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Testing a method for quantifying the output of implantable middle ear hearing devices

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Purpose: Implantable middle-ear hearing devices (IMEHDs) have been used over the last decade to aid hearing function in patients with hearing loss, and multiple IMEHDS either have been or are being developed for use in patients. A significant issue is that it is difficult to compare the performance of different IMEHD devices. In order to provide a testing standard, the Food & Drug Administration of the US government participated in the development and testing of a "standard practice" for quantifying IMEHD output (ASTM International F2504: Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices). This report describes tests of the utility of this practice.

Materials & Methods: Measurements of sound- and IMEHD-driven stapes velocity were made in prepared temporal bones using laser- Doppler vibrometry. Pre-implantation CONTROL measurements of sound-induced stapes velocity were compared with a NORMAL RANGE determined from a collection of stapes-velocity measurements made in temporal bones from laboratories throughout the world (Rosowski et al. ARO 2004). CONTROL measurements that did not fall within the NORMAL RANGE led to exclusion of the bone from further testing. After implantation with the IMEHD electrical- mechanical transducer, measurements of the electrically driven stapes velocity were compared with the sound-driven CONTROL measurements to compute the Equivalent Sound Pressure per electrical input to the IMEHD transducer.

Results: Measurements of Equivalent Sound Pressure were performed for two IMEHD devices. The means and standard deviations were computed from measurements in 5 NORMAL bones. In performing these tests several additional bones failed to meet the NORMAL RANGE criteria.

Conclusions: A "standard practice" has been demonstrated to determine quantitative descriptions of the efficacy of IMEHD electrical-mechanical transducers. [Supported by the US-FDA and various IMEHD manufactures]