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Research Paper

Effects of middle ear quasi-static stiffness on sound transmission quantified by a novel 3-axis optical force sensor

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ABSTRACT

Background: Intra-operative quantification of the ossicle mobility could provide valuable feedback for the current status of the patient's conductive hearing. However, current methods for evaluation of middle ear mobility are mostly limited to the surgeon's subjective impression through manual palpation of the ossicles. This study investigates how middle ear transfer function is affected by stapes quasi-static stiffness of the ossicular chain. The stiffness of the middle ear is induced by a) using a novel fiber-optic 3-axis force sensor to quantify the quasi-static stiffness of the middle ear, and b) by artificial reduction of stapes mobility due to drying of the middle ear.
Methods: Middle ear transfer function, defined as the ratio of the stapes footplate velocity versus the ear canal sound pressure, was measured with a single point LDV in two conditions. First, a controlled palpation force was applied at the stapes head in two in-plane (superior-inferior or posterior-anterior) directions, and at the incus lenticular process near the incudostapedial joint in the piston (lateral-medial) direction with a novel 3-axis PalpEar force sensor (Sensoptic, Losone, Switzerland), while the corresponding quasi-static displacement of the contact point was measured via a 3-axis micrometer stage. The palpation force was applied sequentially, step-wise in the range of 0.1–20 gF (1–200 mN). Second, measurements were repeated with various stages of stapes fixation, simulated by pre-load on the stapes head or drying of the temporal bone, and with severe ossicle immobilization, simulated by gluing of the stapes footplate.
Results: Simulated stapes fixation (forced drying of 5–15 min) severely decreases (20–30 dB) the low frequency (<1 kHz) response of the middle ear, while increasing (5–10 dB) the high frequency (>4 kHz) response. Stapes immobilization (gluing of the footplate) severely reduces (20–40 dB) the low and mid frequency response (<4 kHz) but has lesser effect (<10 dB) at higher frequencies. Even moderate levels of palpation force (<3gF, <30 mN), regardless of direction, have negative effect (10–20 dB) on the low frequency (<2 kHz) response, but with less significant (5–10 dB) effect at higher frequencies. Force-displacement measurements around the incudostapedial joint showed quasi-static stiffness in the range of 200–500 N/m for normal middle ears, and 1000–2500 N/m (5–8-fold increase) after artificially (through forced drying) reducing the middle ear transfer function with 10–25 dB at 1 kHz.
Conclusion: Effects of the palpation force level and direction, as well as stapes fixation and immobilization have been analyzed based on the measurement of the stapes footplate motion, and controlled application of 3D force and displacement.

1. Introduction

Conductive hearing loss is a common cause for surgical interventions in otology. During ossiculoplasty, the surgeon is required to judge the mobility of the ossicular chain by evaluation each ossicle separately. Besides identification of discontinuities in

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the ossicular chain, such as an eroded long process of the incus, any fixation of the ossicles needs to be identified. Manual palpation of the ossicles, by physical contact via a surgical tool, could detect malleus fixation or ossification of the anterior malleus ligament, mobility of the incus as well as stapes fixation, like in otosclerosis. A complete or almost complete fixation of the ossicular chain can be detected by surgeons with limited experience. The detection of partial fixation of any of the ossicles is more challenging and relies on the surgeon's manual dexterity and experience to gauge the compliance of the ossicular chain. It also requires a good surgical exposure to visualize the ossicles and the ligaments in the epitympanon.

Much experience is needed to estimate clinical relevant stiffening of the ossicular chain by manual palpation. In less pronounced cases, stiffening may be below the threshold of the surgeon's tactile sensation. The typical displacement of the ossicular chain due to physiologically relevant (100 dB SPL or less) acoustically induced sound excitation is on the order of 100 nm or less (depending on frequency and stimulation level) (Hato et al., 2003; ASTM F2504, 2014) and typical forces are in the order of 100μN or less (Khaleghi et al., 2016). However, typical palpation forces applied by experienced surgeons are on the order of 30–150 mN (Linder et al., 2015), or 3 orders of magnitude larger than typical acoustically induced forces. This means that touching (palpating) the ossicular chain may not be accurate enough to detect small impairment of the ossicular motion. However, techniques for detection of significant hearing impairment such as tympanometry typically use static pressure changes on the order of 200–300 dPa (2000–3000 Pa) resulting in approximately 100–200 mN of combined force, distributed across the area of the tympanic membrane (assuming approximately 50 mm^2 effective area; Rosowski, 1991), similar to typical manual palpation force range used during middle-ear surgery (Linder et al., 2015).

Objective intra-operative quantification of the ossicle mobility could provide valuable and rapid feedback for the status of the patient's conductive hearing. Before such an approach can be established, the clinical relevant extent of stiffening of the ossicular chain needs to be quantified. Several devices to evaluate ossicular mobility have been described such as a piezoelectric ceramic device that was tested to detect stapes immobilization on dogs and has a frequency range of 1–10 kHz (Gyo et al., 2000). A piezoelectric device was used to determine the relationship between the load and displacement during surgery in 3 patients, in whom it was possible to distinguish between normal and fixed stapes (Koike et al., 2006). A hand-guided electromagnetic device for measuring stapes mobility could distinguish between normal and fixed stapes and to detect partial immobilization not detected by the surgeon (Zahnert et al., 2001). A strain-gage based device “Otopen” (Okland et al., 2017) have been used for quantification of the umbo and stapes stiffness in temporal bones after stapedotomy, ossicular chair repair and fixation.

For this study, a 3-axis force sensor has been used (Sensoptic SA, Losone, Switzerland) to measure the force applied to the ossicular chain (Linder et al., 2015). It consists of an optical force-sensing element, based on a load cell composed of three Fabry-Perot optical strain gages, which measures forces in three orthogonal directions (US Patent 2013/0204142 A). The force-sensing element is incorporated within the front of a 1.5 mm 90° pick tool (Pick 90° #225215, Karl Storz Co, Tuttlingen, Germany) and uses light, transmitted through three optical fibers, from the force sensors to an evaluation unit connected to a PC running custom software, which provides live visual and sound feedback for the currently applied force level and direction.

This study aims to investigate how the middle ear transfer function is affected by changes in the quasi-static stiffness of the ossicular chain. The stiffness of the middle ear was modified by: a) applying constant force (pre-load) at the stapes head, controlled using a novel fiber-optic 3-axis force sensor, simulating a preload between a stapes prosthesis and the middle-ear chain; b) artificially reducing stapes mobility by drying (forced and natural) the middle ear, simulating otosclerosis of the ossicle joints and loss of tympanic membrane mobility; and c) artificial complete immobilization of the stapes by gluing of the stapes footplate, simulating calcification of the stapedial annular ligament.

2. Methods

2.1. Sample preparation

Ten frozen TBs from human cadavers were used in this study, and approval was obtained by the Ethical Committee of Zurich (KEK-ZH-Nr. 2012-0007). The TBs were from four males and six females, with an average age of 74.5 years (range, 61 and 85 years). The frozen TB were harvested within 24 h after death and were frozen immediately. The middle ear transfer function (METF) of all TBs was measured and compared to the American Society for Testing and Materials (ASTM) standard (F2504-05, Philadelphia, 2005). Comparisons between the experimental data and the standard are show in Results section 3.1 and any relative differences (average difference between the mean response of each sample across all test frequencies) are discussed in Discussions section 4.1. Exposure of the middle-ear ossicular chain, which included near full view of the stapes footplate, was made by a mastoidectomy with posterior tympanotomy. The intact tympanic membrane (TM) was confirmed by microscopic view, and all suspensory attachments to the middle-ear ossicles, which include ligaments and tendons, were left intact, during the preparation. The external ear canal was drilled down near the tympanic membrane for stable positioning of an artificial ear canal (AEC) without air leakage. The AEC allowed control of the volume and distance between the microphone probe and the TM center, maintained at 0.5 ml and approximately 5 mm, respectively (Sim et al., 2010, 2012; Lauxmann et al., 2012).

2.2. Measurement setup

A loudspeaker (ER-2, Etymotic Research, USA) and a microphone (ER-7, Etymotic Research, USA) were placed in AEC, to generate the sound stimuli and monitor the sound pressure levels at the tympanic membrane.

A controlled palpation force was applied at the ossicular chain. The palpation force was controlled via a novel 3-axis PalpEar force sensor (Sensoptic, Switzerland) with a noise floor and resolution of <10 mgF (0.1 mN) and 1 mgF (0.01 mN), respectively (Bertholds et al., 2013). In order to calculate the middle ear stiffness from the force and displacement measurements, the stiffness of the force sensor itself was measured by pushing the tip of the force sensor against an approximately solid object (5 cm diameter steel post), and the corresponding displacement was measured with the micro-meter translation stage (10 μm precision, M-423 linear stages with SM-25 Vernier Micrometers, Newport Corp., Irvine, California, USA). Based on this method, the quasi static stiffness of the force sensor in the Y (superior-inferior re. to sample) and Z directions (piston, lateral-medial re to sample) (bending the sensor perpendicular to its longitudinal axis) is 105–110 N/m (±5% variation) and in X direction (anterior-posterior re. to sample) (pushing/buckling the sensor along its longitudinal axis) is approximately 8400 N/m (±20–30%). It should be noted that measuring very high stiffness, for example >5000 N/m, is done with limited accuracy since the resulting displacements are close to