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New implantable chamber stapes prosthesis: assessment of effectiveness and safety- Monika Kwacz- Institute of Micromechanics and Photonics, Warsaw University of Technology, Poland

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New chamber stapes prosthesis (ChSP) is a medical device intended for patients with stapes otosclerosis. The ChSP (Fig.1A) consists of a chamber a membrane and a plate. The introduction of the ChSP to clinical practice requires a number of preclinical and clinical tests to assess its effectiveness and safety. 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 (90 dB 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. The experiments confirmed that the ChSP prototype works correctly and effectively transmits sound for 0.8-8kHz. 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 intracochlear 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.

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