The Laryngoscope

A Partial Ossicular Replacement Prosthesis With a Concentric Ball Joint in the Headplate

Nicholas Bevis, MD; Thomas Effertz, PhD; Dirk Beutner, MD

Objective: In passive middle ear prosthetics, rigid implants have proven successful in reconstructing the ossicular chain. However, these cannot fully replicate the physiology of the ossicular chain. Pressure fluctuations cause high stresses in rigid passive prostheses, which can result in dislocation, protrusion, and pre-tension in the annular ligament resulting in unsatisfactory hearing results.

Methods: In collaboration with MED-EL, we developed a new passive middle ear prosthesis that features a balanced, centered ball joint between the headplate and shaft of the prosthesis. We compared the sound transmission properties of this new prosthesis with those of a standard rigid prosthesis. Using Laser-Doppler-Vibrometry, we measured the sound-induced velocity of the stapes footplate relative to a given acoustic stimulus.

Results: The new prosthesis showed equivalent sound transmission characteristics compared to the rigid prosthesis, whereas retaining the ability to compensate for pressure fluctuations due to its ball joint. This ensures good transmission properties even during displacements of the tympanic membrane.

Conclusion: This development is a further step toward a physiological reconstruction of the ossicular chain.

Key Words: ball joint, Laser-Doppler Vibrometry, middle-ear prosthesis, partial ossicular replacement prosthesis.

Level of Evidence: NA

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INTRODUCTION

Chronic middle ear disease, among others, can cause damage to the ossicular chain and affect sound transmission.[1] In reconstructive tympanoplasty, a secure connection between the ossicles without additional stress is critical for adequate sound transmission.[2] However, postoperative hearing outcome is often compromised by factors such as the rigidity of conventional ossicular replacements and postoperative scarring.[3]

The incudo-malleolar joint (IMJ) is important for balancing pressure fluctuations in the middle ear.[4,5] In ossicular reconstructions, the IMJ is frequently sacrificed, resulting in loss of natural ossicular chain motion and physiologic sound transmission. In addition, pressure on the contact surfaces of rigid implants can result in the protrusion of the prosthesis. Therefore, an optimized implant design that mimics the physiological function of the ossicular chain would be beneficial and could be better adapted to the complex, varying shape of individual middle-ear structures.

To avoid dislocations of prostheses, it is essential to consider the forces and loads acting on the ossicular chain, which are mainly due to non-acoustic, air pressure changes.[6,7] This aspect was considered in the development of recent middle-ear prostheses.[8–11] Using a ball joint has become increasingly popular, as it combines the beneficial properties of a rigid prosthesis with good coupling properties, whereas still ensuring stability during pressure changes.[11–13] In this study, we developed a prosthesis that is equipped with a centered ball joint between prosthesis plate and prosthesis shaft that can mimic the physiologic properties of the ossicular chain.

MATERIALS AND METHODS

Prosthesis

Using an established, proven clip design for coupling the prosthesis to the stapes head[14] we developed, together with MED-EL, a new passive ossicular prosthesis equipped with a 0.5 mm centered ball joint (mCLIP ARC Partial Prosthesis, MED-EL, Fürstenweg 77a, 6020 Innsbruck, Austria). The prosthesis is made of titanium. Connecting headplate and shaft, the ball joint allows the headplate to rotate and deflect relative to the shaft. As a result, the ball joint ensures sufficient coupling to the tympanic membrane (TM) during pressure changes. We adjusted the ball joints stiffness/friction during the development process to be less rigid than the physiological IMJ, described to be 100–250 N/m.[15] For temporal bone measurements, we use a prosthesis length of 3.1 mm, whereas the functional length (length of shaft plus headplate) is 1.5 mm (Fig. 1).

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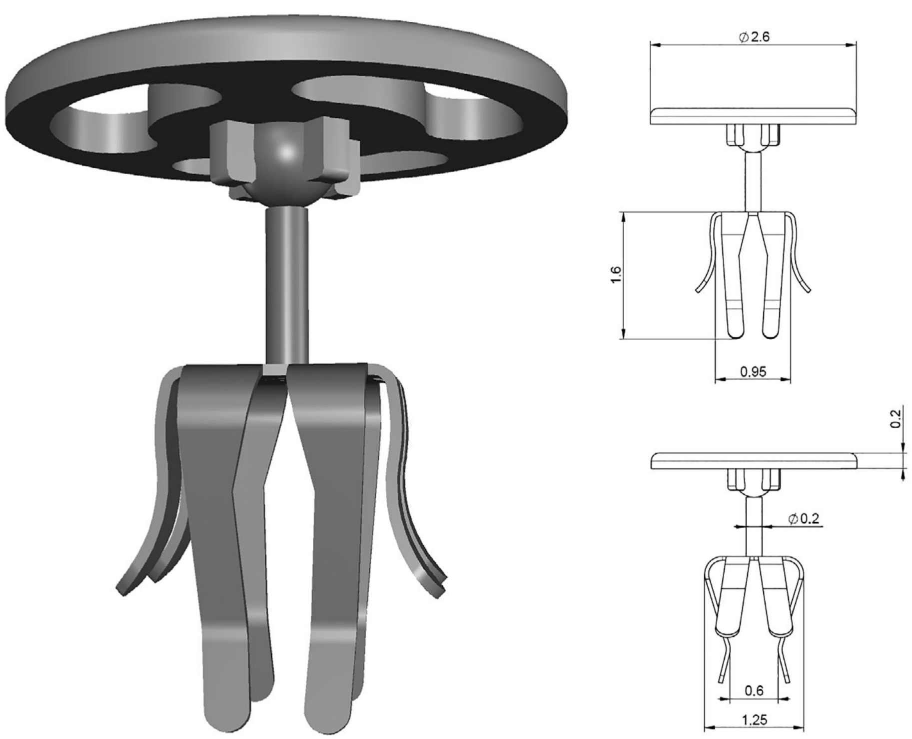


Fig. 1. 3-D rendering of the new ball joint prosthesis (left) and the correlating dimensions in mm (right).

We used temporal bones from body donors to assess the intraoperative handling by comparing the new prosthesis with a conventional rigid prosthesis (mCLIP Partial Prosthesis, MED-EL Medical Electronics, Fürstenweg 77a, 6020 Innsbruck, Austria). This included clipping and unclipping the stapes head and testing stability during and after reconstruction. Six ear surgeons with varying experience tested the subjective manageability of the prosthesis. Handling of the three assessment categories (clipping, unclipping, stability) were rated in five grades: 1 (*very good*), 2 (*good*), 3 (*moderate*), 4 (*poor*), and 5 (*very poor*).

Temporal Bone Preparation

Six temporal bones were frozen postmortem without preservatives according to the recommendations of the American Society for Testing and Materials (ASTM F2504-05)[16,17] and individually thawed immediately before measurements. We obtained the institutional review board (IRB) approval from the local ethics committee of the University of Goettingen. During measurements, the temporal bones were kept moist with a saline solution. Temporal bone preparations were performed with a surgical microscope (OPMI Sensera, Carl Zeiss Germany) and an endoscope (HOPKINS 30°, 2.7 mm, 18 cm, Karl Storz Germany). The middle ear was accessed via a posterior tympanotomy so that the ossicular chain and stapes footplate were easily accessible and could be manipulated. A reflective foil was placed on the stapes footplate. After laser Doppler vibrometer (LDV) measurements on the intact ossicular chain, we separated the IMJ and removed the incus to perform type III tympanoplasty with the rigid prosthesis first. We then covered the headplate of the prosthesis with a thin cartilage plate and coupled it to the TM.[18,19] All preparations were performed through the facial recess, without elevating a tympanomeatal flap. We performed tympanoplasty using both the rigid prosthesis and the ball joint prosthesis (Fig. 2).

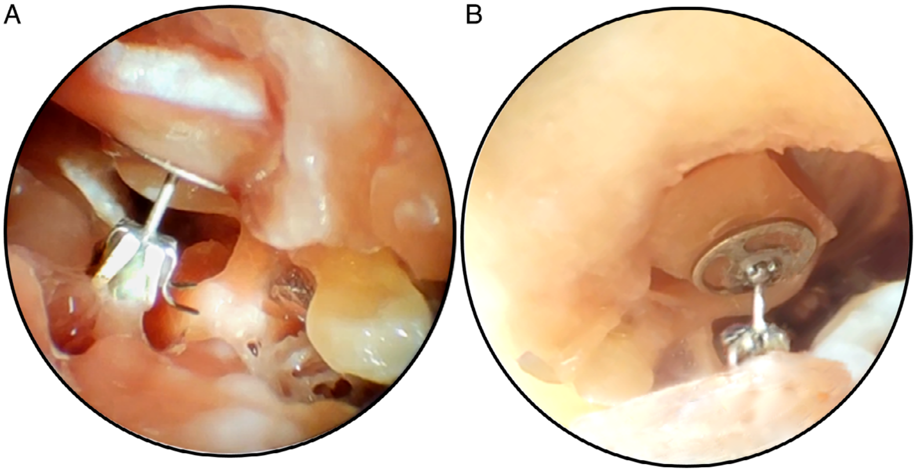
Experimental Setup

The experiments were carried out on a CleanBench™ vibration-isolation table (TMC, Peabody, MA, USA). A closed earpiece was fitted in the outer ear canal and fixed with two-component adhesive. A silicone tube containing a sound source (ER-2, Etymotic Research, Elk Grove Village, IL, USA) and a microphone (ER-7C, Etymotic Research, Elk Grove Village, IL, USA) were located in the closed earpiece. A LDV (CLV 1000, Polytec GmbH, Waldbronn, Germany) mounted on a surgical microscope with a micromanipulator-controlled prism was focused on a reflector foil positioned on the stapes footplate between the posterior and anterior crus. The acceleration of the stapes footplate was recorded with the LDV through the facial recess during sound stimulation. An exponential chirp (from 100 to 10,000 Hz) was used as stimulus.

To simulate a sudden pressure change, the ear canal was fitted with a closed earpiece and pressure was build up from -300 to 300 daPa by an Interacoustics Titan tympanometer (Interacoustics Titan, Audiometer Allé, 5500 Middelfart, Denmark) after LDV-measurements were completed on each prosthesis ($n = 6$). During this pressure cycle, we observed the movement of both prostheses by an otologic endoscope through the facial recess (see Videos S1 and S2).

The stiffness of the ball joint prosthesis as well as the rigid prosthesis were tested in load cell experiments (KA-S/2N/0.2 Angewandte System Technik GmbH, Dresden). The headplate rim of each prosthesis was positioned on the load cell and the prosthesis was pushed against the load cell by a micromanipulator (HS-6 WPI). We recorded the deflections (displacement in µm) of the opposite headplate rim and the forces acting on the load cell (in mN) simultaneously. We moved the prosthesis by up to 400 µm toward the load cell and then returned it to the starting position. We performed the load cell experiments on three prostheses of each type.

Data were recorded using Polytec software (VibSoft Data Acquisition Software) and plotted on a logarithmic scale. Results were analyzed using Origin Pro 8.2 (OriginLab Corporation, Northampton, MA, USA). Graphs were presented as mean values or in relation to measurements. Unless otherwise stated,



Rigid Prosthesis

Ball Joint Prosthesis

Fig. 2. Type III tympanoplasty with a rigid prosthesis (A) and the new ball joint prosthesis (B).

analysis was performed on six individual samples. No replicated measurements were made on the individual specimens. Data were analyzed using an unpaired *t*-test assuming normal distribution or by Wilcoxon-signed rank test. A *p*-value of at least <0.05 was considered significant.

RESULTS

Deformation Properties

The continuous increase in force subjected on the prosthesis results in the displacement of the headplate in the ball joint prosthesis as well as in the rigid prosthesis. Forces required to move the headplate 50 μm averaged 31.59 N/m ($n = 3$) for the ball joint prosthesis, whereas the rigid prosthesis required an average of 1135.43 N/m ($n = 3$). After application of force, the headplate of the ball joint prosthesis could be returned to its original position.

Prosthesis Behavior During a Pressure Cycle

During a pressure cycle ranging −300 to +300 daPa in the ear canal, all ball joint prostheses adapt to the movement of the TM and ensures full contact of the cartilage chip with the prosthesis headplate at all times ($n = 6$) (see Video S1). The rigid prosthesis, on the contrary, loses contact with the cartilage plate located underneath the TM ($n = 6$) (see Video S2).

Laser-Doppler Vibrometry

All middle-ear transfer functions (METF) of the temporal bones largely fall within the range indicated by the ASTM standard.[17] After reconstruction of the ossicular chain, the LDV experiments show that the ball joint prosthesis has similar sound transmission characteristics to the rigid prosthesis. When comparing stapes footplate velocities at different frequencies, the ball joint prosthesis shows a trend for better transmission characteristics around 1000 Hz with 4.29E−05 m/s/Pa (range: 2.23E−05 to 8.27E−05) against the rigid prosthesis with 4.18E−05 m/s/Pa (range: 1.84E−05 to 9.49E−05). At 2000 Hz, the ball joint prosthesis shows velocities of 1.56E−05 m/s/Pa (range: 6.53E−06 to 3.72E−05) compared to the rigid prosthesis with 1.38E−05 m/s/Pa (range: 6.93E−06 to 2.74E−05), which drop to 4.26E−06 m/s/Pa (range: 1.40E−06 to 1.29E−05) compared to 5.15E−06 m/s/Pa (range: 1.87E−06 to 1.42E−05). Measurements show no significant difference between the two prostheses (using a Wilcoxon signed-rank test, $p < 0.05$, 100–5000 Hz; $n = 6$) (Figs. 3 and 4).

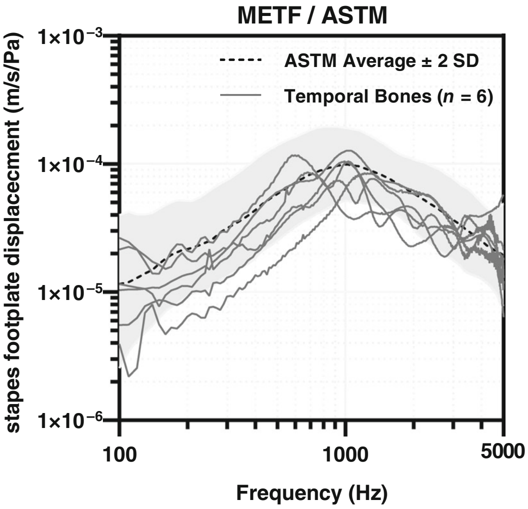


Fig. 3. Middle-ear transfer functions (METF) of each of the six measured temporal bones (grey lines), in comparison to the ASTM F2504-05 standard (dashed line) with the corresponding ±2 standard deviation (grey area).

Simulated Intraoperative Handling

Middle ear surgeons with varying experience performed reconstructions. In the handling tests, the ball

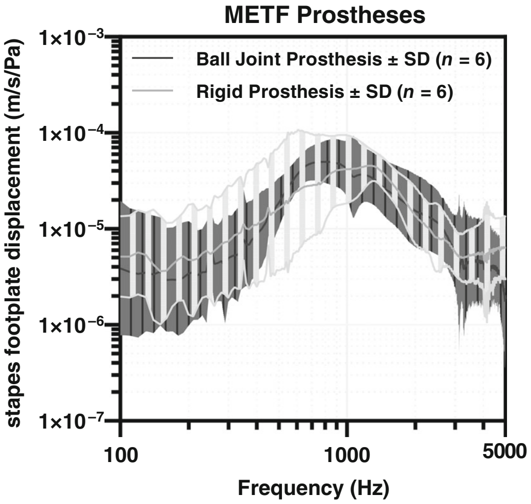


Fig. 4. Averages of middle-ear transfer functions (METF) of the ball joint prosthesis (black line) and the rigid prosthesis (grey line) between 100 and 5000 Hz with standard deviation (area with bars in correlating color). The two prostheses do not differ significantly over the frequency range shown (Wilcoxon-signed rank test; $p > 0.05$; 100–5000 Hz).

joint prosthesis performed better than the rigid prosthesis. Surgeons noted that deflecting the prosthesis headplate allowed full visibility of the stapes footplate. In addition, deflecting the prosthesis allows small length variability during reconstruction. Due to the conical shape of the TM, all reconstructions resulted in an angle of 45–90° between the prosthesis shaft and the headplate. This resulted in a better coupling of the ball joint prosthesis. On a scale from 1 (*very good*) to 5 (*very bad*), the surgeons rated the new ball joint prosthesis 1.72 and the rigid prosthesis 2.00 ($n = 6$).

DISCUSSION

This study focuses on the development of a new prosthesis featuring a balanced, centered ball joint. The prosthesis is designed to ensure good transmission characteristics even in chronic middle ear disease. The ball joint allows the headplate to adapt to the individual anatomical features of the reconstructed TM. In our temporal bone experiments, the new prosthesis shows comparable sound transmission properties compared to a rigid prosthesis.

The ball joint of the new prosthesis allows for simplified intraoperative handling. With deflecting of the headplate, the prosthesis can be placed on the stapes head whereas giving full visibility over all anatomic structures, which in turn can prevent poor placement or traumatic luxation of the ligamentum anulare stapedis.[20]

The new prosthesis function is both individual and universal. Universal, as the functional length can be adjusted by deflecting the headplate. Furthermore, the freedom of movement in the ball joint allows the prosthesis to adapt to the individual, conical shape of the TM. We found that the prosthesis adapts better to the anatomic variations of the TM and umbo than the rigid prosthesis. This results in a larger contact area of the prosthesis headplate and thus better stability, which in turn could theoretically reduce the likelihood of protrusion. The flexible positioning of the headplate prevents tension along the prosthesis shaft and thus prevents pretension of the ligamentum anulare stapedis. With regard to the long-term stability of ball joints, in vitro studies[13] show negligible signs of abrasion due to the movement of the prosthesis.

The natural stiffness of IMJ is described as 100–250 N/m and can be as great as 1300–1500 N/m due to high-pressure changes.[15] One goal in the development of the prosthesis was to keep the frictional resistance of the joint as low as possible so that it could still support the dead weight of the headplate. On the other hand, the frictional resistance in the ball joint should be high enough to ensure sound transmission. The in vivo measurements (see Video S1) show that the ball joint prosthesis adapts to sudden ambient pressure changes and returns to its former position, whereas the rigid prosthesis loses contact to the cartilage plate.

When a conventional prosthesis is subjected to force, for example, due to sudden change of the ambient air pressure of the middle ear, the continuity of the reconstructed ossicular chain is at risk.[3] Moreover, pressure exertion on the ligamentum anulare stapedis can lead to worse hearing outcome[2,21,22] and chronic negative pressure can lead to protrusion of the headplate. The in vivo measurement (see Video S1) show that the ball joint prosthesis adapts to sudden ambient pressure changes and returns to its former position. The results should be considered preliminary due to the small number of temporal bones. Depending on the individual anatomy and position of the manubrium of the malleus, insertion under, or contact with the malleus is not always achieved. We recommend covering the prosthesis headplate with a thin cartilage plate to prevent extrusion. Moreover, adhesions could lead to limitation of mobility postoperatively. Therefore, the long-term stability of the prosthesis must be investigated in a clinical study.

To date, several middle ear prostheses have been developed to mimic the flexible properties of the ossicular chain.[7,11,12,23] Compared to other prostheses with an integrated ball joint,[11,13] the new prosthesis has a balanced, centered ball joint between the headplate and the prosthesis shaft. This gives the new ball joint prosthesis an advantage over other prostheses during reconstruction, as the dead weight of the headplate does not lead to deflection. The headplate can be moved in all directions, allowing greater freedom and easier reconstruction. In addition, the balanced design improves the placement of the prosthesis, allowing for a stable position of the headplate without it being deflected by its own mass, unlike the non-centered joint prostheses. This allows the surgeon to adapt the prosthesis to individual anatomical conditions. In addition, intraoperative handling is simplified by the effortless deflection of the headplate, giving the surgeon a clear view of the stapes footplate at all times.

CONCLUSION

The new prosthesis is suitable for reconstruction of the ossicular chain. The new design simplifies intraoperative handling and allows firm contact with the surrounding anatomical structures, especially during sudden changes in ambient air pressure. Compared to the rigid prosthesis, sound transmission measurements showed similar METF. The experimental results are now awaiting verification in a clinical trial.

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