Aktive Implantate im Incudostapedialgelenk
der Gehörknöchelchenkette

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I. Einleitung

1. Motivation für implantierbare Hörgeräte


2. Einteilung aktiver Hörgeräte

3 Entwicklung vollimplantierbarer Hörsysteme

Er wird entweder an diversen Positionen der Gehörknöchelchenkette oder dem Trommelfell angekoppelt, im runden Fenster des Innenohrs verankert oder über einen Piston direkt mit der Innenohrlüssigkeit verbunden. Der technische Stand implantierbarer Hörsysteme und ihrer Elemente mit deren prinzipiellem Aufbau und Wirkprinzip ist in den einleitenden Kapiteln der diese Dissertationsschrift bildenden Publikationen vorgestellt und referenziert, den umfassendsten Überblick bietet Publikation 3 (Koch et al., 2015).

3. Entwicklung vollimplantierbarer Hörsysteme

4. Anforderungen an implantierbare Sensoren und Aktoren

Für die Implementierung von Mikrofon- und Aktorkomponenten als Bestandteile eines Vollimplantats kommen verschiedene Wirkprinzipien und -orte zur Signalerfassung und Signalgenerierung in Frage. Es kommen hauptsächlich eine Reihe von kapazitiven, elektromagnetischen oder piezoelektrischen Wirkprinzipien und die verschiedensten Ankopplungspunkte wie z.B. subkutan im Gehörgang, am Trommelfell, an der Gehörknöchelchenkette oder auf der Rundfenstermembran zum Einsatz. Dabei müssen verschiedenste Randbedingungen gewährleistet werden. Neben den bloßen Leistungsdaten wie dem Signalertrag des Sensors und dem äquivalenten Pegel des Aktors spielen folgende Kriterien eine große Rolle bei der Auswahl:

- Handhabbarkeit des Sensors/Wandlers, Komplexität des Einbaus
- Reversibilität des chirurgischen Eingriffs
- Biokompatibilität der verwendeten Materialien bzw. des Verbundelementes
- universell nutzbares, von der individuellen Anatomie möglichst unabhängiges Design
- Körperschallentkopplung des Sensors
- Robustheit gegenüber äußeren Einflussfaktoren wie elektromagnetische Strahlung, mechanische Stöße, Feuchtigkeit, Luftdruckschwankungen u.a.

Die Forschungsprojekte aus denen die vorliegenden Publikationen hervorgegangen sind beschäftigen sich mit Sensoren, Aktoren und kombinierten Wandlerelementen die den Anspruch erheben die genannten Anforderungen zu erfüllen. Deren Gemeinsamkeit beruht hierbei auf der prinzipiellen Bauart und dem Incudostapedialgelenk (ISG) der Gehörknöchelchenkette als Ort der Anwendung. Die Publikationen und ihr thematischer Zusammenhang werden in Kapitel II vorgestellt.
II. Inhalt und thematischer Zusammenhang der Publikationen


In der Publikation 1 wurde ein solcher Sensor anhand von Felsenbeinexperimenten mit einem maßstäblichen Musterelement und vergleichend mit einer Finite-Elemente (FE)-Simulation untersucht. Im Fokus lag dabei der Signaltransfer der Sensoren, weiterhin wurde die Empfindlichkeit des Signaltransfers auf außermittige Positionierung und unerwünschte zusätzliche Kontakt punkte mit der umliegenden Anatomie analysiert.

Für die Publikation 2 wurde der Sensor um ein Aktorelement erweitert. Wegen der unvollendeten Miniaturisierung des Musterr wandlers musste für den experimentellen Teil der Untersuchungen auf ein physikalisches Modell des Mittelohrs mit justierbarer Spaltbreite des ISGs zurückgegriffen werden. Der Dynamikbereich zwischen Hörschwelle des Sensors und maximaler äquivalenter Ausgangsleistung des Aktors wurde für den Wandler vergleichend

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\(^1\)Die mechanisch korrekte Bezeichnung hierfür ist eine „Platte“, da eine Membran weder Kräfte senkrecht zu ihrer Ebene, noch Biegemomente aufnehmen kann. In der Akustik ist jedoch zur Beschreibung von entsprechenden Mikrofon- und Lautsprecherbestandteilen die Bezeichnung Membran gebräuchlicher, weshalb diese Bezeichnung in den Publikationen Verwendung findet.
simuliert und gemessen. Mit einer Ansteuerung des Wandlers über einen programmierten Field Programmable Gate Array (FPGA) mit einer Rückkopplungsunterdrückung mittels Least Mean Square (LMS)-Algorithmus konnte die theoretisch mögliche Signalverstärkung im Rahmen des Dynamikbereichs ermittelt werden.

Abstract
There is a great demand for implantable microphones for future generations of implantable hearing aids, especially Cochlea Implants (CIs). An implantable middle ear microphone based on a piezoelectric membrane sensor for insertion into the incudostapedial gap is investigated. The sensor is designed to measure the sound-induced forces acting on the center of the membrane. The sensor mechanically couples to the adjacent ossicles via two contact areas, the sensor membrane and the sensor housing. The sensing element is a piezoelectric single crystal bonded on a titanium membrane. The sensor allows a minimally invasive and reversible implantation without removal of ossicles and without additional sensor fixation in the tympanic cavity. This study investigates the implantable microphone sensor and its implantation concept. It intends to quantify the influence of the sensor’s insertion position on the achievable microphone sensitivity. The investigation considers anatomical and pathological variations of the middle ear geometry and its space limitations. Temporal Bone (TB) experiments on a laboratory model show that anatomical and pathological variations of the middle ear geometry can prevent the sensor from being placed optimally within the Incudostapedial Joint (ISJ). Beyond scattering of transfer functions due to anatomic variations of individual middle ears there is the impact of variations in the sensor position within the ossicular chain that has a considerable effect
on the transfer characteristics of the middle ear microphone. The centering of the sensor between incus and stapes, the direction of insertion (membrane to stapes or to incus) and the effect of additional contact points with surrounding anatomic structures affect the signal yield of the implanted sensor. The presence of additional contact points has a considerably impact on the sensitivity, yet the microphone sensitivity is quite robust against small changes in the positioning of the incus on the sensor. Signal losses can be avoided by adjusting the position of the sensor within the joint. The findings allow the development of an improved surgical insertion technique to ensure maximally achievable signal yield of the membrane sensor in the ISJ and provides valuable knowledge for a future design considerations including sensor miniaturization and geometry. Measurements of the implanted sensor in TB specimens showed a microphone sensitivity in the order of 1 mV/Pa.

1. Introduction

1.1. Cochlea Implants

Today it is possible to restore hearing and speech intelligibility to many deaf people with CIs (Clark, 2003). Modern CIs-Systems include the implant and external body worn components comprising the audio-processor with external microphone and power supply and the external part of the inductive link. The external, body worn components are very much exposed to environmental influences and therefore are susceptible to degradation and damage. There are other motivations for the development of completely implantable devices such as avoiding the stigma of visible hearing aids or allergies of the skin to the materials. Great efforts have been made to develop fully implantable systems, an overview of the wide range of approaches is given by (Backous & Duke, 2006) and (Haynes et al., 2009). An important and challenging structural component of all these assemblies is the microphone or sound sensor component.

1.2. Implantable microphone

Existing devices include encapsulated microphones which are placed under the skin in the ear canal (TICA, Implex GmbH) ((Zenner et al., 1998), (Zenner et al., 2000)) or near the mastoid
Figure 1: A schematic illustration of the inserted sensor.

(CARINA, Otologics) (Bruschini et al., 2010). The other group of sensors picks up vibrations of the eardrum or the ossicles and generates an electric (microphone) signal. The majority of sensors are piezoelectric devices, preferably bending type piezos, with one end fixed in the bone of the middle ear cavity and the other end is coupled to the ossicular chain (Esteem, Envoy Medical, (Barbara et al., 2009); Rion E-Type (Yanagihara et al., 2001)). Another approach is the use of a small accelerometer, attached directly to the incus (Park et al., 2007) or the umbo (Zurcher et al., 2006). The laboratory model of the sensor we examine is designed to be fixed within a gap opened up in the ISJ. It consists of a piezoelectric single crystal bonded to a thin 40 mm thick oval (4 mm x 2.5 mm) membrane in a titanium housing. The thickness of the sensor is 1 mm. It acts as a force sensor that generates a microphone signal from the force transmitted through the ossicular chain. A demonstration of the sensor position in a TB is shown in Figs. 1 and 2.
1 Introduction

1.3. Incudostapedial joint gap as sensor position

The ISJ gap provides advantages for the insertion and for the function of the sensor itself. It enables the sensor to make use of the outer and middle ear sound transfer. The static pressure protection of the middle ear is preserved. The implantation is minimally invasive and there is no additional fixation in the tympanic cavity needed. For implantation or reversing the implantation of the sensor the long process of the incus has to be slightly lifted with a needle and the sensor can easily be inserted or pulled out. In accordance to (Fisch & May, 1994) who open the ISJ to “avoid injury of the inner ear when manipulating along the malleus handle” this opening of the joint should be fully reversible (“reapproximation of the joint ensures full functional recovery”). However there are no investigations how such healing can occur month after chain interruption. Despite these advantages, the limited space for the sensor may cause problems. Normally in a membrane sensor, the membrane should be deflected in response to a force acting on the center of the membrane. However in this experimental application anatomical and pathological variations of the middle ear geometry sometimes prevent the sensor from being placed optimally, and can lead to unwanted additional coupling points to the anatomical structures of the middle ear. Sources of such structural interference include the position and geometry of the malleus handle, the ligament of the tensor tympani, the promontory of the cochlea base and the long

Figure 2: Demonstration of the sensor inserted into a TB.
process of the incus.

1.4. Aims of the study

The study intends to answer the following questions: How strongly is the microphone sensitivity of the implanted sensor affected by additional contact points between the sensor and the middle ear anatomy? To examine the influence of the sensor positioning, experiments were conducted using a laboratory model of the sensor in the TB. To verify the experiments the sensor was also simulated in a Finite-Elemente-Method (FEM)-model of the middle ear.

2. Materials and methods

2.1. Temporal bone experiments

2.1.1. Specimen preparation and experimental setup

The measurements were undertaken with 10 fresh human cadaveric TBs which were stored in NaCl 0.9 % for up to 2 days. The preparation of the TBs and the general measurement setup were similar to previous descriptions and are shown in Fig. 3 (Neudert et al., 2009). The access to the middle ear with the tympanic cavity was done via a mastoidectomy and a modified posterior tympanotomy. The mastoid segment of the facial nerve was removed. The ossicular chain and its ligaments remained intact for the beginning of the measurements. An “Eartone 3A” sound generator was plugged inside the ear canal to stimulate the ear drum with a constant sound pressure level. The stimulation was generated by a software controlled multisinus signal generator within a frequency range of $0.1 \text{kHz} < f < 6 \text{kHz}$ configured by the software (Labview version 2011, National Instruments). To ensure that transfer characteristics of the middle ear remains in the linear region (Asai et al., 1999) the applied Sound Pressure Level (SPL) did not exceed 110 dB SPL. The measurements were undertaken with a Data Acquisition Board (NI PXI 4496, National Instruments). The sampling rate was 12 kHz, the blocksize of the undertaken Fast Fourier Transformation (FFT) was 512 and ten measurements were averaged. The sound pressure level in front of the ear drum as a reference signal was measured with a probe microphone (ER7C-Probe Mike System, Etymotic Research), which was positioned through an additional access. The stapes velocity was measured by means of Laser Doppler Vibrometry (LDV) (Laser
2 Materials and methods

Figure 3: Experimental setup for TB measurements.

CLV 700, Controller CLV1000, Polytec). The laser pointed through the posterior tympanotomy on the center of the stapes footplate and focused on a small reflective foil that was placed there. The dynamic forces of the ossicular chain have been measured with the sensor which is the core element under investigation of this study. The sensor signal has been conditioned by a voltage amplifier (SR 560 Low-Noise Preamplifier, SRS Stanford Research Systems).
2 Materials and methods

Figure 4: Directions for the displacement of the sensor position, example for a lengthwise displacement of 0.75 mm (lower left) and 1.5 mm (lower right).

2.1.2. Experimental protocol

Every experiment started with a reference measurement of the movement of the stapes of the intact ossicular chain to determine the Middle Ear Transfer Function (METF). After that the ISJ was separated with a sickle knife. The sensor was inserted with the membrane centered on the contact area of the incus. The long axis of the sensor was parallel to the tympanic part of the facial nerve. The sensor was placed in nine TBs. It was positioned in the center in eight of the TBs, only in one TB it had to be deviated 0.5 mm lengthwise and 0.25 mm crosswise due to space limitations. The sensitivity of the sensor in the centered position was determined in V/Pa. In case of additional contact areas with other anatomical structures of the sensor in the centered position, different positions of the sensor were tested in order to optimize the signal yield. Therefore small changes in the position of the sensor were introduced to eliminate any additional contact areas. Thus the optimal sensor position and the influence of the choice of the position were determined. After this the sensor was flipped with the membrane pointing to the stapes and the sensitivity was determined again because sometimes this could be an alternative in case there is a risk the membrane will touch additional unwanted points of the middle ear. The METF measurements have been repeated for the measurements with the sensor in the centered
position to determine the influence of the sensor’s mass at the ossicular chain. They have also been repeated for the measurements with the sensor touching the promontory to determine how a coupling point with the promontory influences stapes movement and therefore acts as an additional support for the sensor. To determine how much the change in sensor position itself affects its sensitivity the sensor was placed in a TB which had plenty of space to position the sensor arbitrarily. Its position was varied lengthwise and crosswise to the long axis of the sensor gradually to identify the amount of sensitivity change due to position variation (Fig. 4).

2.2. Simulation in the middle ear FEM model

The comparative simulations of the implanted sensor have been performed by application of a middle ear model (see Fig. 5). The model consists of the ear canal (acoustic fluid with 3rd order boundary condition (Robin boundary condition) at the canal entrance to simulate the infinity of the surrounding air), the eardrum (orthotropic-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 (Bornitz et al., 2010). The air volume of the middle ear cavity is not included in the model which affects the METF by about 5 dB (Voss et al., 2000). This is less than the observed variation in METFs across different middle ears of 10 dB and more. The model does not consider material nonlinearities. Opening the joint and inserting the sensor may, however cause increased stiffness of the annular ligament due to its nonlinear elastic behavior (Gan et al., 2011). In this case we still use linear elastic material behavior but set the annular ligament stiffness to a higher value up to a complete stiffening/fixation of the annular ligament. The sensor is simulated with 3D-20-node solid elements for the housing, the glue and the titanium membrane and with 3D-20-node coupled field solid elements for the single crystal piezo to represent the electromechanical coupling. The contact areas (circles of $d = 1\text{ mm}$) with the ossicles are merged to a fixed area and attached to predefined coupling points in the middle ear model between incus and stapes. The position of the coupling area can be changed to simulate the different position situations of the sensor and provide comparative values for the experiments (see Fig. 4). The position has been changed up to 1 mm in crosswise and up to 1.5 mm in lengthwise direction. The membrane with the piezo pointing to the incus is defined as the normal sensor insertion position. The direction of the coupling can be changed in such a way that the sensor is flipped and the membrane points
towards the stapes. This is defined as the flipped sensor position. The stimulation is performed with a defined sound pressure at the entrance of the ear canal. The simulated output values are the reference pressure in front of the ear drum, the displacement of the footplate center in direction of the longitudinal stapes axis and the voltage at the electrodes of the piezo. The sensitivity of the sensor in the middle ear model has been determined as a frequency response of the sensors voltage related to the pressure at the ear drum. The influence of the contact of additional anatomical structures has not been simulated because the kind of coupling at these contact areas is very variable.

Figure 5: Simulation of the sensor in the middle ear model from (Bornitz et al., 2010).
3. Results

3.1. Insertion of the sensor in the temporal bones

It was possible to insert the sensor into nine of the ten TBs. One TB had a pathological ossified ISJ so the joint could not be opened. Two of the bones had a hypermobile stapes and were used to test the fit of the transducer, but no further measurements were made. There were eight TBs in which the sensor could be inserted into the centered position, but in six of these the sensor could only be centered in the joint in the presence of additional contacts with surrounding structures due to the wide scattering anatomy between different middle ears (Todd, 2008). The anatomic structures touching the inserted sensor in the initial position in most cases were the long process of the incus (seven times), the promontory (two times) and the malleus handle (two times). A structural picture of these contact areas is shown in Fig. 6. A detailed listing of the touching points is given in Table 1. In most of the TBs the sensor could be moved slightly out of the centered position (less than 0.3 mm) to a position without these touching points. In one TB the sensor touched the promontory and the long process of the incus at the same time, so an additional contact area could not be avoided.
Table 1: Description of sensor position (centered = deviation from center point approximately smaller than 0.2 mm) and additional contact areas (A = long process of incus, B = promontory, C = malleus handle, see also Fig. 6) after insertion in best possible position for all determined TBs.

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<td>No</td>
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<tr>
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<td>Yes</td>
<td>No</td>
<td>Stapes hypermobile, not further examined</td>
</tr>
<tr>
<td>5</td>
<td>Centered</td>
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<td>No</td>
<td>No</td>
<td>Stapes hypermobile, not further examined</td>
</tr>
<tr>
<td>6</td>
<td>Centered</td>
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<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Centered</td>
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<td>Yes</td>
<td></td>
</tr>
<tr>
<td>8</td>
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</tr>
<tr>
<td>9</td>
<td>Centered</td>
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<td>No</td>
<td>No</td>
<td>ISJ ossified, not further examined</td>
</tr>
<tr>
<td>10</td>
<td>Centered</td>
<td>No</td>
<td>No</td>
<td>No</td>
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</tbody>
</table>
3 Results

3.2. Sensitivity of the sensor in the temporal bones

The sensitivity of the sensor in the initial position in the middle ear was calculated as frequency response from the measured voltage of the sensor in Volts related to the measured pressure in front of the ear drum in Pascal. The determined sensitivity of the sensor in the initial position in the different TBs is shown in Fig. 7. The variation between the mean values is up to 20 dB between the best (number 1) and the lowest (number 9) sensitivity. This variance is in the same range as the METFs of the TBs with intact OC (see Fig. 8 and literature, e.g. (Rosowski et al., 2007)) Hence it could be assumed that the variation of the sensor performance is caused by the variation of the METFs of the different middle ears but there is no statistical significant evidence for this thesis given by the measured data. After the sensor insertion the measurement of the METF has been repeated and shows a mean loss of about 15 dB (see Fig. 8). This can be partially explained with the inertia mass of the sensor but even more with the stiffening of the annular ligament due to the opening of the ISJ gap for the 1 mm thick sensor since the low frequency region is more affected. There was no correlation found between the reduction in the METF and the sensitivity of the inserted sensor.
3 Results

Figure 7: Sensitivity of the sensor in V/Pa in different TBs.

Figure 8: METFs of examined TBs before opening of the OC and after insertion of the sensor.
3.3. Analysis of the influence of additional contact areas and sensor flipping

The measured sensitivity of the sensor with and without additional contact areas to other middle ear structures was compared. The contact to the long process of the incus or the malleus handle raises suspicion that they similarly decrease the signal yield from the sensor. Therefore they are classified and analyzed together. In Fig. 9 in the upper diagrams the signal gain factor for the three determined cases (contact to long process of incus or malleus handle; contact to promontory; flipped sensor) is demonstrated. It is calculated by the inserted sensors sensitivity with a contact to the described contact points divided by the sensitivity without the contact points. A factor above one adds up to a signal gain and a factor below one implies a signal loss. A median signal gain in decibel for each case is calculated and presented in the three lower diagrams of Fig. 9. The median sensitivity change for an additional coupling of the sensor with the long process of the incus or malleus handle shows a signal loss of about 5 dB for frequencies up to 3 kHz. There is less signal loss at higher frequencies. The contact to the promontory shows a signal gain of 5 to 6 dB. This was thought to be due to an additional support of the sensors back-plane by the promontory. Comparison of LDV measurements of the footplate with and without a contact between sensor and promontory does not show evidence for this hypothesis as there is no significant change in METF (see Fig. 10). The flipped sensor position shows no uniform behavior with a median change in sensitivity of near 0 dB, but extreme values between -10 dB and +10 dB. The results of the FEM simulations also show variations depending on the annular ligament stiffness (Fig. 11). If the annular ligament stiffness remains as in the normal middle ear we observe a loss in sensitivity of about 10 dB (for frequencies above 1 kHz) for the flipped sensor position. If we assume stiffening of the annular ligament (up to a fixed state) due to the inserted sensor we get about the same sensitivity for both positions or an even increased sensitivity for the flipped sensor position for higher frequencies above 2.5 kHz. During measurements the amount of stiffening could not be determined and surely varies between the different TBs which could explain the scattered results for the flipped sensor.
3 Results

Figure 9: Signal gain factor and median signal gain in dB due to: contact with the incus (A) or malleus handle (C) (left), contact with the promontory (center) or flipped position of the sensor (right).

Figure 10: The influence of contact with the promontory on the motion of the stapes footplate.
Figure 11: Simulation (left) and measurement (right) of the influence of a flipped sensor position and a stiffened annular ligament to the sensitivity.
3.4. Influence of the exact sensor position in the membrane-plane

We investigated the effect of variations in the sensor position along its long axis (see Fig. 4). The results for the simulation as well as for the measurements are presented in Fig. 12. The measurement results show better sensor sensitivity than the simulation results but the influence of the different sensor positions is in accordance. Changes in position produced only relatively small changes in terms of signal loss in the sensors output even for variations in position of one millimeter. Only if the sensor is displaced up to the edge (displacement of 1.5 mm) the signal loss is dramatic. The signals are also plotted normalized to the centered position as signal loss in decibel. For variations that are smaller than or equal to 0.5 mm in each direction the signal loss is only 1 dB. The narrow peaks in signal loss in the measurement are due to a small change of the resonance frequency due to the changed sensor position and therefore the two compared sensitivity curves are no more parallel. If the sensor position is changed in crosswise direction the results are similar (see Fig. 13). At 0.5 mm displacement the signal loss is within 2 to 3 dB, a little bit higher than with the lengthwise changed position. This difference occurs because the sensor is smaller in this direction, so the relative variation is greater.
3 Results

Figure 12: Simulation (left) and measurement (right) of the sensitivity variation and the resulting signal loss in dB due to position variation of the sensor in a TB.
Figure 13: Simulation (left) and measurement (right) of the influence of the crosswise sensor position variation in the sensitivity.
4. Discussion

The TBs showed a sound transfer function similar to normal middle ears (Rosowski et al., 2007). The optimal inserted sensor is positioned with the lenticular process of the incus in contact with the center of the sensing membrane. With the current dimensions of the laboratory model of the sensor, additional contact points are likely to appear between the edges of the sensor and the long process of the incus, the malleus handle or the promontory. The median signal loss is 5 dB between 200 Hz and 5 kHz if the sensor edge touches the long process of the incus or the malleus handle. A possibility to prevent the specified signal loss is the displacement of the sensor in a manner that the additional contact points are eliminated. This can be done by the surgeon with careful movements of the sensor with a needle until additional contact is eliminated. This can lead to a significant signal gain provided that the displacement from the centered position is not too big. Referring to Section 3.4 only a displacement smaller than 0.5 mm is recommended which was achieved with all tested specimen. Taking also in account that additional contact points can be avoided with reduced sensor thickness (which is already achievable with advanced manufacturing technology) we do not regard this issue as a serious problem. Another approach to achieve signal gain is an additional contact to the promontory, which sometimes is given automatically by the anatomy and sometimes can be forced if wanted. The achieved signal gain has a median of 5 to 6 dB. The reason was thought to be a decreased translational movement of the stapes due to the additional support but this was not demonstrable (see Section 3.3). Another explanation for the clear improvement of the sensor’s signal yield if it touches the promontory could be its rotational movement. Because it is normally only fixed between two points even a little asymmetry of the fixation can lead to a rotational movement of the sensor which decreases the translational force on the membrane center and therefore the signal yield. This rotational movement could be prevented by the additional support of the promontory contact. This hypothesis was not tested by the data we acquired and would need to be confirmed by three-dimensional measurements of the movement of stapes and sensor. It should be noted that a contact to the promontory might reduce residual hearing because the additional support of the sensor on the promontory could reduce stapes footplate movement although there is no evidence for that. There is no fear of the sensor stimulating promontory bone degeneration because the transferred forces are very small and the contact area is just a touching and not a clamping as sometimes occurs in stapes-plasty, where clamping leads to necrosis of the incus long process. In
conclusion the effects of additional contact areas may be significant, but preventable with design improvement and attentive sensor insertion. It is suggested to consider an intra-operative quality control that enables measuring of the sensors sensitivity during implantation. Thus it would be possible to determine the most appropriate insertion position of the sensor to ensure maximum signal yield and perfect coupling to the ossicles. Another possibility to avoid unwanted contact areas at the sensor membrane is the flipping of the sensor in such away that the membrane is pointing to the stapes. In clinical practice the surgeon could decide the preferred sensor direction during the implantation to optimize signal yield. However the results for this position seem to be unpredictable and the scatter is very big. There are several influencing factors counteracting each other. If the sensor is flipped, unwanted contact areas between the membrane side of the sensor and the long process of the incus can be avoided and this leads to a signal gain. At the same time the flipped position of the sensor itself causes a signal loss due to the mass inertia of the sensor. This effect in turn depends on the pretension of the annular ligament due to sensor insertion. Another open question is how such stiffening behaves over longer times in the middle ear, if it is degraded over time or if it remains. In contrast the normal position of the sensor proved to be less sensitive to annular ligament stiffening than the flipped position because the sensors mass inertia is not placed between sensor membrane and the acting force flow from the OC. In conclusion a clear improvement of the sensor performance due to sensor flipping could not be shown in the experiments and it has to be advised against this possibility for now. The preferable method for improvement of sensor sensitivity if unwanted contact areas appear is the in-plane displacement of the sensor. The considered influencing factors for the sensitivity of the inserted sensor where constrained to the sensor position. There are other parameters which have an impact on the sensitivity and have to be considered for the complete prediction of the microphone characteristics of the implanted sensor. For further specification of the whole system comprising variations in the middle ear anatomy, variations in the sensor’s ISJ insertion position and variations in the OC chain preload, the use of a lumped parameter system model approach presented by (Hellmuth, 2012)) is suggested. To describe and specify a worst case and best case characteristics of the implanted sensor’s sound-induced signal yield the system model’s lumped parameters have to be fitted. Lumped parameter variations due to anatomy are derived from literature, parameter variations of the insertion position can be derived from the presented measurement and FEM calculations results.
5. Conclusion

An implantable middle ear microphone based on the insertion of a piezoelectric membrane sensor into the ISJ gap was investigated. The sensor is designed to measure the sound-induced forces acting on the center of the membrane. It allows a minimally invasive and reversible implantation without removal of ossicles and without additional sensor fixation in the tympanic cavity. The presented TB experiments showed that the sensor’s insertion position influences the microphone sensitivity. Experiments reveal that anatomical and pathological variations of the middle ear geometry can result in additional contact points between the sensor membrane and middle ear structures or an eccentric placement in the ISJ. Remedies to avoid signal losses due to anatomical space limitations and unintended contact points between sensor and anatomy were developed and tested. In all cases we could find a sensor position with no more than 3 dB loss in sensitivity compared to the theoretical optimal position. In conclusion the microphone sensitivity of the implanted sensor is stable against anatomic variations of the middle ear geometry as long as the positive and negative effects of additional contact points between sensor and anatomy are taken into account during sensor insertion. The findings of the study support the development of an improved surgical insertion technique to ensure maximally achievable signal yield of the membrane sensor in the ISJ.
5 Conclusion

Publikation 2
IV. Publikation 2 :

Examination of a mechanical amplifier in the incudostapedial joint gap:
FEM simulation and physical model

Martin Koch, Till Moritz Eßinger, Matthias Bornitz, Thomas Zahnert

Abstract
Implantable assembly components that are biocompatible and highly miniaturized are an important objective for hearing aid development. We introduce a mechanical transducer, which could be suitable as part of a prospective fully-implantable hearing aid. The transducer comprises a sensor and an actuator unit in one housing, located in the joint gap between the middle ear ossicles, the incus and stapes. The setup offers the advantage of a minimally invasive and reversible surgical solution. However, feedback between actuator and sensor due to mechanical coupling limits the available stable gain. We show that the system can be stabilized by digital control algorithms. The transducer is tested both in a Finite-Elemente-Method (FEM) simulation of the middle ear and a physical model of a human middle ear. First, we characterize the sensor and actuator elements separately. Then, the Maximum Stable Gain (MSG) of the whole transducer is experimentally determined in the middle ear model. With digital feedback control (using a Least Mean Square (LMS) algorithm) in place, the total signal gain is greater than 30 dB for frequencies of 1 kHz and above. This shows the potential of the transducer as a high frequency hearing aid.
1. Introduction

1.1. Implantable Hearing Aids

The role of implantable hearing aids as a treatment for hearing loss is increasing. Besides visual advantages, they provide the benefit of a free ear canal and a more natural signal acquisition. Several active implants for the treatment of intermediate hearing loss have been developed to serve as an alternative for conventional hearing aids. The references (Haynes et al., 2009; Green, 2011; Maurer, 2009) give an overview of existing Active Middle Ear Implants (AMEIs). It should also be noted that for severe inner ear pathology, the current state-of-the-art treatment is the Cochlea Implant (CI), which applies an electrical stimulus directly on the auditory nerve. However, in this study, we will focus on the acoustic or mechanical amplification type of implantable hearing aid. Devices of this sort usually consist of a microphone (sensor), a receiver (speaker or actuator) and a digital signal processor. They are either partially or fully implantable. The former category usually implies that the actuator is implantable and the sensor (microphone) is placed outside the ear. Examples of this type of implant are the widely used Vibrant Soundbridge (MedEl Austria) or the Soundtec Direct Drive (Soundtec Inc.). In both of these, the actuator is not fixed to the tympanic cavity, but is clamped onto the Ossicular Chain (OC) as a free-floating mass. If both the microphone and receiver are implanted, the system is called fully implantable. Examples include the Carina (Otologics) and the Esteem (Envoy Medical Corp.). The actuator in these systems is usually permanently fixed in the tympanic cavity. This provides the device with mechanical support, but requires complex surgery during implantation. All currently known implants are designed with separate housings for the microphone and receiver. This is done so as to acoustically and mechanically insulate the sensor from the actuator and to minimize feedback.

1.2. Implantable Transducer inside the Incudostapedial Joint Gap

In this study, we present a bidirectional membrane transducer to be used as an acousto-mechanical amplifier in the middle ear, as shown schematically in Figure 1. A cross-sectional view of the transducer is shown in Figure 2a. It is assembled from two identical oval-shaped titan housings mounted back to back, creating a single frame with two separate air-filled cavities. They are capped with a very thin membrane each. A piezoelectric element is glued to the inside of each
1 Introduction

Figure 1: Transducer schematic diagram.

membrane. They act as bending plates, one for signal acquisition (sensor) and one for signal generation (actuator). The oval-shaped transducer measures $4 \text{ mm} \times 2.5 \text{ mm}$ with a thickness of $1 \text{ mm}$. It is inserted into the OC at the joint gap between the long process of the incus and the stapes head (see Figure 2b). Following a mastoidectomy (the surgical access to the middle ear used for most such implants), the joint is opened by the surgeon. This is a minimally invasive surgery that has been shown to be reversible (Fisch & May, 1994). The transducer is then slid into the joint and is held in place by adhesive forces and the tension in the OC. The piezo sensor thus detects the vibrations of the Tympanic Membrane (TM) through the ossicles and converts these into an analogous voltage signal, which is processed and amplified. The amplified voltage signal drives the piezo actuator and moves the stapes, providing enhanced acoustic stimulus to the inner ear. For the purpose of this study, the necessary signal processing and control software is conducted on a computer with a Field Programmable Gate Array (FPGA) card. Prospective prototypes will likely feature implanted or external signal processors similar to those used in CIs.

1.3. Aims of the Study

The proposed transducer design offers distinct advantages in implantation simplicity and time. However, due to the direct mechanical coupling between sensor and actuator, strong feedback can be expected. Furthermore, the actuator is not braced to the larger structure of the tympanic cavity. This raises the question of how well the actuator is able to transfer its movement into the stapes, knowing the relatively high acoustic impedance of the liquid-filled inner ear. In
this paper, we will examine the proposed device and the surrounding structures both in FEM simulation and in a physical model of the human ear. The results will be compared and collated with existing literature. We aim to show how well the device can be stabilized with digital feedback suppression, determine its dynamic Working Range (WR) as a hearing aid and predict a possible medical indication for its application.

2. Method and Materials

2.1. Simulation

The FEM simulation model of the human middle ear used in this study has been described in (Bornitz et al., 2010). The model is illustrated in Figure 3 and consists of:

- the ear canal as acoustic fluid with a third order boundary condition at the entrance for the simulation of the surrounding air
- the eardrum as orthotropic-elastic shell elements with a constant damping ratio
- the ossicles as rigid bodies
- the ligaments as elastic bars
- the joints as elastic bodies with a constant damping ratio
- the cochlea as a simplified spring-mass-damper model

The transducer housing is made of 3D-20-node solid elements. The sensor/actuator membranes
and piezo crystal are built with 3D-20-node-coupled field elements with electromechanical coupling. According to (aWengen et al., 1995), the mean stapes head diameter is 1.14 mm by 0.83 mm. In this simulation, we assume a circular contact area with a diameter of 1 mm at the stapes head, which is coupled with MPC-rigid184 elements to the attached structure. The simulation is calculated by harmonic analysis with 10 frequency points for up to 5 kHz. The excitation is either a pressure of 1 Pa at the eardrum (equal to 94 dB Sound Pressure Level (SPL)) or a voltage of 1 V at the actuator. The resulting data is either the sensor voltage or the movement of the stapes footplate at the end of the OC. Note that with a linear model, only the open loop can be simulated. The closed loop system (which includes feedback from the actuator to the sensor) is therefore not examined in this simulation. However, due to the mechanical coupling between sensor and actuator, the closed loop system should be expected to exhibit strong feedback. The simulation data will therefore yield an approximate operational range. The measured data is expected to locally deviate from this due to closed loop resonances. The simulation model is
used to determine:

- the Middle Ear Transfer Function (METF) of the OC with the implanted transducer compared to the intact OC
- the sensitivity of the sensor to air pressure at the ear drum (in mV Pa$^{-1}$)
- the output of the actuator in the movement of the stapes footplate (in mm Pa$^{-1}$), used as a measure for hearing impression (in dB SPL equivalent).

The model is also used to compare the idealized impedances of the OC at the ISJ before and after insertion. The former contact partners at the joint, long incus process and stapes head are both excited with a lateral force of 1 N, and the resulting frequency-dependent ossicular movement is compared. Subsequently, the transducer is inserted, and the actuator is excited with a voltage of 1 V. The ossicular movement on both sides of the transducer (long process of the incus and stapes head) is recorded and compared. This serves to evaluate the effectiveness of the transducer concept and to quantify the drawbacks of the free-floating design.

### 2.2. Physical Model of the Middle Ear

In order to perform measurements on the transducer, a partial physical model of the human ear was devised. This provides several advantages compared to measurements in a Temporal Bone (TB): The model is stable over time, which simplifies measurements. Furthermore, the physical model offers reproducible results, while the transfer characteristics of different TBs vary at ±10 dB (Rosowski et al., 2004). This variation and other factors, such as anatomy contact points, can be neglected for the principal considerations in this study. The full range of characteristics can be examined in prospective TBs studies. The model was adapted from a tympanoplasty training model (Hofmann et al., 2007). It is shown in Figure 4 and features an ear canal 1 cm in diameter made of acrylic glass, which sits at an angle of 45° relative to the model’s TM. The membrane is made from silicone foil, which has previously been determined to exhibit sound transfer characteristics similar to a real human TM. The silicone membrane is fixed between a steel plate and a magnetic foil of 0.8 cm thickness, both of which are cut out at an oval shape, creating a TM model of 12 mm length and 1 mm width. The aforementioned ear canal is glued to the magnetic foil. It also features a microphone in order to record the pressure at the TM, which serves as the reference (input) signal. A headphone loudspeaker at the entrance
to the ear canal is used as the excitation source. Attached to the center of the silicone membrane is a PORP (partial ossicular replacement prosthesis). Contrary to its normal usage, the PORP serves as a replacement for the malleus, which was hard to build in the model environment. The clamp at the stapes side of the PORP has been replaced with the long process of an incus. The steel plate is attached to a linear three-axle positioning slide. This allows for the positioning of this upper part of the setup at a resolution of 1 μm. The lower part of the setup begins with a vacuum-cast resin replica of a real stapes. The stapes footplate is attached to a Kapton film membrane simulating the annular ligament. The membrane is set right above one of two separate cavities within a hollow brass cylinder. There is another similar membrane at the top of the second cavity. Two microphones record the pressure inside the cavities separately. This is done so as to separate the air sound transfer from the sound transfer through the OC: by subtracting the microphone signals, the sound transferred through the air is negated in the measurement, as this is present in both cavities. This leaves only the sound transferred through the ossicles as the measured (output) signal. The subtraction of signals is performed by a differential amplifier.
Figure 4: Setup of the experiment: (1) Loudspeaker as the excitation source at the entrance to the model ear canal; (2) Reference microphone; (3) Acrylic glass model of ear canal; (4) Silicone model of the TM; (5) Partial ossicular replacement prosthesis (PORP) and long process of human incus; (6) Bidirectional transducer; (7) Resin cast stapes replica; (8) Inner ear impedance model.
2.3. Experimental Setup and Procedure

The device to be examined here consists of two identical piezoceramic single crystal elements connected by a solid titanium metal frame. It is inserted into the model of the middle ear described above. One of the piezoceramic elements serves as a mechanical sensor. As shown in Figure 2, this side touches the model of the incus and transduces the mechanical vibrations into an analogue voltage signal. The other piezoceramic element serves as a mechanical actuator that drives the movement of the stapes. Note that the device is not firmly attached to the surroundings, but is a free-floating addition to the OC. The inertial mass of the device is about 35 mg. The sensor and actuator are connected to the analogue input terminals of an FPGA (NI PXI-7842, National Instruments) via fourth order Butterworth filters (VPF 8 mk4, KEMO) for anti-aliasing and impedance matching. The analogue inputs of the FPGA have a dynamic range of ±10 V; the corresponding AD-converters feature 16-bit resolution. This calculates to a voltage resolution of:

$$\Delta u = \frac{20 \text{ V}}{2^{16}} \approx 0.000305 \text{ V}. \quad (2.1)$$

As will be shown later (see Section 3), the sensor’s thermal noise is much lower than that. In order to make use of the sensor’s dynamic range, this signal is therefore preamplified by a factor of 1,000 (SR560 Low-Noise Preamplifier, Stanford Research Systems) prior to AD-conversion. Real-time signal processing and control algorithms are written in LabView (version 2011, National Instruments) and implemented on the FPGA. The internal resolution for the control algorithms is 16 bit fixed-point. It includes a variable low-pass filter (fourth order Butterworth filter), which is implemented through the use of the ‘‘Butterworth Filter express VI’’, which is part of the LabView signal processing package. The central control algorithm is a 100-tap LMS adaptive filter as described above. A similar setup of hardware and algorithms has previously been successfully tested on a 10:1 scale model of the proposed device (T.M. Eßinger, 2014). A loudspeaker at the entrance to the model ear canal serves as the stimulation source. The setup furthermore features a microphone each in the ear canal and in the inner ear behind the stapes footplate. Stimulation signals were generated and measurements were performed with a data acquisition board (NI PXI-4496, National Instruments). The software for measurement and signal generation was programmed in LabView (version 2011, National Instruments). The
stimulation signal was either a 2,048-point broadband multisine or a discrete frequency single sine signal. The physical model used here has shown itself to be valid for up to about 2.5 kHz. The sampling rate for both measurement and control software was 10 kHz, which is sufficient in this case. As stated in (T.M. Eßinger, 2014), it is sensible to use greater oversampling for the range beyond 2.5 kHz. However, a higher sampling rate would only shift the resonance frequencies further toward the outside of the desired audiological frequency range. This would actually have a positive impact on system stability, since these resonances could be attenuated without compromising hearing gain. The results obtained for this higher range are therefore expected to be valid as far as feedback control is concerned.

For each measurement, five signals were recorded:

1. Stimulus
2. Ear drum pressure
3. Sensor signal
4. Actuator signal (generated)
5. Inner ear pressure

Prior to conducting the experiment, the relationship of inner ear pressure to the velocity of the stapes footplate was determined (see Figure 5) in the following way: First, the model was separated at the ISJ; second, a floating mass transducer (Floating Mass Transducer (FMT), as used in the Vibrant Soundbridge implant) was fixed at the stapes head for excitation; Third, simultaneous recordings of stapes footplate movement and inner ear pressure were conducted by Laser Doppler Vibrometry (LDV) and by microphone, respectively. From this data, we were able to obtain a calibration data set for the microphone. This was necessary for practical reasons: The movement of the stapes footplate was not accessible directly during the experiment because of the setup geometry. Please note that the values for Stapes Footplate Velocity (SFV) shown in Section 3 were thus calculated from the measurements of the inner ear pressure. The following steps were taken in measuring:

- **Intact OC**: The frequency response of the intact OC model (without the transducer in place) was recorded by stimulation of the loudspeaker. This serves as a reference for the analysis of the device’s performance. Since the transducer is not inserted at this point, the only signals of interest are the two microphone signals at the ear drum and in the inner ear.
2 Method and Materials

- **Insertion of transducer**: The OC model was separated at the stapes head, and the transducer was inserted there. Again stimulating the loudspeaker, the frequency responses were recorded with the transducer in idle mode. The main points of interest in this measurement were the frequency-dependent sensitivity of the sensor to pressure at the eardrum and the attenuation of sound transfer along the OC due to the insertion of the transducer in V Pa$^{-1}$.

- **Noise**: Disconnecting the excitation source, the noise level of the device components was measured. From this measurement, the sensor’s hearing threshold can be characterized.

- **Actuator performance**: The actuator is stimulated with a 1 V excitation. Measurements include the feedback path to the sensor, which we will compare to the simulation and to the frequency response of the converged adaptive filter described in Section 2.4. The main point of interest, however, is the induced movement of the stapes, which shows the upper bounds for the transducer’s amplification. Note that as a free-floating device, the transducer has only its inertial mass to support it. The transfer function of actuator voltage to induced stapes velocity is therefore expected to drop at lower frequencies.

- **Functional gain**: The loudspeaker is stimulated so as to produce a SPL of 50 dB SPL at the ear drum, while measuring the velocity of the stapes footplate. This is done first with the transducer idle, then with the transducer set to a gain that offers a maximum signal yield for the stapes footplate movement without visible distortions and without resonance peaks caused by feedback.
Figure 5: Calibration of the inner ear microphone. A FMT excites the stapes. The velocity of the footplate is recorded by LDV along with the pressure inside the inner ear model cavity below the membrane. (Top) Setup for calibration; (Bottom) Resulting calibration data.
2.4. Feedback Control

The theoretical amplification limit for the transducer is given by the sensitivity of the sensor and the footplate amplitude (or velocity) when the actuator is maximally excited. However, as has been noted above, the device is free floating. With only the inertial mass of the frame to support it, the momentum introduced by the actuator is divided between the movement of the stapes footplate and the recoil of the frame. Since the sensor is likewise attached to the frame, this causes a closed feedback loop in the system. It is well known that in electroacoustic feedback loops, the maximum available gain is limited, because the closed-loop system will begin to oscillate when the MSG is exceeded (T. van Waterschoot, 2011). Let $\mu(\omega)$ be the forward path transfer function. If we define:

$$ G = \frac{1}{2\pi} \int_{0}^{2\pi} |\mu(\omega)| \, d\omega $$  \hspace{1cm} (2.2)

as the broadband gain factor; the MSG is defined as the highest scalar value of $G$ for which the system is stable. Suppression of feedback resonances smoothes the loop gain in the frequency domain and, thus, allows for a higher MSG value. In feedback applications, it is customary to refer to the MSG increase as a measure of the efficiency of the system. The Nyquist stability criterion states that the resonances or critical frequencies are located specifically at those frequencies for which the phase shift is a multiple of $2\pi$ radians, which is a function of the time delay $\Delta t_{FB}$ along the feedback path. MSG is reached when the gain for a critical frequency is increased to unity or beyond. Let us assume the mechanical coupling through the frame to be the dominant feedback path. The small measurements of the device and the solid metal frame lead to very short signal paths and, hence, high frequency resonances. The digital part of the forward path requires a sampling of the sensor signal at a finite sample rate, introducing a time delay $T = 1/f_S$. Such a system cannot oscillate above the Nyquist frequency $f_S/2$. Therefore, if $T \gg \Delta t_{FB}$, the original resonances vanish, and new critical frequencies are introduced in the high end of the desired frequency range (T. M. Eßinger, 2014). The system features an adaptive algorithm for digital feedback control based on the well-known LMS algorithm first introduced by Widrow (B. Widrow, 1990): An adaptive filter is used to approximate the Impulse Response (IR) of the feedback path. Discrete convolution of the output (actuator) signal with the approximated IR yields an approximation of the feedback amplitude for a given input sample. This value is subtracted from the input signal before further processing is conducted. The
3 Results

The measured METF of the physical model and the simulated METF, as well as the literature data (Rosowski et al., 2007) are shown in Figure 6. Inserting the (idle) transducer into the OC affects the METF, as shown in Figure 7. The performance of the individual parts of the transducer is visualized separately for both the sensor and actuator element in Figure 8. The sensor in this setup has a sensitivity of around 1 mV for an excitation of 1 Pa pressure at the eardrum. The measured sensor noise and the measurement of the stapes footplate movement during the sensitivity-measurement are used to calculate the sensor’s hearing threshold. If the actuator is excited with $U = 1$ V, the measured movement of the stapes footplate is up to $3 \times 10^{-1}$ mm s$^{-1}$ V$^{-1}$, which conforms to an equivalent sound pressure level of 120 dB SPL for this model. The dynamic range of the transducer can be derived by combining the characteristics of both the sensor and actuator. Figure 9 shows the dynamic boundaries of the system in equivalent decibel SPL at the ear drum. Theoretically, the transducer is able to amplify input signals at the eardrum of 25 dB SPL and below to a stapes movement, which equals the input pressures of 60 dB SPL up to 120 dB SPL. However, this is limited by the MSG available due to feedback between the actuator and sensor. For the given model using the previously described...
feedback suppression algorithms, a gain corresponding to a 29.5 dB amplification of the sensor signal could be adjusted. The system exhibits linear behavior within the physical limitations of the components. The amplified stapes footplate movement for a 50 dB SPL input signal is shown in Figure 10. This is compared to the intact OC (unaided case) and to the footplate movement with the idle transducer, as shown in Figure 11. For low frequencies up to one kilohertz, the transducer achieves amplifications of stapes footplate movement of 10 to 25 dB; in the high frequency range the sensor achieves a functional gain of 30 dB and more.

4. Discussion

4.1. Validation of Simulation and Model

The limitations of the FEM-simulation model used here have already been discussed in detail in (Bornitz et al., 2010). As a synopsis, it can be said that the fact that the model is valid for linear computations only limits the maximum amplitude to 120 dB SPL. Regarding (Beer et al., 1999), the use of rigid bodies for the ossicles limits the validity of the model’s frequency range to up to 3.5 kHz. According to (Voss et al., 2000), the lack of air volumes in the model causes an inaccuracy of 5 dB, which can be neglected for fundamental studies, because it is below the natural distribution of middle ear transfer characteristics (Rosowski et al., 2004). In the frequency range of 2.5 kHz and below, the measured frequency response for the physical model (Figure 6) matches the literature data well and seems to give a rough approximation for a typical middle ear behavior. The strong resonance between 2.5 and 3 kHz is uncharacteristic for normal METFs. Note that the literature range is an average of different METF. It therefore does not exhibit distinct resonance peaks, such as those seen in the METF simulated for one specific middle ear. Inserting the (idle) transducer into the OC affects the METF, as shown in Figure 7. The simulation shows a down-shift of the resonance frequencies. This is to be expected due to the inertial mass added to the OC. The measurement shows a similar behavior, but also experiences additional distortions. It can be concluded that both the simulation model and the physical model can be used to obtain sufficiently accurate results for the frequency range below 2.5 kHz.
Figure 6: Comparison of simulated and measured METFs with literature data reproduced from (Rosowski et al., 2007). Note that the measurements for the physical model are valid for frequencies below 2.500 Hz.

Figure 7: Influence of transducer implantation on METF. The insertion of the additional mass into the OC primarily causes a shift in resonance peaks. (a) Measurement; (b) Simulation.
4 Discussion

4.2. Evaluation of the Transferability to Temporal Bone Measurements

The results for the sensor element (Figure 8) can be confirmed by former investigations (Koch et al., 2012, 2013). These previous studies were conducted on a sensor element of the same size as the whole transducer examined here. Results inside a calibration sound pressure box revealed a flat sensor frequency response. This suggests that the differences between measurement and simulation are mainly to be attributed to the different METFs. Previous studies have also revealed additional contact points in seven out of ten TBs. The impact on sensor output was found to be quite low (about 5 dB) (Koch et al., 2013). The effect on the transducer sensor is expected to be on a similar scale. However, the effect of additional contact points on actuator output is unknown. Therefore, further studies for the transducer and especially its actuator element are necessary. The maximum stapes movement for the transducer in actuation mode with a voltage of $U = 1 \text{ V}$ is greater for the simulation than for the measurement at higher frequencies (see Figure 8). The difference is even greater at the anti-resonance of the model’s METF with an inserted transducer at 1.2 kHz. (see Figure 7). The actuator is assumed to perform better in future setups in TBs, because the METF will resemble the simulation’s METF more closely. The achievable functional gain of the model (Figure 10) seems to be only partly limited by system stability, but also by the maximum actuator output. This means that a higher actuator performance will conceivably result in a higher functional gain. The physical model and the simulation model are both focused on the linear piston-like mode of the stapes footplate movement. This is said to contribute to the the preeminent part for auditory sensation for lower frequencies up to 1 kHz (Hato et al., 2003) and still the dominant part for higher frequencies up to 4 kHz (Voss et al., 2000). This comprises both the validated frequency range of the simulation model, as well as the physical model. However, because of the high impact of the actuator on the ossicular movement, the complex movement of the stapes can change in the clinical situation. If, e.g., the transducer is not positioned symmetrically, the influence of the rocking stapes motion on auditory sensation, which is described in (Eiber et al., 2012), could be increased and would need attention. It must be noted that the setup examined here does not have a closed tympanic
cavity volume. The following feedback paths are expected in prospective TB experiments:

1. mechanical feedback through the frame
2. electromagnetic feedback
3. acoustic feedback inside the transducer
4. acoustic feedback inside the tympanic cavity
5. body noise through the bone

In this study, the dominant path by far is the mechanical feedback through the frame (1). The first three paths are expected to be realistically represented by the physical model. Reflections and resonances in a closed volume should be expected to introduce additional feedback (4). To estimate the impact of these additional paths, both the magnitude and the phase of the feedback signal must be considered. As explained in Section 2.4, these correspond to the signal attenuation and delay along the paths, respectively. The length of these paths is about 2 cm in air, leading to a delay of $\approx 60 \mu s$. This is still less than the sample interval $T = 100 \mu s$ used here. The measurements presented here show that the compensation algorithms are well suited to handle such feedback delays. Furthermore, the sensor is designed as a force sensor for OC vibrations rather than an acoustic microphone. The coupling of sound from the cavity can therefore be expected to contribute only a minor part to the total feedback magnitude. The OC is connected to the TB only through soft tissue, such as membranes, ligaments and fluids. The effect of feedback through body noise (5) can therefore be expected to be negligible. Further studies in the TB should still be conducted.

4.3. Advantages and Drawbacks of the Transducer Design

The advantages of the transducer design without fixation in the tympanic cavity are primarily in terms of easy operability, surgery time and the reversibility of the surgery. All of these are very important characteristics of modern implants. From a technical point of view, rigid fixations in the tympanic cavity and a physical separation between the sensor and actor element appear to be preferable. In fact, all current hearing implants use either one or both of these approaches (Haynes et al., 2009). To assess the influence of the missing fixation, the impedances of the opened ISJ in the direction of both incus and stapes are simulated and illustrated in Figure 12. The movement response to a force (Figure 12a) is bigger in the incus direction than in the stapes direction for
Discussion

Figure 8: Performance of transducer assembly components. With the transducer in idle mode, the sensor signal for an excitation of 1 Pa at the eardrum is simulated, measured and compared to the sensor’s thermal noise. A voltage of 1 V is applied to the actuator, and the resulting velocity of the stapes footplate is determined. (a) Sensitivity of the sensor; (b) Excitation of the actuator.

lower frequencies and similar for higher frequencies. If the transducer is inserted and the actuator is driven with $U = 1$ V, the incus movement is still much higher than the stapes movement for low frequencies up to 800 Hz (see Figure 12b). This matches the drop in the measured frequency response towards low frequencies (see Figure 11). In the ideal case of a complete fixation of the transducer to the TB, there would be no movement of the transducer frame in the direction of the incus. Hence, the movement of the actuator plate would only drive the stapes side, with a frequency response for the desired stapes movement equal to the sum of the two curves in Figure 12b. This would clearly have a large impact on the low frequency output, but would add only about 2 dB above 1 kHz. Since the most common medical indication is high frequency hearing loss, the advantages of an easy, quick and reversible surgery seem to outweigh the disadvantages of the free-floating design. Combining the sensor and actuator in one assembly causes mechanical coupling, which results in strong feedback. However, as has been noted above, the signal paths are very short, causing high frequency feedback that lies, in fact, outside the desired frequency range. AD conversion in the forward path limits the signal to this frequency band and effectively
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Figure 9: Dynamic range of the transducer in the model.

cuts off the inherent critical frequencies, stabilizing the system. The remaining feedback can be controlled very well with the approach of adaptive primary path filtering. This has also been demonstrated in a larger scale physical model in (Essinger et al., 2016). An MSG increase of up to 29.5 dB is reported here, which compares very well with the current state-of-the-art in feedback suppression in hearing aids (Spriet & Moonen, 2010). In the higher frequency range, added gain is not impeded as much by the aforementioned lack of inertial support. The functional gain achieved at frequencies greater than 1500 Hz is similar to the functional gain of existing hearing aids.

4.4. Medical Indication

The transducer is able to achieve a functional gain of 30 dB and more for higher frequencies. High frequency hearing loss is the most common kind of hearing impairment that occurs in elder people. Figure 13 shows the statistical hearing loss for people of different ages without known hearing diseases (Hesse, 2004). Note that the discomfort level does not rise in the same manner as the hearing loss (Lehnhardt & Laszig, 2009). Therefore, the input signals for the transducer cannot be scaled linearly, but need to be compressed, which leads to a loss of dynamic range for hearing. Furthermore, the gain has to be fitted for each patient, due to the individual variations in hearing discomfort level. Estimations for a medical indication for the proposed transducer
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Figure 10: Performance of the transducer as an acoustic amplifier in the model. In addition to the original and the amplified signal, the frequency response for the intact OC is shown for comparison (dotted line).

can be made from the commonly used gain fitting methods. For example, the Berger method proposes gains for different frequencies that are all near the half hearing loss (Humes, 1986). In Figure 14, the required functional gain as calculated by the Berger method for a statistical mean of 71--80-year-olds is compared to the measured functional gain of the transducer. The comparison indicates that the transducer is appropriate for a large number of patients.
Figure 11: Achieved functional gain of SFV, as compared to both the implanted transducer in idle mode and the unaided case (with an intact OC).

Figure 12: Excitation of the ossicles at the ISJ (FEM simulation). First, a force of 1 N is applied to the opened ISJ; second, the transducer is inserted, and a voltage of 1 V is applied to the actuator. (a) Force on the opened joint; (b) Excitation of the actuator.
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Figure 13: Statistical hearing loss for probands without known former ear diseases according to (Hesse, 2004) in dB hearing level.

Figure 14: Required functional gain for hearing aids as calculated by the Berger method (Humes, 1986) and the functional gain provided by the proposed transducer.
5. Conclusions

A fully-implantable hearing device in the form of a membrane transducer in the ISJ for hearing amplification is introduced. The transducer was evaluated in an FEM-simulation and in a physical model of the middle ear. The sensitivity of the transducers sensor element was around 1 mV per Pascal pressure at the eardrum. The sensor hearing threshold is 25 dB and below, the actuator maximum output equals up to 120 dB equivalent decibel SPL at the eardrum. In the physical model, the achieved functional signal gain for the stapes footplate movement (which was used as a measure for auditory sensation) was greater than 30 dB for frequencies of 1 kHz and above. Comparisons with statistical hearing thresholds of elderly people without known hearing diseases show that the transducers amplification characteristics fit the most common hearing loss precipitated by aging quite well and seem to match the average hearing loss of 71--80-year-olds. This offers a big area of application for the presented transducer. Further research should be undertaken to confirm these results by measurements in human TBs. This could reveal additional unobserved influence factors of the more realistic environment. For example, the preload influence on the OC during transducer insertion or more complex three-dimensional stapes movements could require attention. Classification of the transducer performance by a stapes motion comparison as conducted in this study is the most important parameter for transducer evaluation. Nevertheless, more detailed parameters, like the absence of distortion, that are essential for speech understanding should be included in future transducer assessments.
5 Conclusions

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**Fully implantable hearing aid in the incudostapedial joint gap**

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**Abstract**

A fully implantable hearing aid is introduced which is a combined sensor-actuator-transducer designed for insertion into the Incudostapedial Joint (ISJ). The active elements each consist of a thin titanium membrane with an applied piezoelectric single crystal. The effectiveness of the operating principle is verified in a temporal bone study. We also take a closer look at the influence of an implantation-induced increase in middle ear stiffness on the transducer’s output. An assembly of the transducer with 1 mm thickness is built and inserted into six temporal bones. At this thickness, the stiffness of the annular ligament is considerably increased, which leads to a loss in functional gain for the transducer. It is assumed that a thinner transducer would reduce this effect. In order to examine the performance for a prospective reduced pretension, we increased the gap size at the ISJ by 0.5 mm by removing the capitulum of the stapes in four Temporal Bones (TBs). The Tympanic Membrane (TM) is stimulated with a broadband multisine sound signal in the audiological frequency range. The movement of the stapes footplate is measured with a laser Doppler vibrometer. The sensor signal is digitally processed and the amplified signal drives the actuator. The resulting feedback is minimized by an active noise control Least Mean Square (LMS) algorithm which is implemented on a field programmable gate array. The dynamic range and the functional gain of the transducer in the TBs are determined. The results are compared to measurements from TBs without ISJ extension and to the results of Finite-Elemente-Method (FEM) model simulations. In the frequency range above 2 kHz a functional gain of 30 dB and more is achieved. This proposes the transducer as a
potential treatment for high frequency hearing loss, e.g. for patients with noise-induced hearing loss. The transducer offers sufficient results for a comprehensive application. Adaptations in the transducer design or surgical approach are necessary to cope with ligament stiffening issues. These cause insufficient performance for low frequencies under 1 kHz.

1. Introduction

1.1. Implantable hearing aids

Implantable hearing aids can be classified in three categories based on their working principle or medical indication: Cochlea Implants (CIs), bone conduction hearing aids and Active Middle Ear Implants (AMEIs). CIs apply an electrical stimulus directly to the auditory nerve via electrodes, inserted into the cochlea. They are mainly used to treat severe sensorineural hearing loss. Bone conduction hearing aids like the BAHA, Bonebridge and Sophonics transfer the sound signal to the cochlea via the human skull. This approach is used mainly for cases of conductive hearing loss. AMEIs are placed in the middle ear cavity and amplify the sound transferred to the cochlea. This operating principle is similar to that of external hearing aids. They are indicated for people with sensorineural hearing loss or mixed hearing loss that is not severe enough to indicate treatment with a CI and that cannot be treated with a regular hearing aid. They often act by amplifying the ossicles’ movement with an actuator attached to different parts of the Ossicular Chain (OC). For instance, the Vibrant Soundbridge’s (Vibrant Med-El) Floating Mass Transducer (FMT) can be clamped onto the long or short process of the incus or the stapes head ([Ball et al., 1997];[Beutner & Hütttenbrink, 2009]), and leaves the OC intact. The Esteem’s (Envoy Medical Corporation) sensor is connected to the malleus and the actuator is connected to the stapes head via a coupling element ([Chen et al., 2004], [Maurer & Savvas, 2010]). The OC between the sensor and actuator is disconnected and partly destructed. The Carina’s (Cochlear Inc.) actuator is similarly coupled to the anatomical structures ([Bruschini et al., 2009]; [Devèze et al., 2013]). The sensor is a microphone beneath the skin of the head. The Tübingen hearing system, an actuator consisting of a slotted piezo-equipped bending membrane, is designed specifically for coupling to the round window. Adaptations of the FMT and the Carina actuator for coupling to the round window also exist ([Goll et al., 2013]; [Schraven et al., 2013]).
et al., 2011)). Other systems, such as the DACS or the DACS-PI, are equipped with prostheses which directly stimulate the cochlear fluid ((Häusler et al., 2008); (Maier et al., 2013)). The existing types of implants are mostly partially implantable with the actuator inside the middle ear and the sensor (or microphone) and sound processor outside the human body. Only two approved implantable hearing aids are fully implantable (Esteem and Carina). A good overview of implantable hearing devices is found in (Green, 2011);(Maurer, 2009);(Beutner & Hüttenbrink, 2009); (Counter, 2008); (Dinces & Parikh, 2003); (Lüers et al., 2011) and (Verhaert et al., 2013). The implant presented in this study belongs to the third group, i.e. the AMEIs. The biggest challenges for middle ear implants seem to be the difficulty and complexity of the implantation, the reversibility of the surgical intervention and the bone conduction noise on the sensor.

1.2. Incudostapedial joint transducer

The presented transducer consists of two active elements (sensor and actuator) combined in one housing. The concept builds on the implantable sensor element introduced in (Koch et al., 2013). The actuator element was added to obtain a fully implantable device. Two thin oval-shaped titanium bending membranes are attached to a titanium frame. The device is about 3 mm and 5 mm in diameter and 1 mm in height. A piezoelectric single crystal element is bonded to the inside of each membrane, one acting as a sensor and the other one driving the OC as an actuator”. The sensor acts as a bending sensor with a dominating d31 (transversal) effect and a partial d33 (longitudinal) effect. The transducer is clamped inside the opened ISJ gap with the sensor membrane facing the long process of the incus. The sensor measures the force transmitted in the OC which correlates with the sound signal in the ear canal. The actuator element faces the stapes head and transfers the amplified signal. The transducer in the middle ear and a cross-sectional view of the transducer assembly is depicted in Fig. 2 (top). The piezo elements are wired to a preamplifier and then to a computer for data acquisition, signal conditioning, processing and amplification. The moderate complexity of these functionalities makes it feasible to implement them on a Digital Signal Processor (DSP) that is part of a prospective implant similar in size and placement of a CI in the mastoid. The transducer is designed to be free-floating, dispensing with the need for bone anchoring. The most obvious advantage of this approach in comparison to most others is the simplicity of the insertion and therefore the surgery. The second advantage is that it promises better reversibility of the operation than alternatives which have to remove
ossicles or parts of ossicles. (Fisch & May, 1994) recommended opening the ISJ for inner ear protection during malleus handle manipulation with the claim of full reversibility. Recent studies like (Farahmand et al., 2016) come to a less optimistic conclusion, stating that partial ossicular discontinuity can lead to a high frequency hearing loss of 20 to 30 dB at 4 kHz. As part of this study, we also compared the Middle Ear Transfer Function (METF) before insertion and after removal of the transducer. It must be noted that there are no in-vivo long-term studies on this topic. The transducer preserves sound transmission from the TM to the inner ear to a good extent via the OC. Although its mass being added to the OC does have a measurable impact on the METF, the patient’s natural hearing is expected to be mostly preserved. The transfer of undesirable body noise to the sensor, being an issue for subdermal microphones in the ear canal, is minimized due to the free-floating design. The concept therefore gives hope to preserve important parts of hearing sensation, such as directional hearing, and enables natural hearing to the greatest possible extent. The biggest drawback of the free-floating design is the missing mechanical support of the actuator element, which is braced mainly against the inertial mass of the transducer frame. Especially at lower frequencies, a great deal of the actuator’s energy is lost to recoil in the incus direction of the ISJ and therefore does not contribute to the desired Stapes Footplate Velocity (SFV) amplification. Furthermore, sensor and actuator are mechanically coupled. This suggests that feedback in this setup is more difficult to handle than in other approaches, which usually attempt to separate the sensor and actuator in order to avoid feedback.
2 Methods and material

2.1. Testing environments

In this study, both Finite-Elemente (FE) simulations and TB measurements are presented. The FE model of the middle ear used in this study was presented at MEMRO 2015 (Ossmann, 2015). It comprises the ear canal, TM, ossicles, ligaments and tendons and a simplified spring-mass-damper element as representation of the inner ear. A more detailed description of a previous version of the model can be found in (Bornitz et al., 2010). The structure and the coupling of a transducer in the ISJ gap of the middle ear were described by (Koch et al., 2015). The METF of the model is within the normal range of experimental data ((Rosowski et al., 2007); (ASTM, 2005)). The TBs measurements were performed on fresh unfixed human cadaveric TBs from age range 18 to 80 years stored in NaCl solution. Access to the middle ear cavity was accomplished by mastoidectomy and subsequent posterior tympanotomy (for details refer to (Neudert et al., 2009)). The METF with intact OC was measured for all TBs and compared to
literature data for validation ((Rosowski et al., 2007); (ASTM, 2005)). The SFV was measured with Laser Doppler Vibrometry (LDV) (laser head CLV 700, controller CLV 1000, Polytec GmbH, Waldbronn, Germany) at the footplate center. A small piece of reflective tape was used for signal quality enhancement. The acquired velocity was related to the sound pressure in the ear canal 3 mm in front of the TM, measured by a probe microphone (ER-7C, Etymotic Research Inc., Elk Grove Village, USA) inserted through a small drilled hole in the anterior auditory canal wall. The signal excitation source was a sound generator (Insert Earphone E-ARTONE 3A, Aearo Company, Indianapolis, USA) with an earplug placed into the ear canal. The signal generation and acquisition was realized with a personal computer with a data acquisition board (NI PXI 4462, National Instruments, Austin, USA). A functional transducer with 1 mm thickness was built for the TB measurements. The ISJ was opened carefully using a sickle knife. The transducer was then inserted gently and smoothly with a small tweezer or a needle, while elevating the long process of the incus or pushing down the short process of the incus with a needle. Meanwhile it has been focused on restricting the insertion force to a minimum. The transducer was placed such that the sensor element was facing the long process of the incus and the actuator element was facing the stapes head. Fig. 2 (bottom) shows the transducer in the specimen. In order to validate the proposed reversibility of the implantation, a (nonfunctional) model of the prospective transducer with 0.6 mm thickness was inserted and removed again in 10 TBs. After the transducer’s removal the ISJ was mechanically closed by slightly pushing the long process of the incus down with a needle. The METFs were measured before and after insertion of the transducer model. In order to evaluate the performance of the transducer with reduced OC pretension, four stapes heads were shortened with a CO2 laser (Illumina 755 Heraeus Lasersonics, Milpitas, USA) to extend the ISJ gap to around 0.5 mm. After the dynamic measurements the specimens were split, so that a lateral (incus/malleus/TM) and a medial (footplate/Annular Ligament) component were kept intact, with the cutting plane running through the tympanic cavity at the former ISJ level. Furthermore, the tensor tympani was cut with micro scissors.
Figure 3: Schema of force-displacement measurements: The ISJ is cut open. Incus long process and stapes head are deflected separately using a needle mounted to a microstep manipulator. Forces are measured with a load cell mounted between needle and manipulator. The displacements are measured by a laser triangulation sensor pointing onto the ossicles.

2.2. Examination of the influence of ossicular chain pretension on the transducer output

Inserting the transducer into the opened ISJ causes pretension of the OC. For passive prostheses, an increase in annular ligament stiffness due to prosthesis insertion usually leads to a signal loss in the METF (Morris et al., 2004). Inserting the ISJ transducer has a similar effect on the METF. However, while this passive signal loss affects the residual hearing, the more important question is how the OC pretension affects the active transducer’s performance. There are two effects that have to be considered: a) recoil of the frame, which depends on the ratio of mechanical impedance at the stapes and at the incus side, and b) the nonlinear characteristics of the mechanical impedances, i.e. the change in stiffness with increasing displacement. Note that b) limits the total output of the transducer, while the former is responsible for loss of displacement in the desired direction only. The transducer has no rigid fixation in the tympanic cavity. Therefore, when the actuator is excited, a part of its membrane movement is not transmitted to the stapes footplate, but instead produces recoil of the transducer frame in the direction of the incus. The
proportion of transducer frame displacement is greater at lower frequencies (below the first resonance frequency, i.e. $< 1\text{kHz}$), where the middle ear vibration system is dominated by stiffness. An estimation based on the FE simulation results from (Koch et al., 2014), predicts about 20 dB loss of transducer displacement at the stapes side at low frequencies and 6 dB or less at higher frequencies. Furthermore, the middle ear ligaments, joints and the TM exhibit nonlinear stiffness characteristics. When opening the ISJ, the stiffness of both sides of the chain and thus the mechanical impedance on both sides of the transducer may change differently. To quantify this behavior, we define a displacement $x$ perpendicular to the stapes footplate with the origin at the center of the intact ISJ and the positive direction towards the stapes footplate. The total resulting gap $x_{\text{gap}}$ when opening the ISJ and inserting the transducer, is the difference between the stapes displacement $x_{\text{stapes}}$ and the displacement of the long process of incus $x_{\text{incus}}$.

The force was applied in positive direction for measurement of $x_{\text{stapes}}$ and in negative direction for measurement of $x_{\text{incus}}$.

$$x_{\text{gap}} = x_{\text{stapes}} + x_{\text{incus}}$$

The compliance $\delta$ of both ISJ sides is calculated as the first derivative of displacement by force:

$$\delta_{\text{incus}} = \frac{dx_{\text{incus}}(F)}{dF}$$

$$\delta_{\text{stapes}} = \frac{dx_{\text{stapes}}(F)}{dF}$$

A good measure for the nonlinear behavior of the ligaments is the increase in stiffness, which we will call stiffening $S$. We define $S$ as the ratio of the initial compliance to the pretension-dependent compliance (when incus and stapes are displaced due to a force $F$):

$$S_{\text{incus}} = \frac{\delta_{\text{incus}}(F = 0)}{\delta_{\text{incus}}(F)}$$

$$S_{\text{stapes}} = \frac{\delta_{\text{stapes}}(F = 0)}{\delta_{\text{stapes}}(F)}$$

The rates of stiffening on each side of the OC and their ratio can then be compared with the transducer output to determine influencing factors on transducer performance. Force-displacement diagrams for the two middle ear parts at each side of the ISJ were experimentally determined as
shown in Fig. 3. We used the TBs which were split as explained in the previous section. The two parts of the TB were clamped into a bracket and the ossicles were displaced by a needle mounted on a recalibrated force cell (KA-S 0.5, A.S.T. e Angewandte System Technik GmbH, Dresden, Germany). The movement of the force cell was executed with an Eppendorf 5171 micromanipulator. The displacement of the long process of the incus and of the stapes head was measured with a triangulation laser sensor (optoNCX1402-5, Micro-Epsilon Messtechnik GmbH, Ortenburg, Germany). Small pieces of reflective tape were placed onto the ossicles next to the needle to enhance the signal for the triangulation laser sensor. The measurement data were smoothed by interpolation with exponential functions and then differentiated, according to Eqs. 2.2 and 2.3. The measurements included ten specimen parts with stapes and five parts with incus, malleus and TM. As mentioned above, in addition to the recoil-induced loss in gain, the relation between the transducer’s and its surrounding structure’s impedances can lead to an additional loss in signal gain. This is provoked by a shift in the transducer’s working point which describes the distribution of the transducer’s output in displacement and force. An FE model of the transducer is used to calculate:

1. The maximum free motion of the actuator’s membrane at an excitation of 1 V if it is clamped only on the sensor side of the transducer.

2. The maximum force applied by the actuator’s membrane at an excitation of 1 V if it is clamped on both sides of the transducer, i.e. the sensor side as well as the actuator side.

In reality, the transducer can neither move freely nor is it clamped completely, but is connected to compliances that act like springs and interfere with the transducer’s membrane. For deriving the operating point, a piezo characterization line is the target value for an amplified hearing sensation correlates more with the transducer’s membrane deflection than with its generated force. Therefore, the comparison of the operating point’s y-value (displacement) with the membrane’s maximum free motion delivers the loss in stapes footplate movement due to the transducer’s membrane stiffening.
Figure 4: Schema for transducer characterization from FE simulation with free membrane deflection (1, intersection y-axis), blocking force (2, intersection x-axis) and working point (3) to derive the relation between (1) and (2) to predict SFV loss for stiffness-dominated frequency range due to actuator membrane stiffening.
2 Methods and material

2.3. Transducer working range

The transducer’s Working Range (WR) is limited by the sensor’s threshold and the actuator’s maximum impact on the stapes footplate movement. Within this range the transducer is basically capable of amplifying the stapes’ movement. The upper boundary was determined in the FE simulation by exciting the actuator piezo with a voltage of 1 V and finding the resulting movement of a point in the center of the stapes footplate. The lower boundary was calculated by exciting the model’s ear canal with a pressure of 1 Pa and determining the resulting voltage between the electrodes of the sensor piezo to obtain the sensitivity of the transducer. The sensing threshold can be assessed by comparing the transducer’s sensitivity with its noise level derived from measurements. TB measurements on six human cadaveric TBs were carried out to confirm the simulation results. Twice the transducer was introduced into the ISJ of OCs and four times it was introduced into OCs with extended ISJs (see chapter 2.1). An 8 kHz broadband multisine sound signal was applied to the ear drum with the ear plug in the ear canal and the transducer’s sensitivity was measured with a data acquisition board (NI PXI 4496, National Instruments, Austin, USA) and a preamplifier (SR 560 low noise preamplifier, SRS Stanford Research Systems, Sunnyvale, USA). In the next step, the actuator was excited with a voltage of 1 V with the aid of the data acquisition board and the SFV in mm/s was measured with LDV. The WR thus calculated can be converted to decibel Sound Pressure Level (SPL) (dB SPL) by determining the equivalent sound pressure at the ear canal that produces the same SFV. It can also be related to the output of the system in terms of equivalent stapes footplate movement in mm/s.

2.4. Transducer amplification performance

The transducer’s WR is limited by the boundaries simulated and measured according to chapter 2.3. Its final performance within these boundaries is further limited by the feedback between actuator and sensor. This electroacoustic feedback loop will become unstable and exhibit oscillation as per the Nyquist criterion when overall gain is increased beyond the stable point. The maximum broadband gain for which the system is stable is called the Maximum Stable Gain (MSG). The system comprises digital feedback control based on a LMS algorithm. The control software was implemented on a Field Programmable Gate Array (FPGA) (FPGA, NI PXI 7842R, National Instruments, Austin, USA). The approach is explained in detail in (Koch
et al., 2014). The principal idea is based on a calibration measurement to approximate the feedback path and subtraction of the anticipated feedback from the sensor signal. To measure the attainable gain in terms of SFV, the TMs of the four TBs with extended ISJs were excited with single sine sound signals for the audiologic frequencies (500 Hz, 1000 Hz, 2000 Hz and 4000 Hz). The SFV was measured with LDV for the passive transducer to get the base SFV $SFV_{base}$ in mm/s. The measurement is then repeated with the active transducer set to the MSG to get the amplified SFV $SFV_{amplified}$ in mm/s. The pure amplification as a ratio between $SFV_{base}$ and $SFV_{amplified}$ is only a measure for the transducer’s technical amplification performance. To obtain an application-oriented functional gain ampfunctional in dB the change in METF due to transducer insertion must be taken into account. The functional gain ampfunctional is calculated as follows:

$$amp_{functional} = 20 \cdot \log \left( \frac{SFV_{amplified}}{SFV_{base}} \cdot \frac{METF_{OC\text{intact}}}{METF_{with\text{transducer}}} \right)$$  \hspace{1cm} (2.6)

3. Results

3.1. Implantation process and reversibility

A functional transducer of 1 mm thickness was implemented in four unmodified TBs and four TBs with ISJ gaps extended to approximately 0.5 mm. A geometrical model of a transducer with 0.6 mm thickness was implanted in 10 further TBs. In all cases the available space of the tympanic cavity allowed for insertion of the transducer. The subjectively felt pretension on the OC was very high with the 1 mm transducer in the unmodified TBs and reasonable for the TBs with extended ISJ gap as well as for the thinner transducer model. The stiffness of the transducer’s wire, which is similar to the FMT’s wire, requires a proper positioning of both, the transducer and its wire before insertion into the ISJ. After the TB preparation, the opening of the ISJ and the implementation of the transducer in the ISJ gap was straightforward and took less than 2 min. The METFs of all TB’s were within the range of the literature data. The repetition of the METF measurements for the thin transducer, after explantation of the transducer and closing of the gap, showed METF changes smaller than 5 dB. These results are better than expected compared to the findings of Farahmand but neglect long time changes in the viscoelastic properties of the OC.
Figure 5: Examination of the influence of OC pretension on transducer performance from quasistatic measurements; **Left**: Quasistatic force-related ossicle displacement with standard deviation (error bars) and size of ISJ gap in relation to force on the surrounding ossicles; **Right**: Resulting stiffening of the stapes and incus side of the ISJ related to their initial compliance and resulting loss in transducer-induced SFV.

### 3.2. Influence of OC stiffening

The flexible TM and the compliance of the incudomallear joint suggest that the displacement of the long process of the incus contributes much more to the ISJ gap size than the stapes head displacement. Measurement data from Fig. 5 (left) shows that on average a measured force of 17.5 mN was needed to open up the ISJ by up to 1 mm. The stiffening of the incus side of the ISJ is much lower than the annular ligament stiffening on the stapes side. Fig. 5 (right) shows the stiffening as calculated by Eqs. (2.4) and (2.5), converted to dB. This indicates an expected loss in SFV gain of up to 9 dB for the stiffness-dominated part of the frequency range.

### 3.3. Influence of transducer’s working point shift

The transducer’s simulated maximum generated force (blocking force) when clamped on both sides is about 45 mN. The simulated maximum achievable membrane deflection, if the transducer can move freely, is 54 mm. The resulting transducer characteristic derived from FE simulation is depicted in Fig. 5. For the measurement the compliance even for a 20 mN pretension results in a working point very close to the y-axis of Fig. 6. Therefore, the measured compliances do not
3 Results

Figure 6: Influence of OC pretension on actuator’s operating point (relation between membrane displacement and generated force) and resulting loss in SFV for stiffness-dominated frequency range.

seem to provoke a further reduction in generated SFV due to a shift in the transducer’s working point. This is because the measured compliances are relatively high, compared to our FE model or literature data. The measured compliance for the stapes was 0.07 mm/mN, while our FE model results in 1.3 mm/mN and literature data (which also varies) shows e.g. 0.8 mm/mN by (Lauxmann et al., 2014) or 0.5 mm/mN by (O’Connor & Puria, 2008). If we assume that the relative effect of stiffening can be applied to the higher initial compliances of the FE model, the generated SFV would be reduced by up to 8 dB.

3.4. Transducer performance

The simulation of the transducer’s WR predicts promising system boundaries. The span reaches from 25 dB SPL (corresponding to an SFV of 3e-6 mm/s) and less for the hearing threshold from 80 to 130 dB SPL (SFV of 0.03 mm/s to 1 mm/s) for the actuator’s equivalent output, depending
Figure 7: Measurement of WR and amplification performance for the transducer in six TBs. The WR represents the area in which signals can be amplified by the transducer. It starts from the minimum signal that the sensor element is able to measure and reaches to the maximum output that the actuator is able to generate. For TB 1 and TB 2 the ISJ was just opened, TB 3 to TB 6 are examined with an extended ISJ gap to predict the outcome for a 0.5 mm thick transducer. The WR from FE simulation is depicted for comparison.

on the frequency (Koch et al., 2015). The experiments with unmodified TBs do not confirm the prediction of the FE-model. While the results from simulation and experiment for the sensor’s threshold are in agreement, the measured maximum actuator output is two to three magnitudes worse than predicted, which is equivalent to 40 to 60 dB (see TB 1 and TB 2 in Fig. 7). About 9 dB of this difference can be attributed to stiffening effects within the OC due to the ISJ gap opening (see previous section), since this effect is not included in the simulation model. The four TBs with extended ISJ gaps showed an improved WR (see Fig. 7). The sensor threshold
3 Results

Figure 8: Measured transducer functional gain at the determined MSG for the TBs with extended ISJ gap, the amplification is thereby related to the METF of the TB before transducer insertion.

Figure 9: Resulting medical indication range for current and prospective transducer outcome as a function of Hearing loss in dB HL, compared to presbyacusis and noise-induced high frequency hearing loss literature data ((Hesse, 2004), (Smoorenburg, 1992)).

was equal to or better than the simulation. The actuator’s output matched the simulation result in
4 Discussion

the best case (TB 4 in Fig. 7). With the other TBs it was still up to one magnitude worse than for the simulation, but much better than with the unmodified TBs. Single sine measurements were subsequently performed for the typical audiological frequencies. The corresponding base signals and amplified signals are shown in the WR as dotted and solid red lines (Fig. 7). The related base signals for the METF before transducer insertions are depicted as grey lines. The comparison between the base signal before and after insertion shows the effect of transducer insertion on the METF. Comparing the measured amplified signal to the base signal yields the Added Stable Gain (ASG), which serves as a representation for the efficiency of the control algorithm. These results were similar for all four TBs with an extended joint gap, resulting in an ASG of 15 dB at 500 Hz and rising to 30 dB at 4 kHz. However, the resulting functional gain of the transducer, as calculated according to section 2.4, shows a greater variation between the TBs (see Fig. 8 on the left). All measurements show a high hearing amplification (about 30 dB) at frequencies > 2 kHz, but low frequency performance is significantly worse. For TB 5 the passive influence of the transducer on the METF exceeded the gain at 500 Hz significantly, so that measurements at this frequency were not reliable.

4. Discussion

4.1. Factors influencing performance

There are numerous potential factors that influence the transducer’s overall performance. In this study, the focus is on the effects of the pretension of relevant parts of the OC. The relative change in the compliances of the implanted transducer’s surrounding structures, the incus side in comparison to the stapes side, leads to a reduction in the achieved SFV gain of up to 9 dB, as shown in Fig. 5. The total output performance of the actuator due to the applied loads could contribute up to 8 dB SFV gain reduction as seen in Fig. 6. Both phenomena together could explain a reduction of the SFV of 17 dB due to OC pretension. This is confirmed by the experiment, where the difference in SFV output was about 20 dB between TBs without and with an extended joint gap. Note that the performance measurements and FEM simulation was done over a frequency range, while the compliance measurements were quasistatic. The latter are therefore only significant for the stiffness-dominated part of the frequency range. At higher frequencies, additional effects can account for the remaining differences. However, the output
did not reach the values predicted by simulation in all cases. The difference we found is always less than 20 dB, depending on the frequency and TB sample: In TB 4 and TB 6, the measurement more or less matches the simulation results for a good part of the frequency range, while TB 3 and TB five show a decreased overall output. These discrepancies could be attributed to a number of simulation model inaccuracies and limitations: The most likely explanation is the varying success in reducing the OC pretension. Furthermore, the bonding glue between the piezo and membrane is not part of the model and could contribute to a loss in force transmission between the piezoelectric element and transducer membrane if the connection is too soft. A typical middle ear FE model such as the one used here is most accurate in predicting the natural movement perpendicular to the round window. Its accuracy is limited for predicting movements in other degrees of freedom because it’s fitted with TB measurements made only in the mentioned direction. Tilting of the stapes due to transducer insertion could provoke a considerable part of the stapes’ rocking motion instead of the piston-like motion during actuator excitation. The stapes’ rocking motion could be a considerable issue in cochlea activation as shown by (Eiber et al., 2012). This was considered neither in the current FEM model nor in the measurement setup, because only one point’s motion on the stapes footplate was measured. Slight tilting of the stapes during insertion could also lead to a different annular ligament stiffening behavior compared to the force-distance measurements. It has also been shown that the influence of additional contact points between anatomy and sensor element is moderately high, with about 5 dB of change in the sensor’s sensitivity (Koch et al., 2013). The influence of additional contact points between anatomy and actuator element is still uncertain.

4.2. Medical indication and prospective improvements

The most common way of defining a medical indication for AMEIs with disregard of structural pathologies is by drawing the area of treatable hearing loss in dB HL vs. frequency. Thereafter, a patient’s audiogram can easily be checked against this indication range. The maximum treatable hearing loss e the upper limit of the indication range e is affected by two factors: First, the maximum output of the actuator must match the treatable hearing loss plus minimum headroom of 30 dB to account for a dynamic range sufficient for good speech intelligibility. The second limiting factor is the MSG achieved by the transducer’s active noise control algorithm, which in turn limits the achieved functional gain. As per (Humes, 1986) the Berger method states that a
Figure 10: Count-the-Dots method for evaluating the performance of the transducer with aid of the AI (Mueller & Killion, 1990). For literature data about noise-induced hearing loss, the AI rises from 0.74 to 0.94 which equals a rise in speech intelligibility for monosyllabic words from 91% to 97%. For literature data about 71 to 80 year-olds with presbyacusis, the AI rises from 0.35 to 0.88 which equals a rise in speech intelligibility for monosyllabic words from 49% to 95%.

signal gain of at least half the patient’s hearing loss is necessary. While there are more complex and more accurate methods available (e.g. NAL-N1; (Dillon, 1999)), the Berger method gives a good and easily comprehensible impression. A best-case scenario for the measurements with an extended ISJ gap was examined to assess the medical indication range for a miniaturized transducer with only 0.5 mm thickness, which we expect to be technologically possible. A patient with a hearing loss of only 15 dB for lower frequencies up to 1 kHz but up to 60 dB for high frequencies of 2 kHz and above (see green area in Fig. 9) could be helped with this kind of transducer. In the special case of high frequency hearing loss, (Boeheim et al., 2010) found speech intelligibility for such patients to be significantly better when treated with AMEIs as
opposed to open-fit hearing aids. Together with the inherent advantages of fully implantable hearing aids, this is a good argument for the transducer as a solution for such cases. Another method of evaluating the performance of a hearing aid is the AI. It assesses the question of how difficult it is to understand speech. A method for calculating the AI is the Count-the-Dots audiogram form implemented by (Mueller & Killion, 1990). A hearing loss graph in dB HL which is to be examined is plotted in an audiogram with an area representing the frequencies and sound levels important for speech intelligibility. The audiogram also features one hundred dots, each representing one percent AI. All dots below the hearing loss graph are counted to yield the AI. An example for patients with high frequency hearing loss is given with a study of 200 subjects (400 ears) on patients with noise-induced hearing loss (Smoorenburg, 1992). The 90th percentile of the subjects’ audiograms is added to Fig. 9. Applying the Count-the-Dots method to this data for noise-induced hearing loss, we can compare the unaided AI to that with amplification from the proposed transducer (see Fig. 9). The AI rises from 0.74 without a transducer to 0.94 with an active transducer. According to (Amlani et al., 2002), this equals a rise in speech intelligibility for monosyllabic words from 91% to 97%. Another group of patients with a potential indication for the transducer are those with presbyacusis. Literature data from (Hesse, 2004), for typical high frequency hearing loss in presbyacusis patients is also shown in Fig. 9 and 10. The AI of presbyacusis subjects in the range of 71 to 80-year-olds could be improved from 0.35 to 0.88. This equals a rise in speech intelligibility for monosyllabic words from 49% to 95%. There are further conceivable improvements which would allow for the treatment of patients with more severe presbyacusis. This could be achieved by different methods:

- Increased transducer mass
- Higher actuator voltage (limited by power consumption and mechanical piezo strength)
- Further miniaturization of the transducer to even less than 0.5 mm
- Use of a prospective piezo with better electromechanical coupling coefficients
4.3. Comparison to other approaches

The ISJ transducer has a relatively low impact on the anatomic middle ear structures compared to other fully implantable approaches. The Esteem system requires the incus long process to be cut through. Although the long process can be repaired with cement, this OC interruption is not really reversible. The implantation of the ISJ transducer is expected to be reversible, although long-term effects of the ISJ gap opening have not yet been examined. The surgical procedure for the ISJ transducer requires substantially less effort by the surgeon as compared to other fully implantable systems, it is comparable to the attachment of the FMT actuator at the long incus process. Nevertheless, the stapes is very delicate and the risk of fracturing the crura or a disarticulation in the annular ligament still has to be considered. From our experience the key for minimizing the risk of trauma is the thickness reduction of the transducer (maximum of 0.6 mm thickness if ISJ gap is not extended) and an active ISJ opening by gently elevating the long incus process and thus generating the necessary gap size while inserting the transducer. However, like in all otosurgical maneuvers, even exercising extreme caution cannot fully exclude accidental damage of stapes. The Esteem, Carina and Codacs systems need to be fixed in the tympanic cavity with screws. Their coupling elements have to be positioned in relation to the anatomic structures and sometimes fixed with cement in a complex procedure ((Chen et al., 2004); (Bruschini et al., 2009)). The coupling force has to be adjusted manually to provide proper transmission without ligament stiffening. The ISJ transducer’s coupling force depends solely on its size and is therefore design-specific. Otherwise, the missing rigid fixation to the tympanic cavity could be a critical issue for sensor stability during large pressure changes at the TM. This needs to be examined in a future study. The performance of the other discussed systems is better than the proposed transducer for low frequencies up to 1 kHz with maximum ranges up to 60 to 80 dB. For high frequencies above 2 kHz, the ISJ transducer could prospectively converge to the other systems’ maximum range of 80 dB.
4.4. Conclusion

A transducer with piezoelectric sensor and actuator elements in one housing for insertion into the ISJ gap was introduced. The surgical steps necessary for insertion were feasible and the transducer’s dimensions were appropriate for all examined TBs. The greatest advantages of the proposed transducer concept are the relative simplicity of its insertion compared to most other fully implantable systems and the reversibility of the surgical intervention in the OC. These advantages must be weighed against a loss of transducer performance at low frequencies (< 1kHz). FE model simulations and TB measurements of the transducer’s WR and amplification performance confirm its ability to provide prospective patients with reasonable hearing amplification. A functional gain of more than 30 dB is achieved for high frequencies greater than 2 kHz. The transducer is therefore suitable as the central component of an implant indicated as treatment for high frequency hearing loss which occurs e.g. due to excessive loudness exposure or presbyacusis. Because a high frequency hearing loss, which is very severe (at the top range of the transducers actual amplification abilities) can only be provided with pure amplification in some cases, future improvements should focus on low frequency performance and advanced performance parameters like low distortion.
VI. Ergebnisse und Diskussion

1. Implantation des Sensors und Anatomieabhängigkeit seines Ertrags

Die Implantation sowohl des Sensors als auch des äußerlich annähernd baugleichen Wandlers aus Sensor- und Aktorelement erwies sich für geübte Chirurgen/Chirurginnen als verhältnismäßig einfach. Die Middle Ear Transfer Functions (METFs) der Felsenbeine und somit auch das Restgehör verschlechterten sich durch Einbau der 1 mm dicken Sensoren um 15 dB. Aktuelle Untersuchungen an 0.6 mm dicken Sensoren zeigen den Trend zu signifikant niedrigerer Restgehörminderung um ca. 5 dB auf. Die implementierten Einkristallpiezos lieferten bei einer Schallanregung am Trommelfell von 1 Pa einen Signalertrag zwischen 0.1 mV und 1 mV bei einer Schwankungsbreite ähnlich der gemessenen Schwankung der METFs. Der Signalverlust bei außermittiger Positionierung der Sensoren belief sich sowohl in der Messung als auch in der Simulation auf lediglich 5 dB bei Sensorverschiebungen um bis zu 0.75 mm. Kontaktpunkte mit der umliegenden Anatomie konnten beim Einsetzen des Sensors mit den Abmaßen von 4.5 x 2.5 x 1 mm nicht immer vermieden werden. Es kam beim mittigen Einsetzen in neun Felsenbeine in sieben Fällen zu einem zusätzlichen Kontakt mit dem Ambossfortsatz, in zwei Fällen zum Kontakt mit dem Hammergriff und in zwei Fällen zum Kontakt mit dem Promontorium. Durch Verschieben des Sensors aus der zentrierten Lage konnten die Kontakte teilweise verhindert werden. Ein Kontakt mit Ambossfortsatz und/oder Promontorium resultierte im Median in einem Signalverlust von 5 dB während ein Kontakt mit dem Promontorium im Mittel durch die bessere Lagerung zu einem Signalgewinn von ca. 5 dB führte. Eine Drehung des Sensors dergestalt, dass der Piezo das Signal statt vom Stapes auf der Ambossseite aufnimmt, führte aufgrund der Masseträgheit des Sensorelements erwartungsgemäß besonders hochfrequent zu sehr variierenden Ergebnissen. Deshalb muss von dieser Option abgeraten werden. Der Sensorertrag zeigt sich in Summe der untersuchten Faktoren verhältnismäßig robust. Lediglich die durch die interindividuell anatomisch bedingt variierenden Eingangspegel des Sensors müssen bei der Auslegung der Elektronik Berücksichtigung finden. Aktuelle Untersuchungen an miniaturisierten Sensoren (0.6 mm) zeigen das bei der Messung des Sensorertrags beson-
2 Leistungsfähigkeit des Wandlers in Simulation und physikalischem Modell


3. Einsatz des Wandlers im Humanpräparat

Für die weiteren Untersuchungen standen miniaturisierte kombinierte Wandlerelemente mit einer Gesamtdicke von 1 mm zur Verfügung. Wiederholt man die Untersuchungen aus Abschnitt 2 in Felsenbeinen, so lassen sich die Ergebnisse aus Simulation und physikalischem Modell...
VII. Zusammenfassung

Hintergrund

Fragestellungen

- Welchen Signalertrag kann ein Kraftsensor auf Basis eines Einkristallpiezo im Incudostape
dielgelenk liefern?

- Welchen Einfluss haben die anatomisch variierenden Randbedingungen des Mittelohres
sowie Variationen der Positioniergenauigkeit?

- Welche Leistungsparameter kann ein Wandler erreichen welcher das Sensorkonzept um
ein stapesseitiges Aktorelement erweitert?

- Welche prospektive medizinische Indikation lässt sich aus den Leistungsparametern
abschätzen?

Material und Methode

Untersucht wurden sowohl Sensoren als auch Sensor-Aktor-Elemente, im Folgenden Wandler ge-
nannt, zum Einsatz im ISG des Mittelohres. Die Abmessungen betrugen jeweils
4.5x2.5x1 mm. Die Einkristallpiezos wurden dabei innenliegend auf je eine dünne ovale Biege-
platte aus Titan geklebt. Mit einer entsprechenden Durchführung der Anschlusskabel durch das
Gehäuse ist eine hermetische Dichtung und damit die Biokompatibilität der Gesamtbau gruppe
realisierbar. Durch die Bauform entspricht die Wirkungsweise von Sensor- und auch Aktorele-
ment hauptsächlich einem Biegewandler. Der Sensor ist ein Kraftsensor. Der Aktor arbeitet
abhängig von der Kettenvorspannung als eine Mischung aus Weg- und Kraftgeber.

Die Elemente lagen jeweils als aufgebautes Testmuster vor. Sie konnten sowohl in einem
physikalischen Modell des Mittelohrs als auch in Humanpräparaten untersucht werden. Als
Eingangssignal kam jeweils ein Schallsignal über einen Geber im Gehörgang zum Einsatz,
welches mit einem Mikrofon vor dem Trommelfell als Referenz gemessen wurde. Ein Maß
für den Höreindruck der hypothetischen Patienten/Patientinnen stellt, wie bei Untersuchungen
am Felsenbein üblich, die Bewegung der Steigbügelfußplatte dar. Diese kann im Felsenbein
mit einem Laser Doppler Vibrometrie (LDV) und im Modell mit einem Mikrofon in einer
Hohlkammer unter der Membran, auf welcher der künstliche Steigbügel sitzt, gemessen werden.
Das dynamische Messsignal des Sensors wurde als elektrische Spannung aus dem Piezoelement
nach einer Vorverstärkung von einer Messkarte im PC erfasst. Die Signalverarbeitung im kombi-
nierten Sensor-/Aktorbetrieb erfolgte mit einem Field Programmable Gate Array (FPGA). Das
Aktorelement wurde ebenfalls von diesem angesteuert. Durch einen Vergleich der Stapesfuß-
plattenschwingung bei Aktoranregung und Anregung mit Schalldruck im Gehörgang konnte
jeweils auf einen äquivalenten Schalldruck zurückgerechnet werden. Für den kombinierten
Wandlerbetrieb wurde ein Least Mean Square (LMS) zur Rückkopplungsunterdrückung auf dem
FPGA implementiert.

Der Sensor wurde in zehn Felsenbeinen untersucht, der kombinierte Wandler kam in sechs
Felsenbeinen (zwei ohne und vier mit mittels CO₂-Laser erweitertem Gelenkspalt) zum Einsatz.
Der Zugang erfolgte dabei über eine posteriore Tympanotomie mit Auftrennung des ISGs. Dies
und die Insertion von Sensor oder Wandler erfolgte mit Standardinstrumentarium. Weitere fünf
Felsenbeine wurden entlang der Normalenebene zur Stapeslängsachse auf Höhe des ISGs gespal-
ten um Kraft-Weg-Messungen mit Kraftmesszelle und Lasertriangulationssensor durchführen zu
können. Der laterale Schalleitungsapparat (Gehörgang, Trommelfell, Hammer-Amboß-Komplex)
und der mediale Teil (Stapes, rundes und ovales Fenster, Innenohr) blieben hierbei intakt. Da-
durch konnte die Vorspannung auf den Sensor nach Einbau und die amboss- und sensorseitige
statische Steifigkeitsvariation der Kette bei Auslenkung untersucht werden.

In einem Finite-Elemente-Methode (FEM) Modell des Mittelohrs und des Sensors konnten
zur Validierung der Messergebnisse vergleichende Simulationen durchgeführt werden. Da das
Simulationsmodell auf dynamische Felsenbeinmessungen gefittet ist sind sowohl quasistat-
sche Untersuchungen als auch Aussagen über das Verhalten der Kette bei Vorspannung nur
eingeschränkt möglich. Die Ergebnisse der Wandlermessungen wurden in ein Audiogramm
ingetragen und mit Literaturdaten für typische Formen der Hörschädigung verglichen. Hiermit
konnte eine erste Einschätzung über eine mögliche zukünftige medizinische Indikation getroffen
werden.

**Ergebnisse und Schlussfolgerungen**

Das Sensorelement des Wandlers erzielte bei Schallanregung mit 1 Pa am Trommelfell Signalera-
träge von 0.1 mV bis 1 mV im audiologischen Frequenzbereich. Der Sensor nutzt einen Teil
der natürlichen Übertragung im Gehörorgan (Gehörgang, Trommelfell, Hammer, Amboss).

Die Leistung des Wandlers, insbesondere des Aktorelements, ist sehr stark von der Vorspannung in der Ossikelkette abhängig, welche bei der Wandlerinsertion hervorgerufen wird. Durch ein Aufweiten des Gelenkspalts verstieft sich die Ossikelkette stapesseitig mehr als ambossseitig. Mit Hilfe künstlich erweiterter Gelenkspalte im Felsenbeinexperiment konnte das Verhalten zukünftiger miniaturisierter Wandlerelemente studiert werden. Der Dynamikbereich des Wandlers erstreckt sich experimentell zwischen einer sensorseitigen Hörschwelle mit breitbandig 30 dB Sound Pressure Level (SPL) und einem maximalen äquivalenten Aktorpegel von tieffrequent 70 dB SPL bis zu hochfrequent 120 dB SPL. Die Verstärkungsleistung innerhalb dieses Dynamikbereichs liegt hochfrequent bei 30 dB.

VIII. Summary

Background

Implantable hearing systems have been a research topic for some time. Because of the improving technology especially in terms of electronics miniaturisation and power supply fully implantable devices become the focus of attention. The performance parameters of existing components often meet the technical requirements but lack medical practicability. The insertion of the devices is often a very complex procedure and causes non-reversible changes in the patient’s anatomy. A new transducer system for sensor and actuator elements is introduced. It attempts to account for a reversible minimally invasive approach and feasible handling. The main idea is to insert a transducer into the Incudostapedial Joint (ISJ) gap. The design consists of a titanium housing with one or two titanium bending plates which are internally equipped with single crystal piezos for signal-acquisition or -generation. The attachment of the transducer is free floating in the joint gap without additional fixation points in the tympanic cavity. This concept enables a reduced sensitivity to body noise. The publications deal with the analysis of possible performance parameters of the transducers components in experiment and simulation. A further emphasis of the studies is how the humans highly variable anatomy affects the results.

Questions

- Which signal yields a force sensor based on a bending plate single crystal piezo in the ISJ?
- How does the anatomical variation and the position accuracy influence the results?
- What performance is to be expected of a combined sensor/actuator transducer?
- What is the prospective medical indication of the proposed transducer design?

Material and methods

A sensor and a transducer consisting of a sensor and an actuator element for application inside the ISJ gap were studied. Both could be prospective components of future Cochlea Implants (CIs)
or Active Middle Ear Implants (AMEIs). The dimensions are 4.5x2.5x1 mm. The single crystal piezos are glued inside a thin oval titanium plate, with a proper lead of the wires out of the hermetically sealed housing ensuring biocompatibility of the whole assembly. The sensor- and actuator element mainly act in bending mode. The actuator works in a mix between force- and displacement actuator depending on the ossicular chain pretension.

The elements used were manually constructed prototypes. Measurements were performed with the elements inserted into a physical model of the middle ear as well as in human temporal bones. A sound generator’s signal in the auditory canal was the input into the system. The sound signal was measured in front of the tympanic membrane by a reference microphone. The movement of the stapes footplate was used as a measurement for the theoretical hearing sensation. It was measured either by Laser Doppler Vibrometry (LDV) for the temporal bone measurements or with a small microphone inside a cavity beyond the physical models plastics membrane equipped with the artificial stapes. The dynamic signal of the sensor in the form of an electrical voltage from the piezo element was preamplified and subsequently acquired by a data acquisition card. The signal conditioning and processing for the combined sensor-actuator-transducer was realised with an Field Programmable Gate Array (FPGA) card. With a comparison of the stapes footplate movement at actuator-excitation and sound-excitation a equivalent sound pressure could be calculated. For the combined transducer-operation a Least Mean Square (LMS) was established to suppress the feedback between sensor and actuator.

The sensor was examined in ten temporal bones, the combined transducer was evaluated in six temporal bones (two unaltered and four with a joint gap extended by a CO₂-laser). The access was undertaken in terms of a posterior tympanotomie with separation of the ISJ with needle or sickle knife. The insertion of sensor or transducer was done with standard instruments. Further five temporal bones were split normal to the stapes long axis at the level of the ISJ gap to measure force-displacement relations with load cell and laser triangulation sensor. The lateral sound conducting apparatus (auditory canal, tympanic membrane, malleus-incus-complex) remained intact as well as the medial part (stapes, inner ear with round and oval window). Therefore the pretension on the sensor element after insertion and the variation of the stiffness on both parts of the ossicular chain could be observed.

In an Finite-Elemente-Method (FEM) model of the middle ear and the sensor the measurement results could be validated. Because the simulation model is fitted to dynamic temporal bone
measurements the prediction of the systems behaviour is has some restrictions for quasistatic examinations and the analysis of the ossicular chain under pretension. The results of the transducer measurements are endorsed in an audiogram and compared with literature and typical forms of hearing impairment. This is sufficient for a first estimation of the prospective medical indication.

Results and conclusion

The transducer’s sensing element shows a signal yield from 0.1 mV to 1 mV for a sound pressure excitation of 1 Pa at the ear drum. The sound transmission occurs on the natural pathway. This could be beneficial to parameters like acoustic pattern and directional hearing could operate normally. The sensor is resilient against several factors. Small variations in the sensor position or additional contact points with the surrounding anatomy at long process of incus or malleus evoke a signal loss of up to 5 dB. An additional contact point with the promontory cause a signal gain of 5 dB due to the improved sensor fixation.

The performance of the transducer and especially the actuator element depends strongly on the ossicular chain pretension which is induced during transducer insertion. The ossicular chain is stiffening much more on the stapes-side than on the incus-side during the stretch of the joint gap. By means of artificially widended joint gaps in temporal bone experiments the behaviour of future miniaturised transducers could be studied. The experimental dynamic range of the presented transducer ranges from a sensor’s broadband hearing threshold level of 30 dB Sound Pressure Level (SPL) up to an actuator’s maximum an equivalent sound pressure level of 70 dB SPL low frequency respectively 120 dB SPL for high frequencies. The amplification performance of the transducer within this dynamic range is located at about 30 dB for high frequencies.

A prospective medical indication of the transducers could be the treatment of high frequency hearing loss and therefore also presbyacusis. A treatment for patients with typical noise induced hearing loss seems to be equally feasible. At this stage in development, it seems feasible to implant the sensor-only concept in a number of applications, while the transducer concept faces some questions to resolve but is nevertheless promising. The transducers performance is not on the same level like other approaches in terms of technical characteristics for the whole frequency
range but the concept stands out regarding feasible insertion and minimal invasivity.
Abkürzungsverzeichnis

**AI**  Articulation Index

**AMEI**  Active Middle Ear Implant

**ASG**  Added Stable Gain

**BMBF**  Bundesministerium für Bildung und Forschung

**CI**  Cochlea Implant

**CI**  Cochlea Implantat

**DSP**  Digital Signal Processor

**FE**  Finite-Elemente

**FEM**  Finite-Elemente-Method

**FEM**  Finite-Elemente-Methode

**FIR**  Finite Impulse Response

**FMT**  Floating Mass Transducer

**FPGA**  Field Programmable Gate Array

**HL**  Hearing Loss

**ISJ**  Incudostapedial Joint

**ISG**  Incudostapedialgelenk

**IR**  Impulse Response

**LDV**  Laser Doppler Vibrometry

**LDV**  Laser Doppler Vibrometrie

**LMS**  Least Mean Square
MED-EL  MED-EL Elektromedizinische Geräte Gesellschaft m.b.H.

METF  Middle Ear Transfer Function

MSG  Maximum Stable Gain

OC  Ossicular Chain

SFV  Stapes Footplate Velocity

SPL  Sound Pressure Level

TB  Temporal Bone

TM  Tympanic Membrane

WR  Working Range
Literaturverzeichnis


Literaturverzeichnis


93
Literaturverzeichnis


Danksagung

Essential Science Indicators : Total Citations Graph

Journal Citation Report : Impact factor

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Abbildung 1: Journal Citations Report Hearing Research

99
Essential Science Indicators: Total Citations Graph

Journal Citation Report: Impact factor

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Essential Science Indicators: Total Citations

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Abbildung 2: Journal Citations Report Sensors
Erklärung zu Ko-Autorenschaften

Publikation 1: Influence of the middle ear anatomy on the performance of a membrane sensor in the incudostapedial joint gap
Koch, M.; Seidler, H.; Hellmuth, A.; Bornitz, M.; Lasurashvili, N.; Zahnert, T.

Publikation 2: Examination of a mechanical amplifier in the incudostapedial joint gap: FEM simulation and physical model
Koch, M.; Eßinger, T.M.; Bornitz, M.; Zahnert, T.
ble Gate Array (FPGA) zur Rückkopplungsunterdrückung und unterstützte bei der Durchführung der Messungen und der Ergebnisdiskussion. Die Entwicklung des physikalischen Modells sowie die ingenieurtechnische Betreuung der Publikation wurde von Matthias Bornitz durchgeführt. Thomas Zahnert oblag die Betreuung der Arbeit von medizinischer Seite.

**Publikation 3: Fully implantable hearing aid in the incudostapedial joint gap**

Koch, M.; Eßinger, T.M.; Stoppe, T.; Lasurashvili, N.; Bornitz, M.; Zahnert, T.

Erklärungen zur Eröffnung des Promotionsverfahrens

1. Hiermit versichere ich, dass ich die vorliegende Arbeit ohne unzulässige Hilfe Dritter und ohne Benutzung anderer als der angegebenen Hilfsmittel angefertigt habe; die aus fremden Quellen direkt oder indirekt übernommenen Gedanken sind als solche kenntlich gemacht.


4. Die Arbeit wurde bisher weder im Inland noch im Ausland in gleicher oder ähnlicher Form einer anderen Prüfungsbehörde vorgelegt.

5. Die Inhalte dieser Dissertation wurden in folgender Form veröffentlicht:


7. Ich bestätige, dass ich die Promotionsordnung der Medizinischen Fakultät der Technischen Universität Dresden anerkenne.

8. Ich habe die Zitierrichtlinien für Dissertationen an der Medizinischen Fakultät der Technischen Universität Dresden zur Kenntnis genommen und befolgt.

Dresden, 22.02.2018

[Unterschrift]

Ort, Datum  Unterschrift des Doktoranden

(Diese Erklärungen sind an das Ende der Arbeit einzubinden) Formblatt 1.2.1, Seite 1-1, erstellt 18.10.2013
Hiermit bestätige ich die Einhaltung der folgenden aktuellen gesetzlichen Vorgaben im Rahmen meiner Dissertation

☐ das zustimmende Votum der Ethikkommission bei Klinischen Studien, epidemiologischen Untersuchungen mit Personenbezug oder Sachverhalten, die das Medizinproduktegesetz betreffen
  Aktenzeichen der zuständigen Ethikkommission EK 59022014

☐ die Einhaltung der Bestimmungen des Tierschutzgesetzes
  Aktenzeichen der Genehmigungsbehörde zum Vorhaben/zur Mitwirkung

☐ die Einhaltung des Gentechnikgesetzes
  Projektnummer .................................................................

☐ die Einhaltung von Datenschutzbestimmungen der Medizinischen Fakultät und des Universitätsklinikums Carl Gustav Carus.

Dresden, 22.02.2018

Ort, Datum

Unterschrift des Doktoranden