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On the Simulation of Human Hearing

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Numerical experiments by simulation are a well developed tool in analysis, design and optimization of technical systems. To apply these tools for the investigation of biological systems, their specific properties have to be regarded. Besides big variations between individuals, the system topology is often not clearly defined and the shape and orientation of the elements is often irregular. The joints and connections of elements or bodies are formed by living tissues, for which it is difficult to distinguish between kinematical and force elements. The behavior and characteristics of materials for bodies and coupling elements lead to very different and complex structures of constitutive equations and the belonging parameters. Very often a separation of the elements is not possible and the determination of parameters is difficult due to a complex interaction of the elements and restricted access for measurements. The systems properties are time variant and there are differences between living subjects and post mortem preparations.

Using three-dimensional mechanical models, the hearing process for normal, pathological and reconstructed situations is considered. The models of spatial structures of the middle ear and its adjacent regions are established by applying Multibody Systems and Finite Element modeling approach.

The governing nonlinear differential equations of motion allow the investigation of transient and steady state behavior by time integration and in a linearized form by frequency domain methods.

For the reconstruction of impaired hearing with implants, optimization methods can be applied to determine design parameters such as coupling stiffness and damping, the characteristics of actuator, the position of attachment and direction of actuation.

The development of new concepts and prototypes as well as the optimization and the way of insertion of passive and active implants is facilitated by carrying out virtual tests based on three-dimensional models of the spatial middle ear structures. In particular, the nonlinear behavior of the elements is taken into account. Mechanical models enable non-invasive interpretation of dynamical behavior based on measurements such as LDV from umbo or multifrequency tympanometry. It is shown: The transfer behavior depends on static pressures in the ear canal, tympanic cavity or cochlea. For reconstructed ears, the coupling conditions are governing the sound transfer substantially. Due to restricted coupling forces, the excitation of inner ear is limited and the sound transfer is distorted. Other sources of distortion are nonlinear coupling mechanisms. In reconstructions with active implants, the actuator excites the microphone whereby feedback effects may occur.

Keywords*: mechanical models, middle ear, sound transfer, reconstructed middle ear, nonlinear coupling*

1. INTRODUCTION

The function of organisms in living subjects is a highly complex interaction between a broad variety of scientific subjects. Therefore, medical investigations of human beings are classically based on experiments in the lab and combined with the knowledge in clinical practice where the results are evaluated from statistical data. By means of computer simulation such experiments can be carried out based on mathematical models without using human or animal models.

A particular focus is directed on the investigation of sound transfer through the middle ear of the natural, the impaired and the reconstructed hearing, on the hurtful mechanisms that damage the structures leading to deteriorated hearing and to the assessment of that injuries. Based on the models, a better and more detailed interpretation of measurements can be achieved which may offer an improvement and development of procedures for diagnosis. The main interest is the reconstruction of impaired hearing with passive and active implants.

Improving of existing types and developing new designs based on new principles is aimed by using models of the entire system including middle ear and implant.

Specific problems of such investigations are first to represent the elements of the hearing organ geometrically and to model it numerically, to describe their mechanical properties in form of their constitutive material equations and to determine or at least to estimate the assigned parameters.

It turns out that mechanical models based on Multibody Systems and on Finite Element approach are well suited for such investigations. They allow a deep insight into the mechanical behavior of the hearing organ and the hearing process in case of normal, pathological and reconstructed situations.

2. SIMULATION

Numerical experiments are carried out based on mathematical models. The main tasks are generating suitable and adequate models, finding proper parameters, computing the numerical solution and interpreting it physically.

Modelling comprises two important steps: The reduction of the complex reality to a particular section of interest and the abstraction of this section by a simplified description. By means of numerical simulation, the behavior of this simplified model can be studied. But, the interpretation of the results is always restricted to the grade of reduction and abstraction chosen for the model. Depending on the particular problem and question the model may have different levels of detail in mapping reality.

Purely descriptive models give only a mathematical relation between the input and the output whereas physical models are based on a specific physical analogy. To be as close as possible to reality, it is helpful to preserve the natural structure of the system, i.e. mapping mechanical systems on mechanical models and describing electrical systems with electrical models. In a large part the hearing process is an interaction between forces and mechanical displacements or deformations and therefore mechanical models are the most adequate ones.

Numerical experiments offer an elegant insight into the mechanical properties of systems in particular into their dynamical behavior. This encompasses the prediction of the state of the system evolving with time or analyses concerning eigenvalues and natural modes, sensitivity or stability.

By a distinct variation of particular parameters, boundary conditions or excitation, various pathologies can be studied. Moreover, different principles of function and design variants as well as different surgical procedures of implantation can be investigated.

Of course, such numerical experiments can not completely replace experiments in the lab or tests of practical use of the considered systems or devices. Their main objectives are to get a better insight into the function of complex systems and processes like hearing, and they will shorten the long-lasting and complex test series in the lab as well as the clinical trial and error series on living patients.

The strong demands for such simulation processes are:

All the points and effects of interest must be contained in the model and all others should be disregarded, the model should be as simple as possible but as complex as necessary.

Effects for which the parameters are impossible to measure or to estimate are often neglected in a first instance but its significance should be estimated by a sensitivity analysis.

Depending on the task at hand, the numerical procedures chosen for the solution must fit the structure of the model and must be adequate concerning computational effort and accuracy.

Thus, modelling and simulation is an iterative process which needs a lot of mechanical, numerical and here, medical experience.

In Figure 1, a medial view shows the substantial elements of the middle ear with rigid bodies for malleus, incus and stapes. The ear drum, the air in the outer ear canal and the fluid of the inner ear are represented as lumped mass points or bodies, the ligaments and the two muscles tensor tympani and musculus stapedius are considered as visco-elastic coupling elements with an active part. An active middle ear implant is attached at the incus body. This model has 83 degrees of freedom and the generalized coordinates crucial for hearing are indicated in the Figure.

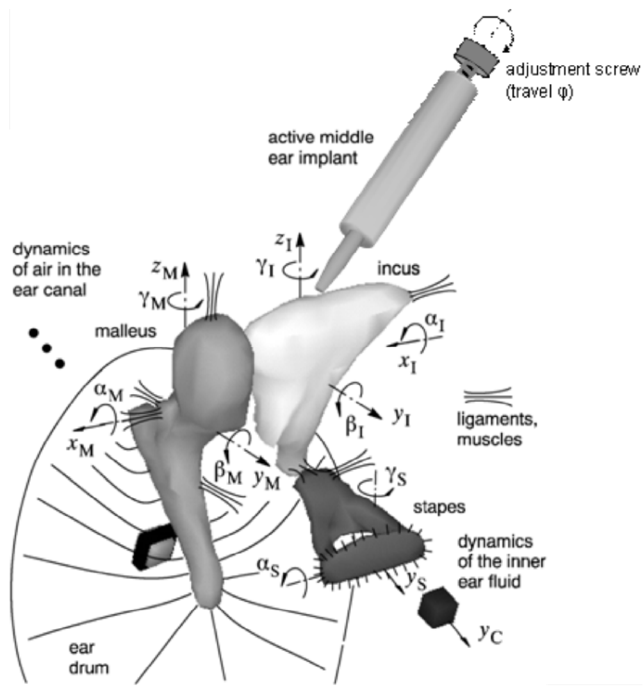


Figure 1: Multibody System model of the middle ear with its adjacent structures and an active middle ear implant acting at the incus [ei 2008]. Screw with angle j for adjustment of actuator

3. HEARING PROCESS

A sound event is a dynamical fluctuation of pressure in the air and humans are able to detect it in the frequency range between 16 Hz and 16 kHz by the hearing organ. The pressure may range from 20 mPa (0 dB) at the hearing threshold, 20 mPa (60 dB) of normal speaking, 20 Pa (120 dB) at the threshold of pain to peak values of transient events of 2 kPa (160 dB) and more, e.g. from firearms.

The transfer to the sensors in the inner ear is done via air conduction or via bone conduction by vibrations of the skull structure. For the first, the airborne sound is grabbed by the outer ear and conveyed by the outer ear canal to the ear drum which brings the three ossicles, malleus, incus and stapes, in motion.

A small fraction of the sound is transferred through the middle ear cavity as airborne sound, producing forces on the surface of stapes, the round window and the walls of the cavity. In this pneumatic system the mastoid cells act as a buffer.

3.1. Function of the Middle Ear

The middle ear has two main scopes, dealing with big static or quasistatic variations of preload and transferring dynamical sound pressure to the inner ear.

A *static preload* to the middle ear may occur due to pressure differences between the outer ear canal, the middle ear cavity and the cranial system connected with the inner ear, Densert *et al.* [dip 1977], Hüttenbrink [hue 1988], Dirckx and Decraemer [dide 1992], Gaihede and Kabel [gaka 2000].

The middle ear cavity is ventilated by the Eustachian tube which is normally closed by the isthmus. It opens when an overpressure in the tympanic cavity exceeds a certain limit (opening ca. 4000 Pa, closing ca. 750 Pa) or muscles are activated, e.g. during swallowing. Further, the resorption of gas at the walls delivers also a pressure regulation. Amongst others, the pressure in the cranial fluid system depends on changes of the posture. The main preload to the ossicular chain is caused by scar tissues after healing or surgical incisions and from inserted implants in the middle ear.

As a consequence, for the description of the ligaments their constitutive equations must be nonlinear.

The *transfer of dynamical sound pressure* is a highly dynamical process which is strongly dependent on the frequency of excitation. Due to the spatial alignment of the ossicles their motion is three-dimensional, too. This is clearly demonstrated carrying out a linear frequency analysis delivering natural frequencies and eigenmodes showing also the low pass character of transfer. The motion of the stapes footplate with a piston component perpendicular to the plate and two rocking motions around its short and around its long axis is the excitation input to the inner ear and plays a governing role in hearing. In the lower frequency range the piston-like motion is dominant but above 1.5 kHz the rocking motion become significant.

For sound pressure levels in the physiological range up to 80 dB this linear theory with the principle of superposition is valid and the system behavior is characterized by its transfer functions.

Taking the sound pressure at the entrance of the outer ear canal as input, the transfer to the piston like motion of the stapes footplate and to their rocking motions a_s and g_s around the long and the short axis is shown in figure 2.

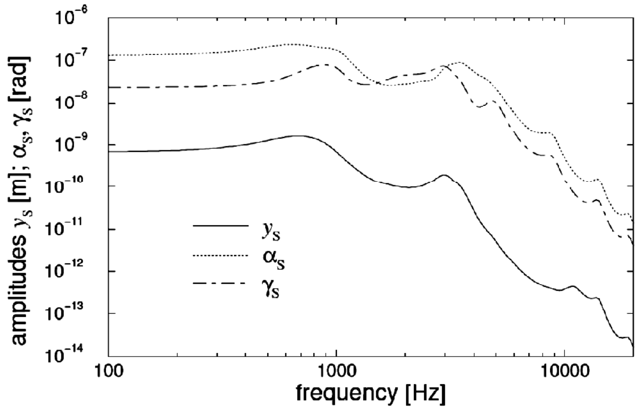


Figure 2: Transfer functions from free field sound pressure (60 dB SPL)to the motions of stapes footplate

To compare these motions, a measure for rocking can be defined as the translation of the vertices of footplate due to rocking in relation to the piston motion shown in figure 3.

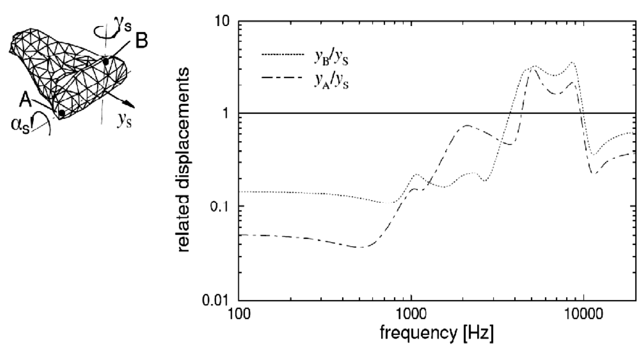


Figure 3: Rocking induced motion of vertices A and B related to the piston motion of stapes, [ei 2003]

A comparison of measured rocking motions taken from human temporal bones and those from guinea pigs is studied in Sim *et al.* [sim 2008]. Due to nonlinear properties of the ear drum and the ligaments, a nonlinear description is necessary for SPL above 80 to 100 dB.

3.2. Function of the Inner Ear

The equilibrium organ is hydraulically connected with the hearing organ in the cochlea. Pressure variations induced by the moving stapes footplate are propagating in the inner ear fluids guided by the complex shaped scalae. There are non-ideal boundary conditions due to the visco-elastic behavior and the gas and fluid resorption capability of the walls.

Reissner´s membrane and the basilar membrane separate the two fluids, perilymph in the scala vestibuli and scala tympani, from the endolymph in the scala media. Both fluids have a different chemical composition, which plays a role in the mechano-chemical processes of hearing.

Dynamical interactions between the membranes and the three-dimensional flow field in the fluid induce a motion of the Reissner´s membrane and in particular of the basilar membrane.

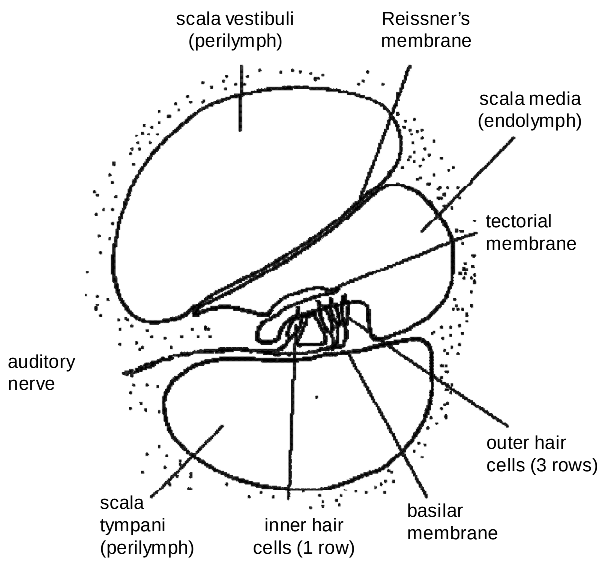


Figure 4: Section of the inner ear with membranes and organ of Corti.

Together with the motions of the tectorial membrane, the basilar membrane governs the fluid motion around the organ of Corti which is essential for hearing. This organ is located on the basilar membrane containing three rows of outer and one row of inner hair cells. Bending the stereocilia of a hair cell opens ion channels within the cell producing an electrical potential. The outer hair cells then contract and deliver an amplification of the motion of the basilar membrane. In the inner hair cells, characteristic sparks with an electrical potential up to 70 mV are transmitted by nerves to the brain evoking a hearing impression.

4. RECONSTRUCTIONS OF IMPAIRED HEARING

For the replacement of damaged or missing ossicles, rather permanent implants are used than absorbable ones. They should be biocompatible without any negative interaction with the natural structures. Particularly, the hearing organ is very sensitive, e.g. granulations around gold particles and toxic reaction of hydroxylapatite with liquor have been observed. A certain activity of osseointegration is desired where the grow factors for tissue and bone growing (modelling, remodelling) may be controlled by adding bioactive material or drugs on the surface or matrix of the materials in use.

Mechanical demands for implants are in a first instance the function of it and a design which can resist the mechanical load and which is easily and safely manageable for the surgeon with a low risk for the patient. Beside the long-time stability the most important point is the coupling of implant to the natural structures. The sound transfer through the reconstructed middle ear is strongly dependent on the points where the implant is attached (this defines orientation and kinematics) and the manner of mounting (this defines the dynamical behavior of transfer), respectively.

4.1. Passive Middle Ear Implants

For replacements of damaged or missing parts of the middle ear the main groups of used materials are autogeneous material like cartilage and fascia from the own body and alloplastic material like ceramics or metals.

Perforated or missing ear drums are commonly reconstructed using cartilage placed as a whole plate, as cartilage islands or in palisade patterns.

Replacements of ossicle parts are called partial ossicle replacement prosthesis (PORP), if the total ossicle is replaced a TORP is given. Typical prostheses are replacing the long process of incus or connecting the malleus handle with the stapes head or its footplate. Others are in between the long process of incus and the stapes. In case of otosclerosis the stapes becomes immobile within the oval window. By means of a piston prosthesis in the perforated footplate of stapes the inner ear fluid is excited. The piston itself is driven by the long process of incus or the malleus handle.

Due to the low weight, reasonable mechanical toughness and an easy manufacturing, modern implants are made from titanium. No negative effects concerning biocompatibility are known till now.

4.2. Active Middle Ear Implants

For an active driving of the ear, mostly electrical actuators controlled by a processor and an amplifier are used. The microphone can be placed behind the ear, in the outer ear canal or in its posterior wall. The driving principle of the actuator may be magnet and coil or piezoelectric bending of beams or discs as well as elongation of piezoelectric staples, Suzuki [suz 1988].

Different media for transmitting a force or displacement to the ear are in use as well as various points of acting at the natural structure. Conventional hearing aids act in the outer ear canal via an air cushion between the loudspeaker and the ear drum. Another type couples the actuator hydraulically with the round window of the cochlea by a pipe. Investigations are ongoing to transmit the driving forces and torques via a magnetic field by a separated alignment of a coil, e.g. behind the outer ear or in the outer ear canal and a magnet attached at the ossicular chain, Eiber [ei 2008].

The widest class is the mechanically coupled actuators. One has to distinguish between the basis point where the actuator is supported and the coupling point where it is attached to the hearing organ. In most of the cases the basis point is at the skull and the coupling point is at the incus, the stapes or even at the round window driving the system reversely. There are two exceptions from them, the floating mass transducer (FMT) which is mounted at the incus without any contact to the skull, Hong *et al.* [hong 2007]. The other one is the bone anchored hearing aid (BAHA) which is mounted at the skull and transmits the vibrations via structure-borne sound to the cochlea, Tjellstroem [tjel 1990]. In both cases, the driving forces are due to the inertia of the actuator core and therefore it is less powerful in the lower frequency range. A similar effect is expected from mounting a FMT at the bony wall of the cochlea near the round window, Kiefer *et al.* [ki 2006]. A mechanical stimulation of the perilymph fluid is realized by driving a classical piston prosthesis in the stapes footplate by an actuator, Häusler *et al.* [ha 2008].

Another direct access to the perilymph was tested by opening the bony wall of the cochlea near the oval niche and coupling a FMT at the cochlear endost, Settevendemie *et al.* [set 2008].

Another class of implants, the cochlear implants (CI), uses the direct electrical stimulation of the auditory nerves by an electrode placed in the scala tympani. They are applicable if the hair cells are destroyed.

4.3. Coupling of Middle Ear Implants

Besides the points of attachment, a crucial point is the force law of coupling characterized by its nonlinear stiffness and damping. Both of them are depending on the size of the graft or the natural structures, the intermediate graft itself and on the form of the gap between ossicle, Zahnert *et al.* [za 2004], Eiber *et al.* [ei 2000]. Depending on the design principle of the connection like crimping, clamping, pushing together or gluing, the coupling shows a more or less nonlinear behavior. It is mainly governed by the applied preload, which consequently plays an important role in sound transfer.

Plastic crimping is always involved with an elastic rebound leading to a weak or even to a loose coupling, and gluing with cement restricts the relative motion and the kinematics of the chain.

Clamping leads to reasonable tight connections and guaranties a good sound transfer. The transmittable force depends on the contact force which can be controlled by the stiffness of the elastic clip and its recess. To cover a broad range of different sizes of the ossicles, the stiffness should not be too high.

A similar tight coupling combined with an elegant mounting is expected by using shape memory alloys for coupling. Problems are undefined coupling forces, the application of heat and the reaction of the body on nickel particles.

Pushing rods are often used in actively driven implants. This unilateral constraint needs a permanent preload for the proper transfer of sound.

In all cases, coupling is the most critical point of reconstruction. The insertion and mounting of an implant by the surgeon should be possible in an easy way without any risk for the patient. The implant should transmit the desired forces and displacements and should preserve the natural structures so that the ossicles are secured form arrosion and degradation. Thus, the application forces should not be too high but on the other hand the contact forces should be in a range that sound is transmitted without distortion.

5. MODELS OF THE MIDDLE EAR

Models of the hearing organ have been developed by acoustical or electrical engineers based on electrical analogies and circuits. Such models are generally one directional described by scalar differential equations, e.g. Zwislocki [zw 1963] and in these models it is difficult to describe the three dimensional nature of ossiclular motion, Hudde and Weistenhoefer [hw 1997]. As another drawback, their model parameters are not directly related to the geometrical dimensions or the physical quantities like mass and stiffness, so that it is difficult to describe a specific anomaly of the hearing organ.

Dealing with mechanical systems, powerful approaches and well developed program packages are available for modelling the combination of different physical effects and different properties of the considered system. In the practical application to biological systems this may cause some problems in defining the appropriate structure of the system and in finding the belonging parameters. In practice it is difficult to define the correct geometrical shape of elements like ligaments and the complex structure of different skin layers. Spatially oriented fibers often prevent also from correct description. Thus homogenization procedures are applied and blurred properties are represented by the parameters.

Finite Element models (FEM) deliver a very detailed description of local stress and allow the incorporation of fluid structure coupling, Prendergast *et al.* [pre 1999], Gan *et al.* [gan 2004]. The calculation of small deformations is straight forward but the models have plenty degrees of freedom and need detailed data for geometry and material, Beer *et al.* [bee 1999], Wada *et al.* [wad 1992].

Boundary Element models (BEM) are suitable for transition of sound between different media.

Multibody Systems (MBS) are widely used for dynamical problems and large spatial motions. Nonlinear behavior of elements can be elegantly implemented and the models have low degrees of freedom.

Modern program packages try to combine the advantages of the different modelling approaches.

For the investigation of the dynamical behavior of the middle ear with the focus on the spatial arrangement of the ossicles and their three dimensional motions in a vectorial description, in general the multibody approach is applied. For particular parts like the ear drum Finite Element models have been established and their results were incorporated into the MBS model.

The ear drum shows different mechanical behavior for the pars flaccida and the pars tensa. Both have a spatially formed shape and a fluid/solid interaction with the adjacent air. It is composed of several layers reinforced with fibers and can be considered as an anisotropic, inhomogeneous material. Nonlinear effects must be regarded due to nonlinear constitutive laws of material and due to large displacements.

The geometrical shape of the ossicles and the attachment points of ligaments and joints have to be regarded in the mechanical models, e.g. Lang [la 1992], Kirikae [kiri 1960]. The material is inhomogeneous and anisotropic and the mass and its distribution has to be measured, Weistenhöfer [wei 2002], Puria et.al. [pu 2007]. In case of physiological sound transfer, their elastic deformations are small in comparison to that of the ligaments and joints which allows to consider them as rigid bodies.

The ligaments are very difficult to determine concerning their length, cross sections, inner structure and mechanical characteristics. Actual models describe the mechanical behavior by simplified force laws even in the alleged detailed FEM analysis. For small deformations, they are considered as linear visco-elastic elements described by 6-dimensional force laws accounting for deformation and their time derivatives. For larger deformations the relations become highly nonlinear, Eiber and Breuninger [eibr 2004]. Such deformations may occur due to sound events with high intensity but also in case of static preload leading to a working position different from the natural one.

In a similar way joints are described. Due to the complex shape, additional kinematical constraints may appear which impede motions in particular directions, e.g. in the incudo-malleolar joint.

In Figure 1, a typical Multibody System model is illustrated 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 derived from a FEM analysis. The ligaments and the two muscles tensor tympani and musculus stapedius are described as massless visco-elastic coupling elements including an active part which is described as a force element. An active middle ear implant attached at the incus body is included which is modelled either as a force element or a kinematical constraint. In the first case, this model has 83 degrees of freedom and the generalized coordinates are in the vector $\boldsymbol{z}$.

The equation of motion

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

describes the dynamical behaviour of the system, 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 like ligaments and joints with progressive, partially degressive, but in most of the cases asymmetrical and non-smooth characteristics.

The typical behavior of implant coupling is similar to that of the incudo-stapedial joint with asymmetry and kinks, such a characteristic may cause a distorted sound transmission. Kinematical nonlinearities due to large amplitudes of ossicles´ motion can be disregarded for physiological hearing.

Static preloads acting at the ossicular chain deflect it with a nonlinear characteristic 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 $\boldsymbol{y}_{wp}$ as

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

where $\boldsymbol{D}$ denotes 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.

By means of time-integration the time history of specific stimulation, in particular of transient sound events, can be investigated based on the equations of motion (1) or (2) of the entire system. They consist of the ear canal, the ear drum, the ossicular chain with inner ear elements as well as the actuator with its control elements. In case of linearized equations (2), frequency domain methods can be used to analyze the system.

5.1. Determination of Parameters

Fundamental problems in biological systems are first its topology and the geometrical shape of the elements under consideration, second the definition of the constitutive equations of their material and third the determination of the belonging material parameters.

In many cases the investigations can only be made on cadaver specimen and these results serve as a base to estimate the system behavior of living subjects.

Using the powerful approaches of image processing like classical histograms, CT or MRT, the geometrical shape of the elements can be reconstructed with a quite high accuracy and transferred into nodal or surface representation of three-dimensional bodies. In order to deal with models adequately for a specific problem at hand, it is necessary to reshape and simplify the geometry.

The appropriate choice of constitutive material laws depends strongly on the problem under consideration and it needs a lot of experience, Bornitz *et al.* [bo1999].

In most of the cases the accessibility to the measurement points is restricted and the interesting parameter which is under focus can only be identified in an indirect way. In our case, the stiffness of ligaments was derived from measured natural frequencies as well as from deformation measurements.

5.2. Measurements

Biological systems like the hearing organ show big interindividual as well as intraindividual variations. This holds for the geometrical shapes and dimensions of the elements as well as for their mechanical properties like mass, stiffness and damping. Therefore, each single measurement has to be taken very accurately and interpreted physically in order to find out whether error influences come from the object, the method of measurement or from environment. The parameters have to be determined and interpreted separately for each individual to obtain the full range on interindividual variations. It has to be mentioned, that averaging over measurements in a series of individuals may blur or even cancel out particular effects in the response of the system.

Due to the small dimensions and the restricted access only a few procedures are applicable. Microphones and hydrophones are in use to pick up the sound pressure in air or fluids of the cochlea. Strain gauges are taken to measure elastic deformation or forces. Very powerful are laser measurements with a laser Doppler vibrometer (LDV) to pick up displacements or velocities of points without any contact.

By a combination of three beams in one camera, the spatial velocities of a point can be measured as illustrated in figure 5.

Considering the stapes as a rigid body with three degrees of freedom these signals can be used for the reconstruction of its spatial motion. Another approach for that is the use of scanning laser where the motion of

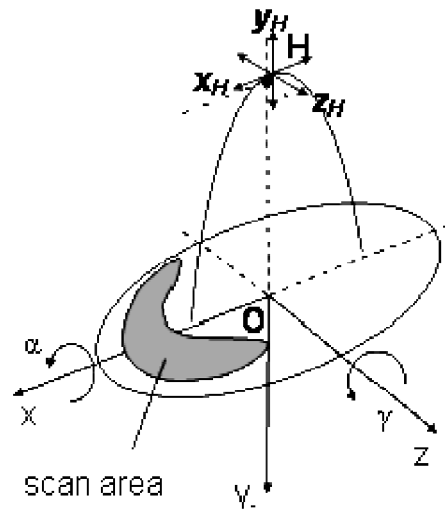


Figure 5: Measurement of the spatial velocities of the stapes head H and area of footplate accessible for a scanning laser

a surface is reconstructed from measurements at different points on the surface.

Due to the measurement principle of a LDV, its output signal is only the projection of the actual vector of velocity onto the direction of laser beam. For the reconstruction of spatial motion, this fact has to be regarded and also the shape of the scanned area should be taken into account using weighting factors, Sim *et al.* [sim 2008].

Measurements with two LDV simultaneously have been carried out to derive the transfer functions of cadaver specimen as shown in figure 6, Eiber [ei 2008b].

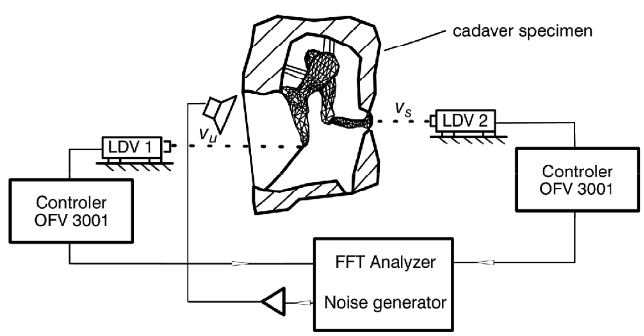


Figure 6: Measurement of the transfer function between Umbo at the tip of manubrium and stapes footplate with two Laser Doppler Vibrometers

Forces can be picked up using load cells e.g. to determine the application forces of implants or to calculate stiffness coefficients. A typical set up and the result for stiffness of a passive clip piston implant is shown in figure 7.

6. SIMULATIONS AND REPRESENTATION OF RESULTS

In biological systems, surfaces and shapes of elements are determined by natural optimization processes

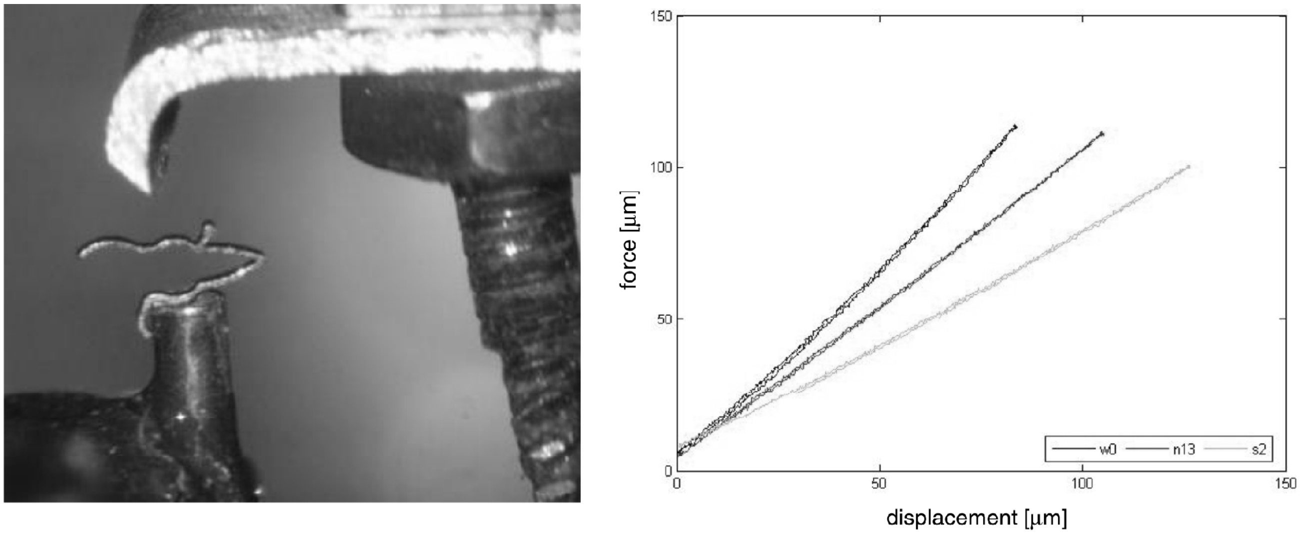


Figure 7: Left: Measurement of force with a load cell and displacements with a LDV. Right: Stiffness of a piston prosthesis, three different clip types are considered

therefore geometry and alignment is quite complex as against technical systems which can mostly well described in cartesian coordinate systems by more or less orthogonal shapes. Thus, the describing coordinates are non-orthogonal and the coordinate systems are arbitrarily oriented in space.

For the discussion of results in an interdisciplinary group of engineers and physicians, the visualization of complex spatial motions of the ossicles in a virtual reality environment can be very helpful. With that, the surgeons may have a deep insight into the dynamical behavior of the system even from viewpoints which are not accessible in reality. It is a powerful approach in the process of understanding the dynamical properties of the system and in the process of model validation or estimation of plausible parameters, too

7. APPLICATIONS

7.1. Redesign of a Passive Clip Prosthesis

In case of severe otosclerosis, the stapes becomes immobile due to calcification of the annular ring which seals the liquid-filled inner ear from the air-filled tympanic cavity. In a stapedotomy, the surgeon removes the crura of stapes and forms a hole in the footplate using a drill or a laser. A piston prosthesis is inserted and has to be fixed at the long process of incus. This attachment can be made by plastic deformation of a loop with the drawback of a small elastic spring back leading to a remaining gap between incus and metal loop.

The existing Clip-Piston prosthesis A‘Wengen for stapes surgery guarantees the desired safe coupling of the clip only for certain dimensions of the long process of incus. In case of small diameters, there is a loose coupling and consequently an insufficient sound transfer. In case of very big diameters, the clamping force is too high and moreover, to slip on the clip at the process of incus, a strong force is necessary. This causes a high risk of damaging the ossicular chain like by luxation of incus.

Based on a Finite Element model the shape of the clip has been redesigned at the entrance-, the contact- and the elastic spring region as depicted in figure 8. Intraoperative measurements at the long process of incus show diameters varying from 0.5 to 1.0 mm, Schimanski and Eiber [schim 2007].

Figure 8: Two elastic clip prostheses made from titanium for stapedotomy (Kurz Medizintechnik, Dusslingen, Germany). Left: type A‘Wengen, right: new design, Soft Clip Piston

The new clip fits optimally even for small and as well for big diameters of incus in the range between 0.55 mm and 0.95 mm and guarantees a good sound transfer. On the other hand, the force to slip it on place is reduced by more than 40% leading to an easier application, which is significantly safer for the patient. Moreover, a homogeneous distribution of mechanical stress within the clip was achieved reducing the risk of plastic deformation during application, Eiber and Schimanski [eisch 2008].

Before a clinical use the implant has to be tested by simulation and by measurements in the lab. Simulation results concerning stiffness and application forces could be verified by measurements, figure 9 and 10. To assess the handling of the prosthesis the process of application was simulated and represented on a virtual reality environment offering a very detailed observation of the extremely difficult surgery step.

The clinical application of the new clip prosthesis has validated all the numerical experiments and measurements in the lab.

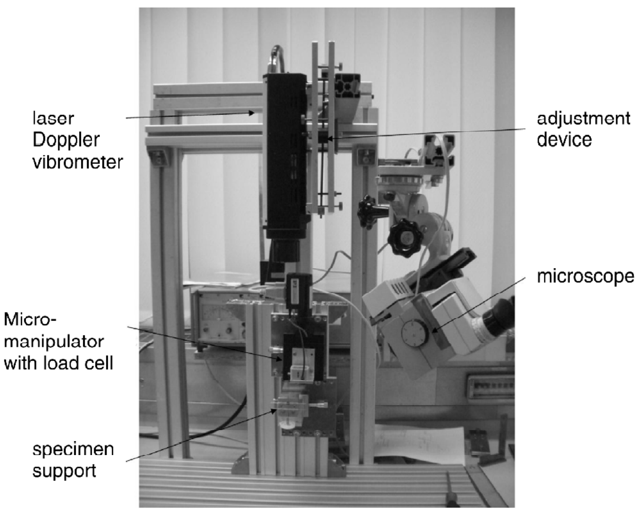
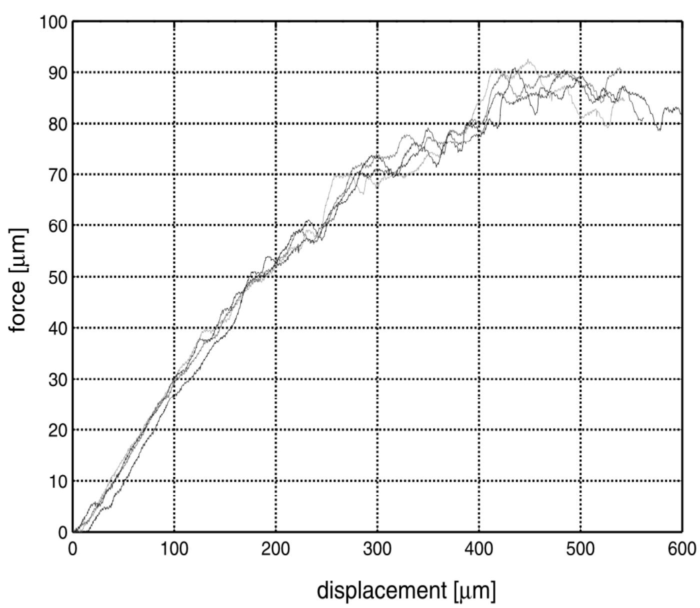


Figure 9: Test rig for measuring the application forces

7.2. Spatial Motions of Stapes and Hearing Sensation

Simulations with three-dimensional models show pronounced spatial motions of the ossicular chain. Particularly in the higher frequency range the stapes carries out significant rocking motions around the long and the short axis of footplate, respectively. According to the classical theory of hearing there is no net volume displacement from the rocking motion and therefore no hearing sensation. It was postulated, that rocking motions will produce a hearing impression, too. For a proof, the stapes of a living guinea pig was exposed by removing the outer ear and the ear drum with malleus and incus. At the stapes head a custom made actuator consisting of three piezoelectric stacks was attached and fixed by a thin thread to drive the stapes in its three elementary motions: translation perpendicular to the footplate (piston) and two rocking motions, Eiber and Breuninger [eibr 2007]. The actual motion of the stapes head was measured using a 3D-laser (CLV-3D Polytec Waldbronn, Germany). This signal was used in an open loop to control the actuator. Parallel to that, an electrode was placed near the round window to pick up the potential of the hearing nerves. In figure 11 the elicited motion patterns of the stapes are illustrated in the row above as a response to an excitation with a low pass filtered click containing frequencies up to 2 kHz. These motions are not purely elementary motions because all three components appear. Nevertheless, they are clearly piston dominant and rocking dominant. In the second row below, the corresponding cochlear potential is shown. In electrocochleographie, two types of neural response is observed: the cochlear microphonics (CM), which is



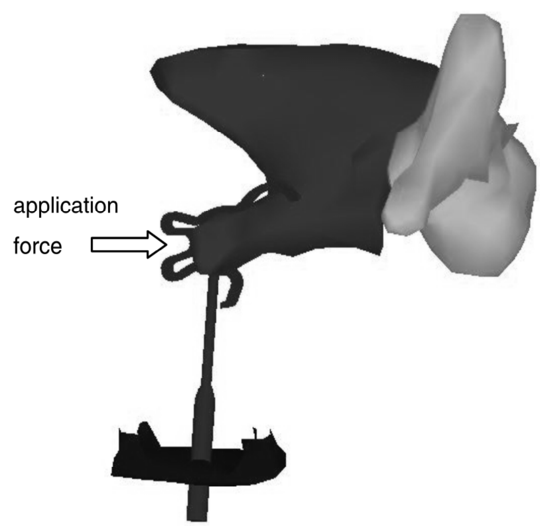


Figure 10: Application of a clip prosthesis on the long process of incus. Left: Force to slip on the prosthesis over the long incus process, diameter of incus is 0.8 mm. Right: Graphical representation of application process in the Virtual Reality Environment (2-D single shot)

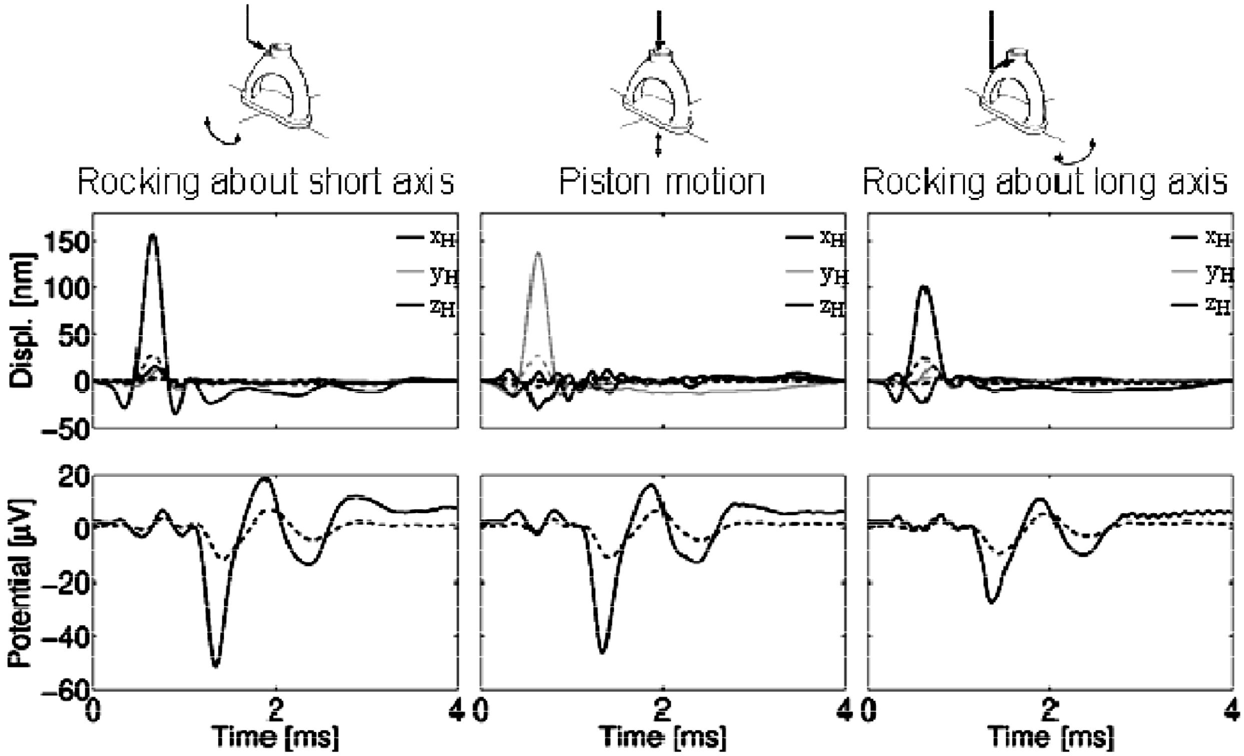


Figure 11: Predominant motion patterns of stapes, left: rocking around short axis, middle: piston motion, right: rocking around long axis. Below: corresponding compound action potential due to a click excitation with low (dashed line) and high intensity (full line)

proportional and time conform to the excitation and the compound action potential (CAP), which has the same sign for positive and negative clicks and a characteristic time delay, Sequeira *et al.* [seq 2007]. This time delay decreases with increasing intensity of excitation as it can be clearly seen.

Evaluating the intensity of excitation and the pattern of motion it becomes obvious that the main part of hearing sensation, represented by CAP, is induced from the piston-like movement of stapes but there is a significant fraction coming from the rocking motion.

7.3. Active Middle Ear Implant

A totally implantable actuator with a driving rod pushed against the incus as shown in figure 1 is considered. The transfer of driving forces is maintained by an unilateral coupling which needs a permanent preload against the ossicle. It must be sufficiently high to maintain a good coupling even in case of static pressure variations in the tympanic cavity or the cochlea. Consequently, the working point of the chain is shifted causing a changed characteristic of sound transfer. But, the high preload of the ligaments leads to a long time relaxation process in which the preload decreases.

During insertion of the actuator, the surgeon gives the demanded preload in form of a pre-deformation by turning an adjustment screw by a certain angle φ or an adjustment travel a_0. The resulting preload as a force is depending on the individual stiffness of the ossicular chain, the stiffness in the coupling region between driving rod and incus and the internal stiffness of the actuator itself. Out of the first two reasons, strongly nonlinear relations come into play. The internal stiffness of the actuator is particularly dependent on its driving principle, a core in a coil is weakly coupled to the coil in comparison to piezoelectric elements. Thus, a magnetically driven implant shows a much better adaptation to changes of preload than a piezoelectric driven one.

In order to calculate the preload in terms of the adjustment travel, a nonlinear model of the entire system is necessary and it is very difficult and cumbersome to define the optimal value as well as to assess the adjustment procedure during surgery, Eiber *et al.* [ebrzm 2007]. This can be done by the help of a running actuator and a microphone in the outer ear canal. It detects the radiated sound from the ear drum when the actuator comes in contact with the incus. An estimation of the actual preload in relation to the adjustment travel can be derived from the equations of motion. Additional information can be drawn from the power consumption of the actuator.

Due to the nonlinear behavior of the unilateral coupling, severe distortion effects may occur in the sound transfer if the preload is below a certain limit. Due to the nonlinear behavior of the chain and the coupling region, a high preload leads to a stiffened chain and higher driving forces are demanded from the actuator in order to get the desired amplitudes of the stapes, i.e. the desired hearing sensation. But the applicable driving forces are limited on the one hand by the capacity of the actuator itself and on the other by the sound which is radiated from the ear drum into the outer ear canal due to its big amplitudes.

Via the microphone, this may lead to feedback effects in the system. As a consequence, high preload restricts the excitation of the inner ear and prevents the implant to a full compensation of a given hearing loss.

A gain margin of amplification as the distance from the maximal applicable amplification to fulfil the stability condition and that amplification which is necessary to compensate an actual hearing loss can be defined. The gain margin depends nonlinearly on the preload and of the frequency of excitation as illustrated in figure 12. In case of high preload, an assumed hearing loss of 40 dB (between mild and moderate hearing loss) can not be compensated in the lower frequency range due to ringing, Eiber *et al.* [eizl 2008].

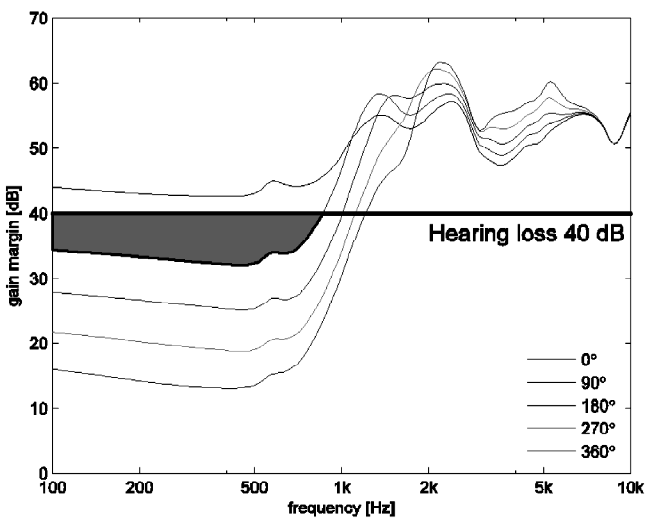


Figure 12: **Gain margin as the potential amplification without ringing for a specific ossicular chain and reconstruction depending on different static preload φ. An assumed hearing loss of 40 dB and the sector of remaining hearing loss after reconstruction are indicated**

As another consequence, big adjustment travels lead to high static loads in the ligaments. The force in the posterior incudal ligament is depicted in figure 13 for different adjustment travels in comparison with the load of 300 daPa during tympanometry and a sound pressure level of 60 dB.

7. CONCLUSIONS

Multibody Systems approach as a well developed modelling technique is capable to describe big classes of

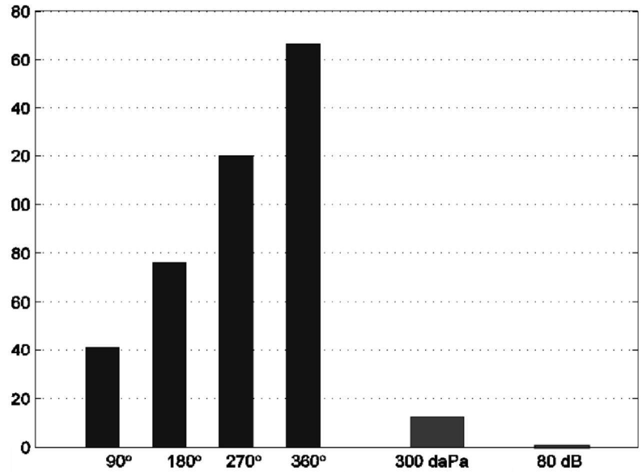


Figure 13: **Force in the lig. incudis post. due to different adjustment travel j of an active implant in comparison to the static load during tympanometry and due to a sound pressure level of normal speaking**

biological systems. They consist of a relative low number of elements and parameters and a broad variety of numerical solution algorithms is on disposal. This modelling technique is very closely adapted to the classical engineering approach that leads to a clear procedure of investigation. It offers a substantial insight into the dynamical behavior of a system and allows a precise interpretation of results. Even for complex systems the determination of model parameters is straightforward and results from other modelling techniques like Finite Elements can be incorporated.

In particular the spatial structure of the middle ear with the fluid filled cavities can elegantly be coupled with passive and actively driven middle ear implants. The nonlinear relations for ligaments and coupling conditions of implants with the natural structures can be easily incorporated. In case of pathologies, the models can be adapted by varying the system parameters.

Simulations offer an insight into the dynamical behavior of normal, pathological and reconstructed ears and facilitate the diagnosis of impairments. They allow the improvement of existing and the development of new passive and active implants for reconstruction of impaired hearing. To the surgeon valuable hints for reconstruction procedures can be given.

These investigations shorten the clinical trial and error series on living patients.

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