Thesis for the Degree of Doctor of Philosophy

On Direct Drive Bone Conduction Devices

Hearing Rehabilitation and Objective Assessment of Stimulation Methods

Cristina Rigato

Department of Electrical Engineering
Division of Signal Processing and Biomedical Engineering
Chalmers University of Technology

Göteborg, Sweden 2019

On Direct Drive Bone Conduction Devices

Hearing Rehabilitation and Objective Assessment of Stimulation Methods

CRISTINA RIGATO

ISBN 978-91-7597-874-1

Doktorsavhandlingar vid Chalmers tekniska högskola
Ny serie nr 4555
ISSN 0346-718X

Department of Electrical Engineering
Division of Signal Processing and 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.

Printed by Chalmers Reproservice
Göteborg, Sweden 2019

We have two ears and one mouth so that we can listen twice as much as we speak.

- Epictetus

Abstract

Bone conduction devices (BCDs) rely on the transmission of sound in form of vibrations generated by a transducer to the inner ear via the skull and surrounding soft tissues. Direct drive BCDs stimulate the skull bone directly, either via a skin-penetrating abutment (BAHAs, Bone Anchored Hearing Aids), or with a transducer implanted under intact skin (active transcutaneous devices).

In this thesis, several aspects related to direct drive stimulation were addressed with objective and subjective measurements. Vibrational measurements were performed to assess how the transducer to bone attachment affects the vibrations transmission to the cochleae. Three different attachments for active transcutaneous stimulation were compared to each other and to the BAHA screw. A comparative study was done also between the BAHA system and the novel active transcutaneous Bone Conduction Implant (BCI), where the transducer is attached to the skull bone via a flat surface contact. The BCI is currently on a clinical trial, and a comprehensive assessment of the rehabilitation after three years of device usage is included in this thesis, reporting on a number of audiometric tests, self-reported questionnaires, and objective measurements. Among the objective measures, a new method for intra and post operative verification of the implant functionality was evaluated, consisting in the measurement of the induced sound pressure in the nostril under bone conduction stimulation. In addition to the test battery from the clinical trial protocol, an exploratory study was conducted to investigate the effect of the BCI in a complex multi-talker listening environment.

The results from the vibrational measurements were strongly frequency-dependent, and indicated that a reduced contact size should be kept for improved signal transmission, especially for frequencies above 5 kHz. Sound field tone and speech tests, and user reported questionnaires show that the BCI provides considerable improvement from the unaided condition and contributes to a general increase of patients' life quality, with consistent outcomes over time. The implant verification method seems promising and showed stable properties of the implant to bone transmission. When compared to BAHAs, the BCI was found to be a viable alternative for indicated patients. In noisy and complex listening environments, the BCI users showed a lower ability to make use of the spatial cues when aided with their device, but an overall greater tolerance to interfering talkers.

Key words: Direct Drive, Bone Conduction Devices, Bone Conduction Implant, active transcutaneous, vibrations, audiology, comparative study, transducers

Preface

This thesis is in fulfilment for the degree of Doctor of Philosophy (PhD) at Chalmers University of Technology.
The work resulting in this thesis was carried out between April 2014 and April 2019 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

We are not even half way into 2019, but I can already say without much hesitation that it's the most important year for me so far. One of the reasons is of course the completion of this PhD thesis, and there are too many persons that I have to thank for making it happen.

I'd like to start with Sabine. I feel incredibly lucky to have had you as my advisor. Over these years I have always felt supported and encouraged, and you managed to do so while still expressing clear and honest opinions. I wish you a bright continuation of your journey, and I am sure you will keep on inspiring and guiding junior and less-junior researchers in your unique way, blending kindness and determination. I'd like to thank also my co-supervisors Bosse and Måns, your knowledge in the field is really precious and your enthusiasm in transferring and expanding it kept me motivated along the way. Myrthe, you are a very competent and strong researcher and clinician, and I am pleased to have had the chance to collaborate with you. Karl-Johan, I want to thank you for being always supportive and ready to help, and for trying to teach me something, not only about bone conduction hearing, but also about hops (sorry, I still like lager beer after all!). Filip, Eric, and Ann-Charlotte, thank you all for sharing your expertise in different fields, and for contributing to make this whole experience as enjoyable as it turned out to be. Allihopa, ni är ett riktigt härligt gäng och jag har inga andra ord än ett stort TACK till er!

Technical guidance is surely essential, but I would have never been able to come this far without the constant support of my family. Mamma e papà, sapere che ci siete sempre e comunque mi dà una forza immensa, e per questo non basta un semplice grazie. Sorellina, anche tu sei sempre stata presente e anche se non lo ammetterò mai, un po' di ispirazione e motivazione me le hai e me le continui a dare. Murad, I am so lucky to have you as part of my family, and I hope you know how much it means for me to have you by my side each and every day.

Without naming every single person, I'd like to thank everyone at the department, from the administration stuff to all the researchers in different fields, all contributing to making the department (and mostly the fika room) a diverse and cheerful place. Last but not least, I thank all the friends in Gothenburg and around the world for being part of my life and for sharing all kind of experiences. A special thanks to Giovanni, for supporting me in both technical and personal issues, and for all the delicious food you share.

I forgot someone for sure, please don't get too upset!

Cristina

List of Publications

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

Paper I
"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.
Hearing Research, no. 361, pp. 103–112, 2018.

Paper II
"Effect of Transducer Attachment on Vibration Transmission and Transcranial Attenuation for Direct Drive Bone Conduction Stimulation", Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Erik Renvall, and Måns Eeg-Olofsson.
Submitted to *Hearing Research* and currently under revision, 2019.

Paper III
"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 IV
"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.
Accepted for publication in *Medical devices: Evidence and Research*, 2019.

Paper V
"Three Year Follow Up With the Bone Conduction Implant", Ann-Charlotte Persson, Sabine Reinfeldt, Bo Håkansson, Cristina Rigato, Karl-Johan Fredén Jansson, and Måns Eeg-Olofsson.
Submitted to *Ear and Hearing*, 2019.

Paper VI
"The Effect of an Active Transcutaneous Bone Conduction Device on Spatial Release from Masking ", Cristina Rigato, Sabine Reinfeldt, and Filip Asp.
Accepted with revision and resubmitted to *International Journal of Audiology*, 2018.

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: Evidence and Research*, vol. 8, pp. 413–23, 2015.

"VEMP using a new low-frequency bone conduction transducer.", Bo Håkansson, Karl-Johan Fredén Jansson, Tomas Tengstrand, Leif Johansen, Måns Eeg-Olofsson, Cristina Rigato, Elisabeth Dahlstrom, and Sabine Reinfeldt. *Medical Devices: Evidence and Research*, vol. 11, pp. 301–312, 2018.

"Robustness and Lifetime of the Bone Conduction Implant - A Pilot Study.", Karl-Johan Fredén Jansson, Bo Håkansson, Cristina Rigato, Måns Eeg-Olofsson, and Sabine Reinfeldt. *Medical Devices: Evidence and Research*, vol. 12, pp. 89–100, 2019.

"The Bone Conduction Implant - Review and One Year Follow Up.", Bo Håkansson, Sabine Reinfeldt, Ann-Charlotte Persson, Karl-Johan Fredén Jansson, Cristina Rigato, Malou Hultcrantz, and Måns Eeg-Olofsson. Submitted to *International Journal of Audiology*, 2018.

Parts of the results in this thesis 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, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Erik Renvall, and Måns Eeg-Olofsson (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.

- Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Erik Renvall, and Måns Eeg-Olofsson (2018). "Vibratorinfästingens Inverkan på Signaltransmission för Aktiva Benledningshörapparater", TeMA Hörsel 2018, Örebro, Sweden.

- Cristina Rigato, Sabine Reinfeldt, Bo Håkansson, Karl-Johan Fredén Jansson, Erik Renvall, and Måns Eeg-Olofsson (2018). "Transducer Attachment for Direct Drive Bone Conduction Stimulation", CAA Conference and Exhibition, Niagara Falls, Ontario (CA).

Abbreviations and Acronyms

ABG	Air-Bone Gap
ABR	Auditory Brainstem Response
AC	Air Conduction
ANSI	American National Standard Institution
APHAB	Abbreviated Profile of Hearing Aid Benefit
ASHA	American Speech-Language Hearing Association
BAHA	Bone Anchored Hearing Aid
BC	Bone Conduction
BCD	Bone Conduction Device
BCI	Bone Conduction Implant
BEST	Balanced Electromagnetic Separation Transducer
BMLD	Binaural Masking Level Difference
dB	deciBel
dB HL	deciBel Hearing Level
dB SPL	deciBel Sound Pressure Level
ECSP	Ear Canal Sound Pressure
EI	Error Index
FDA	Food and Drugs Administration
GBI	Glasgow Benefit Inventory
ILD	Interaural Level Difference

IOI-HA	International Inventory for Hearing Aids
ISO	International Organization for Standardization
ITD	Interaural Time Difference
LDV	Laser Doppler Vibrometer
MAA	Minimum Audible Angle
MAE	Mean Absolute Error
MRI	Magnetic Resonance Imaging
NSP	Nasal Sound Pressure
OAE	Otoacoustic Emission
Pa	Pascal
PTA	Pure Tone Average
RMSE	Root Mean Square Error
SDT	Speech Detection Treshold
SNR	Signal to Noise Ratio
SRM	Spatial Release from Masking
SRS	Speech Recognition Score
SRT	Speech Recognition Treshold
SSD	Single Sided Deafness
TA	Transcranial Attenuation
TM	Tympanic Membrane

Ethical Considerations

Nearly every research study in the field of life sciences needs to be approved by a local or national ethical committee. The criteria applied to grant ethical approvals involve the planned methods to be used, how patients are informed and treated, how their data is handled and many more aspects which are usually regulated in the informed consent, signed by both experimenters and study subjects. 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 and were carried out after receiving ethical approval by competent organs.

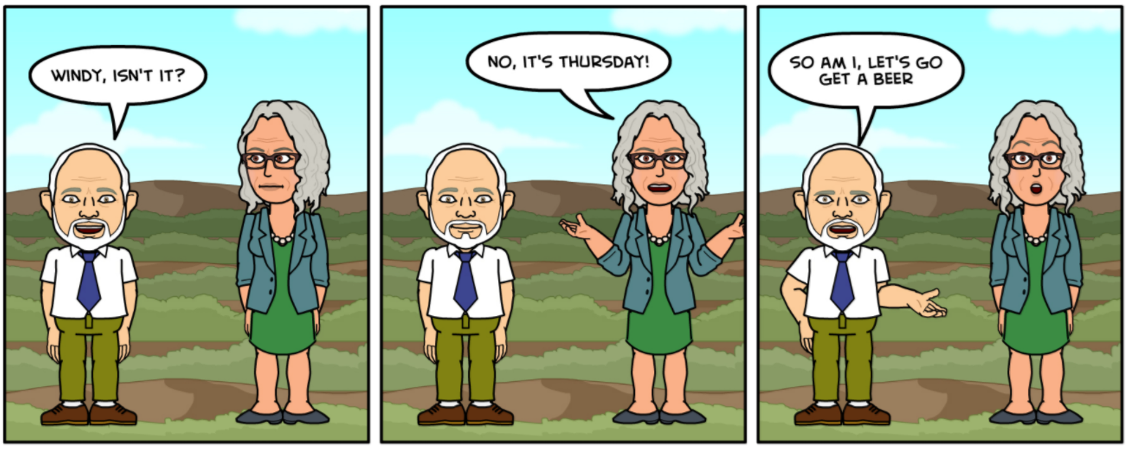


Figure 1: A comic strip illustrating in a humoristic way how hearing loss is generally perceived in our society. *Image courtesy of Hearing Healthcare Centre Ltd.*

However, ethics goes beyond the practical details on how to conduct tests and how to process the collected data. Ethical principles are nowadays also connected to sustainability in all its three pillars: economic development, social development and environmental protection. In this section, some personal considerations are expressed about the project presented in this thesis.
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

shouting over the phone and replying to the wrong questions, as illustrated in comic terms in Figure 1. This stereotype has strong limitations that, if not broadened, may lead to underestimation of the actual impact of hearing loss on the society. In fact, hearing loss is a disability that affects the single person as well as the community as a whole, including welfare and economic aspects.
Different countries have different policies regarding hearing aids dispensation and whether to subsidize them or not. Implantable devices are today mostly paid by public insurance and represent therefore higher expenses with respect to conventional hearing aids. Indeed, conventional devices have lower production costs and do not require surgical implantation and consequent medical follow-ups. Non-implantable and semi-implantable bone conduction devices are considered a valid alternative when conventional devices are not a viable option. Non-implantable devices are cheaper and more easily applied to patients, and are therefore more appealing in the short run. Unfortunately, there are several reported cases of hearing aids that are prescribed, fitted and quickly abandoned by patients due to uncomfortable wearing conditions or unsatisfactory rehabilitation effect. What was a lower cost initially can then become a higher cost in the long run, in terms of disappointment and frustration from both the patient's and the audiologist's side, as well as time and money spent on unfruitful visits and fitting of a suboptimal rehabilitation solution. Furthermore, from a broader perspective, a satisfactory hearing rehabilitation can eventually lead to the possibility for the patients to be fully integrated in the working society instead of being forced to live on someone else's economic support. Hearing loss does not affect only seniors who are approaching the end of their working career, it afflicts men and women of any age. According to the most recent report from the Swedish Association of Hard of Hearing People [1], 12% of the working force (aged 16-64 years) in Sweden suffer from hearing impairment, making up 48% of the total amount of the hearing impaired population. Hearing loss is thus a severe handicap that can threaten equality in terms of working opportunities.
Equality does not regard only working possibilities, but more broadly the ability to have normal interactions and relationships with 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 would probably lead to social isolation and dependency of the person from other people's assistance (most of the time family members). It is important to keep in mind that behind innovations there are users with needs, and that research and development should be driven by the desire of creating a more sustainable society rather than the desire for purely technical advancement.

Contents

Part I

Introductory Chapters

Chapter 1

Introduction

This thesis focuses on hearing rehabilitation with bone conduction devices (BCDs) that provide a direct drive stimulation, partly evaluating their performance and partly investigating specific aspects that may lead to an improvement of their design.

1.1 Background

Hearing impairment is one of the most widespread disabilities, with more than 5% of the world population suffering from disabling hearing loss [2]. In Sweden, approximately 1.5 million adults (roughly corresponding to 18.5% of the population above 16 years of age) have some sort of hearing impairment affecting their daily life and, among them, nearly 500 000 are fitted with a hearing aid, according to what is reported by HRF (Hörselskadades Riksförbund), the Swedish Association of Hard of Hearing People [1]. 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 main dysfunction is located in the outer or middle ear. In subjects with normal hearing, 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 this transmission pathway is not functioning properly, there is an alternative physiological hearing pathway, via bone conduction (BC). In fact, it is well known since long ago that vibrations transmitted through the skull bone stimulate the cochlea and evoke a hearing sensation [3,4], referred to as BC hearing.

Several BCDs have been developed to rehabilitate patients by using BC hearing, and their use has increased during the past few centuries. There are several BCD models available on the market today, from fully externally worn to semi-implantable solutions [5]. The two main components of any BCD are the audio processor and the vibration transducer. The first one picks up and amplifies the sounds from the listening environment, and the second one transforms the sound into vibrations to be transmitted to the skull.

The most effective way to stimulate by BC is to vibrate the skull bone directly, without having skin and other tissues dampening the signal in between. A direct stimulation is achieved in so-called direct drive BCDs, where the transducer is rigidly anchored to the skull bone and the vibrations are conveyed in a direct way. One of the most widespread and effective direct drive BCDs 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 to 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. One example is the need for daily maintenance of the skin-implant interface. To overcome the skin-related issues and other shortcomings of the BAHA, the development of transcutaneous devices has been the focus in recent years, in particular of so-called active transcutaneous BCDs, where the transducer is implanted under intact skin.

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 [6–10]. The BCI is on clinical trial since December 2012 and sixteen patients have been operated without any serious adverse events reported so far.

BCDs does not only bring evident advantages, but also new type of challenges as the implant has to be both effective and safe. The safety aspect is mainly related to surgical procedure and implant material, and is not in the scope of this thesis, where 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 the results presented mostly in relative terms, with the aim of evaluating two or more alternatives with respect to each other or as compared to the BAHA standard. Two studies were conducted to investigate how the transmission of vibrations to the cochleae is affected by how the transducer is coupled to the skull. Potentially, the transducer can be attached to the skull bone in several different ways, and a few options were studied to determine whether they play a role or not. Three attachment types for active transcutaneous stimulation were compared with each other (Paper I) and with the reference BAHA screw attachment (Paper II). Results from the studies indicate that the attachment type and location affect mainly the transmission at mid and high frequencies. While the first two studies address one specific aspect of implantable BCDs and are based on objective measurements, the third study is a comparison between two devices as a whole and involves subjective tests performed on BCD patients. Two BCDs were compared: the transcutaneous

BCI and the percutaneous Ponto Pro Power (Oticon Medical, Askim, Sweden). Audiological outcomes and self-reported questionnaires confirmed the adequacy of the BCI as an alternative to BAHAs for indicated patients. More details about the study are found in Paper III.
In the second part of the thesis, the focus is towards the BCI system and its evaluation in different situations. First of all, the verification of the implanted transducer functionality is addressed. One way to verify that the transducer is properly working is through subjective tests on the implanted patient, but there are circumstances when this is not possible and an objective method is needed. This happens for example during surgery, when the patient is anaesthetised. In Paper IV, the measurement of the sound pressure in the nostril is suggested as a verification tool during surgery as well as during follow-up visits, showing encouraging results so far.
Secondly, after the patients have been implanted and fitted, it is important to evaluate the benefit they receive from the use of the BCI. Device performance evaluation is done regularly as part of the clinical study protocol, through both audiological measurements and self-reported questionnaires. Results from the three years follow-up visit are summarised in Paper V, where the outcomes are evaluated as such and also relative to previous visits. Audiological sound field tests and user questionnaires showed improved hearing ability and quality of life given by the BCI as compared to the unaided condition, and the results appeared stable over time.
Lastly, the field of binaural hearing is approached in Paper VI. Some tasks performed by the auditory system require the combination of information from both cochleae, and are therefore called binaural. One example is recognition of speech in demanding and noisy multi-source listening environments, such as the cocktail party set up. This term refers to a condition when the listener has to concentrate on a frontal target sound, while surrounded by other interfering sound sources. The ability to isolate the target sound is surprisingly good in normal hearing subjects, who are able to effectively take advantage of the different spatial location of the sound sources, among other factors. This ability is not as effective in hearing impaired subjects and in hearing aid users, who experience greater listening effort in corresponding conditions. Binaural abilities are even further challenged when BCDs are used for rehabilitation, as transmitting sound via BC alters the standard cues from airborne signals. Above all, differences in level and time of the signals reaching the two cochleae are altered under BC stimulation as compared to AC. However, different BCDs may have various impact on binaural hearing, and have therefore different rehabilitation effects. The influence of the BCI in a cocktail party situation is therefore investigated in the study presented in Paper VI, for evaluation and future comparison with other devices.

1.2 Aim of the Thesis

The overall aim of this thesis is to provide advancements in the field of direct drive active transcutaneous stimulation for BC hearing rehabilitation, with a focus on the BCI device.
More specifically, the aim can be divided into two main points:

- to compare active transcutaneous and percutaneous stimulation techniques in terms of vibration transmission and rehabilitation effect (Papers I-III);
- to introduce and apply methods methods for verification of the BCI device functionality in patients, from implantation to daily use (Paper IV-VI).

1.3 Thesis Outline

The topic of the thesis was briefly introduced in Chapter 1. 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 alongside with tools to assess the rehabilitation effect. Chapter 4 focuses on BCDs for rehabilitation of indicated groups of hearing impaired patients. The different types of available BCDs are described, starting with a brief historical overview and up to today's state of the art. A brief discussion about remaining challenges in the field of BCDs is also presented. After a summary of the appended publications, given in Chapter 5, the main conclusions and an indication for future research developments are given in Chapter 6.

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 intimately linked to the vestibular organ and essential for the sense of 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, mainly in the vertical but also in the 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 surroundings, for example when chewing or yawning. The

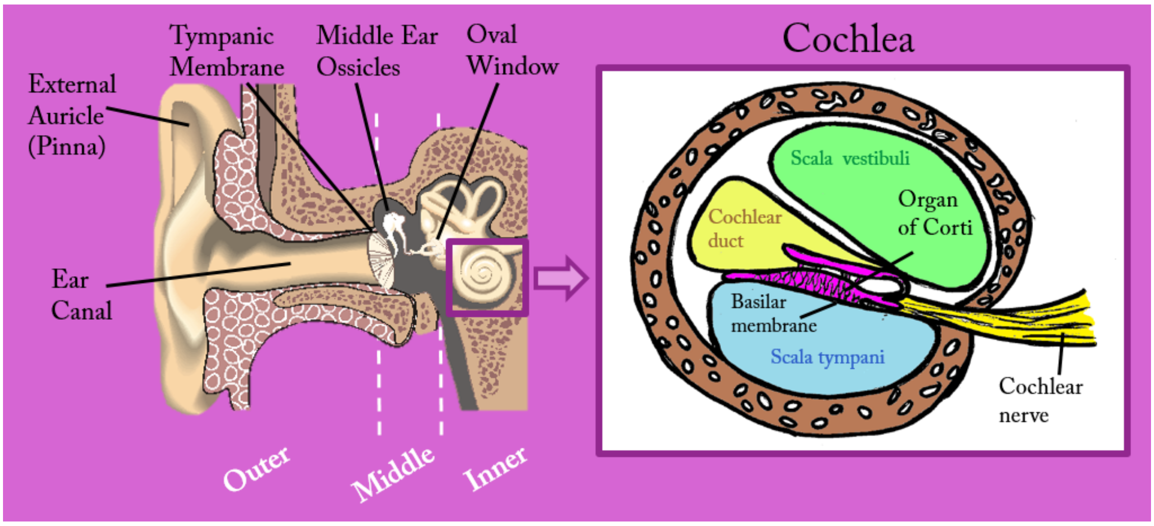


Figure 2.1: Simplified illustration of the anatomy of the human ear. The right side of the image illustrates a cross-sectional view of the cochlea.

TM and the oval window are connected by the so-called auditory ossicles (middle-ear 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 inner ear.
The inner (or internal) ear includes bony and membranous labyrinths, where the former is composed of the cochlea, the vestibule and the 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 (as seen in Figure 2.1, cross-sectional view): 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 the scala vestibuli and the 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: sound pressure gain and sound localisation [11]. 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 localisation are derived differently for horizontal and vertical plane: in the horizontal plane, a sound is understood as coming 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 passive 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 ossicles, leading to a 1.3:1 movement ratio between the stapes and the malleus (approximately 2 dB increase in the total gain); and (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 the 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 a 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 [12].

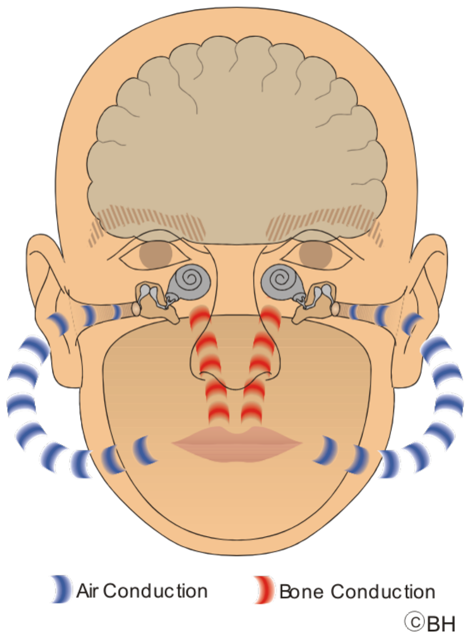


Figure 2.2: Representation of air conduction (blue arrows) and bone conduction (red arrows) pathways when hearing one's own voice. The sound produced during vocalization is radiated in the air and reaches back to the subject's outer ear through air; simultaneously, it is propagated through the nasal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

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

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

Sound waves from external sound fields are able to induce vibrations in 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 cochleae. 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 [13, 14]. 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 over "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 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 [3] 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 human brain via electrodes placed on the scalp (auditory brainstem response) [19].

4. Two tone distortion products: when two primary tones with different frequency are used to stimulate otoacoustic emissions (see sec. 3.1.2 for further explanation), the response occurs at a frequency that is mathematically related to both the primary tones. The same phenomenon has been observed with both AC and BC stimulation [20] and with a combination of one AC and one BC tone [21], providing 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 seen both between air and bone conduction as well as between patients.

2.3.2 Contributing Factors

As mentioned earlier, the contributions to BC hearing are multiple. The first theory in this regard was formulated by von Békésy [24, 25], 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 [26]: (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 contributors, 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 and 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.

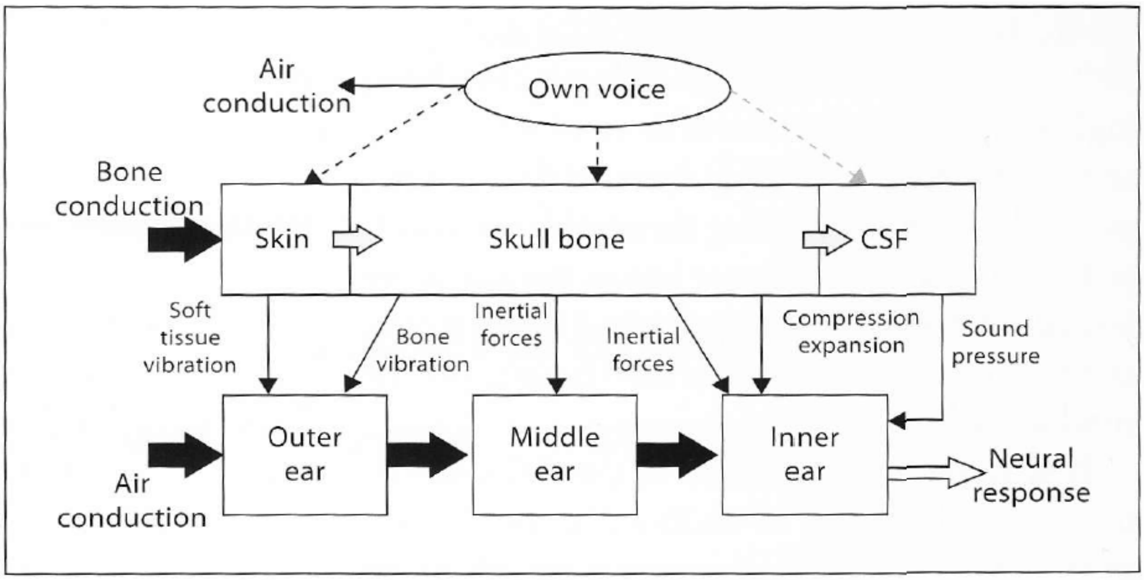


Figure 2.3: Model of the contributions to AC (air conduction) and BC (bone conduction) sound perception from one's own voice, external sound field, and BC stimulation. The sound transmission is indicated by the arrows, with the thin ones showing the contributions to BC sound: soft tissue vibration, bone 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. [27].*

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 found 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

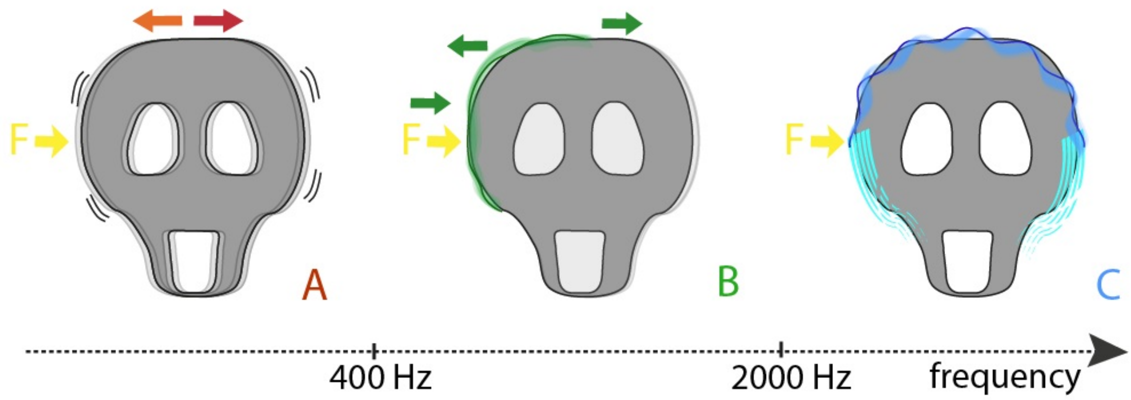


Figure 2.4: Schematic representation of the skull bone motion characteristics at different frequencies. A) Rigid body movement, with the skull moving as a whole rigid body and showing no deformation, apart from the local region around the attachment point; B) Mass-spring movement, with minor deformation 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.

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 transfer functions 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 [3]. Due to unsatisfactory 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 eleven such frequencies on dry skull between 20 and 5000 Hz and nineteen on living subjects in the range 500-7500 Hz. Experimental approaches have been taken also for the characterisation 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 [27], 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, apart from the very local area around the attachment point.

- 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 in a frequency-dependent way. 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 the signal intensity at the cochlear level with 10-20 dB, 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 Binaural Hearing: Why We Need Two Ears

The human auditory system includes two cochleae, each of them functioning as described in the previous chapters. The two cochleae are independent in their operation, and need to be separately stimulated to send electric signals to their corresponding acoustic nerve. However, the information provided by the two cochleae is then combined in the central hearing organ, allowing to perform tasks that would not be possible with only one of them. The way the information from the two sides is combined ranges from relatively straightforward summation to more complex signal processing. The ability of the auditory system to integrate information from both cochleae is referred to as *binaural hearing*, as opposed to *monaural hearing*, where the cues come from each side independently. Binaural cues are especially useful in complex multi-source listening environments, allowing sound source discrimination and localisation, and improving speech understanding in noisy and reverberant environments.

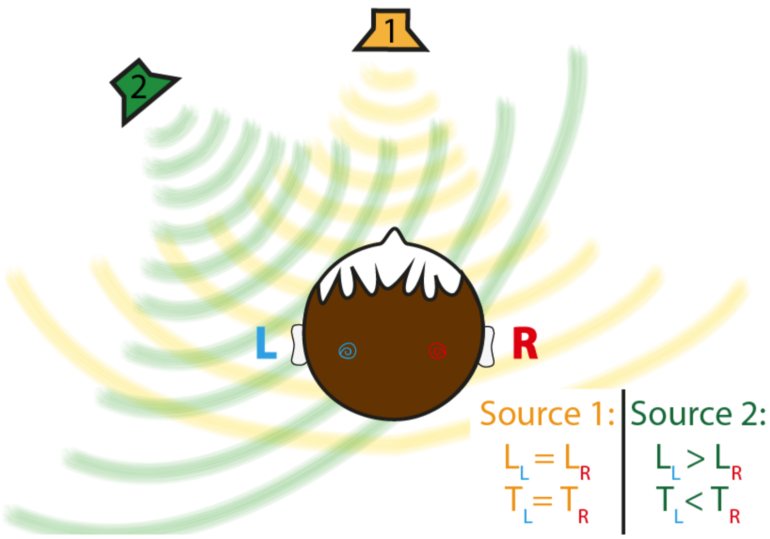


Figure 2.5: Schematic representation of how ITD (Interaural Time Difference) and ILD (Interaural Level Difference) originate when sound propagates in the air from a frontal source (Source 1, yellow), and from a laterally positioned one (Source 2, green). The time of arrival (T) and level of the signal (L) at the left ear (L) and right ear (R) depend on the position and frequency of the source relative to the head.

One of the most utilised cues depends on the so-called head shadow, which is a physical effect given by the head and shoulders: by acting as an acoustic shadow, they dampen the intensity of sounds reaching the contralateral ear. The shadow effect gives rise to interaural level differences (ILDs) of up to 20 dB [43] between the signals received at the ipsi- and the contralateral side. This effect is particularly useful in understanding speech in noise with spatially separated sound sources. In fact, the auditory system is capable of using the head shadow effect in a binaural way, by rapidly identifying the side with the most favourable listening conditions (i.e. higher signal to noise ratio, SNR), and dynamically switching between the two ears accordingly. The resulting better-ear glimpsing strategy [44] allows to maximize the speech intelligibility in complex multi-source configurations [45].

Another important cue originating from the physical separation of the cochleae is the interaural time difference (ITD) [46]. ITD depends mainly on the physical distance separating the two cochleae, combined with the velocity of sound waves in the propagation medium. ILD, instead, is related to how much the propagation medium dampens the signal as a function of distance, and how the wavelength interacts with the head's geometry. Both are frequency-dependent, with ILD being prominent at high frequencies, and ITD at lower ones. When sound propagates in air, ITD value is estimated in the range of $10-700\ \mu s$ [47] and ILD up to 20 dB [43]. In the case of BC sound, the values decrease significantly due to the faster and less lossy transmission of waves in hard skull bone and other tissues of the skull.

Several phenomena are related to binaural hearing, such as:

- **Spatial Hearing**
  Figure 2.5 illustrates schematically the different propagation patterns of airborne sound from a frontally positioned source as compared to a lateral one, giving rise to ITD and ILD cues.
  The availability of binaural cues is fundamental for spatial hearing, which refers to the ability to discriminate between two or more sources at varying locations and to localise sounds in the surrounding space relative to the head position. However, when sound localisation is performed, ITD and ILD help only on the horizontal plane whereas elevation is determined with the help of monaural spectral cues introduced by reflections of the sound waves from pinnae, head, and torso [48].

- **Binaural Unmasking**
  As previously mentioned, binaural cues allow also the listeners to endure high levels of noise when listening to a target speech in complex sound scenarios. This is sometimes referred to as binaural unmasking, where the availability of binaural cues helps to discriminate between target speech and interferers (maskers) when they are spatially separated [48].

- **Precedence Effect**
  In reverberant environments, sound from the same source reaches the ears in several ways, from the most direct one to a number of secondary ways, after being reflected by surrounding surfaces. The signals reaching after one or several reflections present a time delay compared to the direct signal, and they carry localisation cues that can interfere with the original ones. Studies on localisation

have shown that the cues provided by reflections are assigned lower weight compared to the first-arriving sound if the delay between them is short enough. This phenomenon is called precedence effect, and the maximum lag, above which lead and lag sounds are considered as two separate auditory events, is called fusion echo threshold [48].

2.5 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, where 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 e.g. 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, and 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 diagnosed 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. BCDs are effective alternatives for patients suffering from conductive hearing losses, with a sensorineural 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

Evaluation Methods for Clinical Practice and Research

A variety of tests exist for goals, e.g. to assess the hearing abilities of individuals, characterise hearing losses, evaluate how successful a given rehabilitation method is, or carry on fundamental research to increase the scientific knowledge in the field.
In the clinics, which methods of investigation are used depends mainly on the age and general health condition of the patient. In research, measurements are performed also on animals, 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 given parameters.
Methods can be classified as subjective or objective. The 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. There are therefore many variables that may affect the outcome, e.g.:

- *The stimulus.* Test signals that are used as stimuli can be e.g. pure and warble tones, speech material or white noise;

- *The stimulus administration.* Among the several ways to convey a signal there are for example headphones, BC transducers or loudspeakers in a 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 can play a role in determining the final outcome, especially in less experienced subjects.

While subjective methods address the hearing ability directly, objective ones investigate it indirectly, by measuring physical quantities that are physiologically related to the hearing process. Reasons to perform objective measurements instead of subjective ones are multiple, e.g. when the subjects' mental or physical conditions do not allow them to perform the required psychoacoustic tasks (very small babies, mentally ill patients or patients under anaesthesia, just to name a few). Another reason might be that the investigation is done on a non-living subject, such as a cadaver or an artificially produced anatomical model. Furthermore, an advantage of objective measurements over subjective ones, is their higher repeatability and lower intra-subject variability. This allows to detect smaller absolute differences in the measured objective quantities compared to subjective ones.
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. Less homogeneity is there when more complex phenomena are tested, such as binaural hearing abilities. In this case, several indexes can be used, and each of them can be obtained in a variety of ways.
A summary and overview of the most utilised methods and indexes is given in the following sections, with greater emphasis on the ones utilised in the appended publications.

3.1 Assessment of Hearing Level

3.1.1 Subjective Methods

Bearing in mind that many variations exist and that several standards are followed today in the clinical practice, a list of the most commonly performed psychoacoustic measurements is presented.

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 the intermediate frequencies 750, 1500, 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 and it is more easily detectable by patients with tinnitus [49].

For each frequency, the sounds are presented to the test person at varying inten-

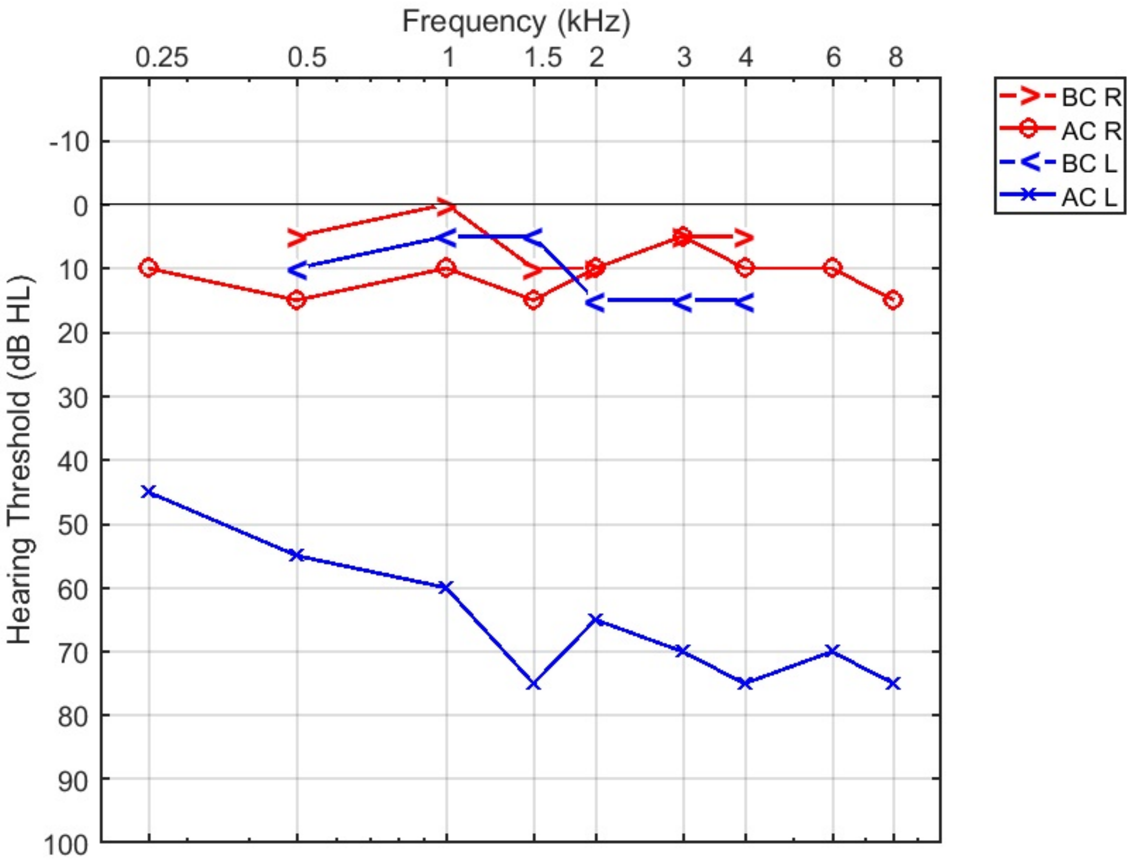


Figure 3.1: Example of an audiogram, where AC (air conduction) and BC (bone conduction) hearing thresholds are measured on both right (R) and left (L) side. The hearing on the right side is normal, while a moderate-to-severe conductive hearing loss can be seen on the left side.

sity 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 [50, 51], and ANSI, the American National Standard Institution [52], and guidelines by ASHA, the American Speech-Language Hearing Association [49].

The outcome of a pure tone audiometric test is the audiogram (see Figure 3.1, 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 an average young adult with normal hearing. The reference levels are specified in standards developed by ISO or ANSI, with very similar values between the two [53, 54]. References are given in equivalent force levels or equivalent sound pressure levels if a BC transducer 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 [55]:

- -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 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. Provided that the AC thresholds are $> 20dB$, the hearing loss categories mentioned in Sec. 2.5 can thus be described in terms of ABG as follows [56]:

Sensorineural hearing loss:
ABG ≤ 10 dB;

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

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

In the example shown in Figure 3.1, the BC and AC thresholds indicate normal hearing on the right side ($< 25\ dB\ HL$), and a moderate-to-severe conductive hearing loss on the left side, where the BC thresholds are $< 20\ dB\ HL$, AC $> 55\ dB\ HL$, and ABG $> 10\ dB$.

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. Most of the energy in the speech signal lies 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 3.2.

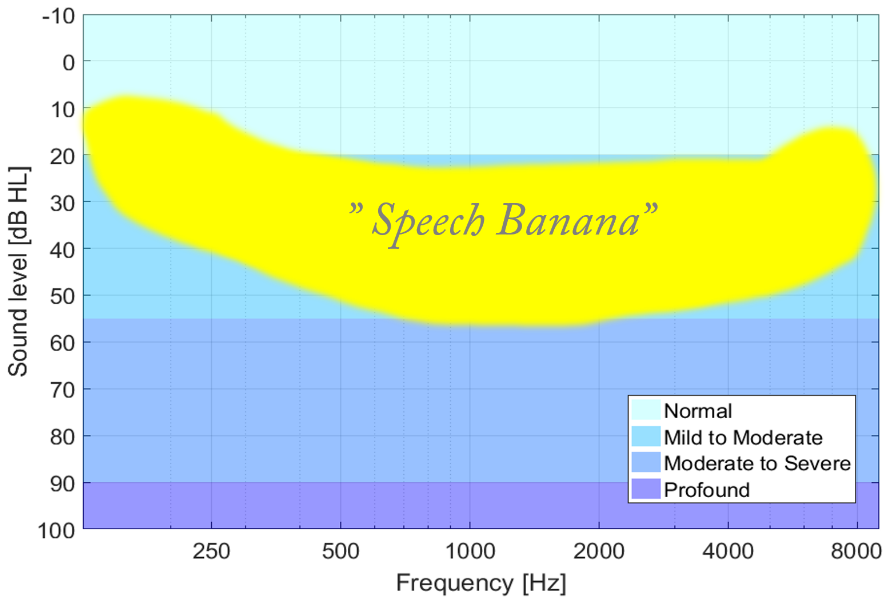


Figure 3.2: A representation of the *speech banana* on an audiogram at average conversational level. The yellow area encloses the main components of speech sounds. Background colours indicate the degree of hearing loss corresponding to thresholds located in the the corresponding shaded areas.

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 method to estimate the speech intelligibility is the so called "count-the-dots audiogram", proposed by Mueller and Killion in 1990 [57] and later reformulated by the same authors [58] 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 the dots are more spread out in the less critical areas. 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 0-1. Different versions 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 instead. 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 [59]. 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 [60]. It was then Gunnar Lidén, around three decades later, who first developed and recorded phonetically balanced lists for diagnostic purpose [61]. 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) [62, 63]. 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 [64].
A list of the most commonly performed measurements follows.

Speech Recognition Threshold The speech recognition threshold (SRT), also called speech reception threshold, 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 [65].

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 necessarily understanding 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 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 repeated words. An alternative way of calculating SRS is to report the percentage of correctly repeated phonemes instead of whole words. SRS is often carried out with a low background noise (approx. 4 dB SNR).

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 environments. SNR is defined as the ratio between 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 indicates that the noise level is higher than the signal level, and the other way round in case of a 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, [66]) and the HINT (Hearing in Noise Test, from Nilsson et al. [67]).
In Sweden, the most used speech material and procedures are the ones developed by Björn Hagerman [62, 63]. The test material consists of three- or 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, and with one ore several sound sources differently located around the test subject.

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, [68,69] and sound localisation ability [70]. They are routinely administered for screening of populations considered at risk, such as professionals often exposed to high sound levels, patients under ototoxic medications or elderly subjects [69]. Akeroyd et al. [71] summarised the variety of questionnaires that are used in hearing assessment and they found 139 hearing-specific questionnaires. Among these, they found that the main focuses are the person's own hearing, its repercussions, and hearing aids in equal shares.
Questionnaires may be used as a first step towards the diagnosis of hearing impairment, and later on as a part of the rehabilitation process when the subject is fitted with hearing aids. In this case, additional aspects including the assessment of the rehabilitation quality are addressed (see Sec. 3.3 for additional details).

3.1.2 Objective Methods

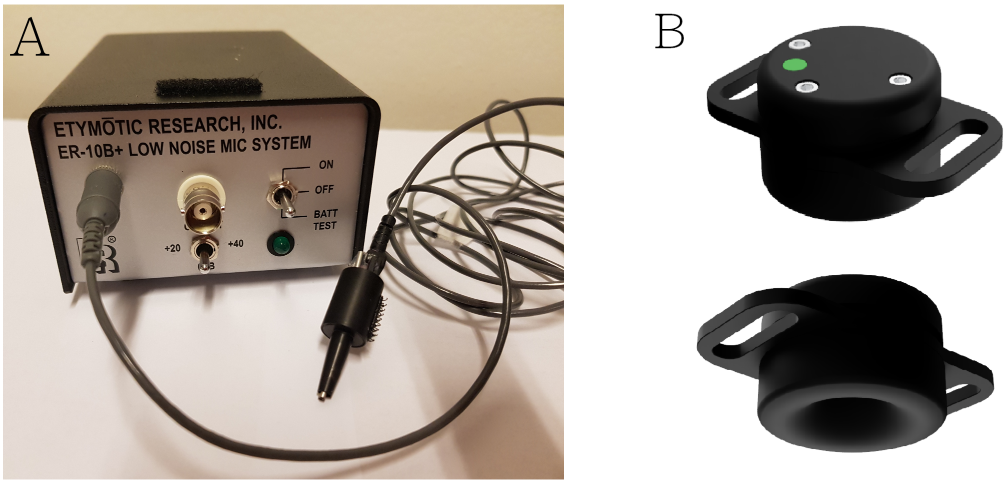
Measures of auditory responses without the patient's active involvement are essential in cases where the patients are not in the conditions for carrying out the required tasks, and can as well complement the information given by subjective measurements. Among other functions, physiologic measurements 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 research and in particular cases.

Immittance Audiometry In this category, tympanometry and acoustic reflex measurements are included. These tests are concerned with the quantification of the energy transfer through the outer and the middle ear [56]. 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 Evoked Otoacoustic Emissions (OAEs) and Auditory Brainstem Responses (ABRs) are examples of responses from the auditory system that are evoked by specific stimuli and are mostly related to hair cells and brainstem functionality. These tests are widely employed for newborn hearing screening. Evoked OAEs are acoustic vibrations in the ear canal resulting from the cochlear activity after a sound stimulation [56]. 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 recorded by electrodes placed on the scalp [56]. The evoking signal can be a click, chirp 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 potential hearing loss and to determine the aetiology.

Sound Pressure Measurements Ear Canal Sound Pressure (ECSP) is a widely used measure in research. 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 μ Pa, 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 different purposes. In the field of BC hearing, microphone measurements have been mainly employed to investigate the occlusion effect [72,73], the transcranial transmission [74], and various other properties of AC and BC sound [75–78]. ECSP measured with a low noise insert microphone (see Figure 3.3a) is used in Paper I and Paper II as a way to evaluate the effectiveness of the transmission of a BC stimulus: the higher the pressure, the more effective the transmission.
Measurement of the ECSP finds also application in the intraoperative verification of



a: Insert low noise microphone ER-10B+ microphone system (Etymotic Research, Inc., Elk Grove Village, IL, USA) for sound pressure measurement in the ear canal.

b: Surface microphone system prototype developed by Hodgetts et al. for sound pressure measurement on the skin. *Image courtesy of D. Scott and W. Hodgetts.*

Figure 3.3: Microphone systems for sound pressure measurement.

correct functioning of implanted hearing devices [79], especially when the device is in the clinical trial phase. As an alternative to ECSP, nasal sound pressure (NSP) is being recently investigated as it seems to offer a valid alternative when the ear canals are not accessible [80]. Upon stimulation from the transducer, 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 advantage 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 IV.
Sound pressure induced by BC stimulation can also be measured externally, on the skin surface. This is used in the verification method recently suggested by Hodgetts et al. [81], who developed a so-called surface microphone. This device, shown in Figure 3.3b, is to be applied on the patient's forehead on a softband during BC stimulation to sense the radiated pressure induced by the stimulation. The results from the pilot study [81] indicate good potential of the surface microphone to be used for verification of BCDs' functionality, to give an estimate of audibility, and to give an

indication about the quality of the fitting.

Vibrational Measurements Vibrational movement of an object can be described as displacement, velocity or acceleration. These three 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

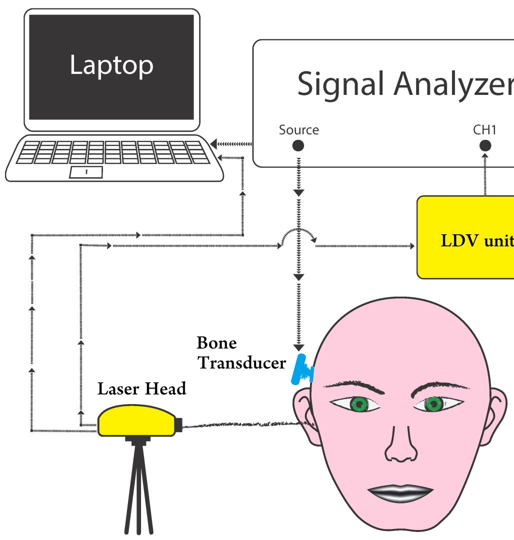


Figure 3.4: Example of a measurement set up with Laser Doppler Vibrometer (LDV) to measure cochlear promontory velocity: the subject is stimulated with a bone conduction transducer transmitting vibrations to the skull. The laser beam is, in this example, pointed at the cochlear promontory through the 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.

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 accelerometers 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 mass 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 contactlessly by sending a laser beam towards the target surface and recording its reflected ray. Figure 3.4 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 each other [78, 79]. Vibrational measurements with both accelerometers and LDVs 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 Sec. 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, 76, 82].

3.2 Assessment of Binaural Hearing Abilities

The interpretation of binaural cues from the central auditory system is a complex process that depends on many factors, and a vast variety of indexes can be used to evaluate and describe binaural hearing abilities. Due to its nature, binaural hearing has to be measured by use of subjective behavioural tests, where the test subject needs to be actively engaged. Methods and set-ups may vary significantly depending on the subjects' age and mental capability, and on the desired outcome. Some common indexes defined to describe binaural processes are listed below.

MAA: Minimum Audible Angle Used to evaluate sound discrimination ability, MAA is defined as the smallest change in angular position of the sound source that can be detected by the subject [83]. MAA was shown to be dependent upon azimuth location of the stimulus, frequency and bandwidth of the stimulus, and subject's familiarity with the task just to name a few. MAA is as small as one degree in normal hearing adults and most favourable listening conditions, i.e. with stimulus from the frontal direction. However, this is a relative measurement, and the relation between

MAA and the absolute ability of localising sound has not been fully determined yet. This means that being able to detect very small changes in sound source location does not translate to having an equally precise localisation accuracy [48, 84].

MAE: Mean Absolute Error In sound localisation, one common way to express error size is the MAE, where the difference between perceived and actual position of the stimulus is determined in absolute terms. Alternatively, the Root Mean Square Error (RMSE) index can be used. MAE and RMSE are defined as follows:

$$MAE = \frac{1}{n}\sum_{i=1}^{n}|e_i| \quad and \quad RMSE = \sqrt{\frac{1}{n}\sum_{i=1}^{n}e_i^2}$$

where n is the number of measurements, and e is the error in localisation (target minus perceived location) for the i^{th} measurement, with i=1:n.

EI: Error Index An alternative way of quantifying localisation ability is to use a normalised error index (ranging between $0 - 1$ or $0 - 100\%$) instead of an absolute error (in degrees or radians) like MAE or RMSE. One example of a normalised index is the EI used by Asp et. al [85], defined as follows:

$$EI = \frac{\sum_{i=1}^{n}|t_i - p_i|}{(\sum_{i=1}^{n}\sum_{j=1}^{m}|t_i - j|)/m}$$

where n is the number of measurements, m is the number of loudspeakers, t_i and p_i are the target and the perceived location of the i^{th} stimulus, respectively. The obtained EI ranges between 0 and 1, corresponding to perfect and average random performance, respectively. Using a normalised index has the advantage of allowing comparisons between set-ups with different number and configuration of loudspeakers.

BMLD: Binaural Masking Level Difference BMLD is considered to be a key aspect in the understanding of speech in complex and noisy listening conditions. It is defined as the difference in masked thresholds when the target is in-phase with the noise at both ears compared to when the target and the noise are out-of-phase at both ears. Altering the phase of target and masker has a similar effect as physically separating the two sound sources, resulting in intracranially colocated or separated conditions. In normal hearing subjects, BMLD as high as 30 dB can be observed, depending on the specific testing condition [48].

SRM: Spatial Release from Masking SRM is a measure of how spatial cues help a listener to focus and understand a target speech in presence of one or more maskers in complex auditory scenarios. When target speech and maskers come from spatially separated sound sources, the speech intelligibility improves as compared to when the sound sources are colocated. The advantage that the auditory system gets from spatial separation of target and interferers is called SRM. This is not a purely binaural phenomenon, as it results from a combination of monaural (head shadow, spectral cues, etc) and binaural cues (ITD and ILD). The degree of SRM can vary significantly and reach up to 10-12 dB with different target-masker spatial distributions, number of interferers, degree of informational masking (i.e. how similar the target and the maskers are), knowledge of the target spectral characteristics and location, and many more factors.

In Paper VI, SRM was evaluated in a sound field set-up where the target speech and four interferers were delivered by loudspeakers positioned around the test person. More specifically, the loudspeakers were positioned at 0°, ±30° and ±120° around the subject. The target was always played at 0°, while interferers were either from frontal (colocated condition) or from the other four symmetrically distributed loudspeakers (separated condition). Speech was used as both target and interferer, giving a high degree of informational masking. SRT was measured in both conditions and SRM was estimated as the difference between separated and colocated SRM. This was a particularly challenging set-up for the listeners, due to the quite high number of interferers, informational masking and symmetric distribution of sound sources.

3.3 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. Results from speech audiometry are also a good indicator of whether the patient is taking advantage of the device in a satisfactory way.

However, these quantitative outcomes highlight only the benefit given by technical features, such as amplification or noise reduction algorithms. However, the process of hearing aid intervention is not limited to the patients' final hearing performance. 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 [86–88] 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 and active transcutaneous BCDs, the impact of surgery and follow ups should also be taken into account. With such a diverse picture, determining 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 [89]. This inevitably leads to a considerable spread in protocols, both in the clinical and in the research practice.
In Paper III and Paper V, three questionnaires are used:

APHAB: Abbreviated Profile of Hearing Aid Benefit The PHAB questionnaire, and its shortened version APHAB, were developed by Cox et al. [90, 91] to get some insights on the hearing aid users' perception of costs and benefits associated to 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 included: I) EC: Ease of Communication, investigating how much effort is required to understand speech under easy listening conditions; II) RV: 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, addressing the reaction to loud or unpleasant sound.

GBI: Glasgow Benefit Inventory The GBI questionnaire is a specifically developed measure of the patient's benefit after ear, nose and throat interventions [92]. 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.

IOI-HA: International Outcome Inventory for Hearing Aids This questionnaire, utilised in Paper V only, was developed as a tool to facilitate the comparison of results from different self-reported questionnaires by providing universally applicable measures [93]. The material was initially thought as a supplement to other investigation tools, but shortly after its publication, it became a self-standing outcome measure thanks to the strong psychometric properties despite the brevity in admin-

istration [94]. Furthermore, abundant normative data is available [95], allowing a reliable evaluation of the hearing aid fitting with respect to standards.
The questionnaire consists of seven items to be answered on a five steps Likert scale. Each question addresses a different outcome domain, namely: daily use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life.

Other questionnaires among the most used ones are:

- Hearing Aid Performance Inventory/Questionnaire (HAPI/HAPQ), to evaluate the direct benefit given by the 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;
- 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.

Chapter 4

Rehabilitation by Bone Conduction Devices

Rehabilitation of hearing impaired patients is one of the main applications of BC hearing. Other utilisation possibilities are for communication systems in situations that are more conveniently approached with BC microphones and headphones compared to 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 and with a final focus on transcutaneous solutions, which the market seems to be moving towards at the moment. Some of the 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 BC hearing mechanism can be dated back to the second century, the idea of using BC to improve hearing ability came many centuries later, sometimes attributed to the Italian physician Girolamo Cardano in 1521 [96]. 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 BCD 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

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 BC 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.

construction of BC vibrators [4, 97]. In 1932, Hugo Leiber from the Sonotone Corporation invented the first wearable hearing aid with the so-called oscillator placed on the mastoid. Commercialised BC 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 the 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, further described in sec.4.2.3. 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 [5], 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 externally 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.

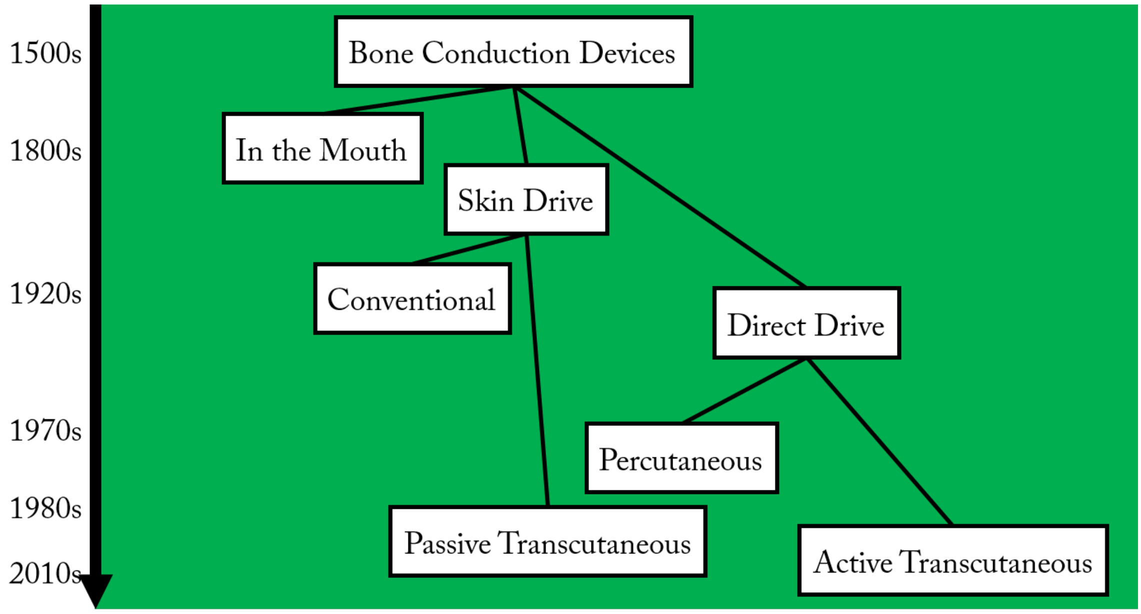


Figure 4.2: Classification of bone conduction devices as in Ref. [5]. The time line to the left gives an approximate indication of when the first devices of each category appeared on the market, from the renaissance (top) to the contemporary years (bottom).

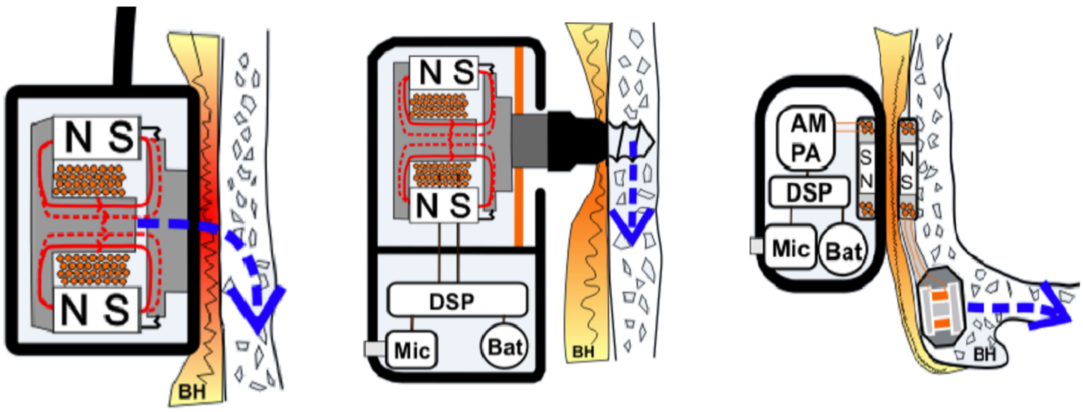
4.2.1 In the Mouth

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 they are safe. This makes them suitable for sensitive populations such as children or mentally challenged persons. 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 (b) Percutaneous (c) Active transcutaneous

Figure 4.3: Principal design of the three different kinds of bone conduction devices. N(north)-S(south) 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. [98]*

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 a surgical operation is needed 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 [99–101].
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 commercialised by MED-EL (Innsbruck, Austria) since 2018 [102].
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 [103, 104]. The first direct drive BCD was the BAHA, developed in the late 1970s [105, 106]. 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 (see e.g. [107–111]). Refinements in the surgical techniques and abutment design made the implantation procedure quick and safe and suitable to a vast number of patients [112, 113]. 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 [114].
Another way to stimulate the skull in a direct way is to have the transducer implanted in the bone. 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 receiving 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^{TM} 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 five years of age. In 2018 the U.S. FDA (Food and Drugs Administration) granted clearance for the BONEBRIDGE^{TM} for patients over twelve years of age with conductive or mixed hearing loss, and SSD. 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, shown in Figure 4.4, is an active transcutaneous BCD currently on clinical trial phase since 2012 [6–10]. 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.

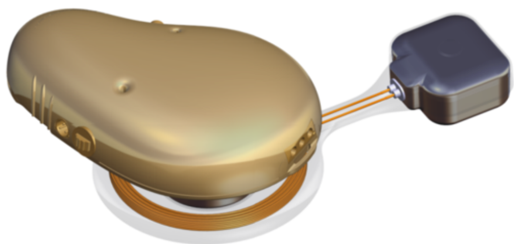


Figure 4.4: The active transcutaneous Bone Conduction Implant with one implanted unit and the external audio processor unit.

This active transcutaneous system consists of one implanted and one externally worn unit. The external 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, a receiving coil, and a titanium casing with outer silicon enclosing the demodulating circuit and the BC transducer. 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 [9]. The transmitter and the receiver coil are tuned to optimise the transmission over a certain skin thickness range.

For devices with implanted units, safety is one of the key aspects to be ensured, both during surgery and 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 have been reported so far [115, 116]. 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 [117, 118].

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 at some frequencies [5, 105], 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 [6, 119]. 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 [9]. 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 III.

The transducer utilised in the BCI is of BEST (Balanced Electromagnetic Separation Transducer) type, presented by Bo Håkansson in 2003 [120]. 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. [121].

4.3 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 BCD users and providers. These are not only related to the technical specifications of the devices, but also to social and assistive factors [114, 122, 123].
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 [124]. 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 [125, 126]. Furthermore, the size of the transducer is related to its power capability, and more powerful devices require a bigger transducer and bigger battery unit [98].
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 power output 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 I and Paper II a pilot study on the effect of the transducer attachment type is presented.
For semi implantable BCDs, another big challenge is to be compatible with diagnostic methods such as X-rays and MRI [127]. 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 scanner, or indirect, if e.g. 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. This puts high demands on the design of the implanted retention magnet as well as electronic components and magnetic materials in the BC transducer.

To conclude, it is important to mention the open problems with hearing aid use in noisy and reverberant environments. The ability to discriminate and understand speech in 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: Direct Bone Conduction Stimulation: Ipsilateral Effect of Different Transducer Attachments in Active Transcutaneous Devices

The aim of this study was to investigate if and how the transducer-to-bone attachment influences vibration transmission to the cochlea for BC hearing rehabilitation. Considering that the market is moving towards transcutaneous solutions, the investigation of the effect of the implantation method on the stimulus reaching the cochlea is of increasing interest. This pilot study was done on four cadaver heads that were

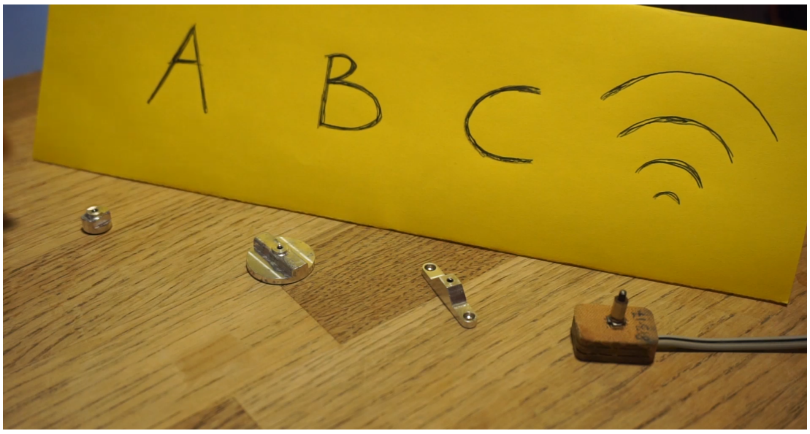


Figure 5.1: The three dummy implants used to achieve different typologies of contact with bone: A) small-sized flat surface, B) wide flat surface and C) rigid bar anchored with a screw at each end of the bar. On the right hand side, the transducer that was utilised is shown. The transducer was screwed on top of each of the adaptors with its M2-threaded screw.

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 active 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 with a screw. The same transducer 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 ECSP and velocity at the cochlear promontory, measured with a low noise microphone and a LDV, respectively. The three adaptors and the transducer to be screwed on top of them are pictured in Figure 5.1.
The difference between the transmission from the adaptors was evaluated and trends indicated that the attachment type has a stronger influence for 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.
The author was responsible for planning the measurements, analysing the data and writing the article, while the measurements required the involvement of all co-authors.

Paper II:
Effect of Transducer Attachment on Vibration Transmission and Transcranial Attenuation for Direct Drive Bone Conduction Stimulation

This study was a continuation of the previous one, aimed at consolidating previous findings and extending them. The primary aim was to investigate the effect of transducer attachment for transcutaneous direct-drive stimulation on the signal transmission to the ipsilateral and contralateral cochlea. The secondary aim was to address the impact of transducer attachment on transcranial attenuation (TA, defined as level of ipsilateral minus contralateral signal), both for transcutaneous and for percutaneous direct drive applications.
Measurements were performed on four human heads, and four typologies of transducer to bone contact were tested on each side: (A) small-sized flat surface, (B) extended flat surface, (C) bar with a screw at both ends, and (D) standard BAHA screw. Adaptors A-C were implanted in the mastoid part of the temporal bone, and adaptor D in the parietal bone, as schematically shown in Figure 5.2. Velocity at the cochlear promontory and ECSP were used to evaluate the vibration transmission at both ipsilateral and contralateral side.
Measurements confirmed the findings from the previous study: for lower and medium frequencies, up to approximately 5 kHz, adaptors A and B seem to give comparable

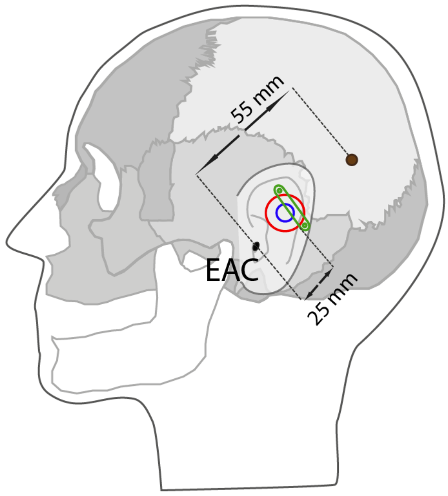


Figure 5.2: Lateral schematic view of a head showing the position where adaptors A-D were implanted in Paper I and Paper II. Adaptors A, B, and C are illustrated in Figure 5.1, adaptor D was a standard BAHA screw.

transmission efficiency, with C generally lower. At mid and high frequencies, keeping a smaller area (adaptor A) seems to be preferable. However, adaptor C appears superior to both A and B in frequencies around 6 kHz. The trend was also seen in contralateral transmission, although less remarkably than in the ipsilateral case.
TA was found to be similar for adaptors A, B, and C, with values up to 20 dB at high frequencies. A lower TA was seen with the percutaneous adaptor D.
Based on the measured contralateral response values, the position and attachment procedure of adaptors A-C seem to be equally suitable for rehabilitation of SSD patients as much as as the D solution. Furthermore, the higher TA obtained with adaptors A-C might be preferable for providing a more side-specific stimulus, i.e. likely facilitating interaural separation, when the implant is placed on the impaired side.
The author was responsible for planning the measurements, analysing the data and writing the article, while the measurements required the involvement of all co-authors.

Paper III: 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 would have not been ethically 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, sex 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. A graphic representation of the study design is shown in Figure 5.3. Results from identical audiometric tests and self-reported questionnaires from both

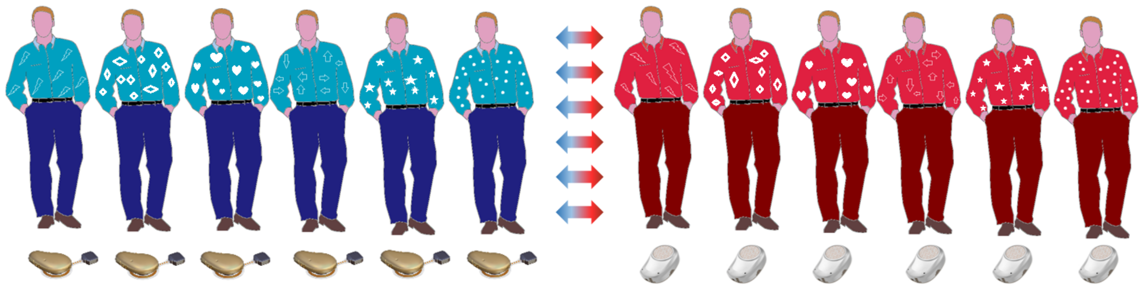


Figure 5.3: Graphic representation of the matched pairs design utilised in Paper III: each of the six BCI users (group on the left) is individually matched to one BAHA user (group on the right), and the results of the two groups are compared.

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, SRS in noise, SRT in quiet, and SNR threshold. No statistically significant difference was found in any of the tests. 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 active transcutaneous BCI is believed to offer a valid alternative to the percutaneous BAHA 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, and performed the data analysis and was the main contributor in writing the article.

Paper IV: 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 transcutaneous 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 was the NSP.

NSP was measured in all the thirteen patients included in Gothenburg in the BCI

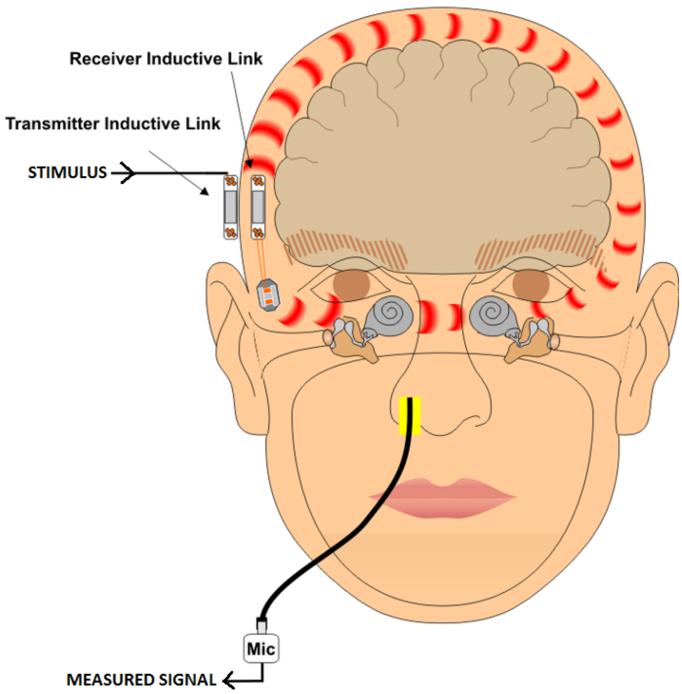


Figure 5.4: Set-up for NSP measurement: the custom-made driver unit is electrically driven with an input signal, and the signal is collected by the implanted receiver coil, demodulated and used to drive the transducer. The microphone (Mic) probe inserted in the nostril.

clinical trial, at surgery and at follow up visits. After the implanted unit was positioned, 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 5.4.
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 in the individual patient was very stable, with some exception at isolated frequencies such as 4 kHz.
The NSP method verified proper function of all devices during surgery, and in the follow-up the NSP has shown stable function over time. The method can be considered 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 the collected data, visualization of the results and partly writing the paper.

Paper V:
Three year follow-up with the Bone Conduction Implant

The aim of this study was to report on the rehabilitation effect given by the BCI measured as hearing and quality of life for the first ten patients in the clinical trial after the three year follow up visit. Additionally, a time analysis of the measured outcomes from fitting to present was carried out to investigate the stability of the rehabilitation.
Following the BCI clinical trial protocol, audiometric measurements and objective measurements were performed at fitting and after 1, 3, 6, 12, and 36 months of use of the device, and self-reported questionnaires were added after 6, 12 and 36 months. Four audiological sound field tests were repeated at each visit: warble tone thresholds, SRS in noise, SRT in quiet, and SNR threshold. Three questionnaires investigating quality of life, benefit from the intervention, and subjective perception of the rehabilitation effect were completed by the patients. The results were compared to the unaided condition and to results obtained prior to the BCI implantation with a reference device on a soft band. At each visit, NSP and magnetic retention force were also measured.
The results from both audiological and self-reported measurements showed significant improvement from the unaided condition for both BCI and reference device. There were no significant differences between the two devices, and all the outcomes appeared to be stable over time. Results after 36 months of use showed that the BCI improves

hearing ability for tones and speech perception in quiet and in noise. Furthermore, the patients subjectively reported a beneficial experience from using the device.
The author was mainly responsible for the statistical analysis and visualisation of the data, and writing the corresponding parts of the article.

Paper VI:
The Effect of an Active Transcutaneous Bone Conduction Device on Spatial Release from Masking

This study investigates how users of the BCI perform in complex and realistic listening conditions, when they have to focus on one target speech while being surrounded by interfering talkers.
In this situation, commonly referred to as "cocktail party" set-up, one known mechanism helping listeners to understand the target speech above the background is the SRM, i.e. the benefit of having spatially separated interferers from the target speech.
The main objective of this study was to quantify the effect of a unilaterally im-

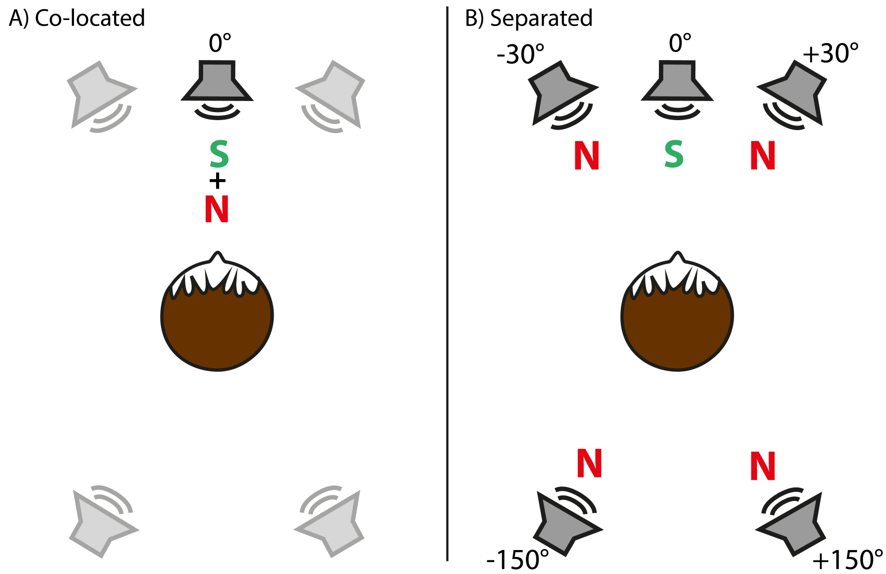


Figure 5.5: Set-up for the SRM measurement: the target speech (S) is played from frontal loudspeaker, the interfering speech (N) is played from either A: the same frontal loudspeaker (co-located configuration), or B: from four loudspeakers symmetrically placed around the subject (separated configuration).

planted BCI on SRM in patients with bilateral and unilateral hearing loss.
Measurements were performed with twelve BCI patients in a sound booth, using five loudspeakers to present the target speech frontally, and interfering speech from either the front (co-located condition) or surrounding (separated condition) locations,

as shown in Figure 5.5. SRM was estimated as the difference between the separated and the co-located SRT.
The results from this study indicate that SRM seems to be present under unilateral direct drive BC stimulation, although reduced when compared to unaided listening condition. No difference was observed in SRM between unilateral and bilateral hearing loss patients.
The author was mainly responsible for the data analysis and writing the article.

Chapter 6

Conclusions and Future Work

The field of BCDs has been extensively growing in the past few decades, and today's market offers several different alternatives, whose number and variety is constantly increasing. Advancements in product design and surgical techniques have contributed to the wide spread of semi-implantable BCDs, which are rigidly anchored on the skull bone and transmit vibrations in a very effective way to the cochleae. In recent years, the development is focusing on 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, the thesis presents various empirical studies concerning direct drive BC stimulation for hearing rehabilitation purposes. BCDs can be investigated at different levels: separate details may be studied with regard to specific aspects to be improved, or alternatively a general evaluation of the device as a whole may be desirable, looking at its rehabilitation effect on patients under standard or more advanced and specific tests. The studies included in this thesis touch upon both levels, with initial investigations on specific aspects of transducer attachment to the skull bone, followed by tests on patients aimed at evaluating the rehabilitation quality. Active transcutaneous stimulation was compared with percutaneous stimulation on cadaver heads as well as on implanted patients, and a method for active transcutaneous implant functionality verification was evaluated. Common hearing tests, such as tone thresholds or speech recognition in quiet, were studied on patients fitted with the BCI, and also more complex situations were evaluated, including speech recognition in complex multi-interferer hearing scenarios.
The main conclusions drawn from the studies are:

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

imum 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.

- The transmission of signals to the ipsilateral side appears to be higher when the stimulation is given by transcutaneous implants on the temporal bone as compared to the percutaneous attachment on the parietal bone. The contralateral transmission is instead comparable for both stimulation conditions, resulting in a higher TA (difference in level between the signal at the ipsilateral and the contralateral side, given the same stimulation) in transcutaneous attachments. This opens clinical implications for rehabilitation of SSD patients: transcutaneous systems may be considered equally indicated as BAHAs for this set of patients, when the device is to be implanted on the deaf side but has to transfer the signal to the working cochlea on the contralateral side. For other applications, where the device is implanted at the hearing impaired side, the stimulation conditions leading to higher TA may be preferable with regards to increased interaural separation, possibly leading to improved binaural cues.

- 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 at 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 twelve months period of time after surgery.

- 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 matched patients.
  In BC hearing rehabilitation, BAHAs are today the golden standard due to their high sound quality and effectiveness. The reason that drives active 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 indicates a very attractive alternative to a percutaneous solution. Furthermore, the BCI is still in its first generation,and improvements are likely to come in future releases.

- The clinical trial of the BCI is so far showing positive results, both on the audiometric measurements and on the user reported outcomes. The patients are generally satisfied with the performance of the device, and they use it on a regular basis. The trends are stable over time, giving a positive long term expectation.

- In the complex listening scenario of a cocktail party, patients fitted with the BCI seem to take advantage of the spatial separation of the interfering speech sources. Nine of twelve patients achieved in fact positive SRM, although in a generally reduced extent compared to the unaided condition. These results suggest that when fitted with the BCI, some of the binaural cues contributing to understanding of speech in spatially separated target-interferer configurations may be altered or suppressed.

Being promising so far, the clinical study of the BCI is going to continue until all the patients implanted in Gothenburg have reached five years of usage. The 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. However, in its current design, the NSP measurement system is not suitable for routine clinical application, and future efforts may be focused on simplifying and optimising this setup. An open question regarding NSP values is to explain the difference seen between the curve obtained at surgery and the ones at follow-up visits on the same patient. The curve obtained at implantation, when the patient is anaesthetized, is distinctly different from the ones obtained at several follow-ups, when the patient is sitting and holding the breath. However, the cause of this variability was not identified so far, and further investigation would be needed in this regard.

During the measurement session for Paper II, more data than has been in this thesis presented was collected. This includes e.g. impedance measurements, phase measurements, and tests involving mastoidectomy and radical cavity surgeries. All this data needs to be analysed to extrapolate important information: the analysis of the phase could be used to get some insights on TA and wave propagation velocity, and the effect of mastoidectomy on the vibrational response will give important knowledge of the potential effect of having a more backward located attachment when needed. To study how the transducer attachment affects TA is particularly interesting if this can be related to subjective measurements on patients.

Testing of binaural cues and spatial hearing on BCI patients is at a very initial phase at the moment, opening a vast set of opportunities for future tests. Correlating measure of TA to hearing tests outcomes may constitute a great advance in the BC rehabilitation field. The comparison between percutaneous and transcutaneous stimulation is therefore planned to be extended to SRM and localisation tasks. Making use of a matched-pairs design analogous to the one used in Paper IV, a study is planned in the near future, where BAHA users matched to the BCI users will be asked to perform the same tasks as in Paper VI. This would give the possibility to identify whether the trend in SRM is somehow related to the differences in TA seen from the different attachments.

Bibliography

[1] HRF, "Hörselskadade i siffror 2017," Tech. Rep., November 2017.

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

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

[4] 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.

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

[6] 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.

[7] 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.

[8] 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.

[9] 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.

[10] 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.

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

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

[13] 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.

[14] 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.

[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, "Simultaneous cancellation of air and bone conduction tones at two frequencies: Extension of the famous experiment by von békésy," *Hearing Research*, vol. 225, no. 1, pp. 105 – 116, 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] G. v. Békésy, “Note on the definition of the term: Hearing by bone conduction,” *The Journal of the Acoustical Society of America*, 1954.

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

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

[27] 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.

[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 in vivo," *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] S. Stenfelt and R. 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] R. Y. Litovsky, *Development of Binaural Audition and Predictions for Real-World Environments.* New York, NY: Springer New York, 2001, pp. 25–35.

[44] D. S. Brungart and B. D. Simpson, "The effects of spatial separation in distance on the informational and energetic masking of a nearby speech signal," *J Acoust Soc Am*, vol. 112, no. 2, pp. 664–76, 2002.

[45] A. Lingner, B. Grothe, L. Wiegrebe, and S. D. Ewert, "Binaural glimpses at the cocktail party?" *Jaro-Journal of the Association for Research in Otolaryngology*, vol. 17, no. 5, pp. 461–473, 2016.

[46] A. W. Bronkhorst and R. Plomp, "The effect of head-induced interaural time and level differences on speech intelligibility in noise," *J Acoust Soc Am*, vol. 83, no. 4, pp. 1508–16, 1988.

[47] T. Van Den Bogaert, T. J. Klasen, M. Moonen, L. Van Deun, and J. Wouters, "Horizontal localization with bilateral hearing aids: Without is better than with," *J Acoust Soc Am*, vol. 119, no. 1, pp. 515–526, 2006.

[48] R. Y. Litovsky, *Development of Binaural and Spatial Hearing.* New York, NY: Springer New York, 2012, pp. 163–195.

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

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

[51] 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.

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

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

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

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

[56] 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.

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

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

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

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

[61] 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.

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

[63] 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.

[64] 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.

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

[66] 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.

[67] 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.

[68] 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.

[69] 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.

[70] 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.

[71] 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.

[72] 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.

[73] 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.

[74] 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.

[75] 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.

[76] 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.

[77] 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.

[78] 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.

[79] 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.

[80] 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.

[81] W. Hodgetts, D. Scott, L. Westover, and P. Maas, "Development of a novel bone conduction verification tool using a surface microphone: Validation with percutaneous bone conduction users," *Ear and hearing*, vol. 39, no. 6, pp. 1157–1164, 2018.

[82] 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.

[83] A. W. Mills, "On the minimum audible angle," *Journal of the Acoustical Society of America*, vol. 30, no. 4, p. 237, 1958.

[84] W. M. Hartmann and B. Raked, "On the minimum audible angle–a decision theory approach," *Journal of the Acoustical Society of America*, vol. 85, no. 5, pp. 2031–41, 1989.

[85] F. Asp and S. Reinfeldt, "Horizontal sound localisation accuracy in individuals with conductive hearing loss: effect of the bone conduction implant," *Internaional Journal of Audiology*, vol. 57, no. 9, pp. 657–664, 2018.

[86] 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.

[87] 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.

[88] 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.

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

[90] 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.

[91] 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.

[92] 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.

[93] R. Cox, M. Hyde, S. Gatehouse, W. Noble, H. Dillon, R. Bentler, D. Stephens, S. Arlinger, L. Beck, D. Wilkerson, S. Kramer, P. Kricos, J. P. Gagné, F. Bess, and L. Hallberg, "Optimal outcome measures, research priorities, and international cooperation." *Ear And Hearing*, vol. 21, no. 4 Suppl, pp. 106S – 115S, 2000.

[94] R. M. Cox and G. C. Alexander, "The international outcome inventory for hearing aids (ioi-ha): psychometric properties of the english version." *Internaional Journal of Audiology*, p. 30, 2002.

[95] R. M. Cox, G. C. Alexander, and C. M. Beyer, "Norms for the international outcome inventory for hearing aids." *Journal of the Acoustical Society of America*, no. 8, p. 403, 2003.

[96] 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.

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

[98] 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.

[99] D. Chen, Stephanie Y.and Mancuso and A. K. Lalwani, "Skin necrosis after implantation with the baha attract: A case report and review of the literature," *Otology & Neurotology*, vol. 38, pp. 364–367, 2017.

[100] M. Iseri, A. Kara, M. Durgut, K. S. Orhan, Y. Guldiken, U. Tuncer, and O. Surmelioglu, "Transcutaneous bone-anchored hearing aids versus percutaneous ones: Multicenter comparative clinical study," *Otology and Neurotology*, vol. 36, no. 5, pp. 849–853, 2015.

[101] P. A. Dimitriadis, M. R. Farr, A. Allam, and J. Ray, "Three year experience with the cochlear baha attract implant: a systematic review of the literature," *BMC Ear, Nose and Throat Disorders*, vol. 16, no. 1, p. 12, 2016.

[102] P. Westerkull, "An adhesve bone conduction system, adhear, a new treatment option for conductive hearing losses," *Journal of Hearing Science*, vol. 8, no. 2, pp. 35–43, 2018.

[103] B. Håkansson, A. Tjellström, and U. Rosenhall, "Acceleration levels at hearing threshold with direct bone conduction versus conventional bone conduction," *Acta Oto-Laryngologica*, vol. 100, no. 3/4, p. 240, 1985.

[104] S. Stenfelt and B. Håkansson, "Sensitivity to bone-conducted sound: excitation of the mastoid vs the teeth," pp. 190–198, 1999.

[105] B. Håkansson, A. Tjellström, and U. Rosenhall, "Hearing thresholds with direct bone conduction versus conventional bone conduction," *Scandinavian Audiology*, vol. 13, no. 1, pp. 3–13, 1984.

[106] B. Håkansson, A. Tjellström, U. Rosenhall, and P. Carlsson, "The bone-anchored hearing aid: Principal design and a psychoacoustical evaluation," *Acta Oto-Laryngologica*, vol. 100, no. 3/4, p. 229, 1985.

[107] A. F. M. Snik, E. A. M. Mylanus, D. W. Proops, J. F. Wolfaardt, W. E. Hodgetts, T. Somers, J. K. Niparko, J. J. Wazen, O. Sterkers, C. Cremers, and A. Tjellström, "Consensus statements on the baha system: Where do we stand at present?" *Annals of Otology Rhinology and Laryngology*, vol. 114, pp. 2–12, 2005.

[108] C. W. Newman, S. A. Sandridge, and L. M. Wodzisz, "Longitudinal benefit from and satisfaction with the baha system for patients with acquired unilateral sensorineural hearing loss," *Otology & Neurotology*, vol. 29, pp. 1123–1131, 2008.

[109] F. Pfiffner, M. D. Caversaccio, and M. Kompis, "Audiological results with baha in conductive and mixed hearing loss," *Adv Otorhinolaryngol*, vol. 71, pp. 73–83, 2011.

[110] C. C. Liu, D. Livingstone, and W. K. Yunker, "The role of bone conduction hearing aids in congenital unilateral hearing loss: A systematic review," *International Journal of Pediatric Otorhinolaryngology*, vol. 94, pp. 45–51, 2017.

[111] A. L. McDermott and P. Sheehan, "Bone anchored hearing aids in children," *Current Opinion in Otolaryngology & Head and Neck Surgery*, vol. 17, no. 6, 2009.

[112] I. J. Kruyt, H. Kok, A. Bosman, R. C. Nelissen, E. A. M. Mylanus, and M. K. S. Hol, "Three-year clinical and audiological outcomes of percutaneous implants for bone conduction devices: Comparison between tissue preservation technique and tissue reduction technique," *Otol Neurotol*, vol. 40, no. 3, pp. 335–343, 2019.

[113] E. Verheij, A. Bezdjian, W. Grolman, and H. G. Thomeer, “A systematic review on complications of tissue preservation surgical techniques in percutaneous bone conduction hearing devices,” *Otol Neurotol*, vol. 37, no. 7, pp. 829–37, 2016.

[114] R. Powell, A. Wearden, S. M. Pardesi, and K. Green, “Understanding the low uptake of bone-anchored hearing aids: a review,” *The Journal of Laryngology & Otology*, vol. 131, no. 3, pp. 190–201, 2017.

[115] B. Håkansson, S. Reinfeldt, A. C. Persson, K. J. Fredén Jansson, C. Rigato, M. Hultcrantz, and M. Eeg-Olofsson, “The bone conduction implant - review and one year follow up.” *Ahead of publication*, 2019.

[116] A. C. Persson, S. Reinfeldt, B. Håkansson, C. Rigato, K. J. Fredén Jansson, and M. Eeg-Olofsson, “Three year follow up with the bone conduction implant,” *Ahead of publicaion*, 2019.

[117] 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: Evidence and Research*, vol. 8, pp. 413–23, 2015.

[118] K. J. Fredén Jansson, B. Håkansson, S. Reinfeldt, H. Taghavi, and M. Eeg-Olofsson, “Mri induced torque and demagnetization in retention magnets for a bone conduction implant,” *IEEE transactions on biomedical engineering*, vol. 61, pp. 1887–1893, 2014.

[119] H. Taghavi, B. Håkansson, and S. Reinfeldt, “Analysis and design of rf power and data link using amplitude modulation of class-e for a novel bone conduction implant,” *IEEE Transactions on Biomedical Engineering*, no. 11, p. 3050, 2012.

[120] 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.

[121] 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.

[122] P. Kricos, *The Challenge of Non-Audiological Variables*, 2009.

[123] M. A. Ferguson, A. Woolley, and K. J. Munro, “The impact of self-efficacy, expectations, and readiness on hearing aid outcomes,” *International Journal of Audiology*, vol. 55, p. S34, 2016.

[124] 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," *Otol Neurotol*, vol. 36, no. 4, pp. 631–7, 2015.

[125] A. F. M. Snik, E. A. M. Mylanus, and C. Cremers, "The bone-anchored hearing-aid compared with conventional hearing-aids - audiological results and the patients opinions," *Otolaryngologic Clinics Of North America*, vol. 28, no. 1, pp. 73–83, 1995.

[126] H. Taghavi, B. Håkansson, S. Reinfeldt, M. Eeg-Olofsson, and S. Akhshijan, "Feedback analysis in percutaneous bone-conduction device and bone-conduction implant on a dry cranium," *Otol Neurotol*, vol. 33, no. 3, pp. 413–20, 2012.

[127] A. Snik. (December 2017) Chapter 5. comparison of interventions in certain groups of patients - mri compatibility and stability of these implantable devices. [Online]. Available: http://www.snikimplants.nl/?p=241#512-mri-compatibility-and-stability-of-these-implantable-devices