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1Jae Hoon Sim, 1Michail Chatzimichalis, and 1Alexander M. Huber

1University Hospital Zurich

Abstract

In the surgical treatment of otosclerosis, the coupling between the stapes prosthesis and the long process of the incus is critical. After surgery, connective tissue and mucosa may grow over the coupling area and thereby influence the sound transmission properties of the incus-prosthesis interface.

It was the hypothesis of this study that tissue ongrowth in the incus-prosthesis interface has little influence on sound transmission following stapes surgery. The goals of the study were to: 1) investigate the extent of postoperative tissue ongrowth over the stapes prosthesis; 2) objectively evaluate intra- and postoperative sound transmission properties of revision stapes surgery and compare the findings to those from primary surgery; 3) quantify the influence of ongrown tissue on sound transmission after stapes surgery.

A group of 10 patients undergoing revision stapes surgery was investigated with audiological evaluations and intraoperative laser Doppler interferometry, and with scanning electron microscopy of the explanted incus with its adherent prosthesis in 6 patients. Results were compared to a group of patients undergoing primary otosclerosis surgery and temporal bone experiments.

Results indicated that tissue grows over the prosthesis, as identified in all specimens. Sound transmission properties were evaluated intraoperatively (i.e., incus mobility and prosthesis fixation quality), and found to correlate well with the functional hearing.
results. Ongrowing mucosa in the incus prosthesis interface had only a minimal effect on sound transmission properties and cannot compensate adequately for insufficient prosthesis fixation. Therefore, it is essential that the stapes prosthesis is properly fixed during primary otosclerosis surgery.

**Keywords:** Air-bone gap (ABG), Incus, Laser Doppler Interferometry (LDI), Mucosa, Mucosa Ongrowth, Otosclerosis, Prosthesis, Revision, Sound Transmission Loss (STL), Stapes, Stapes Surgery.

**Introduction**

Otosclerosis is a progressive condition that causes primary conductive hearing loss by fixating the stapes at the oval window. Surgical treatment with a stapes piston prosthesis that connects the mobile incus to the cochlear fluid through a small opening in the stapes footplate (incus stapedotomy) has been the most successful treatment. Only in a fraction of cases is the hearing outcome unsuccessful because the air-bone gap (ABG) is not closed. Unexpected failures of the primary surgery are the result of multiple factors, which can only be investigated and evaluated during revision surgery. Possible reasons include a displaced, fixed or loose prosthesis, a subluxated, fixed or eroded malleus or incus, and fibrosis or regrowth of otosclerotic bone in the oval window (Fisch et al., 2001). Since revisions are usually performed only with conductive hearing losses having air-bone gaps of more than 20 dB HL, the causes of minor inadequate sound transmission remain unknown in many cases.

In the surgical treatment of otosclerosis, the coupling between the long process of the incus and the prosthesis is critical. Van der Waals force, adhesion and
friction are involved in this coupling (Eiber et al., 1999). These forces are mainly
determined by the quality of fixation (crimping). After surgery, however, connective
and mucosal tissue will grow over this coupling area and will also change its sound
transmission properties depending on the amount of covered surface area of the
prosthesis as well as the thickness and stiffness of the tissue. If this tissue has a
strong influence on coupling, then insufficient crimping may be compensated for by
tissue adhesion over time, and good functional results could be reached. Recently it
was shown that a tight coupling of the stapes prosthesis to the incus leads to
improved clinical outcomes. Therefore, the ongrowth of tissue probably has only a
small effect on transmission properties because there was no compensation for an
incomplete fixation (Huber et al., 2008).

It is the hypothesis of this study that tissue ongrowth over the incus-prosthesis
interface has little influence on sound transmission following stapes surgery. The
goals of the study were to: 1) investigate the extent of postoperative tissue ongrowth
over the stapes prosthesis; 2) objectively evaluate intra- and postoperative sound
transmission properties of revision stapes surgery and compare it to primary surgery;
3) quantify the influence of on-grown tissue on sound transmission after stapes
surgery.

Method

Data acquisition and analysis

In this study, a group of patients undergoing revision stapes surgery (referred
to as the “revision group,” because all measurements were done before the original
prosthesis was removed and the revision prosthesis was put in place) was
investigated with preoperative hearing tests, intraoperative assessment of ossicular-
chain mobility and prosthesis-fixation quality using laser Doppler interferometry (LDI), and scanning electron microscopy of the explanted incus with its adherent prosthesis when available. Results were compared to a group of patients undergoing primary otosclerosis surgery investigated with the same technique and in the same institution (referred to as the “primary group,” because all measurements were done after the primary prosthesis was put in place) (Huber et al., 2008) and temporal bone experiments (Huber et al., 2003). No adhesive tissue influenced the coupling in the primary group and temporal bone intraoperative LDI measurements, while in the revision group, tissue had grown onto the prosthesis-incus interface. This difference was used to draw conclusions about the influence of this tissue on sound transmission.

The results from the large group of primary patients (n = 75) evaluated previously were considered as the standard (i.e., postoperative air bone gap, ossicular mobility and fixation quality), because good functional results were documented 1 yr after the surgery. Incus mobility may be reduced with fibrosis of the ossicular chain, with fibrosis in the oval window, or with a defective incudo-malleolar joint. The sound transmission from the incus to the prosthesis may be reduced with incomplete prosthesis crimping or with a partially eroded incus. Assuming that these factors can be quantified by intraoperative LDI measurements, the difference in intraoperative measurements between groups of the primary and revision subjects should be equal to the difference of their air bone gaps, except for the influence of ongrowing mucosa in the incus-prosthesis interface. The effect of this ongrowing mucosa can therefore be calculated.

Patients
Ten patients with an average age of 52 (38 to 64) years (6 women, 4 men) were included in the revision group. The time between primary and revision surgeries was 0.5 to 25 years (mean of 9.8 yrs). The piston prosthesis materials used initially were platinum-teflon and titanium. All patients underwent routine audiometric testing and pure-tone audiograms were obtained preoperatively before the revision surgery. Air-bone gaps (ABGs) and pure-tone averages (PTAs) were calculated in accordance with the recommendations from the Committee on Hearing and Equilibrium (Monsell et al., 1995). None of the patients had a dislocated prosthesis.

Intraoperative LDI measurements were performed with all patients. In 6 patients, the incus and prosthesis were harvested and examined by scanning electron microscopy. Informed consent was obtained from all patients prior to surgery, and the study was conducted in agreement with the Declaration of Helsinki. The study protocol was reviewed and accepted by the local ethical committee.

**Intraoperative LDI Measurements**

A scanning LDI (PSV200; Polytec, Waldbronn, Germany) mounted to a microscope stand was used to assess the vibrations of the long process of the incus and the prosthesis loop. The LDI measurement system is based on a He-Ne laser beam that is aimed onto a moving target while the reflected laser light is analyzed by Doppler technology, providing amplitude and phase information of the target velocity. The sensitivity and accuracy allow measurement of displacements of the structures down to below 1 nm over a frequency range of 100 Hz to 20 kHz. Scanning LDI, which automatically records motion and coordinate information of multiple points on a surface, provides visualization of vibrating objects and allows convenient graphical analysis of the data. Measuring points with coherence of less than 80 %, which corresponds to a signal-to-noise ratio of 10 to 15 dB, were rejected. For the
stimulation of the ossicular chain, electro-magnetic rather than acoustical stimulation was used because the opened tympanic membrane would react unpredictably to acoustic excitation. A sterilized samarium-cobalt magnet weighing 0.05 g was placed onto the umbo and was fixed by the tympanomeatal flap, which was folded over the magnet. A current-conducting coil bundle (15 cm in diameter) covered by sterile drapes was placed around the ear to force the magnet to vibrate. The coil currents were driven by a signal generator (HP 33120A; Hewlett Packard, Palo Alto, CA, USA) and a power amplifier (Revox A78; Regensdorf, Switzerland). The coil currents were calibrated according to earlier experiments in human temporal bones (TBs) (Huber et al., 2003) to achieve vibration amplitudes of the ossicular chain within the physiological range of acoustical excitation. The vibration of the incus and the prosthesis hook was measured along three lines parallel to the long process of the incus in each ear. The mean difference of the vibration between the incus and the prosthesis was then calculated and converted into decibels. Thereby, a measure of the crimping quality was generated expressing the sound transmission loss (STL) at the incus-prosthesis interface. Details of the procedure are described in earlier publications (Huber et al., 2001; Huber et al., 2003).

**Surgical technique**

An endaural approach was carried out and a tympanomeatal flap was developed. The chorda tympani was identified and conserved. When visualization of the facial nerve and pyramidal process was not possible, a posterior canaloplasty was performed to allow for better access. The LDI measurement was then made. There was no prosthesis luxation or displacement within the revision subject group. In 2 patients, revision incus-stapedotomy using a Nitinol prosthesis was performed while in the other 8 patients a malleo-stapedotomy with a titanium prosthesis fixed to
the manubrium was performed. Before the incus was removed, the tissue in the oval
window connected to the prosthesis was separated. The long process of the incus
was then gently removed using a malleus nipper, while carefully avoiding tension on
the prosthesis-incus interface. The prosthesis, with its incus, was removed and
prepared for scanning electron microscopy.

**Scanning electron microscopy**

After the incus and stapes prostheses were removed, the sample was fixed in
4 % phosphate-buffered formalin for 72 hours. The specimens were then washed in
buffer and dehydrated in a graded series of ethanol, critical point dried in CO₂,
mounted on stubs with colloidal silver, and sputter-coated with gold–palladium. For
each specimen, the attachment, shape, and remaining opening of the loop were
individually assessed. The interface between the prosthesis and the long process of
the incus was documented by scanning electron microscopy to determine either no
crimping, loose crimping, or tight crimping.

**Reference parameters**

The measurements of a group of patients who underwent regular primary
stapes surgery with conventional prostheses that were published earlier Huber et al.,
2008 were used as a reference. These results were considered as the standard
because functional results comparable to the results found in the literature were
obtained. Means and standard deviations of ABG, incus mobility, and crimping
quality of the primary group were extracted from our database. Similarly, data from a
temporal bone study were used for comparison of the crimping quality (Huber et al.,
2003). The stapes surgeries were performed with 17 temporal bones, and the STL at
the incus-prosthesis interface was assessed by the LDI measurements. When the
gap between the long process of the incus and the prosthesis hook was observed by microscopic view, the interface was considered as “bad” crimping, and otherwise it was considered as “good” crimping.

Statistics

Two-tailed $t$-tests were performed for comparison of ABG, incus mobility, and STL at the incus-prosthesis interface between the primary and revision groups, which were different in size. Statistical analyses were computed using StatMate V3 software (ATMS), and $p$ values of less than 0.05 were chosen as the level of significance.

Results

Scanning electron microscopy

Of the six explanted specimens, the stapes prosthesis and long process of the incus were completely covered with ongrown mucosa in three subjects and were covered partially along its circumference in three other subjects (approximately 2/3s of the surface area in two and 1/3 of the surface area in one). There was no correlation between the time interval between the primary and revision surgery and the amount of mucosa coverage. Slight erosion of the incus was found in two specimens. In four cases, the loop was considered to be tightly crimped as no gap between the prosthesis and the incus was visible. In two subjects there was an obvious gap present. Figure 1a illustrates a representative specimen with a partial mucosal ongrowth and tight crimping with a small posterior gap. There was a thin layer of fibrous tissue covering the bone in the prosthesis-incus interface (figure 1b). The gap in non-optimal crimping subjects was not filled by tissue. There was no
association of the quality of crimping and the erosion of the incus and no relation
between mucosa ongrowth at the incus-prosthesis interface and the sound
transmission loss (STL) at the interface.

Hearing results

Figure 2 illustrates differences in air-bone gaps between primary and revision
groups. At most of the measurement frequencies, the air-bone gaps were
significantly different ($p < 0.05$ at 0.25 and 0.5 kHz, and $p < 0.01$ at 1, 3, and 4 kHz).
In the frequency range of 0.5 to 4 kHz, the mean air-bone gaps of the revision group
were larger by 13.3 ± 4.2 dB than the corresponding values of the primary group. The
maximum difference occurred at 0.25 kHz (20.0 dB), and the minimum difference
occurred at 2 kHz (7.5 dB). The difference of PTA between the two groups was 12.8
dB ($p < 0.01$), which was similar to the mean differences in the frequency range of
0.25 to 4 kHz.

Loss in Incus Mobility

Figure 3 illustrates comparison of intraoperative measurements of incus
mobility between primary and revision groups. In the frequency range of 0.25 to 4
kHz, the mean incus mobility of the revision group shows a decrease of 9.6 ± 2.2 dB
compared to the mean incus mobility of the primary group. The difference between
primary and revision groups was statistically significant at some frequencies.

Crimping Loss

Figure 4 represents STL at the interface between the long process of the incus
and the prosthesis hook, in comparison with the values of “good” and “bad” crimping
in temporal bone measurements. The values of the primary group were similar to
those of “good” crimping, while the results of the revision group were generally in the middle of the categories, “bad” and “good” crimping based on the temporal bone measurements. At 0.25 and 0.5 kHz, the crimping loss between the primary and revision groups, which was defined as a difference between the two groups, was relatively large compared to the corresponding values at other frequencies (5.3 dB at 0.25 kHz and 2.5 dB at 0.5 kHz), and the values for crimping loss in the frequency range 0.75 to 4 kHz were maintained at less than 2 dB. A significant crimping loss was found only at 0.25 kHz ($p < 0.05$). In the frequency range of 0.25 to 4 kHz, the mean crimping loss between primary and revision groups was 2.0 dB, with a standard deviation of 1.7 dB.

Contribution of Mucosa Ongrowth to Hearing Degradation

Figure 5 represents the contributions of incus mobility loss (incus mobility in the primary group minus incus mobility in the revision group) and crimping loss (STL at the incus-prosthesis interface in the revision group minus STL at the incus-prosthesis interface in the primary group) to the air-bone gap increase (ABG in the revision group minus ABG in the primary group) during the period between primary and revision surgeries. The difference between the total air-bone gap increase and the sum of the incus mobility and the crimping losses is considered as a possible effect of mucosa ongrowth on hearing degradation during the period between primary and revision surgeries. This amount was less than 4 dB in the frequency range from 0.5 to 4 kHz and was 1.5 dB in the frequencies constituting the PTA.

Discussion
The hearing deterioration following primary stapes surgery for the 10 patients in this study was caused primarily by losses in incus mobility and crimping. The mean amount of loss in incus mobility between the primary and revision groups corresponded to 78 ± 23 % of the mean difference in air-bone gap between the two groups. The crimping loss at the incus-prosthesis interface between primary and revision groups contributed to the air-bone gap difference between the two groups by 5 to 27 % (mean of 14 % with a standard deviation of 8 %).

Although it is known that the transmission of sound involves the three-dimensional movement patterns of the ossicles and the prosthesis, in the ears reconstructed with a stapes prosthesis, only the one-dimensional movements in the direction of the stapes prosthesis were assumed and measured in this study. Hearing loss caused by the incus mobility loss and loose fixation between the incus and the stapes prosthesis can be different from the results based upon one-dimensional measurements of incus and prosthesis motions.

One of the possible reasons for incus-mobility loss is progressive extension of otosclerosis or scar tissue formation on the incus, incudo-malleolar joint or the malleal ligaments. It has been shown that malleostapedotomy (i.e., prosthesis connection from the malleus to the inner ear fluid) may lead to better results in revision stapes surgery than conventional incus stapedotomy (Fisch et al., 2001). Another possibility is fixation of the stapes prosthesis at the interface to the oval window. Such findings have been described intraoperatively in revision cases. The "locking" of the prosthesis in the oval window could be due to the bony regrowth at the fenestra (Han et al., 1997), to fibrosis tissue over the oval window niche (Fisch et al., 2001), or to friction between the prosthesis and the fenestra because of a tight fenestra or an unfavorable angle (Huttenbrink, 1988). The "locking" of the stapes prosthesis at the oval window causes a reduction in the degree of freedom of the
incus motion at the incus-prosthesis interface, and only limited motion of the incus is thus allowed. The reason, however, for the many possibilities of loss of incus mobility cannot be distinguished by this study.

Coupling of the stapes prostheses is a critical step in surgery. A study by Huber et al. (2003) in fresh human temporal bones evaluated the connection between the incus and stapes prosthesis. They concluded that optimal crimping of the prosthesis resulted consistently in good results in sound transmission. In that study, it was also determined that loose or no crimping may still provide excellent sound transmission; however, there is an unpredictable range of sound transmission loss up to 28 dB.

Several prostheses have been proposed to produce better functional results. A Nitinol prosthesis, which is composed of a shape memory metal, is activated by heating to a preassigned condition. Such tight fixation leads to improved functional results because of better sound transmission properties at the incus-prosthesis interface (Huber et al., 2008).

This study of results from 10 patients undergoing stapes revision surgery revealed tissue growth over the prosthesis in all examined specimens. However, no correlation between the amount of mucosa ongrowth and STL at the incus-prosthesis interface was found. Therefore, its contribution to hearing was small -- within the range of measurement error or individual difference. From these findings, it is presumed that tissue ongrowth after stapes surgery does not provide significant enhancement of coupling between the incus and the prosthesis as previously assumed. Eiber et al. (1999) investigated the coupling interaction between a PORP (Partial Ossicular Replacement Prosthesis) middle ear prosthesis and stapes superstructure. It was found that with good prosthetic fixation, an additional
viscoelastic coupling (overlapping with tissue) plays no significant role in sound
transfer.

Although gaps between the prosthesis and the incus were found in some
specimens, these gaps were not filled with tissue but only a thin layer of fibrous
tissue was covering the bone (Fig. 1b). This indicates that no tissue grows into the
incus prosthesis interface that may uncouple the interface and dampen the
transmission properties.

In this study, the reference values for the post-revision group were obtained
from the large number of patients (n = 75), while only 10 patients were involved in the
revision group. The primary surgeries of the 10 patients in the revision group were
done with conventional platinum-teflon and titanium prostheses. Stapes surgeries
with the Nitinol prosthesis have only been performed recently, and it was difficult to
find cases of its revision. Also, the revision group did not include a case of a
dislocated prosthesis, and thus the role of tissue ongrowth at the incus-prosthesis on
preventing dislocation of the prosthesis was not considered.

Conclusion

Tissue ongrowth was found on the incus-prosthesis interface in all examined
samples. Although we identified only a partial ongrowth in three of the six examined
samples, no correlation of the time interval between primary and revision surgery and
the ongrowth pattern was found. Also no correlation of the tissue ongrowth to air-
bone gap, incus mobility, or crimping quality was found.

It was possible to document the sound transmission properties in otosclerosis
surgery intraoperatively (i.e., incus mobility and prosthesis fixation quality). There
was a high correlation of intraoperative measurements and functional hearing results.
Ongoing mucosa in the incus prosthesis interface has only a small effect on sound transmission properties and can therefore not compensate for insufficient prosthesis fixation. It is essential to fix the stapes prosthesis properly during primary otosclerosis surgery.

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References


Figure captions

Fig. 1. Morphological evaluation of the incus and stapes prosthesis using scanning electron microscopy. a) Tight crimping with a small gap posteriorly and partial mucosa ongrowth at the prosthesis incus interface and the piston is visible. b) A thin layer of fibrous tissue has grown onto the bone in the incus prosthesis interface.

Fig. 2. Air-bone gaps at primary (blue, n=75) and revision (red, n=10) groups. Vertical lines indicate 1 standard deviation, and * (p< 0.05) and ** (p < 0.01) indicate frequencies where significant differences occurred.

Fig. 3. Incus mobility for primary (blue, n=23) and revision (red, n=10) groups. Vertical lines indicate 1 standard deviation, and * (p< 0.05) and ** (p < 0.01) indicate frequencies where significant differences occurred.

Fig. 4. STL (sound transmission loss) at the interface between the long process of the incus and the prosthesis hook for primary (blue, n=7) and revision (red, n=10) groups. Vertical lines indicate 1 standard deviation.

Fig. 5. Contribution of loss in incus mobility (blue) and crimping loss (red) to air-bone gap degradation (green) between primary and revision surgery groups. The difference between the total air-bone gap degradation and the sum of the incus mobility and the crimping losses is considered as a possible effect of mucosa ongrowth on hearing degradation between primary and revision surgeries.