

# CHALMERS



## Development of an intraoperative evaluation method for a novel Bone Conduction Implant using nasal sound pressure

*Master of Science Thesis in Biomedical Engineering*

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## Abstract

This thesis primarily aims to develop a non-invasive intraoperative method to verify the functionality of a new Bone Conduction Implant (BCI) using Nasal Sound Pressure (NSP) before the surgical incision is closed. The reason behind this verification process is due to the risk of damages to the implant, during surgery or during the preceding sterilization process. In addition, this method is intended to be used in further evaluation and analysis of the implant after the surgery in follow-up stages. Bone conduction hearing is when vibrations in the skull bone stimulate the cochlea, which leads to sound perception. Bone conduction hearing aids use this phenomenon to provide an alternative solution for patients who have impairment mainly in the outer ear or middle ear. The BCI, which is designed and developed at Chalmers University of Technology and Sahlgrenska University Hospital is an alternative to the percutaneous Bone Anchored Hearing Aid (BAHA) that is attached to the skull bone via a skin penetrating titanium screw. Although BAHA has been successful for three decades, the skin penetration requires a life-long daily care and may lead to complications such as skin infections or loss of implant. In the BCI, no skin penetration is required and the skin is kept intact. The BCI consists of an external sound processor with a transmitter coil to transmit the sound via an inductive link to a receiving coil in the implanted unit. Then, the sound signal is converted to the mechanical vibrations by a Balanced Electromagnetic Separation Transducer (BEST). Evaluating the functionality of the implant is a challenging task since the access to the implant is limited during and after surgery. Previously Ear-Canal Sound Pressure (ECSP) had been suggested and investigated as a method to verify the function of the BCI. However, the ear-canal is close to the surgical site and difficult to reach during the surgery, and some patients do not have ear-canal.

To evaluate the efficiency of the NSP method, the technique has been optimized by performing preparation measurements on authors using bone conduction stimulation through the skin. Then, the method has been tested on a cadaver by both bone conduction stimulation through the skin and direct bone conduction stimulation from the implanted BCI transducer. In the next stage, 20 normal-hearing subjects participated in the study to evaluate and compare the efficiency of NSP and ECSP before testing the NSP method during surgery on the first BCI patient.

Different factors and constraints that can affect the results were considered and this study shows that the NSP provides higher magnitude than the ECSP. Stimulation at BCI position provided a higher NSP signal than stimulation at the BAHA position, which is consistent with results from previous studies investigating hearing thresholds, ECSP and vibrations of the cochlear promontory.

The results clearly imply that the NSP method is suitable for the test and verification of the implanted part of the BCI. This has been confirmed in the first surgery. The NSP method is also used in follow-up of patients to verify the functionality of the implanted unit of the BCI.



## Acknowledgements

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**List of abbreviations and acronyms:**

AC	Air Conduction / Air Conducted
BAHA	Bone Anchored Hearing Aid
BC	Bone Conduction / Bone Conducted
BCI	Bone Conduction Implant
dB	decibel
ECSP	Ear-Canal Sound Pressure
HL	Hearing Level
NSP	Nasal Sound Pressure
SPL	Sound Pressure Level
TM	Tympanic Membrane

# 1

## Introduction

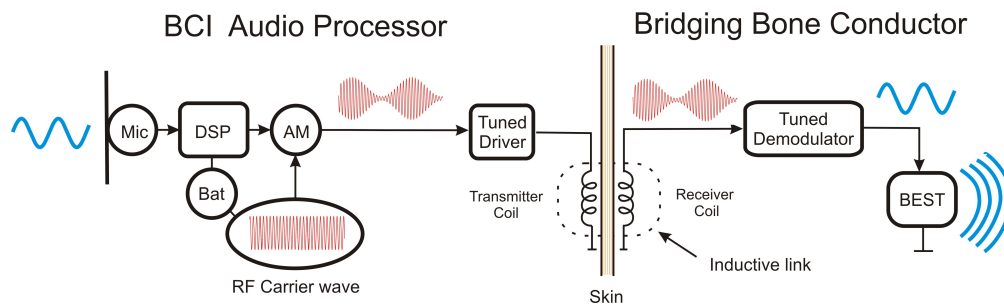
**H**EARING disease is the most frequent sensory failure in humans, affecting more than 360 million people in the world [1]. Communication, social and economic problems are only some aspects of this impairment. Receiving acoustic stimulation through the auditory system and converting it to auditory sensation will result in hearing. The acoustic stimuli received by the ears is converted into mechanical vibrations and generates cochlea stimuli, where neural impulses are produced. For auditory perception, two transmission pathways exist including air conduction and bone conduction. In air conduction hearing, an acoustic signal travels through the outer ear, middle ear and then arrives at the cochlea. Bone conduction is the pathway where an acoustic signal cause vibration within the skull bones and stimulates the cochlea. The conversion mechanism of mechanical vibrations into neural impulses, which occur in the cochlea, is the same for bone conduction and air conduction hearing [2].

People who suffer from conductive hearing loss can not be treated by conventional hearing aid, because the sound does not reach the cochlea properly. However, using a bone conduction hearing aid would be a solution for these patients, to transmit the sound data into the cochlea, bypassing the middle ear. Nowadays, using a percutaneous Bone Anchored Hearing Aid (BAHA) is an appropriate alternative for such patients, as well as patients with mixed hearing loss and single-sided deafness. This hearing aid has a percutaneous bone anchored implant with a snap coupling for the sound processor and bone conduction transducer. A microphone receives the sound and amplifies it. This amplified sound will be transmitted directly as vibrations within skull bone to the cochlea, by-passing the middle ear. BAHA has been successful for patients with a pure conductive deafness, mixed hearing loss and single-sided deafness. However, the skin penetration requires a life-long daily care and will sometimes cause infections. Some drawbacks have been reported, such as skin redness, skin infection and loss of implant (accidental or spontaneous) [3] [4] [5].

To overcome the aforementioned problems, a full Bone Conduction Implant (BCI)

has been designed at Chalmers University of Technology and Sahlgrenska University Hospital, by which no skin penetration is required and therefore the skin is kept intact [3].

The BCI system is divided into an external part, an implanted unit and an inductive link. The external part consists of a microphone, signal processor and tuned driver, which transmit the signal into the inductive link. The implanted unit, called the Bridging Bone Conductor (BBC) unit, includes transducer, receiving coil and demodulator [6][3].



**Figure 1.1:** The block diagram of a BCI system [6].

Furthermore, the BCI transducer is positioned closer to the cochlea compared to a BAHA, which leads to an increased sensitivity to bone conducted sound that will compensate for the loss in the inductive link [3][7].

A method for assessing and evaluating the functionality of the implanted unit (BBC) during surgery needs to be developed. The test should be performed before the surgeon stitches the wound. The main purpose of the test is to assure that the device work properly as there is always a risk for the implant to be damaged during surgery or during the preceding sterilization process. The secondary goal for this assessment procedure is to build a reliable reference to be used for further evaluation and analysis of the implant after the surgery in follow up stages.

The previous studies by Reinfeldt et al.[3][8] showed that the sound pressure in the ear canal (ECSP) relates to BC hearing thresholds and therefore the sensitivity of the cochlea. The aim in Reinfeldt et al.[3] was to show the differences in sensitivity between stimulation at the BAHA and BCI positions.

By electrically stimulating the implant and measuring the ECSP, the functionality of the implant would be possible to determine. To measure the ECSP, a probe tube microphone can be used to detect sounds which are propagated in the skull in a three-dimensional manner. In Reinfeldt et al. [3], stimulation was given transcutaneously (through the skin) in 20 normal hearing subjects, showing that the BCI position, which is closer to the cochlea, gives higher sensitivity than the BAHA position. However, two main limitations prevent this method to be applicable for measurements during surgery. Firstly, there are patients who suffer from eczema in the ear canal, congenital malformations, draining ears and chronic ear infections and this method cannot be applicable for them since it is not possible to enter the ear canal. Secondly, the position is too close to the position of the surgery, which is sterile. It would not be possible to reach the ear

canal since the pinna, which is sterile, is folded above the ear canal. Another possible measurement method would be to use the nasal sound pressure (NSP). This method has not previously been investigated.

### 1.1 Aim of study

The aim of the study was to develop a NSP method, which can be used during surgery in order to assure the functionality of the implant. The method was then to be tested on normal hearing subjects to investigate the relationship between NSP and ECSP. The method was also tested on a cadaver and on the first BCI patient. The main idea behind this project is to use electrical stimulation of the implant and to measure the frequency response of the propagated sound by a microphone in the nostril. In this way the problems, which were faced in the ECSP method, are solved. This research study has been divided in four main phases, which will be discussed deeply in the next chapters:

- Method development
- Cadaver study
- Normal-hearing subject measurements
- Patient measurements

# 2

## Background

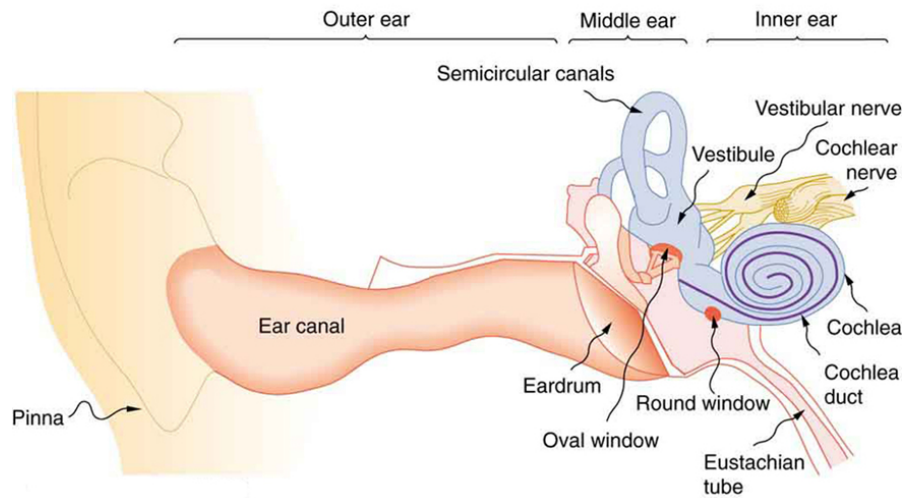
IN this chapter a brief background about anatomy and physiology of human hearing is given. The aim is to familiarize the reader with available alternative solutions for hearing impairments and to introduce the previously proposed method of ear-canal sound pressure (ECSP) for test and verification of the Bone Conduction Implant (BCI).

### 2.1 Air Conduction Hearing

Hearing is a process in which the transmission of sound energy and related vibrations produce nerve impulses and result in a hearing sensation. The acoustic pressure waves enter the ear canal, pass through the middle ear and are converted into fluid vibrations in the inner ear and result in a hearing sensation. The hearing process can be divided into air conduction (AC) and bone conduction (BC) hearing. To have a better understanding of the AC hearing, a brief overview of the anatomy and physiology of the ear and hearing sensation is given [2].

The main parts of the ear are shown in figure 2.1. The outer ear, which consists of pinna and ear canal, transmits sound to the tympanic membrane. The pinna, which is made of cartilage covered by skin, collects and amplifies the higher frequencies and transmits them into the ear canal. In other words, the crinkled shape of the pinna has a filter effect and helps to localize sound. The ear canal is an almost four centimeter s-shaped canal, encompassing an inner part (bony part) and outer part (soft tissue part). The ear canal functions as a resonating tube and amplifies sounds at frequencies between 3 kHz and 4 kHz [2].

The outer ear is separated from the middle ear via a cone-shaped membrane called tympanic membrane (TM). TM is the first section in the sound transmission procedure, which converts the acoustic energy into the mechanical vibrations. The mechanical vibrations are then passed through the middle ear via three small bones in the middle



**Figure 2.1:** Schematic illustration of the ear [9].

ear [10].

The middle ear, which is an air-filled space, is connected to the back of the nose and pharynx area via Eustachian tube and houses three tiny bones: malleus, incus and stapes. The Eustachian tube is responsible to equalize the difference of pressure between the middle ear and the environment outside while one is swallowing or yawing. The footplates of the stapes are joined to the oval window and the malleus is connected to the TM. A loud sound exposure will result in contracting the middle ear muscles to reduce the transmission of the sound; this is called acoustic reflex. These muscles contract also when the person is vocalizing in order to weaken the sound of one's own voice [10]. The surface of stapes footplate is very smaller than the TM and therefore amplification is taken place in the middle ear. The sound will be amplified about 30 dB while passing from the middle ear into the inner ear [2].

The inner ear is responsible for transducing vibrations into nervous impulses. The cochlea is the sense organ of the ear and houses the organ of hearing, which is called membranous labyrinth and is surrounded by the fluid named perilymph. More than 30,000 hair cells in the cochlea are responsible to transmit mechanical vibrations into nervous impulses and about 19,000 nerve fibers are responsible for transmission of the signals from and to the brain [2].

The membranous labyrinth has three sections including Scala vestibule (connected to the oval window), Scala tympani (connected to the round window) and the cochlear duct (also called Scala media). The first two sections are filled with perilymph while the cochlear duct is filled with endolymph. These three sections are separated from each other by Reissner and the basilar membrane.

The sound vibrations pass through the inner ear fluid, which has higher resistance than the air and therefore needs higher energy to stimulate and cause movement of the

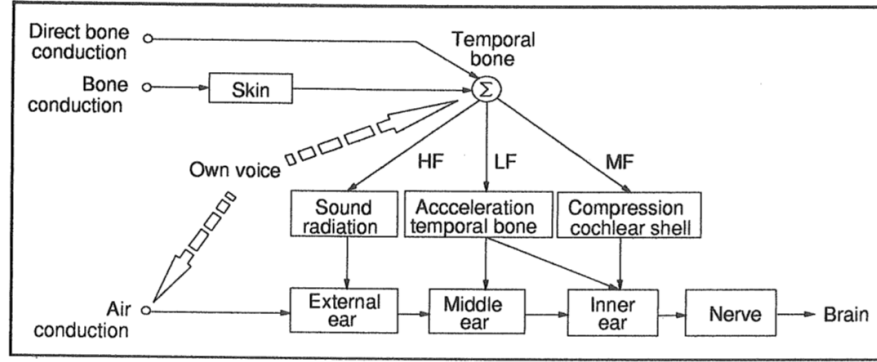
basilar membrane hair cells. Every part of the basilar membrane is made to receive its specific frequency and a particular response is stimulated in the hair cells of that specific location; the base of cochlea is devoted to the high frequencies and the apex to the low frequencies. Cilia on the hair cells will be displaced because of vibrations of the hair cells (against tectorial membrane) leading to chemical reactions in the hair cells that produce electrical response in the auditory nerve whose production is directly proportional to the sound intensity. Every electrical nerve impulse will be transferred to a specific part of brain where they will be processed to interpret the origin of the sound. This specific part of brain is called auditory cortex, which is located in the temporal lobes at each side of the brain. It is mainly the gray matter in the brain that is responsible for processing, sorting and sensation of sound. The left and right lobes communicate to compare different signals. This analyzing process will result in suppressing the background noise and hearing the desired sounds [2].

## 2.2 Bone Conduction Hearing

A hearing perception can also take place through bone conduction (BC). Hearing through bone conduction as a phenomenon was first described in the 19th century [11]. It refers to the ability of hearing through vibrations in the skull or neighbor limbs of the body that transmit the vibrations and end up with hearing sensation. In other words, the effect of surrounding sound waves on the skull will result in mechanical stimuli of the skull and gives an auditory sensation. This phenomenon is particularly used in testing hearing thresholds to determine type of hearing loss by showing the difference between bone and air conduction thresholds [11].

While producing vocalization, the vocal cords, teeth and oral cavity will vibrate and this vibration is transmitted into the inner ear, creating BC hearing. The skull bone vibrates and based on the stimuli's direction, the stapes remain steady or start vibrating with a delay because of the inertia. These vibrations will then result in vibrating the cochlear fluid and cause hearing sensation [12]. The factors that contribute to a BC sensation could be summarized as radiation of sound in the ear-canal, inertia of ossicles and cochlea fluid, cochlear wall compression and transmission of pressure through cerebrospinal fluid [13]. Figure 2.2 shows both AC and BC hearing's contributing factors from both direct BC stimulation and BC stimulation through the skin. The dashed arrows represent one's own voice pathway of sound transmission while the solid arrows show two different hearing pathways; i.e. BC (both direct and through skin) and AC hearing [14].

### 2.3. BONE CONDUCTION STIMULATION



**Figure 2.2:** Contributing factors of AC and BC sound. The dashed arrows represent one's own voice pathway of sound transmission while the solid lines show two different hearing pathways; i.e. BC and AC hearing. As seen in the figure, in BC hearing pathway the sound will be transmitted more or less directly to the inner ear [14].

### 2.3 Bone conduction stimulation

The bone conduction sensation can be received through different sources including one's own voice, surrounding sounds, or a BC transducer that generates vibrations in the skull. The sound waves in the air can induce vibrations in the skull. One's own voice gives approximately the same contribution of BC and AC. The bone conduction sound from surrounding sound waves is approximately 40-60 dB lower than the air conduction sound [13]. A bone conduction transducer, which is extensively used in hearing aids and hearing threshold tests, is responsible for transforming the electrical signal energy to mechanical vibratory energy without causing any distortion of the original signal. A BC transducer can be placed on the skin, on a screw or be implanted. During the electromechanical conversion, the electrical signal can be degraded due to nonlinearities and result in distortions, which deteriorates the vibratory energy as an output. Hence, the preliminary demand in achieving trustful bone conduction threshold testing and obtaining high quality sound in the BC hearing aids is minimizing the distortion as much as possible; otherwise it can lead to an incorrect diagnosis of patient's hearing defects [15].

The drawbacks that the conventional transducers for BC hearing aids and threshold testing faced are related to their general design. A new version of transducer, which has a small size, high efficiency and more linearity, is termed as the Balanced Electromagnetic Separation Transducer (BEST) [15].

### 2.4 Deafness and Hearing Loss

Hearing losses are classified as sensorineural, conductive and a combination of both called mixed hearing loss. It can also be categorized as central, in which the nervous system of the brain (or brainstem) is damaged, or non-organic where no physiological or



anatomical defect is detected while the patient suffers from hearing loss. AC hearing aids are mostly used for sensorineural hearing defects, while BC hearing aids are preferred to improve conductive and mixed hearing losses [13].

Improper conduction of sound through the middle ear, outer ear or both, will result in a conductive hearing loss while the inner ear still functions normally. Large amount of earwax formation, chronic infections in the middle ear (Chronic otitis media), malformed ear canal and otosclerosis (stapes footplate's fixture to the oval window) are examples of conductive hearing loss [13]. Sensorineural hearing loss is due to sensitivity decrement in the cochlea or in the auditory nerve. Most of sensorineural hearing losses are referred to disabilities of hair cells of an organ in the cochlea (the organ of Corti) [13].

## 2.5 Air Conduction Hearing Aids

Patients with sensorineural hearing loss will be treated in a great majority with air conduction hearing aids, which collects sounds from the environment by a microphone, then processing and amplifying the sounds [13]. The sound intensity is amplified to an appropriate level and then it will be sent to a miniature loudspeaker [16].



**Figure 2.3:** Air conduction hearing aid [17].

## 2.6 Bone Conduction Hearing Aids

Although a bone conduction hearing aid consists of the same microphone, amplifier and processor like an air conduction hearing aid, a vibrating transducer is used as a loudspeaker [18]. Bone conduction hearing aids works by increasing the natural bone conduction transmission as a pathway for sounds to be able to travel into the inner ear, while bypassing the middle ear and external auditory canal [16].

### 2.6.1 Conventional Bone Conduction Hearing Aid

In the early twentieth century, the electric BC hearing aid was designed for the first time [19]. A BC transducer was placed onto the skin over the skull bone by a soft-band or headband and the microphone was usually positioned on the opposite side of the head in order to prevent acoustic feedback. However, the soft tissue between the skull bone and

transducer acts like a low-pass filter, which attenuates the high frequencies and affects the hearing quality by performing poorly at high frequencies. Besides, the continuous pressure applied to the skull bone causes pain and annoyance and if the microphone is close to the transducer, feedback occurs.



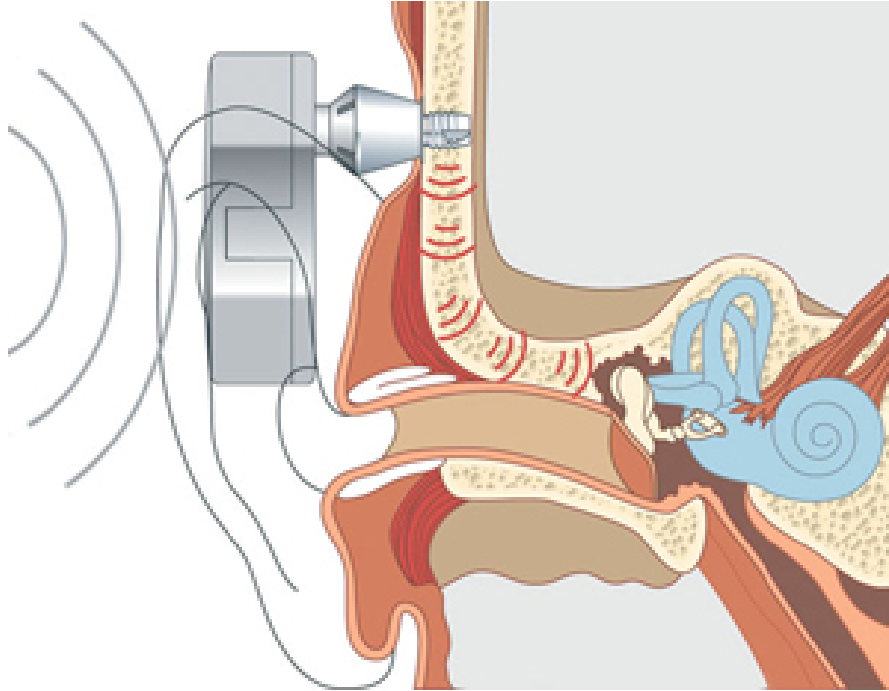
**Figure 2.4:** Conventional BC hearing aid with a headband [13].

### 2.6.2 Percutaneous Bone-Anchored Hearing Aid (BAHA)

Since the conventional BC hearing aid faced some drawbacks, a more sophisticated version of BC hearing aid was needed for the patients with single sided deafness and conductive hearing loss. The development of a new BC hearing aid, BAHA, started in 1977 and three patients were operated initially that year [13]. Today, about 100 000 patients have been treated with a BAHA (Cochlear, 2013).

By using BAHA, the vibrations are transmitted directly to the skull bone and since the vibration is directly transferred to the skull bone via an osseointegrated titanium fixture, it does not have the problems of the conventional hearing aids that required stimulation on the skin. A sound processor is also attached to the skull bone through the bone anchored implant. The transducer within the sound processor is placed on the screw via an abutment and is responsible for transmitting the signal to the titanium implant. These vibrations are transmitted to the inner ear via the transducer buried within the skull bone, which result in stimulating the nerve fibers in the inner ear and causing hearing sensation [16]. The principal of BAHA design is widely presented by Tjellström et al. [21].

To be able to use a BAHA, the patients' cochlea should function properly or to a certain extent. Another group of patients who use the BAHA are the patients with single sided deafness (SSD). In a SSD case, the sound is transmitted from the deaf side through the skull bone to the functioning cochlea on the opposite side which helps to reduce the head shadow effect [22]. Despite the satisfaction of the BAHA, some drawbacks are included, relating to the percutaneous implant. Lifelong regular care is needed and



**Figure 2.5:** Bone Anchored Hearing Aid [20].

drawbacks are infections, granulation tissue formation, accidental or spontaneous loss of implant and esthetic or personal reasons for rejection [13].

### 2.6.3 Bone Conduction Implant (BCI)

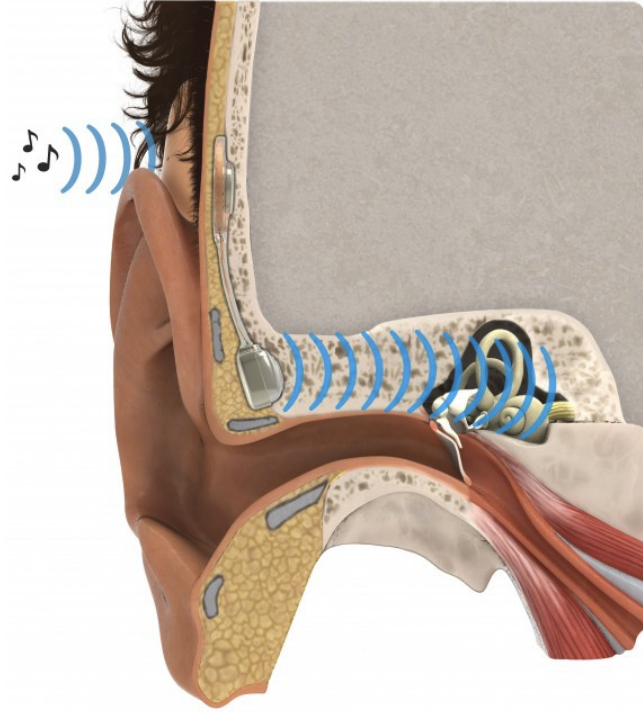
As a further development of the BAHA, a transcutaneous BCI system was developed at Chalmers University of Technology and Sahlgrenska University Hospital. This new system leaves the skin intact by placing the implant inside the skull bone closer to the cochlea. As it is shown in figure 1.1, the BCI system is divided into an external part, an implanted unit and an inductive link. The external part consists of a microphone, analog and digital signal processor and tuned driver, which transmit the signal and the sound waves energy into the inductive link. The implanted unit, called the Bridging Bone Conductor (BBC) unit, includes transducer, the receiving coil and tuned demodulator [13] [6]. The transducer of a BCI system is a vibrator of BEST type. An amplitude modulation is applied to transmit the signal to the transducer. After amplitude modulation of the sound data to a radio frequency carrier, the data is transmitted through the inductive link. A permanent magnet retention system is used in order to keep the transmitter and the implanted receiver coil attached [16].

The excitation point of such a BCI system is closer to the cochlea than the excitation position for the BAHA system, which results in an increased sensitivity [3]. Studying related literature, measurements on both cadaver [23] and dry skull [24] show that the

## 2.7. EAR CANAL SOUND PRESSURE (ECSP)

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vibration in cochlea will be increased as the excitation point gets closer to the cochlea. Reinfeldt et al. [3] showed that the increase in vibration of the cochlea means increased hearing sensation [3].



**Figure 2.6:** Function of Bone Conduction Implant (BCI). The sound is received by the sound processor on the skin and transmitted to the implant where the transducer provides a vibration corresponding to the received sound. The vibration is sensed by the cochlea, giving a hearing sensation [25].

## 2.7 Ear Canal Sound Pressure (ECSP)

The variation of pressure in the air is measured in Pascal and constitutes airborne sound. Sound pressure uses a logarithmic scale due to the logarithmically scaled perception of sound. The reference sound pressure is considered  $20\mu\text{Pa}$  and the sound pressure level is measured to be  $20\log(\frac{p}{20*10^{-6}})$ , with the unit defined as decibel Sound Pressure Level (dB SPL), in which  $p$  is the sound pressure measured in Pascal. As we double the sound pressure, we get 6 dB higher SPL [13].

The term ear canal sound pressure is referred as the measurement of the sound pressure in the ear canal by a microphone. There have been various methods used for measuring the ear canal sound pressure (ECSP), such as using a field microphone-in-real-ear (MIRE). A dual-element microphone probe is applied in this method to measure noise reduction to give the sound pressure differences outside and inside an earplug. Another

method, which was also used to measure the noise reduction from earplugs, is called Insertion loss (IL) [26].

One of the methods of measuring the ECSP, which has been applied by Sabine Reinfeld, is described in this part [13]. A probe tube microphone (shown in figure 3.6A), which is attached to a very soft and narrow probe tube made of silicone, is applied as close as possible to the Tympanic Membrane (TM) without touching it. This could be achieved by measuring the ear canal length before the measurement. The probe tube is inserted into an earplug and then through the ear canal until it is precisely close to the TM without touching it. Deep insertion is used to avoid/minimize the occlusion effect, which is described in next section. For normal-hearing subjects, the stimulation is done by the BC transducer, placed on an already marked position on the skull. A swept-sine signal generated by the signal analyzer is run and the signal received by the microphone is amplified and displayed in the signal analyzer. This method is extensively described in the method part.

### 2.7.1 Occlusion effect

The occlusion effect is the amplification of low frequencies due to the occlusion of the ear-canal opening in presence of bone conduction stimulation. One example can be the change of one's own voice while occluding the ear canal opening; this alternation is due to the increment of low frequency bone conduction sound affiliated with the decrement of air conduction sound because of ear canal occlusion. The occlusion effect is dependent on the precise position and type of the device we apply for occluding the ears. If the device is deeply inside the ear canal, the occlusion will be minimal [27] as well as applying a large adequate volume [28], such as a circumaural ear muff with large internal volume [28]. The different effects of occlusion are extensively discussed in the literature as the alteration of ECSP [29] [30] and the alteration of the sound perception [31][32]. More description about occlusion can be found in [14][28].

# 3

## Materials and Methods

IN this part, the equipment and test setup that has been used for different measurements are introduced. In addition, the NSP method is explained in detail. This chapter consists of method development measurements, methodology of measurements in cadaver study, normal-hearing subjects measurements and finally the approach for patient measurement is discussed.

### 3.1 Method development measurements

In this section, the initial nasal sound pressure method is introduced. It was tested to see whether the suggested method can be a replacement for the ear canal sound pressure. This study aimed to evaluate and understand the NSP measurement method with presence of conditions that can occur during surgery and how they affect the result. The measurements were performed on the authors in the hearing lab at the Department of Signals and Systems at Chalmers University of Technology. The following measurement methods and conditions are described as:

- Equipment
- Nasal sound pressure measurement
  - Breathing
  - Leakage problem
  - Probe tube length
  - Probe tube depth
  - Usage of probe tube
  - Ear-plug depth with tube
  - Test and re-test effect

- Sitting and lay down positions
  - Coherence measurement
- Calibration

#### 3.1.1 Equipment

##### Dynamic signal analyzer

A dynamic signal analyzer (Agilent 35670A, Agilent Technologies Inc, USA) with built-in source has been used for the signal generation and frequency analysis (see figure 3.1A). This device plays the main role in all the measurements in this thesis. Linear spectrum, Power Spectrum, frequency response, coherence function, time waveform and correlation are functions that were used in this study [16]. For the data transformation a direct connection was provided by the Agilent 82357A USB/GPIB Interface (see figure 3.1B). A Labview code developed by Hamidreza Taghavi was used to store files in text format.



**Figure 3.1:** A: Agilent 35670A (Agilent Technologies Inc, USA). B: USB/GPIB Interface

##### Anechoic Test Chamber

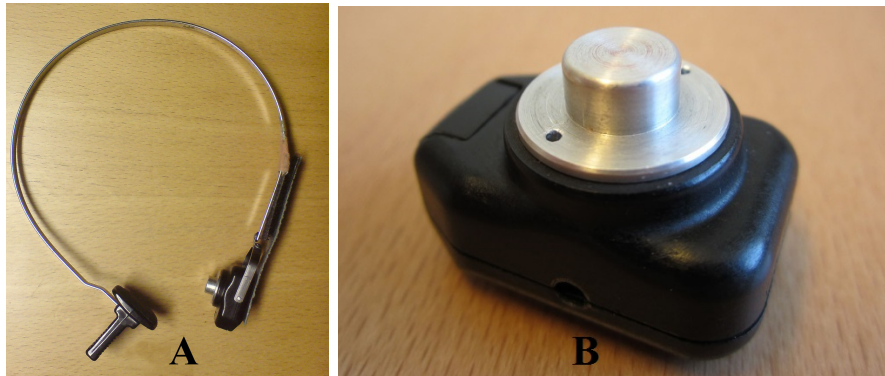
The Brüel & Kjær type 4222 Anechoic Test Chamber (Brüel & Kjær Sound & Vibration Measurement A/S, Denmark) with an internal speaker mounted in the top is suitable for acoustic testing of small objects that is illustrated in figure 3.2 . This has been used during measurements that demanded a noise-free environment [16].



**Figure 3.2:** Brüel & Kjær type 4222 Anechoic Test Chamber [16].

#### **BEST transducer**

The BC stimulation in the method development measurements was done with the BEST<sup>©</sup> transducer which gives low distortion and high efficiency [15]. The transducer was attached to a steel spring headband with special arrangement that stabilizes the transducer (see figure 3.3A). To have a similar behavior as the BCI transducer with a smaller surface contact, an adapter was designed with a tip diameter of 7 mm and a height of 4 mm (see figure 3.3B) [3].



**Figure 3.3:** Bone conduction transducer and adapter.(A) Transducer with steel spring headband, and (B) adapter for smaller contact surface area[13].



#### Power amplifier

A power amplifier (ROTEL RB-976 Mk II, ROTEL<sup>®</sup>) with six channels has been used for amplification and generation of acoustic sound with desired gain. The ROTEL amplifier is shown in figure 3.4.



Figure 3.4: ROTEL RB-976 Mk II.

#### Microphone and pre-amplifier

An omni-directional microphone (EM-23346, Knowles Electronics, Itasca, Illinois, USA) with a built-in amplifier has been used to detect the nasal sound pressure. The size of the microphone is 3.61mm x 3.61mm x 2.21mm and its given normal sensitivity is -52 dB (see figure 3.5A). A battery operated low noise linear pre-amplifier (Gennum LC506; Semtech Corp., USA) (see figure 3.5B) has been used to amplify the detected sound pressure signal by the microphone (EM-23346) to be able to record the signal in the signal analyzer (Agilent 35670A).

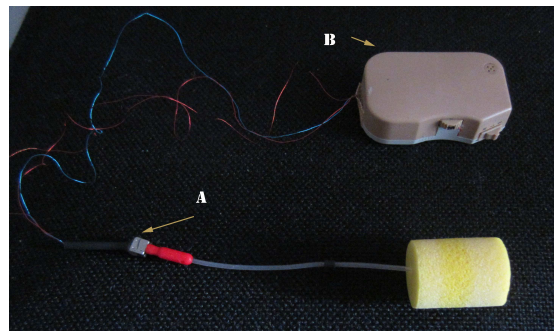
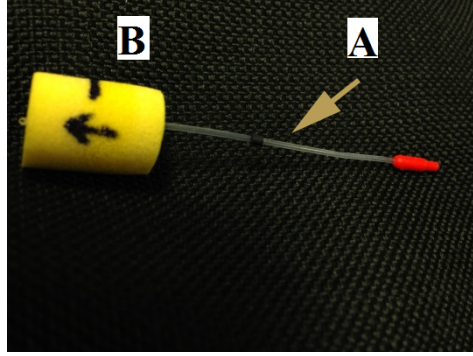


Figure 3.5: A: Microphone (EM-23346). B: Pre-amplifier.

#### Probe tube

The NSP was measured attaching an Etymotic Research ER7-14C probe tube (see figure 3.6A) to the probe microphone. The probe tube is made of silicone with a length of 74 mm and an inner diameter of 0.5 mm. The nostrils were isolated from outside by an

ear plug (E-A-R Classic) (see figure 3.6B) so that the microphone only picked up sound pressure in nostrils. The probe tube was inserted into the ear plug using a catheter.



**Figure 3.6:** A: Probe tube (ER7-14C) and B: Ear plug (EAR Classic).

#### Condenser microphone and calibrator

A microphone power supply Type 2804 from B&K was used as power supply for the condenser microphone (see figure 3.7A). A Brüel & Kjær Type 4134 condenser microphone has been used for calibrating the EM microphone (see figure 3.7B). The Brüel & Kjær 4134 microphone is based on a feedback loop to make a highly steady sound pressure level with respect to variation of static pressure and temperature. A calibrator from Brüel & Kjær type 4230 has been used to generate a pure sinusoidal signal at 1 kHz with 93.8 dB SPL (sound pressure level) for the calibration purposes (see figure 3.7C) [16].



**Figure 3.7:** A: B&K microphone power supply and B: B&K type 4134 condenser microphone. C: B&K Calibrator type 4230 [16].

#### Skull simulator

To mimic the load properties of the skull, skull simulator TU-1000 [33] is used. The dynamic behavior of this simulator acts as a rigid body with a significantly heavier weight than the weight relating to dynamic mass of the transducer. This device can be

### 3.1. METHOD DEVELOPMENT MEASUREMENTS

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used to obtain dynamic output force of the transducer which is translated to voltage for use in signal analyzer. The device is shown in figure 3.8A with a separate power supply in figure 3.8B.



**Figure 3.8:** A: TU-1000 skull simulator. B: power supply [16].

#### Artificial mastoid

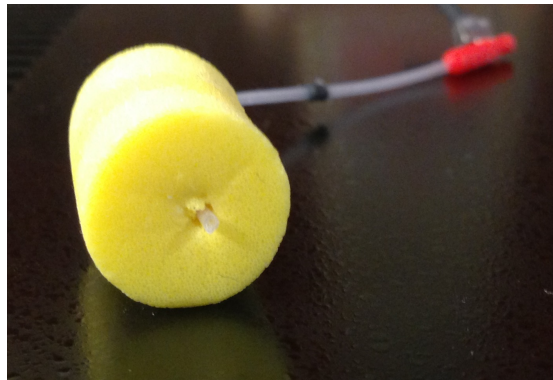
Brüel & Kjær type 4930 artificial mastoid (see figure 3.9A), which is a mechanical model of the human head was used for the calibration of BEST transducer. A Brüel & Kjær mini shaker type 4810 (see figure 3.9B) was used to provide vibration and an impedance head from B&K type 8000 (see figure 3.9C) to measure the force and acceleration, respectively. Two Brüel & Kjær types 2635, 2651 were used to convert the output charge from the transducer to output voltage (see figure 3.9D,E).



**Figure 3.9:** A: Brüel & Kjær type 4930 artificial mastoid. B: Brüel & Kjær mini shaker type 4810. C: B&K impedance head type 8000 D,E: B&K Charge amplifier types 2635, 2651.

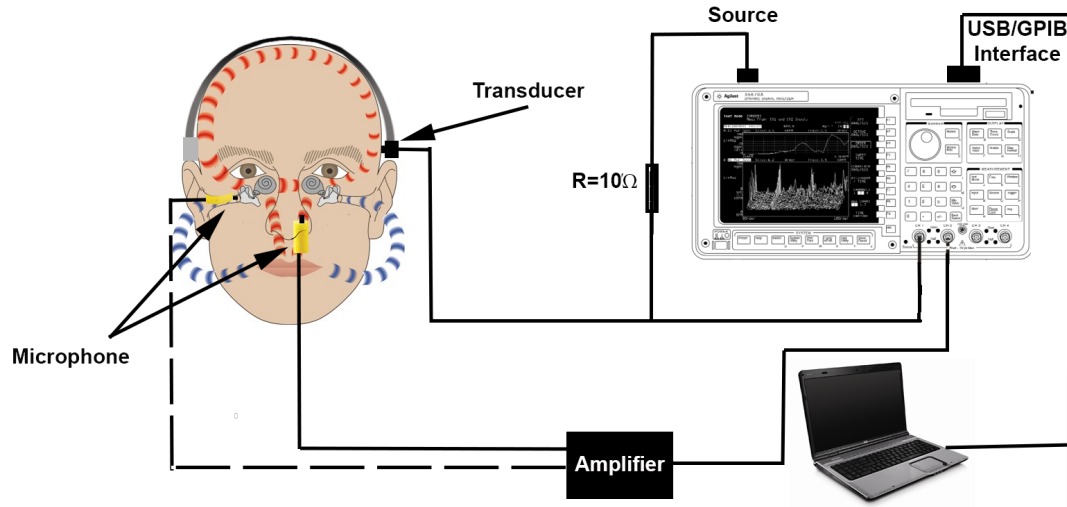
#### 3.1.2 Nasal Sound Pressure measurement

The Nasal Sound Pressure (NSP) is referred to the frequency response function of the skull in response to the vibration stimulus and it is measured in the nostrils by a microphone. The stimulation was done by the BEST transducer placed at two different positions, which were marked before measurement. Position A (BAHA position) is the point where the extended line from the corner of the eye to the upper part of the auricle meets the extended line 55 mm away from center of the ear-canal. Position B (BCI position) is a point as close as possible to the posterior part of the auricle on the line extended from the center of the ear canal to position A. The steel spring headband of the transducer eased the placement at positions on the skull. The Nasal Sound Pressure (NSP) was measured by the microphone via the probe tube. The probe tube was inserted into nostrils through an ear plug, which was then placed into the desired nostril to isolate the cavity from the sound waves outside. The ending point of the probe tube was placed exactly on the surface of the ear plug (see figure 3.10) inside the nostril and the ear plug was located 8 mm into the nostril as the final set up. However, during method development measurements, the lengths of the ear plug and probe tube in the nostrils were changed to find the best conditions. The ear plugs were precisely marked with insertion depth to be accurate in all measurements.



**Figure 3.10:** The probe tube is placed on surface of the ear-plugs.

A swept-sine mode signal was generated by the signal analyzer (AGILENT) to be the stimulus and the amplitude of the signal was 250 mVrms within frequency range of 100 and 10000 Hz. This signal was connected to channel one of the analyzer and to transducer via a 10 ohm protecting resistor to avoid high current flow in transducer. The signal from microphone was amplified by the pre-amplifier and connected to channel two of the analyzer. Then, the electrical signal was converted to mechanical vibration through the BEST transducer. The frequency response of the system was recorded via the USB/GPIB interface with prepared user interface software in LabVIEW. To measure the noise floor, the same setup as described for the NSP was used, but the stimulation signal was disconnected. NCSP measurements were performed using the setup in figure 3.11.



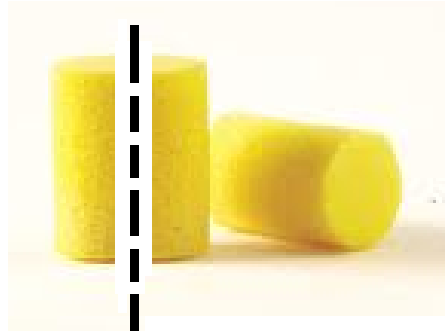
**Figure 3.11:** Measurement setup for NSP and ECSP if the microphone inserted into the ear canal. ECSP measurement has been described in section 2.7 and [13].

#### Breathing

As breathing is a situation which might be hard to control, this case has been taken into account and the subjects were asked to breath normally and also to hold their breath during the measurement. The measurement normally takes about 15 seconds if the breathing is stopped and it takes longer time while the subject is breathing. The measurement was performed in the same way as it was described in NSP measurement in section 3.1.2.

#### Leakage problem

A leakage measurement case was performed to understand how surrounding can influence the result if there is leakage between the nostril cavity and outside. To simulate the situation where there is a leakage in the measurement system the ear plug was cut on its longitudinal dimension (see figure 3.12) and the measurement was performed in the same way as it was described in NSP measurement in section 3.1.2.



**Figure 3.12:** The ear-plug that was cut to give leakage.

#### **Probe tube length**

To understand if there are effects regarding the length of the probe tube, the NSP was measured with complete and half probe tube length. The tube was cut to its half and the length became 37 mm where the total length is 74 mm.

#### **Probe tube depth**

By changing the position of the probe tube in the nostrils vertically, the variation was shown and evaluated. The probe was placed 3 mm and 5 mm deeper in nostrils than the inner surface of the ear plug. The ear-plug has been located 5 mm inside the nose.

#### **Usage of probe tube**

The goal of this investigation was to evaluate the result of NSP measurement method using probe tube or without using it. To detect the sound pressure in the nostrils, the probe tube was attached to the EM microphone and was inserted into an ear plug on its surface. The ear plug was placed at certain distance inside one of the nostrils and as described in section 3.1.2 the NSP was measured. The other scenario was when the probe tube was not employed and the microphone itself was placed into the ear plug where its diaphragm was exactly located on the surface of the ear plug in the nostril.

#### **Ear-plug depth**

To find out how the insertion of the ear plug into the nostrils can influence the output results, three cases have been taken into account where the plug placed 5 mm and 8, 10 mm into the nostril. The NSP measurement was done based on the NSP measurement procedure described in section 3.1.2.

#### **Test and retest**

The same measurement setup and conditions were applied to one of author in a period of three weeks and the NSP was measured and shown. The ear-plug was placed 8 mm in the

nostril and probe exactly on the surface of the ear plug. The measurement was used to evaluate how the NSP measurements can differ from each other with same measurement setup and conditions.

#### **Sitting and lay down position**

The same measurement setup and conditions were applied to authors for NSP measurement while the person was sitting on the chair in the lab and lay down on a bed. The ear-plug was placed 8 mm in the nostril and probe exactly on the surface of the ear plug.

#### **Coherence**

In order to study the relation of the two signals the coherent function was estimated based on the cross spectral density of two signals and is defined as:

$$C_{xy} = |G_{xy}|^2 / (G_{xx}G_{yy}) \quad (3.1)$$

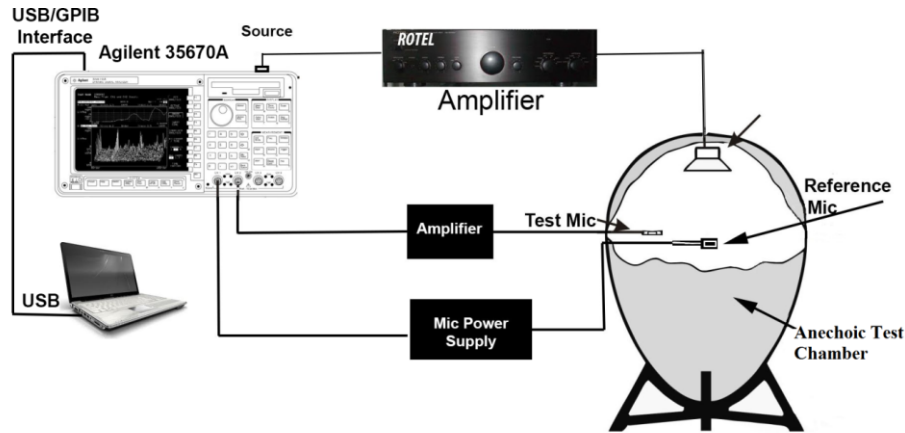
where  $G_{xy}$  is cross spectral density of the two signals,  $x$  and  $y$ , and  $G_{xx}$  is autospectral density (power spectra) of  $x$  and  $G_{yy}$  is autospectral density (power spectra) of  $y$ . The value of the coherence function varies between zero and one, and higher values of the coherence function are related to highly correlated two signals. Practically, the broadband white noise was provided by the Agilent as an input signal and having the analyzer in cross spectral mode the sound pressure was measured by EM microphone. The frequency response function was then calculated using Hanning window and averaging (Number of averaging signals=15).

#### **3.1.3 Calibrations**

##### **Calibration of microphone**

The calibration setup for the microphone is shown in figure 3.13. The source from Agilent provided a sinusoidal signal with the range of frequency between 100 Hz and 10 kHz (Swept-sine mode). The signal was connected to the built-in internal speaker of the anechoic test chamber via the ROTEL amplifier with a fixed gain. The EM microphone with probe tube and the reference microphone were placed close together to detect the same sound pressure in the Anechoic Test Chamber and were connected to channel two and one respectively. The frequency response of channel two over one was recorded to give the difference in sensitivity between the probe tube microphone and the reference microphone.





**Figure 3.13:** Calibration setup for microphone measurements [16].

The calibrator from Brüel & Kjær type 4230 that generates a pure sinusoidal wave with 98.8 dB SPL at 1 kHz was used to calibrate the reference microphone. The frequency spectrum of the reference microphone was measured by the signal analyzer in FFT mode using a Hanning window technique with averaging ( $n=15$ ). The corresponding voltage to the 98.3 dB SPL was measured from the spectrum to determine reference sensitivity. The product of reference sensitivity and EM microphone calibration determines the EM microphone sensitivity.

#### Calibration of bone conduction transducer

To obtain the result relevant to dynamic force another calibration has been done using the Brüel & Kjær type 4930 artificial mastoid (see figure 3.9). This calibration procedure gives the output relevant to the force corresponding to the BC transducer vibration. Basically, the artificial mastoid, which is a complex quantity should be calibrated by taking a number of steps to compensate for the difference between the stimulation position and measuring point and applying the calibration factors to convert from voltage to force. To be able to do the calibration a mini shaker type 4810, an impedance head type 8000 and an extra mass of 100g from Brüel & Kjær has been used.

### 3.2 Cadaver study

The subject in this study was a female and measurements were performed in the anatomy dissecting room at Sahlgrenska University Hospital in Gothenburg in September 2012. The measurement protocol can be found in appendix A. In this stage of the study, two main types of measurements that are relevant to this thesis work are described. Initially, skin-driven NSP and ECSP measurements were performed, stimulating with the BEST transducer. The measurement setup was the same as described in NSP measurement in



### 3.2. CADAVER STUDY

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section 3.1.2. The other important measurement was to measure NSP and ECSP using BCI stimulation where the implant was operated and a special measurement setup was employed to transmit the stimulation signal to the implant. It should be mentioned that the noise floor measurement has been performed for each case separately. The ECSP and NSP for position A and B were measured and the difference between these two measures was calculated. The difference between ipsilateral and contralateral NSP at position A was also calculated. The ipsilateral ECSP and NSP were also measured by BCI stimulation. There was not a significant difference between contralateral and ipsilateral measurement for NSP so it was only measured ipsilaterally for position B.

#### 3.2.1 BCI Measurement setup

The measurement setup for the BCI stimulated NSP and ECSP is shown in figure 3.14. The Agilent 33220A was used as the signal generator to generate the modulation carrier signal, and a sinusoidal signal with frequencies between 100 Hz and 10 kHz has been provided by the Agilent Dynamic Analyzer 35670A to be combined with the carrier signal in amplitude modulation (AM) mode and the frequency of the carrier was 120 kHz. The output signal is transmitted through the inductive link. Finally, the demodulation was done on the implant side and the vibrations were produced by the transducer. The transmitter (including processor) and receiver coils are linked to each other by a magnet. The NSP and ECSP were detected by the probe tube and EM microphone with the same procedure as described in section 3.1.2 and analyzed in the signal analyzer (Agilent 35670A).

### 3.3. NORMAL-HEARING HUMAN STUDY

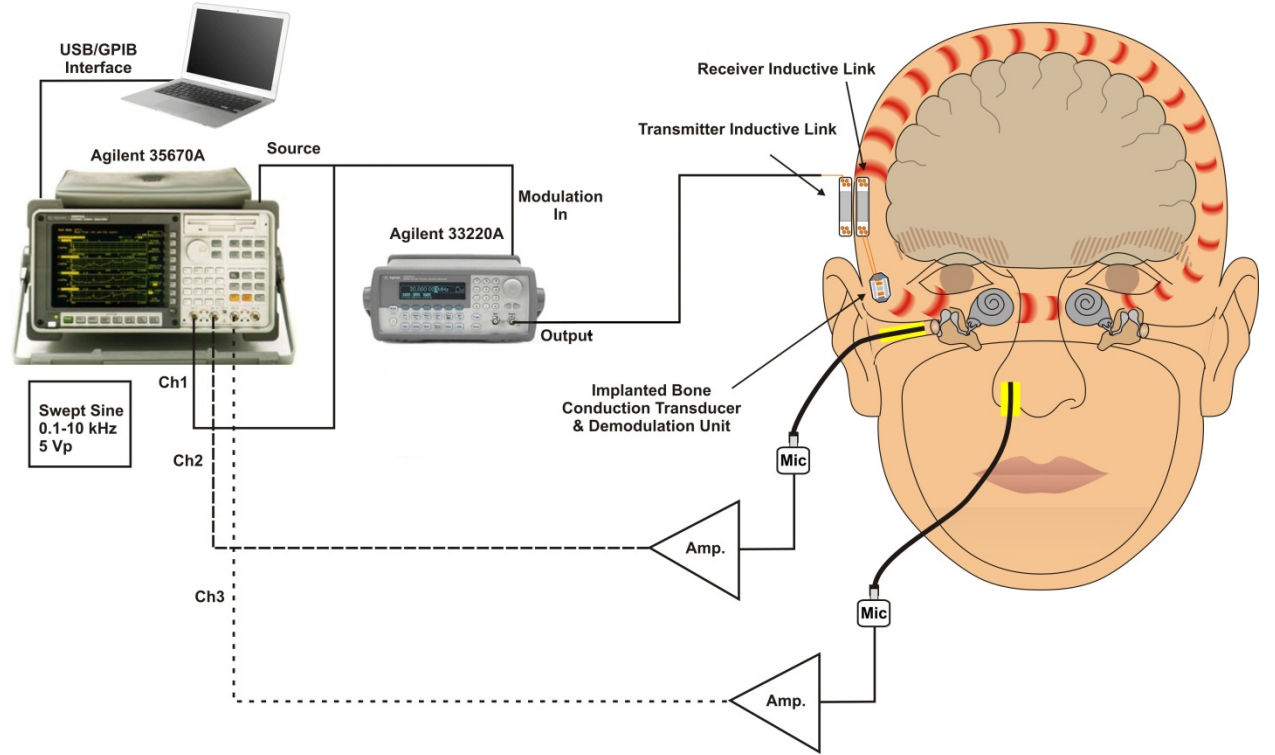


Figure 3.14: BCI measurement setup for NSP and ECSP[16].

### 3.3 Normal-hearing human study

Twenty normal-hearing subjects, including ten female and ten male with an average of 27 years old age (24 to 36 years), participated in the measurements in this part of the study. To investigate whether they were normal-hearing an audiometric threshold test was performed. All participants who had hearing level better than or equal to 20 dB HL and an inter-aural difference less than or equal to 15 dB were included in the study. The hearing thresholds were done by TDH39 head-phones with a digital audiometer (AC40; Interacoustics A/S, Assens, Denmark). The sound pressure measurements of this study were performed in the hearing lab and the preceding audiometric tests in a sound insulated room of 16 m<sup>3</sup> located in the same lab at the Department of Signals and Systems at Chalmers University of Technology. The tests started by ECSP measurements by stimulation at position A and B and detecting the sound pressure from ear-canals. Ipsilateral and contralateral measurements were performed for all the subjects. To gain more precise result and to do as few changes as possible, all measurements for one ear were performed before switching to the other ear. The number of measurements for each ear was four and in total eight measurements was performed. The same procedure was then done for NSP measurements. Based on the results from method development measurements, the subjects were asked to stop breathing during NSP measurement. The

### 3.3. NORMAL-HEARING HUMAN STUDY

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**Table 3.1:** Table ECSP and NSP measurements list; the rows with same colors illustrate the same type of the measurements only in different sides, so they are combined.

No. Measurement	Stimulation at	Position A/B	Type
1	Right side	Pos A	Ipsi
2		Pos B	Ipsi
3		Pos A	Contra
4		Pos B	Contra
5	Left side	Pos A	Ipsi
6		Pos B	Ipsi
7		Pos A	Contra
8		Pos B	Contra

NSP measurement usually took about 15 seconds. All measurements were recorded in the signal analyzer (Agilent 35670A) on a Floppy disc and after the whole measurement session, they were transferred to a computer with MATLAB with file names based on written protocol which recorded personal information for each subject and names of the files for measurements (See appendix). It is necessary to mention that the number of ipsilateral and contralateral NSP measurements are 20 for right and 20 for left side. To increase the statistical reliability of the result, these two measurements were combined therefore all statistical quantities have been derived from 40 available signals. The same procedure was performed for ECSP measurements. This can easily be illustrated in table 3.1 where the same color signals in rows are combined (for example row No. 1 with row No. 5).

#### 3.3.1 NSP vs ECSP

The average of four measures shown in table 3.1 were calculated (right and left) and shown in separate figures for NSP and ECSP. All the measurements were calibrated to be shown relevant to  $20 \mu\text{Pa}/\text{N}$ , as explained in section 3.1.3. The difference between average of each of four types of measurements (four colors) were then shown for evaluation purposes. In addition, the differences between NSP and ECSP were calculated for all conditions shown in table 3.1.

#### 3.3.2 Comparison between Position B and A

The average of four different measurements of NSP and ECSP (right and left together 3.1) were calculated for all subjects and the difference between position A and B was visualized.

#### 3.3.3 Ipsilateral vs Contralateral

To show the perceived hearing of contralateral cochlea compared to the ipsilateral cochlea, the differences between average of ipsilateral and contralateral measurements for each position were shown. This difference is called transcranial attenuation since it describes the attenuation of sound waves propagating from one side to the other.

### 3.4 Patient measurements

The NSP skin drive test was measured on the first patient the day before the surgery with same procedure as subject measurement ipsilaterally stimulating at position B at the right side where the surgery was planned. Before the surgery equipment were placed in the surgery room, the BCI measurement setup was prepared and tested to ensure the proper functionality of the equipment. The ear-plug was placed 8 mm inside the nostril and the cables were connected to the analyzer and source before the surgery to be safe with respect to the sterilization condition in surgery room. The implant was placed on its position and mounted by a holding bar. Eventually, the NSP was measured and the result was recorded. The noise floor was also measured with the same procedure, explained in section 3.1.2. Finally, the result from the surgery and skin drive test of the patient was compared with the result from normal-hearing measurements and cadaver study to confirm the functionality of the BCI. The follow-up measurement was performed four to six weeks after surgery when the external sound processor was fitted.

# 4

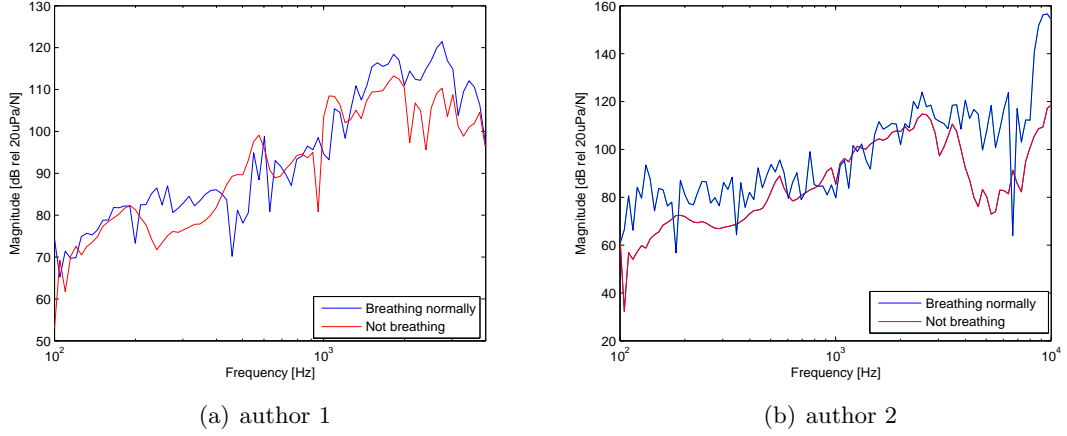
## Result

This part encompasses all the results of this study, method development measurements cadaver study, normal hearing subject measurements and patient measurements. All NSP and ECSP measurements are in the frequency domain.

### 4.1 Method development measurements

#### 4.1.1 Breathing

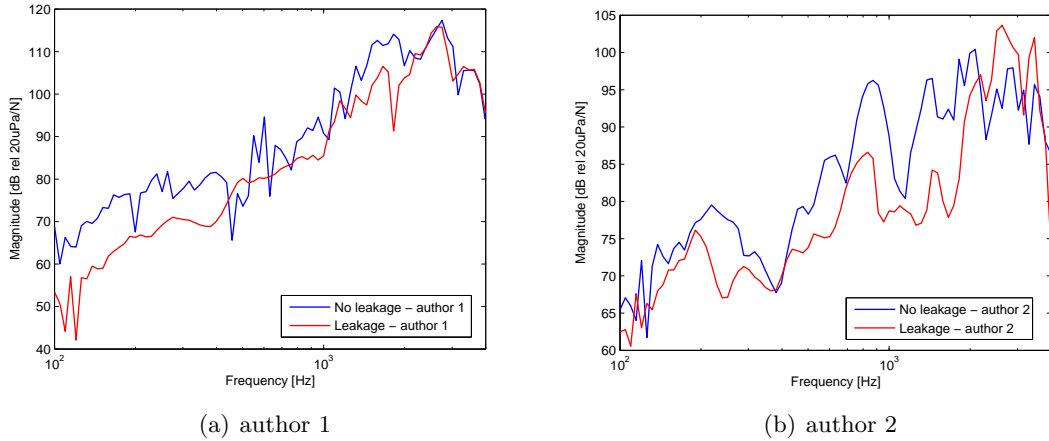
The figures 4.1a and 4.1b show the effect of breathing. The blue lines in the figures are concerned with the condition when the authors were breathing normally during the measurements while the red lines refer to the situation when the authors were holding their breath. There is a significant variation in the signals in normal breathing condition.



**Figure 4.1:** Effect of Breathing (blue) and not breathing (red) during the measurements on a: Author 1. b: Author 2.

##### 4.1.2 Leakage problem

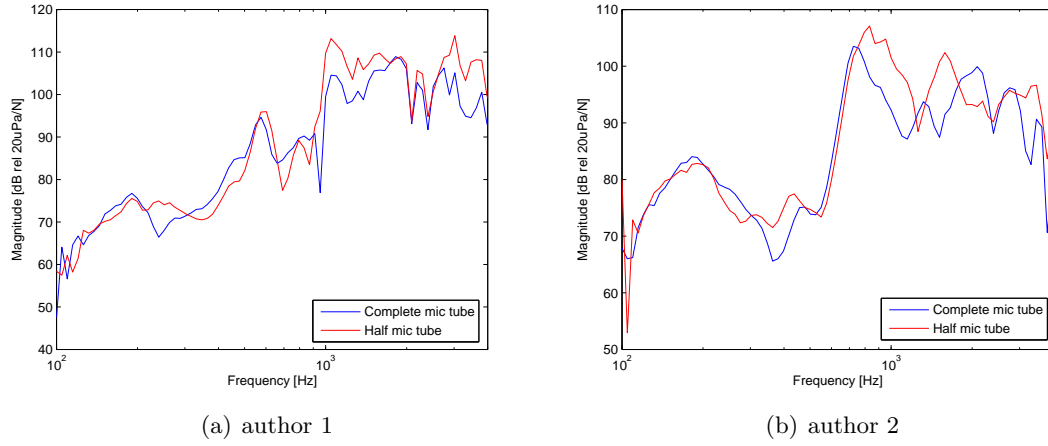
In order to investigate the effect of leakage, the ear-plug was cut to its half so that it could not fill the whole nostril when inserted. Hence, figure 4.2 compares the situation when the nostril was totally obstructed by the ear plug and even by using some cotton in case of wider nostrils and when there was a leakage due to using the half of the ear plug in the nostril. The solid lines are referred to the case where the nostril was closed to isolate any sound from surrounding. The dashed lines are corresponding to the measurements in which the ear-plug has been halved so that the microphone could detect some extra sounds from outside due to the leakage.



**Figure 4.2:** Leakage effect in NSP measurement. Blue lines refer to NSP when there is no leakage and red lines refer to NSP when there was leakage in the NSP measurement.

### 4.1.3 Probe tube length

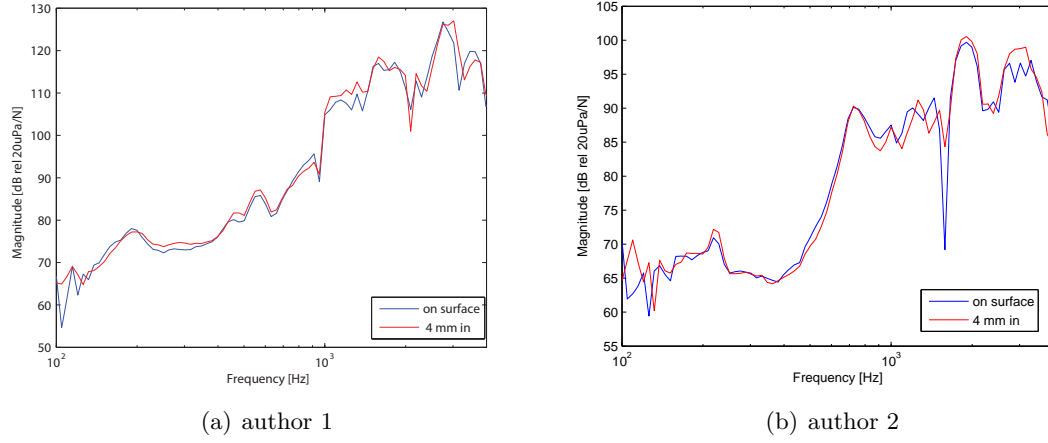
Figure 4.3 shows that the length of the probe tube can influence the NSP measurements. The blue lines are for a complete tube in the NSP measurements, while the red lines refer to half tube.



**Figure 4.3:** Blue lines refer to NSP using complete tube and red lines refer to NSP using half tube. (a) author 1, and (b) author 2.

### 4.1.4 Probe tube depth

In figure 4.4, the changes in the nasal sound pressure were illustrated while the length of the probe tube in the nostrils varies from shallowest to deepest possible condition. The ear-plug was placed 5 mm inside the nostrils in all four cases. As it is shown in the figure, the red lines relate to the condition when the probe tube was placed 4 mm in the nose from the surface of ear plug and the blue lines refer to the situation when the probe tube is placed on the surface of ear plug.

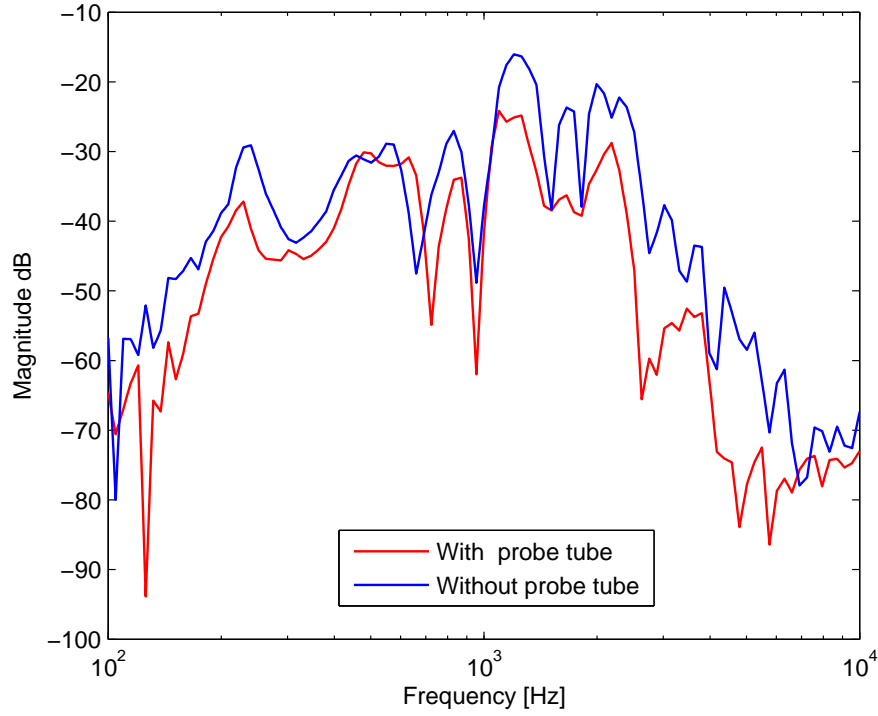


**Figure 4.4:** Effect of probe microphone tube depth in NSP. Red lines relate to the condition where the probe tube was placed 4 mm in the nostril on top of the ear plug surface. Blue lines relate to the case where the probe tube was placed on the surface of ear plug in the nostril.

### 4.1.5 Usage of probe tube

Figure 4.5 shows that placing the ear-plug inside the nostril with probe tube and without probe tube. This experiment without using the probe tube means that the microphone was directly placed inside the plug so that the microphone's tip was exactly on the surface of the ear-plug. The blue line refer to the case where the microphone was placed into the ear plug without tube and red line corresponds to the situation where microphone was located into the nostril via probe tube on the surface of ear plug and in both cases, the plug was inserted 8 mm into nose.

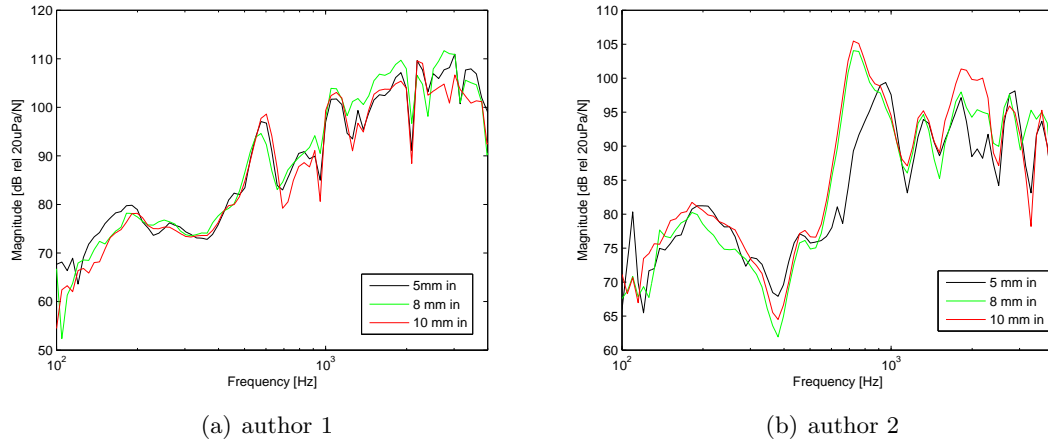




**Figure 4.5:** Effect of probe microphone tube length in NSP. Blue line relate to the condition without using probe tube and red line refers to the case where the probe tube was placed in the nostril.

#### 4.1.6 Ear-plug depth

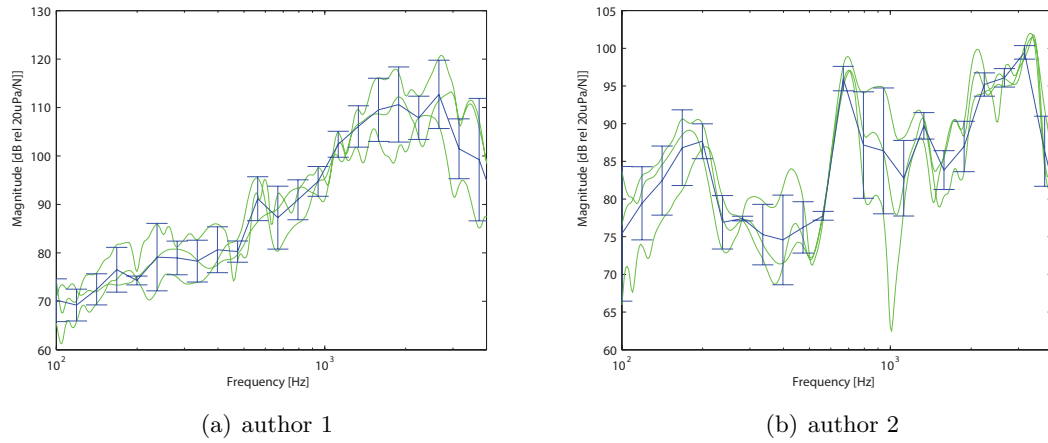
In figure 4.6 the difference between nasal sound pressures is insignificant between inserting the ear-plug 5, 8 mm and 10 mm in the nostrils. This experiment has been done using probe tube microphone placed exactly on the surface of ear-plug. The result from both of authors can be seen.



**Figure 4.6:** Effect of ear-plug depth in nostrils with tube in NSP. The black, green and red lines correspond to the case where the ear plug was placed 5, 8 and 10 mm in the nostril.

##### 4.1.7 Test and retest

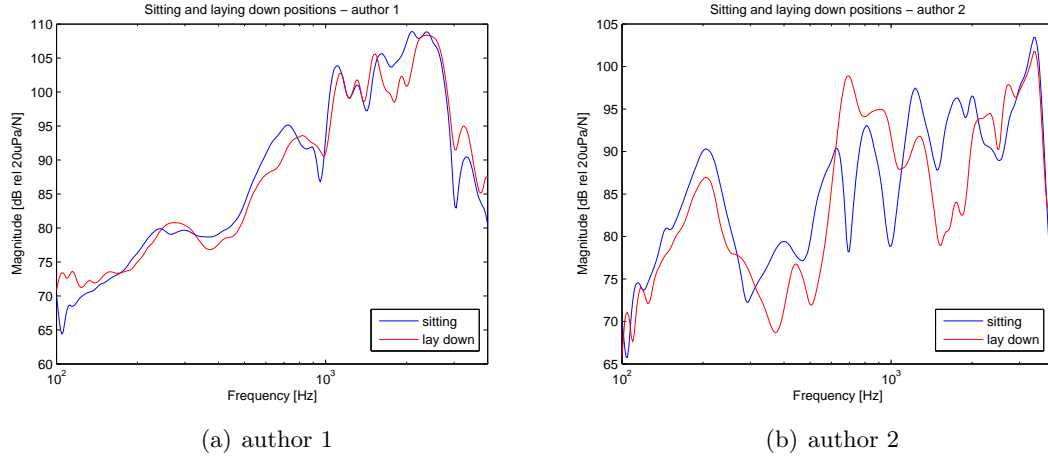
The results from the same type of NSP measurement which have been done in three times in three weeks period are shown in figure 4.7 for both of the authors. The variation between each test is visible by the spread of the signals.



**Figure 4.7:** The test and retest of three ipsilaterally NSP measurements. The green lines refer to the signals and blue lines and bar refer to the mean and standard deviation of those signals.

### 4.1.8 Sitting and laying down position

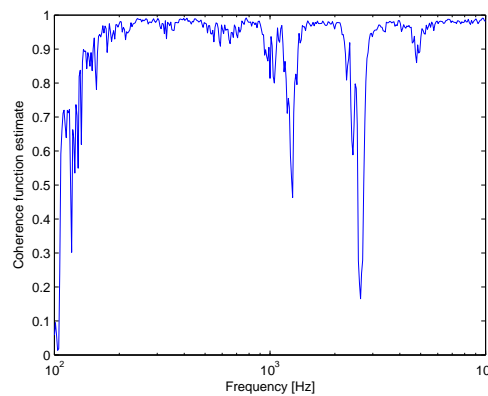
The results from ipsilateral NSP measurements which have been done when the authors were sitting and laying down is shown in figure 4.8.



**Figure 4.8:** The sitting and laying down positions in ipsilaterally NSP measurements for author 1 and 2.

### 4.1.9 Coherence of the signal

The spectral coherence has been shown in the figure 4.9. The figure shows the relation between the NSP and input signal. Ideally, the coherence is one for two totally dependent signals at a specific frequency. It is seen that the coherence function shows a high dependency between the source and its response.

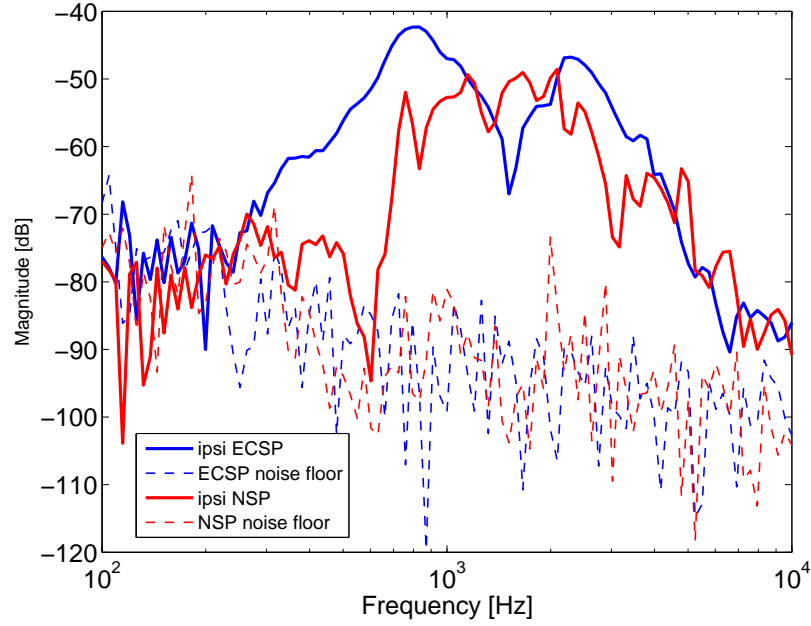


**Figure 4.9:** Spectral coherence signal

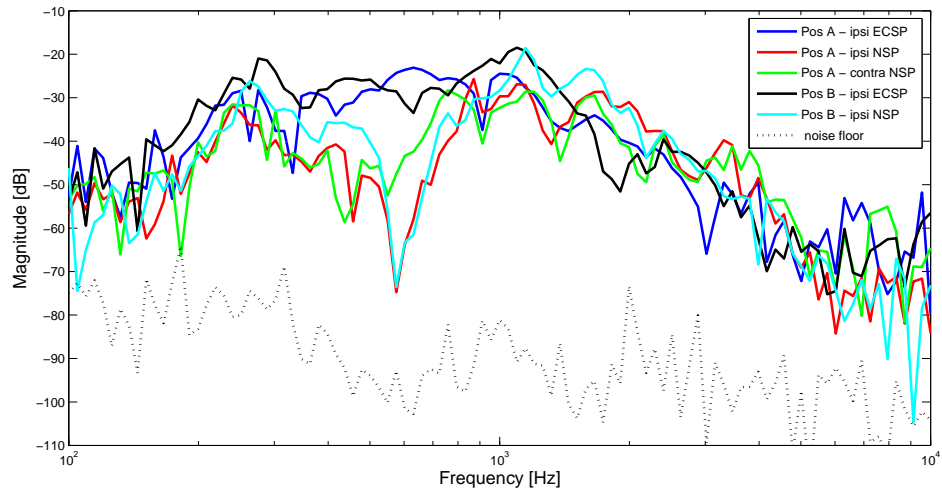
### 4.2 Cadaver study

Figure 4.10 shows the NSP and ECSP measurements on the cadaver which were performed ipsilaterally with BCI stimulation. The red lines correspond to the NSP measurements while the blue lines belong to the ECSP measurements. ECSP in the lower frequencies below 1 kHz is significantly higher than the NSP. The NSP and ECSP noise floor are also shown as dotted lines.

The ipsilateral and contralateral NSP and ECSP measurements with stimulations at position A and B are shown in figure 4.11. The noise floor for each case is shown. The solid blue and red lines show the ipsilateral ECSP and ipsilateral NSP measurements both performed for stimulation at position A, respectively. The dashed blue and red lines show their respective noise floor. The black and cyan lines show the ipsilateral ECSP and ipsilateral NSP respectively, both for stimulation at position B. The green signal represents the contralateral NSP measurement, which has been performed on position A. The frequency response of NSP and ECSP are shown in dB scale (dB rel 1v).



**Figure 4.10:** ECSP and NSP on the cadaver by BCI implant stimulation and corresponding noise floors.

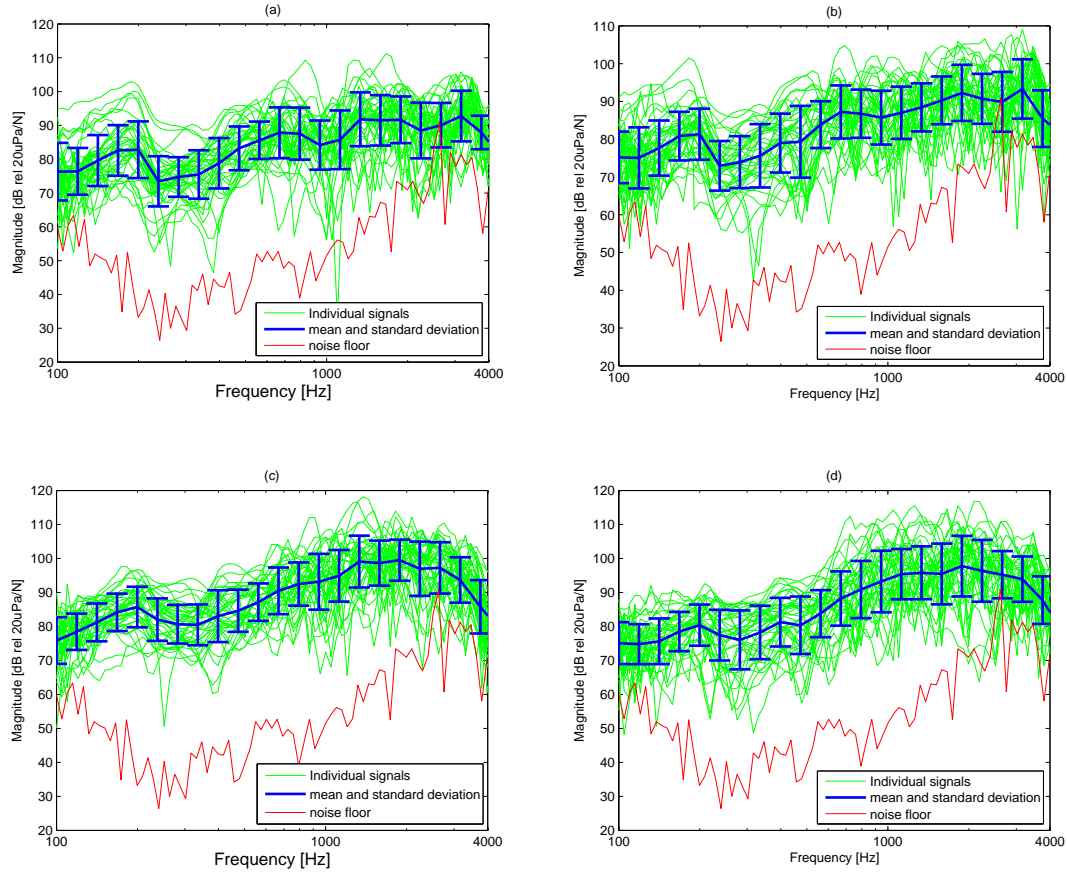


**Figure 4.11:** ECSP and NSP for skin-driven stimulation at position A and B.

### 4.3 Normal hearing measurements

The results from the normal hearing measurements are shown in this chapter. The figure 4.12 shows the nasal sound pressure (NSP) signals obtained from 20 normal-hearing subjects stimulated at the position A and B, and measured both ipsilaterally

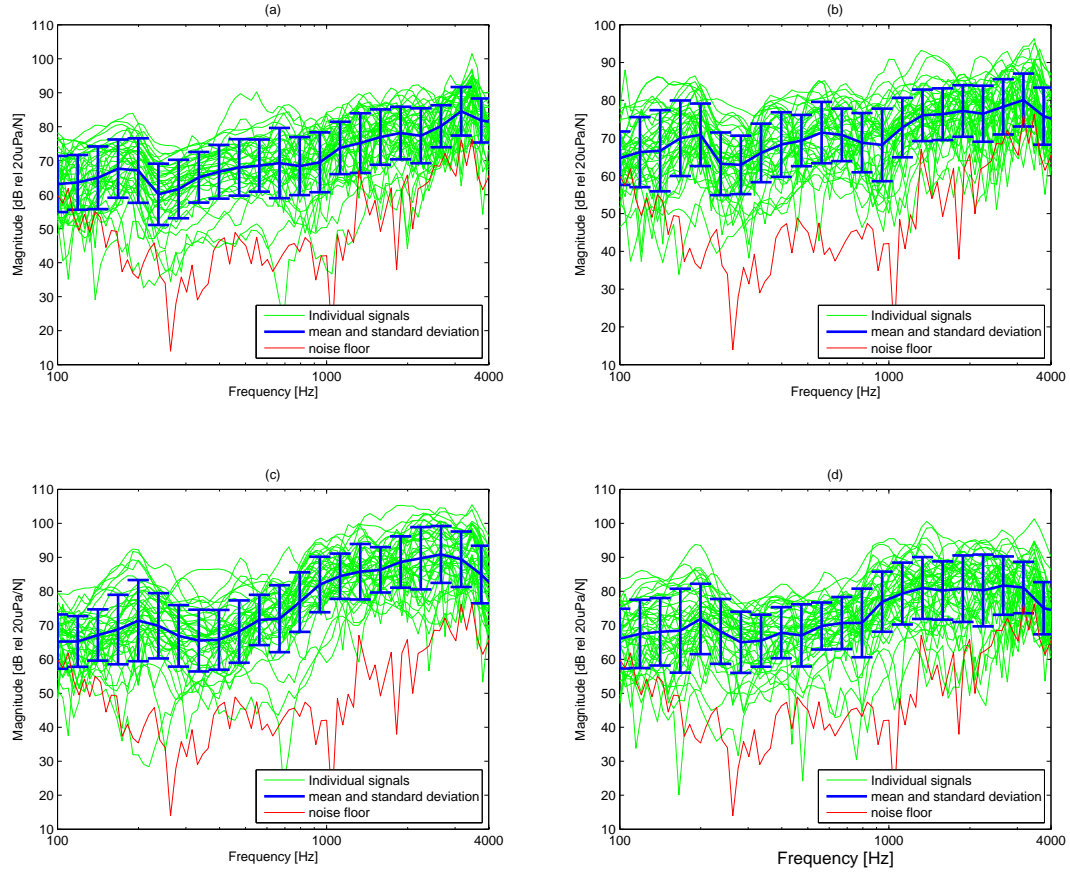
### 4.3. NORMAL HEARING MEASUREMENTS



**Figure 4.12:** A(top-left): NSP measurement from 20 normal hearing subjects, **ipsilaterally**, for stimulation at **position A** (Green); Average of 40 NSP signals (left and right together); noise floor (Red). B(top-right): NSP measurement from 20 normal hearing subjects, **Contralaterally**, for stimulation at **position A** (Green); Average of 40 NSP signals (left and right together); noise floor (Red). C(bottom-left): NSP measurement from 20 normal hearing subjects, **ipsilaterally**, for stimulation at **position B** (Green); Average of 40 NSP signals (left and right together); noise floor (Red). D(bottom-right): NSP measurement from 20 normal hearing subjects, **Contralaterally**, for stimulation at **position B** (Green); Average of 40 NSP signals (left and right together); noise floor (Red).

and contralaterally including right and left stimulation side in the same plot. The average of each 40 (right and left together) signals has been shown with its standard deviation in each figure. The noise floor in each case is also shown as a red signal. Figure 4-12.A and B show the ipsilateral and contralateral NSP measurements respectively with stimulation at position A. Figure 4-12.C and D show ipsilateral and contralateral NSP measurements with stimulation at position B. The same procedure has been followed to measure the ear canal sound pressure (ECSP) which is shown in figure 4.13.

### 4.3. NORMAL HEARING MEASUREMENTS



**Figure 4.13:** A(top-left): ECSP measurement from 20 normal hearing subjects, **ipsilaterally**, for stimulation at **position A** (Green); Average of 40 ECSP signals (left and right together); noise floor (Red). B(top-right): ECSP measurement from 20 normal hearing subjects, **Contralaterally**, for stimulation at **position A** (Green); Average of 40 ECSP signals (left and right together); noise floor (Red). C(bottom-left): ECSP measurement from 20 normal hearing subjects, **ipsilaterally**, for stimulation at **position B** (Green); Average of 40 ECSP signals (left and right together); noise floor (Red). D(bottom-right): ECSP measurement from 20 normal hearing subjects, **Contralaterally**, for stimulation at **position B** (Green); Average of 40 ECSP signals (left and right together); noise floor (Red).

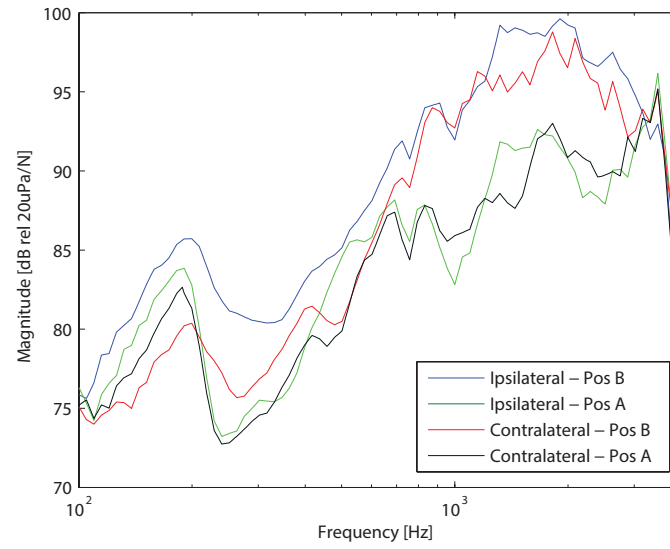
#### 4.3.1 NSP vs ECSP

The figure 4.14 shows the average of the NSP and ECSP stimulated at positions A and B, measured ipsilaterally and contralaterally. The green and blue lines show to the contralateral NSP, stimulating at position A and B, respectively. The cyan and red lines shows the ipsilateral NSP measurements from position A and B, respectively. The same line properties are used for the ECSP. The figure 4.14a shows the average of NSP and 4.14b illustrates the ECSP measurements. The measurement method was described in section 3.3.1. The difference between average of ECSP and NSP are shown in the figure 4.15. Positive values means higher amplitude for NSP and it is illustrated that the NSP is higher than ECSP in frequencies between 100 Hz and 4 kHz.

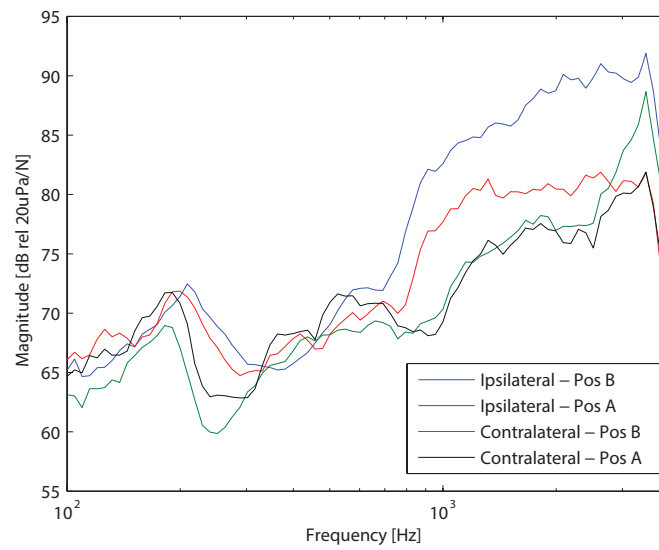


#### 4.3. NORMAL HEARING MEASUREMENTS

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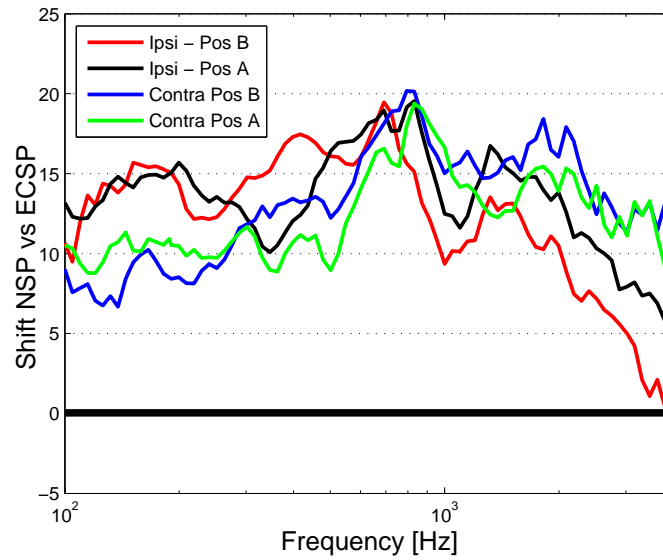


(a)



(b)

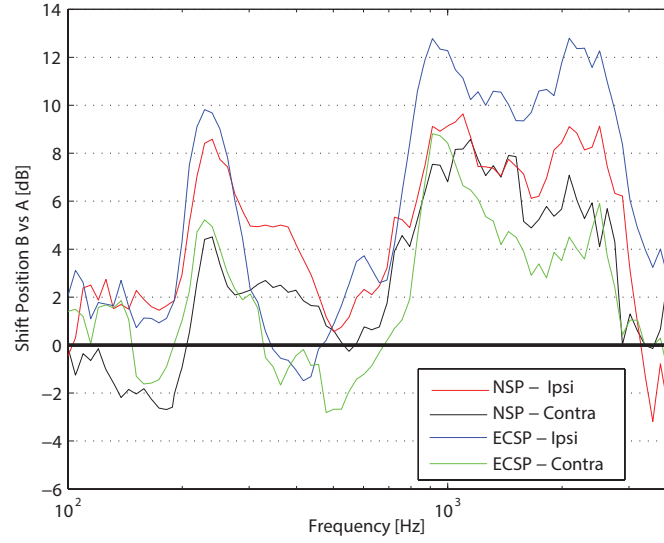
**Figure 4.14:** Average of (a): NSP, (b): ECSP measurement from 20 normal-hearing subjects.



**Figure 4.15:** Difference between NSP and ECSP. The average of NSP measurements are subtracted from corresponding measurements in ECSP.

#### 4.3.2 Position B vs. A

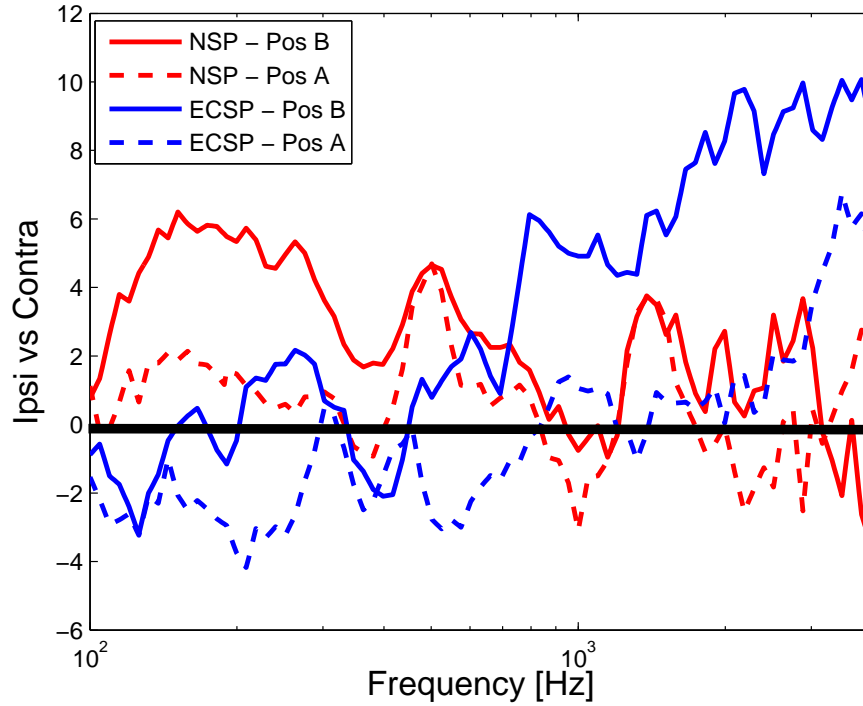
The stimulation at position A and B generates different amplitudes in NSP and ECSP that has been illustrated in figure 4.16. A significant shift can be seen in ECSP measurements when stimulation position moves from position A to B, whereas this difference is smaller in NSP.



**Figure 4.16:** The difference between NSP when stimulating at position A and B. The same difference is shown for ECSP.

#### 4.3.3 Ipsilateral vs Contralateral

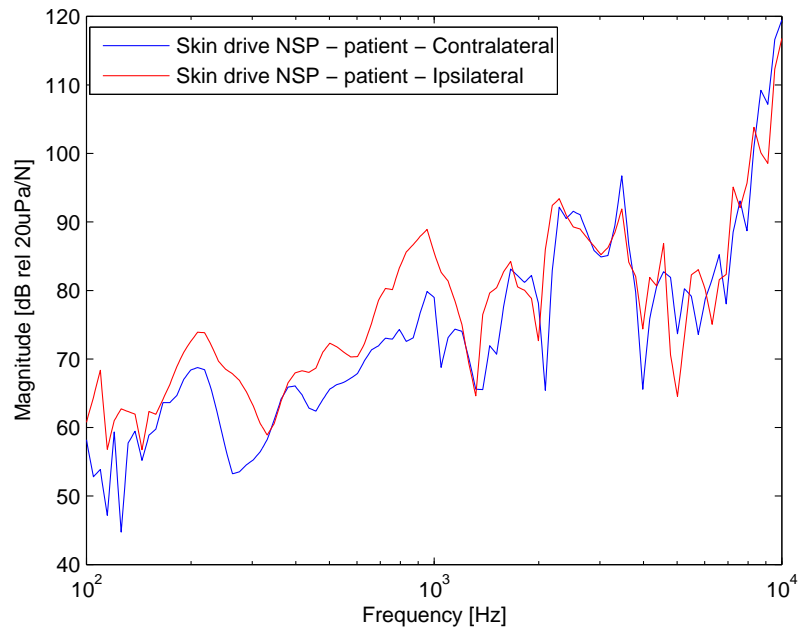
Figure 4.17 shows the difference between ipsi and contralateral measurements both for NSP and ECSP. The procedure to obtain this result has been described in section 3.3.3. The solid and dashed blue lines belong to the ECSP measurements at position B and A, respectively. The solid and dashed red lines belong to the NSP measurements at position B and A, respectively. The increasing pattern of this shift in ECSP is clearly seen, while the shift in NSP measurements has more fluctuation around zero but mostly positive, which means higher amplitude for ipsilateral stimulation.



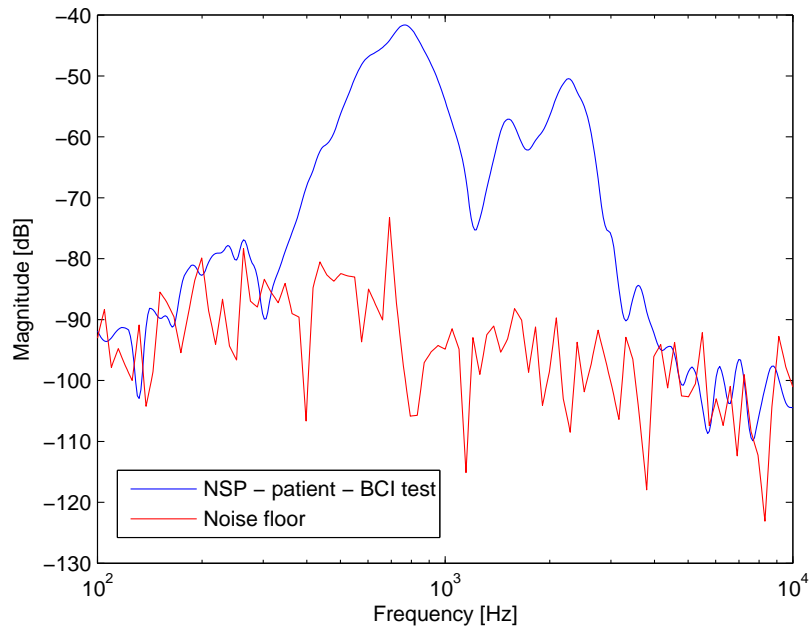
**Figure 4.17:** The difference between ipsi and contralateral measurement with stimulation at position A and B for NSP and ECSP.

## 4.4 Patient measurements

Figure 4.18 shows the ipsilateral and contralateral NSP measurements using skin drive stimulation at position B. These measurements have been done in the lab before the day of surgery to have a reliable reference measurement for surgery. The ipsilateral condition for NSP has been chosen to be used at surgery because it provides a higher signal to noise ratio than the contralateral condition. The ipsilateral measurement is also preferable during surgery, since the head of the patient is tilted on the contralateral side and it is easier to access. The NSP measurement, which was done during the surgery, is shown in figure 4.19. It was measured after fixation of implant by an orthopedic bar before closing the surgical incision. The stimulation of the BCI was done by electric transmission setup 3.2.1. The noise floor is also shown in the figure 4.19. The scale in figure 4.19 is dB relative to 1 Volt since it was not calibrated. The reason was to avoid such calibrations during the verification of BCI which is time consuming. Moreover, the comparison between skin drive and BCI measurements can be done conveniently since the analyser provides the output in dB scale.



**Figure 4.18:** Ipsi- and contralateral NSP measurements on the patient, one day before surgery.



**Figure 4.19:** NSP measurement on patient at surgery and corresponding noise floor.

# 5

## Discussion

### 5.1 Method development measurements

In order to achieve a reliable method that can be used during surgery to evaluate the functionality of implantable part of the BCI (the BBC), different challenges have been faced. By comparing different signals obtained from various measurements, the best method was chosen to be applied both during the surgery and the follow-up stages after the surgery to analyze the implant's function. The procedure to achieve an appropriate method for evaluating the BCI is necessary because there is not enough scientific research about the functionality of such vibrating implant in vivo. During this project, different experiments have been performed to find out the most proper and applicable method. There are conditions, which can happen during the measurements on an anaesthetized patient. For example, the effects of breathing were investigated by performing the measurements on the authors both when they breathed normally and held their breath. The result, which is illustrated in figure 4.1, shows a significant fluctuation when the subject is breathing normally. Since the "not-breathing" measurement gives a much smoother signal, the authors decided to ask all of the subjects to hold their breath so that results of the measurements lead to smoother signals. However, the breathing and not-breathing signals have almost the same magnitude and follow each other and there is an insignificant difference between them as it can be seen in figure 4.1. In the patient measurement described in this thesis, the patient was breathing through a tube inserted in the throat, and the nose was not involved in the breathing process. Hence, subjects in normal-hearing study were asked to hold breath to form a smoother signal, comparable with cadaver and patient measurements.

Another experiment was performed when the earplug was halved vertically to create a leakage and compare it to the signal when there was no leakage. The reason for simulating such a situation was based on the fact about the individual variations of the nostrils diameter and shape that can lead to a leakage problem during the sound

pressure measurement. In that case, the probe tube microphone could pick up a lot of background noise. Another limitation that can cause leakage is in the surgery where there are not proper control of the ear-plug placements. In the created leakage scenario, with the half ear-plug, the microphone could detect sound from outside the nostrils. As seen in figure 4.2, there has been up to 10 dB lower signal when the leakage was present. One reason can be the closed end canal in sound pressure measurement that can lead to higher sound pressure amplitude because of reflections that can happen in a chamber will be summed up and generate higher amplitude. With leakage, the signal gives especially higher sound pressure at low frequencies. If we compare it to the previous study [13], some similarities are detected. When the occlusion effect (described in section 2.7.1) was presented in the ECSP measurements, the received sound pressure was about 10 dB higher specially at low frequencies. One reason is that the open ear canal functions as a high pass filter and attenuates the low frequencies (below 1 kHz); however, when the ear canal is occluded, the low frequency signal will be increased due to removal of the filter effect [14]. Hence, the increment of the signal when the nostril is occluded can be related to the occlusion effect, which is more explained in 2.7.1.

Another issue was to decide about the position of the microphone or probe tube in the nostrils. Different scenarios have been investigated including changing the position of the ear plug itself in the nostrils while keeping the end of tube position constant, and displacing the end of tube position while keeping the ear plug depth constant. Firstly, different depths of ear plug into nostrils were tried including the shallowest to the deepest condition. The shallowest (5 mm) was not accepted since the plug could be positioned loosely and the deepest (10 mm) was not desired because the probe tube could touch the nostril wall and/or the moisture could occlude the probe tube opening to cause an unreliable measurement. The best and most suitable depth has been considered to be 8 mm inside the nose.

In the other experiment, the length of the probe tube inside the nose was changed while keeping the depth of the ear plug constant to see how the NSP depends on the probe tube length inside the nostril. The result, which is shown in figure 4.1.3, did not give any differences to help deciding which length that would be preferred; therefore the probe tube was placed precisely on the surface of the ear plug to avoid any moisture entering the tube during the measurements. In addition, longer probe tube in nostril can lead to problem because it can touch the nostril wall.

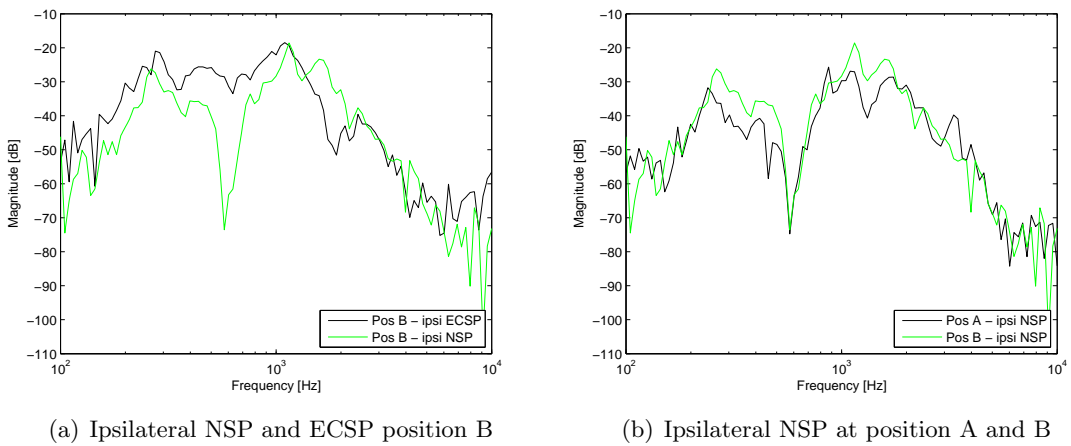
Experiments were also performed without using the probe tube, which means that the microphone was directly placed inside the plug so that the microphone's tip was exactly on the surface of the ear-plug. Since the microphone had a square shape, there was some leakage through the ear plug. Hence, using the probe tube was preferred instead of inserting the microphone directly into the plug. Another reason for choosing the probe tube was that the microphone was very sensitive and to insert it into the ear plug could cause damage on the microphone diaphragm and to its connections. By investigating the variance of the result when the same measurement method is applied on the same person has been investigated on the authors and the result can be seen on figure 4.7. Up to 15 dB difference can be seen in the same measurement. This can

be due to the health condition of the each individual and small unavoidable changes in the measurement setup cause very significant difference. During the measurement on patients in surgery room, the measurements are done while they lay down on the bed, however, in normal-hearing and when the patient is tested at Lab before and after surgery for follow-up they sit on a chair. This possible difference was investigated and shown in figure 4.8. As seen, there was insignificant difference in the amplitude of the NSP.

### 5.2 Cadaver study

In the cadaver study, the BCI measurement setup (described in section 3.2) was used to measure both NSP and ECSP. Figures 4.10 shows lower NSP than ECSP especially in the frequencies lower than 1 kHz. This result was not expected and the reason could be due to the sound propagation in the anatomy dissection room. A very powerful air-conditioning system was on during the whole session and the problem of isolating the nostril from background noise using ear-plug was much more difficult than isolating the ear canal because of the shape of the nostril. In addition, the room and the steal-made bed had produced a lot of reflections that caused an anti-resonance dip at 600 Hz in the measured frequency response. This effect was also seen in the skin drive measurements when the subject was stimulated by the transducer at position A and B.

When comparing the NSP and ECSP in the cadaver skin drive measurements, there was higher amplitude for the ECSP shown for position B in figure 5.1(a), which was opposite to the result found in the human subjects study. It was discussed that it could be due to the leakage in the NSP measurements. An anti-resonance can be seen in the figure 5.3 around 600 Hz for ipsilateral NSP. Figure 5.1(b) shows up to 8 dB higher amplitude in frequency response of the skin drive stimulation at position B than at position A for some frequencies around anti-resonance.



**Figure 5.1:** Ipsilateral NSP and ECSP, skin drive on cadaver.



### 5.3 Normal-hearing human study

As it was seen in figure 4.15, the NSP provide a higher amplitude in comparison with ECSP as all the values are above zero. This difference at 700 Hz in ipsilateral measurement at position B is about 19 dB which is significant. This result indicates that the NSP provides a better signal to noise ratio.

The result presented in figure 4.16 shows that stimulation at position B provide a higher NSP and ECSP than position A, almost in all the frequency range between 100 Hz and 4 kHz. The result also illustrates that this difference in NSP is up to 9 dB ipsilaterally. Ipsilateral ECSP provides the largest difference in frequencies between 1 kHz and 3 kHz, about 12 dB. This is due to that the distance to the stimulation position in ipsilaterally ECSP is the nearest. This effect has been investigated in Reinfeldt et al. [3] to prove that the sound perception in BCI leads to about 10 dB higher signal to compensate the loss of transmitting energy via inductive link in the BCI in comparison with BAHA.

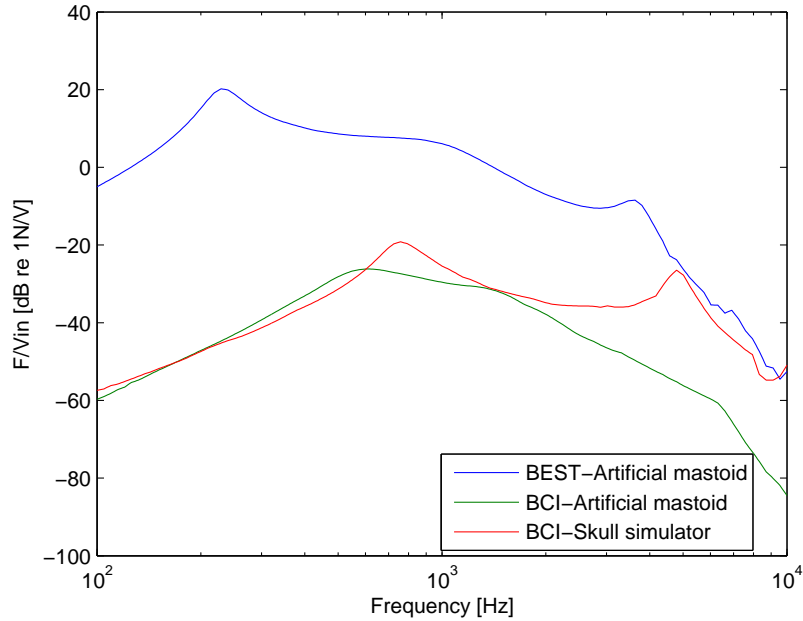
The difference between the average of the ipsilateral and contralateral measurements in NSP and ECSP shows higher amplitude in ipsilateral measurements. Stimulation at position B is higher both ipsilaterally and contralaterally at most frequencies. The difference is a result of distance between the ipsilateral and contralateral positions so that longer distance would increase attenuation of the propagated sound. This difference in ECSP is referred to as transcranial attenuation and explains how much the sound attenuates when it travels from one side of the head to the opposite side. In fact, the transcranial attenuation determines how much vibration reaches the contralateral cochlea in comparison to the vibration that reaches the ipsilateral side. As it can be seen in figure 4.17 the transcranial attenuation increases at higher frequencies in ECSP. In other words, at lower frequency the difference between ipsilateral and contralateral is very small. This could be explained because it attenuates the high frequency vibrations. The low-frequency vibration are not attenuated because the skull moves as a rigid body at low frequencies. On the other hand, this effect is not significant in the NSP and it could be due to the almost equal distances between the stimulation positions and ipsilateral and contralateral nostrils. Therefore, there is only a fluctuation around zero with slightly higher ipsilateral NSP.

The result of ECSP measurements (ipsi vs contra) is expected, comparing to the results in previous studies [3][8]; i.e. the ECSP gives slightly higher amplitude in the ipsilateral measurements than the contralateral ones. Transcranial attenuation is discussed extensively in the literature [34] in which the vibrations were measured close to the cochlea and shows attenuation up to 15 dB at high frequencies and a small increment at low frequencies. More information about transcranial transmission will be found in Reinfeldt et al.[3] [8].

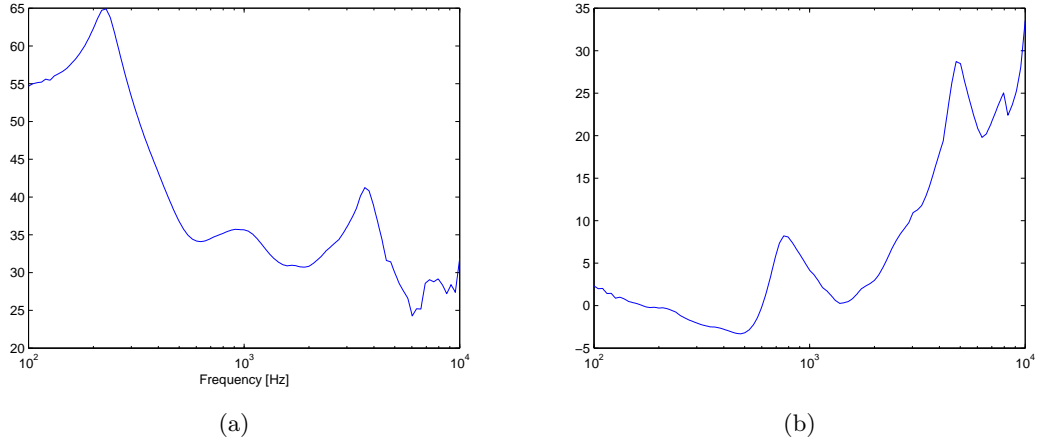
## 5.4 Patient measurements

To be able to compare the result from the cadaver study with the results from the human subject measurements, another compensation was also required, namely the difference between the implanted BCI transducer and skin drive transducer (the direct and indirect BC stimulation). The compensation curve for difference of the transducers was obtained using the frequency response function of these transducers that were measured on the skull simulator in the Anechoic Test chamber type 4222. The difference between the frequency responses was later applied to the normal-hearing measurements to have an equivalent transducer by compensating for the differences.

The frequency response of the BCI transducer on the artificial mastoid and skull simulator were measured (see figure 5.2). The skull simulator mimics the characteristics of the skull for direct BC stimulation [33]. Firstly, the difference between BEST and BCI transducer, measured by artificial mastoid, was calculated (see figure 5.3(a)), giving the difference between the transducers with skin drive stimulation. Difference between BCI on the skull simulator and BCI on the artificial mastoid was calculated and shown in figure 5.3(b), illustrating the difference between direct BC stimulation and skin drive stimulation.



**Figure 5.2:** Force frequency response of BCI and BEST transducers.

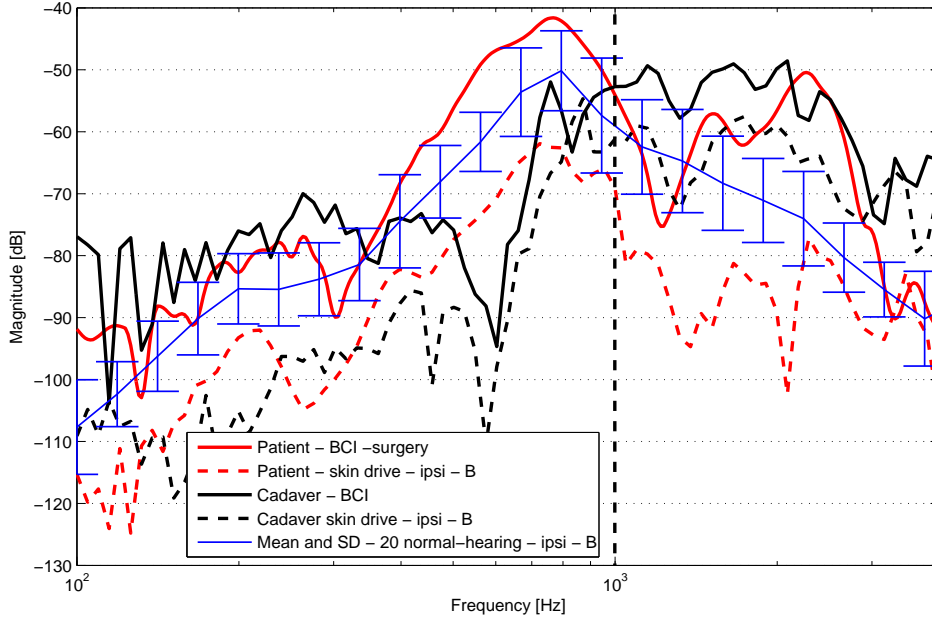


**Figure 5.3:** (a) Difference between frequency response of BEST and BCI transducers on artificial mastoid. (b) Difference between frequency response of BCI transducer on artificial mastoid and skull simulator.

By subtracting the difference shown in figure 5.3(a) and adding the difference in 5.3(b) to signals obtained by BEST stimulation the difference between the BCI transducer with direct BC stimulation and the BEST transducer with skin drive stimulation can be compensated. As seen in figure 5.4 and table 5.1, the mean value of NSP for the human subject study is about -59 dB at 1 kHz and the NSP for the BCI measurement on the cadaver is -52 dB at 1 kHz. The skin drive stimulation NSP on cadaver is about -61 dB. Hence, there is 9 dB difference between skin drive and BCI test in cadaver. The skin drive test on NSP measurement on the patient, the day before the surgery shows about -69 dB at 1 kHz. Hence, it was expected to get 9 dB higher signal for the patient at surgery by stimulation of the implant. As seen in figure 5.4, the obtained value (-54 dB) from the patient at surgery is higher than the expected value.

**Table 5.1:** he values for ipsilateral NSP in Cadaver, normal-heaing subjects and patient. All values are in dB scale.

	Cadaver	Normal-hearing (mean)	Patient
Skin drive	-61	-59	-69
BCI	-52	-	-54

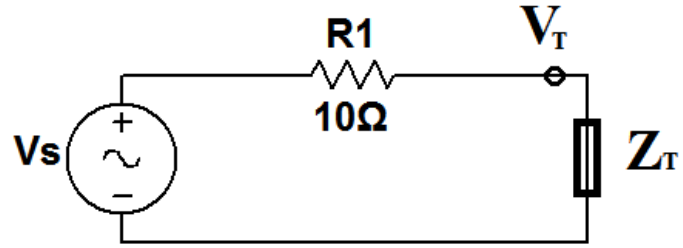


**Figure 5.4:** Result for comparison from normal-hearing subjects (ipsilaterally, stimulation at position B), cadaver (skin drive and BCI test) and patient (skin drive and BCI).

## 5.5 Measurement features

The 10 Ohm resistor that was placed in the measurement setup to protect the transducer from high current flow and damage as a result of an improper voltage drop at the transducer input. Basically, the desired signal is  $F_{out}/V_T$ , where  $F_{out}$  is the output dynamic force of the transducer and  $V_T$  is the voltage over the transducer, but the signal which was detected with the measurement setup is the voltage of the source ( $v_s$ ) in the human subjects study (see figure 5.5). For compensation of this effect, the  $V_T/V_S$  was calculated by a voltage division and included in the frequency response measurement to reach to desired transfer function.

$$\frac{V_T}{V_S} = \frac{Z_T}{Z_T + R_1} \implies \frac{F_{out}}{V_T} = \frac{F_{out}}{V_s} \times \frac{V_s}{V_T}$$



**Figure 5.5:** Compensation circuit.

The spectral coherence, shown in figure 4.9, presents the relation between the NSP and source. The coherence functions shows a proper relation between stimulation signal and detected signal that illustrate this measurement is accurate.

# 6

## Conclusions

The aim of this Master thesis was to develop a method, which can be used during surgery in order to assure functionality of a new Bone Conduction Implant (BCI). The results obtained from this thesis work show clearly that the method can be used both during surgery and the follow-up stages. Compensating the signals obtained from skin drive measurements then comparing them to the measurements with BCI direct bone conduction stimulation leads to achieve a useful and reliable method to estimate the expected values of the NSP in certain frequencies. The method can show functionality of the implant properly during the surgery before stitching the skin, which was proven in practice during surgery on first patient. The method can also be applied after the surgery to assure functionality of the implant and to evaluate any change that may happen in prior to the follow up stages because of implant failure. In other words, by applying the same method both during the surgery and in the follow-up stages under the same conditions, comparison of the obtained signals will lead to investigating any differences.

The most appropriate method of measuring NSP was by using probe tube microphone inserted into an ear plug and then 8 mm into the nostril while avoiding sound leakage. With this method on 20 normal hearing subjects, it was shown that the magnitude of the frequency response of NSP is significantly higher than ECSP. Therefore the accuracy of the measured NSP signal is improved in terms of better signal to noise ratio in comparison to ECSP signals.

# 7

## Future work

Since the BCI device has not been operated on many patients so far, the drawbacks and modification regarding this method cannot be elicited completely. However, one desire is to develop a device, which can fix and assure a constant depth of the ear plug during all measurements as well as covering any leakages at the same time to ensure a complete isolation from surrounding noise. In this way errors will be minimized, especially in comparing the surgery signal to the follow-up ones. Besides, the reference signal, resulted from comparing different subjects, will be more accurate and reliable.

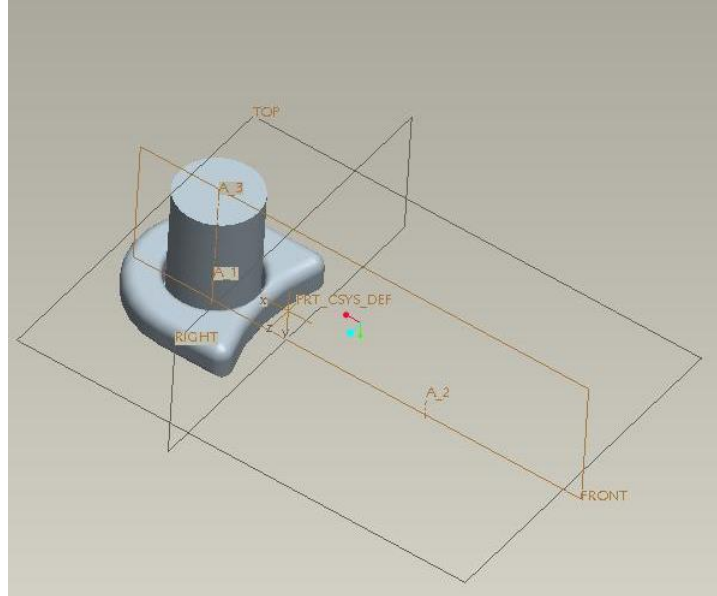
The other tricky point is that people have different nostril lengths. Hence, when the ear plug is inserted 8 mm into the nostril, the distance between the ear plug end and the nasal bone (the end of the nostril) will be different and therefore remains unknown. This can be a challenge while comparing signals from different subjects to obtain a reference signal. In conclusion, an accurate measurement device would be desirable to do all compensations (regarding different nostril lengths) and decide then the depth of the plug itself.

Another issue to be inquired is finding the exact depth of the ear plug inside the nostril to avoid the occlusion effect. The occlusion effect is very important issue in invention of hearing aids because in presence of this effect, the noises from the patient body while chewing or moving vigorously, as well as heartbeats, will be amplified and deteriorate the quality of sound at low frequencies. As described in the literature [28], by placing the ear plug deep in the ear canal without touching the TM, the occlusion effect will be minimal. The same research is needed related to the NSP measurement to find out the best placement of the ear plug inside the nostril to avoid the occlusion effect.

A CAD-model has been developed to design such an ear-plug. This model requires further development to fix the position of ear-plug depth in the nostrils. The model is shown in figure 7.1. The main part of the future work is to focus in selecting appropriate frequencies for transmitting a signal to the implant and receiving it by a microphone to

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verify the functionality of the implant. This is significantly important to have a simple and portable device that can be used by physicians and staff in a surgery room.



**Figure 7.1:** CAD model of ear-plug placement.



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# A

## Appendix

Name:		Date:	Birthdate		M/F    N/AN
Frequency Response=Mic/input			Input level=		EC length:R:    L:
Measurement 1			Threshholing		
Frequency(Hz)	RE		LE		Comment
125					
250					
500					
750					
1000					
1500					
2000					
3000					
4000					
6000					
8000					
Measurement 2:			ECSP		
Plug-Mic	Transducer		Check Box	file name	Comment
Right	Pos A	IPSI			
	Pos B	IPSI			
	Pos A	CONTRA			
	Pos B	CONTRA			
Left	Pos A	IPSI			
	Pos B	IPSI			
	Pos A	CONTRA			
	Pos B	CONTRA			
Measurement 3:			NCSP		
Plug-Mic	Transducer		Check Box	file name	Comment
Left	Pos A	IPSI			
	Pos B	IPSI			
	Pos A	CONTRA			
	Pos B	CONTRA			
Right	Pos A	IPSI			
	Pos B	IPSI			
	Pos A	CONTRA			
	Pos B	CONTRA			
Measurement 4:			Noise floor measurement		
Measurement 4	Noise				
Further explanation:					

**Figure A.1:** Protocol for normal-hearing subjects measurements.