New Total Ossicular Replacement Prostheses With a Resilient Joint: Experimental Data From Human Temporal Bones

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Hypothesis: New flexible total ossicular prostheses with an integrated microjoint can compensate for large static displacements in the reconstructed ossicular chain. When properly designed, they can mimic the function of the joints of the intact chain and ensure good vibration transfer in both straight and bent conditions.

Background: Prosthesis dislocations and extrusions are frequently observed after middle ear surgery. They are mainly related to the altered distance between the coupling points because of large static eardrum displacements.

Methods: The new prostheses consist of 2 titanium shafts, which are incorporated into a silicone body. The sound transfer function and stapes footplate displacement at static loads were evaluated in human temporal bones after ossicular reconstruction using prostheses with 2 different silicones with different hardness values. The stiffness and bending characteristics of the prostheses were investigated with a quasi-static load.

Results: The sound transfer properties of the middle ears with the prostheses inserted under uncompressed conditions were comparable with those of ears with intact ossicular chains. The implant with the soft silicone had improved acoustic transfer characteristics over the implant with the hard silicone in a compressed state. In the quasi-static experiments, the minimum medial footplate displacement was found with the same implant. The bending characteristics depended on the silicone stiffness and correlated closely with the point and angle of the load incidence.

Conclusion: The titanium prostheses with a resilient joint that were investigated in this study had good sound transfer characteristics under optimal conditions as well as in a compressed state. As a result of joint bending, the implants compensate for the small changes in length of the ossicular chain that occur under varying middle ear pressure. The implants require a stable support at the stapes footplate to function properly.

Key Words: Middle ear mechanics—Ossiculoplasty—Total ossicular replacement prostheses.


The middle ear conducts acoustic stimuli effectively and functions as a sensitive static pressure receptor as well (1). The vibration amplitude of the intact ossicular chain ranges from the scale of molecular dimensions (acoustic stimulation) to movements visible to the naked eye (during swallowing, pneumatic otoscopy, and tympanometry). Nevertheless, only acoustic function is generally considered, whereas static ossicular micromechanics often are neglected by the ear surgeons and engineers involved in designing prostheses.

Reconstruction with a total ossicular replacement prosthesis (TORP) is indicated in cases of a destroyed or severely defective stapedial arch. The ossicular chain, which has 2 joints, is replaced with a rigid implant that connects the tympanic membrane or malleus handle directly to the stapes footplate. Sufficient rigidity of the middle ear implant is essential for good sound conduction. However, the intact ossicular chain is nonrigid under static air pressure variations. Because of the gliding motions within the joints, the medial movements of the stapes are reduced, thereby protecting the inner ear from excessively high static loads (2). Therefore, according to
Ringeval et al. (3), “the ideal ossicular implant should not only provide good transmission but also be flexible enough to absorb strong pressure shocks.”

The handling and biocompatibility of middle ear prostheses have improved significantly in recent years (4,5). Generally, most of the tested TORPs display excellent vibroacoustic characteristics in temporal bone models. However, in practice, even good short-term postoperative results frequently deteriorate with time. Persistent Eustachian tube dysfunction with negative pressure development in the tympanic cavity is a common problem in ears with prostheses. The severely retracted eardrum pushes the TORP and the stapes footplate medially. Increased tension in the reconstructed chain because of the “too long” prosthesis under altered static conditions leads to the attenuation of acoustic vibrations (6).

Prosthesis migration and extrusion, well-known complications after middle ear surgery, also are related to the large loads at the implant coupling points in response to varied static conditions. Considering that the distance between the coupling points often changes postoperatively because of the effects of healing, scar tension, ambient, and middle ear pressure variations, it would be desirable to have the prosthesis with constant tension after middle ear surgery (7).

The large inward displacements of the tympanic membrane, together with the coupled prosthesis, might be related to the risk of cochlear damage (3,8). A stapes footplate previously weakened by chronic irritation or foreign body reaction can predispose the dislocation of the prosthesis into the vestibulum (9). Few clinical reports have addressed this grave complication (9–11); however, because of the significant impact such events would have on hearing, any potential risk of this complication should be minimized.

Previously, a prosthesis with a self-adjusting length that incorporated a microjoint was considered a valid mechanical solution to the compensation of static eardrum displacements (12). New titanium TORPs with a resilient joint have been developed in the Dresden Middle Ear laboratory and built in collaboration with the Heinz Kurz company (Dusslingen, Germany). The aim of the present experimental study was to investigate the sound transfer function and static performance of the TORPs in a human temporal bone model using laser Doppler vibrometry and a microphone at the sealed round window. The bending characteristics of the prostheses and the stability of the implant joint under compression also were investigated.

**MATERIALS AND METHODS**

**Prostheses Design**

The new prostheses are split TORPs made of pure titanium (ASTM F67 Medical Grade). The ball-ended shafts of the 2 parts are incorporated into a silicone body. Two types of medical silicone with different Shore hardness (soft and hard) were used (Alpina, Munich, Germany). The 2 types of prostheses will hereafter be referred to as TORPsoft and TORPhard (Fig. 1). A conventional titanium Duesseldorf-type TORP was used for comparison (Heinz Kurz Co., Dusslingen, Germany). Prostheses of 4.5- and 4.75-mm total length were available; the new prostheses had a varying upper shaft length (1.5 or 1.75 mm).

When the force acts directly along the axis of the prosthesis, the prosthesis remains straight; however, it buckles at higher static loads. Forces applied eccentrically or at an angle to the prosthesis axis cause the bending of the prosthesis (Fig. 1). The silicone body acts as spring-damper element, restoring the initial straight condition if the load is released.

**Prostheses Bending Characteristics**

Prosthesis stiffness was tested with a quasi-static (i.e., slowly varying) load. The prostheses were glued at the foot to a rigid block, and force was applied at 3 locations on the prosthesis plate (center, midpoint, and edge) at 3 angles (0, 10, and 20 degrees) to the vertical axis of the prosthesis (Fig. 2). These load conditions represent the different insertion angles and attachment points of the prosthesis plate to the malleus handle because of varying middle ear anatomy. Measurements were repeated 10 times for each combination of prosthesis, load incidence, and angle.

Force was measured by a force cell (KA-S 0.2, A.S.T., Dresden, Germany), and the displacement of the point of load incidence was measured with a laser Doppler vibrometer (OVF-302, OVF-3000, Polytec PI, Waldborn, Germany). Loads...
Temporal Bone Preparation

A total of 10 frozen adult human temporal bones were used. The temporal bones were obtained within 48 hours after the death of the patient using a Schuknecht saw (mean age of the patients at death, 70.6 yr). The specimens were deep frozen at −25°C. Immediately before the experiments, the specimens were slowly thawed and dissected. Microscopically, the external ear canals and middle ears were without any pathologic changes. The middle ear cavity was opened with posterior tympanotomy and hypotympanotomy approaches, leaving the cochlea intact. The bone around the round window niche was partially drilled to permit microphone measurements. The round window was then drilled into the anterior bony canal wall (except for the specimens for the quasi-static experiments), and a probe microphone was placed in front of the tympanic membrane. During the experiments, the specimens were kept constantly moistened with physiologic saline solution.

Three temporal bones were used for the static experiments. In these specimens, the inner ear was opened, exposing the stapes footplate from the vestibular side. Reflective foil was placed on the center of the stapes footplate. A silicone tube was glued to the bony part of the external ear canal and connected to a pressure pump.

Measurement of Transfer Function

The experimental setup for middle ear transfer function measurements is presented in Figure 3. The sound source (E-A-RTONE 3A; Aearo Technologies, St. Paul, MN, USA) was inserted into the ear canal. The reference sound pressure was measured with the probe microphone (ER7c; Etymotic Research, Elk Grove Village, IL, USA) at approximately 3 mm in front of the center of the tympanic membrane. Displacement of the stapes footplate was obtained with a laser Doppler vibrometer. These measurements followed the ASTM F 2504-05 standard. The radiated sound pressure at the round window was measured in a sealed cavity with a small microphone (KE 4; Sennheiser, Wennebostel, Germany). This method has already been used for middle ear response measurements (13) and is well suited for cases of middle ear reconstruction with TORPs, for which access to the footplate is restricted. The first method was used with 2 specimens and the second method with 5 specimens.

Measurements were performed with a PC with a data acquisition board (DSP2200) and software based on LabVIEW (National Instruments, Austin, TX, USA). We used pure tone stimulation with frequencies from 0.1 to 5 kHz in steps of 100 Hz at sound pressure level of 94 dB. The sound pressure level was kept constant in front of the umbo. The response of the middle ear system was measured in terms of the displacement of the stapes footplate (the center point in the normal direction of the footplate) and radiated sound pressure at the round window, each with reference to the sound pressure in front of the tympanic membrane.

After completing the baseline measurements in the intact temporal bones. These data were used as the baseline and calibration for further investigations within the same specimen. This means that the transfer function of the reconstructed middle ear was divided by the transfer function of the intact middle ear of the same specimen. This method allowed us to compare the reconstructions using different specimens and measurement methods and also avoided the need to calibrate the microphone at the round window cavity.

One ossicular chain was reconstructed with prostheses that were 0.25 mm longer than the optimal length. The insertion of the prostheses caused pretension of the ossicular chain (annular ligament) and bending of the flexible prostheses. The degree of pretension and bending depended on the stiffness of the prosthesis.

Quasi-Static Measurements

The experimental setup for the quasi-static measurements is presented in Figure 4. The pressure pump was connected to the tube at the ear canal. The pressure in the external ear canal varied continuously between −4 and +4 kPa and was measured with a pressure sensor (GDH 12AN, Greisinger electronic, Regenstauf, Germany). Stapes footplate displacements were measured using the laser Doppler vibrometer. The quasi-static pressure-induced stapes footplate displacement in the intact middle ear was measured first. The incus and stapes superstructure were then removed. The chain was successively reconstructed with the conventional TORP and the 2 flexible TORPs, and the measurements were repeated. The
measurements were performed with 3 specimens in total. In all the specimens, the prostheses were inserted between the distal one-third of the malleus handle and the center of the stapes footplate. The test-retest reliability of the static experiments was rather high, with a displacement measurement variation of approximately 15%.

RESULTS

Bending Characteristics

The bending characteristics of the flexible TORPs were evaluated on the basis of the measured force-displacement diagram, where the applied force is plotted against the displacement of the point of load incidence (Fig. 5A). Buckling and slippage within the joint could be clearly observed in the cases of off-center force application (Fig. 5B). In the force-displacement diagram, the slippage seems as a vertical force drop, indicated by the arrow in Figure 5A. The implant did not return to its initial shape when the slippage occurred.

To account for all occurrences within the joint, the 2 types of flexible TORPs were compared in terms of their overall stiffness (maximum applied force divided by maximum displacement of the point of load incidence). In the cases of buckling and slippage within the joint, the overall stiffness was significantly lower than the initial stiffness obtained by the slope of the force-displacement curve (Fig. 5A).

With the point of load incidence at the center of the prosthesis plate, no obvious buckling or slippage could be observed. The flexible implants acted like conventional TORPs. The stiffness values were between 7,000 and 50,000 N/m, and there was no statistically significant difference between the prostheses (Fig. 6A).

In all the cases of off-center force application, bending of the implants at the joint region could be clearly observed, and the stiffness decreased significantly. The overall implant stiffness was then overwhelmingly determined by the stiffness of the silicone. There was a statistically significant difference between the 2 types of flexible TORPs (TORPsoft and TORPhard); TORPsoft had a much lower overall stiffness than TORPhard in all cases (Fig. 6, B and C). The stiffness decreased when the load was moved from the midplate position to the edge of the prosthesis plate, and it also decreased with increases in the angle of the applied load. The highest degree of stiffness (mean value, 55 N/m) was exhibited by the TORPhard with the force applied at a midplate position at a 0-degree angle. The lowest degree of stiffness (mean value, 1 N/m) was measured for TORPsoft with the force applied at the edge of the plate at a 20-degree angle.

Static Performance

Figure 7 shows the displacement of the stapes footplate over the pressure at the external ear canal for intact ossicular chains and for reconstructed middle ears using normal and flexible TORPs. When slowly increasing pressure is applied at the ear canal of a specimen with an intact ossicular chain, the degree of stapes footplate displacement quickly approaches a nearly constant value. We measured a mean displacement of approximately 6 μm for a pressure of up to 4 kPa. Reconstructed middle ears with the flexible TORPs also showed this nearly constant stapes footplate displacement with increasing pressure; however, displacement in the middle ears with TORPs was higher than for the intact ossicular chains. Stapes footplate...
displacement reached an average maximum value of 12 µm for TORPsoft and 26 µm for TORPHard. Reconstructed middle ears with normal TORPs exhibited a less decreasing slope of the displacement-pressure curve, and the average maximum displacement was approximately 50 µm. The maximum displacement at 4 kPa was significantly different between the intact ossicular chains and all the reconstructed chains as well as between the different types of TORPs.

The results of the quasi-static temporal bone experiments reflect the bending characteristics of the different TORPs. The more flexible TORPsoft caused less stapes footplate displacement with quasi-static pressure changes than did TORPHard. Ossicular chain reconstructions with the flexible TORPsoft exhibited static behavior very similar to that of the intact ossicular chain.

### Sound Transfer Properties

The frequency transfer functions (FTFs) of intact middle ears and of reconstructed ears with conventional and new flexible TORPs were measured. The transfer functions of the reconstructed middle ears were calculated as gain with reference to the transfer function of the corresponding intact middle ears: 20 * log (FTF of the reconstructed chain / FTF of the intact chain). Thus, the 0-dB line in Figure 8 corresponds to the transfer function of the intact middle ear. Reconstructed middle ears with TORPs of optimal length inserted in a straight configuration yielded transfer functions very close to those of the intact middle ear. The average maximum difference from the intact middle ear was approximately 5 dB. The variations between measurements were within ±5 dB. Reconstructions with the conventional TORP and with TORPHard showed a slightly better transfer function; however, the differences between the reconstructions with prostheses in a straight configuration were not statistically significant.

For 1 temporal bone specimen, TORPs of nonoptimal length were used for reconstruction, resulting in pretension within the ossicular chain with the normal TORP and bending of the flexible TORPs. The corresponding transfer functions are marked as “compressed” in Figure 8. The transfer functions of these compressed TORPs were 5 to 20 dB worse than those of TORPs with a straight configuration at frequencies between 100 and 4,000 Hz. The more flexible TORPsoft reconstruction provided better...
Sound transfer functions under large transient pressure changes are similar to those under compressed conditions. The force acting on the prosthesis results from the pressure gradient across the tympanic membrane. The compressed condition of a prosthesis 0.25 mm longer than optimal corresponds to approximately 0.3 kPa under pressure in the middle ear (assuming a 50 mm² area of the tympanic membrane; TORP contact at midpoint at a 10-degree angle producing a stiffness of approximately 30 N/m; and 50% of the load born by the tympanic membrane, the force acting on the prosthesis will be 7.5 mN, inducing a 0.25 mm displacement of a TORPsoft).

Under compression, the upper titanium ball of the prostheses glided on the surface of the lower ball within the silicone body. The latter held the titanium balls together and allowed a wide range of flexion in all directions. The flexibility of the implant and the stability of the titanium balls within the joint depended to a great extent on the hardness of the silicone.

It is important to note that the slender shafts of the prostheses allowed the complete visualization of their lower parts as well as the stapes footplate. However, under higher static loads, the silicone bodies did not hold the titanium parts tightly within the joint. Lateral and even inferior dislocations between the titanium balls occurred at some off-center force application positions (Fig. 5B). The soft silicone joint also may influence handling during reconstruction, as this new prosthesis will provide less stable support for tympanic membrane reconstruction and will therefore require a more skillful approach by the surgeon.

In clinical studies, almost all cases of prosthesis extrusions were related to eardrum retractions and atelectasis (10,17). The negative pressure in the middle ear can cause the head of the prosthesis to exert increased pressure against the tympanic membrane, causing ischemia and necrosis (18). The overlaid cartilage can be displaced or resorbed over time. Relieving the tension in the reconstructed chain with the new generation of flexible implants might prevent prosthesis extrusion.

Several previous attempts have been made to construct prostheses that are self-adjusting in length, automatically adapt to middle ear pressure and corresponding dimensional changes, and compensate for large static eardrum displacements (7,8,15,16). Simulations with a finite element model of the middle ear showed that prostheses with pure springlike elements are usually either too soft, resulting in poor dynamic transfer characteristics, or too stiff, causing high pretension in the reconstructed middle ear (12). In the intact middle ear, 5-mN forces within the ossicular chain stiffen the annular ligament by a factor of 5 and reduce the middle ear transfer function by as much as 10 dB. If a prosthesis is designed with a soft spring element allowing for an approximately 0.5 mm change in prosthesis length at 5 mN, there will then be a middle ear transfer function drop of approximately 20 dB (because of the soft prosthesis). We therefore preferred to use the silicone-bending element in our design. It produces viscoelastic behavior in the prosthesis (visible in

FIG. 8. Curves of the sound transfer gain (in decibels) for new flexible prostheses and rigid conventional TORP under uncompressed and compressed conditions. The 0-dB line corresponds to the transfer function of the intact middle ear. Means (of 6 measurements) and standard error bars for the means are shown for the reconstructions with the different TORPs in the uncompressed (straight) condition.

DISCUSSION

Under experimental conditions, nearly all TORPs conduct sound as effectively as the normal ossicular chain. On the other hand, the clinical outcome of TORP-ossiculoplasty is far from optimal in many cases. In the present investigation, we focused on the problem of prosthesis functioning under a changing static load and continued developing a bendable TORP with automatic length adjustment (15,16). It is probable that both middle ear types (those with 3 ossicles and those with 1 ossicle) contain a mechanism to compensate for large static eardrum displacements (16). The avian conduction mechanism, with a joint-like connection between the bony columella and flexible cartilaginous extracolumella, provided the bionic idea for our new prosthesis design.

The sound transfer functions of the straight flexible prostheses were almost indistinguishable from those of the intact ossicular chains. We simulated increased tension in the reconstructed chain by using prostheses that were 0.25 mm longer than optimal. In this situation, the flexible prostheses bent at the microjoint without shaft dislocation. Generally, the implant with the soft silicone introduced less pretension in the reconstructed middle ear and had better sound transfer function at low frequencies. At high frequencies, the sound transfer function of all implants in the compressed condition improved. In our experiments, the rigid TORP that was 0.25 mm longer than optimal exhibited the largest drop in the sound transfer function, mainly below 2.0 kHz.

The prostheses with a soft silicone bending element allow a wide range of flexion in all directions. In the intact middle ear, 5-mN forces within the ossicular chain stiffen the annular ligament by a factor of 5 and reduce the middle ear transfer function by as much as 10 dB. If a prosthesis is designed with a soft spring element allowing for an approximately 0.5 mm change in prosthesis length at 5 mN, there will then be a middle ear transfer function drop of approximately 20 dB (because of the soft prosthesis). We therefore preferred to use the silicone-bending element in our design. It produces viscoelastic behavior in the prosthesis (visible in

the hysteresis loop in Fig. 5A), thus avoiding the drawbacks of pure springlike elements. Other functional, successful concept entailed the use of prosthesis with polyurethane sponge (7). The viscoelastic properties of the sponge combine spring and damping behavior in this prosthesis concept.

The quasi-static experiments showed that in reconstructions using the implant containing low-hardness silicone, the stapes footplate displacement was comparable to that of the normal middle ear. In middle ear reconstructions using the rigid TORPs, a footplate displacement higher by as much as 14 times was observed. We expect that the potential risk of damage to the annular ligament and the inner ear will be minimized with flexible prostheses, as they compensate for inward eardrum excursions.

In the present study, the stiffness of the bent prostheses depended on the stiffness of the silicone used and correlated closely with the angle and point of prosthesis exposure. When the forces were applied exactly at the center of the prosthetic plates, no bending movements were observed at the joints of the flexible implants. Forces acting eccentrically at the upper prosthesis plate are more likely to occur postoperatively. Stiffness was minimal when the quasi-static load acted at a 20-degree angle to the vertical axis of the prosthesis and was applied to the midpoint/edge of the upper plate of the implant. It should be noted that in all the quasi-static temporal bone measurements, flexion at the prosthesis microjoint was observed.

The present study suggests that implants with a resilient joint that allows length variability may be an alternative or even have an advantage over standard rigid TORPs, especially in problematic ears with chronic Eustachian tube dysfunction and in patients who are planning to continue leisure activities such as scuba diving. The current investigation showed that length variability could be achieved with a new prosthesis design. However, this length variability is limited because of variations in middle ear pressure, and this new prosthesis is not designed to compensate for anatomic variations that may require prostheses lengths of 3 to 7 mm.

CONCLUSION

The new flexible TORPs have good acoustic characteristics under normal conditions. They show good transfer function quality under compression. The flexible TORPs can compensate for small changes in length (approximately 0.25 mm) of the ossicular chain. However, they require a stable support at the footplate, such as a cartilage “shoe” (14) or omega connector (19), for proper functioning. The flexible joints can thus far not be incorporated into partial ossicular replacement prostheses because of their limited design space. Silicone of a lower hardness should be incorporated into the joint to decrease the tension in the reconstructed chain. The new implants functioned well in quasi-static experiments. Joint bending allowed the prostheses to compensate for eardrum inward excursions. The stiffness of the implants depends on the stiffness of the silicone and correlates closely with the point and angle of load incidence.

These initial results from the new prostheses are promising, but further development is required to extend these results.

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