Thomas Stoppe*, Matthias Bornitz, Nikoloz Lasurashvili, Kirsten Sauer, Thomas Zahnert and Thomas Beleites

Middle ear reconstruction with a flexible prosthesis

Abstract: The middle ear plays a crucial role in the quality of hearing. This complex construct performs different tasks like the protection against large air pressure input, the transmission of sound and its adaption to the inner ear impedance. Traumas, erosion by chronic otitis media or cholesteatoma, as well as other degenerative or damaging diseases, are reasons for a necessary reconstruction of specific middle ear structures. The reconstruction of the ossicular chain is very often performed by using rigid ossicular replacement prostheses made out of titanium, ceramics or bone. Tilting and dislocation of these passive implants are some of the known complications after middle ear surgery. They are related to loads at the implant coupling points in response to a tension change in the middle ear. The healing process, scar tension and ventilation problems are possible causes.

To increase the sound transmission quality of total reconstructions and safety in case of pressure dependent movement of the tympanic membrane, a novel flexible total ossicular replacement prosthesis (TORP) with a silicone coated ball joint prototype was developed and investigated. Besides measurements of first middle ear transfer functions of temporal bones, the mechanical properties of the flexible TORP were examined with stress relaxation investigations.

The novel silicone coated ball and socket joint TORP provides a sound transfer equivalent to the intact human middle ear at normal pressure and negative pressure in the middle ear. Together with the low stiffness values at an anatomically typical deflection of about 500 µm the prevention of a stiffening of the stapes annular ligament could be approved. Thus, improved acoustic transmission quality and reconstruction stability in comparison to common rigid titanium TORP could be determined. Nevertheless, further design improvements should be accomplished. The demonstrated flexible TORP can solve some common problems in middle ear reconstruction.

Keywords: middle ear reconstruction, ball and socket joint, flexible TORP

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***Corresponding author: Thomas Stoppe:** Technische Universität Dresden, Carl Gustav Carus Faculty of Medicine, Otorhinolaryngology, Fetscherstraße 74, 01307 Dresden, Germany, e-mail: Thomas.Stoppe@uniklinikum-dresden.de
Matthias Bornitz, Nikoloz Lasurashvili, Kirsten Sauer, Thomas Zahnert, Thomas Beleites: Technische Universität Dresden, Carl Gustav Carus Faculty of Medicine, Otorhinolaryngology, Fetscherstraße 74, 01307 Dresden, Germany

1 Introduction

In order to enable communication, mobility and orientation our hearing is besides vision the most important sense. The organ of hearing is usually divided into the external auditory canal, the middle ear and the inner ear. The part of the skull which surrounds the middle as well as the inner ear is called the temporal bone. The ear receives acoustic signals via the auditory canal, transmits them in a defined manner via the middle to the inner ear. There they're converted into electrical signals and transmitted to the brain via nerve fibers.

Traumas, erosion by chronic otitis media or cholesteatoma, as well as other degenerative or damaging diseases, are reasons for a necessary reconstruction of specific middle ear structures. The reconstruction of the ossicular chain, from the tympanic membrane/malleus to the stapes footplate, is very often performed by using rigid total ossicular replacement prostheses (TORP) made out of titanium, ceramics or bone. Their construction consists of a shaft, a head plate and a foot, so that a placement between the tympanic membrane/malleus and the stapes footplate for direct sound transmission is possible (see **Figure 1**). Tilting and dislocation of these passive implants are some of the known complications after middle ear surgery. They are related to loads at the implant coupling points in response to a tension change in the middle ear. The healing process, scar tension and ventilation problems are possible causes.

The ossicular chain in comparison has flexible joints, like the incudomallear joint (IMJ), allowing a defined

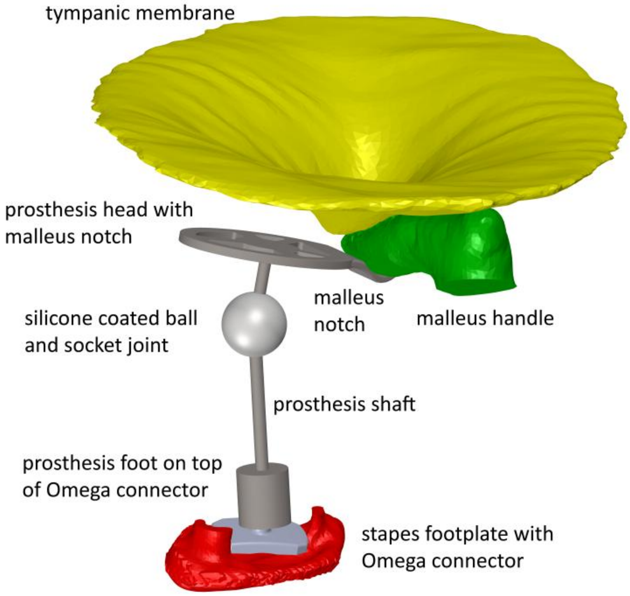

Figure 1: The novel flexible total ossicular replacement prosthesis (TORP) design and its placement in the ossicular chain; the notch of the TORP is attached at the malleus handle (green) and the prosthesis foot is placed onto the Omega connector (Heinz Kurz GmbH Medizintechnik, Dusslingen, Germany) on the stapes footplate (red) for a better stability

movement within the ossicular chain. With a simple rigid design, drawbacks in patient safety and acousto-mechanical function, due to the direct connection between tympanic membrane (about +/- 500 µm deflection range at typical quasi-static movement) and stapes footplate / annular ligament (about +/- 50 µm deflection range at typical quasi-static movement) seem obvious. The flexibility of the IMJ is said to reduce the load at the stapedial annular ligament at large quasi-static movement of the tympanic membrane. A stiffening of the stapes annular ligament may cause reduced signal transfer [1, 2, 3, 4]. The aim of developing a TORP being capable of compensating length variations is consequential.

2 Materials and methods

The new flexible TORP (see **Figure 1**) is based on a regular rigid TORP design (malleus notch prosthesis from the Heinz Kurz GmbH Medizintechnik, Dusslingen, Germany). A ball and socket joint was added between the prosthesis head and the prosthesis foot. It was coated with silicone, for implementing a viscoelastic component like in tissues, which also provides a reset force and joint stability. The titanium ball and socket joint (friction element) offers the necessary rigidity at low forces for the sound transfer [5], while it slides at larger forces, e.g. static pressure changes, to compensate length variations.

2.1 Stress relaxation setup

The mechanical behaviour in the quasi-static pressure regime of the new TORP design was investigated with stress relaxation tests on four flexible TORP. The prostheses shafts were fixed by clamping. No mobility of the TORP shafts could be observed. The initial measurement position (origin of z-coordinate) was defined at the notch of the TORP head (the coupling point to the malleus; see **Figure 1**).

Each measurement consisted of five deflection steps of 100 µm, leading to 500 µm total displacement (comparable to the umbo deflection range at negative pressure in the tympanic cavity), each followed by a relaxation phase (see **Figure 2**).

The positioning and deflection was applied via the piezo actuator Eppendorf Mikromanipulator 5171 (Eppendorf AG, Hamburg, Germany) and a rigid needle tip with a smoothed cylindrical ending. The resulting force was measured with a KA-S load cell at an AE 703 amplifier (both A.S.T. GmbH, Dresden, Germany). The deflection was measured with a triangulation laser optoNCDT1402-5 (MICRO-EPSILON MESSTECHNIK GmbH & Co. KG, Ortenburg, Germany).

2.2 Middle ear transfer function

For determining the METF on five temporal bones, the stapes footplate vibration was measured using a laser Doppler vibrometer (LDV, sensor head CLV 700, controller CLV 1000 with modules M300, M050 and M003, Polytec, Germany). The preparation of temporal bones and measurement setup were performed like in [6]. A microphone ER-7C (Etymotic Research, USA) was placed with about 3 mm distance to the tympanic membrane, through a hole at the anterior side of the ear canal, for measuring the applied sound pressure in front of the tympanic membrane. The multisinus excitation signal was applied at about 90 dB SPL between 200 Hz and 5 kHz. The following METF measurements on the five temporal bones with TORP reconstruction were done on the back side of the stapes footplate. Quasi-static pressure was applied to simulate tympanic membrane movement and to increase or decrease the tension between the prosthesis coupling points. Thus, 2.5 kPa positive pressure was applied to the ear canal, for simulating negative pressure in the tympanic cavity.

3 Results

3.1 Relaxation measurements

The prostheses were preconditioned with two full deflection cycles. The prostheses were assumed to be therefore in an implantation-like condition, having already undergone some load cycles.

The measurements took about 10 minutes for each deflection step. The decay rate then was below about 0.5 % per minute. A maximum angle of about 25 degrees at 500 µm deflection between the foot shaft and the head shaft of the flexible TORP was optically determined, compared to a deflection angle of about 5…10 degrees of the malleus handle [7].

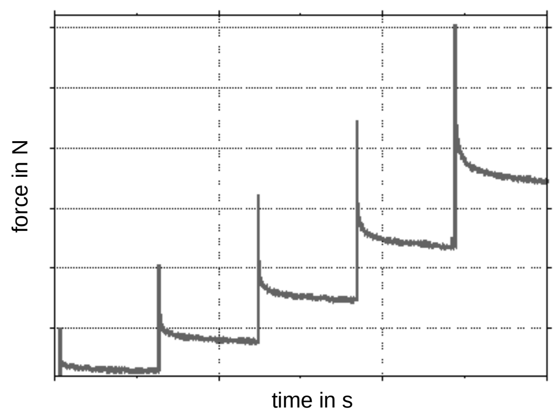

Figure 2: Qualitative strain relaxation process of the five 100 µm deflection steps. The relaxation phase persisted about 10 minutes for each step.

TORP1 and TORP2 didn't reach their initial position. This could be caused by changes in the attachment silicone-titanium. For that reason the first deflection step is left out in **Figure 4**. The maximum of the prosthesis stiffness was reached at about 150 µm (an equivalent tympanic membrane deflection at about 1.5 kPa).

3.2 Middle ear transfer function

The METF of the five flexible TORP reconstructions at 2.5 kPa static pressure in the ear canal is shown in **Figure 3**. The resonance frequency is shifted to higher frequencies because of the pressure application. In the lower frequencies up to about 1 kHz the magnitude decreases. The curves are within the range of the same previously measured intact middle ears at -2.5 kPa in the tympanic cavity.

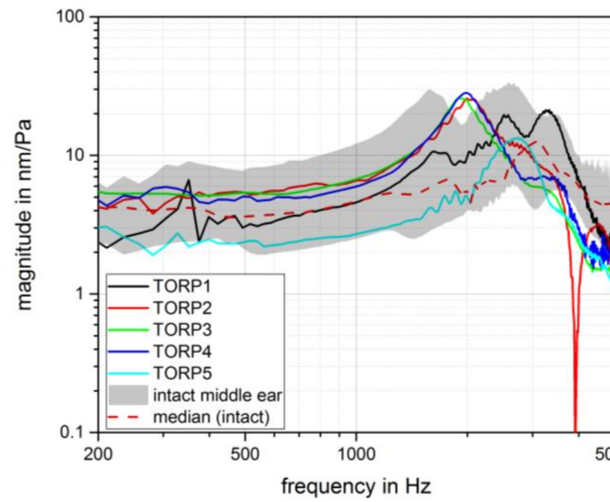

Figure 3: Middle ear transfer functions (METF) of five temporal bones with flexible TORP reconstruction at 2.5 kPa in the auditory canal. They are comparable to the intact middle ear METF (grey area and red median.

4 Discussion and conclusion

The ascertained stiffening of the flexible prostheses at increasing deflection (maximum of about 38 N/m for the initial stiffness and about 24 N/m for the maximum relaxation stiffness, see **Figure 4**) was multiple times smaller compared to the IMJ (about 100 N/m at low deflections, over 1000 N/m at high deflections; [4, 8]). Because of the construction and the coupling of the prosthesis, its stiffness slightly changed with the applied load. The deflection of the prosthesis head changed the lever arm of the applied force and reduced the obtained stiffness. Large deformations of the silicone joint lead to an increased stiffness. The latter effect was dominant at small deflections (up to about 150 µm) while the first effect was dominant for larger deflections. The IMJ stiffness characteristics on the other hand are defined by its fibre structure, giving a strong nonlinear increasing stiffness [8].

The novel silicone coated ball and socket joint TORP construction provided a protection function like the IMJ at ambient pressure differences due to the low stiffness at an anatomically typical deflection of about 500 µm [1]. At the same time a sound transfer equivalent to the intact human middle ear at normal pressure and negative pressure in the middle ear could be gained. Therefore, the prevention of a non-physiological stiffening of the stapes annular ligament could be approved.

With passive implants, especially with more complex mechanics like shown in the flexible TORP, it is possible to mimic middle ear functions, while restoring normal hearing.

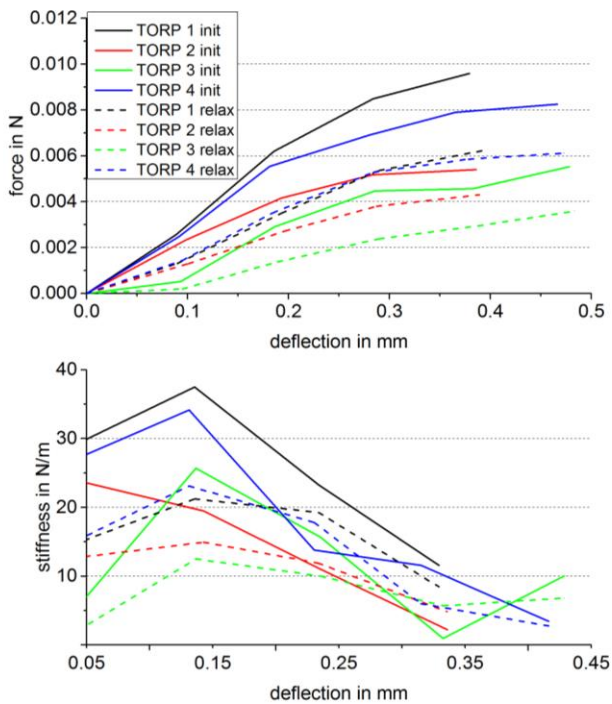

Figure 4: Initial and relaxed force-deflection and iteratively determined stiffness curves of four flexible TORP; TORP 1 and 2 didn't reach their initial position. This could be caused by changes in the attachment silicone-titanium. This load step is left out. The curves start with the first load application step.

Further investigations and clinical studies need to follow the recent findings for further improvements.

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Author's Statement

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