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Management of the Incus Body in Ossiculoplasty

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Abstract

Objective. (1) Evaluate the sound transfer impact of removal of the incus body in ossicular chain reconstruction (OCR) using an incus strut prosthesis. (2) Provide basic science data to assist clinical decision making in ossiculoplasty.

Study Design. Basic science.

Setting. Cadaveric temporal bone research laboratory.

Subjects and Methods. Ossicular chain reconstruction with an incus strut prosthesis was performed on 7 human temporal bones with and without the incus body. The difference in round window membrane (RWM) peak-to-peak displacements (90-dB sound pressure level, 250-8000 Hz) using single-point laser Doppler vibrometry (LDV) was compared with observed baseline, intact ossicular chain values.

Results. Comparing OCR using an incus strut prosthesis to an intact ossicular chain across all 7 temporal bones, the largest differences in RWM velocity occurred at 1011 and 2011 Hz. With increasing frequencies, RWM velocities of the OCR approached the intact ossicular chain. Using a Wilcoxon rank-sum test comparing the ossicular chain with and without the incus body showed no statistically significant difference across all frequencies (P = .925). Removing the incus body resulted in improved median RWM velocity (×10⁻² mm/s) by 0.6 at 1011 Hz and a decrease of 0.6 at 2011 Hz. A rank-sum test to evaluate the difference at 1011 and 2011 Hz did not demonstrate statistical significance.

Conclusion. Removal of the incus body in OCR using an incus strut prosthesis did not significantly change sound transfer function of the middle ear relative to its preservation. Our data suggest the impact of the retained mass in OCR to be minimal.

Keywords

ossiculoplasty, incus, laser Doppler vibrometry, round window membrane, mass, incus body, incus strut prosthesis, middle ear, sound transmission, ossicular chain reconstruction

Ossicular chain reconstruction (OCR) has long been viewed as an art, with the experience, technique, and skill of the surgeon being strong determinants of outcome. Over the past 50 years, OCR has evolved into an increasingly reliable procedure, with multiple reconstructive options available to restore conductive sound transmission.¹ Using advanced mathematical modeling techniques as well as other precision observational modalities (eg, laser Doppler vibrometry [LDV], scanning laser vibrometry, intra-cochlear pressure measurements), basic science investigators are able to objectively evaluate and design novel reconstruction techniques. Clinically, otologists are frequently faced with a situation in which the incudomalleolar (IM) joint is intact but the long process is no longer in continuity with the stapes capitulum because of erosion or dislocation of the joint. To determine if the management of the remnant incus body plays a role in OCR success, we designed a temporal bone model using LDV recordings of round window membrane velocities to evaluate the sound transfer impact of incus body removal vs preservation in OCR using an incus strut prosthesis.

Methods

This was an exempt protocol that did not require institutional review board approval. Human anatomical specimens

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were obtained and handled in accordance with applicable institutional and Department of Defense regulations.

Seven human temporal bones were harvested from fresh cadavers and prepared using a complete mastoidectomy with facial recess exposure of the middle ear space. The round window membrane (RWM) was exposed by drilling the round window niche with a 1-mm diamond bur and extending the facial recess by sacrificing the facial nerve and chorda tympani and thinning the incus buttress. Ossicular chain integrity and mobility along with an intact tympanic membrane (TM) were confirmed at this time. A single-point LDV (model CLV 2534; Polytec, Waldbronn, Germany) with a micromanipulator (Polytec A-HLV MM30) mounted on an operating microscope (model ST2; Carl Zeiss, Oberkochen, Germany) was used to measure the velocity of the RWM.2 An ER-2 sound transducer (Etymotic Research, Elk Grove Village, Illinois) generated sound at specific frequencies in the range of 250 to 8000 Hz at a sound pressure level (SPL) of 90 dB. The speaker output was measured using an ER-7 probe microphone system (Etymotic Research). The speaker and microphone were positioned in the external auditory canal (EAC) through a foam ear plug.2 The LDV with micromanipulator was centered on the RWM in a near perpendicular plane while the acoustic stimulus was applied into the EAC. Baseline RWM peak-to-peak displacements were recorded for an intact ossicular chain on each of the 7 temporal bones at 20 individual frequencies (Figure 1). After baseline RWM velocities were determined, the incudostapedial (IS) joint of each temporal bone was disarticulated and the long process of the incus was removed. Ossicular chain reconstruction was performed using a Kartush Incus Strut Prosthesis (Gyrus ACMI, Southborough, Massachusetts) spanning from the head of the stapes to the manubrium of the malleus. Measurements of RWM velocity were taken with the incus body intact (Figure 2) and with the incus body removed (Figure 3). Round window membrane velocity (dB mm/s), sound output (dB), and sound frequency (Hz) and intensity (dB) were obtained using a data acquisition PC and software package (bwAnalyzer version 1.29; Otologics LLC, Boulder, Colorado). Round window membrane velocity...
was converted from dB mm/s to mm/s using the transfer formula \((= 10^{A/20})\).

Differences \((\Delta)\) values in RWM velocities of OCR with and without the incus body from baseline were computed (Figure 4). The \(\Delta\) values were compiled and analyzed using a Wilcoxon rank-sum test. Statistical significance between OCR techniques was set at \(\alpha = 0.05\).

**Results**

When comparing OCR using an incus strut prosthesis to an intact ossicular chain across all 7 temporal bones, the largest differences in round window membrane velocity occurred at 1011 and 2011 Hz. With frequencies above 1425 Hz, round window membrane velocities of incus strut OCR approached baseline velocities of the intact ossicular chain. Using a Wilcoxon rank-sum test to compare the ossicular chain with and without the incus body, there was no statistically significant difference in our data across all frequencies \((P = .925)\). Removing the incus body resulted in an improvement in median RWM velocity by .006 at 1011 Hz and a decrease of .006 at 2011 Hz. A Wilcoxon rank-sum test to evaluate the difference at 1011 and 2011 Hz did not demonstrate statistical significance (Table 1). In both study arms, a reduction in \(\Delta\) (gain in velocity) occurred in each of the 7 temporal bones above 1425 Hz with values approaching zero near 4011 Hz. Direct comparison of the change in velocity from 1200 to 1693 Hz within the retained incus body OCR technique showed an improvement in velocity of .017 mm/s \((P = .025)\).

**Discussion**

The incus plays a prominent role in middle ear pathology, and its surgical management has been the subject of extensive research. Among the 3 ossicles, the long process of the incus is the most common site of ossicular erosion and subsequent disruption of the ossicular chain.3-6 The resultant discontinuity of the ossicular chain has been shown to cause a disruption of ossicular coupling and reduced sound input into the cochlea. Thus, in the presence of an intact tympanic membrane, a moderate to severe conductive hearing loss can be predicted in the discontinuous middle ear.7-9

In an attempt to optimize reconstructed middle ear biomechanics, Merchant et al7 consider 4 variables that affect the outcome of OCR: stiffness, tension, positioning, and mass of the reconstructed chain. Stiffness is represented by the rigidity of the prosthetic strut. Research has shown that sound conduction below 1 kHz appears to be most influenced by this factor.8,10 As long as the prosthetic stiffness is greater than the stapes-cochlear impedance, stiffness is typically not an issue in outcome.7 Tension along the tympanic membrane and annular ligament as a result of prosthetic length may lead to a significant air-bone gap in hearing. It has been shown that high-tension conditions improve sound conduction above 3 kHz, whereas a mid-tension system optimizes outcomes between 0.5 and 4 kHz.3,7,11 Optimal sound transmission is also affected by prosthetic positioning. The optimal angle between the prosthesis and the promontory appears to be within 45 degrees from the perpendicular plane. The mid-manubrium position appears to maximize both angulation and TM coupling in OCR.3,6,7,11

The other major factor in OCR biomechanics appears to be mass of the reconstructed ossicular chain. Much research has been done evaluating the effects of prosthesis mass on sound transmission, but the retained ossicular mass may also play a role. An intact incus weighs 31.5 mg, and this additional mass should have the effect of increasing ossicular inertia, which may impair the overall transfer function.11,12 Conversely, a reduction in weight should have the opposite effect. Gan et al13 examined the effects of 2 different mass loads on the ossicles at the incudostapedial joint and the resultant sound transmission to the inner ear. Their results showed minimal stapedial displacement changes at frequencies less than 1 kHz and maximal effects above this frequency. In particular, they showed impaired stapes displacement at high frequencies with increased mass loading.13 Nishihara et al10 studied mass loading effects at different locations ranging from the tympanic membrane to the stapes.

![Figure 4. Median difference (Δ) of displacement across all sound frequencies from baseline intact ossicular chain in ossiculoplasty with and without the incus body present. OCR, ossicular chain reconstruction.](image)

**Table 1.** Comparison of Median Difference (\(\Delta\)) Round Window Membrane Velocities \((\times 10^{-2}\text{ mm/s})\) in All 7 Temporal Bone Ossicular Chain Reconstructions (OCRs) from Baseline at 1011 and 2011 Hz

<table>
<thead>
<tr>
<th>Incus Body Present</th>
<th>Incus Body Absent</th>
<th>(\Delta) OCR-OCR without Incus</th>
<th>Rank-Sum P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1011 Hz</td>
<td>2.37</td>
<td>1.76</td>
<td>0.6</td>
</tr>
<tr>
<td>2011 Hz</td>
<td>0.47</td>
<td>1.08</td>
<td>-0.6</td>
</tr>
</tbody>
</table>
Regardless of location, the greatest detriment to stapes vibration occurred above 3 kHz. Specific to location of the load, malleus head loading had the least effect and stapes head loading had the greatest effect on sound transmission. As mass loads increased, they found that sound transmission worsened. Collectively, it has been observed that effects of mass are seen above 1 kHz but are most dramatic above 3 kHz, resulting in 10- to 15-dB losses in hearing.

A favorable effect of preservation of the incus body may also be found in the rotation and medialization of the manubrium. Although the motion of the malleus is primarily in an inward-outward direction, the motion at the IS joint is multidirectional. The lenticular process has been shown to move in all 3 planes, predominately upward and downward. This suggests that some rotation of the malleus exists. With retention of the incus in OCR, this may allow for an inertial effect on the malleus head, which may dampen the rotational component of the manubrium. The result may be enhanced sound transmission. To effectively test this theory, a scanning laser vibrometer directly comparing relative malleus and stapes movement would be more suitable. Scarring is another factor that cannot be accounted for in cadaveric temporal bones.

In this pilot study, we sought to obtain objective data regarding the impact of removing the incus body in OCR. To our knowledge, no such previous study has been performed. Each of the 7 reconstructed temporal bones showed decreased velocity of the RWM across all frequencies when compared with corresponding intact ossicular chains. As the frequencies increased above 1425 Hz, these differences from baseline were less substantial and showed an improvement in RWM velocity compared with the OCR peaks at 1425 Hz. When directly comparing the OCR technique of retaining the incus body at 1200 and 1693 Hz, median RWM velocity improved by .017 mm/s ($P = .025$). In frequencies above 4 kHz, RWM velocities in both OCR arms neared intact ossicular chain values. When the 2 methods of OCR were directly compared, there was no difference in RWM velocity ($P = .925$).

On the basis of this study, we might expect that any reduction in incus mass load on a reconstructed ossicular chain would have a positive effect on sound transmission, particularly at frequencies above 4 kHz, in which a strongly mass-dominated state exists. Our data do not support this thesis; however, some literature suggests the idea that a quantitative limit to mass loading may exist in OCR, and any load in excess of this limit may have detrimental effects.

### Table 2. Comparison of Median Difference ($\Delta$) Round Window Membrane Velocities ($\times 10^{-2}$ mm/s) from Baseline in All 7 Temporal Bone Ossicular Chain Reconstructions across All Frequencies Including 95% Confidence Intervals (CIs)

<table>
<thead>
<tr>
<th>Hertz</th>
<th>Incus Body Present (95% CI)</th>
<th>Incus Body Absent (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>261</td>
<td>0.05 (0.02 to 0.14)</td>
<td>0.05 (0.02 to 0.13)</td>
</tr>
<tr>
<td>308</td>
<td>0.05 (0.03 to 0.22)</td>
<td>0.05 (0.03 to 0.20)</td>
</tr>
<tr>
<td>364</td>
<td>0.07 (0.02 to 0.34)</td>
<td>0.07 (0.00 to 0.31)</td>
</tr>
<tr>
<td>431</td>
<td>0.14 (0.02 to 0.33)</td>
<td>0.15 (–0.04 to 0.26)</td>
</tr>
<tr>
<td>511</td>
<td>0.26 (0.12 to 0.50)</td>
<td>0.25 (0.04 to 0.42)</td>
</tr>
<tr>
<td>605</td>
<td>0.56 (0.19 to 0.83)</td>
<td>0.47 (0.13 to 0.83)</td>
</tr>
<tr>
<td>718</td>
<td>0.92 (0.24 to 1.47)</td>
<td>0.92 (0.20 to 1.47)</td>
</tr>
<tr>
<td>852</td>
<td>1.59 (0.36 to 2.57)</td>
<td>1.49 (0.20 to 2.43)</td>
</tr>
<tr>
<td>1011</td>
<td>2.37 (0.41 to 3.61)</td>
<td>1.76 (0.20 to 3.63)</td>
</tr>
<tr>
<td>1200</td>
<td>2.29 (0.58 to 3.51)</td>
<td>2.38 (–0.02 to 3.56)</td>
</tr>
<tr>
<td>1425</td>
<td>1.22 (0.71 to 1.47)</td>
<td>1.10 (0.52 to 1.44)</td>
</tr>
<tr>
<td>1693</td>
<td>0.51 (0.16 to 2.06)</td>
<td>0.73 (0.48 to 2.08)</td>
</tr>
<tr>
<td>2011</td>
<td>0.48 (–0.20 to 1.71)</td>
<td>1.09 (0.09 to 1.70)</td>
</tr>
<tr>
<td>2389</td>
<td>0.65 (0.00 to 2.37)</td>
<td>0.79 (–0.06 to 2.16)</td>
</tr>
<tr>
<td>2839</td>
<td>0.62 (–0.01 to 4.77)</td>
<td>0.56 (–0.01 to 4.32)</td>
</tr>
<tr>
<td>3374</td>
<td>0.45 (0.02 to 3.24)</td>
<td>0.34 (0.04 to 3.00)</td>
</tr>
<tr>
<td>4011</td>
<td>0.11 (–0.01 to 1.87)</td>
<td>0.11 (0.01 to 1.89)</td>
</tr>
<tr>
<td>4768</td>
<td>0.19 (–0.03 to 1.77)</td>
<td>0.06 (–0.02 to 1.76)</td>
</tr>
<tr>
<td>5668</td>
<td>0.07 (–0.01 to 2.61)</td>
<td>0.01 (0.00 to 2.48)</td>
</tr>
<tr>
<td>6738</td>
<td>0.03 (0.00 to 0.61)</td>
<td>0.00 (–0.01 to 0.55)</td>
</tr>
</tbody>
</table>
hearing results. Furthermore, Nishihara and Goode suggest in their study that when reconstructing the middle ear, one should take into account the combined weights of the remnant incus and prosthesis. However, we did not seek what that limit would be in our study, but further research would be useful in elucidating the threshold.

Collectively, we recognized that interspecimen variability was difficult to overcome and could result in errors to our findings (Table 2). Asai et al. compiled normative data for the use of the LDV from 22 temporal bones. Their data showed that RWM displacement was linear with increases in SPL at the TM from 50 to 110 dB SPL. They found that 20-dB SPL increments occurred with a change in displacement by a factor of 10^{1} units. Although their research differed from ours, it did allow us to extrapolate their normative LDV data and apply them to our findings. Doing this, we found that at most no greater than a 10- to 20-dB SPL difference exists within the 95% confidence intervals of our data. This suggests that if a type II error does exist, it is likely to occur within this dB SPL range. Also, some variability may be due to placement of the prosthetic itself. In each temporal bone, we used the same type and length of incus prosthesis. Although this controlled for prosthetic mass, it did not control for tension, a factor that is difficult to quantify and may have detrimental effects, particularly at lower frequencies. The angle of the prosthesis between the malleus and stapes also adds variability to the study, although Shimizu and Goode argue the effect is likely a small difference. Nonetheless, every attempt was made to be consistent with the placement of the prosthesis onto the mid-manubrium to control for this variation. To reduce the impact of interspecimen variability, each specimen was compared with its own intact ossicular chain baseline. Last, the limited number of temporal bones may preclude statistical significance when in fact it may exist. Previous research on this subject is lacking and, therefore, no previous basis for which to judge these data exists. Thus, these data should serve as a foundation for future experiments.

Conclusion

Background literature has shown a reduction in sound transfer, particularly at high frequencies, with increasing ossicular chain mass. We report objective data on this subject regarding the impact of removing the incus body in OCR. Across this study’s 7 temporal bones, our data showed no substantive difference between the 2 methods, which suggests the impact of the retained mass to be minimal if any. This project serves as a pilot study to help guide future research on this subject.

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Author Contributions

Gregory G. Capra, conception, design, acquisition, analysis, interpretation, drafting, revision, final approval; Xianxi Ge, conception, design, acquisition, analysis, interpretation, revision, final approval; Ben J. Balough, conception, design, interpretation, revision, final approval; Anil N. Shah, conception, design, acquisition, analysis, interpretation, drafting, revision, final approval; David P. Mullin, conception and design, revision, final approval; Travis J. Pfannenstiel, conception, design, acquisition, analysis, interpretation, drafting, revision, final approval.

Disclosures

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