Thesis for the Degree of Licentiate of Engineering

Direct Drive Bone Conduction Stimulation: Experimental Studies on Functionality and Transmission

with Focus on the Bone Conduction Implant

Cristina Rigato

CHALMERS

Department of Electrical Engineering
Division of Biomedical Engineering
Chalmers University of Technology

Göteborg, Sweden 2017

Direct Drive Bone Conduction Stimulation: Experimental Studies on Functionality and Transmission

with Focus on the Bone Conduction Implant
CRISTINA RIGATO

Technical report number: R011/2017
ISSN 1403-266X

Department of Electrical Engineering
Division of Biomedical Engineering
CHALMERS UNIVERSITY OF TECHNOLOGY
SE–412 96 Göteborg
Sweden
Telephone: +46 (0)31 – 772 1000
Email: rigato@chalmers.se

Front Cover: 3D model of a human skull, created by the author with Blender 2.79 (Blender Foundation, Amsterdam, The Netherlands).

Typeset by the author using LaTeX.

Chalmers Reproservice
Göteborg, Sweden 2017

A chiunque contribuisca a farmi sorridere

Abstract

Sound is conducted to the inner ear in two ways: by air and by bone. Air conduction (AC) hearing consists of sound waves entering the ear canal and reaching the cochlea, the main hearing organ, via the middle ear. In bone conduction (BC) hearing, instead, the transmission is through soft tissues and bone. These two pathways coexist and complement each other, although in normal hearing subjects the AC part is prevalent over the BC part in most of the ordinary hearing situations.

BC hearing can represent an effective way to rehabilitate hearing impaired patients who would not benefit from conventional AC hearing aids. This is the case when the hearing impairment is located in the outer or middle ear, or if the patients have chronic infections or malformations preventing them from wearing earmolds. The key idea in bone conduction devices (BCDs) is to generate vibrations with a transducer and transmit them via the skull bone to the inner ear.

At present, the most common BCD is probably the bone anchored hearing aid (BAHA), consisting of a single-unit device attached to a skin penetrating screw in the parietal bone. To overcome the issues related to the skin penetration, the development of BCDs is recently focusing on so-called active transcutaneous devices, whose main feature is to have the bone transducer implanted under intact skin.

In this thesis, the novel active transcutaneous bone conduction implant (BCI), currently in advanced clinical trial phase, was compared to BAHAs in terms of audiological tests and perceived rehabilitation effect. The outcomes showed that the BCI can be a valid alternative to BAHAs for indicated patients.

Preliminary investigations were also performed on how the transmission of vibrations is affected by different ways of attaching the transducer to the skull bone. It was found that the relation varies substantially with frequency, with a general trend of improved transmission when the contact area between transducer and bone is limited.

Finally, a new verification method of the implant functionality was evaluated intra- and post- operatively. The method, consisting in the measurement of the sound pressure in the nostril, seems promising and the implant to bone transmission was found stable over time.

Key words: Bone Conduction, Bone Anchored Hearing Aids, Bone Conduction Implant, transcutaneous, vibrations, audiological tests, comparative study

Preface

This thesis is in partial fulfilment for the degree of Licentiate of Engineering at Chalmers University of Technology.

The work resulting in this thesis was carried out between April 2014 and September 2017 at the Division of Signal Processing and Biomedical Engineering, Department of Electrical Engineering, Chalmers. Associate Professor Sabine Reinfeldt is the main supervisor and examiner. In addition, Professor Bo Håkansson (Chalmers University of Technology), Associate Professor Måns Eeg-Olofsson (The Sahlgrenska Academy, University of Gothenburg) and Doctor Myrthe K S Hol (Radboud University Medical Centre, Nijmegen, Netherlands) are the co-supervisors.

The main financial support for this work comes from the Swedish Research Council (VR) and the Hearing Research Foundation (HRF).

Acknowledgements

Time to say *thank you*. So many names and faces in my mind... maybe I should just leave this page blank, to be fair and not to forget anyone... no, that's not my style. Let's get this started.

First of all, Sabine. You are a great supervisor and woman, combining leadership and kindness as very few people are capable of. Next is Bosse. Your knowledge and your experience are so inspiring and valuable, and it's always pleasant to talk with you, whether it's about work or free time. Måns, I truly admire your dedication and skills, combining clinical work and research and yet finding some time for being a great co-supervisor, with your straight-to-the-point way of giving feedback which I really appreciate. To complete the co-supervisors list, Myrthe: even if it only happens from time to time, it's lovely to meet you and get inspired by your expertise and strong character. I'd finally like to thank Karl-Johan for being always very helpful, especially in the lab, and Filip, for coming all the way from Stockholm to join our group and for being always so positive and cheerful.
I'd like to thank you all also for the language support, for training me and being patient when speaking Swenglish with me. And thanks for that little lie you say every time you define my Swedish *imponerande*!

Another person I definitely want to thank is Hana Trefna, for making my Master's thesis work a fun experience, encouraging me to stay in academia, and for all the conversations we have standing on the doorway! When I started this PhD project, everything was new and I would have had such a hard time without the help from everyone in the group, and especially from Hamid. Unfortunately you are not in our group anymore, but I really want to thank you for being so supportive and showing me everything I needed to have a smooth start in this field.
Without naming each single person, I would like to thank everyone at the department for their contribution in creating such a lively environment to work in. Thank you for the small talks at the coffee machine or in the corridors, for the fikas and lunches together and for stopping by even just a couple of minutes when passing in front of my ever-open office door.

Now it's time for family. Mamma e papà, non ho parole per descrivere quanto vi sono grata, ma probabilmente non serve, perché lo sapete già. O almeno spero. Grazie per essere sempre al mio fianco, che sia fisicamente o no, ci siete sempre. E grazie per tutti gli aerei che avete preso e che prenderete. Sorellina, grazie anche a te, per il bel rapporto che abbiamo, per tutte le volte che ci lasciamo un po' andare, perché poi alla fine lo sappiamo entrambe che non dura molto.
È importante avere dei punti di riferimento, e voi lo siete per me, sempre.

Now you, Murad. I don't even know where to start from. Just thank you for everything really, for the person you are and for being my perfect half. Thank you for your (almost) infinite patience, for the way you handle me when I'm not in my best mood, for being more thoughtful than I could even wish, and for all the big and small things you do that make it so easy and fun to live with you, every single day.

I want to thank all friends and sport mates for spending fun time together outside of work, because research is exciting and stimulating, but life out there is as well!
To conclude, I'd like to thank goats. Yes, because I like to believe that if I am in this position now, it is also partly thanks to my love for goats. I know most people won't understand this statement, but I wish at least a couple will!
Time to put an end, otherwise who am I going to thank in the final thesis? I'll just conclude by thanking everyone that I did not mention explicitly but who contribute to making my everyday life a bit more fun. Over and out!

Cristina

List of Publications

This thesis is based on the work contained in the following appended papers:

Paper I
"Audiometric Comparison Between the First Patients With the Transcutaneous Bone Conduction Device and Matched Percutaneous Bone Anchored Hearing Device Users", Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Myrthe K.S. Hol, and Måns Eeg-Olofsson *Otology and Neurotology*, vol. 37, no. 9, pp. 1381–1387, 2016.

Paper II
"Direct Bone Conduction Stimulation: Ipsilateral Effect of Different Transducer Attachments in Active Transcutaneous Devices", Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Erik Renvall, and Måns Eeg-Olofsson. Submitted to *Hearing Research*, 2017.

Paper III
"Nasal Sound Pressure as Objective Verification of Implant in Active Transcutaneous Bone Conduction Devices", Sabine Reinfeldt, Cristina Rigato, Bo Håkansson, Karl-Johan Fredén Jansson, and Måns Eeg-Olofsson. *Manuscript*, 2017.

Other publications by the author not included in the thesis:

"Magnetic Resonance Imaging Investigation of the Bone Conduction Implant - a Pilot Study at 1.5 Tesla.", Karl-Johan Fredén Jansson, Bo Håkansson, Sabine Reinfeldt, Cristina Rigato,and Måns Eeg-Olofsson. *Medical devices (Auckland, N.Z.)*, vol. 8, pp. 413-23, 2015.

Parts of Paper I and Paper II have been presented by the author in conferences as follows:

- Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, and Måns Eeg-Olofsson (2015). "Audiometric results of the Bone Conduction Implant: a comparative study with the Bone Anchored Hearing Aid", TeMA Hörsel 2015, Malmö, Sweden.

- Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, and Måns Eeg-Olofsson (2015). "Audiometric comparison in BCI and BAHA matched patients", Osseo 2015 5^{th} International Congress on Bone Conduction Hearing and Related Technologies, Lake Louise, Alberta, Canada.

- Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, and Måns Eeg-Olofsson (2016). "Audiometric comparison between Bone Anchored Hearing Aid and Bone Conduction Implant", AudiologyNOW!2016, Phoenix, Arizona (USA).

- Cristina Rigato (2017). " Effect of transducer attachment on bone conducted vibrations", Svensk Teknisk Audiologisk Förening (STAF), Göteborg, Sweden.

- Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Erik Renvall, and Måns Eeg-Olofsson (2017)."Direct bone conduction stimulation: effect of different transducer attachments", Osseo 2017 6^{th} International Congress on Bone Conduction Hearing and Related Technologies, Nijmegen, The Netherlands.

Abbreviations and Acronyms

ABG	Air-Bone Gap
ABR	Auditory Brainstem Response
AC	Air Conduction
APHAB	Abbreviated Profile of Hearing Aid Benefit
BAHA	Bone Anchored Hearing Aid
BC	Bone Conduction
BCD	Bone Conduction Device
BCI	Bone Conduction Implant
BEST	Balanced Electromagnetic Separation Transducer
dB	deciBel
dB HL	deciBel Hearing Level
dB SPL	deciBel Sound Pressure Level
ECSP	Ear Canal Sound Pressure
GBI	Glasgow Benefit Inventory
LDV	Laser Doppler Vibrometer
MRI	Magnetic Resonance Imaging
NSP	Nasal Sound Pressure
OAE	Otoacoustic Emission
Pa	Pascal
PTA	Pure Tone Average
SDT	Speech Detection Treshold
SNR	Signal to Noise Ratio
SRS	Speech Recognition Score
SRT	Speech Recognition Treshold
SSD	Single Sided Deafness
TM	Tympanic Membrane

Contents

Part I

Introductory Chapters

Chapter 1

Introduction

This thesis focuses on hearing rehabilitation with transcutaneous bone conduction devices, partly evaluating their performance and partly investigating specific aspects that may lead to improvement of their design.

Hearing impairment is one of the most widespread disabilities worldwide, with more than 5% of the total population suffering from disabling hearing loss [1]. In Sweden, approximately 1.4 million inhabitants are affected and, among them, 445 000 are fitted with a hearing aid, according to what reported by HRF (Hörselskadades Riksförbund), the Swedish Association of Hard of Hearing People [2]. The need for high quality diagnosis and rehabilitation in this field is massive. Although hearing impairment is often associated with ageing in the collective imagination, there are different types of hearing loss and they need to be treated in different ways.

This thesis focuses on rehabilitation for patients with conductive and mixed hearing loss, i.e. when the dysfunction is located in the outer or middle ear. In normal hearing subjects, most of the acoustic signal is effectively transmitted via the conventional airborne route, with the sound waves entering the ear canal, vibrating the eardrum and finally reaching the cochlea through the middle ear ossicle chain. When something along this transmission pathway is not working properly, there is another physiological way of hearing that can be exploited for rehabilitation: bone conduction (BC). In fact, it is well known since long time that vibrations transmitted through the skull bone are capable of stimulating the cochlea to evoke a hearing sensation [3]. This phenomenon is referred to as BC hearing.

Making use of BC hearing, bone conduction devices (BCDs) have been developed and their use for rehabilitation has increased during the last few centuries. There are several models available on the market today, from fully externally worn ones to semi-implantable solutions [4]. The two main components of any BCD are the audio processor and the bone transducer. The first one is to pick up the sounds from the listening environment and amplify them, and the second one to transform the sound into vibrations to be transmitted to the skull.

Today, one of the most widespread and effective bone conduction rehabilitation devices on the market is the bone anchored hearing aid (BAHA), where both microphone and transducer are housed in the same casing, together with all the required electronics. This audio processor is snapped onto an abutment that penetrates the skin and is anchored directly on the skull bone with an osseointegrated screw. The rehabilitation effect achieved with such devices is generally very satisfying, but issues related to the skin penetration remain, first of all the need for daily maintenance of the skin-implant interface. This has been driving the development of so-called transcutaneous solutions, where the skin is kept intact. More specifically, active transcutaneous BCDs, where the transducer is implanted under intact skin, are in the spotlight in recent years.

A joint project between Chalmers University of Technology and Sahlgrenska Academy (Gothenburg, Sweden) started the development of an active transcutaneous device named BCI, Bone Conduction Implant [5–9]. The BCI is on clinical trial since December 2012 and 16 patients have been operated without any serious adverse events reported so far.

Implanting the transducer for active transcutaneous BCDs brings evident advantages but challenges as well. The implant has to be effective and safe. The safety aspect is mainly related to surgical procedure and implant material, and is not in the scope of this thesis. The effectiveness aspect is investigated instead. Effectiveness can be assessed in absolute or relative terms, via comparative studies. In this thesis the studies are designed and results presented mostly in relative terms, with the aim of evaluating two or more alternatives with respect to each other.

The first study is a comparison between two hearing aid systems, the transcutaneous BCI and the percutaneous Ponto Pro Power (Oticon Medical, Askim, Sweden), representing active transcutaneous devices and percutaneous BAHA devices, respectively. Audiological and self-reported questionnaires outcome confirmed the adequacy of the BCI as an alternative to BAHAs for indicated patients. More details about the study are found in Paper I.

Focusing on active transcutaneous devices, a study was conducted on the effect of changing the way the transducer is implanted. Since several ways to attach the transducer to the skull bone can potentially be implemented, different options were investigated to determine whether they play a role or not. The study included three attachment types tested on cadaver heads and is described in Paper II. Results from this study indicate that keeping a smaller contact area between the transducer and the bone may improve the transmission at frequencies above 5 kHz. However, clear trends were not found over a wider frequency range, and further investigations on the topic are planned and discussed in the concluding section of this thesis.

Related to the effectiveness of a BCD is also the verification of the transducer functionality. A malfunctioning transducer clearly leads to lower rehabilitation quality. One way to evaluate the transducer functionality is through subjective tests on the implanted patient, but there are circumstances when an objective method is needed. This happens for example in the operating theatre, when the surgery takes place and the patient is anaesthetised. After implantation, it is important to check the correct functioning of the transducer before the surgical wound is closed, to confirm that the attachment is firm and that the transducer itself did not suffer any damage. In Paper III the measurement of the sound pressure in the nostril is suggested as a verification tool with encouraging results so far.

1.1 Aim of the Thesis

The overall aim of this thesis is to provide advancements in the field of direct drive transcutaneous stimulation for bone conduction hearing rehabilitation.
More specifically, the aim can be divided into the following points:

- to assess whether the transcutaneous BCI can give a competitive rehabilitation when compared to percutaneous BAHAs based on the first 6 BCI patients (Paper I);
- to get an indication on the effect of the transducer attachment method on the transmission of vibrations to the cochlea (Paper II);
- to test the feasibility of a new method for verification of transducer functionality during surgery and follow-up visits (Paper III).

1.2 Thesis Outline

Chapter 2 describes the anatomy of the human hearing organ as well as the physiology of hearing, both by air and bone conduction. A categorisation of the different hearing impairment types is also given. Some of the most common tests that are performed to assess the hearing ability of patients for screening or diagnostic reasons are presented in Chapter 3. Chapter 4 focuses on bone conduction devices for rehabilitation of indicated groups of hearing impaired patients. The different types of devices that are available are presented, starting with a brief historical overview and up to today's state of the art. Tools to assess the rehabilitation effect are introduced and a brief discussion about what challenges are still open in the field of bone conduction rehabilitative devices is presented. After a summary of the appended publications, given in Chapter 5, the main conclusions and an indication of future plans are given in Chapter 6.

1.3 Ethical Considerations

In the biomedical field, ethics is something that should not be disregarded. Ethics is related to the methods used, how patients are treated, how their data is handled and many more aspects which are usually regulated and approved by ethical committees and by the participants signing the informed consent. This is done mainly to guarantee that patient safety, personal dignity, anonymity, professionalism and other fundamental scientific and human principles are respected. All the studies included in this thesis were conducted according to such principles.

However, ethics goes beyond the practical way to run tests. Ethical principles are

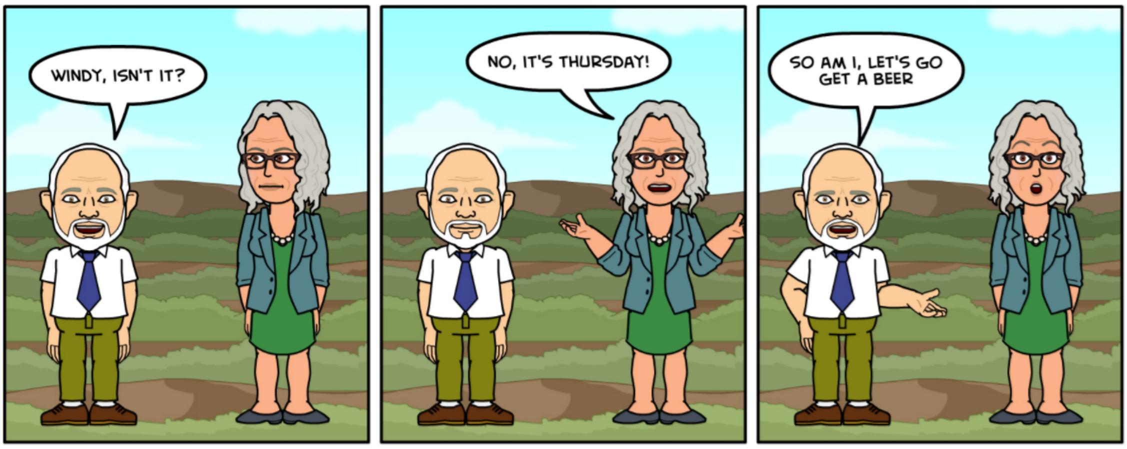


Figure 1.1: A comic strip illustrating in a humoristic way how hearing loss is generally perceived in our society. *Image courtesy of Hearing Healthcare Centre Ltd.*

nowadays strictly connected to sustainability in all its three pillars: economic development, social development and environmental protection. When working with disabilities, social and economic development are greatly involved.

In this section, I would like to take the chance to express some personal considerations about the project I am involved in from an ethical and sustainability point of view.

In the common imaginary, hearing loss is a handicap that most people experience in the late stages of their life, associated with the stereotypical funny grandparent that shouts over the phone and replies to the wrong questions. Such perception is illustrated in comic terms in Figure 1.1. This point of view, if not broadened, has strong limitations which could lead to underestimation of the actual impact of hearing losses on our society. In fact, hearing loss is a disability that affects the single person as well as the society as a whole, in the sense of welfare and economic aspects.

Different countries have different policies regarding hearing aids dispensation and whether to include them or not in the healthcare insurance. Implantable devices are today mostly paid by public insurance and represent therefore higher expenses with

respect to conventional air conduction hearing aids. Indeed, conventional devices have lower production costs and do not require surgical implantation and consequent follow-ups. When air conduction devices are not a possible choice, effective alternatives can be non implantable and semi-implantable bone conduction devices. In the short run, non implantable devices might look more appealing as they are cheaper and more easily applied to patients. There are several cases, though, of hearing aids that are prescribed, fitted and then not used by patients due to uncomfortable wearing conditions or unsatisfactory rehabilitation. What was a lower cost initially can then become a higher cost in the long run, when the patient will maybe decide to go for an implanted solution and will need new visits and new procedures that could have been done already in the first place. Furthermore, from a broader point of view, a satisfactory hearing rehabilitation can eventually lead to a possibility for the patients to be integrated in the working society instead of being forced to live on someone else's economic support due to the impossibility of having a job. The patients whom we address are not only seniors who have already finished their working career, they are men and women down to 18 years of age who still have a lot to offer if they are given the possibility. Even though not life threatening, hearing loss is a severe handicap that can seriously threaten equality in terms of working opportunities.
Equality does not regard only working possibilities, but more generically the ability to have a normal interaction and relationship with other people in the surrounding. Nearly everyone has experienced the difficulty in communicating with persons suffering from medium to severe hearing loss and it is easily understood that, if not treated, this can lead to social isolation and dependency of the person from other people's assistance (most of the time family members). The aim of research and development should always be to work towards the achievement of a more sustainable society and this should not be shadowed by the desire for purely technical advancement.

Chapter 2

Hearing Physiology

The human ear is a very complex organ, made up of several different parts that cooperate to finally give a sound perception. Besides hearing, the ear is also responsible for balance. The general anatomical and physiological principles behind the hearing mechanism are briefly described in this chapter. Different ways to perceive sounds are presented along with their main differences and similarities. In the end, an overview of different types of hearing losses is also given.

2.1 Anatomy of the Ear

The anatomical structure of the human ear is commonly described as composed of three parts: outer, middle and inner ear, as shown in Figure 2.1.
The outer (or external) ear collects sound waves to transfer them inwards. The outermost part is the auricle (or pinna), a flap of elastic cartilage covered with skin and individually moulded. The auricle helps to collect sound waves and to direct them to the auditory canal, a curved tube reaching the eardrum. In the auditory canal, ceruminous glands secrete cerumen to prevent external objects from entering the ear. The outer ear terminates with the tympanic membrane (TM), most commonly known as eardrum, a flexible partition that can be vibrated by sound waves. An important feature of the outer ear is that it acts as a sort of amplifier for mid-frequencies and provides clues for the detection of sound direction. The latter is achieved mostly thanks to the shape of the external auricle, which collects and filters the sound waves differently depending on their source position, both in the vertical and horizontal plane.

The middle ear is an air cavity located between the eardrum and the inner ear. The Eustachian tube, or auditory tube, connects this cavity also to the upper part of the throat, with the main function of balancing the pressure difference between the middle ear and the surrounding, for example when chewing or yawning. The TM on the outer side and the oval window on the inner side are connected by the

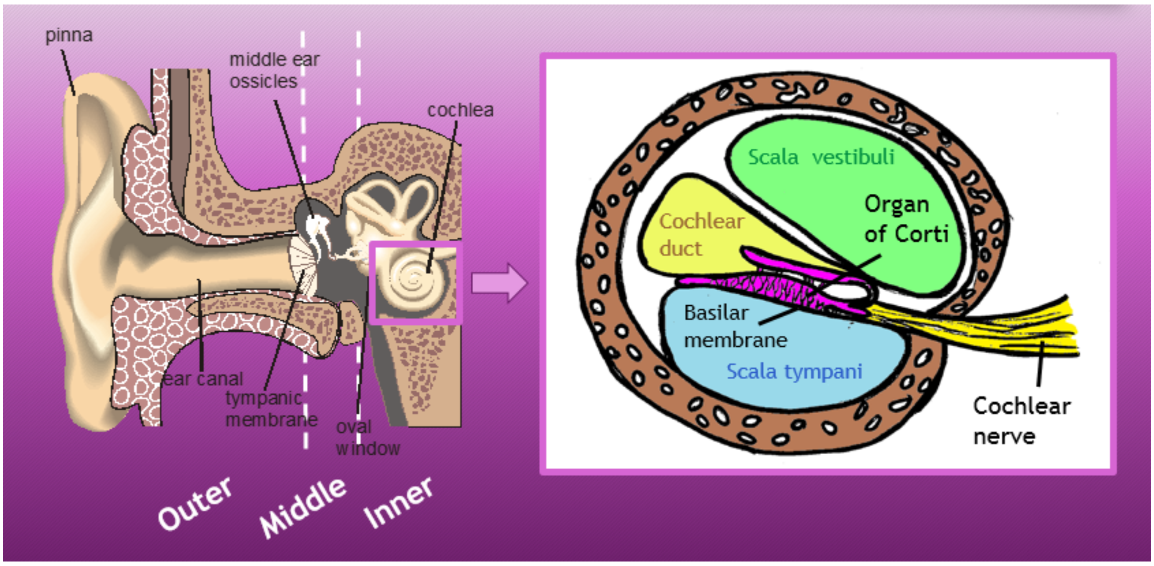


Figure 2.1: Simplified illustration of the anatomy of the human ear. The right side of the image illustrates a cross-sectional view of the cochlea.

so-called auditory ossicles, three tiny bones forming a chain which is kept in place by the middle ear ligaments. The movement of the three ossicles, namely malleus (hammer), incus (anvil) and stapes (stirrup), is controlled by tiny muscles whose main function is to prevent damage in case of excessively loud sound. The middle ear is responsible, among other things, for matching the impedance in the transition between air in the external ear and fluid in the internal ear.

The inner (or internal) ear includes bony and membranous labyrinth, where the former is composed of cochlea, vestibule and semicircular canals. The cochlea is the sense organ for hearing sensation, while the vestibule, together with the three semicircular canals, is the sense organ for equilibrium and balance. The membranous labyrinth is located inside the bony labyrinth and consists of tubes and sacs filled with a liquid called endolymph, containing receptors for senses of hearing and equilibrium. The cochlea takes its name from the Greek *kokhlias*, meaning “snail shell”, due to its spiral shape. Its conical structure is internally composed of three channels: the cochlear duct in the middle, scala vestibuli above and ending at the oval window, and scala tympani below, ending at the round window. The cochlear duct is filled with endolymph while vestibular and tympanic ducts contain perilymph. Between scala vestibuli and cochlear duct is the vestibular membrane, while the basilar membrane separates the cochlear duct from scala tympani. On the basilar membrane lies the organ of Corti (also called spiral organ), covered with hair cells that connect with synapses to the auditory nerve neurons. Hair cells act as transducers, transforming mechanical stimuli to electrical pulses.

2.2 Air Conduction Hearing

Air Conduction (AC) hearing refers to the hearing sensation induced by airborne sound waves from the external environment entering the outer and middle ear. Sound waves hit the auricle, travel through the auditory canal and reach the TM inducing a vibration. The movement of the TM is frequency and loudness dependent, where the amplitude is proportional to sound intensity and the speed increases with frequency. The outer ear contributes to the processing of the incoming sound in two different ways: pressure gain and sound localization [10]. Mid-frequency sounds, between 2 and 7 kHz, are amplified by approximately 15-20 dB as a result of the resonances in the ear canal. Clues for sound localization are derived differently for horizontal and vertical plane: in the horizontal plane, a sound is understood to come from left or right mainly based on the time and intensity difference between the signals at both ears; in the vertical plane, localisation is based on the fact that sound coming from behind the pinna interferes with the wave that is scattered off the pinna, creating a notch filter in the region 3-6 kHz.

The vibration of the eardrum propagates through malleus, incus and stapes, which finally pushes the oval window in- and out-wards. With its movement, the ossicular chain acts as a transducer between sound pressure and mechanical vibrations. The middle ear has an important function of matching the low impedance of the TM with the high impedance of the oval window preventing a massive energy loss when vibrations are transferred from air to fluid medium. For this reason, the middle ear can be regarded as a mechanical amplifier where the amplification is achieved through three principles: (1) the area of the TM is significantly larger than that of the oval window resulting in a pressure at the oval window increased by the size of the ratio of the two areas, approximately 18.6 times (25 dB); (2) the lever action of the bony ossicules, leading to a 1.3:1 movement ratio between the stapes and the malleus (approximately 2 dB increase in the total gain); (3) the so called curved membrane advantage, given by the conical shape of the TM, resulting in a 6 dB increased pressure at the oval window. Two small muscles in the middle ear, stapedius and tensor tympani, serve an important function called acoustic reflex, to protect the ear from excessively loud sound. The stapedius muscle is the smallest in the human body. It is connected to the stapes and contracts when sound loudness is above 70-80 dB HL (deciBel Hearing Level, for a more precise definition see Chapter 3), attenuating sound transmission at frequencies below 2 kHz. Tensor tympani is instead sensitive to tactile stimuli and, when activated, it increases the stiffness of the TM resulting in a lower sound transmission.

The pressure of the stapes on the oval window causes fluid pressure waves in the perilymph of the vestibular and tympanic duct. Since the fluid is mainly incompressible, pressure in the ducts results in a movement of the membranes separating them. Pressure waves are therefore propagated to the endolymph in the cochlear duct, eventually creating a travelling wave along the basilar membrane, from the base (close to oval and round window) towards the apex. The position of the peak of the travelling wave along the membrane is related to the frequency of the stimulation. The membrane is indeed narrower and stiffer at the base and wider and softer at the apex, making it tuned for increasingly lower frequencies as the distance from the windows increases. While the frequency of the stimulus determines the position of the wave on the basilar membrane, its intensity affects the amplitude of the wave, with a louder sound resulting in a larger vibration of the membrane. However, the propagation of the motion wave through the basilar membrane cannot be fully described with passive models based on stiffness and mass inertia, which has led to the hypothesis of the presence of an active region where mechanical force would be added to the wave, increasing its amplitude. The source of this hypothetical mechanical active process is still unknown but seems to be related to the mechanical amplification supplied by the outer hair cells [11].

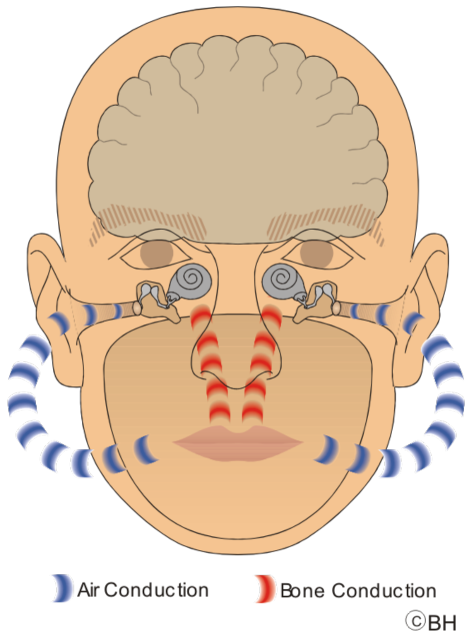


Figure 2.2: Representation of air conduction (blue arrows) and bone conduction (red arrows) pathways when hearing one's own voice. The sound produced during vocalization is radiated in the air and reaches back the subject's outer ear through air; simultaneously, it is propagated through nasal hard and soft tissues and skull bone. Both pathways sum up to stimulate the cochleas.

The transduction of the signal from fluid motion to electrical impulses is done by the hair cells covering the organ of Corti. These specific sensory cells have protruding hair-like structures called stereocilia that, when stimulated, induce chemical changes in the hair cells leading to elicitation of nerve impulses. Electrical impulses come from differently located cells according to the stimulation frequency and are transmitted at a higher rate when excited by a higher stimulus intensity. The electrical impulses travel through the auditory nerve along the auditory pathways to the auditory cortex, the dedicated part on each side of the brain where the final signal processing takes place. The analysis of signals from both sides allows listeners to remove potential background noise and to isolate and focus on specific sound sources.

2.3 Bone Conduction Hearing

Bone conduction hearing is the alternative and complementary way to AC for inducing hearing sensation. As suggested by the name, BC hearing relies on transmission through bone rather than air, and more specifically the skull bone. When hearing by BC, the movement of the skull reaches directly the cochlea bypassing outer and middle ear and stimulating directly the inner ear to produce a hearing sensation.

Sound waves from external sound field are able to vibrate the skull thus allowing a listener to hear by AC and BC simultaneously. However, in normal hearing subjects with open ear canals, the BC component from sound field stimulation is negligible compared to the AC part. On the other hand, during vocalization the situation is different. When a subject is producing sound, vibrations are transmitted in two directions: (1) through air: the voice is emitted in the sound field, vibrations are picked up by the outer ear and follow the regular AC path; (2) through internal tissues: vibrations propagate from the oral cavity, teeth and vocal cords through internal tissues directly to the cochlea. Both paths, shown schematically in Figure 2.2, are roughly equally contributing to the final hearing sensation. Therefore, when hearing one's own voice, AC and BC components are approximately equivalent, with BC contributing mostly at low and AC at middle-high frequencies [12, 13]. Perception of one's own voice is indeed the most common and straightforward way to explain and give a practical example of the effect of BC hearing: the difference in the pitch perceived when listening to a recorded version of one's own voice compared to the one perceived while vocalizing can be simply motivated by the fact that in the recorded version, the BC part is missing, cutting off much of the low-frequency content that is otherwise transferred through internal tissues.

The term "Body Conduction" is sometimes preferred to "Bone Conduction" when referring to the hearing component which is not from airborne sound. This is to emphasize that the contribution to the final hearing sensation comes not only from the bones but also from fluids in the body, soft tissues, skin and cartilage. However, these contributions are very difficult to study separately and have not been found to have a prominent role in the normal hearing process; therefore they will be disregarded here.

2.3.1 Stimulation of the Basilar Membrane

One important question to answer is whether BC and AC sound are perceived in the same way, i.e. if they induce the same stimulus on the basilar membrane of the cochlea. Several studies have been done in this regard, with the conclusion that at the basilar membrane level, AC and BC components are indistinguishable as the stimulation happens in the same way. This has been confirmed in several ways:

1. Tone cancellation: if AC and BC sound stimulate the cochlear basilar membrane in the same way, then two waves reaching the cochlea with equal amplitude and opposite phase should suppress each other resulting in no hearing sensation. Tone cancellation was the first method used to support the hypothesis of identical stimulation from AC and BC sound at the basilar membrane and it was originally formulated and performed by von Békésy [14] with a 400 Hz tone. Further experiments on animal models [15] as well as on humans [16, 17] gradually extended the cancellation results to a wider frequency range, finally covering almost the whole audible spectrum, 0.1-15 kHz.

2. Analysis of basilar membrane motion: the stimulation of the basilar membrane results in a traveling wave from the base to the apex of the cochlea with a motion that is independent on whether the stimulation is by AC or BC, as confirmed by simulations on theoretical models as well as direct measurements of the membrane motion [18].

3. Electrophysiological measurements: observing electrical potentials generated in the cochlea and auditory nerve in response to sound stimulation, similar response patterns for BC and AC stimulations are found. Potentials have been measured directly in the cochlea on animal models [16] as well as in the brain via electrodes placed on the scalp (auditory brainstem response) [19].

4. Two tone distortion products: when two primary tones at different frequency are used to stimulate otoacoustic emissions, the response occurs at a frequency that is mathematically related to both the primary tones. The same phenomena have been observed with both AC and BC stimulation [20] as well as with a combination of one AC and one BC tone [21], giving one more supporting point to believe that AC and BC stimulation induce the same response in the cochlea.

In a study from Adelman et al. [22], the investigation of interactions between different stimulation pathways was extended to non-osseous forms of BC, with stimuli applied to the eyelid, neck and chin. The conclusion from the study, which included among others masking, tone matching and two tone distortion products, was that all of these forms of auditory stimulation (AC, osseous and non-osseous BC) result in the same mechanism of cochlear excitation, eventually resulting in the same neural representation.

Even though the neural representation is identical regardless of the mode of stimulation (AC or BC), very high variations are found in the input level needed to evoke the same neural representation [23]. Such variations are both between air and bone conduction as well as between patients.

2.3.2 Contributing Factors

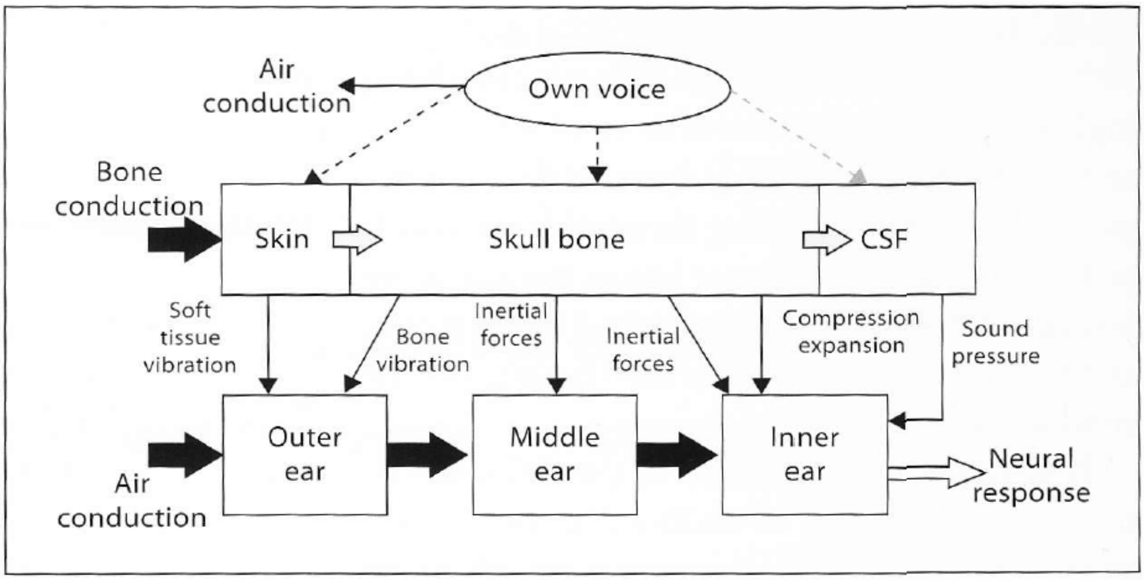


Figure 2.3: Model of the contributions to AC and BC sound perception from one's own voice, external sound field and BC stimulation. The sound transmission is indicated by the arrows, with the thin ones indicating the contributions to BC sound (soft tissue vibration, bone vibration, inertial forces, compression/expansion and sound pressure). The final neural response (arrow in the bottom-right corner) is a combination of AC and BC sound. *Figure from Ref. [24].*

As mentioned earlier, the contributions to BC hearing are multiple. The first theory in this regard was formulated by von Békésy [25, 26], who hypothesised influences from all three parts of the hearing organ as well as from the movement of the lower jaw. Further investigations by Tonndorf led to the identification of seven factors [27]: (i) inertia of middle ear ossicles, (ii) compliance of middle ear cavity, (iii) compression of the cochea, (iv) mobility of the round window, (v) mobility of the oval window, (vi) cochlear fluids inertia and (vii) compliance effect via the cochlear aqueduct. The relative importance of each way is frequency-dependent, and according to more recent studies, some of the aforementioned factors have a minor influence [28]. Five factors are finally identified as the main contributions, each in different frequency ranges [29]:

1. Sound radiated into the ear canal: in ordinary listening conditions, i.e. for a normal ear with an open ear canal, this contribution is found mainly at

frequencies below 0.5 kHz, but not as predominant. However, when the ear canal is occluded, the sound radiated into the ear canal is the predominant factor for BC hearing between 0.4 and 1.2 kHz.

2. Middle ear ossicle inertia: mainly contributing at low and mid frequencies, up to approximately 3 kHz, though not as a predominant factor.

3. Inertia of the cochlear fluids: this is believed to be the main contributor to BC, especially for frequencies below 4-5 kHz.

4. Compression of the cochlear walls: not affecting low and mid frequencies, this factor may play a role at high frequencies, from 4 kHz up.

5. Pressure transmission from the cerebrospinal fluid: this factor has not been thoroughly investigated so far, and even though it is believed to have an influence on BC hearing, this is still uncharacterised.

Different pathways act upon different anatomical structures to eventually stimulate the inner ear, from where the neural signal is generated and transmitted to the brain. A comprehensive visual representation of the different pathways for sound transmission is shown in Figure 2.3, where interactions between skin, soft tissues, skull bone and hearing organ are depicted.

2.3.3 Skull Bone Response to BC Stimulation

The whole mechanism of how vibrations propagate through the human skull is still not adequately understood and far from being satisfactorily modelled, although several measurements have been performed in the past decades on dry skulls, cadaver heads, full bodies and living subjects. Most of the difficulties against coming to a comprehensive description of the phenomenon are due to the fact that the human skull has a very complex geometry with ridges, sutures and irregularities and is a combination of several tissues with different mechanical properties. Furthermore, the inter-subject variability is very high, with each skull being unique in its shape, dimension and relative position and size of plates.

There are potentially two different approaches to the study of the transmission of vibrations in the skull: the analytical approach and the experimental approach. The first focuses on describing the physical structures to try and formulate a purely mathematical model to simulate the skull dynamics, while the second one is based on empirical measurements. A third method is modal analysis, which combines both approaches by studying resonance frequencies and mechanical point impedance of the skull as inputs to mathematical models.

The analytical approach was taken at first by von Békésy, who attempted to analyse the vibration mode by modelling the skull as a sphere [14]. Due to unsatisfactory

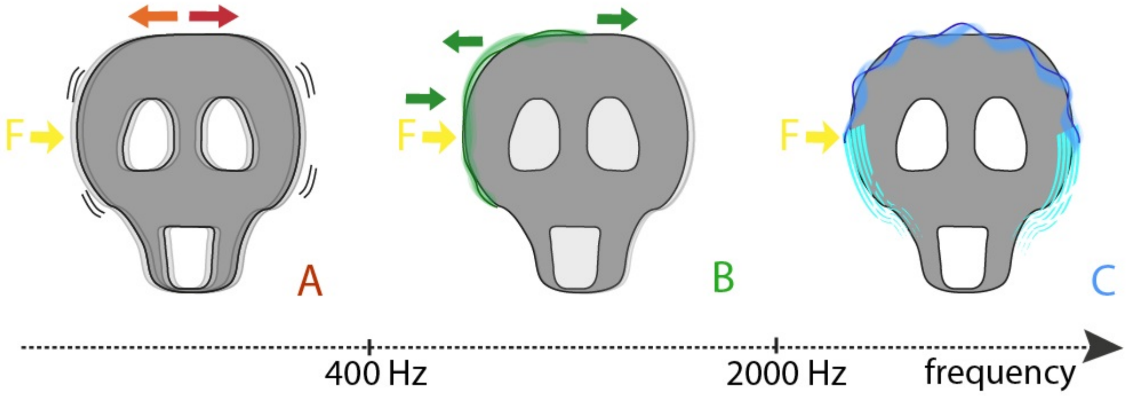


Figure 2.4: Schematic representation of the skull bone motion characteristics at different frequencies. A) Rigid body movement, with no deformation of the skull which is moving as a whole rigid body; B) Mass-spring movement, with minor deformation of the skull due to areas moving in opposite directions; C) Wave transmission, with mostly longitudinal waves on the base and bending motion on the vault. The yellow arrow indicates where the driving force (F) is applied.

results, he then tried to estimate the characteristics of wave propagation in terms of mode and velocity [30]. Since then, efforts to determine the dynamic characteristics of human skulls under vibrational excitation have been focusing on the description and identification of mode shapes and resonance frequencies as in the modal analysis approach. The most comprehensive investigations of resonance frequencies were done by Khalil et al. [31] and Håkansson et al. [32] through experiments on dry and living human skulls, respectively. They were able to identify up to 11 such frequencies on dry skull between 20 and 5000 Hz and 19 on living subjects in the range 500-7500 Hz. Experimental approaches have been taken also for the characterization of mechanical point impedance of the skull at different stimulation-measurement configurations [33–36].
On the analytical approach side, recent advancements have been made by You et al. [37], who developed a whole head finite element model able to simulate transmission of BC sound with fairly good consistency when compared to experimental data.

In qualitative terms, the vibrational characteristics of the human skull can be divided into three regions depending on the frequency range [24], as schematically shown in Figure 2.4.

- At very low frequencies, below 150-400 Hz, the skull moves as a rigid body with its movement being mainly mass-controlled. No deformation of the skull appears in this frequency range.

- At medium-low frequencies, up to approximately 1 kHz, the skull behaves like a

mass-spring system, with large parts of the skull moving sequentially in opposite directions. Deformation of the skull is present in this kind of motion.
At medium-high frequencies, between 1 and 2 kHz, wave transmissions start to appear.

- For frequencies above 2 kHz, the motion is dominated by wave transmission and the modes are different for the cranial vault and for the skull base. At the skull base mostly longitudinal waves with approximately constant speed are formed, while at the cranial vault a mixture of longitudinal and bending waves is seen, with frequency-dependent wave speed.

The intensity of the vibrations depends on several factors, such as intensity and application position of the stimulus and presence of soft tissues. Vibrations can be induced by direct stimulation of the skull or through the skin. The modality of stimulation affects the intensity of the stimulus differently at different frequencies. If vibrations are applied externally via the skin, there will be a substantial damping of the signal at higher frequencies. The pressure and contact area through which vibrations are transmitted have also an influence on the received signal [38, 39]. The stimulation position affects 10-20 dB the intensity of the signal received at the cochlear level, with a higher sensitivity achieved when the stimulation is closer to the cochlea and on the mastoid bone rather than on the parietal bone or the forehead [40–42].

2.4 Hearing Impairments

Hearing impairment is a condition where the sensitivity to sound is poor or totally absent. Such condition can affect one or both ears in different degrees, and it can be present at birth or developed later in life. Some of the causes for hearing loss are for example congenital disorders or malformations of the hearing organ, infections, exposure to excessive noise, physical trauma and ageing. Some kinds of hearing loss are preventable, mainly by the use of hearing protection when exposed to loud environments.
Hearing impairments can be categorised into three main groups:

- Conductive hearing loss originates in the middle or outer ear, when the mechanical transmission of the sound does not function normally, i.e. the sound is not “conducted” properly to the cochlea. Conductive hearing losses can be caused by anatomical malformations (such as atresia of the auditory canal), damaged parts (e.g. perforated eardrum), infections (e.g. otitis) or diseases such as otosclerosis or tumours.

- Sensorineural hearing loss arises in the cochlea or the auditory nerve. The causes can be for example acoustic trauma, use of ototoxic drugs or persistent infection in the cochlea, while for the auditory nerve the principal cause of damage is tumour. Presbyacusis, or age related hearing loss, is the most common type of sensorineural hearing loss, which consists in a progressive and irreversible decay of the structures in the inner ear and auditory nerve resulting in a gradual decrease of hearing sense.

- Mixed hearing loss is a combination of conductive and sensorineural hearing loss.

Additionally, hearing loss can also be central or non-organic. Central hearing losses are caused by damage in the brain due to tumour, trauma or auditory processing disorders. When a patient is found with a hearing impairment without any apparent organic damage, the hearing loss is defined as non-organic.

Depending on the type of hearing loss, different rehabilitation alternatives are chosen. Mild to moderate sensorineural and age-related hearing losses are usually rehabilitated with conventional AC devices, that basically pick up sounds from the environment and deliver them with amplified intensity to the ear. For profoundly deaf or severely hearing impaired patients, instead, the only alternative is often to have a cochlear implant, with electrodes that are surgically placed in the cochlea to directly stimulate the hearing nerve endings. Bone conduction devices are effective alternatives for patients suffering from conductive hearing losses, with impaired AC hearing and BC hearing loss up to moderate-to-severe (for hearing loss classification, refer to Chapter 3). This kind of device can be a good alternative also in case of patients who are unable to wear conventional AC devices for various reasons, such as infections or malformations of the outer and middle ear.

Chapter 3

Hearing Assessment

A variety of tests exist to assess the hearing level of an individual and to characterise eventual hearing losses. Different methods are used depending on the age and general health condition of the patient. In research, measurements are performed also on animal subjects, in vitro samples and other type of models in order to investigate more in detail the underlying mechanisms of the hearing process and how these are affected by different parameters.
Methods can be classified as subjective and objective, where subjective tests require the subject to be conscious and compliant in performing the required task, while objective measurements do not need an active participation from the tested subject, as these are based on the observation of physical quantities which are physiologically related to the hearing process.
Historically, the development of hearing assessment methods dates back to the 16^{th} century, and since then quite a few steps have been taken forward. Techniques have been developed to make the screening process more accurate, and in the last decades efforts have been done to establish standard procedures for instrument calibration as well as test routines, in order to enhance the comparability between measurements from different examiners or centres.
A summary and overview of the most utilised methods is given in the following sections.

3.1 Subjective Measurements

Also called psychoacoustic methods, subjective measurements require the test subject to be actively participating in carrying out the required task, which may consist in detecting, discriminating or identifying different types of stimuli.
Each test has specific settings that determine the final result and its interpretation. Just to name a few variables:

- *The stimulus.* Test signals that are used as stimuli can be for example pure tones, speech material or white noise;

- *The stimulus administration.* Among the several ways to convey a signal there are for example headphones, bone vibrators or sound field.

- *The non-test ear.* If only one of the ears is being tested, the other one can be dealt with in basically two ways: either its functionality is inhibited, or it is left untouched. If the requirement is to isolate the non tested side, this can be achieved by physically obstructing the ear (with ear muffs or plugs) and/or it can be acoustically masked. Masking consists in sending a confounding sound that will disturb the perception of the test stimulus from the non-tested side.

- *The task description.* How a task is introduced to the subject can play a role in determining the final outcome, especially in less experienced subjects.

Bearing in mind that many variations exist and that no single international standard is today followed in the clinical practice, a list of the most commonly performed psychoacoustic measurements is presented as follows.

Tone Audiometry

The aim of tone audiometry tests is to determine the individual sensitivity to sounds for specific frequencies. Standard frequencies that are tested are the octave frequencies 250, 500, 1000, 2000, 4000 and 8000 Hz. Sometimes also intermediate frequencies 750, 3000 and 6000 Hz are used. The test consists in presenting a series of tones to the subject varying the intensity level of the stimulus until the lowest audible level is found for each of the analysed frequencies. Tones can be continuous or pulsed, pure or warbled (frequency modulated). The latter type is preferable in sound field as it reduces the risk for standing waves in the room as well as it is more easily detectable by patients with tinnitus [43].
For each frequency, the sounds are presented to the test person at varying intensity levels following iterative procedures of several kinds. In clinical practice, the most used is the Hughson-Westlake technique, also referred to as +10/-5-method. However, different alternatives exist and are described, among others, in standards by ISO, the International Organization for Standardization [44, 45], and ANSI, the American National Standard Institution [46], and guidelines by ASHA, the American Speech-Language Hearing Association [43].
The outcome of a pure tone audiometric test is the audiogram, a chart where the obtained thresholds are reported for various test conditions (left or right ear, masked or unmasked, AC or BC) with a standard set of symbols. Thresholds are given in dB HL (Hearing Level), a measurement unit defined as the softest sound audible by

a normal hearing young adult. The reference levels are specified in standards developed by ISO or ANSI, with very similar values between the two standards [47, 48]. References are given in equivalent force levels or equivalent sound pressure levels if a bone vibrator or headphones are used in the test, respectively. A 0 dB HL hearing threshold indicates that the subject's sensitivity is exactly at the average level, while negative or positive thresholds indicate better or worse hearing respectively when compared to the normal hearing population average. A useful index to summarise an audiogram is the Pure Tone Average (PTA), typically consisting in the average of thresholds at 500, 1000 and 2000 Hz. The PTA index gives a good indication of the patient's hearing in the frequencies which are considered most important for speech perception. Sometimes the PTA is calculated on four frequencies, with the fourth one being either 3000 or 4000 Hz, and therefore it is often clearer to refer to PTA_3 or PTA_4 depending on the number of frequencies being considered.

From the audiogram, a general classification of hearing loss degree can also be done in six main categories according to how much AC pure tone thresholds differ from 0 $dB\ HL$ [49]:

- -10 to 20 dB: Normal hearing;
- 21 to 40 dB: Mild hearing loss;
- 41 to 55 dB: Moderate hearing loss;
- 56 to 70 dB: Moderate-to-severe hearing loss;
- 71 to 90 dB: Severe hearing loss;
- $>$ 90 dB: Profound hearing loss.

The type of hearing loss is also definable from the audiogram curves by looking at the so called air-bone gap (ABG), i.e. the difference between the AC and the BC thresholds. The hearing loss categories mentioned in section 2.4 can thus be described in terms of ABG as follows [50]:

Sensorineural hearing loss:
ABG $\leq$ 10 dB;

Conductive hearing loss:
ABG$>$ 10 dB, BC $\leq$ 25 $dB\ HL$;

Mixed hearing loss:
ABG $>$ 10 dB; BC $>$ 25 $dB\ HL$.

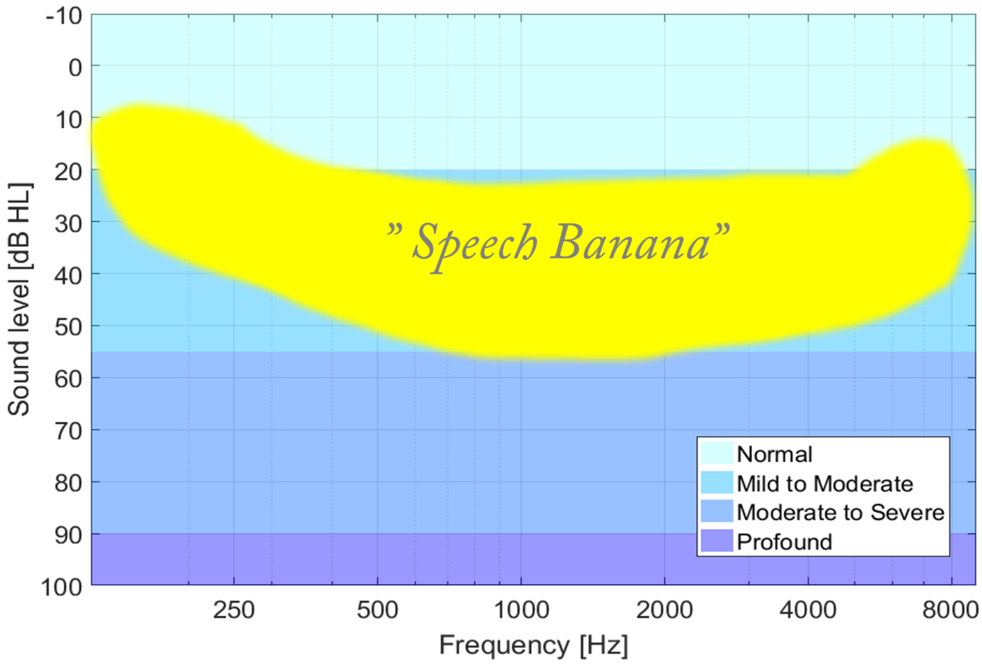


Figure 3.1: A representation of the *speech banana* on an audiogram at average conversational level. The yellow area encloses the main components of speech sounds. Background colours indicate the degree of hearing loss corresponding to thresholds located in the the respective shaded areas.

Speech Audiometry

Speech audiometry, unlike pure tone audiometry, is concerned with the quantification of the patient's ability to perceive and understand complex sounds where more than one frequency component is found.

Speech audiometry complements pure tone testing by measuring a condition that is more representative of what we hear in everyday life. The importance of speech audiometry lies also in the fact that it can give good indications for hearing aid prescription and fitting. The frequencies mostly found in speech are between 500 and 4000 Hz, but components are found at lower and higher frequencies as well, depending on the type of speech sound. The distribution of speech acoustic features across the audiogram at conversational level is referred to as the *speech banana* due to its shape, shown in Figure 3.1.

Even though analysing the audiogram can give an indication of how the subject would perform in speech understanding, the inference is not as simple due to differences in the relative contribution of different frequency regions to the overall speech intelligibility. Furthermore, speech signals contain a high degree of redundancy, which makes the relation between frequency specific hearing thresholds and speech understanding

ability quite complicated and non linear. Methods for extracting predictions of speech recognition from the pure-tone audiogram have been investigated in research. Today's most known and used prediction is the so called "count-the-dots audiogram", proposed by Mueller and Killion in 1990 [51] and later reformulated by the same authors [52] and by others in different variants. The count-the-dots audiogram basic idea is to represent frequency and amplitude components of speech as 100 dots placed inside the speech banana. Areas which are more important to speech understanding have higher dot density, while less critical areas have the dots more spread out. By overlaying the patient's audiogram to the dots audiogram template, the dots that would be audible (i.e. above the hearing thresholds for the patient) are counted and the resulting percentage gives an estimate of speech understanding in terms of the so-called speech intelligibility index, ranging from 0 to 1. Different variants are characterised by changes in the distribution of the dots within the banana area.
However, still today such methods have not been adopted as a clinical routine and direct measurement of speech recognition ability is performed. This is done with a battery of tests where speech material is used as stimulus, alone or accompanied by noise. The tests are most commonly performed in the patient's original language with pre-recorded verified speech material and following standardised procedures [53]. Because the cognitive aspect cannot be separated by the purely auditive aspect, the choice of the listening material utilised in the tests is crucial in order to obtain inter-patient comparable results. The first speech material in Swedish language was developed in the 1930's by professor Lennart Holmgren, mostly intented for hearing aid testing [54]. It was then Gunnar Lidén, around three decades later, who first developed and recorded phonetically balanced lists for diagnostic purpose [55]. Test material consisting of sentences to be tested with competing noise was afterwards formulated by Björn Hagerman in the late 80's (more details in the Speech in Noise Tests paragraph) [56, 57]. In the late 90's, further material was developed and recorded by Lennart Magnusson, who introduced phonetically balanced lists of Swedish words pre-mixed in speech-weighted noise [58].
A list of the most commonly performed measurements follows.

Speech Recognition Threshold The speech recognition threshold (SRT), also called speech reception method, measures the lowest level at which the patient is able to detect and understand speech material. SRT uses spondee words, which consist of two syllables with equal stress on each of them. The test is performed by presenting a series of words from recorded material at varying intensity with no or low background noise, and the test subject is asked to repeat each word. The final outcome of the test is expressed in $dB\ HL$ and represents the level at which the subject is able to correctly detect 50% of the words. The SRT outcome should be within $\pm$ 10 dB of the PTA calculated at 500, 1000 and 2000 Hz and it can therefore serve as a check for the reliability of the audiogram [59].

Speech Detection Threshold Sometimes called speech awareness threshold, the speech detection threshold (SDT) aims at detecting the lowest level at which the patient can detect the speech, without correctly recognising the words. The SDT is used as an alternative test when SRT can not be obtained, for example in cases of severe to profound hearing loss, mentally disturbed patients or young children. The result for SDT is usually 5-10 dB better than SRT.

Speech Recognition Score The speech recognition score (SRS) measures the ability of the patient to understand speech at conversational level, typically around 60 $dB\ SPL$. Tests which are performed at comfortable hearing levels are called supra-threshold speech tests and diverse speech material can be used. The SRS test is performed with single syllable words or, less commonly, with nonsense combinations of vowels and consonants that resemble speech material. A list of usually 50 words is presented to the patient at a fixed level, and the final outcome is the percentage of correctly detected words. An alternative way of calculating SRS is to report the percentage of correctly detected phonemes instead of whole words.

Speech in Noise Tests This kind of test is performed to investigate the person's ability to understand speech in noisy situations, which are especially challenging for hearing impaired listeners. The main purpose is to have a measure of speech recognition able to represent more closely the performance in everyday life listening environment. Signal to noise ratio (SNR) is defined as the level of the signal of interest (in this case, the speech) over the noise. Usually SNR is expressed in dB, in which case a negative SNR indicated that the noise level is higher than the signal level, and the other way round in case of positive SNR. The noise itself can be of several types, from speech-spectrum noise to babble noise and competing speech. Common tests are, for example, the QuickSIN (Quick Sentence in Noise test, from Etymotic Research, [60]) and the HINT (Hearing in Noise Test, from Nilsson et al. [61]).
In Sweden, the most used speech material and procedures are the ones developed by Björn Hagerman [56, 57]. The test material consists of five-words sentences that are played together with speech-spectrum noise, i.e. noise with the same frequency content as speech. The speech level is kept constant at a conversational level, while the noise is stepwise increased or decreased depending on the patient's response rate. Such adaptive procedure allows to finally determine the SNR threshold, defined as the SNR level at which the test person is able to detect 50% of the presented speech material. Versions of the procedure can be found where the speech level is varied while the noise is kept constant.

User Questionnaires

A variety of questionnaires have been developed and validated in order to give an estimate of the hearing loss from the patient's perspective and to quantify its impact on the person's quality of life. Self-reported measurements are useful both as a screening tool as well as to determine the patient's rehabilitative needs.
Questionnaires have been developed for assessing general hearing disability and handicap, including mostly communicative and psychosocial impact of hearing ability, [62, 63] and sound localisation ability (SSQ, SHQ) [64]. They are routinely administered for screening of populations which are considered at risk, such as professionals that are often exposed to high sound levels, patients under ototoxic medications or elderly subjects [63].
Akeroyd et al. [65] summarised the variety of questionnaires that are used in hearing assessment and they found 139 hearing-specific questionnaires. Among these, the author found that the main focuses are the person's own hearing, its repercussions and hearing aids in equal shares.

3.2 Objective Measurements

Objective measurements are based on physical entities that are physiologically related to the hearing process. This implies that objective measurements do not quantify directly the hearing ability, but rather investigate it indirectly. Reasons to perform objective measurements instead of subjective ones are multiple, for example in the case of subjects whose mental or physical conditions do not allow them to perform the required psychoacoustic tasks, such as very small babies, mentally ill patients or patients under anaesthesia. Another reason might be that the investigation is done on a non-living subject, such as a cadaver or an artificially produced anatomical model. Some methods are used in the clinics for diagnostic purposes, while others are mostly employed for research purposes. An overview of both categories follows.

Clinical Methods

Measures of auditory responses without the patient's active involvement are essential in cases where the patients are not in the conditions for carrying on the required tasks, and can in any case complement the information given by subjective measurements. Among other functions, physiologic measurements can help to localise where the hearing loss is located, for example discriminating between cochlear and neural impairments. Tests like tympanometry and acoustic reflexes are routinely performed in the clinics, while other investigations are done in particular cases.

Immittance Audiometry In this category, tympanometry and acoustic reflexes measurements are included. These tests are concerned with the quantification of the energy transfer through the outer and the middle ear [50]. The term immittance is used to address two reciprocal properties, admittance and impedance. Given an applied amount of energy, the admittance quantifies the amount of energy that is transferred through the system, while the impedance expresses the amount of opposition to the energy flow. Impedance and admittance are reciprocal quantities, meaning that a system with a high impedance would have low admittance and vice versa, and they can be obtained from each other. In audiometry, immittance is measured by sending a test-tone in the ear cavity through a probe assembly that guarantees the sealing of the ear, and measuring the response with a recording probe microphone. Immittance is mainly dependent on the size of the middle ear cavity.
Tympanometry is the study of immittance as a function of the applied pressure level, and the shape of the resulting curve gives important information about the middle ear functionality. In acoustic reflex threshold measurements, a tone is used to elicit middle ear reflex (contraction of the stapedius ossicle) and immittance is recorded to detect the event.

Auditory Evoked Responses Measurement Otoacoustic Emissions (OAEs) and Auditory Brainstem Responses (ABRs) are examples of responses from the auditory system which are evoked by specific stimuli and are mostly related to hair cells and brainstem functionality. The test of these signals is widely employed for newborn hearing screening.
OAEs are acoustic vibrations in the ear canal resulting from the cochlear activity after a sound stimulation [50]. Their intensity is very low and they have to be measured with highly sensitive microphones placed in the ear canal. The absence of OAEs may indicate a malfunction of the cochlear organ.
The ABR consists instead of a series of wave peaks that can be recorded by electrodes placed on the head [50]. The evoking signal can be a click or a tone-burst with a short duration, as the ABR is related to neural activity following rapid stimuli. Several peaks are recognised, and their latency and intensity is studied to identify a possible hearing loss and to determine the aetiology.

Research Methods

In the research context, clinical measurements are performed as well as alternative ones. The reason for not being part of the clinical routine is either their complexity, or that they investigate properties of the hearing process not necessarily related to hearing loss diagnosis and rehabilitation.

Ear Canal and Nasal Sound Pressure Measuring the sound pressure in the ear canal (ECSP) is a common method in hearing research in living humans. The airborne sound physically consists of variations of pressure in the air, which is in turn the quantity being measured. The standard measurement unit for pressure is Pascal (Pa), and in hearing context the sound pressure is usually given in dB SPL (decibel sound pressure level), i.e. relative to the reference pressure of 20 μPa, as the logarithmic scale correlates better with the sensitivity of the human ear.
ECSP is usually measured with low-noise probe microphones more or less deeply inserted in the ear canal. Measurements can be carried out with the ear canal open or closed in various ways, from deep ear plugs to external earmuffs. Several studies can be found in the literature where ECSP is used for many different purposes. In the field of BC hearing, microphone measurements have been mainly employed to investigate the occlusion effect [17, 66], transcranial transmission [67] and various other properties of AC and BC sound transmission [68–71].
Measurement of the sound pressure in the ear canal finds also application in the verification of correct functioning of implanted hearing devices intraoperatively [72], especially when the device is in the clinical trial phase. As an alternative to ECSP measurement, nasal sound pressure (NSP) is being recently investigated as it seems to offer a valid alternative when the ear canals are not accessible [73]. When the implanted transducer is stimulated, the vibrations are transmitted to the skull bone, and vibrations are induced in the surrounding tissues and in the cavities of the skull. As a result, the sound pressure originated from BC stimulation can potentially be recorded in any of the cavities. Being nasal and aural cavities connected, the measurement of NSP is hypothesised to give the same information as the ECSP. One advantages of using the nostril instead of the ear canal is that the nose area is more easily accessible during surgery, when the patient is sedated and usually lying in a lateral head rest position. Furthermore, the area around the ear is sterile and the opening of the external canal is often covered by the pinna that is folded for surgery purpose. The NSP measurement technique is further discussed and investigated in Paper III.

Vibrational Measurements Vibrational movement of an object can be described as displacement, velocity or acceleration. All these quantities are tightly related as they can be obtained from each other through derivation or integration with respect to time. Vibrations are commonly measured either by accelerometers or with a Laser Doppler Vibrometer (LDV).
An accelerometer is a tiny instrument that is rigidly anchored on the object to be measured and equipped with a seismic mass mounted on top of a sensing element. The displacement of the mass from its neutral position is used to detect the acceleration, and the mechanical movement is converted into electrical signal by piezoelectric, piezoresistive or capacitive components. One of the main advantages of accelerom-

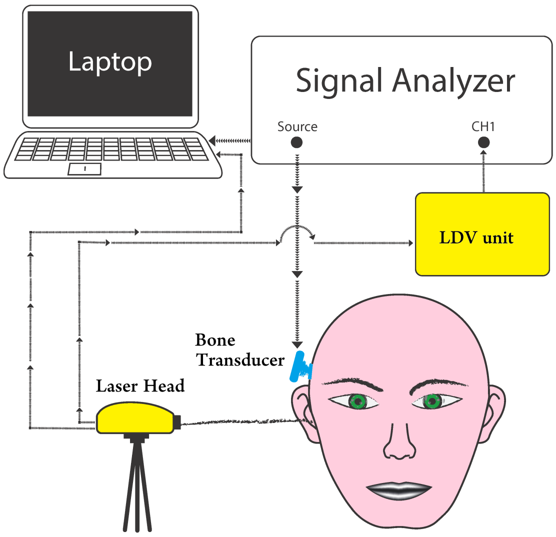


Figure 3.2: Example of a measurement set up with Laser Doppler Vibrometer (LDV) to detect cochlear promontory velocity: the subject is stimulated with a bone transducer which transmits vibrations to the skull. The laser beam is, in this example, pointed at the cochlear promontory through the ear canal to measure the velocity of its surface. The laser beam can be pointed at the cochlear promontory if the middle ear is open, otherwise the forehead or eardrum are common alternatives. Stimulation and recorded signals can be handled with a signal analyser and/or a computer.

eters is that they are not affected by movements outside the object where they are mounted. On the other side, the main drawback is that the accelerometer itself has a certain weight which inevitably loads the surface where it is attached and influences its vibrational response.
A LDV is a measurement instrument that senses velocity of a certain object by sending a laser beam towards the target surface and recording its reflected ray. Figure 3.2 shows an example of how LDV can be used to measure the velocity of the cochlear promontory under BC stimulation.
The instrument's working principle is based on the Doppler effect: a wave emitted at a certain frequency by a source and hitting a reflective surface is bounced back with a phase shift that depends on the relative velocity between emitter and receiver. By comparing the emitted beam with the received one, the velocity of the target surface can be determined with very high precision. The main advantage of this method is that it is contactless, thus avoiding mass loading of the surface and allowing to reach very small and otherwise inaccessible regions. Drawbacks are the need for a reflective surface and the susceptibility to external vibrations (such as the system where the laser head is mounted). Basic LDVs measure on a single point and along a single direction, but more advanced models can perform three-directional measurements as

well as surface scanning.
LDV measurements have been used in combination with probe microphone measurements to validate and complement ECSP measurements [71, 72]. Vibrational measurements with both accelerometers and LDV have been used extensively to investigate sound propagation mechanisms not only on living subjects, but also on temporal bones, dry skulls and cadavers, in the studies cited in section 2.3.3.
Objective vibrational measurements have also been shown to correlate well on a group level with hearing thresholds, making it possible to use detected shifts in ECSP or LDV measurements to estimate corresponding variations in hearing sensitivity [42, 69, 74].

Chapter 4

Rehabilitation by Bone Conduction Devices

Rehabilitation of hearing impaired patients is one of the main applications of bone conduction hearing. Other utilisation possibilities are in communication systems, in situations when using BC microphones and headphones can be more convenient than conventional AC systems, or in audiometry, to characterise the nature of a patient's hearing loss. This chapter is focused on the rehabilitative aspect, starting with a brief historical overview of BCDs development with a final focus on transcutaneous solutions, which the market seems to be moving towards at the moment. Main challenges in this field are also quickly addressed in the final part of the chapter.

4.1 Brief History of Bone Conduction Devices

Although the knowledge of bone conduction hearing mechanism can be dated back to the second century AD, the idea of using BC as a way of improving hearing ability came many centuries later, sometimes attributed to the Italian physician Girolamo Cardano in 1521 [75]. Yet, written reports of the earliest hearing aids held against the teeth, dating back to those days, were independently published in various countries. However, it was not until the 19^{th} century that the first bone conduction hearing aid was commercialised: it was the Audiphone, patented and produced by Richard Silas Rhodes (1842-1902) in 1879. As seen in Figure 4.1, the device was quite big in size, consisting of a leaf of vulcanite 24 cm wide, 27.7 cm long, and 1 mm thick, shaped like a fan in an attempt to make it confusable with a regular fan.
Several versions and upgrades were developed after the release of the Audiphone, keeping teeth stimulators popular hearing aid devices until the beginning of the 1920s. A tremendous technical advancement of the field was achieved in the 1920s with the development of the carbon microphone and the magnetic receiver, which led to the construction of bone conduction vibrators [3,76]. In 1932, Hugo Leiber from the Sono-

Figure 4.1: Black and white photograph of a woman holding Rhodes' Audiphone in her mouth, c.1926. Patented in 1879, the Audiphone was the first commercialised hearing aid based on bone conduction sound propagation through teeth and skull bone. The device was to be held in the hand with the upper end pressed against the upper teeth. The thresholds of patients with conductive loss could be improved by up to 30 dB.
Image courtesy of The Central Institute for the Deaf-Max A. Goldstein Historic Devices for Hearing Collection, Becker Medical Library, Washington University School of Medicine.

tone Corporation invented the first wearable hearing aid with the so-called oscillator placed on the mastoid. Commercialised bone conduction eyeglasses with embedded electronics came out some years later, in the mid 1950s, and gained much popularity. However, uncomfortable wear and poor sound quality caused a rapid decline in their usage and BCD field was commercially quiescent for few years.
The breakthrough came by the end of the 70's, when partially implantable osseointegrated solutions were developed. Today plenty of alternative BCDs are available and their number is constantly growing.

4.2 Bone Conduction Devices Today

A comprehensive overview of the BCD market state of the art is given in [4], where BCDs are characterised based on the way the signal is transmitted to the bone. As can be seen in Figure 4.2, three main groups are identified: skin drive, direct drive and in the mouth. In the first category, the transducer is placed on the head and vibrations are transmitted through intact skin. On the contrary, direct drive BCDs are characterised by a direct stimulation of the skull bone, either with intact or perforated skin. In the mouth devices transmit vibrations through the teeth and are included in the review although not commercially available at the moment. A brief description of the devices in each group and subgroup is given in the following paragraphs, together with main pros and cons associated to each of them.

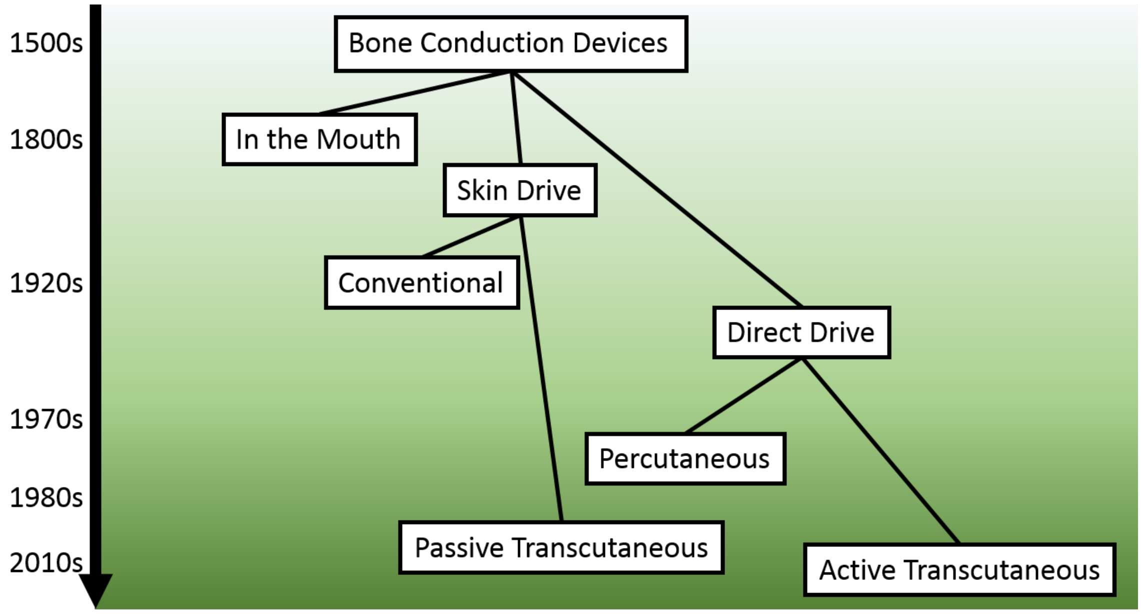


Figure 4.2: Classification of bone conduction devices as in [4]. The time line to the left gives an approximate indication of when the first devices of each category appeared on the market, from the renaissance (top) to the contemporary years (bottom).

4.2.1 In the Mouth

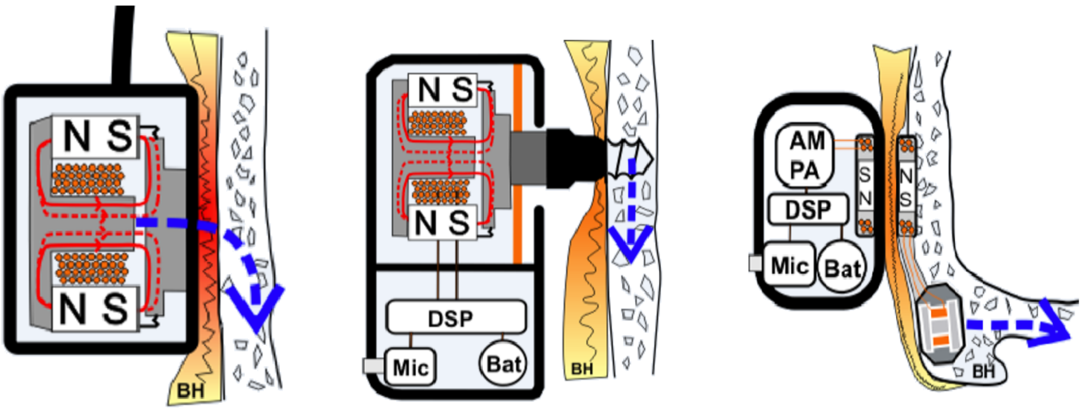
In the first reported BCDs, the transmission of the vibrations was achieved through the teeth. The connection between teeth and skull bone is direct and firm, providing a potentially efficient way to be exploited. On the other hand, the oral environment is not optimal to house electronic devices due to its acidic nature. Another challenge with in the mouth devices is their size: given the limited space, the size of the device needs to be kept very compact, which leads to great limitations in the power output. A commercial in the mouth device came to the market in 2013, the SoundBite™ by Sonitus Medical (San Mateo, CA, USA). It consisted of a transducer placed in the upper back teeth, receiving the signal from a wirelessly connected microphone worn behind the impaired ear. Although the reported outcomes were quite positive, the production of this device was interrupted in January 2015 and no other similar products have been released since then. The main limitations faced by the users were acoustic feedback, discomfort and noise disturbance, especially during meals.

4.2.2 Skin Drive

BCDs where vibrations are transmitted through the skin are referred to as skin drive and can be either conventional or passive transcutaneous.
Conventional devices do not require any surgical intervention, as all the components

are external (Figure 4.3a). A conventional BCD consists of an audio processor and transducer held in place by for example eyeglasses, steel springs or soft headbands. The microphone and transducer are housed in the same casing or in separate ones depending on the design of the device. The early versions had major feedback problems, and therefore the microphone and the transducer were placed on different sides of the head.

The main advantage of such devices is that they are simple to wear and safe. This makes them suitable for sensitive populations such as children or mentally challenged subjects. It is also clinical practice to fit patients with conventional BCDs for trial periods, in order for the patients to experience the rehabilitative feeling and more consciously evaluate the possibility of implanted BCDs.



(a) Conventional transcutaneous.

(b) Percutaneous.

(c) Active transcutaneous.

Figure 4.3: Principal design of the three different kinds of bone conduction devices. N-S indicate the polarity of the magnets, Mic = micophone(s), Bat = battery, DSP = digital sound processor, AM = amplitude modulator, PA = power amplifier. The blue arrows indicate the main vibrations transmission path.
Figures from Ref. [77]

However, several drawbacks come along with the use of conventional BCDs. The main issue is that, in order to get a satisfactory transmission, the transducer has to be pressed against the skin with a certain force, usually around 2 Newton. In the long run, headache, discomfort and skin irritation can arise due to the static pressure if the device is worn for long periods of time. Furthermore, the quality of rehabilitation is decreased by two main factors: acoustic feedback (sound radiated from the transducer that reaches back to the microphone) and signal attenuation through the soft tissues. Especially at high frequencies, the vibrations are highly damped by the skin and other soft tissues before reaching the skull bone, resulting in a substantial

loss of intensity before the cochlea is reached.
Passive transcutaneous BCDs function in the same way as conventional ones, with the only difference being that they have an implanted magnetic unit to retain the device on the skin. Therefore, they do not require any external retention mechanism, but they require a surgical operation to place the magnet. With such implantation, not only is the aesthetic greatly improved, but also the device is kept in the right position ensuring a better transmission compared to a removable head wear. The drawbacks related to the need for static pressure, however, are still present.
A newly developed solution to the complications due to constant pressure and aesthetics is to have the device simply glued to the skin. This is achieved with an adhesive patch holding an abutment where the device is snapped onto. The solution is implemented in the so-called ADHEAR system, currently in a clinical trial supported by MED-EL (Innsbruck, Austria).
Today, there are several companies producing conventional BCDs, while passive transcutaneous are only available in two models: Sophono® (Boulder, CO, USA), and Baha® Attract (Cochlear Bone Anchored Solutions AB, Mölnlycke, Sweden).

4.2.3 Direct Drive

When the vibrations are applied directly to the skull bone, the device is defined as direct drive. The intuitive advantage of such method is that the transmission is not damped by soft tissues and a stronger signal is sent directly to the cochlea.
The first direct drive type of BCD was the BAHA, developed in the late 1970s. The design of BAHAs (Figure 4.3b) includes a single housing where microphone, transducer and all the required electronics are contained, and an attachment to hold it in place. The attachment consists of a titanium screw fixed to the parietal bone, connected to a skin-penetrating abutment to be coupled to the audio processor. In this way, the vibrations produced by the transducer are effectively transmitted to the skull through the osseointegrated fixation. Since its appearance on the market, the BAHA has been largely used and represents still now the golden standard for implantable BCDs. Several BAHA systems are currently available from two manufacturers, Cochlear Bone Anchored Solutions AB and Oticon Medical (Askim, Sweden).
The rehabilitation effect has been shown to be satisfactory in the great majority of patients. Refinements in the surgical techniques and abutment design made the implantation procedure quick and safe and suitable to a vast number of patients. However, the abutment area needs daily care, cases of skin complications are still being reported and there is always a risk for implant loss, due to infection or trauma. Furthermore, cosmetic reasons make BAHAs not appealing for certain populations.
Another way to stimulate the skull bone in a direct way is to have an implanted transducer. This is the case for active transcutaneous BCDs, composed of two parts (Figure 4.3c): an externally worn audio processor and an implanted unit with receiv-

ing coil and transducer. The implant is placed under intact skin and the external part is magnetically retained on top of it. The transmission of the signal through the skin takes place via an inductive link, avoiding mechanical signal loss in the soft tissues and reducing the requirement on the static force needed. The main advantage of active transcutaneous solutions is that they stimulate directly the skull bone while avoiding skin penetration with all its related complications. Furthermore, feedback is greatly reduced thanks to the physical separation of microphone (externally worn) and transducer (implanted). On the other side, the surgical procedure is a bit more complex and power attenuation occurs in the inductive link over the skin.
At present, only one active transcutaneous device is available on the EU market, the Bonebridge™ from MED-EL. This device was introduced to the market in 2012 for adult patients with conductive and mixed hearing loss as well as SSD (Single Sided Deafness). Two years later, in 2014, the device obtained also the approval to be used in children older than 5 years of age. The market today is strongly moving towards active transcutaneous devices, and ongoing clinical studies will soon end up in more commercially available options.

4.2.4 The BCI - Bone Conduction Implant

The BCI,visible in Figure 4.4, is an active transcutaneous BCD currently on clinical trial phase since 2012 [5–9]. The development of this BCD started in the late 1990s, driven by the wish to provide a valid alternative to the percutaneous BAHAs by overcoming complications related to the skin penetration. The project is a joint effort between Chalmers University of Technology and Sahlgrenska Academy, University of Gothenburg, Sweden.

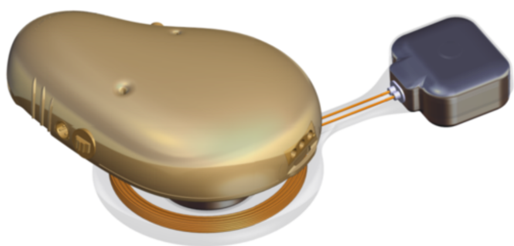


Figure 4.4: The active transcutaneous Bone Conduction Implant with one implanted unit and one external audioprocessor.

This active transcutaneous system consists of one implanted and one externally worn unit. The audio processor unit includes the external retention magnet, two directional microphones, a 675 hearing aid battery, a digital signal processor and a modulating circuit with transmitter coil; all contained in a plastic casing. The implanted unit comprises the internal retention magnet, receiving coil, demodulating circuit and bone transducer, all sealed in a titanium casing and outer silicon enclosure. The implant is placed on the skull bone under intact skin and soft tissues, and the external part is magnetically retained on the head. The audio signal picked up by the microphones is electromagnetically transmitted through the inductive link. The signal is amplitude modulated in order to achieve a more efficient transmission over the skin, and demodulated before being fed to the transducer [8]. Transmitter and receiver coil are tuned to optimise the transmission.

For devices with implanted units, safety is one of the key aspects to be ensured, both during surgery as well as afterwards. The preclinical investigations and the ongoing clinical study have demonstrated that the surgical procedure to implant the BCI is safe and easy to perform, and no serious adverse events were reported so far. The safety of the implanted unit has also been investigated in a pilot study with regards to magnetic resonance imaging (MRI) scan compatibility, and the results suggest that the BCI implant is likely to obtain a MRI conditional approval for 1.5 Tesla scanners [78].

Another important aspect to consider is the power output of the device. In order to stimulate the cochlea and get a satisfactory rehabilitation, the device must be able to convey a sufficiently strong signal. When compared to percutaneous devices, transcutaneous BCDs suffer from signal attenuation between the external and the implanted unit: in the case of skin-drive BCDs the attenuation is due to absorption by soft tissues and can be up to 20 dB in some frequencies [4], while in the case of the BCI inductive link, the loss is due to the link itself and is estimated to be around 10-15 dB [5]. Two factors in the BCI design are balancing out this loss of sensitivity: (I) the transducer is placed as close as possible to the cochlea, which has been proven to enhance the hearing sensitivity by 3 to 14 dB when compared to the BAHA screw position [40, 42], and (II) the transducer has a high frequency boost in the region 2500 to 6500 Hz to increase its output force [8]. Considering these features, the BCI is expected to rehabilitate indicated patients as effectively as a percutaneous BAHA. This hypothesis was confirmed in the pilot study presented in Paper I.

The transducer utilised in the BCI is of the BEST (Balanced Electromagnetic Separation Transducer) type, presented by Bo Håkansson in 2003 [79]. The balanced suspension principle of the BEST reduces distortion and allows for a smaller size of the transducer, whilst making it more efficient in terms of current consumption for a given voltage. The reduced size has the advantage of allowing a wide cohort of patients to be anatomically eligible to be fitted with the transducer in the temporal bone, as shown in a study by Reinfeldt et al. [80].

4.3 Assessment of Rehabilitation Effect

After the patient has been fitted with a hearing device, it is important to keep the rehabilitation process monitored and to assess how effective it is, in order for the patient to benefit as much as possible from the intervention.
One way of assessing the rehabilitation effect is to compare the results from audiological tests without and with the device in a sound field. Tone thresholds are routinely evaluated, and the improvement at each frequency is used as an indicator of rehabilitation quality as well as a guideline for possible changes in the device settings for the fitting. Result from speech audiometry is also a good indicator of whether the patient is taking advantage of the device in a satisfactory way.
However, these quantitative outcomes summarise the benefit given by technical features such as amplification or noise reduction algorithms, which do not describe the whole process of hearing-aid intervention. In order to evaluate the entire process, on top of audiometric tests, self-reported questionnaires are routinely administered. The subjective tests outcome is influenced by many factors other than the purely technical performance of the hearing aid, such as patient's expectations, counselling quality, daily use of the device and a number of additional psychosocial factors. It is not uncommon to find a discrepancy between functional outcome (improvement in tone thresholds, speech recognition scores, etc) and self-experienced outcome, which has raised interest in investigating the relation between objective and subjective measures [81–83] and fostered the development of assessment tools.
A great number of questionnaires are currently available, both hearing specific as well as generically addressing assistive devices. For implantable devices, such as BAHAs or transcutaneous BCDs, the impact of surgery and follow ups should also be taken into account. With such a diverse picture, the choice of which questionnaire is the most suitable to be administered to the patient is quite challenging, especially due to the potential multi-functionality of self-reported questionnaires: they can be useful tools for evaluating the quality of a hearing aid fitting as well as for comparing several hearing aid outcomes or monitor a patient's rehabilitative process over time. Furthermore, in addition to individual experience optimisation, there are applications of self-reported data even for global objectives such as to assess the success of a practitioner's service overall, evaluate the impact of new technologies or management programs in healthcare structures, provide evidence of performance quality and many more [84]. This inevitably leads to a considerable spread in protocols, both in the clinical as well as in the research practice.
In Paper I two questionnaires are used:

- APHAB = Abbreviated Profile of Hearing Aid Benefit
  The PHAB questionnaire, and its shortened version APHAB, were developed by Cox et al. [85,86] to get some insights on the hearing aid users' perception of costs and benefits associated to the use of their device. The PHAB consists of

66 questions, which are reduced to 24 in the abbreviated version, developed to be more suitable to clinical practice. Here four categories are present: I) EC: Ease of Communication, investigating how much effort is required to understand speech under easy listening conditions; II) RS: Reverberant Sound, when speech has to be understood in reverberant environments; III) BN: Background Noise, investigating the effect of noise interfering with the communication; IV) AV: Aversiveness of Sound, regarding the reaction to loud or unpleasant sound.

- GBI=Glasgow Benefit Inventory
  The GBI questionnaire is a specifically developed measurement of the patient's benefit after ear, nose and throat interventions [87]. Three subscales are included, focusing on generic health status, social support issues and physical health. The test has been largely used to monitor BAHA implantations.

Just to name a few other questionnaires among the most used ones:

- Hearing Aid Performance Inventory/Questionnaire (HAPI/HAPQ), to evaluate the direct benefit given by te use of the hearing aid;
- Glasgow Hearing Aid Benefit Profile (GHABP), addressing differences between pre- and post- hearing aid intervention;
- Profile of Aided Loudness (PAL), more focused on the quality of fitting;
- Amsterdam Inventory, also concerned with the quality of fitting;
- International Outcome Inventory for Hearing Aids (IOI-HA), to evaluate the fitting with respect to standards;
- Satisfaction with Amplification in Daily Life (SADL), addressing generic perceived satisfaction;
- Auditory Lifestile and Demand (ALD), where the richness of auditory environments encountered by the device user is investigated

and many more [88, 89].

4.4 Challenges with Bone Conduction Devices

Despite the impressive technical advancements that have been achieved in the last decades, there are still a number of aspects that challenge BCDs users and providers. These are not only related to the technical specifications of the devices, but also to social and assistive factors.
Even though hearing impairment is a very common form of disability, the acceptance of the problem and the use of rehabilitative devices is still a sensitive issue. Patient engagement is essential in the rehabilitation process as much as in the development of new solutions. Clinical trials are successful when the participants are compliant, keep an open relation with the professionals and are not ashamed of using their device. From this point of view, the importance of developing discreet and pleasant devices is not to be underestimated. Customisable, appealing and graceful devices are to be aimed for, though without compromising on the performance.
One of the main obstacles to achieve high performance, aesthetic pleasantness and comfort all together is the size of the device. Smaller audio processors are less noticeable and easily camouflaged with for example hair, and smaller implanted units are more easily fitted to average and smaller size skulls. On the other hand, housing all the required electronics in a small case is technically challenging, and can lead to increased feedback problems when microphone and bone stimulator are in the same unit, which is the case for all BCDs except for active transcutaneous. Furthermore, the size of the transducer is related to its power capability, so a smaller transducer may imply insufficient output power.
Limiting the power consumption is an important aspect for all hearing devices, thus for BCDs as well. The need to change the batteries very frequently is not only bothersome, but also unworthy from an economical and environmental point of view. Even without considering the energy source issue, devices have limitations on the maximum output power that they are able to deliver, mainly for technical reasons.
For transcutaneous devices, the power constraint has been so far the most limiting factor. Active transcutaneous BCDs have the potential of overcoming such limitations by optimising the position and attachment of the implanted transducer on the skull bone. The implantation involves the decision of which position and type of attachment to choose. Although some studies have been done on the effect of positioning the transducer at varying distance and direction from the cochlea, the overall effect of the attachment type in combination with its position is still to be clarified. One challenge is then to understand the importance of various factors related to the implant installation and to apply this knowledge to the design of the devices. In Paper II a pilot study on the effect of the attachment type is presented.
For semi implantable BCDs another big challenge is to be compatible with diagnostic methods such as X-rays and MRI. Safety issues related to the use of metal and magnetic materials inside scanners are either direct, for example excessive induced

torque on the implanted magnet by the external magnetic field in the MRI scan, or indirect, if for example the image artefact created by the device prevents the patient from being correctly diagnosed. MRI investigations are today heavily employed in various branches of medicine and it is not uncommon for an individual to be in need of taking such an examination at least once in life. Explantation of the device if needed is an option, but in the ideal case the implanted unit would be kept in place without compromising the examination. The design of the bone transducer is a key part in this regard.

To conclude, it is important to mention the open problems with hearing aid use in noisy environments. The ability to discriminate and understand speech in noisy situations such as parties or reverberant rooms has always been troublesome for hearing aid users, regardless of the type of hearing device. Despite the advancement in signal processing algorithms and the invention of accessories to ameliorate this condition, the need for improvement is still big in this regard.

Chapter 5

Summary of Papers

Paper I: Audiometric Comparison Between the First Patients With the Transcutaneous Bone Conduction Device and Matched Percutaneous Bone Anchored Hearing Device Users

In this paper the aim was to compare the rehabilitation provided by the transcutaneous BCI with the one from percutaneous BAHAs on implanted patients. The hypothesis was that the rehabilitation given by the BCI is comparable to a BAHA for patients that satisfy the inclusion criteria. As it was not possible to test implanted BCI and implanted BAHA on the same patient, the study was designed so that each of the first six BCI users was matched to one BAHA user in terms of hearing, gender and age characteristics. This matched-pairs design is unique in the field and is believed to allow a more fair and reliable comparison over a random patient selection given the limited number of BCI patients.

Results from identical audiometric tests and self-reported questionnaires from both groups were compared to evaluate the difference in performance between BCI and BAHA. In total, four audiological sound field tests were used: warble tone thresholds, speech recognition score in noise, speech recognition threshold in quiet, signal to noise ratio threshold. No statistically significant difference was found in either of the tests (results are shown partly in Figure 5.1). The outcome of the questionnaires, the APHAB and the GBI, showed slightly superior results for the BCI although not statistically significant.

The overall conclusion from the study was that the initial hypothesis was solid, and the transcutaneous BCI is believed to offer a valid alternative to percutaneous BAHAs for indicated patients. However, conclusions could not be drawn in a definitive way, mainly due to the limited number of patients.

The author was responsible for planning and taking part in the measurements on BAHA patients, analysing the data and writing the article.

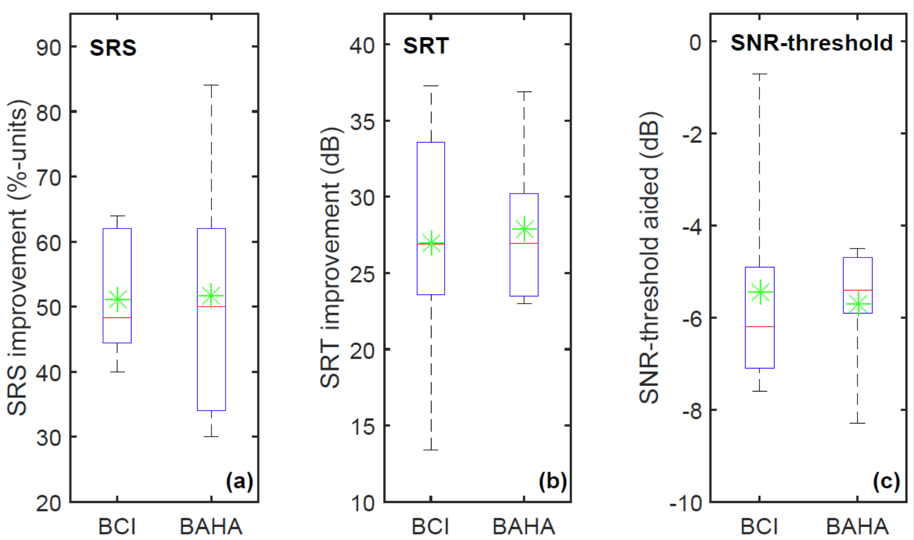


Figure 5.1: The results from speech tests in six BCI patients and six BAHA patients showed that the two devices gave comparable rehabilitation. Median values are indicated by the red line, mean values with a green star, 25th and 75th percentiles are included in the boxes. SRS=Speech Recognition Score, SRT=Speech Recognition Threshold, SNR=Signal to Noise Ratio.

Paper II: Direct Bone Conduction Stimulation: Ipsilateral Effect of Different Transducer Attachments in Active Transcutaneous Devices

The aim in this study was to investigate if and how the way the transducer is attached to the bone can influence vibration transmission to the cochlea. With a market moving towards transcutaneous solutions, the investigation of the effect of the implantation method on the stimulus reaching the cochlea is gaining more and more interest.
This pilot study was done on four cadaver heads that were implanted on both sides (giving a total of eight test sides) with three different attachment methods. The attachments were meant to represent some of the alternatives that are available for transcutaneous BCDs and were chosen as: A) a flat small-sized contact surface, B) a flat wider surface and C) a bar anchored on each side via screws. The same tranducer was used to stimulate the skull bone with a swept sine 0.1-10 kHz in all three cases, and the transmission was evaluated in terms of ear canal sound pressure and velocity at the cochlear promontory, measured with a low noise microphone and a

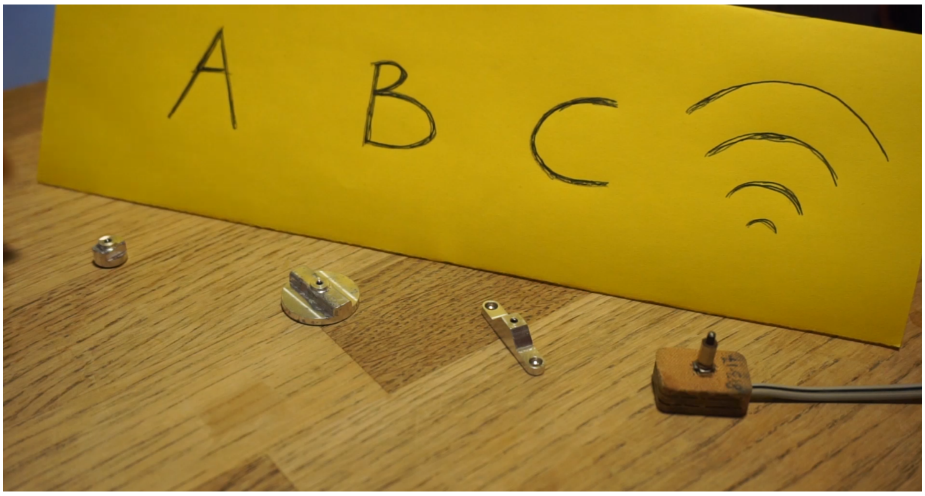


Figure 5.2: The three dummy implants used to achieve different typologies of contact with bone: A) small-sized flat surface, B) wide flat surface and C) rigid bar anchored with two screws at the extremities. On the right hand side, the transducer that was utilised is shown. The transducer was screwed on top of each of the adaptors with its M2-threaded screw.

laser Doppler vibrometer, respectively. The three adaptors and the transducer to be screwed on top of them are pictured in Figure 5.2.

The difference between the transmission from the adaptors was evaluated and trends indicated that the attachment type has a stronger influence at frequencies above approximately 5 kHz. Results from the three attachment techniques were found to be comparable if the whole frequency range was considered, while a slight advantage was seen for smaller contact areas at mid and high frequencies.

Two main limiting factors prevented to reach firm conclusions: only eight measurement sides were available, and the inter subject variability was high. Further measurements to extend this study are planned in order to reach more clear outcomes and examine the contralateral side as well.

The author was responsible for planning and taking part in the measurements, analysing the data and writing the article.

Paper III:
Nasal Sound Pressure as Objective Verification of Implant in Active Transcutaneous Bone Conduction Devices

In this study, the aim was to evaluate a new methodology for intra-operative verification of the BCI implant functionality as well as to monitor the implant to bone transmission stability over time. The increasing focus on the development of transcu-

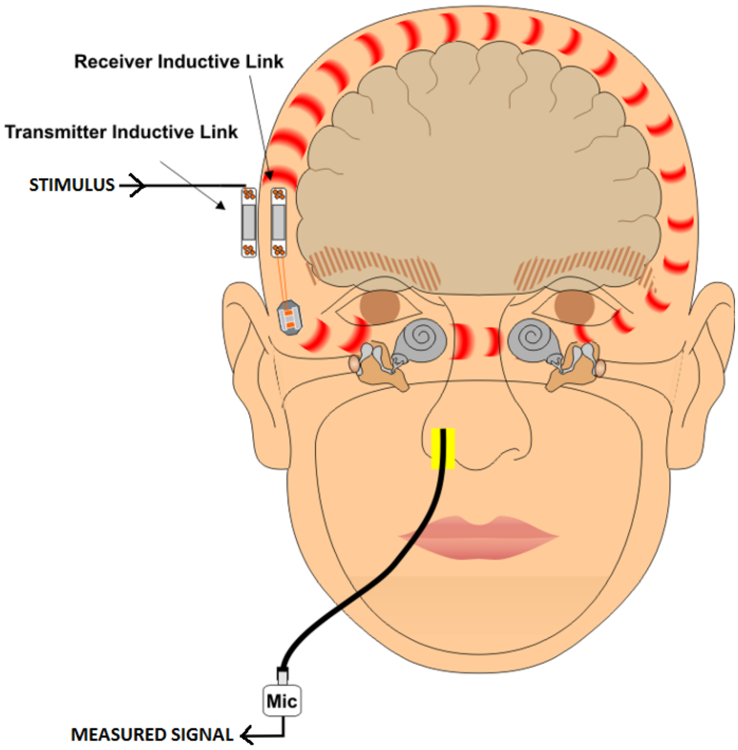


Figure 5.3: Measurement set-up for NSP measurement: the custom-made driver unit is electrically driven with an input signal, the signal is collected by the implanted receiver coil, demodulated and used to drive the transducer. The microphone (Mic) probe inserted in the nostril measures the induced sound pressure in the ear and nose cavities.

taneous devices with implanted transducer calls for the availability of tools to easily verify their functionality in a safe and fast way. The method for intra-operative and post-operative verification of implanted units investigated in this study is the nasal sound pressure (NSP).

NSP was measured in all the 13 patients included so far in Gothenburg in the BCI clinical trial, at surgery and at follow up visits. After the subcutaneous unit was implanted, before closing the surgical wound, a custom-made driver unit was utilised to stimulate the implant with a swept sine 0.1-10 kHz. The NSP was recorded in the ipsilateral nostril as an alternative to the sound pressure in the ear canal, as during the surgery the operated ear is a sterile area which is not easily accessible. The same measurement was repeated at follow up visits with the patient holding the breath. A simplified illustration of the measurement set-up is shown in Figure 5.3.

Data at surgery for different patients was investigated to evaluate the validity of the method as a control for implant functionality when the patient is lying down anaesthetised. Additionally, NSP data measured over time from the same patient was analysed as an indicator of implant stability over time.

Valid measurements above the noise level were obtained for middle frequencies, approximately between 0.4 and 5 kHz. The absolute NSP level was found to be highly

variable between subjects, but with good potential for being used as a functionality verification method of the implanted unit. The NSP value over time for each patient was very stable, with some exception at isolated frequencies such as 4 kHz.
It was concluded that the method can be a valid tool for verification of active transcutaneous BCDs, with the main concern being the need for a simplified set-up to be used in the clinical routine.
The author was mainly responsible for the statistical analysis of data and partly writing the paper.

Chapter 6

Conclusions and Future Work

The field of bone conduction hearing rehabilitative devices has been extensively growing in the past few decades, and today's market offers several different alternatives, whose number and variety is constantly increasing. In recent years, the development is moving towards active transcutaneous solutions, where the transducer is permanently implanted on the skull under intact skin, and the externally worn audio-processor unit is magnetically retained on the skin. In this context, this thesis presents various experimental studies concerning direct drive bone conduction stimulation for hearing rehabilitation purposes. Active transcutaneous stimulation was compared with percutaneous stimulation on implanted patients, and alternative methods for transmitting the sound vibration to the skull were compared among each other. Finally, a method for active transcutaneous implant functionality verification was evaluated.

The main conclusions drawn from the studies are:

- Audiometric tests and self-reported user questionnaires showed that the quality of the rehabilitation offered by the BCI is comparable to the one offered by BAHAs for indicated patients.
  In BC hearing rehabilitation, BAHAs are today the golden standard due to their high sound quality and effectiveness. The reason that drives transcutaneous devices development is the desire for overcoming complications related to the skin penetration rather than to technically outperform BAHAs. Therefore, a comparable result obtained transcutaneously can be a very attractive alternative to a percutaneous one.

- When the transducer is directly anchored to the skull bone (direct drive BCDs), the attachment method and the resulting contact to bone type appear to play a significant role for frequencies above 5 kHz. This indicates that a reduced contact size should be kept for improved signal transmission.
  As one of the main limitations of transcutaneous devices is their maximum

power, choosing a convenient method to anchor the transducer to the skull bone can contribute to improving the level of the vibrations that effectively reach the cochlea upon stimulation.

- Measuring the sound pressure level in the nostrils (NSP) is a promising way to verify the transducer functionality during surgery and follow up visits.
  Maintaining the functionality of the transducer is an essential requisite for a satisfactory rehabilitation, therefore it is crucial to double-check it during the surgery, before the surgical wound is closed. The same safe and quick measurement can be done on follow up visits to monitor the implant to bone transmission over time. In this regard, the transmission was shown to be stable in BCI patients over a 12 months period of time after surgery.

Being promising so far, the clinical study of the BCI is going to be continued for long time follow up results, up to 5 years from implantation. NSP measurement data will be regularly collected and analysed, and possible relations between the measurements and the osseointegration and ageing process of the implant could be investigated.

Additional measurements on vibrations transmission in relation to alternative attachments are planned in the near future. More precise recommendations for the attachment of transducers in active transcutaneous BCDs would be achievable if clearer conclusions were drawn from the studies on human heads. To increase the number of subjects is one way to get a clearer picture. Another way would be to minimise the variability of measurements caused by the set-up, thus more stable measuring conditions will be looked for in the next sessions.
From vibrational and sound pressure measurements on cadaver heads, a great amount of information can be extracted. First of all, the effect of transducer attachment will be studied contralaterally, i.e. looking at the signal at the opposite ear with respect to the stimulation position. Furthermore, analysis of the phase of the received signal from the LDV could be used to get some insights on transcranial attenuation and wave propagation velocity. Additionally, the effect of mastoidectomy on the vibrational response of the skulls requiring a more backward located attachment will be tested.

Bibliography

[1] WHO. (updated February 2017) Deafness and hearing loss, fact sheet no.300. [Online]. Available: http://www.who.int/mediacentre/factsheets/fs300/en/

[2] HRF, "Årsrapport 2014: Hörselskadade och hörselvård i siffror," Tech. Rep., 2014.

[3] A. Mudry and A. Tjellström, "Historical background of bone conduction hearing devices and bone conduction hearing aids," *Implantable Bone Conduction Hearing Aids*, vol. 71, pp. 1–9, 2011.

[4] S. Reinfeldt, B. Håkansson, H. Taghavi, and å. Eeg-Olofsson, "New developments in bone-conduction hearing implants: a review," *Med Devices (Auckl)*, vol. 8, pp. 79–93, 2015.

[5] B. Håkansson, M. Eeg-Olofsson, S. Reinfeldt, S. Stenfelt, and G. Granström, "Percutaneous versus transcutaneous bone conduction implant system: a feasibility study on a cadaver head." *Otology and Neurotology*, vol. 29, pp. 1132–9, 2008.

[6] B. Håkansson, S. Reinfeldt, M. Eeg-Olofsson, P. Östli, H. Taghavi, J. Adler, J. Gabrielsson, S. Stenfelt, and G. Granström, "A novel bone conduction implant (BCI): engineering aspects and pre-clinical studies." *International Journal of Audiology*, vol. 49, pp. 203–15, 2010.

[7] M. Eeg-Olofsson, B. Håkansson, S. Reinfeldt, H. Taghavi, H. Lund, K.-J. Fredén Jansson, E. Håkansson, and J. Stalfors, "The bone conduction implant-first implantation, surgical and audiologic aspects," *Otology and Neurotology*, vol. 35, pp. 679–685, 2014.

[8] H. Taghavi, B. Håkansson, S. Reinfeldt, M. Eeg-Olofsson, K.-J. Fredén Jansson, E. Håkansson, and B. Nasri, "Technical design of a new bone conduction implant (BCI) system," *International Journal of Audiology*, vol. 54, pp. 736–744, 2015.

[9] S. Reinfeldt, B. Håkansson, H. Taghavi, K.-J. Fredén Jansson, and M. Eeg-Olofsson, "The bone conduction implant: Clinical results of the first six patients," *International Journal of Audiology*, vol. 54, pp. 408–416, 2015.

[10] J. O. Pickles, *An Introduction to the Physiology of Hearing*, 4th ed., ser. 10. London: Academic Press, 7 1988, vol. 4.

[11] J. Ashmore, "Cochlear outer hair cell motility," *Physiological Reviews*, vol. 88, no. 1, pp. 173–210, 2008.

[12] G. v. Békésy, "The structure of the middle ear and the hearing of one's own voice by bone conduction," *The Journal of the Acoustical Society of America*, vol. 21, no. 3, pp. 217–232, 1949.

[13] S. Reinfeldt, P. Ostli, B. Håkansson, and S. Stenfelt, "Hearing one's own voice during phoneme vocalization–transmission by air and bone conduction," *The Journal of the Acoustical Society of America*, vol. 128, no. 2, pp. 751–62, 2010.

[14] G. v. Békésy, "Zur theorie des hörens bei der schallaufnahme durch knochenleitung," *Annalen der Physik*, vol. 405, no. 1, pp. 111–136, 1932.

[15] K. Lowy, "Cancellation of the electrical cochlear response with air and bone conducted sound," *The Journal of the Acoustical Society of America*, vol. 14, no. 2, pp. 156–158, 1942.

[16] E. Wever and M. Lawrence, *Physiological Acoustics*. Princeton: Princeton University Press, 1954.

[17] S. Stenfelt and S. Reinfeldt, "A model of the occlusion effect with bone-conducted stimulation," *International Journal of Audiology*, vol. 46, pp. 595–608, 2007.

[18] S. Stenfelt, S. Puria, N. Hatho, and R. L. Goode, "Basilar membrane and osseous spiral lamina motion in human cadavers with air and bone conduction stimuli," *Hearing Research*, vol. 181, no. 1-2, pp. 131–143, 2003.

[19] B. Schratzenstaller, T. Janssen, C. Alexiou, and W. Arnold, "Confirmation of G. von Békésy's theory of paradoxical wave propagation along the cochlear partition by means of bone-conducted auditory brainstem responses," *ORL : Journal for Oto-Rhino-Laryngology and Its Related Specialties*, vol. 62, no. 1, pp. 1–8, Jan 2000.

[20] D. Purcell, H. Kunov, P. Madsen, and W. Cleghorn, "Distortion product otoacoustic emissions stimulated through bone conduction," *Ear and Hearing*, vol. 19, no. 5, pp. 362–370, 1998.

[21] T. Watanabe, S. Bertoli, and R. Probst, "Pathways of vibratory stimulation as measured by subjective thresholds and distortion-product otoacoustic emissions," *Ear and Hearing*, vol. 29, no. 5, pp. 667–673, 2008.

[22] C. Adelman, R. Fraenkel, L. Kriksunov, and H. Sohmer, "Interactions in the cochlea between air conduction and osseous and non-osseous bone conduction stimulation," *European Archives of Oto-Rhino-Laryngology*, vol. 269, no. 2, pp. 425–429, 2012.

[23] W. E. Hodgetts, "Contributions to a better understanding of fitting procedures for BAHA," Ph.D. dissertation, University of Alberta (Canada), 2008.

[24] S. Stenfelt, "Acoustic and physiologic aspects of bone conduction hearing," in *Implantable Bone Conduction Hearing Aids*, ser. Advances in Oto-Rhino-Laryngology. Karger, 2011, vol. 71, no. 71, pp. 10–21.

[25] G. v. Békésy, "Note on the definition of the term: Hearing by bone conduction," *The Journal of the Acoustical Society of America*, 1954.

[26] G. v. Békésy, *Experiments in hearing.* United States: New York: Mc Graw, 1960.

[27] J. Tonndorf, "Bone conduction. Studies in experimental animals," *Acta Oto-Laryngologica*, pp. 213–1, 1966.

[28] S. Stenfelt and R. L. Goode, "Bone-conducted sound: Physiological and clinical aspects," *Otology and Neurotology*, vol. 26, no. 6, pp. 1245–1261, 2005.

[29] S. Stenfelt, "Bone conduction and the middle ear," in *The middle ear: science, otosurgery, and technology*, ser. Springer Handbook of Auditory Research. Springer, 2013, vol. 46, no. 46, pp. 135–69.

[30] G. v. Békésy, "Vibration of the head in a sound field and its role in hearing by bone conduction," *Journal of the Acoustical Society of America*, vol. 20, no. 6, pp. 749–760, 1948.

[31] T. B. Khalil, D. C. Viano, and D. L. Smith, "Experimental analysis of the vibrational characteristics of the human skull," *Journal of Sound and Vibration*, vol. 63, no. 3, pp. 351–376, 1979.

[32] B. Håkansson, A. Brandt, P. Carlsson, and A. Tjellström, "Resonance frequencies of the human skull invivo," *The Journal of the Acoustical Society of America*, vol. 95, no. 3, pp. 1474–1481, 1994.

[33] E. L. R. Corliss and W. Koidan, "Mechanical impedance of the forehead and mastoid," *The Journal of the Acoustical Society of America*, vol. 27, no. 6, pp. 1164–1172, 1955.

[34] G. Flottorp and S. Solberg, "Mechanical impedance of human headbones (forehead and mastoid portion of the temporal bone) measured under ISO/IEC conditions," *J Acoust Soc Am*, vol. 59, no. 4, pp. 899–906, 1976.

[35] B. Håkansson, P. Carlsson, and A. Tjellström, "The mechanical point impedance of the human head, with and without skin penetration," *J Acoust Soc Am*, vol. 80, no. 4, pp. 1065–75, 1986.

[36] J. B. Smith and C. W. Suggs, "Dynamic properties of the human head," *Journal of Sound and Vibration*, vol. 48, no. 1, pp. 35–43, 1976.

[37] Y. Chang, N. Kim, and S. Stenfelt, "The development of a whole-head human finite-element model for simulation of the transmission of bone-conducted sound," *The Journal of the Acoustical Society of America*, vol. 140, no. 3, pp. 1635–1651, 2016.

[38] E. R. Nilo, "The relation of vibrator surface area and static application force to the vibrator-to-head coupling," *Journal of Speech Language and Hearing Research*, vol. 11, no. 4, p. 805, 1968.

[39] E. Y. Yang, A. Stuart, R. Stenstrom, and S. Hollett, "Effect of vibrator to head coupling force on the auditory brain stem response to bone conducted clicks in newborn infants," *Ear and Hearing*, vol. 12, no. 1, pp. 55–60, 1991.

[40] M. Eeg-Olofsson, S. Stenfelt, A. Tjellström, and G. Granström, "Transmission of bone-conducted sound in the human skull measured by cochlear vibrations." *International Journal of Audiology*, vol. 47, pp. 761–9, 2008.

[41] R. Stenfelt, S. Goode, "Transmission properties of bone conducted sound: measurements in cadaver heads." *Journal of the Acoustical Society of America*, vol. 118, pp. 2373–91, 2005.

[42] S. Reinfeldt, B. Håkansson, H. Taghavi, and M. Eeg-Olofsson, "Bone conduction hearing sensitivity in normal-hearing subjects: Transcutaneous stimulation at BAHA vs BCI position," *International Journal of Audiology*, vol. 53, no. 6, pp. 360–369, 2014.

[43] ASHA, "Method for manual pure-tone threshold audiometry." *American Speech-Language Hearing Association*, 2004.

[44] ISO 8253-1, *Acoustics - Audiometric test methods - Part 1: Pure-tone air and bone conduction audiometry*, International Organisation for Standardization Std., 2010.

[45] ISO 8253-2, *Acoustics - Audiometric test methods - Part 2: Sound field audiometry with pure-tone and narrow-band test signals*, International Organisation for Standardization Std., 2009.

[46] ANSI, *Method for Manual Pure-Tone Threshold Audiometry.*, American National Standard Institution Std. ANSI S3-2004, 2004.

[47] ISO 226, *Acoustics - Normal equal-loudness-level contours.*, International Organisation for Standardization Std., 2003.

[48] ANSI S3.6, *American National Standards for Audiometers.*, American National Standard Institution Std., 2004.

[49] B. Taylor, H. G. Mueller, and E. C. (e-book collection), *Fitting and dispensing hearing aids.* San Diego: Plural Pub, 2011.

[50] S. Kramer, *Audiology: Science to Practice, 2nd Edition.* ProtoView, Apr 18 2014, vol. 1, no. 16, copyright - Copyright Ringgold Inc Apr 18, 2014; Last updated - 2015-02-06.

[51] H. G. Mueller and M. C. Killion, "An easy method for calculating the articulation index," *The Hearing Journal*, vol. 43, no. 9, September 1990.

[52] H. G. Mueller and M. C. Killion, "The new count-the-dot audiogram," *The Hearing Journal*, vol. 63, no. 1, p. 10, January 2010.

[53] ISO 8253-3, *Acoustics - Audiometric test methods - Part 3: Speech audiometry*, International Organisation for Standardization Std., 2012.

[54] S. Arlinger, *Nordisk lärobok i audiologi*, 1st ed. Ca Tegér AB, 2007.

[55] G. Lidén and G. Fant, "Swedish word material for speech audiometry and articulation tests," *Acta Oto-Laryngologica*, vol. 43, no. sup116, pp. 189–204, 1954.

[56] B. Hagerman, "Sentences for testing speech intelligibility in noise," *Scandinavian Audiology*, vol. 11, no. 2, pp. 79–87, 1982.

[57] B. Hagerman and C. Kinnefors, "Efficient adaptive methods for measuring speech reception threshold in quiet and in noise," *Scandinavian Audiology*, vol. 24, no. 1, pp. 71–77, 1995.

[58] L. Magnusson, “Reliable clinical determination of speech recognition scores using swedish pb words in speech-weighted noise,” *Scandinavian Audiology*, vol. 24, no. 4, pp. 217–223, 1995.

[59] B. Taylor, H. G. Mueller, and E. C. (e-book collection), *Fitting and dispensing hearing aids.* San Diego: Plural Pub, 2011.

[60] M. C. Killion, P. A. Niquette, G. I. Gudmundsen, L. J. Revit, and S. Banerjee, “Development of a quick speech-in-noise test for measuring signal-to-noise ratio loss in normal-hearing and hearing-impaired listeners,” *Journal of the Acoustical Society of America*, vol. 116, no. 4 I, pp. 2395–2405, 2004.

[61] M. Nilsson, M. Nilsson, S. D. Soli, S. D. Soli, J. A. Sullivan, and J. A. Sullivan, “Development of the hearing in noise test for the measurement of speech reception thresholds in quiet and in noise,” *Journal of the Acoustical Society of America*, vol. 95, no. 2, pp. 1085–1099, 1994.

[62] C. G. Newman, B. E. Weinstein, G. P. Jacobson, and G. A. Hug, “The hearing handicap inventory for adults: Psychometric adequacy and audiometric correlates,” *Ear and Hearing*, vol. 11, no. 6, pp. 430–3, 1990.

[63] M. E. Demorest, D. J. Wark, and S. A. Erdman, “Development of the screening test for hearing problems,” *American Journal of Audiology (Online)*, vol. 20, no. 2, pp. 100–10, Dec 01 2011.

[64] R. S. Tyler, A. E. Perreau, and H. Ji, “Validation of the spatial hearing questionnaire,” *Ear and Hearing*, vol. 30, no. 4, pp. 466–474, 2009.

[65] M. A. Akeroyd, K. Wright-Whyte, J. A. Holman, and W. M. Whitmer, “A comprehensive survey of hearing questionnaires: how many are there, what do they measure, and how have they been validated?” *Trials*, vol. 16, no. S1, 2015.

[66] T. Zurbrügg, A. Stirnemannn, M. Kuster, and H. Lissek, “Investigations on the physical factors influencing the ear canal occlusion effect caused by hearing aids,” *Acta Acustica united with Acustica*, vol. 100, pp. 527–536, 2017.

[67] S. Reinfeldt, S. Stenfelt, and B. Håkannson, “Transcranial transmission of bone conducted sound measured acoustically and psychoacoustically,” *The Journal of the Acoustical Society of America*, p. 276, 2007.

[68] S. Reinfeldt, S. Stenfelt, T. Good, and B. Håkannson, “Examination of bone-conducted transmission from sound field excitation measured by thresholds, ear-canal sound pressure, and skull vibrations,” *Acoustical Society of America*, vol. 121, no. 3, pp. 1576–1587, 2007.

[69] S. Reinfeldt, S. Stenfelt, and B. Håkansson, "Estimation of bone conduction skull transmission by hearing thresholds and ear-canal sound pressure," *Hearing Research*, vol. 299, pp. 19–28, 2013.

[70] M. E. Ravicz, J. T. Cheng, and J. J. Rosowski, "Sound pressure distribution in natural or artificial human ear canals in response to mechanical ossicular stimulation," *The Journal of the Acoustical Society of America*, vol. 141, no. 5, pp. 3896–3896, 2017.

[71] C. Röösli, D. Chhan, C. Halpin, and J. J. Rosowski, "Comparison of umbo velocity in air- and bone-conduction," *Hearing Research*, vol. 290, no. 1, pp. 83 – 90, 2012.

[72] M. Ghoncheh, G. Lilli, T. Lenarz, and H. Maier, "Outer ear canal sound pressure and bone vibration measurement in SSD and CHL patients using a transcutaneous bone conduction instrument," *Hearing Research*, vol. 340, pp. 161–168, 2016.

[73] M. Shirinkar and M. Ghoncheh, "Development of an intraoperative evaluation method for a novel bone conduction implant using nasal sound pressure," Master's thesis, Institutionen för signaler och system, Chalmers tekniska högskola, 2013.

[74] M. Eeg-Olofsson, S. Stenfelt, H. Taghavi, S. Reinfeldt, B. Håkansson, T. Tengstrand, and C. Finizia, "Transmission of bone conducted sound - correlation between hearing perception and cochlear vibration," *Hearing Research*, vol. 306, pp. 11–20, 2013.

[75] N. Bauman, "The hearing aids of yesteryear - a brief history of hearing aids from then to now," *Signal, the journal of the Association of Hearing Instrument Practitioners of Ontario*, vol. 100, pp. 22–28, 2014.

[76] K. W. Berger, "Early bone conduction hearing aid devices," *Archives of Otolaryngology*, vol. 102, no. 5, pp. 315–318, 1976.

[77] B. Håkansson, "The future of bone conduction hearing devices," in *Implantable Bone Conduction Hearing Aids*, ser. Advances in Oto-Rhino-Laryngology. Karger, 2011, vol. 71, no. 71, pp. 10–21.

[78] K.-J. Fredén Jansson, B. Håkansson, S. Reinfeldt, C. Rigato, and M. Eeg-Olofsson, "Magnetic resonance imaging investigation of the bone conduction implant - a pilot study at 1.5 Tesla," *Medical devices (Auckland, N.Z.)*, vol. 8, pp. 413–23, 2015.

[79] B. E. V. Håkansson, "The balanced electromagnetic separation transducer: A new bone conduction transducer," *Journal of the Acoustical Society of America*, vol. 113, no. 2, pp. 818–825, 2003.

[80] S. Reinfeldt, P. Östli, B. Håkansson, H. Taghavi, M. Eeg-Olofsson, and J. Stalfors, "Study of the feasible size of a bone conduction implant transducer in the temporal bone," *Otology and Neurotology*, vol. 36, pp. 631–637, 2015.

[81] L. L. N. Wong, L. Hickson, and B. McPherson, "Hearing aid satisfaction: What does research from the past 20 years say?" *Trends in Amplification*, vol. 7, no. 4, pp. 117–161, 2003.

[82] G. H. Saunders and J. W. Jutai, "Hearing specific and generic measures of the psychosocial impact of hearing aids," *Journal of the American Academy of Audiology*, vol. 15, no. 3, pp. 238–248, 2004.

[83] M. D. Vestergaard, "Self-report outcome in new hearing-aid users: Longitudinal trends and relationships between subjective measures of benefit and satisfaction," *International Journal of Audiology*, vol. 45, no. 7, pp. 382–392, 2006.

[84] R. Cox, "Choosing a self-report measure for hearing aid fitting outcomes," *Semin Hear*, vol. 26, no. 3, pp. 149–156, 2005.

[85] R. M. Cox, C. Gilmore, and G. C. Alexander, "Comparison of two questionnaires for patient-assessed hearing aid benefit," *Journal of the American Academy of Audiology*, vol. 2, no. 3, pp. 134–145, 1991.

[86] R. M. Cox and G. C. Alexander, "The abbreviated profile of hearing aid benefit," *Ear and Hearing*, vol. 16, no. 2, pp. 176–186, 1995.

[87] K. Robinson, S. Gatehouse, and G. G. Browning, "Measuring patient benefit from otorhinolaryngological surgery and therapy," *Annals of Otology, Rhinology and Laryngology*, vol. 105, no. 6, pp. 415–422, 1996.

[88] W. Noble, *Self-assessment of hearing and related functions*. London: Whurr, 1998.

[89] R. A. Bentler and a. S. E. Kramer, "Guidelines for choosing a self-report outcome measure," *Ear and Hearing*, vol. 21, no. 4 Suppl, pp. 37S–49S, 2000.