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#### Research Paper

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



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#### 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 unfixated 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.

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#### 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

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#### **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

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 supermagnet 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 supermagnet 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<sup>®</sup> 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 200  $\mu m$  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 mm  $\times$  0.4 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 (Bruel & 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 0.5–4 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, Innsbruk, 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

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