

Comparison of AMEI Output Level Predicted with Two Experimental Methods to Clinical Results

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Objectives

The ASTM F2504-05 standard describes a method to predict the output level of implantable middle ear hearing devices (IMEHD) from cadaver studies. To validate intracochlear pressure difference (ICPD) as an alternative method to quantify the output level of IMEHDs experimentally in cadaver studies we compared results to LDV and in vivo results from clinical data.

Methods

Clinical results were analyzed retrospectively of 24 patients with a MET® Middle Ear Implant System (Cochlear™). Bone conduction thresholds and "direct thresholds" determined with the sound processor were used to determine the actuator output level at a given driving voltage. Cadaver experiments were performed with the same T2 actuator used in the Cochlear MET and Cochlear Carina® Systems in 10 human cadaveric temporal bones (TBs) compliant to the ASTM F2504-05 acceptance criteria. The eardrum was stimulated acoustically and the incus body was stimulated mechanically by the T2 actuator at a controlled static contact force. In both stimulation modes, stapes footplate (SFP) vibration was measured by LDV (Polytec) and intracochlear pressures differences between scala tympani (ST) and scala vestibuli (SV) were measured using FISO FOP-M260 pressure sensors. Equivalent sound pressure levels (eq SPLs) generated by the actuator stimulation were calculated based on SFP vibration, ICPD and from clinical results.

Results

The mean MET output level measured in cadaveric TBs by ICPD was 100 to 120 eq dB SPLFF @1VRMS. The output levels calculated from SFP vibration as recommended by ASTM F2504-05 were similar. At 5mN contact force the output levels from ICPD in cadaver experiments were nearly identical to clinical results within approx. 3 dB.

Conclusion

In incus stimulation IMEHD actuator output levels calculated from ICPD were similar to output levels determined by SFP vibration (ASTM) and identical to clinical data. Based on our results, clinical output levels of IMEHDs stimulating the ossicles can be predicted by cadaver studies with a high precision. Furthermore both, SFP vibration and ICPD are reliable measures to predict expected IMEHD output level preclinically in cadaver studies.