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1 **Towards quantitative diagnosis of ossicular fixation: measurement of stapes**
2 **fixations using magnetically driven ossicles in human temporal bones**

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8 **Abstract**

9 *Conclusion:* Information on the degree of stapes fixation can be found by measuring
10 the ratio of stapes to umbo and stapes to incus velocity. *Objectives:* To evaluate a
11 method of quantifying ossicular fixation in an ear with elevated tympanic membrane.
12 *Method:* Measurements were made on four fresh-frozen human temporal bones.
13 After elevating the tympanic membrane a small magnet was attached to the
14 manubrium and an electromagnetic excitation coil was used to vibrate the ossicles.
15 The vibration response of the umbo, the tip of the incus long process, and the
16 posterior crus of the stapes were measured before and after partially fixing the
17 footplate with luting cement. *Results:* The velocities at the different measurement
18 points were unequally affected by the fixation. The difference in the velocity ratio
19 between different points provides an indication of the degree of footplate fixation.

20 **Keywords:** otitis media, otosclerosis, laser vibrometry

22 **Introduction**

23 Various kinds of pathologies, such as otosclerosis and otitis media, can result in a
24 stiffening of the middle ear ossicular chain. Surgical treatment is often considered
25 necessary to remedy the situation and improve a patient's hearing ability. In such
26 procedures, the best surgical outcome naturally requires knowledge of which
27 ossicles are fixed, and the degree to which they are fixed. Despite the fact that a
28 number of promising techniques have been proposed to measure ossicular fixation
29 [1–3] , the final assessment is still most often made by manual palpation. Yet
30 determining the degree of fixation manually is subjective and may be a difficult task,
31 even for an experienced surgeon. Thus a method that could objectively quantify the
32 fixation would be of value.

33 A previous paper in this journal [4] reported measurements of incus and umbo
34 vibrations through the ear canal using laser vibrometry. In this method a small
35 magnet was attached to the manubrium and was used to drive the ossicles after the
36 tympanic membrane (TM) was elevated. Measurements were made at the tip of the
37 incus long process and at the umbo before and after the incus was artificially fixed
38 using glass ionomer luting cement. The results showed an increase in the ratio
39 between incus and umbo velocity with increasing fixation, and indicated that the
40 method may be useful to determine the degree of ossicular fixation during surgery.

41 This previous article only reported measurements of incus fixation. The present
42 study expands on these results, and reports further evaluation of the method in
43 which artificial fixation of the stapes footplate is assessed.

44 **Materials and methods**

45 Four fresh-frozen human temporal bones (TBs) were acquired from Medcure inc.,
46 Portland, Oregon, USA. These were allowed to defrost at room temperature before
47 the measurements, and were examined for signs of abnormality.

48 The measurement set up consisted of a laser Doppler vibrometer (Polytec model
49 OFV-534) coupled to a surgical microscope (OPMI Sensera / S7, Carl Zeiss). A
50 joystick controlled mirror was used to position the laser beam (spot size 200 μm at a
51 distance of 30 cm) as previously described [5].

52 An acoustic stimulus was provided by a free field loud speaker system, the output of
53 which was measured by a probe microphone (Bruel & Kjaer probe microphone, type
54 4182). The signal was designed in a PC using MATLAB and generated using an A/D-
55 D/A conversion board with 24-bit resolution and a sampling rate of up to 192 KHz
56 (RME HDSP 9632). A stepped sine signal consisting of logarithmically spaced
57 frequencies (with 16 per octave) between 1 and 4 kHz was used. The sound
58 pressure level was adapted at each frequency to match an equal loudness curve at
59 80 phons (the relationship between loudness and sound pressure level for humans is
60 defined in ISO norm 226:2003). The range of 1 to 4 kHz was chosen because
61 previous measurements showed maximal sensitivity of the instrument in this region.

62 A small custom made neodymium magnet (1 mm diameter x 0.5 mm thickness,
63 0.003 g), in combination with a custom built pancake coil (100 mm inner and 200 mm
64 outer diameter, 97 spiral coiled windings) was used for the magnetic stimulation. The
65 coil was driven by a power amplifier (DP P-900 Vintage Stereo Amplifier) with the
66 signal being constructed in MATLAB, the same as for the acoustic signal.

67 With the TM intact, the vibration response of the umbo was first measured in
68 response to acoustic stimulation from the free field speaker. Next, after elevating the
69 TM, a small magnet was attached to the manubrium using glass ionomer luting
70 cement (GC Corporation, Tokyo, Japan), and the coil was used to vibrate the magnet
71 and thereby also the middle ear ossicles. The signal to the coil was adjusted until the
72 umbo responded in the same way as before the TM was elevated.

73 The custom built pancake coil was placed over the ear, with the opening to the ear
74 canal near its centre, as if the coil were resting on a patient's head. The signal was
75 then output to the coil to vibrate the magnet, and the vibrometer was again used to
76 measure the response of the umbo. The vibration response measured with magnetic
77 stimulation was compared to that achieved with the earlier acoustic stimulation. The
78 signal to the coil was then adjusted, by means of an iterative procedure, until the
79 response of the magnetically driven manubrium (measured at the umbo) matched
80 the response of the acoustically driven manubrium to within 1 dB.

81 Measurements were then made at the three locations: the umbo, the tip of the incus
82 long process and on the posterior crus of the stapes. To improve the strength of the
83 reflected vibrometer signal, small pieces of reflective tape of approximately 1x1 mm
84 were cut and attached to the ossicles at each of the measurement points (as shown
85 in figure 1). The tape is produced by the vibrometer manufacturer (Polytec) and is
86 self-adhesive.

87 Subsequently, the mobility of the stapes was reduced by applying a few drops of
88 glass ionomer luting cement around the footplate. The cement was applied using a
89 syringe connected to an ear suction tube. Figure 1 shows one specimen (TB3)

before and after application of the cement. As can be seen from the figure, the tympanic membrane was removed in this study. This was done as clear access was needed in order to place the cement around the footplate. In the clinical situation it would not be necessary to completely elevate the membrane.

After artificial fixation, measurements were again made at all three measurement points.

Results

All TBs were examined for signs of pathology, and three of the four appeared normal. In one, called TB2, the TM appeared flat and wrinkled, and some fluid was found in the middle ear cavity. However, despite these differences, the ossicles remained firmly attached to the TM and in further measurements they appeared to behave normally.

Figure 2 illustrates the change in stapes velocity after the cement was applied. In this and all the following graphs, the results obtained on different temporal bones are presented in different colours (green, red, purple and orange), and are referred to as TB 1-4. The method to fixate the stapes footplate using luting cement delivers variable results, but this proved advantageous by producing ossicular chains with different levels of footplate fixation. In TB1 the overall stapes velocity was reduced the least amount, while in TB4 the decrease in stapes velocity was strongest. Stapes velocity in TB3 showed some different behaviour from the others, being the least fixed around a peak at 2000 Hz and the third most fixed either side of the peak.

111 The noise level was determined for each temporal bone by measuring on the
112 promontory while stimulating the ossicles magnetically.

113 Figure 3 shows the effects of artificial fixation on the stapes velocity in TB4. We have
114 shown TB4 as this was the only temporal bone in which the vibration response
115 reached the level of the noise floor which was determined by measuring on the
116 promontory. In all other measurements, the vibration of the bones was above the
117 noise floor.

118 Figure 4 shows the ratio of stapes to umbo velocity. The ratio displayed in the
119 unfixed condition remained within a fairly narrow band across all frequencies. The
120 mean remained at around 8 dB until above 2000 Hz, where it showed a slight
121 tendency to move towards zero. Partial fixation of the footplate caused the ratio to
122 drop below the unfixed condition in all TBs, but the amount by which it changed was
123 different in each TB and varied by frequency. In TB1 the fixed ratio remained at
124 around -10 to -15 dB across most frequencies, while the ratio for TB4 averaged
125 around -40 dB but dropped to almost -60 dB at some frequencies. TB2 and TB3 are
126 both in the range -25 to -30 dB, with TB3 having the lowest ratio below 1500 and
127 above 2500 Hz, and TB 2 having the lower ratio between those frequencies.

128 Figure 5 shows the ratio of stapes to incus velocity. The velocity ratio for the unfixed
129 condition was essentially zero in all TBs, it varied by a few dB each way but never
130 more than 5 dB. In the partially fixed condition, TB1 remained close to the unfixed
131 response, and mostly within one standard deviation from the mean. TB2 showed an
132 increase in the ratio below 1500 Hz, meaning the stapes was moving more than the

133 incus along the measured direction. Above 1500 Hz the ratio settled at around -3 to -
134 5 dB.

135 Below 1200 Hz, TB3 remains close to the normal range but begins to drop at higher
136 frequencies. Its ratio falls to around 10 - 15 dB above 2200 Hz, making it the lowest
137 at these frequencies. TB4 is the only one that never gets close to the normal ratio. It
138 dropped as low as -40 dB at around 1500 Hz, before settling at around -10 dB above
139 2000 Hz.

140 **Discussion**

141 *Practicality of the Method*

142 The equipment is easy to set up and measurements are easy to perform. The
143 magnet can be attached to the ossicles with luting cement, which is known to be
144 biocompatible [6], and is easily removed with a common otosurgical suction device.
145 The cement takes around five minutes to harden while each individual measurement
146 takes only a few seconds. The analysis is not computationally demanding and
147 results can be presented immediately after measurements are made.

148 *Normal values*

149 In the clinical situation, the surgeon will not have access to data before fixation. Thus
150 it is necessary to establish a range of normal values for the unfixed condition so that
151 deviations from the normal can be detected in cases of fixation.

In the measurements presented in this paper, the ratio of stapes to umbo velocity and of stapes to incus velocity remained within a fairly narrow band across all frequencies in the unfixed condition. The stapes to incus ratio deviated at most by a few dB from zero, while the stapes to umbo ratio varied at most by around five dB from the mean. These results indicate that a normal range is well defined, and that ossicular fixations can be detected as soon as the ratio differs more than 5 to 10 dB from the mean normal value.

Quantification of the level of stapes fixation

Although nature often presents us in surgery with a fully fixated stapes, it proved difficult to artificially mimic this situation. After applying the cement, stapes velocity only dropped to the noise level of the measurement method in one of the four TBs (TB4 below 2000 Hz). In the others cement application delivered variable results, probably because the adherence of the cement to the ossicle surface is not always the same. This meant that different levels of fixation were produced in different temporal bones, with the changes in stapes velocity acting as a reference for the degree of fixation. Figure 2 gives an indication of the degree of success of fixation by showing how the stapes velocity was affected.

Due to the narrow shape of the ear canal, stapes velocity can only be measured along one direction. Stapes motion is only piston-like in the lower frequencies and becomes more complicated at higher frequencies [7,8], the single-axis measurement thus delivers variable results at higher frequencies, sometimes even showing an apparent increase of stapes motion. Therefore only the lower frequencies, at around 1000 Hz, in figure 2 were used to rank the temporal bones in order of fixation.

175 *Determining the degree of stapes fixation*

176 The measurements showed that the ratios deviate significantly from the normal
177 values after the footplate was partially fixed, and thus a measurement that showed
178 the ratio to be outside the 'normal' is indicative of partially fixed ossicles.

179 In figure 4 all TBs are outside the normal range at some frequencies indicating that
180 they are partially fixed. The order of the ratios from highest to lowest follows the
181 same pattern as seen in figure 2, with TB1 having the smallest ratio, and TB4 having
182 the largest.

183 In the stapes to incus ratio (figure 5) the same general pattern as figure 2 is also
184 partly visible. In this graph TB1 remains almost entirely within the normal range,
185 meaning that it would not be possible to detect its fixation with this data, while TB4
186 was the only TB to remain outside the normal range at all frequencies.

187 Each ratio has a range of a several tens of dBs within which the degree of partial
188 fixation can be quantified. The ratio of stapes to umbo velocity varies by 30 to 40 dB
189 and more from the normal when going from unfixed to fully fixed, while the stapes to
190 incus varies by 20-30 dB although it does change as much as 40 dB at some
191 frequencies. This means that for each ratio there is a range of about 30 to 40 dB in
192 which the degree of fixation can be determined.

193 **Summary and Conclusion**

194 The measurements demonstrate that magnetic stimulation can be used to mimic
195 acoustic input to the middle ear after the TM has been elevated. This allows for easy
196 measurements of the vibration response at different points along the ossicular chain.
197 Measurements were made of the vibration response of the umbo, the tip of the long
198 process of the incus and on the posterior crus of the stapes. The stapes to umbo
199 velocity ratio, as well as the stapes to incus ratio, showed correlation with the degree
200 of stapes fixation, which was determined by looking at the change in stapes velocity
201 after fixation. The stapes to umbo ratio proved to be the most sensitive parameter.

202 The results demonstrate the potential of the method to objectively quantify the
203 degree of fixation of the stapes. In cases of partial ossicular fixation, often
204 encountered in otosclerosis and tympanosclerosis, the surgeon assesses the
205 ossicular mobility by manual pressing with an instrument. Thereby a subjective
206 impression of the quasi-static mobility of the ossicles is obtained. However,
207 particularly in cases of partial fixation, it is difficult for the surgeon to translate the
208 finding into the degree of hearing impairment, which renders an uncertainty when
209 deciding which surgical procedure might result in the best hearing outcome. In cases
210 with multiple points of fixations, such as at the stapes footplate and the incus, or the
211 stapes and the anterior malleolar ligament, it becomes even more difficult. The
212 present method may then be advantageous as it can provide objective values of the
213 degree of mobility of individual parts of the ossicular chain. It may thereby provide
214 the surgeon with a better base for decision making when choosing a surgical
215 procedure to handle situations with partial and multiple fixations.

216 Further measurements will be needed to fully characterize the middle ear's response
217 to partial fixation, and use the method to determine the location as well as the

218 degree of the fixation. Measurements of different mimicked clinical situations are
219 planned for future work in order to evaluate what types of fixation the method can
220 distinguish.

221

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

224

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- 261

Figure Captions

Figure 1. Photographs obtained through the operating microscope using an ordinary compact camera (Olympus MyTough, Japan) before and after the application of luting cement around the stapes. The magnet and pieces of reflective tape are visible on the ossicles.

Figure 2. Fixed/unfixed stapes velocity for all four temporal bones.

Figure 3. Stapes velocity in the unfixed (full lines) and fixed (broken line) conditions. The black line indicates the noise level as measured on the promontory.

Figure 4. The stapes-to-umbo velocity ratio before and after footplate fixation. The shaded area indicates 1 SD either side of the mean (solid black line) for the TBs in the unfixed condition. The individual ratios for each TB in the unfixed condition are shown as grey lines, while the solid coloured lines show the ratio after the TBs were artificially fixed.

Figure 5. The stapes-to-incus velocity ratio before and after footplate fixation. The shaded area indicates 1 SD either side of the mean (solid black line) for the TBs in the unfixed condition. The individual ratios for each TB in the unfixed condition are shown as grey lines, while the solid coloured lines show the ratio after the TBs were artificially fixed.

283 **Figure 1**

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286 **Figure 2**

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290 **Figure 3** 292 **Figure 4** 294 **Figure 5**