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Evaluation of Vibrant® Soundbridge™ positioning and results with laser doppler vibrometry and the finite element model

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Abstract. The etiology of hearing loss originates from genetic factors and includes several other events including infections, working or living environment, as well as several endocrine and metabolic disorders. The Vibrant® Soundbridge™ (VSB) is an implantable hearing aid whose floating mass transducer (FMT) is attached to the long process of the incus. The device is used for pure sensorineural hearing loss with an intact middle ear. Variations in the manner of attachment may occur. Knowledge of the impact of such variations on the overall device performance may guide towards optimal transducer attachment during surgery. A mechanical modelling of the ear was first reported by von Békésy and indicated that the tympanic membrane (TM) moves as a stiff plate, and that the mallear and incudal ligaments act as a rotation axis for the ossicular chain at low frequencies. Experimental investigations and simulations with the model yield the same main results. The first fitting situation, where the FMT floats freely in the middle ear, provides by far the worst possible results. Contact to the stapes supra-structure of the FMT is necessary for optimal performance of the FMT. The mastoid specimen preserves its acoustic properties that have been shown to be similar to those in the vital human ear, under these conditions. Properly coupling the electromagnetic transducer to the ossicles can be difficult and it requires a certain degree of experience. A finite-element model (FEM) is useful for functional evaluation of the VSB since it enables easy modelling of the complicated middle ear structures and simulation of their dynamic behavior which makes it easy to understand it in detail without experiments.

Introduction

The external auditory canal (EAC) and the middle ear ossicular chain (OC) couple the air-transmitted sound wave from an external source to the aqueous fluids of the inner ear. The coupling mechanism is both subtle and ingenious; the EAC collects the pressure wave which moves the tympanic membrane (TM) into a particular shape leading to motion of the ossicles (1). The stapes footplate moves within the oval window stimulating the perilymph fluid in the cochlea, a spirally coiled organ of the inner ear (2). Research into sound transmission began as early as 1941 with the works of von Békésy (3) and have evolved during decades to create a clearer image of acoustic transmission.

A mechanical modelling of the ear was also first reported by von Békésy and indicated that the TM moves as a stiff plate, and that the mallear and incudal ligaments act as a rotation axis for the ossicular chain at low frequencies. The OC rotates about the center of mass at high frequencies (3). Various methods were devised for the study of the mechanics of the middle ear: Scaled replicas of the outer ear canal (4), electrical analogues of the middle ear (5,6), finite-element modelling (FEM) (7,8).

The etiology of hearing loss originates from genetic factors and includes several other causes including infections, working or living environment, as well as several endocrine and metabolic disorders; all of them associated with various degrees of the loss of hearing. When we approach the neuroendocrine system, we discover that thyroid-parathyroid, hypothalamic-pituitary, adrenal and diabetes disorders (9) play an important role in this pathology together with metabolic bone diseases such as osteogenesis imperfect (10) or Paget's disease (11).

Hearing loss of variable etiology represents one of the most serious public health issues confronting the world's population. According to data reported in 2020 by the World Health Organization (WHO), over 466 million people (5% of the world's population) currently suffer from a form of hearing loss (12,13). In addition, the integrity of the auditory system is one of the prerequisites for the acquisition and the proper development of oral language (14).

Implantable hearing-aids, initially developed against sensorineural hearing loss are recently becoming more important

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with the extension of indication towards mixed hearing loss. This might also revive the application for pure sensorineural hearing loss.

Advantages of implantable hearing aids against conventional ones are as follows: No ear canal closure, higher possible gain at the high frequency range and no visible parts (in case of totally implantable systems) (15).

The Vibrant® Soundbridge™ (VSB) is an implantable middle ear hearing device to treat sensorineural hearing loss which involves damage to the inner ear (aging, prenatal and birth-related issues, viral and bacterial infection, heredity, trauma, exposure to loud noise, fluid backup, benign tumor of the inner ear) and represents 60% of all hearing loss. In the case of the VSB, defining the optimal position for transducer attachment during surgery could mean optimization of functional results. The VSB directly drives the ossicular chain, bypassing the ear canal and tympanic membrane.

Materials and methods

Investigations were performed with the help of a FEM of the middle ear which consists of the ear canal (acoustic fluid with matched impedance at the canal entrance to the surrounding air), the eardrum (orthotrop-elastic shell with constant damping ratio), the ossicles (rigid bodies with mass and inertia properties), ligaments (elastic bars), joints (elastic bodies with constant damping ratio) and a spring-mass-damper model of the cochlea (15) (Figs. 1-3).

FEM has been developed for investigations on middle ear reconstructions with focus on the acoustic transfer characteristics and the frequency range of speech. Accordingly, the model is limited to the linear region (sound pressure up to 120-130 dB) and to frequencies up to 6 kHz. The model has been validated against experimental data from measurements on human temporal bone specimen.

We investigated the VSB connected to the long process of the incus in 3 different conditions: The floating mass transducer (FMT) vibrating freely in the middle ear in the direction of the longitudinal stapes axis, without contact to the stapes; the FMT in contact to the stapes supra-structure, vibrating in the direction of the longitudinal stapes axis; the FMT in contact to the stapes supra-structure, vibrating in a direction of 45-60 degrees off the longitudinal stapes axis.

The three situations were investigated experimentally on temporal bone specimens and theoretically by means of a finite element simulation model of the middle ear. The displacement of the stapes footplate was measured using laser Doppler vibrometry (LDV) and calculated with the simulation model. The Polytec LDV (CLV-700 sensor head, CLV-1000 vibrometer controller; Polytec GmbH) was mounted onto a Zeiss surgical microscope (Zeiss Co.). A micromanipulator was used to focus the helium-neon laser on the target (squares of foil of 0.5 mm^2 with reflective polystyrene microbeads). The sound generator (insert earphone, eartone 3A) was inserted into the ear canal and the probe microphone (ER7c; Ethymotic Research Inc.) positioned through an extra opening in the external ear canal next to the eardrum for reference measurements (16).

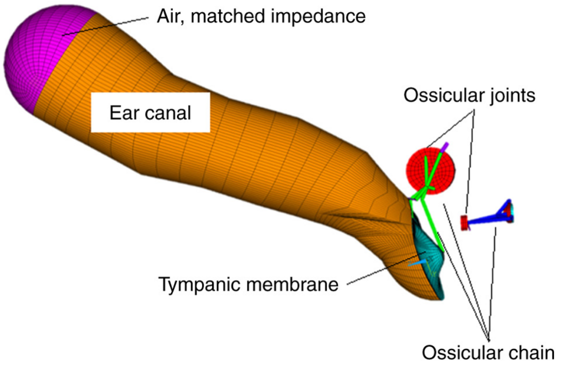

Figure 1. Schematic representation of the FEM. FEM, finite element model.

We compared the results obtained from these measurements and simulations to determine the influence of variations of coupling of the FMT.

The study was performed using unfixed human cadaveric temporal bones (TBs). The temporal bones were harvested within 48 h after death, using the classical techniques described in literature (17) and stored in isotonic NaCl saline until preparation for approximately 1 h.

All TBs were carefully inspected using an operating microscope to exclude diseased middle ear or perforation of the TM.

Results and discussion

The measurements on human temporal bones, as shown in Fig. 4 for each of the studied positions, yielded a graphic representation depicted for comparison (Fig. 5).

The FEM experiments for FMT coupling with contact to the stapes parallel to its long axis and tilted at a 15, respectively 45 angle showed similar changes in middle ear transfer function (METF) to those obtained on temporal bone (Figs. 6 and 7).

While fresh frozen or thawed-frozen temporal bones may not be a perfect model, due to loss of some elasticity of the ossicular chain and the post-mortem effects caused by inner ear pressure change, tissue oedema, temperature change, humidity, they do represent an adequate model for relative performance gains due to slight changes in prosthesis positions, provided that comparisons are made within the same temporal bone.

LDV measurements of METF represents a suitable method for monitoring of the VSB placement and functional results. It is also reliable, easily applicable, not time consuming and relatively cheap bearing in mind the possible long-term benefits.

The FEM (a three-dimensional human outer and middle-ear model, including muscles, ligaments and middle-ear cavity) became popular after the massive development of computers and allows the investigation of the motion of the entire ossicular chain and precise definition of the outer ear canal and middle ear space geometry (Table I).

The disadvantage of FEM over experiments on biological structures (LDV) is that the models can be difficult to validate since the geometries differ between individuals, and because

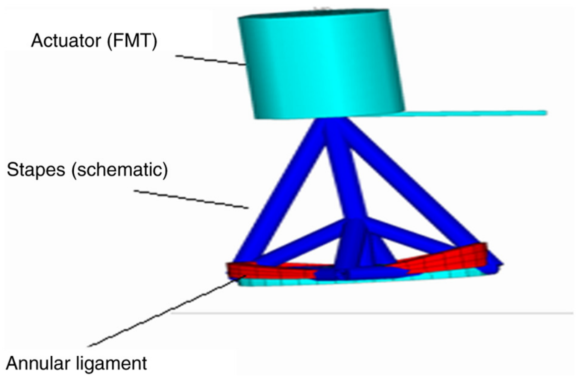

Figure 2. Schematic representation of the FEM. FEM, finite element model.

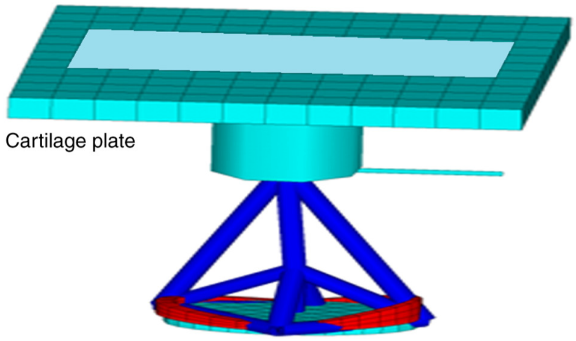

Figure 3. Schematic representation of the FEM. FEM, finite element model.

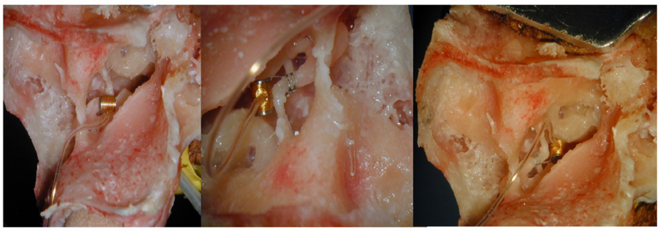

Figure 4. Positioning of the FMT (3 different positions) in regard to the stapes structure during the temporal bone experiments. FMT, floating mass transducer.

material property data are usually not precisely known (18). However, the finite-element modelling approach may help explain the differences in the clinical performance of ossicular replacement prostheses (19). It also has applications for the feasibility of new passive and active middle ear implant design concepts, especially since medical research can sometimes require a high degree of abstraction (20).

In conclusion, experimental investigations and simulations with the model yield the same main results. The first fitting situation, with the FMT floating freely in the middle ear, provided by far the worst possible results. Contact to the stapes supra-structure of the FMT is necessary for optimal performance of the FMT. Tilting the FMT off the longitudinal axis of the stapes reduces the vibration of the stapes footplate. But this reduction is less than for the first situation of the freely floating FMT.

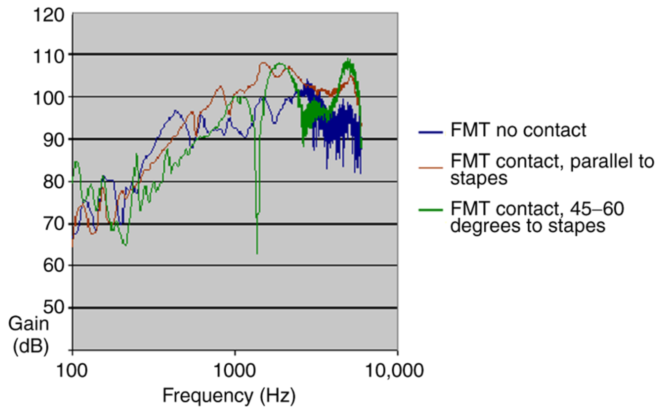

Figure 5. Change in transfer function when direction of excitation changes from no contact to the stapes to 0° and 45°-60° (on temporal bone). FMT, floating mass transducer.

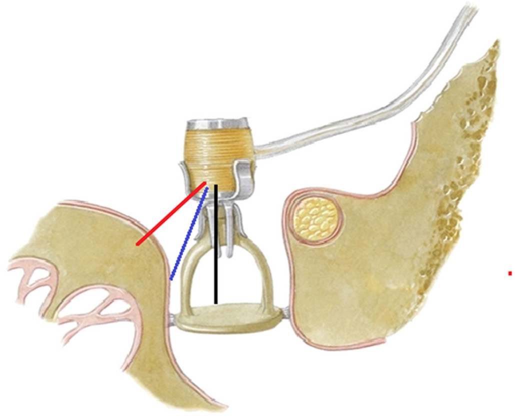

Figure 6. Scheme of the FMT attached to the stapes head with direction of excitation of 0° (black line), 15° (blue line) and 45° (red line). (modified from the original image, courtesy of Med-El GmbH).

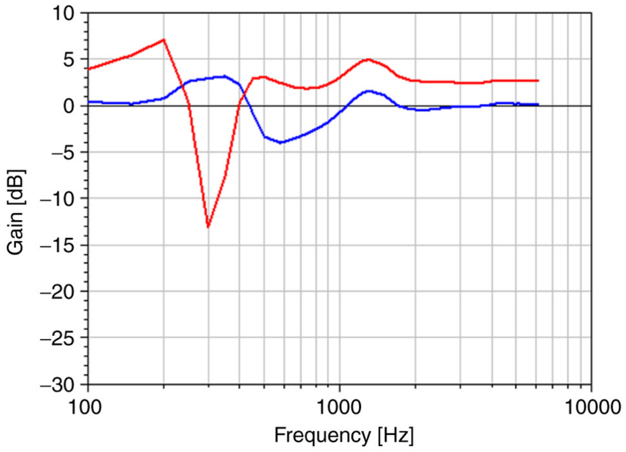

Figure 7. Change in transfer function when direction of excitation changes to 15° and 45° (on FEM). FEM, finite element model.

The mastoid specimen preserves its acoustic properties that have been shown to be similar to those in the vital human ear, under these conditions.

Table I. Previously published finite element models of the outer and middle ears[a].

Author(s) (year)	Description of FEM experiments	(Refs.)
Funnell and Laszlo (1978)	Three-dimensional model of feline TM (cat), including curvature, isotropic elasticity, static pressure load	(7)
Funnell and Laszlo (1978)	Undamped natural frequency analysis of previously presented three-dimensional model	(7)
Williams and Lesser (1990)	Three-dimensional model of human TM; calculations of mode shapes for different curvatures, thicknesses and stiffness	(8)
Lesser *et al* (1991)	Two-dimensional plane strain model of the ossicular chain under a static displacement; stress contours in bones and joints reported	(21)
Wada *et al* (1992)	Three-dimensional human middle-ear model, including curved TM with peripheral sprung restraints	(22)
Williams and Lesser (1992)	Three-dimensional model of the TM using shell elements and using beam elements for a Fisch II spandral prosthesis; natural frequencies reported	(23)
Ladak and Funnell (1996)	Three-dimensional human middle-ear model, including curved TM with peripheral sprung restraints; static displacement analysis	(24)
Koike *et al* (1996)	Three-dimensional human outer and middle-ear model, including muscles, ligaments and middle-ear cavity	(25)
Beer *et al* (1997)	Three-dimensional model of TM and malleus, static and modal analyses	(26)
Williams *et al* (1997)	Analyzing the mode shapes of an intact and damaged TM by use of the finite element model	(27)
Eiber (1997)	Three-dimensional multibody analysis of the ossicular chain (no TM) for passive and active prostheses	(28)
Eiber (1999)	Laser Doppler Vibrometry and mechanical models used for simulations of the dynamics of middle ear prosthesis	(29)
Zahnert *et al* (1997)	Three-dimensional model with a Dresden partial ossicular replacement prosthesis (PORP)	(19)
Blayney *et al* (1997)	Three-dimensional model of a stapedectomy, with damping at the stapes footplate; forced harmonic response	(30)
Bornitz (2010)	Evaluation of implantable actuators by means of a middle ear simulation model (finite element model)	(15)

[a]Modified from Prendergast *et al* (1). TM, tympanic membrane; FEM, finite-element model.

Properly coupling the electromagnetic transducer to the ossicles can be difficult and it requires a certain degree of experience.

A FEM is useful for functional evaluation of VSB since it enables easy modelling of the complicated middle ear structures and simulation of their dynamic behavior which makes it easy to understand it in detail without experiments.

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Authors' contributions

HM contributed to all the stages of the article; he designed the article and revised the manuscript for important scientific content. MB, NL, TZ acquired the data and applied the surgical procedure technic. HM also contributed to the conception of the work and revised the language. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Investigations did not involve studies in humans or animals. Ethics approval for the use of human temporal bone specimen was obtained by the Ethics Committee of the Technische Universität Dresden (EK 59022014).

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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