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Comparisons of the mechanics of partial and total ossicular replacement prostheses with cartilage in a cadaveric temporal bone preparation

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Abstract

Conclusions—Reconstruction of the ossicular chain differentially affects the motion of the tympanic membrane (TM) and the stapes.

Objectives—Determine the effect of different ossicular replacement procedures on the sound-induced motion of the TM and stapes.

Method—A combination of digital stroboscopic holography and laser Doppler vibrometry were used to determine the sound-induced motion of the TM and stapes in cadaveric temporal bones in which the ossicular chain was reconstructed using 12 varied standard techniques. The variations included the use of total or partial ossicular prosthesis, size of cartilage interposed between the TM and the prosthesis, and the length or fit of the prosthesis between the TM and stapes. The measurements were carried out in repeated measures format, so that each manipulations was performed in each temporal bone.

Results—The volume displacement of the TM was in general reduced by reconstruction with the largest reductions occurring with high-frequency stimulation in the reconstructions with a ‘Large’ cartilage oval interposed between the TM and the prosthesis. Larger stapes motions in response to low-frequency sound were observed with either ‘Loose’ or ‘Best’ fit TORP with a ‘Small’ cartilage plate between the TM and the prosthesis.

Introduction

Tympanoplasty is the surgical procedure used to reconstruct the middle ear after disease or trauma¹. Reconstruction of the ossicular chain is required in 40-90% of all tympanoplasties, making ossiculoplasty a frequently performed operation; however the results of such reconstructions vary greatly^{2,3}. Causes of the variable post-operative hearing results (conductive hearing losses of 5-60 dB) are only partially understood: failures are often

associated with poor coupling of the prosthesis to the TM or inner ear, or lack of aeration of the middle-ear spaces. A common form of ossicular chain reconstruction uses an ossicular-replacement prosthesis in conjunction with a thin sheet of cartilage to reduce the chance of the prosthesis extruding through the tympanic membrane (TM)^{4,5}.

A major mechanical factor in ossicular reconstructions is the tension produced by the prosthesis, which affects (i) the stiffness of both the annular ligament of the footplate and the TM, and (ii) the coupling of TM motions to the stapes. This tension changes with the length of the ossicular replacement prosthesis. Others have investigated the effects of reconstructions of different lengths and tensions on the motion of the stapes footplate⁶. The general results of such studies has been that a looser reconstruction with a shorter ossicular prosthesis leads to larger footplate velocities at lower frequencies, a snug 'best-fit' prosthesis yields the best broadband results, and a 'too-tight' prosthesis yields decreased responses at low and high frequencies.

In the present study, we investigate how prostheses of different lengths, and different tensions, affect both TM and stapes motion in a temporal bone model of ossiculoplasty. Laser-Doppler vibrometry (LDV) measurements of stapes motion together with stroboscopic holography (SH) measurements of the motion of the TM surface were made before and after removal of the incus and the placement of Partial and Total Ossicular Replacement Prostheses (PORPs and TORPS) of different lengths. The effect of different sizes of a cartilage disk interposed between the TM and the prosthesis was also investigated.

Methods

Temporal Bone (TB) Preparation and Measurement System

Five human temporal bones without history of otologic disease were used. TBs were obtained at autopsy within 24 hours of death from donors, and were used fresh or after refrigeration in normal saline at 3°C. Bones were prepared using universal precautions. The preparation included removal of the bony external auditory canal to expose the majority (>80%) of the TM surface, and a canal-wall-up mastoidectomy with wide posterior tympanotomy, including removal of the second genu and mastoid segment of the facial nerve to access the ossicles. The stapedius tendon was severed by KTP laser to maximize the exposure of the stapes.

The lateral surface of the TM was painted with a 60 mg / ml suspension of ZnO powder in saline to increase the light reflected from the TM surface. The tympanic ring of the TB was positioned perpendicular to the illumination beam of our stroboscopic holography system (Figure 1). Retroreflective balls were placed on the posterior crus of the stapes, and an LDV laser beam aimed on the reflectors through the open facial recess. The sound stimuli were tones of 0.2 to 14 kHz and 80 to 120 dB SPL. The stimuli were generated by an earphone coupled by flexible tubing to a speculum at the end of the holographic system. The speculum terminated a short distance (~ 1 cm) before the tympanic ring. No effort was made to seal the TM to the speculum. The tip of a calibrated probe-tube and microphone was positioned at the superior aspect of the tympanic ring to measure the sound pressure of the

stimulus tones. The middle ear and mastoid were kept open to the atmosphere, and the bones were periodically moistened by soaking in saline.

Stroboscopic Holographic and Laser-Doppler Vibrometry

The methods used in stroboscopic holography (SH) have been described elsewhere⁷. Briefly full-field holograms were gathered using stroboscopic illumination of the tympanic membrane while it was stimulated with continuous tones of 0.5, 1, 4 and 8 kHz. Eight stroboscopic holograms, each gathered at one of eight specific stimulus phases (phases of 0, $\pi/4$, $\pi/2$, ... 2π relative to the sinusoidal stimulus), were used to reconstruct the time waveform of displacement at more than 200,000 locations on the TM surface. These waveforms were used to calculate the magnitude and angle of the sinusoidal motion at each location. Such data are displayed in full-field maps of these quantities (Figure 2).

Because the manipulations were performed outside of the measurement device, and the bone returned to the device, differences in the relative position of the camera and the measured sample between repeated measurements induce differences in magnification, shape and location of the resulting TM image. These differences were corrected by a process that first detected the edge of the membrane while assuming the phase in response to low-frequency stimulation varied slowly along the TM surface. Further assuming the TM is roughly ellipsoidal, allowed calculation of its centroid, long and short axes, and orientation using a matrix of covariance⁸. The images were rotated, scaled and stretched to normalize orientation, size, and position to the control image.

Laser Doppler vibrometry (LDV) was used to measure the sound-induced velocity of the stapes using techniques that have been described elsewhere⁹. The laser was focused on small reflective beads placed on the posterior crus of the stapes via the widened facial recess. Stepped tonal sequences of frequencies from 0.2 to 15 kHz and levels of 80 to 110 dB SPL were used as stimuli under the control of a computer. The laser and probe-microphone response at each tone were averaged for a second and the magnitude and phase of the averages stored. The velocity was normalized by the sound pressure to compute a transfer function with units of (mm/s)/Pa.

Incus removal and ossicular reconstruction

Control SH and LDV measurements were made in bones with an intact ossicular chain. Then, (i) a KTP laser or joint knife was used to disarticulate the incudo-stapedial joint, (ii) the posterior incudal and incudo-malleal ligaments were severed, and (iii) the incus was removed. Titanium PORPs (the TTP Variac produced by the Kurz Co, Germany) of varied lengths were used to couple the stapes to the posterior-superior quadrant of the TM. Each reconstruction started with the placement of a 0.5 mm thick cartilage oval on the TM coupled to a prosthesis length that was judged to be the surgical 'Best' fit by a trained otologic surgeon (CHU). Two cartilage ovals were used: a 'Small' cartilage oval (8 mm²) approximated the oval head of the PORP, the 'Large' cartilage oval had an area that was twice the Small area. The ovals were placed in the posterior-superior quadrant of the TM with minimum contact with the manubrium of the malleus. After measurements with these two reconstructions a 'Loose' fit reconstruction with a PORP shaft 0.25 mm shorter than

Best fit was placed and measurements with the Small and Large cartilage repeated, a third set of measurements were made with a 'Tight' fit PORP shaft 0.5 mm longer than the Best fit. In total, SH and LDV measurements were made in six PORP-cartilage configurations.

On completion of the PORP reconstruction series, a KTP laser was used to remove the stapes head and anterior crus and a titanium TORP (Kurz Co, Germany) was placed between the stapes footplate and the Small or Large cartilage oval placed on the posterior superior TM. A series of SH and LDV measurements were made with the Best, Loose and Tight fitting TORPs with each of the two cartilage ovals. Not all measurements were completed in all five temporal bones, but three bones were measured in all 6 PORP and TORP conditions.

Data Analysis & Statistics

The SH measurements were used to define the total volume displacement of the TM normalized by the stimulus sound pressure at 0.5, 1, 4 and 8 kHz. We also computed the mean stapes velocity measured over narrow bands centered at the same 4 frequencies. The primary data analysis was done on the change in measured values from the mean control measurement. Paired student T-tests and three-way ANOVA analyses (StatPlus:mac by AnalystSoft Inc, USA) were used to investigate the effect of the PORP vs TORP reconstructions, the differences between the three fits of the ossicular prosthesis and the differences between the two cartilage conditions.

Results

Control condition

The SH measurements of TM displacement and the LDV stapes-velocity measurements in all bones were consistent with other 'normal' measurements. The patterns and magnitudes of displacement observed on the TM surface (e.g. the left column of Fig. 2) are consistent with reports in normal temporal bones^{7,10}. The stapes velocities measured with intact ossicular chains were also consistent with 'normal' measurements reported by others¹¹.

Effect of manipulation and reconstruction on the motion of the TM

Figure 2 illustrates the effect of incus removal and two ossicular reconstructions on the motion of the surface of the TM. With 1 kHz tonal stimulation (the top rows of Figure 2), the Control (intact ossicular chain) condition shows the isolated magnitude peaks in motion at locations in the posterior-superior quadrant of the TM as seen in other measurements, where the local peak in magnitude superior to the manubrium occurs in the *pars flaccida* of the TM. The phase of motion of the entire TM surface varies between +/- 1 radian relative to the phase of the umbo. The motions opposite the umbo of the manubrium (the lower portion of the region described by the narrow white-outline) are of lower magnitude than most other TM locations. Removing the incus, leads to increased motion of the most of the TM surface, though the region of the TM attached to the umbo continues to move less than most other parts of the TM. Reconstructing the ossicular chain with a Best-fit PORP coupled to a Large cartilage oval (the black outlined oval) placed in the superior-posterior quadrant reduces the magnitude and alters the phase of the motion of the TM surface opposite the cartilage relative to the incus-removed condition. A similar pattern of TM motion is observed after

reconstruction with a Best-fit TORP and Small cartilage oval (the black oval); the reduced size of the region of decreased motion reflects the smaller cartilage surface.

With 8 kHz stimulation (the bottom rows of Figure 2) the magnitude of TM motion under all conditions is decreased as seen by the pale blue and light yellow coding of many of the local maxima. In the control condition there are multiple local maxima of displacement, with small-spatial-extent, that are associated with small cyclic phase changes (± 0.5 radians), and again the motions of locations opposite the manubrium are lower in magnitude than those at most other regions. Interrupting the incus or reconstructing the ossicular chain with cartilage and a PORP produces relatively little qualitative change in the patterns of motion, though as with lower frequency sound stimulation, the motion of locations opposite the cartilage ovals are reduced.

One quantitative metric of the motion of the TM is to compute the volume displacement of the TM divided by the sound pressure of the stimulus. Measurements of the dB change in this quantity are summarized for all twelve reconstruction conditions in three individuals at the four frequencies of stimulation in Figure 3. Each of the four graph panels illustrates the dB value of the volume displacement per stimulus sound pressure measured post manipulation divided by the mean of the control (ossicular chain intact) volume-displacement measurements. The bars and whisker plots within each panel illustrate the results from the three individuals (3) of reconstructions with PORPs or TORPs (2 conditions), with Large or Small cartilage ovals (2 conditions), for the three fitting conditions (3: Loose, Best and Tight), for a total of $3 \times 2 \times 2 \times 3 = 36$ data values in each plot panel. The three individuals are coded by plotting the median and the range of the individual values for each reconstruction condition. The results from these graphs indicate: (i) the variability between the three bones at any one condition tends to be larger at low stimulus frequencies, and is on the order of or larger than many of the differences between conditions (Loose vs Best vs Tight, PORP vs TORP, or Small vs Large Cartilage); (ii) At 0.5 kHz about 35% (13/36) of the reconstructions resulted in an increase in volume displacement (+ dB values), but the incidence of such increases fell as stimulus frequency increased, such that with the 8 kHz stimulus only one reconstruction (a Best fit TORP with Small cartilage) produced a displacement larger than control; (iii) On average the volume displacement of the TM produced by stimulation at 4 and 8 kHz was reduced by about 10 dB regardless of the reconstruction procedure. The mean reduction in volume displacement increased as frequency increased.

A series of three-way ANOVA's were used to investigate the effects of (a) stimulus frequency (Low or High), (b) cartilage size (Large or Small), (c) prosthesis type (PORP or TORP) and (d) the three different fitting conditions (Loose, Best and Tight). A three-way ANOVA using measurements in each of the three bones, and including cartilage size, prosthesis type and prosthesis fit (for 72 values at each frequency) failed to identify any statistically significant difference between these sets of conditions. The inclusion of frequency as a factor (either Low – 0.5 and 1 kHz – or High – 4 and 8 kHz), with different pairings of the other factors identified a significant effect of frequency (with smaller decreases in volume displacement at lower frequencies) with a p -value of 0.033, and a highly significant effect of cartilage size with a p -value of 0.007. The interaction of

frequency and cartilage size was further investigated with a set of paired two sample t-tests, comparing the results of the Small and Large cartilage reconstructions at each of the four frequencies (Table 1). The difference between the Small and Large cartilage results were highly significant at 8 kHz. There were no significant differences at the other frequencies, though in each case the average reduction produced by the Small cartilage reconstruction was smaller than the reduction associated with Large cartilage reconstructions.

Effect of manipulation and reconstruction on the motion of the stapes

The effects of the various reconstructions on the motion of the stapes are illustrated in Figure 4. Removal of the incus reduced the sound-driven motion of the stapes into the noise floor, a reduction of 30-40 dB, a significant part of which was reversed by the different reconstructions. The arrangement of the data in Figure 4 is similar to that of Figure 3. The illustrations indicate that with 0.5 kHz stimulation, 14 of the 36 reconstructions lead to an improvement in stapes velocity relative to the control, with seven cases of improvement occurring with Loose reconstructions, and only 1 with a Tight reconstruction. The number of cases of improved stapes velocity with reconstruction decreases as frequency increases. There is a general trend of poorer results (larger losses) as frequency increases. Another observation is that the Large cartilage reconstructions generally yield poorer results; this is most apparent at the higher frequencies. There is also a tendency for the Tight reconstructions to yield poorer results at frequencies of 0.5, 1 and 4 kHz, but not at 8 kHz, where the results of most of the reconstructions were poor (> 20 dB decrease from controls).

A series of three-way ANOVA's were used to investigate the effects of (a) Low or High stimulus frequency (*LoHi*), (b) Small or Large cartilage size (*ScLc*), (c) PORP or TORP reconstruction (*PvT*) and (d) the three different fitting conditions, Loose, Best and Tight (*Fit*). The significance of the different factors noted in the different analyses are tabulated in Table 2. The most significant factor is stimulus frequency, but all of the factors were shown to be significant. The analysis did not identify any significant interaction of the factors.

In order to help quantify the differences between the different reconstructions, paired *t*-tests were performed comparing the different fitting lengths, and the other classification parameters (Table 3). The 'Loose' and 'Best' tight reconstructions were on average superior to the 'Tight' fit by 6 dB ($p < 0.0015$). The TORP reconstructions were superior to the PORP reconstructions by 3.5 dB ($p = 0.0031$). The Small cartilage reconstructions were superior to the Large cartilage by 5.1 dB ($p < 0.0001$), and the loss of displacement produced during Low frequency stimulation was 13.5 dB less than the loss at High frequencies ($p < 0.0001$).

Discussion

In this report we compared multiple ossicular reconstruction techniques using a repeated measures paradigm in three temporal bones. All reconstructions were between the stapes head (or footplate) and the posterior-superior quadrant of the TM. Three reconstruction parameters were varied: (i) The length or "fit" of the ossicular prosthesis (Best, Loose or Tight), (ii) the size of a 0.5 mm thick cartilage sheet interposed between the head of the replacement (Small or Large), and (iii) reconstruction to the stapes head with a PORP, or to

the footplate with a TORP. Our techniques allowed us to separately assess the effect of the reconstruction on the sound-induced volume displacement of the TM and the velocity of the stapes. One general finding was a considerable variability within individual reconstructions. This variability is on the order of the differences observed between different reconstructions. While this variability increases the difficulty of isolating significant differences, the repeated measurements paradigm of our study (in which each of the three bones were each used in six PORP and six separate TORP reconstructions, half of these (6) reconstructed with small cartilage and half (6) with large cartilage, and in four separate Best fit, Loose fit and Tight fit prosthesis placements) allowed us to reduce the contribution of inter-individual variability and tease out significant trends.

Effect of reconstruction technique on the sound-induced motion of the TM

While our results confirmed that the placement of the cartilage plate on the medial surface of the TM reduced (Fig. 2) the sound-induced motion opposite the plate¹², surprisingly we saw little difference in the measured motion with the different reconstruction techniques, and the changes in TM volume displacement relative normal were generally small, less than 10 dB on average (Table 1, and Fig. 3). The only significant effect of reconstruction techniques that we observed was an increased loss at the highest frequency (8 kHz) with the Large cartilage reconstruction. It may be that the cartilage plate acts as an additional mass that limits the high-frequency motion of the TM^{13,14}.

Effect of reconstruction technique on the sound-induced motion of the stapes

Our results demonstrate that while all of the reconstruction techniques increased the motion of the stapes relative to the ossicular interruption, the reconstructed middle ears (Fig. 4, Table 3) produced stapes motions that were on average 5 to 20 dB smaller than the motions in the control ears. The largest post-reconstruction stapes motions were observed in cases of Best or Loose fitting TORPs with a Small cartilage plate interfacing between the prosthesis head and the TM. Furthermore, the best results were observed with lower-frequency stimulation. This frequency dependence and the superior results of the Small cartilage reconstructions are the only commonality between the observed reconstruction-related decreases in motion of the TM and stapes, and it may be the two are causally related, since the decreased motion of the TM opposite the prosthesis head is the drive to the stapes. Correlation analysis comparing the reconstruction related changes in stapes velocity and TM volume displacements yield a Pearson's product-moment correlation coefficient of 0.526 consistent with a highly significant correlation ($p < 0.001$); however the value of the correlation coefficient suggests that only 25% of the variation in the normalized stapes velocity is explained by the variation in the normalized TM volume velocity.

Implications for middle-ear reconstructive surgery

The results of this analysis are similar to those suggested by others. The use of large cartilage plates in cases of PORP or TORP reconstructions may yield poor high-frequency hearing responses, because of the increased mass of the cartilage sheet^{13,14}. Loose or Best fitting prostheses produce superior acoustic results⁶; this may be related to the increase in tension at the TM and stapes footplate that results from a Tight fitting reconstruction. Our

observation that TORPS provide somewhat better results than PORPS may be due to angulation, where the prosthesis shaft of a TORP may be more perpendicular to both the footplate and the TM¹⁵.

The general conclusion of this work is that the performance differences between the different reconstructions is generally small (on the order of 5-10 dB) except at frequencies less than 1 kHz, where the Loose and Best fit reconstructions are superior in stapes motion, and at frequencies above 4 kHz, where the Large cartilage leads to significantly larger losses in stapes motion. The data also suggest the type of reconstruction has little effect on the displacement of the TM with stimulus frequencies of 1 kHz and higher. A more detailed analysis of the effect of the different reconstructions on TM motion is being prepared, which will include estimates of the displacement of the cartilage by itself and comparisons between the motion of the cartilage and the stapes.

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Figure 1.

Schematic of a prepared left temporal bone with an implanted cartilage disk and PORP prosthesis. The view of the temporal bone is from the posterior aspect via the facial recess. The Holographic beam and sound stimulus are conducted down a speculum that is not sealed against the tympanic ring. A probe microphone is placed to measure the sound pressure at the tympanic ring.

Figure 2.

The magnitude and phase angle of the displacement of the surface of the tympanic membrane measured in one temporal bone, at two frequencies and four measurement conditions. The top two rows are the magnitudes and phase of the displacement of TB04 in response to a 1 kHz continuous stimulus. The bottom two rows are the same in response to an 8 kHz stimulus. The magnitudes are presented as the dB value of the transfer function (microns/Pa) with 1 micron/Pa as the reference. The angles are coded in radians of phase relative to the motion of the umbo. The four columns arranged left-to-right are for: (i) the control/intact ossicular chain condition, (ii) after incus removal, (iii) after reconstruction with a Large 0.5 mm thick cartilage disk and a Best fit PORP, and (iv) after reconstruction with a Small 0.5 mm thick cartilage disk and a Best fit TORP. Similar data were gathered in the other reconstruction conditions. The larger white ellipsoid traces the boundaries of the

TM. The interior white outline describes the position of the manubrium of the malleus. The black ovals in column iii & iv outline the Large and Small cartilage respectively.

Figure 3.

Change in the sound-induced volume displacement of the TM produced by the different reconstructions. The ordinate scale codes the dB change in volume displacement relative to the mean measurement made with an intact ossicular chain. Positive dB values code for increases in displacement after reconstruction, negative values code for decreases in displacement. There are four panels (one for each stimulus frequency), with three groups of bars (one for each fitting condition (Loose, Best, or Tight)). Within each group are four bars: The two blue bars code PORP reconstructions, the two red bars code TORP reconstruction, the two solid bars code for the Small cartilage disk, the two striped bars code for the Large cartilage disk. Each bar illustrates the results from three temporal bones: The median value of the three is coded by the bar length; the whiskered line covers the range (maximum to minimum) of the three values.

Figure 4.

Change in the sound-induced stapes velocity produced by the different reconstructions. The ordinate scale codes the dB change in velocity relative to the mean measurement made with an intact ossicular chain. Positive dB values code for increases in velocity after reconstruction, negative values code for decreases. There are four panels (one for each stimulus frequency), with three groups of bars (one for each fitting condition (Loose, Best, or Tight)). Within each group are four bars: The two blue bars code PORP reconstructions, the two red bars code TORP reconstruction, the two solid bars code the Small cartilage disk, the two striped bars code for the Large cartilage disk. Each bar illustrates the results from three temporal bones: The median value of the three is coded by the bar length; the whiskered line covers the range (maximum to minimum) of the three values.

Table 1

Results of Paired t-Tests investigating the Difference between the Small and Large cartilage on the change in volume displacement of the TM each of the four stimulus frequencies

Frequency (kHz)	Mean Change in Displacement Small Cartilage	Mean Change in Displacement Large Cartilage	degrees of freedom	Two-tailed probability, <i>p</i>
0.5	-4.23 dB	-6.34 dB	17	0.172
1	-3.52	-5.11	17	0.161
4	-6.01	-7.93	17	0.153
8	-4.22	-10.62	17	<0.001

Table 2

Three-Way ANOVAs of Stapes Velocity Data

Factors	pLoHi	pSCvsLc	pPvsT	pFit
<i>ScLc, PvsT, Fit</i>	–	0.0180	ns	0.0297
<i>LoHi, ScLc, PvT</i>	<<0.001	0.0057	0.0481	–
<i>LoHi, PvT, Fit</i>	<<0.001	–	0.0454	0.0074
<i>LoHi, ScLc, Fit</i>	<<0.001	0.0047	–	0.0067

Table 3

Paired t tests of Stapes Velocity data

Factors	Mean 1	Mean 2	degrees of freedom	two-tailed <i>p</i>
Best Fit vs Loose Fit	-10.7	-10.8	47	<i>ns</i>
Best Fit vs Tight Fit	-10.7	-16.7	47	<0.0005
Loose Fit vs Tight Fit	-10.8	-16.7	47	0.0011
PORP vs TORP	-14.5	-11.0	71	0.0031
Small vs Large Cartilage	-10.2	-15.3	71	<0.0001
Low Frequency vs High	-6.0	-19.5	71	<0.0001