This item is the archived peer-reviewed author-version of:

Minimally invasive laser vibrometry (MIVIB) with a floating mass transducer : a new method for objective evaluation of the middle ear demonstrated on stapes fixation

Reference:

Wales Jeremy, Gladiné Kilian, Van de Heyning Paul, Topsakal Vedat, von Unge Magnus, Dirckx Joris.- Minimally invasive laser vibrometry (MIVIB) with a floating mass transducer : a new method for objective evaluation of the middle ear demonstrated on stapes fixation
Hearing research - ISSN 0378-5955 - 357(2018), p. 46-53
Full text (Publisher's DOI): <https://doi.org/10.1016/J.HEARES.2017.11.007>
To cite this reference: <https://hdl.handle.net/10067/1472350151162165141>

Minimally invasive laser vibrometry (MIVIB) with a floating mass transducer – a new method for objective evaluation of the middle ear demonstrated on stapes fixation.

Jeremy Wales^{1,a}, Kilian Gladiné^{1,b}, Paul Van de Heyning^c, Vedat Topsakal^c, Magnus von Unge^d and Joris Dirckx^b.

¹ The first two authors contributed equally to this work.

^a Department of Otorhinolaryngology, Karolinska University Hospital, Stockholm, Sweden.

^b Laboratory of Biomedical Physics, University of Antwerp, Antwerp, Belgium.

^c Department of Otorhinolaryngology and Head & Neck Surgery, Antwerp University Hospital, University of Antwerp, Belgium

^d Department of Otorhinolaryngology, Akershus University Hospital and University of Oslo, Oslo, Norway.

Corresponding author:

Dr Jeremy Wales MD, PhD

Department of Otorhinolaryngology

Karolinska University Hospital

Huddinge

18146 Stockholm

Sweden

Tel: +46 (0)8 58580000

E-Mail: jeremy.wales@sll.se

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Author contributions: JW, KG, PH, MU and JD were involved in experimental design. JW, KG, VT, MU and JD performed the studies. KG and JD performed data analysis. All authors were involved in interpretation of results and in writing the manuscript and approve the final submission.

Full address of all authors

- Dr Jeremy Wales MD, PhD
Department of Otorhinolaryngology
Karolinska University Hospital
Huddinge
18146 Stockholm
Sweden
Tel: +46 (0)8 58580000
E-Mail: jeremy.wales@sll.se
- Kilian Gladiné
E-mail: kilian.gladine@uantwerpen.be
- Professor Paul Van de Heyning
Email: paul.vandeheyning@uantwerpen.be
- Professor Vedat Topsakal
Email: vedat.topsakal@uza.be
- Professor Magnus von Unge
Email: magnus.von.unge@medisin.uio.no
- Professor Joris Dirckx
Email: joris.dirckx@uantwerpen.be

Abstract

Ossicular fixation through otosclerosis, chronic otitis media and other pathologies, especially tympanosclerosis, are treated by surgery if hearing aids fail as an alternative. However, the best hearing outcome is often based on knowledge of the degree and location of the fixation. Objective methods to quantify the degree and position of the fixation are largely lacking. Laser vibrometry is a known method to detect ossicular fixation but clinical applicability remains limited. A new method, minimally invasive laser vibrometry (MIVIB), is presented to quantify ossicle mobility using laser vibrometry measurement through the ear canal after elevating the tympanic membrane, thus making the method feasible in minimally invasive explorative surgery. A floating mass transducer provides a clinically relevant transducer to drive ossicular vibration. This device was attached to the manubrium and drove vibrations at the same angle as the longitudinal axis of the stapes and was therefore used to assess ossicular chain mobility in a fresh-frozen temporal bone model with and without stapes fixation. The ratio between the umbo and incus long process was shown to be useful in assessing stapes fixation. The incus-to-umbo velocity ratio decreased by 15 dB when comparing the unfixed situation to stapes fixation up to 2.5 kHz. Such quantification of ossicular fixation using the incus-to-umbo velocity ratio would allow quick and objective analysis of ossicular chain fixations which will assist the surgeon in surgical planning and optimize hearing outcomes.

Key words: Hearing loss; Otitis media; Otosclerosis; Laser vibrometry; Floating mass transducer

Abbreviations

A/D-D/A	Analog to digital – digital to analog
FMT	Floating mass transducer
LP	Long process (malleus)
MIVIB	Minimally invasive laser vibrometry
SPL	Sound pressure level
TB	Temporal bone
TM	Tympanic membrane

1. Introduction

It has been reported that 17% of the total population in the USA suffers from some form of hearing loss. This is increased to 1/3 in those aged over 65 (Agrawal et al., 2008). The majority of these are related to sensorineural hearing loss (reduced function of the inner ear) but a significant number of these adults suffer from a conductive hearing loss (reduced function of the ear canal or middle ear). Immobility of the middle ear ossicles is one form of conductive hearing loss.

Immobility of the middle ear ossicular chain can occur due to multiple pathologies such as otosclerosis, tympanosclerosis, malformations and the sequelae of otitis media. Objective otosclerosis, with or without symptoms, has been reported in as many as 2.1% of the adult population (Browning and Gatehouse, 1992), although others report this figure to be much lower (Declau et al., 2007; Hannula et al., 2012). In the case of ossicular fixation, surgical treatment is often the best option to improve a patient's hearing if this is not successful with a hearing aid. The best surgical result is however based on knowledge of which ossicles are fixed and the degree that they are fixed. Despite a range of pre-operative audiological tests available to the surgeon, the assessment of fixation is often performed by manual palpation during the surgical procedure despite several promising objective measures (Huber et al., 2001; Koike et al., 2006; Rosowski et al., 2008).

Laser Doppler Vibrometry has shown promise to accurately measure the vibrational response of the ossicles. During ossicular surgery, the tympanic membrane (TM) must be elevated which renders sound-driven vibrometry impossible. To overcome this problem our group has previously published work where the vibrational response of the umbo, the long process of the incus and posterior crux of the stapes was measured with laser vibrometry after elevation of the tympanic membrane (Peacock et al., 2014, 2015, 2016). In this method, a small super magnet was attached to the manubrium and an electromagnetic excitation coil was used to vibrate the ossicles. However, the clinical applications of this method were limited as attaching the super magnet with luting cement could be considered too invasive and time consuming and the positioning of the driving magnetic coil difficult (Zahnert et al., 2016).

A clinically relevant alternative could be the use of the Med-El ® floating mass transducer with a suitable audio connector to vibrate the ossicles during measurement with laser vibrometry (minimally invasive laser vibrometry, MIVIB). This alternative is less invasive and less time consuming for the surgeon while providing valuable intra-operative information on the site and extent of fixation. This in turn would help surgical planning and therefore optimize surgical outcomes. It could also provide information on the outcome the surgeon might expect from an ossicular reconstruction and the immediate perioperative feedback may give the surgeon a chance to revise the reconstruction to the patients benefit (Zahnert et al., 2016). We therefore investigated the use of the floating mass transducer to drive ossicular vibration and assessed the changes in response to fixation of the stapes as seen in otosclerosis.

2. Material and Methods

Five fresh-frozen human temporal bones (TBs) were allowed to defrost at room temperature before the measurements and were examined for signs of abnormality such as external acoustic canal malformation or tympanic membrane abnormalities.

The measurement set up consisted of a laser Doppler vibrometer (Polytec model OFV-534) coupled to a surgical microscope (OPMI Sensera/S7, Carl Zeiss, Jena, Germany). A joystick controlled mirror was used to position the laser beam (spot size 200µm at a distance of 30 cm) as previously described (Peacock et al., 2013). To improve the strength of the reflected vibrometer signal, small pieces of reflective tape were cut and attached to the measurement points. The mass of the patches is less than 0.04 mg and are about 0.4 mm0.4 mm in size (Niklasson et al., 2016).

A free field speaker positioned at 30 cm away from the temporal bone was used to generate the acoustic stimulus during measurements with an intact TM. Sound pressure was measured using a probe microphone (Brüel&Kjær probe microphone, type 4182, Nærum, Denmark) with its probe needle positioned immediately above the entrance of the ear canal. The signal was designed in a computer using MATLAB and generated using an A/D-D/A conversion board with 16-bit resolution and a sampling rate of 50 kHz (National Instruments, USB-6251 BNC, Austin, TX, USA). For the excitation, pure sine waves were used with frequencies ranging from 0.5 kHz to 4 kHz and a sound pressure level of 90 dB SPL. At each frequency, the stimulation signal contained 50 periods of that frequency and was extended by 0.1s in order to exclude any transient effect. The first 0.1s was not used in the analysis, and the 50 periods within the remaining stimulation window were used to calculate the amplitude in the Fourier domain at the frequency line of the stimulation frequency. Measurements were taken at 16 lines per octave. The range of 0.5e4 kHz was chosen because previous measurements showed maximal sensitivity of the instrument in this region. The laser Doppler vibrometer has a very broad frequency range, up to 350 kHz, and the microphone has a nearly flat frequency response up to 20 kHz and the speaker can generate 90 dB SPL up until frequencies of about 10 kHz. The limitation of the usable frequency band was therefore mainly given by the FMT, which was not always able to generate the motion equivalent to that of a 90 dB acoustic input at frequencies above 4 kHz.

The measurement angle of the laser vibrometer beam was restricted by the practical circumstances of measuring through the ear canal. In general, this meant that the incidence of the beam was somewhat perpendicular to the plane of the stapes footplate, as demonstrated in Fig. 2 of (Peacock et al., 2013) showing the incidence of the laser beam in a 3D X-ray scan model of the temporal bone. The exact angle can however not be well defined. No cosine correction was applied to the measured vibration amplitudes.

With the TM intact, a reflective patch was placed at the umbo and the vibration response was measured in response to acoustic stimulation from the free field speaker. Next, after elevating the TM, reflecting patches were placed on the umbo and the lateral surface of the distal (inferior) end of the incus long process. A floating mass transducer (FMT) with a suitable audio connector and the fixed clip removed (Med-El, Innsbruck, Austria) was clipped on the manubrium of the malleus using a left Incus-LP coupler that was manipulated so that the incus clip was orientated perpendicular to the FMT. The transducer was positioned in such a way that the longitudinal axis of the transduced body was parallel to the axis of the stapes, so that the transducer's main component of motion was aligned with the direction of the piston-motion of the stapes. Reflective tape and FMT are shown in Fig. 1.

The FMT was directly driven by a custom made low-distortion amplifier. The signal to the FMT was again generated in MATLAB. The driving signal to the FMT was adjusted until it produced an umbo velocity equivalent in level to the velocity produced by a 90 dB SPL stimulus in the intact ear (within 2 dB). Measurements were then made at three locations: the umbo, the tip of the incus long process, and on the temporal bone wall (as a negative control).

Subsequently, the mobility of the stapes was reduced by applying a few drops of glass ionomer luting cement (GC, Tokyo, Japan) around the footplate. The cement was applied

using a syringe connected to an ear suction tube. Partial footplate fixation was achieved by placing one drop of the ionomer cement on the posterior stapes footplate. Full stapes fixation was achieved by placing ionomer cement around the whole of the stapes footplate. This was removed by lifting the cement with a small hook. Fig. 1 shows one specimen before and after application of the cement. After artificial fixation, measurements were again made at all three measurement points.

The FMT was rated for a maximal input voltage of 300 mV. To make sure to not damage the device, the input was limited to 200 mV. The signal coming from a D/A converter was sent to a custom-made current amplifier to drive the FMT. Fig. 2 shows the FMT input voltages as function of frequency.

Fig. 1. Photographs of TB4 obtained through the operating microscope. 1A, placement of the floating mass transducer and reflective tape (arrows). 1B, fixation of the stapes with ionomer luting cement seen as white material (arrow).

Fig. 2. FMT input voltage as a function of frequency when the umbo velocity amplitude response, using FMT stimulation, is matched with the umbo velocity amplitude response using sound stimulation at 90 dB SPL.

3. Results

Four of the five TBs were considered normal. In one TB, a large exostosis was observed which obscured the stapes and was therefore excluded from the study. The FMT was able to match (within 2 dB) the umbo velocity produced by a 90 dB SPL stimulus with the exception of sample 4 for three frequencies between 2.7 and 3.3 kHz (Fig. 3). Data acquired at these frequencies for this sample were therefore excluded from the study.

Fig. 3. The ratio of the sound driven umbo velocity response to the FMT driven umbo velocity response.

To define the noise floor of the vibrometry measurements, we directed the beam at a reflective target positioned on the temporal bone wall. A typical result is shown in Fig. 4. The noise floor is well below all measured responses of the incus during different states of fixation, except for some frequencies when the stapes was fully fixed.

Fig. 4. LDV noise floor as a function of frequency in comparison with the incus velocity amplitude for different states of fixation (sample 1).

3.1 Change in umbo velocity amplitude

Fig. 5(a – d) shows the change in umbo velocity amplitude of each sample in different fixation states. After partial stapes fixation, the umbo velocity amplitude decreased mainly below 1.6 kHz for sample 1 and 3 with a change ranging from -10 dB to 0 dB. The umbo

velocity of sample 2 was only slightly affected by the partial fixation. In some higher frequency regions, an increase was seen. This occurred between 1.6 and 2.4 kHz for sample 1 and 2-2.3, 2.5-4 kHz for sample 3. Sample 2 showed a spike at 3.2 kHz, the same frequency for which the FMT input voltage was maximal for this sample. The spike was visible for all fixation states.

After full stapes fixation, the umbo velocity amplitude decreased further for samples 1 and 3. Sample 1 showed net changes ranging from -20 dB around 0.8 kHz to approximately 0 dB around 2 kHz and above 3.4 kHz. The same holds for sample 3, but the decrease was limited to frequencies below 2 kHz. At higher frequencies, small changes occurred but the net change was still positive. Sample 2 was again only slightly affected, showing a small decrease between 1.3 and 1.9 kHz and an increase between 1.9 and 3 kHz. Sample 4 showed a net change of -10 dB mainly for frequencies below 2 kHz.

After attempts to remove the fixation, the umbo velocity increased for all samples. Below 1.7 kHz, sample 1 reached a net change of 0 dB at some frequencies, while at others it was close to the results seen during partial fixation. For frequencies above 1.7 kHz, the net change was lower than for the state of partial fixation, and for frequencies above 2.8 kHz the umbo velocity had reduced even further. The umbo velocity of sample 2 showed a small increase at most frequencies and a further decrease above 3.3 kHz. Sample 3 showed an increase for up to 2.2 kHz, surpassing the state of partial fixation but not reaching a net change of 0 dB. A decrease in umbo velocity was present above 2.2 kHz, bringing the net change closer to 0 dB. Sample 4 mainly showed local increases. A positive spike was seen at around 2 kHz.

On average, partial fixation caused a change of about -5 dB up to 1.7 kHz (Fig. 6). A net change up to -10 dB occurred after full fixation. After fixation removal, an increase in umbo velocity occurred, bringing the net change close to 0 dB at some frequencies or at the level of partial fixation at all other frequencies.

Fig. 5. The change in umbo velocity amplitude in different states of fixation for samples 1 – 4, presented as graphs A-D respectively.

Fig. 6. The mean change in umbo velocity amplitude in different fixation states of samples 1 – 4 as described individually in Fig. 5

3.2 Change in incus velocity amplitude

Fig. 7(a – d) shows the change in incus velocity amplitude of each sample in different fixation states. After partial fixation, samples 1e3 all showed a decrease in incus velocity up to about 3.1 kHz. In that region, the minimal change occurred at around 2 kHz. The net change was as large as -15 dB. Sample 2 showed a smaller decrease overall.

After full fixation, the incus velocity of samples 1-3 decreased for almost all frequencies. Sample 1 and 3 showed net changes around -25 dB up to 1.7 kHz. Sample 1 showed a plateau of -20 dB from 1.7 to 2.7 kHz after which the net change went up to -2 dB. From 1.6 kHz, the net change of sample 3 went from -20 dB to -7 dB at 2 kHz. Sample 2 and 4 showed net changes of -17 and -22 dB respectively.

After attempts to remove the luting cement, incus velocity increased again for all frequencies for sample 1 – 3. Sample 1 reached a net change between -5 dB and 0 dB at most frequencies and was above the partial fixation state for all frequencies except those above 2.5 kHz. Sample 2 reached the level of the partial fixation state for most frequencies. Sample 3 was above the level of the partial fixation state but still showed a net change of -5 dB up to 1.9 kHz. Sample 4 mainly showed increases in the incus velocity but again local variations and a spike at around 2 kHz were seen.

On average, partial fixation caused a change of -10 dB up to 2.5 kHz with a local minimal difference seen at 2 kHz. After full fixation, the change reached values of -25 dB up to 1.6 kHz. At higher frequencies, the incus velocity change was closer to -15 dB. After fixation removal, an increase in incus velocity occurred, bringing the net change close to 0 dB or at the level of partial fixation (Fig. 8).

A

B

C

D

Fig. 7. The change in incus velocity amplitude in different states of fixation for samples 1 – 4, presented as graphs A-D respectively.

Fig. 8. The mean change in incus velocity amplitude in different fixation states of samples 1 – 4 as described individually in Fig. 7

3.3 Change in incus-to-umbo velocity ratio

Fig. 9(a – d) shows the change in incus-to-umbo velocity ratio of each sample in different fixation states. After partial fixation, a decrease in incus-to-umbo ratio up to 3.3 kHz was present for sample 1. Sample 2 and 3 showed a decrease for all frequencies. The net change was -6 dB, -4 dB and -4 dB for samples 1 – 3 respectively.

After full fixation, the incus-to-umbo velocity ratio was further decreased for all samples and all frequencies. The net change varied from -10 dB to -15 dB for most frequencies.

After attempts to remove the fixation, the incus-to-umbo ratio was almost restored for samples 1 and 3, showing a net change around 0 dB for most frequencies. For sample 2 the net change showed a movement towards 0 dB but for many frequencies it was still below the level of the partially fixed state. Similarly, for sample 4 mainly a movement towards 0 dB was seen but the net change was still around -5 to -10 dB.

On average, a partial fixation caused a net change in the incus-to-umbo ratio of -5 dB up to 3 kHz. A full fixation resulted in a net change of -15 dB. The removal of the fixation resulted in a movement towards zero but was nearer the level of the state of partial fixation.

A

B

C

D

Fig. 9. The change in the incus-umbo velocity ratio in different states of fixation for samples 1 – 4, presented as graphs A-D respectively.

Fig. 10. The mean change in the incus-umbo velocity ratio in different fixation states of samples 1e4 as described individually in Fig. 9

4. Discussion

From Fig. 2 we see that the FMT driving voltage differs between each ear, especially in the low frequency region where the differences could be large. For instance, the driving voltage in the region between 0.5 kHz and 0.8 kHz differed with a factor of 10 between sample 2 and 3. For sample 4, in the frequency region between 2.7 kHz and 3.3 kHz, the maximal driving voltage of 200 mV was insufficient to obtain the same umbo response as with acoustic stimulation. The differences between the needed stimulation voltages are partly due to the differences in umbo response for the different specimens, but can also be partly due to the inevitable differences in exact placement of the FMT on the manubrium. For this reason, we feel it is preferable to use ratios between umbo and incus velocity rather than using incus response normalized for FMT input voltage directly.

As measurements were taken through the ear canal, little liberty was available in choosing the incidence angle of the laser vibrometer. As the orientation of the ossicles with respect to the ear canal is largely constant over different subjects, the measurement angle will also be largely the same, but it cannot be controlled or measured exactly. For this reason, we did not apply a cosine correction to the measured data. As the ossicles are very close together,

moving from one ossicle to the other would change the beam angle by less than a few degrees and not affect the results in a significant manner. Although the motions of the ossicles become more complicated in the higher frequency region, the main motion component remains in one direction (Hato et al., 2003) and the effect of the measurement angle is constant. The inevitable variability in laser vibrometer measurement angle will therefore have a limited effect on the measured response ratios.

The data from sample 2 shows that the umbo velocity amplitude is not always affected after partial/full fixation. For the other samples, the effect of fixation was less for the umbo velocity than for incus velocity. The net change in umbo velocity was only negative up to about 2 kHz. This indicates that using only umbo velocity measurements to determine stapes fixation is unreliable.

The dB change in incus velocity was clearer than the dB change in umbo velocity. On average, the net dB change in incus velocity was below zero for frequencies below 3 kHz in the case of partial fixation. For all samples with full fixation, the dB change in incus velocity was well below zero and easy to perceive over the entire frequency range.

The incus-to-umbo ratio changes after fixation were more constant across the entire frequency spectrum compared to the individual incus and umbo velocity changes. The net dB change for partial fixation was on average negative up to 3.5 kHz. For all samples with full fixation, the dB change in incus-to-umbo velocity ratio was well below zero and easy to perceive over the entire frequency range.

Removal of the cement increased incus and umbo velocity amplitudes and their ratio for most frequencies. For two samples (2 and 4), the removal was less successful as there was some residual cement left in the TB. The umbo velocity data of sample 2 does not show this, as the umbo velocity was not affected by the fixation in the first place. However, the changes in incus velocity and incus-to-umbo velocity ratio do reflect this unsuccessful removal of cement. Although samples 1 and 3 showed good restoration based on their incus-to-umbo ratios, incus and umbo velocity amplitudes were on average about 3 dB lower compared to those of the unfixed TBs with peak differences of about -9 dB.

A firm attachment of the FMT to the manubrium is important. When the FMT is not firmly clamped, it requires a higher input voltage at certain high frequencies to mimic the acoustically induced vibrations obtained at 90 dB SPL with an intact membrane. This could explain the results in sample 4 for which there was not sufficient power in the frequency range of 2.7-3.3 kHz.

Sample 2 shows a spike in input voltage around 3.2 kHz. At the same frequency, a spike appears in the change in umbo velocity. A possible explanation is that the sub-optimally attached FMT required more power, but that this need was reduced if small changes in the FMT position occurred when placing the luting cement. As a consequence, more power was given to the FMT than actually needed to reproduce the umbo velocity levels with sound stimulation of 90 dB in the unfixed state.

Recently it has been reported that the measurement of stapes vibrations intra-operatively can give real-time feed-back to the surgeon for the placement of a prosthesis (Zahnert et al., 2016). In that paper a variant of the magnet stimulation method was used which was originally presented by Peacock et al. (2014). In the 2014 paper, magnetic stimulation was used to investigate vibration of the umbo and incus. Zahnert et al. measured the stapes response to test prosthesis placement, so the incus could not be used as a measurement point. Our new stimulation method could be used in the same way to quantify ossicle fixation, though we did find it easier to measure the incus as this ossicle is easier to target. The incus-to-umbo velocity ratio can also be more sensitive and reproducible for initial analysis of the ossicular chain and the location of fixations, but more data obtained in the clinical setting will be needed to determine the best analysis method. It is certainly possible that other fixations of

the ossicular chain, such as fixation of the incus, may produce a similar incus-to-umbo ratio, however our previous data does not follow this pattern (Peacock et al., 2016). It is possible that absolute velocities of individual bones may also be useful to differentiate fixations (Nakajima et al., 2005; Rosowski et al., 2008).

As a surgeon does not have access to the velocity amplitudes of the ossicles of the patient without stapes fixation, a baseline level is needed. In this work, mean incus-to-umbo velocity ratio was -4.6 dB, however in other studies, different ratios were found (Dobrev et al., 2016; Gyo et al., 1987; Peacock et al., 2014, 2016). A standardised approach and a database of norms would assist the surgeon intraoperatively.

In this study, only stapes fixations were investigated. As mentioned above, the incus velocity amplitude dropped more than the umbo velocity amplitude. For this reason, the incus-to-umbo ratio was found to be the parameter of choice to detect the fixation. However, it cannot be inferred that this holds for all types of fixations (Nakajima et al., 2005).

4.1 Clinical applicability

Clinical applicability of the method is an important aspect of this work. The combination of a vibrometer with a surgical microscope allows for easy positioning of the laser beam on the reflective tape placed at the umbo or incus. The reflective tape can easily be sterilized (Zahnert et al., 2016) and can be removed after the procedure. The FMT of the clinically approved Vibrant Soundbridge® middle ear implant was used instead of a coil and a magnet cemented onto the ossicles as done in previous work (Peacock et al., 2014). The placement of the FMT is completely reversible and it can be taken away leaving the ossicular chain in its original state. The whole procedure of making a sound stimulated umbo response measurement, lifting the eardrum, placing the FMT, and iteratively reproducing the same umbo response can be done in less than 10 min. The measurements of incus and umbo velocity amplitudes after the FMT has been setup correctly merely takes a few seconds.

In all, this method would consume little operative time while still giving clinically relevant data on ossicular fixation.

The data should also be easy to interpret in the operating theatre. Fig. 9A shows the change in incus-to-umbo velocity ratio for sample 1, and Fig. 10 shows the average for all samples, in various degrees of fixation. One can interpret the degree of fixation quickly where in loose terms the lower the incus-to-umbo ratio, the more fixed the stapes.

The incus-to-umbo velocity ratio has several advantages over the individual incus and umbo velocities. First, the incus-to-umbo velocity ratio is more constant over the entire frequency range than the individual incus and umbo response curves. Second, the shape of the incus-to-umbo velocity ratio response is independent of the FMT input at each frequency. This makes visual interpretation of the results easier.

Zahnert et al. (2016) have recently shown that laser vibrometry can be used to improve prosthesis placement in the middle ear and that this is clinically feasible and relevant to improve outcomes. Another advantage could be the immediate feedback during an ossicular reconstruction. If the ossicular vibration does not meet a minimal standard then the surgeon can revise the reconstruction within the same operation. The new MIVIB method also allows to apply this procedure without having to glue a magnet to the ossicles.

The FMT has been used in thousands of Vibrant Soundbridge® operations throughout the world and the authors are unaware of any trauma that has been reported, including sensorineural or physical damage to the ossicles. As the manubrium can be more easily reached than the normal locations for FMT attachment, it is fair to say that minimal risk is involved to implement our method, especially since the device can also be very easily removed without leaving any traces of glue or other material. On the other hand, it should be

noted that any manipulations of the ossicles always involves some degree of risk, as does any other explorative surgery.

The FMT is produced in such a way that it can be sterilized. When using the implant in the clinic, it is delivered sterilized by the producer however in our experiments this was connected to a mini-stereo jack. Both the cable and the jack, as well as the FMT, can be sterilized using standard techniques such as a gas or gamma-ray sterilization. Heat sterilization would not be possible as this may damage the isolation of the FMT coils.

One drawback of this method is that due to the endaural approach, it does limit the angles from which the laser beam can be directed onto the reflector tape on the ossicles. However, assessment of ossicular vibration through other approaches, such as the facial recess, would provide an inferior angle for ossicular measurement and the endaural approach is preferred. However, as this system is proposed to assist the surgeon in intraoperative decision making, then endaural assessment is likely sufficient.

5. Conclusions

The aim of this paper was to present a new method to quantitatively investigate ossicle mobility using laser vibrometry in minimally invasive explorative surgery. The essence of the method is that we use a clinically proven device, the FMT, which can be placed and removed in a minimally invasive way. We will coin our method Minimally Invasive Intraoperative Vibrometry, MIVIB.

MIVIB will assist the surgeon in objective intraoperative planning and determine which prosthesis or operation is most appropriate for the best hearing outcomes. The same stimulation method can be used to optimize prosthesis placement and possibly even to optimize and predict surgical interventions.

We have shown that the degree of stapes fixation can be determined using an FMT to induce vibrations in the ossicular chain and in turn assess these by measurement of the umbo and incus long process with laser vibrometry. Our previous work, using a magnet to induce vibrations has shown that laser vibrometry can be used to assess fixations in other regions of the ossicular chain (Peacock et al., 2016). We plan to investigate the applicability of MIVIB for these cases, and to assess its possibilities as an intraoperative testing tool to optimize surgical interventions. This data can be used to create a database for assessment of middle ear pathologies intra-operative.

Acknowledgements

We thank the Med-El company for putting the floating mass transducer with a suitable audio connector and fixed clip at our disposal. This work was supported by the Paul Frenckners fund (Svenska Läkarsällskapet), the National Fund for Scientific Research Flanders (FWO) and the Surgical Division of Akershus University Hospital, Norway.

References

- Agrawal, Y., Platz, E.A., Niparko, J.K., 2008. Prevalence of hearing loss and differences by demographic characteristics among US adults: data from the National Health and Nutrition Examination Survey, 1999-2004. *Arch. Intern Med.* 168, 1522-1530.
- Browning, G.G., Gatehouse, S., 1992. The prevalence of middle ear disease in the adult British population. *Clin. Otolaryngol. Allied Sci.* 17, 317-321.
- Declau, F., van Spaendonck, M., Timmermans, J.P., Michaels, L., Liang, J., Qiu, J.P., van de Heyning, P., 2007. Prevalence of histologic otosclerosis: an unbiased temporal bone study in Caucasians. *Adv. Otorhinolaryngol.* 65, 6-16.
- Dobrev, I., Ihrle, S., Roosli, C., Gerig, R., Eiber, A., Huber, A.M., Sim, J.H., 2016. A method to measure sound transmission via the malleus-incus complex. *HearRes.* 340, 89-98.
- Gyo, K., Aritomo, H., Goode, R.L., 1987. Measurement of the ossicular vibration ratio in human temporal bones by use of a video measuring system. *Acta Otolaryngol.* 103, 87-95.
- Hannula, S., Bloigu, R., Majamaa, K., Sorri, M., Maki-Torkko, E., 2012. Ear diseases and other risk factors for hearing impairment among adults: an epidemiological study. *Int. J. Audiol.* 51, 833-840.
- Hato, N., Stenfelt, S., Goode, R.L., 2003. Three-dimensional stapes footplate motion in human temporal bones. *Audiol. Neurotol.* 8, 140-152.
- Huber, A.M., Schwab, C., Linder, T., Stoeckli, S.J., Ferrazzini, M., Dillier, N., Fisch, U., 2001. Evaluation of eardrum laser doppler interferometry as a diagnostic tool. *Laryngoscope* 111, 501-507.
- Koike, T., Murakoshi, M., Hamanishi, S., Yuasa, Y., Yuasa, R., Kobayashi, T., Wada, H., 2006. An apparatus for diagnosis of ossicular chain mobility in humans. *Int. J. Audiol.* 45, 121-128.
- Nakajima, H.H., Ravicz, M.E., Merchant, S.N., Peake, W.T., Rosowski, J.J., 2005. Experimental ossicular fixations and the middle ear's response to sound: evidence for a flexible ossicular chain. *Hear Res.* 204, 60-77.
- Niklasson, A., Ronnblom, A., Muyschondt, P., Dirckx, J., von Unge, M., Tano, K., 2016. Ossiculoplasty on isolated malleus fractures: a human temporal bone study using laser doppler vibrometry. *Otol. Neurotol.* 37, 895-901.
- Peacock, J., von Unge, M., Dirckx, J., 2013. Measurement of the vibration of the middle ear ossicles with removed eardrum: a method for quantification of ossicular fixation. *Med. Eng. Phys.* 35, 1786-1792.
- Peacock, J., Dirckx, J., von Unge, M., 2014. Magnetically driven middle ear ossicles with laser vibrometry as a new diagnostic tool to quantify ossicular fixation. *Acta Otolaryngol.* 134, 352-357.
- Peacock, J., Dirckx, J., von Unge, M., 2015. Towards quantitative diagnosis of ossicular fixation: measurement of stapes fixations using magnetically driven ossicles in human temporal bones. *Acta Otolaryngol.* 135, 880-885.
- Peacock, J., Dirckx, J., von Unge, M., 2016. Intraoperative assessment of ossicular fixation. *Hear Res.* 340, 99-106.
- Rosowski, J.J., Nakajima, H.H., Merchant, S.N., 2008. Clinical utility of laser-Doppler vibrometer measurements in live normal and pathologic human ears. *Ear Hear* 29, 3-19.
- Zahnert, T., Metasch, M.L., Seidler, H., Bornitz, M., Lasurashvili, N., Neudert, M., 2016. A new intraoperative real-time monitoring system for reconstructive middle ear surgery: an experimental and clinical feasibility study. *Otol. Neurotol.* 37, 1601-1607.