Thesis for the degree of Licentiate of Engineering

A Novel Bone Conduction Implant System

by

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Cover:
A BCI audio processor (on the right) and a BCI Bone Bridge (on the left) with an amplitude modulation circuit of a Class-E power amplifier in the background.

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To my family

A Novel Bone Conduction Implant System

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Abstract

Bone conduction is the process by which an acoustic signal vibrates the skull bones to stimulate the cochlea. Patients with pure conductive hearing loss, mixed hearing loss, and single sided deafness are sometimes poorly rehabilitated by conventional air conduction hearing aids due to for example the functionality losses in the middle ear. With these hearing impairments, the cochlea may function perfectly and a bone conduction hearing device can transmit the sound signal more efficiently to the cochlea.

Today, the percutaneous bone anchored hearing aid (BAHA) is an important alternative for such individuals. This device uses a percutaneous snap coupling together with a bone anchored implant to transmit the sound vibrations to the skull bone and has proven to offer very good hearing rehabilitation. However, such a system with permanent skin penetration requires a life-long commitment of care every day, may cause skin infections, and there is a risk for implant damage due to trauma and hence improvements are called for in these aspects.

A novel bone conduction implant (BCI) device is designed as an alternative to the percutaneous BAHA device, because it leaves the skin intact. The BCI device provides a specific hearing aid digital signal processor, and analog signal processing parts. By applying amplitude modulation technique, the sound signal is transmitted to a permanently implanted transducer via an inductive link system through the intact skin. An efficient wireless power and data transmission system for the BCI device has been designed and implemented. Maximum power output (MPO) of the BCI was designed to occur at 4 mm skin thickness. The power output variability for 1 to 8 mm skin thickness variations was within 1.5 dB. Maximum MPO was found to be 109 dB relative to 1 μN at transducer resonance frequency. This implant system consumes 14.6 mA of battery current at 1 kHz at 65 dB input sound pressure level. It was also found that the gain headroom improvement with the BCI versus the BAHA was in the range of 10-30 dB, if the mechanical output of the devices were normalized at the cochlear level.

Keywords: bone conduction implant, implantable hearing devices, bone anchored hearing aid, bone conduction devices, implantable transducer, feedback, sound radiation, gain headroom, RF power and data link, RF power amplifier, wireless power and data transmission, amplitude modulation, low-power systems.

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I would like to acknowledge ”VINNOVA”, the Swedish Governmental Agency for Innovation Systems, which has granted and supported the project.

List of papers

This thesis is based on work reported in the following papers, referred to by Roman numerals in the text.

I	A Novel Bone Conduction Implant (BCI): Engineering Aspects and Pre-clinical studies. Bo Håkansson, Sabine Reinfeldt, Måns Eeg-Olofsson, Per Östli, Hamidreza Taghavi, Johannes Adler, John Gabrielsson, Stefan Stenfelt, Gösta Granström, International Journal of Audiology 2010; 49: 203-215.
II	A Novel Bone Conduction Implant - Analog Radio Frequency Data and Power Link Design. Hamidreza Taghavi, Bo Håkansson, Sabine Reinfeldt, In the Proceeding of the 9^{th} IASTED International Conference on Biomedical Engineering 2012, 327-335.
III	Feedback Analysis in Percutaneous Bone Conduction Device (PBCD) and Bone Conduction Implant (BCI) on a Dry Skull. Hamidreza Taghavi, Bo Håkansson, Sabine Reinfeldt, Måns Eeg-Olofsson, Shirin Akhshijan, Accepted for Publication in the Journal of Otology & Neurotology.
IV	Analysis and Design of RF Power and Data Link Using Amplitude Modulation of Class-E for a Novel Bone Conduction Implant. Hamidreza Taghavi, Bo Håkansson, Sabine Reinfeldt, In Manuscript.

Please note
Parts of Papers I, II and IV have been partly presented as follows:

- Taghavi, H. (2010) ”Electronic design aspects of a novel Bone Conduction Implant (BCI) system,” Svensk Teknisk Audiologisk Förening (STAF) 2010, Eskilstuna, Sweden,
- Taghavi, H., Håkansson, B., Östli, P., Reinfeldt, S., Eeg-Olofsson, M., Granström, G. and Stenfelt, S. (2010) ”A Novel Bone Conduction Implant (BCI) System,” 11^{th} International Conference on Cochlear Implants and other Auditory Technologies 2010, Stockholm, Sweden,
- Taghavi, H., Håkansson, B., Reinfeldt, S., Östli, P., and Eeg-Olofsson, M. (2011) ”A Novel Bone Conduction Implant (BCI) System,” 3^{rd} International Symposium on Bone Conduction Hearing and Craniofacial Osseointegration, Florida, USA,
- Taghavi, H., Håkansson, B., and Reinfeldt, S. (2012) ”A Novel Bone Conduction Implant - Analog Radio Frequency Data and Power Link Design,” 9^{th} IASTED International Conference on Biomedical Engineering 2012, Innsbruck, Austria, and will be presented
- Taghavi, H. (2012) ”A novel Bone Conduction Implant (BCI) Device,” TeMA Hörsel 2012, Linköping, Sweden.

Parts of Paper III will be partly presented as follows:

- Taghavi, H., Håkansson, B., Reinfeldt, S., Eeg-Olofsson, M., Akhshijan, S. (2012) ”Feedback Analysis in Percutaneous Bone Conduction Device (PBCD) and Bone Conduction Implant (BCI) on a Dry Skull,” 12^{th} International Conference on Cochlear Implants and other Auditory Technologies 2012, Baltimore, USA.

Contents

Abbreviations and Acronyms

AC	Air Conduction
AM	Amplitude Modulation
ASIC	Application Specific Integrated Circuit
BAHA	Bone Anchored Hearing Aid
BC	Bone Conduction
BCI	Bone Conduction Implant
dB	decibel
DBC	Direct Bone Conduction
LDV	Laser Doppler Vibrometer
MPO	Maximum Power Output
MRI	Magnetic Resonance Imaging
OFL	Output Force Level
PBCD	Percutaneous Bone Conduction Device
RF	Radio Frequency
SNR	Signal-to-noise ratio
SPL	Sound Pressure Level
SSD	Single Sided Deafness
WHO	World Health Organization

Part I

Introductory chapters

Chapter 1

Introduction

This thesis presents some recent developments on ongoing challenges in implantable bone conduction hearing devices. In view of the large number of problems and challenges in designing implantable electronics for medical devices, this thesis focuses on areas that will advance transcutaneous bone conduction implant devices for hearing impaired patients. It will be described in greater details in the upcoming chapters that the implanted bone conduction transducers need to receive power and data wirelessly through the intact skin. Furthermore, this transmission should be designed to be very efficient to reach the desired output force levels in the bone and also to consume less power, which is an important factor of cost. Efforts are focused on the design and implementation of an efficient wireless power and data transmission system for the use in bone conduction implants. If successful, this device can improve the quality of life for patients suffering from different hearing impairments and make it feasible to use this technology all over the world.

It is reported in the World Health Organization (WHO) fact sheet that in 2005, about 278 million people had moderate to profound hearing impairment (Deafness and hearing impairment Fact sheet N°300, April 2010). This shows the great importance of improving the design of hearing aid devices to the society.

Whereas conventional hearing aids transmit sound to the tympanic membrane via air conduction (AC), bone conduction (BC) devices transmit sound via vibrations through the skull directly to the cochlea. In most hearing impaired patients with conductive and mixed hearing loss and single sided deafness who can not sometimes be rehabilitated by air conduction hearing aids, a conventional bone conduction hearing device is an efficient alternative.

Major drawbacks with the conventional BC devices reported are the discomfort of the static pressure over the skin, reduced high frequency gain and

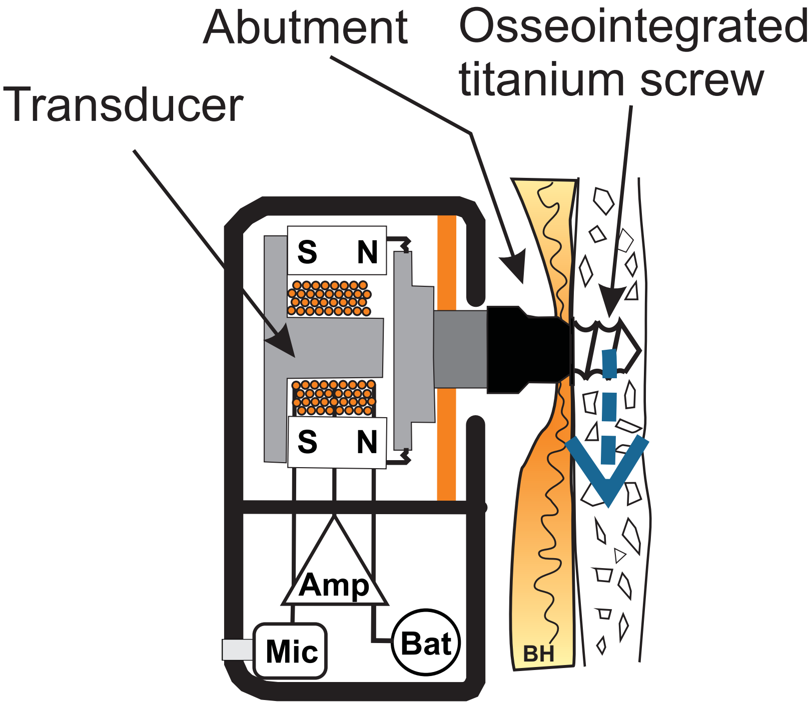

Figure 1.1: Principal design of a generic percutaneous bone anchored hearing aid (BAHA) with a screw attachment to the skull bone. It comprises a microphone (Mic), battery (Bat) and pre and power amplifiers (Amp) that drives the bone conduction transducer.

feedback problems. An alternative can be a direct bone conduction device with a permanent skin penetrating titanium screw called the bone anchored hearing aid (BAHA) (see Figure 1.1). Even though very successful implantations have been reported with the BAHA, the permanent skin penetrating implant needs life-long commitment of care every day. Loss of implant may happen as a result of trauma and skin infection and redness is also appearing to some patients.

A solution to these drawbacks can be a novel bone conduction implant (BCI) device. The BCI is novel because the skin is kept intact by implanting the transducer within the skull bone near to the cochlea, which also might increase the sensitivity of the bone conducted sound, see Paper I and Håkansson et al. (2008). In the BCI, no screw attachment to the skull bone is used. Instead there is a flat direct contact between the transducer housing and the skull bone. Moreover, the BCI has an improved gain headroom than the BAHA that allows for the possibility to increase the real gain of the BCI without getting feedback problems, see Paper III.

1.1 Aim of thesis

The overall aim of this thesis is to design and implement an efficient wireless power and data transmission system for the BCI device. There are three main areas to be explored.

First of all, efforts are focused on better understanding and designing efficient radio frequency (RF) inductive links for power and signal transmission. An intuitive model of the RF link can help to better understanding the effects of the coupled resonators and loss mechanisms for transferring energy through the intact skin (Papers I, II).

Secondly, designing the inductive link power driver to be very efficient and fairly insensitive to changes in the transmitter circuit impedance and quality factor as the skin thickness (coupling between coils) changes in different patients. Furthermore, several RF power amplifier topologies are designed and implemented such as analog linear power amplifier and Class-E switching tuned power amplifier with minimized switching losses (Papers II, IV).

Thirdly, during the development of the BCI and particularly in previous cadavers studies (Paper I; Håkansson et al. (2008)) it has been noted that the BCI device was less prone to fall into feedback problems than the BAHA especially at higher frequencies. This finding indicates that the BCI can allow a higher gain setting than the BAHA without problems of feedback. An increased amplification, especially at high frequencies, can be very beneficial for speech understanding. Therefore, a study was formed to investigate the gain headroom (how much extra gain can be provided before the device will oscillate) in the BCI and in a generic bone anchored hearing device (Paper III).

1.2 Thesis outline

Chapter 2 explores the hearing physiology in human and explains the hearing by air and bone conduction and the hearing impairments. An overview on the technologies in the area of existing bone conduction hearing devices and the future devices are described with more details and illustrations in Chapter 3. Next, in Chapter 4, a summary of the papers is presented. Finally, Chapter 5 includes a summary of the project achievements by discussing the efficient system design role in the bone conduction implant device and the future work of the BCI device.

Chapter 2

Hearing physiology

2.1 Hearing by air and bone conduction

The process of hearing contains the transmission of sound energy and vibrations, which finally generates the nerve impulses in the auditory organs. Basic structure of the anatomy of the human ear including outer ear, middle ear and inner ear organs are illustrated in Figure 2.1. In the air conduction hearing the sound waves enter the ear canal and the vibrations are transmitted through following sequences of structures: vibrations travel through the ear canal and strike the tympanic membrane, causing the tympanic membrane and the middle ear ossicles to start vibrating. As the tympanic membrane has a larger surface than the oval window, the vibrations are delivered with more force to the inner ear fluid. This is an amplification or impedance transformation of the sound wave that is essential for transmission to the fluid of the inner ear. There is a protection of the inner ear against too loud sounds by some small muscles in the middle ear that reduce the transmission of sound by constriction; this is known as acoustic reflex.

The vibrations then deliver the sound wave pattern to the inner ear and the fluid in the upper and lower cavities (scala vestibuli and scala tympani) of the cochlea. These waves cause a motion of the hair cells supported by the basilar membrane. Each frequency of the sound wave affects more specifically a particular part of the basilar membrane and stimulates a response of the hair cells at that location. High frequency sounds cause enhanced movements of the cells near the base of the cochlea and lower frequencies produce enhanced movements near the tip of the cochlea. Hair cells in the basilar membrane move relative to the tectorial membrane, displacing the cilia on the hair cells. It results in a chemical reaction within the hair cells triggering electrical responses in the auditory nerve. The louder or intense

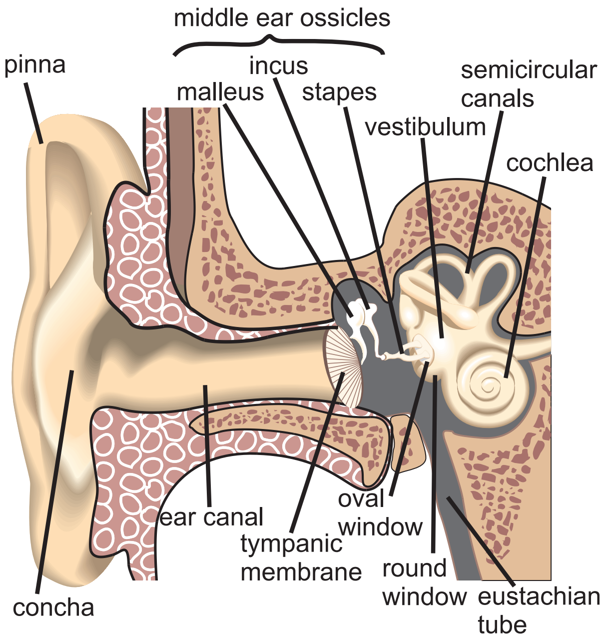

Figure 2.1: Basic structure of the anatomy of the human ear showing outer ear, middle ear and inner ear organs.

the sound, the more impulses are generated. These electrical impulses travel through the auditory nerve to different sound signal processing parts of the brain which interprets the sound. This interpretation takes place in the auditory cortex located in the temporal lobes on each side of the brain. Most of the sorting, processing and sensation of the sound occur in the gray matter. Interaction between the right and the left side takes place as cross talk in olivary nuclei along the nerve pathways to the brain and in the temporal lobes. This analysis has a role in background noise suppression and allowing a person to focus on the desired sounds.

The peripheral hearing mechanism includes both the conductive and sensorineural mechanisms. The conductive mechanism involves the outer and middle ear, sensorineural mechanism includes the inner ear and the auditory nerve. In the central auditory mechanism the central auditory pathway to the brain is involved.

On the other hand, the bone conduction hearing is the process of transmitting sound energy through vibrations of the skull directly to the cochlea. This results in an auditory sensation and hearing. Bone conduction hearing is the secondary auditory pathway that supplements the air conduction process. The sound waves are impacting the human skull either directly from the surrounding environment, by direct mechanical stimulation of the skull by

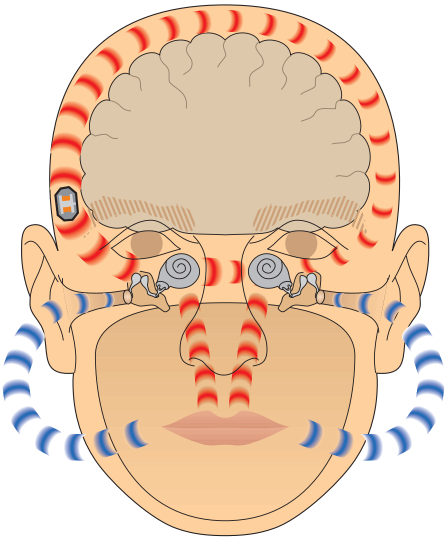

Figure 2.2: Bone conduction and air conduction paths: blue path represents the air conduction part of the one's own voice, red path shows the bone conduction part of one's own voice and from an implanted BCI transducer (Reinfeldt, 2009).

a vibratory source, or from one's own voice. Main air conduction and bone conduction hearing paths are illustrated in Figure 2.2. The main difference between hearing through air conduction and bone conduction is how sound is transmitted to the cochlea. In the air conduction process, sound energy travels in a unidirectional path through the external ear canal, vibrates the tympanic membrane, travels across the ossicular chain and creates movements of the stapes against the oval window of the cochlea.

In bone conduction, the bones of the skull vibrate and depending on the direction of the stimulation, vibrations may also be reflected backwards from the cochlea fluid. The vibrations of the skull coming from different directions will add together to vibrate the fluids in the cochlea (Henry, 2007). On the other hand, at the cortical level, a 1 kHz tone at a patient's threshold of hearing will have the same neural representation regardless of the mode of stimulation, whether it is air conducted or bone conducted (Békésy, 1955). However, there will be many differences between the input levels of BC and AC excitations needed for generating that same neural representation to the patient (Hodgetts, 2009).

There exist several contributing factors in the bone conduction hearing process and the most important ones are (Stenfelt and Goode, 2005):

- Sound radiated in the ear-canal
- Middle ear ossicle inertia

- Inertia of the cochlea fluids
- Compression of the cochlear walls
- Pressure transmission from the cerebrospinal fluid

The inertia of the cochlear fluid is the most dominant contributor below 4 kHz and may be less important at higher frequencies. Middle ear ossicle inertia influences the BC sensitivity in the mid-frequencies between 1.5 and 3.1 kHz (Stenfelt, 2006).

2.2 Hearing impairments

Hearing impairment or hearing loss is a full or partial loss in the capability of detecting and understanding sounds. It can be due to biological or environmental factors. Hearing losses are divided into three different types of impairments: conductive loss, sensorineural loss and mixed hearing loss. The sensorineural loss can be divided into cochlear losses and losses in the auditory nerve or brain, which sometimes also are referred to as retrocochlear hearing loss.

Conductive hearing loss occurs when the sound is not properly conducted through the outer ear, middle ear or both. In this case, the sound can still be detected by the inner ear with a functional cochlea. In a sensorineural hearing loss, the cochlea or the nervous system lose their sensitivity to the sound. The great majority of human sensorineural hearing losses are caused by noise induced or hereditary abnormalities in the hair cells of the organ of Corti in the cochlea.

Chapter 3

Bone conduction hearing devices - an overview of existing and future devices

In this chapter, a brief overview of the present and future bone conduction hearing devices will be given. The conventional bone conduction device, the Sophono system, the bone anchored hearing aid, the bone conduction implant and finally the SoundBite system will be presented and partly summarized from Håkansson (2011). The advantages and drawbacks of each device will be shortly discussed.

3.1 Transcutaneous bone conduction devices - vibrations through the intact skin

3.1.1 The conventional bone conduction device

In air conduction hearing aids, the sound is collected from the environment by a microphone and then is fed into the amplifier and sound processor. The amplifier will increase the intensity of the sound to a desired level and then the processed sound will be sent into the output transducer, which is a miniature loudspeaker.

In contrast, a conventional bone conduction hearing device has the same microphone, processing and amplifier parts as the conventional AC hearing aids, except that the transducer replaced by a bone conduction transducer. The BC transducer can be connected to a flexible headband or onto the earpiece of a pair of eyeglasses. As the vibrations here are transmitted through

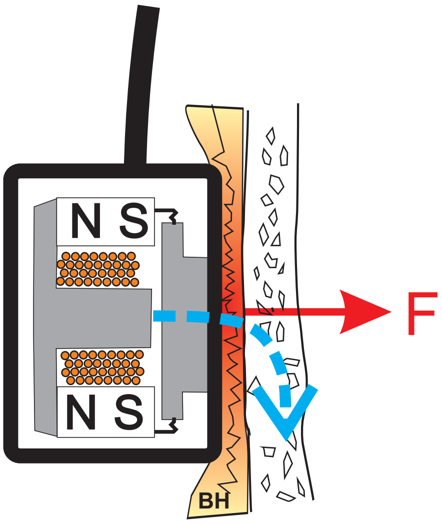

Figure 3.1: Conventional bone conduction device with static pressure force (F) against the patient's skin sometimes referred to as transcutaneous BC. The blue dash arrow represents the vibration transmission path from the transducer, through the skin and soft tissue into the skull.

the skin and subcutaneous tissue, this mode of transduction often is referred to as transcutaneous BC. The primary and major problem with conventional BC hearing devices, headband as well as those applied with the frames of a pair of glasses, is related to a static pressure force (F) of a couple of Newton towards the skin and soft tissue that is needed to transmit the vibration energy (see Figure 3.1). This often gives the patient discomfort and the skin will suffer from circulatory problems and sometimes irritation and eczema will develop. Recent developments to use low capillary pressure show how these comfort aspects can be improved (Raicevich et al., 2008). Developments have been done by a Danish company Ortofon (http://ortofonmicrotech.com) using a new smaller BC transducer based on the Balanced Electromagnetic Separation Transducer (BEST) principle (Håkansson, 2003). A secondary problem is related to the dampening effect of the skin that attenuates the transmission sensitivity at higher frequencies, essentially over 2 kHz. This reduces the electroacoustical function of the aid (Håkansson et al., 1984). Yet another problem is related to feedback, where the aerial sound is radiated from the transducer back to the microphone; this causes howling and ringing sound (oscillations) and as a consequence the microphone must be placed on a safe distance from transducer.

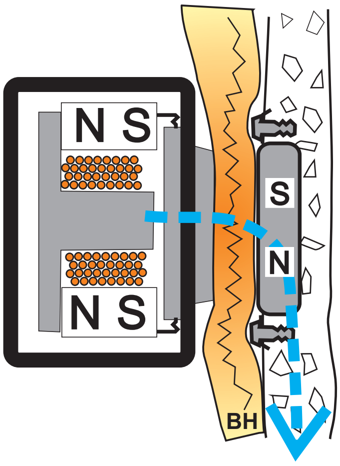

Figure 3.2: The Sophono system with a conventional external BC transducer that is held in place by use of an implanted retention magnet system.

3.1.2 The Sophono system

A new partially implantable bone conduction device without a percutaneous abutment is suggested by Siegert (2011) known as the Sophono (originally Otomag) system, as principally illustrated in Figure 3.2. The principle of this bone conduction device is a magnetic coupling and acoustic transmission between implanted and external magnets. In this system there are two separate magnet systems. The transducer has its own magnet system that is optimized for maximum electromechanical transduction generically identical to the transducer used in conventional BC. The implanted magnet system is thus solely used for retention of the external transducer with the intact skin in between. It should be noted that vibrations of transducer case or plate are still transmitted by vibrations through the soft tissues (reduced to 4-5 mm thickness, Siegert (2011)) and hence it is a trancutaneous BC device. As a consequence one might expect that there is a high frequency transmission loss of energy like as in conventional BC relative to a percutaneous system. One might also expect that the skin in the contact area is under constant pressure, which might cause some wearing comfort problems and that there is a potential risk for circulatory problems.

However, this system might be an alternative to a conventional BC system as the externally worn transducer here is more precisely attached to one and the same spot of the patient's skull bone day after day. This system might be more aesthetically appealing than a conventional BC device as no steel spring is needed. As usual one has to balance these potential advantages against the more invasive surgery required and increased cost.

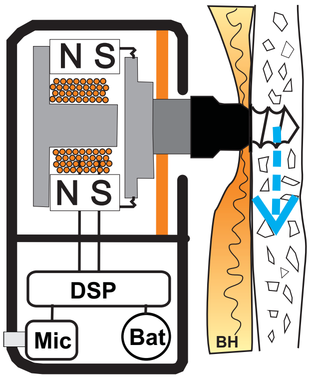

Figure 3.3: Principal design of a generic percutaneous bone anchored hearing aid (BAHA) with a screw attachment to the skull bone. Moreover, it comprises a microphone (Mic), battery (Bat) and pre and power amplifier (Amp) that drives the bone conduction transducer.

3.2 The bone anchored hearing aid (BAHA)

As an alternative to the conventional BC hearing devices a permanent skin penetration has made it possible to develop a bone anchored hearing aid (BAHA) with all components in one housing. The BAHA has a titanium fixture that is anchored to the skull bone and the output transducer is coupled to the implant. The sound is transmitted directly from the vibrator to the skull bone (Håkansson et al., 1985). This type of vibration transmission obtained with the BAHA is sometimes referred to as "Direct Bone Conduction" (DBC). DBC hearing opened possibilities for an improved rehabilitation of these patients both in terms of wearing comfort and sound quality (Håkansson et al., 1990; Tjellström et al., 2001). Figure 3.3 illustrates the principal design of the BAHA device. Today, the BAHA is the "golden standard" in many countries for patients with chronic middle ear diseases and congenital malformations, and who cannot use air conduction hearing aids. A summary of the current candidacy criteria, and audiological and surgical considerations of the present BAHA system, is given by Hodgetts (2010). Even though there are very good long term rehabilitation results reported with the BAHA (see for example Snik et al. (2005)), there are also some known associated drawbacks.

One main drawback is related to the fact that the skin penetration site needs lifelong daily care. Some patients may acquire a skin reaction with persistent infection and also granulation tissue may be formed that requires surgical revision or re-implantation. Also, the bone anchored fixture can be lost spontaneously or as a result of trauma. There are a number of potential BAHA patients that reject a BAHA because they cannot accept a skin penetration implant for stigma reasons. See also (Tjellström and Granström, 1994; Myers et al., 2000; Battista and Littlefield, 2006; Shirazi et al., 2006; Wazen et al., 2011; Dun et al., 2012) for a more detailed description of potential complications associated with the permanent skin penetration. Finally, it should be mentioned that the gain of the BAHA has been reduced to maintain stability; this implies that the gain headroom is lower than desired.

3.3 The bone conduction implant (BCI)

As an alternative to the percutaneous BAHA device, a novel solution called the bone conduction implant (BCI) device has been proposed and developed (see Paper I). A principal design of a trancutaneous direct bone conduction device with an implanted transducer is shown in Figure 3.4. The generic feature of these systems is that the skin is kept intact and it is the sound signal that is transmitted transcutaneously by a magnetic inductive system from the external processor to the implanted transducer that is attached directly to the skull bone. Hence, it is the electric/magnetic signal that is transmitted transcutaneously (not the vibration) and the vibrations are still induced directly to the skull bone with DBC like in the BAHA.

In Paper II, Taghavi et al. (2012a) has proposed an analog RF data and power link design for the BCI first generation to produce the highest possible output force level and reasonable robust power transmission for different skin thicknesses.

In principal a BCI system can have an active or a passive drive of the implanted transducer. In an active drive system, not only the signal is transmitted, but also the electric power to supply the implanted active circuits, like in cochlear implants. In the passive drive systems the modulated signal is transmitted, and then after demodulation it drives the transducer directly. An active drive system will be more complex than a passive system but it may be possible to drive a higher current into the transducer that way. However, if the power is sufficient in terms of hearing level produced there is an advantage to have a passive system as it will be less complex, more reliable and also cheaper. Obvious technical challenges with this type of system are related to:

- placement and type of attachment of the implanted transducer,
- design of the implanted transducer,
- design of the RF inductive link, and

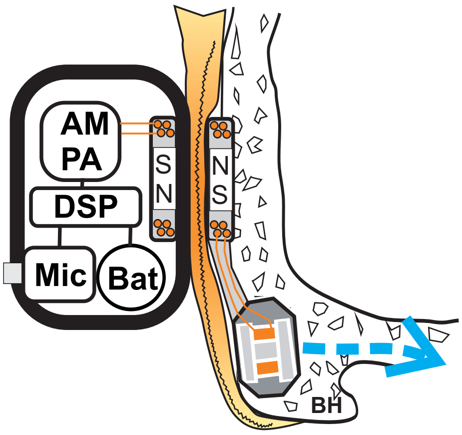

Figure 3.4: The BCI system with an implanted and capsuled bone conduction transducer with a flat surface contact to the skull bone. It comprises also an inductive link and an externally worn audio processor.

- design of the RF power driver.

It was discussed that this system will suffer from "losing too much power in the inductive link", "difficulties to screw attach the transducer" and "vulnerability and too big a size of the implanted transducer". However, several studies have shown different challenges where the results look promising (Håkansson et al. (2008); Håkansson (2011); Paper I). It has been shown in Paper I on cadavers that the sensitivity to bone-conducted sound would increase if the excitation point approaches cochlea, which is the case in the BCI device position comparing with the BAHA position (Stenfelt et al., 2000; Stenfelt and Goode, 2005; Eeg-Olofsson et al., 2008). Moreover, it was shown by Taghavi et al. (2012b) in Paper III that the BCI device has an improved gain headroom compared with the BAHA.

3.4 In the mouth bone conduction system

It is well-known that BC sound can be induced by the transducer attached to the teeth. Also, a significant part of the own voice is heard via the teeth and jaw (Reinfeldt, 2009) so this route is definitely viable for transmission of bone conducted sound.

The major advantage to attach the transducer to the teeth for long term hearing rehabilitation compared with other DBC systems is that it is completely non-invasive. Several companies have announced that they have developed this idea further e.g. Sonitus Medical (http://www.sonitusmedical.com). Their SoundBite system, now commercially available in the US, consists of

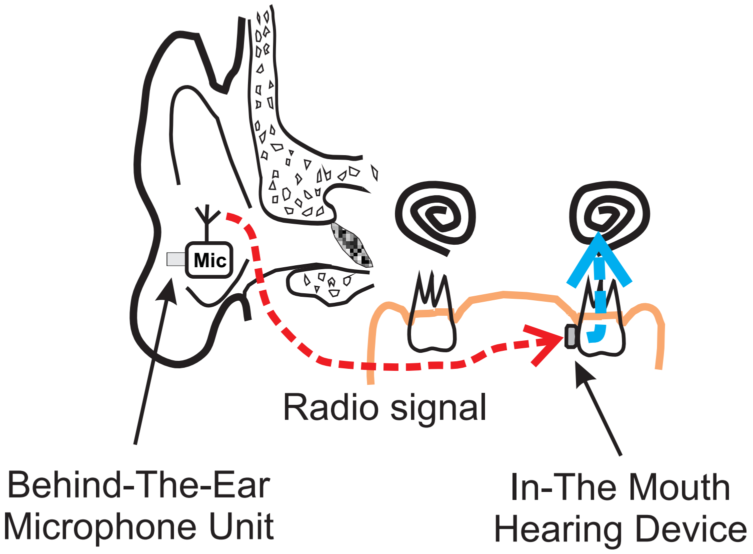

Figure 3.5: SoundBite device. The sound is picked up by an external microphone, worn behind the ear and then is transmitted wirelessly to the (In-The Mouth) hearing device attached to the teeth. The piezoelectric transducer converts the sound to vibrations that travel via the teeth, through the bone to the cochlea.

a transducer that is applied to the upper left or right back teeth, principally illustrated in Figure 3.5. It should also be noted that the sound here has to be picked up by an external microphone, preferably worn behind the ear as also illustrated in Figure 3.5. This microphone should then transmit the sound wirelessly to the internal device attached to the teeth. Initial evaluations of this system have been made by Popelka (2010) and Popelka et al. (2010).

Whereas this idea from an electro acoustical point of view will work, one might be wondering how convenient it will be to wear the device in the mouth during one normal day. For single sided deafness patients this device may from acoustical point of view be a good alternative as these patients only need high frequency gain to overcome the head shadow effect and in that frequency range the transducer can be designed to consume less power. If this device should be aimed for those having conductive and mixed hearing loss, there might be a power issue at low frequencies. The SoundBite transducer has a relative low power output below 1 kHz as compared to the BAHA and the BCI systems (see Fig 2 in Popelka et al. 2010).

Chapter 4

Summary of papers

4.1 Engineering aspects and preclinical studies of the BCI (Paper I)

Percutaneous bone anchored hearing aids (BAHA) are today an important rehabilitation alternative for patients suffering from conductive or mixed hearing loss. Despite their success, they are associated with drawbacks such as skin infections, accidental or spontaneous loss of the bone implant, and patient refusal for treatment due to stigma. A novel bone conduction implant (BCI) system has been proposed as an alternative to the BAHA system because it leaves the skin intact. Such a BCI system has now been developed and the encapsulated transducer uses a non-screw attachment to a hollow recess of the lateral portion of the temporal bone. The aim of this study was to describe the basic engineering principals and some preclinical results obtained with the new BCI system. Laser Doppler vibrometer (LDV) measurements on three cadaver heads showed that the new BCI system produces 0-10 dB higher maximum output acceleration level at the ipsilateral promontory relative to conventional ear-level BAHA at speech frequencies. At the contralateral promontory the maximum output acceleration level was considerably lower for the BCI than for the BAHA.

In short, when comparing the "acoustically" generated frequency responses between the different devices only the maximum power output (MPO) gives an adequate comparison of the potential capacity of the systems. At levels below the MPO the response curves in each device can be changed by amplifier settings in a multitude of ways. Therefore, only the MPO velocity difference (BCI vs. Baha® Classic and BCI vs Baha® Intenso) at the ipsilateral and contralateral side were calculated as the average among the

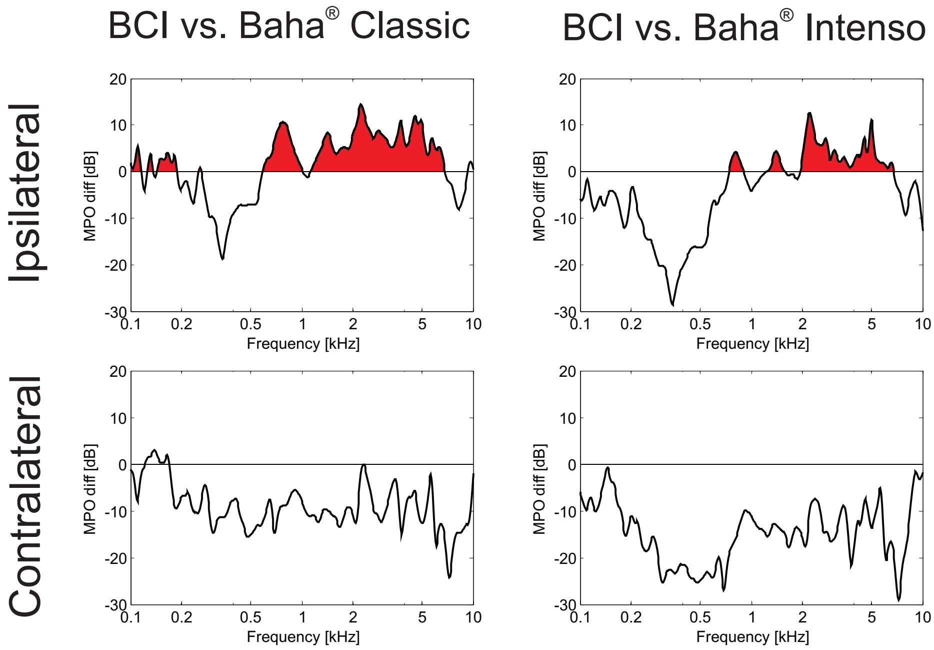

Figure 4.1: Ipsilateral and contralateral average (three subjects) MPO difference as BCI vs. Baha® Classic (left), and BCI vs. Baha® Intenso (right).

subjects. The results are presented in Figure 4.1. The improvements (red area) in acoustic response curves at MPO (average among the three subjects) indicate what will be experienced by the patients regarding maximum loudness with each device. Hence it seems from ipsilateral measurements that the BCI will be 5-10 dB stronger than the Baha® Classic and 0-5 dB stronger than the Baha® Intenso for frequencies 700 Hz to 7 kHz. At the contralateral side, however, it was found that the BCI produced a considerably lower MPO than the Baha® Classic as well as the Baha® Intenso.

4.2 Analog RF data and power link design (Paper II)

The bone conduction implant (BCI) is designed as an alternative to the percutaneous BAHA, because it leaves the skin intact. It comprises an external audio processor and an implanted unit called the BCI Bone Bridge. Sound is transmitted to the implant via an inductive radio frequency (RF) link through the intact skin using amplitude modulation.

This paper presents an analog RF data and power link design as a first implementation for the BCI. The RF link is designed to operate in critical

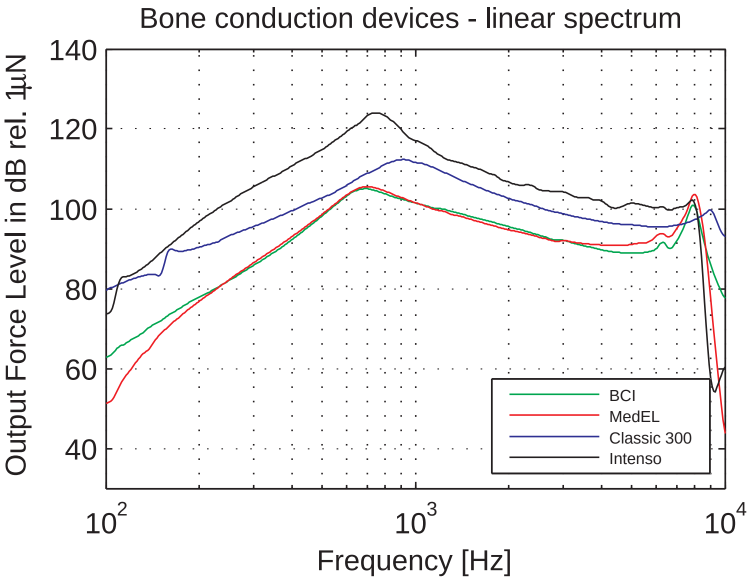

Figure 4.2: Comparison of output force level between implantable bone conduction devices when measured on a Skull simulator.

coupling to transmit maximum power to the implant. Maximum power output of the BCI was measured at 2 mm skin thickness and was found to be 105 dB relative to 1 μN at the transducer resonance frequency. This output force is fairly robust in 2 to 6 mm skin thickness range.

Consequently, Figure 4.2 presents a comparison of the BCI with existing bone conduction devices and a middle ear audio processor driving a naked BEST transducer. MPO curves of the Baha® Classic 300, the Baha® Intenso and the MedEl audio processor loaded by the BCI Bone Bridge were measured. A 2 mm coil spacing was used in the BCI and the MedEl measurements. Most importantly, the BCI with the analog RF drive can generate the same MPO as the MedEl device that uses some kind of switching drive circuit topology. Both devices use RF links that keeps the skin intact whereas the Intenso and Classic 300 are percutaneous bone anchored devices as they are directly coupled to the bone or the Skull simulator.

By comparing the BCI with Classic 300, it can be concluded that this first RF link design results in a loss of 10-15 dB in the output force of the device when measured on a Skull simulator. On the other hand it was shown by Håkansson et al. (2008) and in Paper I, measuring with laser Doppler vibrometer (LDV) on cadaver heads that the sensitivity to bone conducted sound increases with the same amount or more when the excitation point of the device moves to a position closer to the cochlea, which is the case in the BCI.

4.3 Feedback in the BAHA and the BCI (Paper III)

The hypothesis in this study was that the bone conduction implant (BCI) can use a higher gain setting without feedback problems as compared with a percutaneous bone anchored hearing aid (BAHA). It was experienced in previous cadaver studies by Håkansson et al. (2008) and in Paper I that the BCI is less prone to fall into feedback oscillations thus allowing more high frequency gain. It should be noted that the notation PBCD (stands for percutaneous bone conduction device) is used in the US journals synonymous to the BAHA mainly for reimbursement issues.

In this study, loop gains of the Baha® Classic 300 (most used linear BAHA from Cochlear Bone Anchored Solutions, Mölnlycke, Sweden) and the BCI were measured in the frequency range of 100 Hz to 10 kHz with the devices attached to a Skull simulator and a dry skull. The BAHA and the BCI positions were investigated. The devices were adjusted to Full-on Gain (maximum volume control setting). It was found that the gain headroom using the BCI was generally 0-10 dB better at higher frequencies than using the BAHA for a given mechanical output. More specifically, if the mechanical output of the devices were normalized at the cochlear level, the improvement in gain headroom with the BCI versus the BAHA was in the range of 10-30 dB. It was concluded that when using a BCI, a significantly higher gain setting can be used without feedback problems as compared with using a BAHA.

In the overall analysis, Figure 4.3 shows the BAHA loop gain and the BCI loop gain compensated once for the same mechanical output and to give the same cochlear acceleration as the BAHA, which gives additional 0-25 dB more gain headroom as compared with the BAHA. It can be observed that the compensated BCI for the same cochlear acceleration level has 10-30 dB higher gain headroom than the BAHA in the range of 600 to 7500 Hz. The gain headroom improvement at the critical frequency is 17 dB. The improved gain headroom indicates how much the amplification can be increased with the BCI device, as compared with the BAHA, without obtaining feedback oscillations. Recall for improving the high frequency gain in the BAHA (which is now inherently limited by feedback) as compared with conventional air conduction devices, this improved gain headroom with the BCI may show to be of great clinical value.

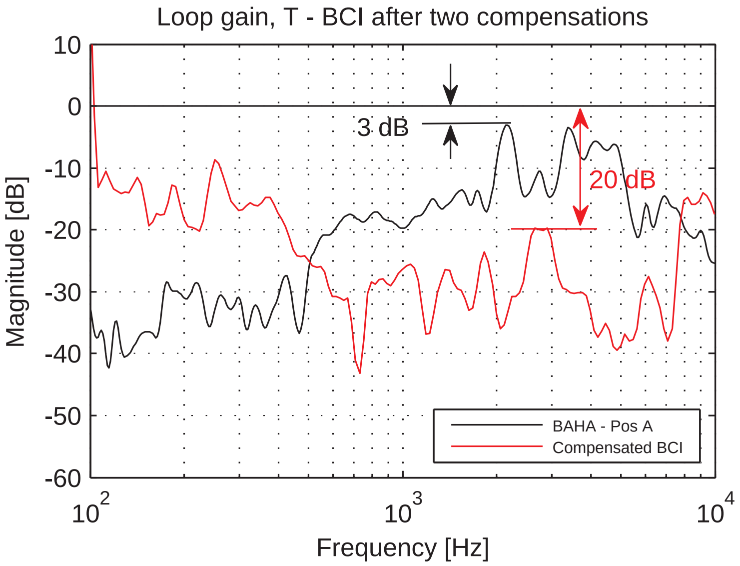

Figure 4.3: The BAHA and the compensated BCI loop gain magnitudes on dry skull. BCI compensations were done to obtain the same cochlear acceleration level as the BAHA.

4.4 RF power and data link using AM of the Class-E (Paper IV)

This paper presents an efficient technique for analysing and designing the RF power and data link for a novel bone conduction implant (BCI) system. Patients with pure conductive hearing loss, mixed hearing loss and single sided deafness can be rehabilitated by bone anchored hearing aids (BAHA). Whereas the conventional hearing aids transmit sound to the tympanic membrane via air conduction, the BAHA transmits sound as vibrations via the skull directly to the cochlea. The novel BCI is developed as an alternative to the percutaneous BAHA device since it leaves the skin intact. The BCI comprises an external audio processor unit with a radio frequency (RF) transmitter coil and an implanted unit called the BCI Bone Bridge, which also has a RF coil that is implanted inside the body. A Class-E tuned power amplifier drives the RF inductive link. Using Amplitude Modulation (AM) of the Class-E power amplifier, the sound signal is transmitted to the implanted unit through the intact skin. Maximum power output (MPO) of the BCI was designed to occur at 4 mm skin thickness. The power output variability for 1 to 8 mm skin thickness variations was within 1.5 dB. Maximum MPO was found to be 109 dB relative to 1 μN at the transducer resonance frequency. The battery current consumption of the BCI was 14.6 mA at 1 kHz and 65

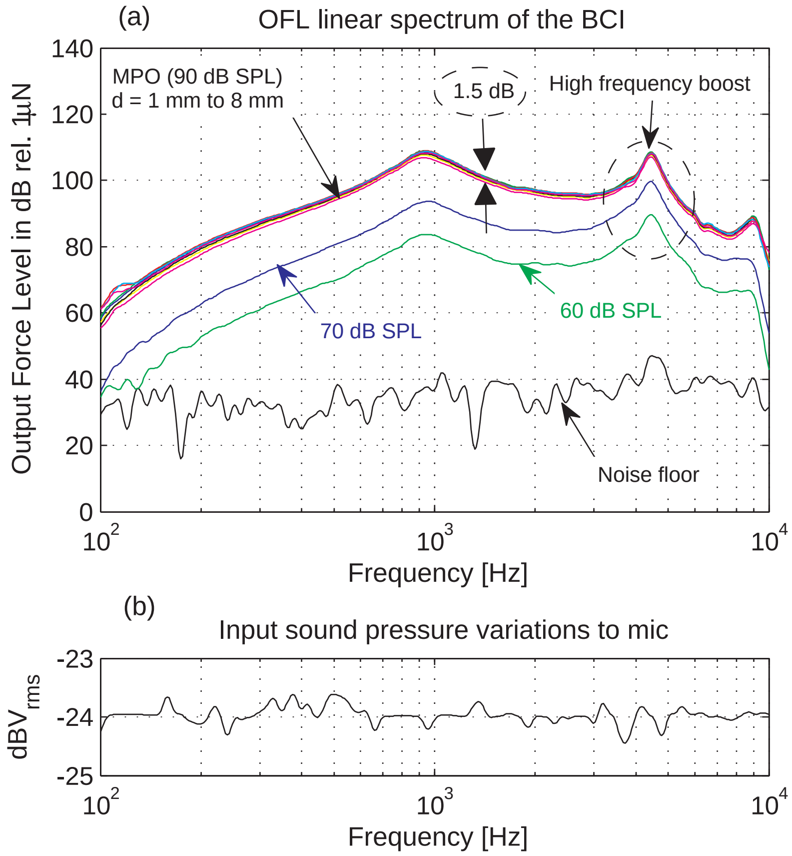

Figure 4.4: (a) Output force levels measured at 60, 70 and 90 dB SPL. MPO curves were measured where the coil spacing was varied from 1 to 8 mm. Highest MPO occurs in the 4 mm skin thickness. The noise floor curve shows that the measurements were done with a high SNR. Between 4-5 kHz the BEST transducer has a second resonance frequency to boost the high frequency response. (b) The sound pressure was kept fairly constant during the entire frequency sweep (±0.5 dB).

dB input sound pressure level (SPL). The acoustical performance of the BCI device is shown in Figure 4.4(a).

As a result, output force levels (OFL) of the BCI were measured at 60, 70 and 90 dB SPLs where the 60 and 70 dB SPL curves reveal that the device is linear as 10 dB increase in the input sound pressure level results in 10 dB increase in the output force level. The most important curve is the maximum power output when the device is saturated and limited by the battery voltage capacity at the output. The MPO curves were also measured for different coil spacing (skin thickness). It can be seen that the MPOs will change 1.5

dB over the skin thickness range of 1 to 8 mm. It is illustrated that the new BEST design has the high frequency boost that can be beneficial for speech understanding. Furthermore, it is illustrated in Fig. 4.4(b) that the input sound pressure to the microphone was fairly constant and changing only ±0.5 dB in the entire frequency sweep.

Chapter 5

Conclusions and future work

The purpose of this thesis was to investigate the feasibility of designing and implementing an efficient wireless power and data transmission system for the BCI device. The most important factor was that the efficient transmitter design can deliver high enough power to the implanted transducer. Two main areas in this respect were explored in this study.

First, better understanding and designing efficient radio frequency inductive links for the power and signal transmission was performed. The effects of the coupled resonators and loss mechanisms for transferring energy through the intact skin assisted in the design of the RF links were studied.

Then it was very important to design the inductive link power driver to be efficient and fairly insensitive to variations in the transmitter circuit impedance and quality factor as the skin thickness (coupling between coils) changes between patients. Analog linear power amplifier and Class-E switching tuned RF power amplifier with minimized switching losses were implemented and investigated.

Furthermore, during development of the BCI and particularly in previous cadaver studies (Håkansson et al. (2008); Paper I), it has been noted that the BCI device was less prone to fall into feedback problems than the BAHA especially at higher frequencies. Therefore, an investigation was done to measure the gain headroom (how much extra gain can be provided before the device will oscillate) in the BCI and in a generic bone anchored hearing device.

- In Paper I, it was generally concluded that the generic design of the BCI can be a realistic alternative to a percutaneous BAHA. One obvious advantage is that no permanent skin penetration is needed. However, more investigations are required to prove that this new approach will acoustically as well as medically work at least as good as the BAHA in a clinical setting. Most importantly, the BCI had 5-10 dB higher ipsilateral MPO promontory acceleration level than the Baha® Classic in the frequency range 700 Hz to 7 kHz. The BCI had approximately 0-5 dB higher ipsilateral MPO promontory acceleration level than the Baha® Intenso in the frequency range 700 Hz to 7 kHz. The contralateral MPO promontory acceleration levels are generally approximately 10-15 dB lower for the BCI than for the Baha® Classic and Baha® Intenso. The results in this study indicates that the screw attachment used in previous studies can be replaced with a flat surface attachment under a static force, this attachment has a lower profile and is relatively easy to install. It was concluded that the BCI did not suffer from feedback problems in this setting for the preset gain whereas neither the Baha® Classic nor the Baha® Intenso could be used at a full volume setting (volume 3) because of feedback. The feedback was also investigated in another study, which is published in Paper III.

- In Paper II, a first generation of the BCI device with a transcutaneous analog RF link was developed. It was concluded that the BCI device can generate enough output force level for the indicated patients who cannot use conventional air conduction or bone conduction hearing aids. This analog design is still sensitive to skin thickness variations and needs a better power amplifier design to prevent saturation of the output transistor. Therefore, to get higher efficiencies and robustness in the RF link sensitivity, switching topologies such as Class-E and Class-D tuned power amplifiers will be developed. These topologies may also use a series tuned RF link instead of a parallel tuned tank circuit that was used in this study.

- In Paper III, the gain headrooms of the BCI and the BAHA were investigated. In cadavers studies it has been noticed that the BCI was less prone to fall into feedback problems than the BAHA devices. Hence this study was performed to investigate feedback in the BAHA and the BCI. It was concluded that the BCI had an improved gain headroom of 10-30 dB versus the BAHA, if the mechanical output of the devices were normalized at the cochlear level. More specifically the improvement in gain headroom at the most critical frequency was 17 dB. One reason for the improvement might be due to the higher mechanical point impedance of the position B (BCI) compared with position A (BAHA), which implies that less sound is radiated for a given force level. Another explanation might be that the transducer in the BCI is completely encapsulated and is mechanically separated from the microphone in the audio processor. The improved gain headroom will allow a possibility to increase the real gain of the BCI compared to the BAHA. This may have a significant clinical importance for the hearing rehabilitation of patients. Finally, it was concluded that the BCI was less prone to fall into feedback problems than the BAHA, but these tests should also be conducted on real patients to confirm the clinical benefits.

- In Paper IV, it was concluded that the BCI with a properly designed Class-E power amplifier
  - can generate high enough output force level for candidate patients as compared to conventional BAHA devices,
  - is fairly insensitive to skin thickness variations for power transmission to the implant, and
  - has acceptable current consumption especially in relation to maximum power output.

The second generation of the BCI device presented in the Paper IV, consumes high battery current in low SPLs due to the high quiescent currents of the filtering circuitry and the gate-driver. In future work, the filtering and gate-driver circuitry as well as the power amplifier will be designed in an application specific integrated circuit (ASIC). Since the Class-E power amplifier behaves more like a current source than a voltage source, other amplitude modulation topologies will be tested using Class-D or Class-DE, which operate as voltage sources. To improve the efficiency of the BCI in silence and in low SPLs, a second modulation can be used for reducing the current consumption of the device.

The most important next step of the BCI project is to implant the device in a patient and investigate the performance of the BCI device. Then, more investigations are required to show that the BCI system will acoustically as well as medically work at least as good as a BAHA in a clinical setting.

On the other hand, Magnetic Resonance Imaging (MRI) can affect the implanted unit of the BCI; this should also be studied. Investigations are needed to clarify adverse effects by MRI on the implant, on the patient and on the image generated. Possible solutions to minimize these adverse effects will be studied.

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