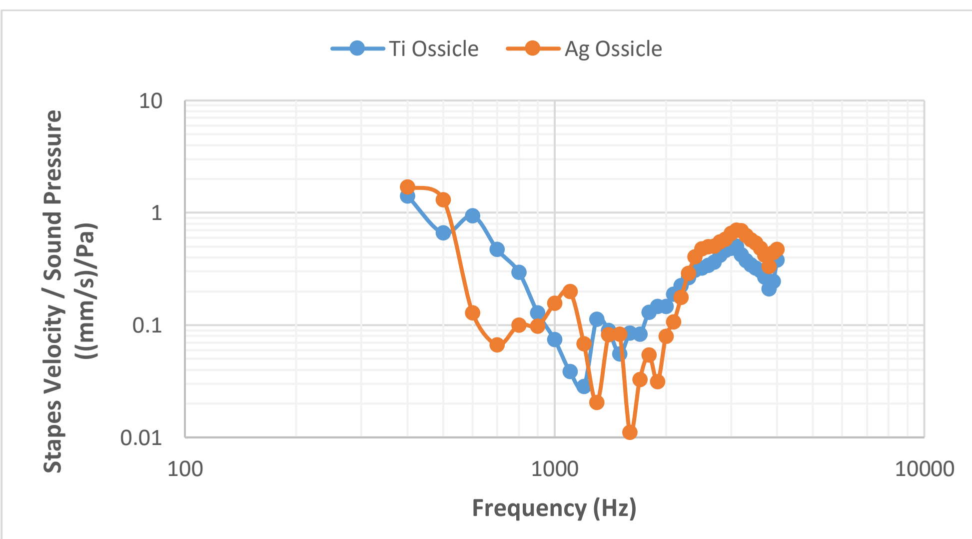

Fig. 7. The sound transfer function (v/P) of the titanium and silver additively manufactured ossicle prostheses over the test frequency range.

Figure 8 compares the additively manufactured prostheses sound transmission function to those measured in temporal bones in literature and the ASTM standard (9). Both additively manufactured prostheses have higher sound transmission at lower frequencies below 1000Hz and higher frequencies above 2000Hz than the ASTM standard. A study by Dong et al. (10) characterized the sound the transmission of temporal bones under different ossicle conditions. A normal condition measured the sound transmission with a human bone ossicular chain and a PORP condition measured sound transmission when a partial ossicular replacement prosthesis was placed into the temporal bones. A comparison of the additively manufactured prostheses found that the titanium prosthesis had better sound transfer below 900Hz and also above 1600Hz. The silver prosthesis also had better sound transmission than the two conditions at frequencies below 1600Hz and above 2000Hz. Essentially the additively manufactured prostheses displayed better sound transmission below 1000Hz and above 200Hz. Mention must be made though, that this is a rough estimation as the additively manufactured ossicles were tested in a simulated temporal bone set up.

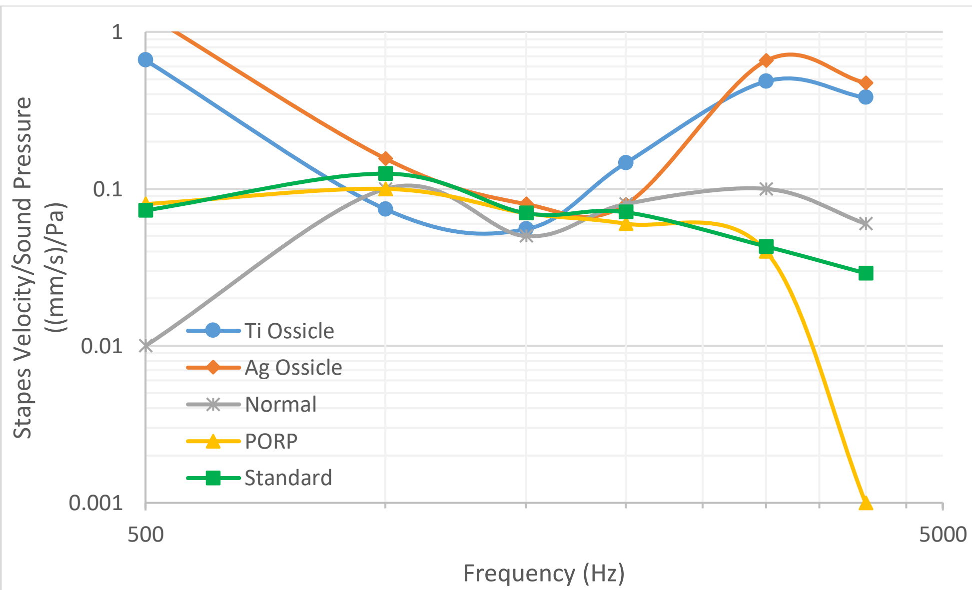

Fig. 8. A comparison of the sound transfer function (v/P) of the titanium and silver additively manufactured to ASTM standard and literature.

4 Conclusion

The stapes velocity of additively manufactured titanium and silver ossicle prostheses was measured by laser doppler vibrometry on a simulated middle-ear setup. Stapes velocity was measured in the 400Hz-4000Hz frequency range. The stapes velocity of the additively manufactured ossicle prostheses increased with increase in frequency from 400 – 3300 Hz, after which it decreased. The sound transfer function of each ossicle prosthesis faired better than the other at different frequencies within the test frequency range. When compared to the ASTM standard and literature studies, the additively manufactured prostheses showed better sound transmission at frequencies below 1000Hz and above 2000Hz. Subsequent test work will involve measuring the sound transfer of these prostheses on human temporal bones.

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