Abstract Title: New implantable chamber stapes prosthesis – assessment of effectiveness and safety

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Abstract

New chamber stapes prosthesis (ChSP) is a medical device intended for patients with stapes otosclerosis. The ChSP (Fig.1A) consists of a chamber (1,4), a membrane (2), and a plate (3). The introduction of the ChSP to clinical practice requires a number of preclinical and clinical tests to assess its effectiveness and safety.

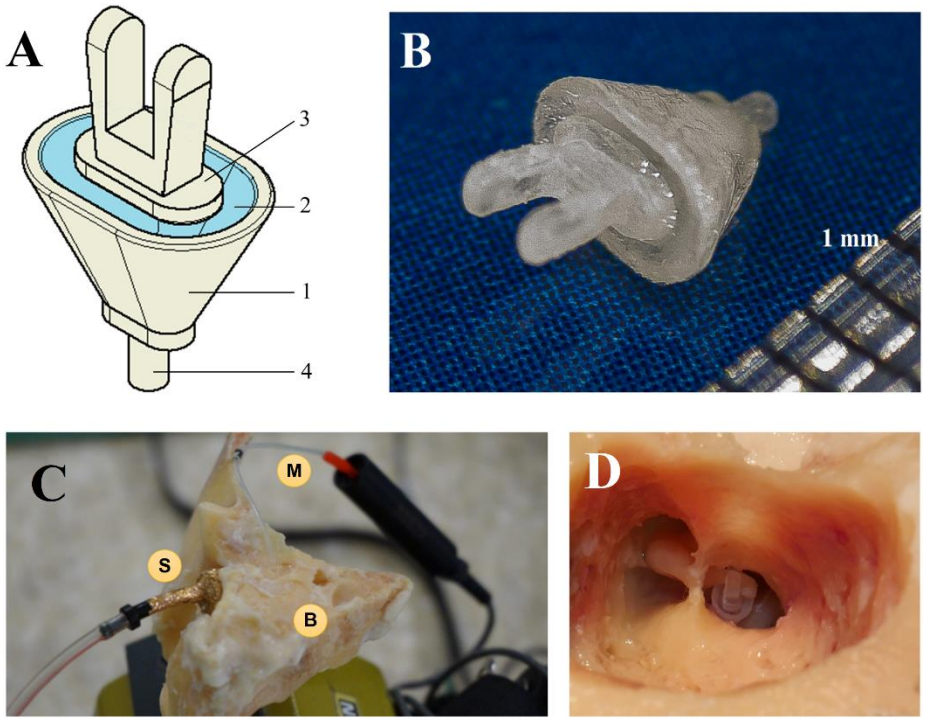


Fig. 1. The ChSP prototype (A,B) and experimental setup (C,D). B-temporal bone, S-speaker, M-microphone

First, the functioning of the ChSP was verified by numerical simulations. The results showed that the ChSP has a significant advantage over the piston prosthesis and effectively transmits vibration for frequencies 0.4-10 kHz.

Next, the ChSP prototype (Fig.1B) was made and the experimental studies were carried out. The prototype was implanted in a human cadaveric temporal bone (Fig.1C,D). The vibrations of the round window membrane (RWM) were measured using a scanning laser Doppler vibrometer before and after experimental stapedotomy. The vibrations were induced by the

acoustic stimulation (AC). The sound (90dB SPL, 0.8-8 kHz) was introduced to the external ear canal via a loudspeaker and controlled by a microphone. Based on the measured displacement amplitudes, the magnitude of fluid volume displacement at the RWM was calculated in both the normal and the implanted ear (Fig.2). The experiments confirmed that the ChSP prototype works correctly and effectively transmits sound for 0.8-8kHz.

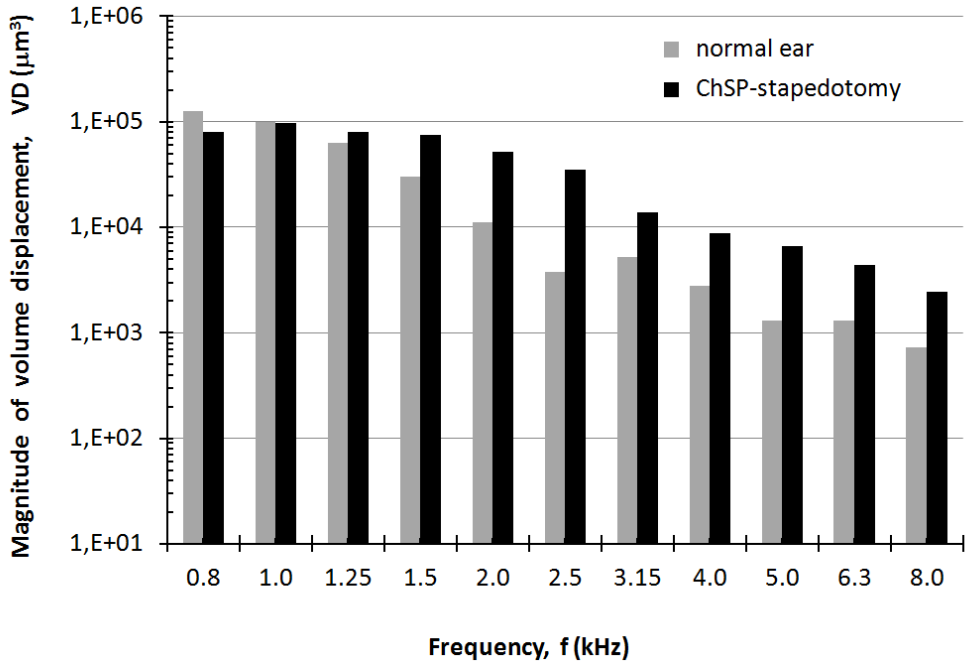


Fig. 2. Fluid volume displacement at the RWM in the normal and implanted ear.

In subsequent experiments, we measured pressure in the perilymph fluid before and after ChSP-stapedotomy. The pressure was induced by the AC and measured using two optical pressure sensors placed in the scala vestibule and the scala tympani. The differential intra-cochlear pressure was calculated and the results were compared between the healthy and implanted ears.

Finally, we performed a preliminary risk analysis and assessed the risk-benefit ratio according to ISO 14971.

Keywords— *otosclerosis, stapedotomy, chamber stapes prosthesis, ChSP*

Professional Biography

Monika KWACZ has completed his PhD from Warsaw University of Technology (Poland). She works as associate professor at the Institute of Micromechanics and Photonics. She conducts biomedical research, manages R&D projects and is the scientific supervisor of the PhD students. She has published more than 25 papers in reputed journals, e.g. Kwacz M, et al. *A three-dimensional finite element model of round window membrane vibration before and*

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Any Comments:

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