Evaluation of artificial fixation of the incus and malleus with minimally invasive intraoperative laser vibrometry (MIVIB) in a temporal bone model.

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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
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<tr>
<td>A/D-D/A</td>
<td>Analog to digital – digital to analog</td>
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<tr>
<td>FMT</td>
<td>Floating mass transducer</td>
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<td>LP</td>
<td>long process (incus)</td>
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<td>MIVIB</td>
<td>Minimally invasive laser vibrometry</td>
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<tr>
<td>SD</td>
<td>standard deviation</td>
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<td>SPL</td>
<td>sound pressure level</td>
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<td>TB</td>
<td>Temporal bone</td>
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<td>TM</td>
<td>Tympanic membrane</td>
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Abstract

A significant number of adults suffer from conductive hearing loss due to chronic otitis media, otosclerosis or other pathologies. An objective measurement of ossicular mobility is needed to avoid unnecessarily invasive middle ear surgery and to improve hearing outcomes. Laser vibrometry has shown promise in this area but its clinical application is limited. Minimally invasive intraoperative laser vibrometry (MIVIB) provides a method that is compatible with middle ear surgery, where the tympanic membrane is elevated, and has previously been shown to identify stapes fixations. Utilising this method, we assessed both the absolute velocities of the umbo and incus long process as well as the incus-to-umbo velocity ratio during artificial fixation of the incus alone or incus and malleus together. Fixation at these points reduced both umbo and incus velocity as expected. The reduction of absolute velocities was 8dB greater at the umbo and 17dB at the incus long process for incus-malleus fixations when compared to incus fixation alone. Incus fixation alone resulted in no change to the incus-to-umbo velocity ratio where incus-malleus fixations reduced this ratio (-11dB). Through the use of absolute velocities and the incus-to-umbo velocity ratio we are able to distinguish between fixation of the incus and, incus and malleus. When the whole frequency range is analysed, one can also differentiate these two fixations from stapes fixation, where the higher frequencies are less affected. MIVIB provides a promising objective analysis of ossicular mobility that could be useful intraoperatively.

Key words: Hearing loss; Otitis media; objective evaluation; Laser vibrometry; Floating mass transducer
1. Introduction

A significant number of adults suffer from a conductive hearing loss due to reduced mobility of the middle ear ossicles. The hearing loss is due to multiple pathologies such as otosclerosis, tympanosclerosis, malformations and the sequelae of otitis media. In the case of ossicular fixation, hearing aids can partly alleviate the problem but surgical treatment is often the best option to improve a patient’s hearing. The best surgical result is based on knowledge of which ossicles are fixed and the degree that they are fixed. Traditionally, ossicle mobility is assessed by manual palpation. More recently, laser Doppler vibrometry was proposed as an objective alternative to assess mobility of the ossicular chain (Peacock et al., 2013; Peacock et al., 2016; Rosowski et al., 2008; Zahnert et al., 2016).

Intraoperative implementation of laser Doppler vibrometry faces some difficulties. (Rosowski et al., 2008) demonstrated the clinical utility of laser vibrometry of intact tympanic membranes (TMs) with sound driven stimulation. However, during ossicular surgery, the TM is elevated which allows the surgeon access to the middle ear to assess the vibration of each of the ossicles individually providing greater information. The use of a magnet and a large stimulation coil to vibrate the ossicles has been reported (Peacock et al., 2013; Peacock et al., 2016; Zahnert et al., 2016) but this technique is invasive due to the use of glue to attach the magnet to the ossicles. To overcome this problem, we recently reported on the use of the Med-El® floating mass transducer (FMT) to vibrate the ossicles during measurement with a laser vibrometry method, called minimally invasive intraoperative laser vibrometry (MIVIB) (Wales et al., 2017). This method makes use of materials already accredited for medical use while providing valuable intra-operative information on the site and extent of fixation. In the previous study, we were able to accurately identify artificially induced fixation of the stapes footplate by assessing the velocity ratio between the incus and umbo.

It is vital for hearing outcomes that the surgeon is able to identify where a fixation lies in the ossicular chain so as to evaluate whether to perform a stapedotomy, partial ossicular replacement (PORP) or total ossicular placement (TORP), amongst other solutions. Through the identification of fixations in the ossicular chain, the MIVIB method will be able to improve surgical planning and therefore reduce the likelihood of unnecessarily invasive surgery while improving hearing outcomes.

Stapes fixation in otosclerosis can often be identified through a carhart’s notch (Carhart, 1964). However, there a no clear pattern on the audiogram to differentiate between other fixations. For example, malleus or incus fixations can occur regularly in chronic otitis media where the surgeon must decide during the operation if one or both of these bones must be replaced. This article builds upon the method described in (Wales et al., 2017) where we now investigate the use of MIVIB to assess the changes in vibration of the ossicles in response to fixation of the incus and malleus that may prevail in ears with chronic middle ear disease. This is then compared to our previous work on stapes fixation.
2. Material and Methods

Ten fresh-frozen human temporal bones (TBs) were allowed to defrost at room temperature. TBs were examined with an otology microscope where gross pathology in either the external canal, tympanic membrane or middle ear were ruled out. Other pathology visually identifiable after tympanoplasty or drilling during the experiment is also discussed.

The measurement set-up previously reported in (Peacock et al., 2016) consisted of a laser Doppler vibrometer (Polytec model OFV-534) coupled to a surgical microscope (OPMI Sensera/ S7, Carl Zeiss, Jena, Germany). Small pieces of reflective tape or aluminium foil from suture packaging were cut and attached to the measurement points to improve the strength of the reflected vibrometer signal. The protocol has been extensively described in (Wales et al., 2017) in which stapes fixations were investigated and a summary is reported here with changes as specified.

A small acoustic chamber (10ml volume) was placed over the ear canal opening and was acoustically sealed to the temporal bone using silicone paste (Dreve Otoplastik GmbH, Otoform AK, Unna, Germany). An anti-reflection coated window at one side allowed access by the laser beam. The sound pressure at the level of the TM was measured using a probe microphone (Bruel & Kjaer, type 4182, Nærum, Denmark), connected to a 25 mm long flexible tube which was put through a tightly fitting hole in the acoustic chamber. Sound pressure in the cavity was generated using a horn driver speaker (TOA, TU-650, Surrey, United Kingdom), which was connected to the cavity via a tube of 300 mm length. The signal was designed in a computer using MATLAB where pure sine wave excitation was used as described in our previous work (Wales et al., 2017). The range of 0.25–4 kHz was chosen because previous measurements had shown maximal sensitivity of the instrument in this region. With the TM intact, a reflective patch was placed at the umbo and the vibration response was measured in response to acoustic stimulation at 90dB SPL.

The TB was then rotated 90 degrees superiorly with a custom-built clamp to expose the middle fossa for a straight angle access to the tegmen tympani. An otologic drill (W&H Dentalwerk, Bürmoos, Austria) was used to open the tegmen tympani sufficiently to expose the incudo-malleolar joint and surrounding structures. The temporal bone was then rotated back 90 degrees so as to have exactly the same angle of the TB to the laser beam as with previous measurements. After elevating the TM, reflective patches were placed on the umbo, the lateral surface of the distal (inferior) end of the incus long process (LP) and on the bony ear canal (as a negative control). As previously (Wales et al., 2017), an FMT with a suitable audio connector (Med-El, Innsbruck, Austria) was clipped onto the manubrium of the malleus using a left Incus-LP coupler that was manipulated so that the transducer was positioned in such a way that the longitudinal axis of the transducer body was parallel to the piston axis of the stapes. Therefore, the transducer’s main component of motion was aligned with the direction of the piston-motion of the stapes. The signal to the transducer was again generated in MATLAB and amplitudes were adjusted until it produced an umbo velocity equivalent in level to the velocity produced by a 90 dB SPL acoustic stimulus in the intact ear (within 2dB), as shown in supplementary figures 1 and 2. Measurements were then made at the three locations discussed above.

The procedure of making the acoustic stimulated measurement and achieving the equivalent umbo velocity using the FMT takes less than 4 minutes. Subsequent measurements take less than 8 seconds which is important for clinical applications.
Subsequently, the mobility of the ossicles was reduced by applying a few drops of glass ionomer luting cement (GC, Tokyo, Japan) through the opening created in the tegmen tympani. In three TBs the incus and malleus were both fixed in one step before measurement. In the 6 remaining TBs the incus was fixed independently before measurement and subsequently the malleus was fixed in a second step before measurement of both fixations. The TBs were moistened before each measurement. Both types of fixation are illustrated in figure 1. Due to technical reasons, the cement was not removed as could be done in our previous studies.

3. Results

The ten temporal bones were examined for abnormalities after defrosting at room temperature. One TB had a small exostosis but this did not obscure the TM. Another TB was seen to have a shallow and narrow attic above the head of the malleus and the body of the incus. There were some connective tissue adherences but no bony fixation between the ossicles and the tegmen bone. Both of these TBs were included in the study. One bone was excluded from the study as it was seen to have a TM which was severely retracted against the malleus, incus LP, crura of the stapes and promontory. Therefore 9 TBs were included in this study. Figure 2 shows the mean umbo velocity of the intact temporal bones compared to other temporal bone measurements (Nakajima et al., 2005) and clinical measurements (Rosowski et al., 2012).

The FMT was able to match, within 2dB, the umbo velocity produced by 90dB SPL except for some frequencies in TB 2 and 6 (supplementary figure 2). Data points at these frequencies of these TBs were therefore excluded from the study. A section of the annulus of the TM of TB7 was accidentally lifted before performing the acoustic measurement. Therefore, the FMT input voltage was adjusted to match the umbo response of TB6 as this TB was of similar anatomy. The FMT input voltages are provided in supplementary figure 1. As a negative control, vibration of the external bony ear canal was assessed during stimulus by the FMT (supplementary figure 3). This “noise” level was below the absolute velocities of the umbo and incus. Supplementary figure 4 shows the absolute velocities of the umbo (a) and incus (b) when unfixed. The velocity of the incus was smaller than the velocity of the umbo, and the characteristics were similar to samples in previous work (Wales et al., 2017).

Small pieces of reflective tape were used to improve the strength of the reflected laser vibrometer signal. In some bones, aluminium foil was used instead. This performed in a similar manner to the reflective tape used previously (Wales et al., 2017) and in this study.

3.1 Change in umbo velocity amplitude

Figure 3A shows the mean change in umbo velocity amplitude for a fixation of the incus alone (incus) or both the incus and malleus together (incus-malleus) and their standard deviations (SDs). In general, a reduction in the absolute velocity of the umbo was seen after fixation. The largest reduction was observed for frequencies below 0.5 kHz.

The incus fixation caused a mean change in umbo velocity amplitude which was on average -14.51dB below 0.5 kHz, -9.4dB between 0.5-1.5 kHz and -3.3dB above 1.5 kHz.

The incus-malleus fixation showed higher reductions, on average -22.2dB below 0.5 kHz, -15dB between 0.5-3 kHz, and -11dB above 3 kHz.
On average, the reduction in umbo velocity of an incus-malleus fixation was 8dB greater than for an incus fixation. This difference is most noticeable at the lower (<0.5 kHz) and higher frequencies (>1.5 kHz).

3.2 Change in incus velocity amplitude

Figure 1B shows the mean change in incus velocity amplitude for an incus and incus-malleus fixation and their SDs. Again, a reduction in incus velocity was seen for both types of fixation.

After incus fixation, this decrease was on average -16.0dB below 0.5 kHz, -12.5dB between 0.5-1.5 kHz and -6.2dB above 1.5 kHz.

The mean change in incus velocity after malleus-incus fixation was fairly constant and was around -30dB, except between 0.7-1 kHz for which it was around -25dB and above 3 kHz for which the values ranged from -30dB to -19dB.

On average, the reduction in incus velocity of an incus-malleus fixation was 17dB greater than for an incus fixation. This difference was smallest between 0.8-1.2 kHz and, as with umbo velocity, affected the lower and higher frequencies the most.

3.3 Change in incus-umbo velocity amplitude ratio

Figure 1C shows the mean change in incus-umbo velocity amplitude ratio for an incus and incus-malleus fixation and their SDs.

After incus fixation, the average change in incus-umbo velocity ratio was fairly constant across all frequencies. This change ranged from -5.6dB to 0.4dB with a mean value of -2.6dB.

The mean change in incus-umbo velocity ratio after a malleus-incus fixation ranged from -16dB to -3.4dB with a mean value of -11dB. The reduction was seen to be smallest below 0.5 kHz.

On average, the reduction in incus-umbo velocity ratio of an incus-malleus fixation was 9dB greater than for an incus fixation. This difference was smallest below 0.5 kHz.
4. Discussion

The mean umbo velocity was compared to other temporal bone measurements (Nakajima et al., 2005) and clinical measurements (Rosowski et al., 2012) (fig. 2). Our data is in good agreement with the referenced data. Our data did not differ more than 3.5dB from clinical measurements (Rosowski et al., 2012), confirming that the TBs were normal. The largest deviations were seen around the resonance frequency of 1 kHz.

As previously reported by us (Merchant et al., 2016; Nakajima et al., 2005; Peacock et al., 2016), this work confirms that a fixation in the attic can be simulated by utilizing cement to fix the malleus or incus to the tegmen. MIVIB was able to show that this fixation led to a significant reduction in the absolute velocities of both the umbo and incus.

For an incus fixation, the reduction of incus velocity was similar to that of the umbo velocity. This was reflected by the change in incus-umbo velocity ratio which was close to 0dB. An incus-malleus fixation resulted in a larger reduction of incus and umbo velocity, but the amount of incus velocity reduction was greater. For an incus-malleus fixation the change in incus-umbo velocity ratio was therefore larger (-11dB).

Once we placed cement in the attic, the incus was fixated on the lateral and superior surfaces of its corpus incudis, as compared to the malleus which was only fixated at the attic. This can explain why the incus was more affected than the umbo once the malleus was fixated. Another explanation can be that if the malleus head is fixed extensively, the transmission to the incus is reduced drastically, but the umbo velocity is reduced less since the manubrium can still bend (Nakajima et al., 2005). The change in incus-umbo velocity ratio therefore allows to distinguish between an incus and incus-malleus fixation.

In our previous work, stapes fixations were investigated using the same protocols as described in this work (Wales et al., 2017). Fixation of the stapes resulted in a reduction of the absolute velocities of both the incus and umbo and the incus-umbo velocity ratio (Wales et al., 2017). The change in incus-umbo velocity ratio allows again for distinguishing an incus fixation from a stapes fixation (figure 4C). In contrast, it is impossible to distinguish an incus-malleus fixation from a stapes fixation using only the change in incus-umbo velocity ratio.

However, if one compares the velocity of the incus and umbo over the entire frequency range (Figure 4A & 4B) malleus-incus fixations led to a large reduction in these absolute velocities over all frequencies. Stapes fixations, however, led to a smaller reduction in those absolute velocities where the higher frequencies (>2kHz) were less affected, similar to the effect of experimental and clinical stapes fixations measured by (Nakajima et al., 2005) and (Nakajima et al., 2012) respectively. In our previous study (Peacock et al., 2016), and others (Dai et al., 2007), fixation of the anterior ligament of the malleus showed a resulting reduction in umbo and incus velocities that were less significant in the higher frequencies. This shows that although both fixations occur in the attic, a fixation of the anterior mallear ligament and a bone-to-bone fixation, as in our study, can elicit different patterns with laser vibrometry. A thorough assessment of several types of fixations in several temporal bone studies would enable us to deduce a more consistent pattern.

An experimental study (Nakajima et al., 2005) assessed the umbo and stapes velocity for several types of fixations. The stapes velocity was correlated with the air-bone gap. If the stapes and umbo velocity were sufficient to differentiate between fixation types, then this differentiation could be done non-invasively by measuring the air-bone gap and the umbo
velocity through the ear canal. The study showed that stapes fixations can clearly be

distinguished from malleus fixations. In the same study on two temporal bone specimens,
incus fixations were differentiated from stapes fixations through the greater loss in umbo
velocity with incus fixations. This pattern at the umbo was not observed in our study.
However, we found that there was an average difference of 9.79 dB change in incus velocity
between stapes and incus fixations.

Distinguishing between malleus, malleus-incus or malleus-stapes fixations is impossible using
only stapes and umbo velocity data (Nakajima et al., 2005). Future experiments may show
whether incus velocity measurements can aid to resolve this problem. Overall, it is clear that
it is important to compare both absolute velocities (Nakajima et al., 2005; Rosowski et al.,
2008) and the incus-umbo velocity ratio (Dobrev et al., 2016; Wales et al., 2017) over the
whole frequency range to distinguish between different fixations.

The input voltages required for the FMT to generate an umbo velocity that is equivalent to
90dB SPL acoustic stimulation is generally shown to be a smooth curve which requires a
higher input in the lower (<1kHz) and higher (>2kHz) frequencies while requiring less input
in the middle frequencies (Supplementary figure 1). This is in accordance with the ossicular
resonance frequency of human middle ear (Hommia et al., 2009). TB3 did not produce a
smooth curve. We suspect this was due to the fact that the same Incus-LP coupler had been
used for the previous two bones and therefore had become worn-out. This reflects that in a
clinical application one cannot use the same coupler between patients, even with sterilization,
as the coupler will become worn-out and results will likely be difficult to interpret. This
would especially be a problem if absolute velocities are used for analysis rather than relative
velocities. A recent systematic review of Vibrant Soundbridge® use (Bruchhage et al., 2017)
reported device failure as 2.6%, of which 18.4% was due to coupling failure or dislocation
post-operatively. Therefore, although rare, single use of the coupler between patients would
be recommended when utilizing the MIVIB system.

A drawback of the surgical technique used in this study was that the middle fossa approach
utilized may have resulted in the detachment of adherences or mucosal folds from the malleus
head or incus short process. Although the function of these structures has not been determined
in-depth, this could theoretically result in a change in the resonance pattern of the ossicles.
However, Dai et al. have reported that superior mallear ligament detachment does not affect
TM or stapes footplate mobility (Dai et al., 2007).

4.1 Clinical applicability

Clinically, the MIVIB system would be useful to assess where a fixation is located, a quality
control in ossiculoplasty (Zahnert et al., 2016) or to assess new prosthesis systems (Gottlieb et
al., 2016). A combination of the absolute velocity of the incus and umbo, and the incus-umbo
velocity ratio, could be used to discriminate between stapes, incus and incus-malleus
fixations. Where, the inclusion of stapes velocity could be useful to differentiate between
other fixation combinations (Nakajima 2005). However, one should be careful to use strict
quality control so as not to use a “tired” coupler.

5. Conclusions

The use of the MIVIB system can discriminate between a variety of fixations in the middle
ear. We believe the use of this system would improve surgical planning to reduce the risk of
doing an unnecessarily extensive operation in the middle ear and therefore improve surgical outcomes.
Acknowledgements

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References


Figure captions

Figure 1: Illustration of both fixations types in this study. Incus fixation (a) and incus-malleus fixation (b).

Figure 2: Comparison of the mean umbo velocity of the intact temporal bones in this study to clinical measurements (Rosowski 2011).

Figure 3: Change in umbo velocity (a), change in incus velocity (b) and change in incus-umbo velocity ratio (c) in temporal bones where the incus or both the incus and malleus were fixated. Standard deviations are indicated as transparent bands.

Figure 4: Mean change in umbo velocity (a), mean change in incus velocity (b), and mean change in the incus-umbo velocity ratio (c) when the ossicular chain was fixated at the incus, malleus-incus or stapes (Wales et al., 2017).

Supplementary Figure 1: FMT input voltage as a function of frequency required to generate an umbo velocity within 2dB of that of 90dB SPL.

Supplementary figure 2: Umbo velocity amplitude seen with 90 dB SPL sound stimulation in comparison to the amplitude seen with velocity produced by the FMT.

Supplementary figure 3: Noise floor in comparison to the umbo and incus velocity response of TB 1.

Supplementary figure 4: Umbo (a) and incus velocity (b) in the unfixed temporal bones during stimulus by the FMT.