ELECTRONIC DEVICES FOR RECONSTRUCTION OF HEARING

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Abstract: The effect of specific hearing impairments can be alleviated or compensated using electrically driven hearing aids. There is a broad variety of devices for stimulating the hearing either acoustically, mechanically or electrically. Their applications depend on the type, the severity and the location of a particular impairment. In order to get an optimal reconstruction, additionally to the medical aspects the dynamical behavior of the implant has to be regarded together with the individual situation of the patient simultaneously. Because of the broad variation of individuals and situations, the belonging parameters are time dependent and vary in a wide range, too. Thus, the design of a hearing device must be robust or insensitive against parameter variation and a sensitivity analysis with respect to parameters of the device, variation of anatomy and variation of insertion is needed. By means of mechanical simulation models enhanced by the behavior of the actuator and its control, the dynamical behavior of implants can be calculated and optimized. Such simulations helps to shorten series of experiments in the lab and in clinical practice and guidelines for the designer and for the surgeon can be derived.

1 INTRODUCTION

Hearing is a highly dynamical process, a sound event expressed as fluctuation of pressure in the air acts at the ear drum and excites the three tiny ossicles malleus, incus and stapes to vibrate. Due to the coupling of the stapes footplate, these motions are transmitted to the fluid of the inner ear bringing the basilar membrane in motion. The stereocilia of the inner hair cells are bended and electrical spikes are transferred to the brain by the nerves. For low excitation, the outer hair cells of the organ of Corti are activated serving as an amplifier.

Impairments may have various reasons: mechanical defects in the middle ear like missing ossicles, stiffened ligaments or damaged hair cells in the inner ear. In order to get an appropriate reconstruction, the surgeon must know the mechanical behavior of the available implants, their function and use as well as their dynamical behavior when they are inserted in the body.

2 RECONSTRUCTION

Depending on the specific impairment, several possibilities of reconstruction exist. Conventional devices act at the outer ear canal driving the natural ear acoustically. A mechanical reconstruction may be a simple replacement of a natural structure or a directly driven element of the hearing like an ossicle of the middle ear or the skull. Moreover, a direct electrical stimulation in the inner ear is possible.

Implants replacing missing ossicles are passive mechanical elements. Actively driven devices consist of a microphone, a sound processor, an amplifier, a power source and an actuator. Conventional devices produce an amplified sound pressure applied to the outer ear canal, they can be used in case of intact hearing with moderate hearing loss.

Other implants are imposing mechanical vibrations directly to the middle ear ossicles (middle ear implants, MEI) or to the skull for transferring the sound by structural vibrations to the inner ear (bone anchored hearing aids, BAHA). These implants can be used in case of a sensorineural defect in the inner ear.

Another possibility is to stimulate the nerves of the inner ear electrically via an electrode inserted into the cochlea (cochlear implant, CI) or acting at the brainstem. Such implants work even when the hair cells are inactive or destroyed.

3 ACTIVE MIDDLE EAR IMPLANTS

Depending on the degree of integration into the body, totally and partially implantable hearing aids are distinguished. Further categories are due to the driving principle, the transfer of actuation to the hearing organ, the point of actuation, the manner of coupling to the driven ossicle, the type of suspension to the base and of the location the elements between the force is acting.

3.1 Driving Concept

Two different principles of driving are common: magnetic coils like in classical loudspeakers and piezoelectric elements. Such elements may work in diverse modes of operation like bending effect of beams or discs as well as elongation of staples.

3.2 Force/Displacement Transmission

Due to the transfer of force or displacement from the actuator to the ossicles, the devices can be categorized in groups working with an acoustical coupling via air cushion, hydraulical coupling via fluid in a tube and mechanical coupling.

Principally, an actuator can be attached at an ossicle transferring its forces due to inertial effects of a moved internal mass. This type is called floating mass transducer (FMT) (Hong et al, 2007). It needs a proper coupling to an ossicle.

If such type of actuator is attached to the skull, the sound information is transferred to the inner ear via structural vibrations of the skull and the device is called bone anchored hearing aid (BAHA). It needs a fixed coupling which is maintained by an osseo-integrated screw (Tjellstroem, 1990).

Other actuators are placed between ossicle and temporal bone, they may act even as force transducer or as displacement transducer and need an appropriate coupling at both ends.

3.3 Mechanical Coupling

One of the most important issue in reconstruction is the mechanical coupling of the actuator to the ossicle or/and skull because it governs significantly the dynamical behavior of the reconstructed ear. It is important to which ossicle and at which location the actuator is coupled, in which spatial direction the actuation takes place and how the coupling is maintained.

Coupling of implants to the skull is commonly achieved by means of screws in a mechanical ideal way. More problematic is the connection to an ossicle, it is achieved by gluing, crimping or clamping. In the latter cases, mucosa, fascia or cartilage is present as an intermediate layer between the implant and the ossicle.

The mechanical description of such coupling elements leads to nonlinear force/displacement laws similar to the description of the ligaments or joints. Generally, the relative displacements in the coupling area are smaller than in the joints, but depending on the specific design of coupling, pronounced asymmetry in push-pull direction up to unilateral coupling is possible. Moreover, kinks and discontinuities may occur, leading to distorted sound transfer.

4 MODELS AND MECHANICAL BEHAVIOR

Classical models of the hearing organ have been developed by acoustical or electrical engineers based n electrical analogies. These circuit models are mostly one directional described by scalar differential equations (e.g. Zwislocki, 1963) and it is difficult to describe the three dimensional nature of ossicles motion (Hudde and Weistenhoefer, 1997). Moreover, the parameters of such models are not directly related to the geometrical dimensions or physical quantities like mass and stiffness.

Due to the anatomy of the hearing organ and the function based on the relation between forces and displacements, three-dimensional mechanical models are adequate for description and simulation, well developed modelling techniques like Multibody Systems approach (MBS) or Finite-Element-Method (FEM) are available (Wada et al, 1992; Beer et al, 1999; Gan et al, 2004; Prendergast el al, 1999; Eiber et al, 1999).

The mechanical considerations presented here take into account the spatial arrangement of the ossicles and their three dimensional motions in a vectorial description. They allow to regard the spatially oriented direction of excitation, the mechanical properties of the coupling of implants and the nonlinear behavior of the coupling region, of the joints and of the ligaments.

In Figure 1, a typical Multibody System model is shown with its rigid bodies malleus, incus and stapes. The ear drum, the air in the outer ear canal and the fluid of the inner ear are modelled as lumped mass points or bodies. The ligaments and the two muscles tensor tympani and musculus stapedius are described as visco-elastic elements with an active part. The model has 83 degrees of freedom and the vector $\boldsymbol{z}$ contains the generalized coordinates. The crucial ones are indicated in the Figure.

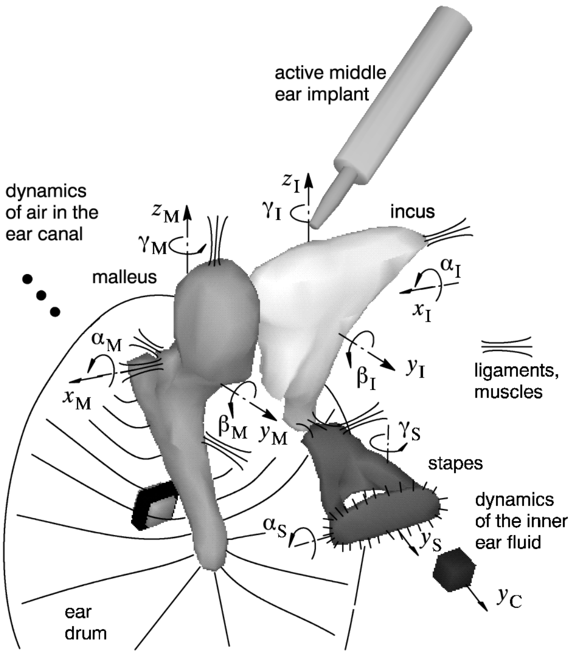

Figure 1: Multibody System model of the middle ear with its adjacent structures and an active middle ear implant acting at the incus.

The dynamical behaviour of the system is described by the equation of motion

$$\boldsymbol{M}(z) \cdot \ddot{z} + \boldsymbol{k}(z, \dot{z}) = \boldsymbol{q}(z, \dot{z}, t) , \qquad (1)$$

where $\boldsymbol{M}$ denotes the mass matrix, $\boldsymbol{k}$ the vector of generalized forces, $\boldsymbol{q}$ the vector of applied generalized forces. Generally, such models are highly nonlinear due to nonlinear coupling elements, i.e. ligaments and joints of ossicles or due to large amplitudes of ossicles´ motion (Eiber and Breuninger, 2004 a). The latter is not the case in the physiological range of hearing (Eiber and Breuninger, 2004 b). Figure 2 shows some typical force/displacement relations of ligaments and joints of the middle ear. Typically, coupling of implants are similar to that of the incudo-stapedial joint with asymmetry and kinks causing a distorted sound transmission.

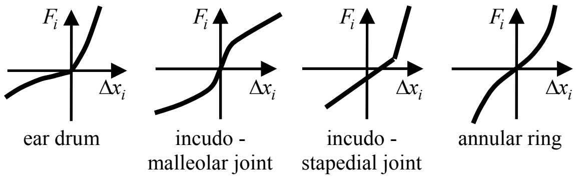

Figure 2: Nonlinear characteristics of middle ear elements.

Static preloads acting at the ossicular chain deflect it to a specific working position $\boldsymbol{y}_{wp}$, where the small physiological sound pressure variations are superposed.

For the investigation of these small variations, the equation of motion (1) can be linearized with respect to $\boldsymbol{y}_{wp}$

$$\boldsymbol{M}(\boldsymbol{y}_{\mathrm{WP}}) \cdot \ddot{\boldsymbol{y}} + \boldsymbol{D}(\boldsymbol{y}_{\mathrm{WP}}) \cdot \dot{\boldsymbol{y}} + \boldsymbol{K}(\boldsymbol{y}_{\mathrm{WP}}) \cdot \boldsymbol{y} = \boldsymbol{h} , \qquad (2)$$

where $\boldsymbol{M}$ denotes the mass matrix, $\boldsymbol{D}$ the damping matrix, $\boldsymbol{K}$ the stiffness matrix and $\boldsymbol{h}$ the vector of applied forces. Thus, the dynamical behavior of the chain depends on the working position and shows changed natural frequencies. Such static prestress may occur due to static pressure differences in the outer ear canal, in the middle ear cavity or in the inner ear, due to scar tissues of healing structures or preloads from inserted implants. Particularly active implants with a driving rod acting at the incus need such a preload.

After linearization, the linear equation of motion (2) is valid and frequency domain procedures can be applied to investigate the dynamical behavior represented by the linearized vector $\boldsymbol{y}$. For specific nonlinearities like unilateral constraints or kinks in the force/displacement relation as illustrated in Figure 2, linearization is not possible and there is a distorted sound transfer even for small sound pressure variations.

By means of time-integration the time history of specific stimulations of hearing, in particular of transient sound events, can be investigated based on the equations of motion of the entire system consisting of ossicular chain and the actuator with its control elements.

5 CASE STUDIES

Two different types of hearing aids driven by magnetic coils and piezo elements are considered for the case of totally implantable device. They are very compact but the surgical effort for insertion is very high. In case of partially implantable device the core respectively the magnet are arranged in different positions leading to a simpler surgery process.

5.1 Totally Implantable Hearing Aid

A magnetically driven device on the market is the Otologics Middle Ear Transducer MET (OTOlogics, LLC). All components even the microphone are placed in a cavity of skull behind the ear. The battery is inductively charged once per day. In particular, the actuator is mounted in the mastoid behind the ear canal, it pushes against the ossicular chain by means of a driving rod (Waldmann et al, 2004).

Because of the unphysiological orientation of the actuator, the motion imposed to the stapes contains much higher components of rocking of stapes around its short and the long axis of footplate when compared to the natural hearing. Recent studies revealed the influence of such motions on hearing (Sequeira, 2007).

Coupling of the driving rod with the incus is accomplished by pressing the rod against the ossicle. In order to have a fixed attachment point, a notch has to be burred using a drill or burned using a laser. Mechanically, such a contact is nearly an unilateral constraint, which needs a reasonable preload leading to a pre-stressed ossicular chain. Due to the shifted working point, the middle ear shows higher natural frequencies but in particular, higher amplitudes of the actuator are necessary to achieve the vibrations of stapes which are demanded for compensation of a hearing loss.

As a negative consequence, the malleus and the ear drum are driven with larger amplitudes, too, radiating sound into the outer ear canal. Picked up by the microphone, this sound may lead to ringing effects because of a loop. Such effects have been observed particularly on implants driven by piezoelectric actuators.

Thus, depending on nonlinear behavior of the chain and the coupling, even powerful actuators are not able to compensate a severe hearing loss.

For optimizing a reconstruction, the entire system of ossicular chain, the particular impairment, the characteristics of implant and its coupling to the chain has to be regarded. A very sensitive entity in the function is the adjustment of the actuator with respect to the skull during surgery, which defines the applied preload (Rodriguez Jorge et al, 2006), (Eiber et al, 2007).

In Figure 3, the mechanical model of the considered actuator is sketched showing the adjustment of the device relative to the skull and the inner stiffness between the mass of housing frame and the driven mass. For a magnetically driven actuator, this stiffness is relatively low in comparison to the piezo actuator.

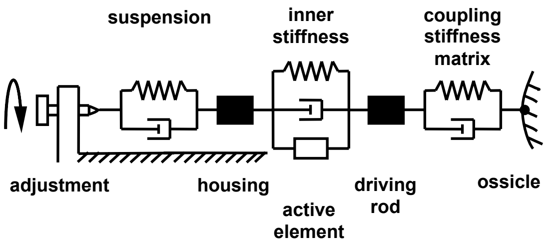

Figure 3: Model of actuator attached at the ossicle and the skull.

Concerning the two driving principles there are significant differences. The piezo elements can produce high forces imposing prescribed displacements to the chain. But due to its high inner stiffness, such devices show a high sensitivity against the adjustment of preload given by the surgeon during insertion and also against static pressure variations during daily use.

Therefore, a relatively high preload is commonly applied by the surgeon, which leads to extremely shifted working points with the effects of feedback and distortion as described above. On the other hand, ligaments exhibit a time dependent mechanical behavior. In a long time range they elongate under static load in a creeping effect releasing the imposed preload.

Due to the lower internal stiffness, the implants driven by magnetic coils are less sensitive against variations in static pressure or preload. But even in this case, the sensitivity against adjustment travel as shown in Figure 3 remains and is crucial for the surgeon. A high preload stiffens the chain and requires higher force amplitudes with a significant sound radiation by the ear drum as a consequence. Modelling this feed back loop allows a stability analysis and the calculation of a gain margin. It defined as the maximal allowed amplification so that the system is still stable. This amplification can be used to compensate a hearing impairment of the inner ear. In Figure 4 this gain margin is shown qualitatively for various adjustment travel a_0 and it becomes clear, that there is a trade-off between a good coupling and the risk of feedback particularly in the lower frequency range. For that calculation, the microphone was placed in the mastoid at the posterior wall of the outer ear canal.

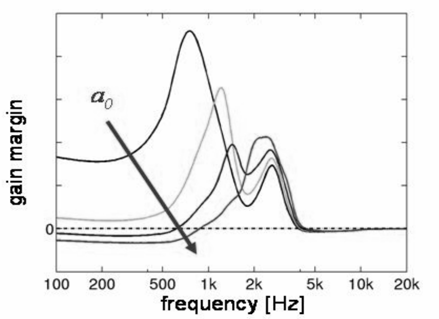

Figure 4: Gain margin for different travels of adjustment screw. Increasing adjustment cause higher static preload. A negative gain margin signifies risk of ringing.

Totally implantable hearing aids are a very elegant reconstruction because there is no obvious stigmatization of the patient. They are technically sophisticated devices, their insertion is challenging for the surgeon and needs some experience.

5.2 Partially Implantable Hearing Aid

In order to reduce the surgical effort, parts of the active hearing aid are placed outside the skull like in conventional devices. Another concept is to separate the coil of actuator from the core.

In a current project, the placement of a permanent magnet at the manubrium driven by a magnetic coil placed behind the ear is investigated as illustrated in Figure 5.

That concept ensures the kinematical unconstrained motion of the ossicular chain free of static preload. The chain is able to find its natural working position and the actuator can work at this particular position.

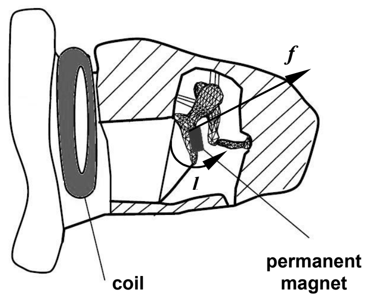

Figure 5: Partially implantable hearing aid with separated coil and magnet. Force ***f*** and torque ***l*** imposed to the magnet.

Depending on the orientation of the magnetic field and the direction of magnetization of the permanent magnet, there is a moment superposed to the force acting at the magnet to drive the ossicular chain in a quite physiological way. The position and the mass of the magnet influence both the dynamical behavior of the chain and the applied force effects. Based on mechanical models of the chain together with Finite Element models of the electrical part, an optimization of the components could be accomplished. First tests in the lab show an easy and safe procedure to couple the magnet at the malleus handle using an elastic clip. This is a mechanically stable coupling, which guaranties a perfect transfer of forces from the magnet to the ossicle.

6 CONCLUSIONS

Mechanical models serve as a base for simulating the hearing process and for the design of active hearing implants. Three-dimensional models are able to describe the complex spatial motion of the ossicular chain and their relation to the forces and moments applied by an implanted hearing aid. A crucial point is the coupling of implants to the natural structures of the ear, which is governed by nonlinear force/displacement relations. As a consequence, the transmitted forces are limited leading to an incomplete compensation of hearing loss, the transfer of sound may be distorted leading to a bad sound discrimination due to higher overtones or the gain of amplification must be restricted to avoid ringing due to feedback.

Due to their close relation to the anatomy, mechanical models give a better insight into the dynamic behavior of the middle ear than electrical circuit models. Multibody system models with a low number of degrees of freedom are well suited to describe the global behavior of systems regarding their nonlinear properties and to design the mechanical part of hearing implants. Finite Elemente models with a high number of degrees of freedom are capable to describe distributed properties like magnetic fields and mechanical stress. Simulations with mechanical models facilitate an optimization during design of hearing aids and may shorten the clinical trial and error process.

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