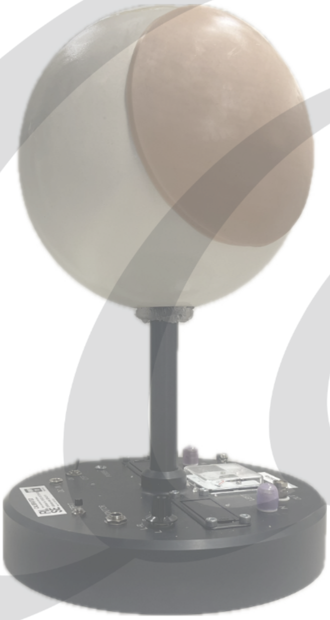

Replicating Human Scalp Properties for Enhanced Accuracy in the Testing of Bone Conduction Hearing Devices

Master's Thesis in Biomedical Engineering

Anna Fassih, Elina Sandoff

Department of Electrical Engineering, Division of Signal Processing and Biomedical Engineering
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2025
www.chalmers.se

Master's Thesis 2025

Replicating human scalp properties for enhanced accuracy in the testing of bone conduction hearing devices

Anna Fassih
Elina Sandoff

CHALMERS
UNIVERSITY OF TECHNOLOGY

Department of Electrical Engineering
Division of Signal Processing and Biomedical Engineering
Chalmers University of Technology
Gothenburg, Sweden 2025

Replicating human scalp properties for enhanced accuracy in the testing of bone conduction hearing devices

Anna Fassih and Elina Sandoff

Supervisor: Dan Nyström, Cochlear Bone Anchored Solutions AB
Examiner: Sabine Reinfeldt, Department of Electrical Engineering, Chalmers University of Technology.

Master's Thesis 2025
Department of Electrical Engineering
Division of Signal Processing and Biomedical Engineering
Chalmers University of Technology
SE-412 96 Gothenburg
Telephone +46 31 772 1000

Typeset in LaTeX
Printed by Chalmers Reproservice
Gothenburg, Sweden 2025

Abstract

This thesis investigates and develops an artificial human scalp replica for use in bone conduction hearing device testing, with the goal of improving the accuracy and reliability of bone conduction hearing device evaluations. The work was motivated by Cochlear Bone Anchored Solution's need to enhance their existing head simulator, which previously lacked a component mimicking the mechanical properties of human scalp tissue. To achieve this, a wide range of silicone-based scalp materials were evaluated using three primary performance metrics: mechanical point impedance, attenuation and acoustic feedback. All measurements were conducted using a standardized measurement setup involving Cochlear's HeadSim1 simulator. Additionally, a market investigation was conducted to collect new mechanical point impedance reference data from 19 human subjects under identical conditions to ensure comparability with the artificial materials. Multiple types of artificial scalps, including Ecoflex and FS10 variants, in-house crafted silicones, and molded custom shapes, were assessed through repeated measurements to ensure consistency and minimize errors. The findings reveal that Ecoflex0010, particularly the adaption developed in this thesis, best replicates human scalp properties. It demonstrates the lowest mean absolute error (MAE) in mechanical point impedance and attenuation combined, and performs well within acceptable ranges for acoustic feedback compared to clinical reference data. The aim of this study was fully achieved: a validated, usable artificial scalp that improves the fidelity of bone conduction hearing device testing was identified. The broader implication is an enhancement in preclinical evaluation tools for bone conduction hearing devices, leading to more reliable data and potentially reducing the need for clinical testing iterations. This contributes to better design decisions, increased patient safety, and faster innovation cycles in the field of bone conduction hearing device technology.

Keywords: Cochlear, Bone Conduction Hearing Devices, Mechanical Properties, Mechanical Point Impedance, Attenuation, Acoustic Feedback, Head Simulator, HeadSim1 Artificial Scalp.

Aknowledgements

We would like to extend our heartfelt gratitude to everyone who supported us throughout the course of this thesis. This work would not have been possible without the contributions of these dedicated and brilliant individuals.

First and foremost, we wish to express our deepest gratitude to our supervisor at Cochlear Bone Anchored Solutions AB, Dan Nyström, for his constant guidance and support. Thank you for trusting us to explore and evolve freely, while always providing support whenever needed. Your help has been invaluable.

We are also incredibly grateful to our examiner at Chalmers University of Technology, Dr. Sabine Reinfeldt, for her continuous support and insightful feedback. Your attentiveness, availability, and expertise have greatly enriched our work and provided clarity.

A sincere thank you goes to Henrik Fyrlund at Cochlear for consistently challenging us to improve and for contributing to the development of this project. Your input and encouragement have been of great support.

We would also like to thank Theres Björk, whose expertise and guidance during the market investigation were instrumental. Your thoughtful perspectives and willingness to teach have given us valuable insights that we will carry with us into our professional lives.

Our appreciation also goes to Isabella Nilsen, Armin Azhirnian, and Felicitas Bederna for their patience and assistance in helping us get started with the measurements and equipment. Your support and availability have been greatly appreciated throughout the project. Furthermore, we are sincerely thankful to all individuals at Cochlear who took their time and participated in the market investigation by allowing us to collect data. Your time and cooperation were crucial to the success of this study, and we are truly grateful for your involvement.

Lastly, we acknowledge the use of AI language models for minor language refinements. This was done with care and did not affect the substance or integrity of the thesis in any way.

Anna Fassih, Gothenburg, May 2025 & Elina Sandoff, Gothenburg, May 2025

Contents

1 Introduction **1**
1.1 Introduction to Cochlear . . . 1
1.2 Aim & Research Questions . . . 1
1.3 Limitations . . . 2

2 Theory **3**
2.1 Bone Conduction Hearing Devices . . . 3
  2.1.1 Cochlear's Baha System . . . 3
  2.1.2 Osia implant . . . 4
2.2 Anatomy of the Human Head . . . 4
  2.2.1 Anatomy of the Brain . . . 4
  2.2.2 Anatomy of the skull . . . 5
  2.2.3 Anatomy of the scalp . . . 6
2.3 The anatomy and function of the ear . . . 6
  2.3.1 Air Conduction . . . 7
  2.3.2 Bone Conduction . . . 7
2.4 Hearing loss . . . 8
  2.4.1 Conductive Hearing Loss . . . 8
  2.4.2 Sensorineural Hearing Loss . . . 8
  2.4.3 Mixed Hearing Loss . . . 8
  2.4.4 Single Sided Deafness (SSD) . . . 8
2.5 Cadaver head . . . 9
2.6 Skull simulator . . . 9
2.7 Head simulator . . . 9
2.8 Artificial Mastoid . . . 11
2.9 Attenuation . . . 12
2.10 Mechanical Point Impedance . . . 12
2.11 Acoustic Feedback . . . 13
2.12 Reference Data Used for Comparison . . . 13

3 Method **16**
3.1 Materials and Fabrication . . . 16
  3.1.1 Cochlear's existing scalps . . . 16
  3.1.2 Crafted silicone scalps . . . 17
  3.1.3 Adapted made-to-order scalps . . . 18
3.2 Data collection . . . 18
3.3 Attenuation Measurements . . . 19
3.4 Mechanical Point Impedance Measurements . . . 20
  3.4.1 Artificial Mastoid Measurements . . . 21
3.5 Acoustic Feedback Measurements . . . 22
3.6 Analysis & Evaluation . . . 23
3.7 Attenuation & Mechanical Point Impedance Evaluation . . . 23
3.8 Acoustic Feedback Evaluation . . . 24

4 Results **25**
4.1 Data Collection . . . 25
4.2 Cochlear's Existing Scalps . . . 25
  4.2.1 Attenuation Measurements . . . 25
  4.2.2 Mechanical Point Impedance measurements . . . 26
4.3 Crafted Silicone Scalps . . . 27
  4.3.1 Attenuation Measurements . . . 27
  4.3.2 Mechanical Point Impedance measurements . . . 28
4.4 Adapted Made-to-order Scalps . . . 29
  4.4.1 Attenuation Measurements . . . 30
  4.4.2 Mechanical Point Impedance measurements . . . 30
4.5 Comparison . . . 31

4.5.1 Shape comparison 31
4.5.2 Attenuation Measurements 32
4.5.3 Mechanical Point Impedance measurements 35
4.5.4 Acoustic Feedback Measurements 39

5 Discussion 41
5.1 Choice of Measurements and Evaluation 41
5.2 Variations in Scalp Properties 42
5.3 Measurement Characteristics 42
5.3.1 Attenuation Characteristics 42
5.3.2 Acoustic Feedback Characteristics 42
5.3.3 Mechanical Point Impedance Characteristics 43
5.4 Material Durability 43
5.5 Contact force 44
5.6 Adaption of scalps 44
5.7 Ethical, ecological and societal considerations 45
5.7.1 Ethical Considerations 45
5.7.2 Ecological Considerations 45
5.7.3 Societal considerations 45

6 Conclusion 47

7 Future Work 48

Litterature 49

Appendix A 52

Appendix B 53

Appendix C 54

1 Introduction

Approximately 1.5 billion people worldwide currently suffer from hearing loss, including 430 million affected by severe or profound hearing loss [1]. By 2050, this number is projected to exceed 700 million. Cochlear, a leader in implantable hearing solutions, has developed advanced technical aids to address this issue. These technical aids include bone anchored hearing aids and various hearing implants. To test these devices, Cochlear's technology development team created a head simulator that replicates the mechanical properties of the human head, except for the absence of a scalp. To further enhance test reliability, the development of an artificial scalp that mimics the mechanical properties of a human scalp is essential in order to achieve more accurate testing conditions.

1.1 Introduction to Cochlear

Cochlear, an Australian based company founded in 1981, is a global leader in implantable hearing solutions [2]. Specializing in the design, manufacturing, and supply of advanced hearing devices, Cochlear offers products such as cochlear implants, bone-anchored hearing aids (BAHA), and Osia implants. Their mission is to help people of all ages to hear and be heard, with more than 750,000 implantable devices provided worldwide. Cochlear aims to establish cochlear implants as the primary treatment for individuals with severe to profound hearing loss, while also offering bone conduction solutions for conductive hearing loss, mixed hearing loss, and single-sided deafness.

Founded in 1999 in Gothenburg, Sweden, Entific Medical Systems specialized in the development and manufacturing of BAHA systems [3]. In 2005, the company was acquired by Cochlear, leading to the establishment of the new division Cochlear Bone Anchored Solutions AB. This division assumed responsibility for the development and manufacturing of bone conduction systems under the Baha brand. Today, the global headquarters for Cochlear's Acoustics solutions is located in Gothenburg.

1.2 Aim & Research Questions

The main purpose of this thesis is to investigate artificial materials that closely mimic the mechanical properties of human scalp. The goal is to find a usable solution that enables more reliable implant testing and increases testing accuracy in Cochlear's head simulator for bone conducted hearing devices. To qualify as a suitable replica, the material should match or closely approximate the mechanical point impedance, attenuation characteristics and acoustic feedback of human scalp. The objective of this study can be addressed through the following research questions:

- How closely do the materials mimic attenuation properties of human scalp?
- How closely do the materials mimic mechanical point impedance properties of the human scalp?
- How closely do the materials mimic acoustic feedback properties of the human scalp?
- Does the shape of the scalp replica have an impact on its performance?

1.3 Limitations

The thesis work is restricted to some limitations, due to both time and resources. Human mechanical scalp properties vary among individuals based on factors such as age and gender. Therefore, this study focuses on aligning the replica's mechanical properties with existing average clinical reference data rather than accounting for individual variations. Additionally, the work is limited to using Cochlear's head simulator as the foundation for all scalp measurements and adaptations. The evaluation of how accurately the replica mimics scalp properties is solely based on measurements of attenuation, mechanical point impedance and acoustic feedback.

2 Theory

This section provides an overview of the foundational concepts essential for understanding the work presented in this report. It begins with an introduction to bone conduction hearing devices and their underlying mechanisms. This is followed by a description of the anatomical structures relevant to hearing, including the brain, skull, scalp and ear. Various types of hearing loss are then described. Furthermore, the section presents different evaluation and calibration models for these devices, such as cadaver heads, skull simulators, head simulators and artificial mastoids. Finally, the mechanical properties central to this study are introduced.

2.1 Bone Conduction Hearing Devices

Bone conduction hearing devices are designed for patients with conductive or mixed hearing loss as well as single-sided deafness [4]. These devices are particularly effective when traditional air conduction hearing aids are unable to restore hearing. Bone conduction hearing devices transmit sound vibrations through the bone to the functioning inner ear, bypassing the damaged or impaired parts of the hearing pathway. A typical bone conduction hearing device consists of an external sound processor, an internal implant, and a connector that links them together [5]. There are multiple different manufacturers on the market, but as this thesis is conducted in collaboration with Cochlear Bone Anchored Solutions AB, their devices will serve as the basis for the research at hand.

2.1.1 Cochlear's Baha System

Cochlear's Baha system is an implantable bone conduction hearing device that can be either percutaneous or transcutaneous [6]. The Baha Connect system (see Figure 1) is percutaneous and consists of an external sound processor, a titanium implant, and a scalp penetrating titanium abutment that connects the external and internal components [6] [7]. The Baha Attract system (see Figure 2), on the other hand, is a passive transcutaneous system that uses magnets to connect the external and internal components, leaving the scalp intact [7]. In both systems, the titanium implant is placed on the mastoid bone behind the ear to achieve osseointegration [6]. The sound processor detects and converts sound into vibrations, which are transmitted to the implant. The implant then transfers the vibrations to the cochlea, bypassing the impaired part of the hearing pathway.

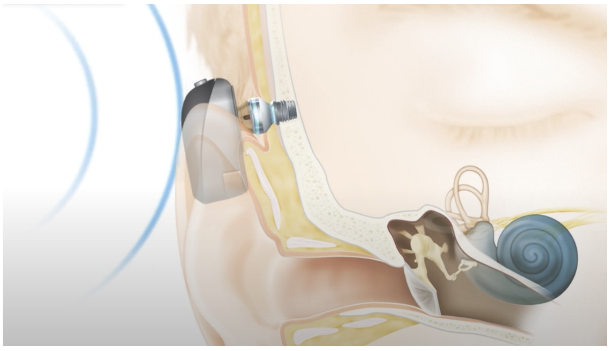

Figure 1: An illustration of the Baha connect system [6].

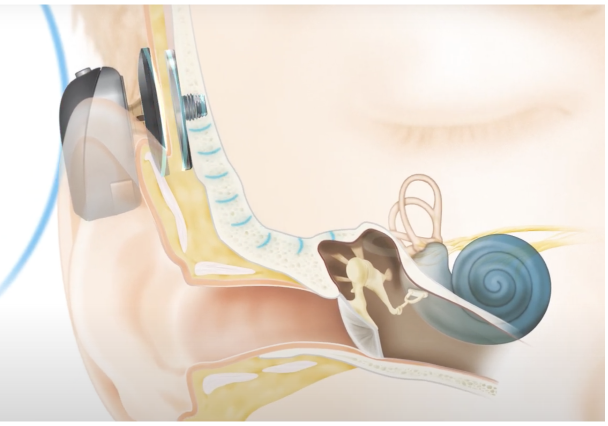

Figure 2: An illustration of the Baha attract system [6].

2.1.2 Osia implant

The Osia OSI300 is an active transcutaneous bone-anchored hearing implant that utilizes bone conduction [8]. By bypassing the impaired parts of the hearing pathway, the Osia system transmits sound vibrations directly through the bone to the inner ear [8] [9].

As can be seen in Figure 3, the Osia implant consists of an external sound processor and an internal titanium implant [9]. The implant is placed under the scalp behind the ear, and the external sound processor is held in place by a magnetic connection. Microphones in the external processor capture sound, which is converted into a digital signal. This signal is transmitted through the scalp to the implant coil that forwards it to the piezo power transducer. The transducer then converts the signal into vibrations that are transmitted through the bone to the cochlea [9].

Figure 3: The internal titanium implant and external sound processor of an Osia implant. [9]

2.2 Anatomy of the Human Head

This section provides an overview of the anatomical structures relevant to auditory processing and bone conduction, including the brain, skull and scalp.

2.2.1 Anatomy of the Brain

The brain is a complex organ responsible for both sensory and motor functions [10]. Along with the spinal cord, it forms the central nervous system. There are three major parts of the brain: cerebrum, cerebellum and the brainstem, as shown in Figure 4. The cerebrum is the largest part of the brain and is divided into the left and right hemispheres. Both hemispheres contain an inner subcortical white matter and an outer layer called cerebral cortex, which is composed of gray matter. The cerebrum is responsible for processing motor and sensory information, regulating behavior and emotions, and facilitating memory and intelligence. The cerebrum is further divided into four lobes: frontal, parietal, temporal and occipital. The parietal and temporal lobes are responsible for hearing.

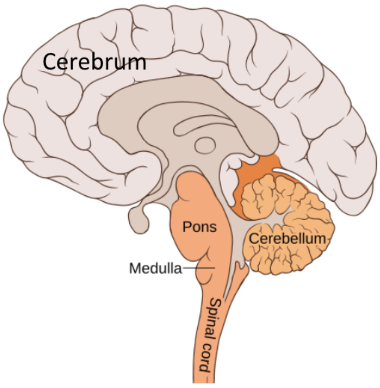

Figure 4: The three main parts of the anatomical human brain.
[11]

The cerebellum is located in the back of the head, between the cerebrum and the brainstem [10]. It is responsible for coordinating voluntary movements, maintaining balance and posture, and assisting with cognitive functions such as language and attention.

The brainstem connects the cerebrum to the cerebellum and consists of white and grey matter [10]. It is divided into the midbrain, pons and medulla. Among these, the pons plays an important role in processing auditory information.

2.2.2 Anatomy of the skull

The human skull consists of 22 bones and is divided into two main parts: the neurocranium and viscerocranium [12]. The neurocranium serves to protect the brain, while viscerocranium forms the structure of the face. The primary role of the skull is to support critical brain regions, including the cerebellum, cerebrum and the brainstem. Additionally, the skull provides attachment points for muscles via tendons.

The skull features three cranial fossae: the anterior, middle, and posterior cranial fossae as illustrated in Figure 5 [12]. Anterior cranial fossa contains the frontal lobe of the brain, the middle cranial fossa contains the temporal lobe, and the posterior cranial fossa contains the cerebellum. The middle cranial fossa serves as a pathway for the cochlear nerve, a part of cranial nerve VII, known as the vestibulocochlear nerve [13]. The cochlear nerve plays a vital role in hearing by transmitting auditory signals from the inner ear to the brain.

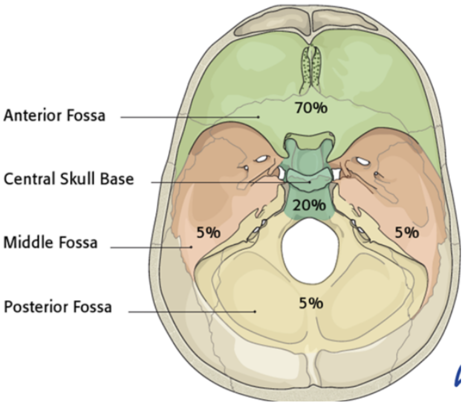

Figure 5: The anatomy of the skull, depicting the three cranial fossae.
[14]

Effectiveness of bone conduction is dependent on the properties of the skull bone [15]. At low frequencies, the skull acts like a rigid body. At higher frequencies, different types of sound waves occur.

2.2.3 Anatomy of the scalp

The scalp is the outermost layer of soft tissue that covers and protect the cranium from trauma and pathogens [16]. It consists of five layers: skin, dense connective tissue, epicranial aponeurosis, loose areolar connective tissue, and periosteum, as seen in Figure 6.

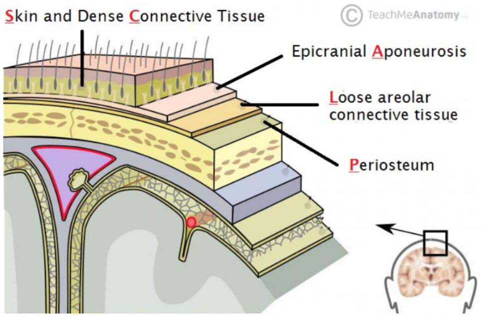

Figure 6: The anatomy of the human scalp.
[17]

The periosteum is the deepest layer, attached to the skull [16]. It is made of dense irregular connective tissue and is responsible for supplying blood to the underlying bone. Above the periosteum is the loose areolar connective tissue, which separates the upper layers from the pericranium. The epicranial aponeurosis is a strong connective tissue layer tightly connected to the dense connective tissue, preventing excessive stretching of the scalp. Next is the dense connective tissue, which contains nerves, lymphatics, and blood vessels that provide vascular supply to the scalp. The skin is the outermost thick layer, containing hair follicles and sebaceous glands that produce sebum to protect and hydrate the scalp.

The skin consists of three layers: the epidermis, dermis and hypodermis [18]. The epidermis is the outermost layer, serving as both a physical and immune barrier that protects the body from damage and pathogens [19]. It contains five layers of keratinocytes, held together by desmosomes. The dermis, the middle layer of the skin, is composed of two layers of connective tissue, hair follicles and hair, sweat glands, muscles, neurons and blood vessels [18]. The hypodermis is the deepest layer of the skin, consisting of fat, sensory neurons, blood vessels that supply the skin, and hair follicles.

The skin of the scalp is structurally similar to the skin on the rest of the body. However, it produces more sebrum, has a different hydration balance, and a specific pH range [20].

Ungar et al. (2018) examined scalp thickness in different individuals [21]. Findings showed that the average adult human scalp thickness is 8 mm. However, scalp thickness varies with age. In children under 7 years old, the scalp thickness typically ranges from 3 to 4 mm [22]. In older children, the scalp thickness tends to increase and shows greater variation with age. In comparison, Cochlear's existing scalps have a thickness of 4 mm.

2.3 The anatomy and function of the ear

The ear is the organ responsible for hearing and balance, and is divided into three sections: the external ear, also known as the outer ear, the middle ear, and the inner ear, depicted in Figure 7 [23]. The external ear consists of the pinna (the visible outer part), the external auditory canal (a passage connecting the outer and middle ear), and the tympanic membrane, also called the eardrum, which separates the external ear from the middle ear. The middle ear contains the ossicles which are three tiny bones called the malleus, incus, and stapes. These bones transmit sound to the inner ear. It also includes the eustachian tube, which connects the middle ear to the back of the nose and helps equalize pressure for effective sound transmission. The inner ear features the cochlea, responsible for hearing, as well as the vestibule and semicircular canals, both of which contain receptors that maintain balance.

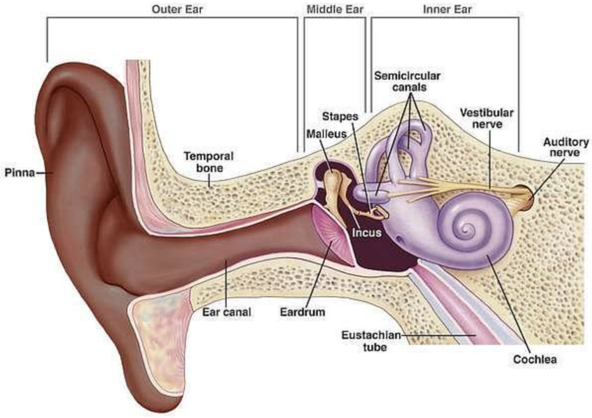

Figure 7: The anatomy of the human ear.
[24]

2.3.1 Air Conduction

Air conduction is the primary way sound is transmitted, where sound waves move through the air and are detected by the ears [23] [25]. As the waves enter the ear canal, they set the eardrum into motion, creating vibrations. These vibrations pass through the tiny bones of the middle ear and move through the fluid in the cochlea located in the inner ear. The vibrations cause the hair cells in the cochlea to move. This movement converts the vibrations into chemical signals to the hearing nerve. The nerve then sends electrical impulses to the brain, enabling us to hear. This process forms the basis for how most audio devices, such as hearing aids, function.

2.3.2 Bone Conduction

Bone conduction is a process in which vibrations travel through the bones of the skull to reach the cochlea and associated sensory structures, allowing sound to be perceived without having to go through the ear canal [26]. Unlike air conduction, where sound waves travel through the air, enter the ear canal, and pass through the eardrum and middle ear ossicles, bone conduction bypasses these pathways and either directly or indirectly stimulate the inner ear's sensory organs solely through bone vibrations.

Because bone conduction bypasses the outer and middle ear, it can be particularly beneficial for individuals with conductive hearing loss, where there is a blockage or malfunction in the ear canal or middle ear[27]. It is also used in single-sided deafness to reroute sound from the non hearing side to the functioning cochlea on the other side of the head.

In general, bones transmit lower frequency sounds better than higher frequencies compared to air conduction [15]. This explains why people perceive their voices as lower and deeper when speaking compared to hearing a recorded version. When speaking, both bone conduction and air conduction contribute to how the voice is heard, whereas a recording relies solely on air conduction. Both bone and air conduction ultimately cause the cochlea's basilar membrane to vibrate, triggering stimulation of the cochlear nerve and enabling sound perception.

2.4 Hearing loss

Hearing loss is a highly common health issue that affects millions of individuals worldwide [27]. It affects people of all ages, from newborns to the elderly, and is particularly common in those over the age of 70. Effectively managing hearing loss involves a comprehensive understanding of its causes. There are multiple types of hearing loss including single sided deafness (SSD), sensorineural, conductive and mixed hearing loss.

2.4.1 Conductive Hearing Loss

Conductive hearing loss occurs when the transmission of sound waves is obstructed and unable to reach the cochlea effectively, meaning that the obstruction is located before the cochlea [27]. This can result from abnormalities in the pinna, external auditory canal, tympanic membrane, or ossicles. Congenital conditions such as aural atresia, caused by improper development of the first and second branchial arches, can lead to incomplete formation of the external ear [28]. More commonly, obstruction in the ear canal due to earwax buildup, foreign objects, or debris can interfere with sound transmission. Perforation of the tympanic membrane, often caused by trauma from cotton swabs, barotrauma from deep diving, or complications from otitis media, can also contribute to conductive hearing loss. In case of conductive hearing loss, the transmission of sound waves needs to bypass the damaged outer or middle ear and directly stimulate the cochlea.

2.4.2 Sensorineural Hearing Loss

Sensorineural hearing loss, in contrast to conductive hearing loss, refers to obstruction at or after the cochlea [27]. This entails that the sound waves can be transmitted all the way to the cochlea before they are obstructed, meaning that the signals do not reach the brain. This type of hearing loss may result from malfunctioning hair cells or an issue with the eighth cranial nerve. Unlike conductive hearing loss, where sounds are simply reduced in volume, sensorineural hearing loss (SNHL) can cause both a decrease in sound intensity and distortion in perception.

2.4.3 Mixed Hearing Loss

Mixed hearing loss refers to the combination of both conductive and sensorineural hearing loss [27] [28]. This means that the transmission of sound waves is obstructed both before reaching the cochlea (in the outer or middle ear) and at or after the cochlea (in the inner ear). As a result, sound waves do not reach the cochlea, and signals fail to be transmitted to the brain.

2.4.4 Single Sided Deafness (SSD)

Single-sided deafness (SSD) is a form of unilateral hearing loss [29]. It is a condition in which a person experiences complete or non-functional hearing loss in one ear while the other ear remains unaffected. SSD can be congenital, meaning that the patient is born with it, but typically develops over time. Although SSD is rarely acquired, its most frequent cause remains unknown. Other potential causes include cholesteatoma, infections, cerebellopontine angle tumors, and, less commonly, head trauma, autoimmune disorders, or Meniere's disease. Unlike other forms of hearing loss that may reduce or distort sound, SSD primarily affects the ability to determine the direction and source of sounds.

2.5 Cadaver head

The feasibility of bone conduction hearing implants can be evaluated using cadaver heads, with implants either inserted into the cranial bone or positioned directly on the scalp [30]. When using cadaver heads for measurements, methods and preparation vary across studies, and it remains unclear how these factors influence the outcome of the study. However, when stimulation is applied directly to the scalp, the outcomes align closely between cadaver heads and living humans.

Håkansson et al. (2008) performed measurements on a female cadaver head [31]. In this study, two BAHA implants were placed in the dense bone of the cadaver. The overlying scalp and subcutaneous tissue above the receiving coil measured approximately 4 mm in thickness. Results revealed that the performance of bone conduction implants in the cadaver head exceeded expectations compared to data on skull simulators and dry skull studies. However, the cadaver head had been embalmed, which may have altered its physical properties relative to living tissue.

While cadaver studies provide valuable insights, they have certain limitations, including tissue degradation and complex preparation, which make them less practical compared to alternative evaluation methods.

2.6 Skull simulator

The skull simulator (as seen in Figure 8), designed by Prof. Bo Håkansson, is a system intended to mimic the properties of the skull as a mass, with the estimated skull weight of 2.5 Kg [32]. Introduced in 1989, it allowed for objective force output measurements. The skull simulator serves as an attachment platform for bone anchored hearing devices. It transforms the force output of these devices into an electrical signal, allowing for precise measurement. This innovation enables users to assess the performance of bone anchored hearing devices and determine whether they are operating correctly. The underlying principle is that the mechanical impedance of the load, in this case the skull simulator, must exceed that of the transducer, and the load's weight should be at least three times greater than the transducer's. When these conditions are met, the system functions as a constant force source, enabling simulation of skull behavior. This innovation was important in advancing percutaneous bone-anchored hearing devices like BAHA.

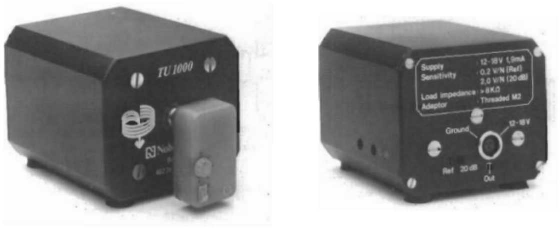

Figure 8: The TU1000 Skull Simulator, developed by Prof. Bo Håkansson in 1989. [32]

However, a study by Woelflin et al. comparing the mechanical point impedance of the simulator to clinical reference values in human subjects revealed discrepancies [33]. Moreover, the development of the skull simulator has not kept pace with advancements in hearing devices, limiting its ability to evaluate newer implantable technologies. This highlights the need for improved models that more accurately replicate real world clinical conditions.

2.7 Head simulator

Henrik Fyrlund at Cochlear's technology development department has led the development of two different types of head simulators, HeadSim1 and HeadSim 3D. They are both designed to closely mimic the mechanical properties of the human head. These head simulators allow for the placement of a bone conduction implant and a layer of artificial scalp, with the processor positioned on top. This setup helps analyze how vibrations are distributed and ensures that the quality and settings of the implants are tested in conditions that closely mimic reality. As seen in Figure 9, there are two versions of HeadSim1, differing in skull materials. However, both versions possess the same properties.

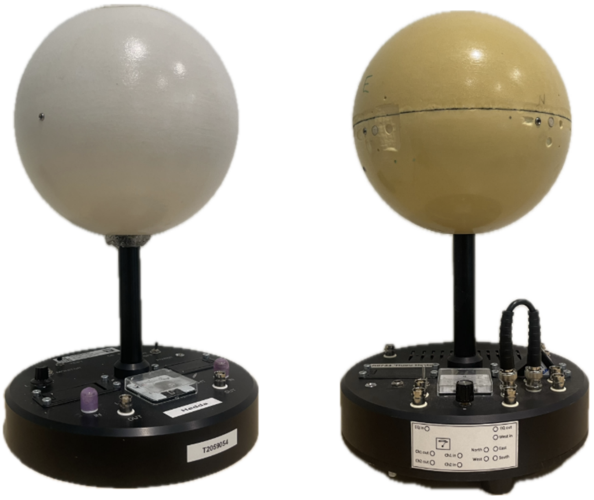

Figure 9: Two versions of Cochlear's Head Simulator, model HeadSim1.

HeadSim 3D (see Figure 10) was developed based on the anatomy of two employees, through MRI imaging. Unlike HeadSim1, which has a single axis accelerometer positioned near the implant, HeadSim 3D has a more realistic, three axis accelerometer placed near the cochlea. HeadSim 3D also incorporates the transfer function from the implant to the cochlea, making it particularly useful for testing different positions or systems. However, HeadSim 3D is still in an experimental development phase while HeadSim1 is established and used for both development and verification purposes today.

Figure 10: Cochlear's Head Simulator, model HeadSim 3D.

The thesis by Kumaar Murali Dharan (2021) explored various materials to find the most accurate representation of the human brain within the simulator [34]. Ballistic gel was identified as the most suitable material and is now used in Cochlear's head simulator. The skull of the head simulator is a 3D printed bone-like material. The next phase focuses on identifying an artificial scalp replica that closely mimics the mechanical impedance, attenuation and acoustic feedback of human scalp. Integrating this artificial scalp to the head simulator will enhance Cochlear's ability to test bone conduction hearing devices with greater accuracy and reliability.

2.8 Artificial Mastoid

An Artificial Mastoid is a device used to simulate the mechanical properties of the human mastoid bone [35]. The Artificial Mastoid Type 4930 from Brüel & Kjær is designed for testing and calibration of bone conduction devices. It consists of an integrated force transducer to measure the performance of the device being calibrated. This Artificial Mastoid complies with the International Electrotechnical Comission standard IEC 60373, as well as the British Standard BS 4009 and the American National Standards ANSI S3.13-1987 and ANSI S3.26-1981. It is widely recognized and used as a standard within the industry.

It consists of an inertial mass that represents the head, mounted on a baseplate [35]. As illustrated in Figure 11, the baseplate is placed on three springs filled with foam, to minimize movement. Attached to the plate is a movable arm that holds the hearing device being tested. This arm presses the device against the artificial mastoid with a force that can be adjusted between 2 and 8 N. There is a built-in scale to ensure the force is applied correctly. Soft rubber bands hold the device in place without adding extra weight during calibration.

Figure 11: The Artificial Mastoid Type 4930 from Brüel & Kjær [35].

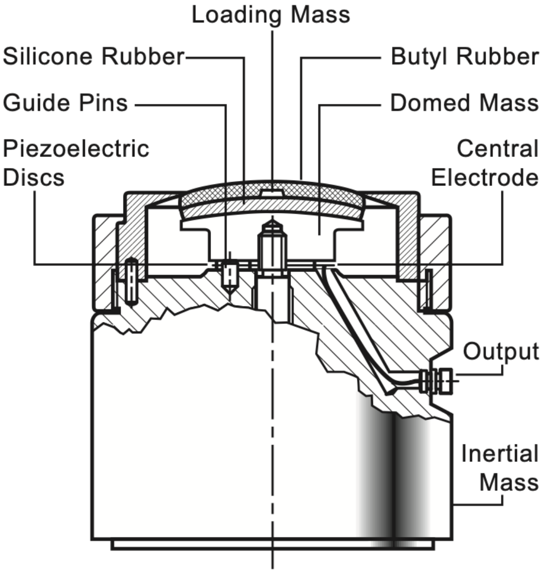

Figure 12: Inside of the Artificial Mastoid Type 4930 from Brüel & Kjær [35].

As seen in Figure 12, a smaller domed mass is positioned above the inertial mass [35]. The two components are tightly connected by a bolt that applies pressure to the piezoelectric discs made of rubber, which make up the force sensor. A small guide pin helps guide the discs into place, and an electrode carries the signal from the discs to an output socket, where it can be measured.

A neoprene rubber pad and a butyl rubber pad, which includes a loading-mass, are placed above the domed mass [35]. This design ensures that the artificial mastoid simulates the impedance of the human scalp overlying the mastoid bone. The calibration data for the Artificial Mastoid from RISE Research Institutes of Sweden can be seen in Figure 13. The plot shows how the artificial mastoid is calibrated in order to mimic the mechanical point impedance of the human mastoid bone. Here it can be seen that the impedance magnitude is frequency dependent.

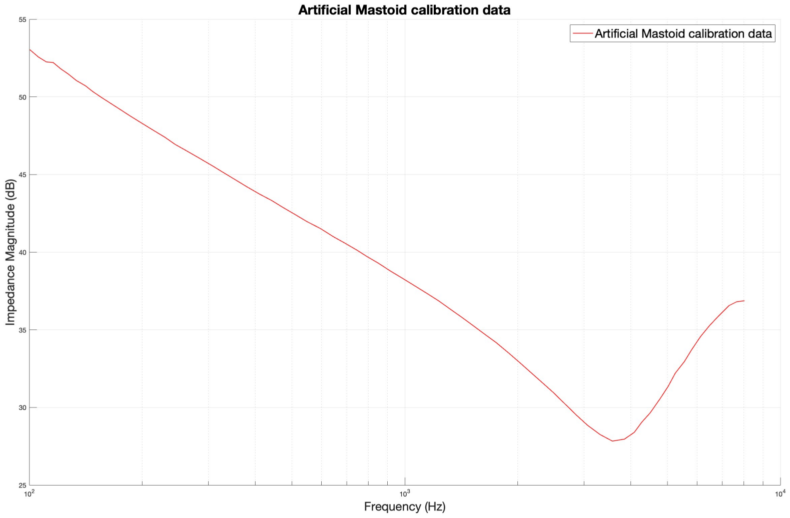

Figure 13: Artificial Mastoid calibration data from RISE Research Institutes of Sweden.

2.9 Attenuation

Attenuation refers to the reduction in the transmission of mechanical vibrations as they propagate through different materials or biological tissues [36]. When vibrations pass through layers of tissue, they are partially absorbed and scattered. The degree of scattering and absorption depends on the properties of each tissue type. In the context of the human scalp, this plays a critical role in how sound and vibrations are transmitted from an external source, such as a bone conduction hearing device, to the inner auditory system. Therefore, to accurately represent human scalp in testing scenarios, its attenuation properties must be closely replicated.

Attenuation can be determined using an Actuator Characterization Tool (ACT) to measure sensitivity, defined as the ratio of the output force to the input voltage (force per volt). A sensitivity baseline can be established using an abutment, serving as a reference surface. Then, the same measurement is conducted on the material being tested. By comparing the sensitivity between the abutment and the material, the attenuation can be determined. Specifically, the attenuation is calculated from the difference between the two signals, where a lower sensitivity in the material indicates greater attenuation. This entails how much vibrational energy is lost due to the material's attenuation properties, and thereby serves as an important metric in evaluating how well a material replicates the attenuation properties of, in this case, a human scalp.

2.10 Mechanical Point Impedance

Mechanical point impedance refers to an object's, in this case the scalp's, resistance to motion when subjected to an external force [37]. When dynamic force $F(j\omega)$ is applied, it results in a specific velocity and can be expressed as:

$$Z(j\omega) = \frac{F(j\omega)}{v(j\omega)} \; [Ns/m] \tag{1}$$

where $\omega = 2\pi f$ represents the excitation angular frequency and $Z(j\omega)$ is a frequency dependent complex quantity with both magnitude and phase components [37]. A higher impedance leads to lower vibration for a given force input. Bone conduction hearing devices generally produce greater output force when applied to high mechanical impedance loads compared to low impedance loads. Therefore, accurately replicating the mechanical impedance at a specific point is crucial when mimicking the mechanical properties of the scalp.

2.11 Acoustic Feedback

Acoustic feedback occurs when a microphone picks up the sound produced by a speaker and feeds it back into the system, creating a continuous loop [38]. The gain of the amplifier determines how much the sound signal is amplified within the system. When the gain is too high, the sound picked up by the microphone is amplified to a level where it re-enters the system, reinforcing the loop and increasing the intensity of the feedback. This cycle causes the sound to grow louder and more intense until the loop is broken. Feedback is commonly recognized as a sharp, high-pitched screeching noise that can become loud and unpleasant. In the case of some bone anchored hearing implants, acoustic feedback occurs due to the interaction between the transducer and the microphone in the external sound processor. This creates a feedback loop from the output to the input of the sound processor, resulting in a ringing noise in the hearing implant. To replicate human scalp, the acoustic feedback when using artificial scalp should align with that of real scalp based on clinical patient data.

2.12 Reference Data Used for Comparison

The following scientific studies provide clinically relevant data used as references in this thesis. Their findings serves as a clinical reference data for evaluating the performance of potential scalp materials.

Cuda et al. 2021 "Postoperative Benefit of Bone Anchored Hearing Systems: Behavioral Performance and Self-Reported Outcomes"

In 2021, Domenico Cuda, Alessandra Murri, Paolo Mochi and Anna Mainardi conducted a study to evaluate the effectiveness of the Ponto Bone Anchored Hearing System (BAHS) [39]. The study focused on both behavioral responses (ability to detect tones) and self-reported outcomes (reflecting user satisfaction). The study compared unaided and aided performance, as well as evaluated differences between using the sound processor with a Softband versus an abutment.

The study involved fourteen adult BAHS users (3 males and 11 females) [39]. Among them, two participants had unilateral conductive or mixed hearing loss, while twelve had bilateral conductive or mixed hearing loss.

Sound-field thresholds were measured under unaided and aided conditions using both Softband and abutment [39]. Warble tones were presented through a loudspeaker positioned one meter from the participant. The average bone conduction hearing thresholds from the study are shown in Figure 14. To determine scalp attenuation, the threshold values obtained with the abutment can be subtracted from those obtained with the Softband for each frequency. These values can serve as clinical reference data when comparing the attenuation of different scalp materials, as the Softband and snap connection used in this study are similar to those used in this thesis.

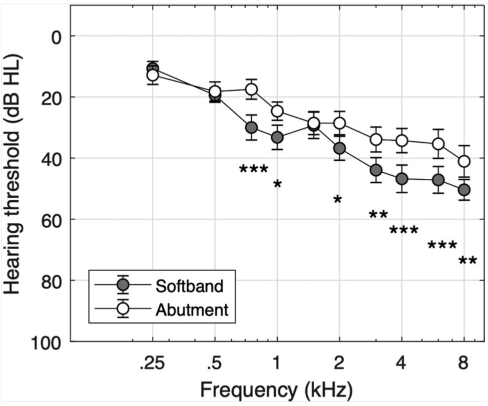

Figure 14: Mean bone conduction hearing thresholds for 14 patients using Softband and abutment [39]. The standard error of the mean is shown as error bars. Statistically significant differences between the Softband and abutment are marked as follows: * p<0.05; ** p<0.01; *** p<0.001.

Verstraeten et al. 2009 “Comparison of the audiologic results obtained with the bone-anchored hearing aid attached to the headband, the testband, and to the “snap” abutment”

In 2009, Nadia Verstraeten, Andrzej Zarowski, Thomas Somers, Daphna Riff and Erwin Offeciers conducted a study to evaluate the differences in hearing performance between preoperative and postoperative use of BAHA system [40]. Specifically, the study compared hearing results when the BAHA was attached to a headband or testband before surgery to the outcomes after it was attached to an implanted abutment. One secondary objective was to compare performance of the headband and testband. Finally, the aim of the study was to determine how much sound is dampened by the skin when using the testband.

The study involved ten adult BAHA patients (6 males and 4 females) [40]. Their audiometric free-field thresholds (hearing thresholds) and speech audiometry scores (ability to hear and understand speech) were tested under three conditions: with the BAHA attached to the implanted abutment, on a headband and on a testband. The attenuation of the skin, calculated by subtracting the abutment value from the testband value for each frequency, is shown in Figure 15.

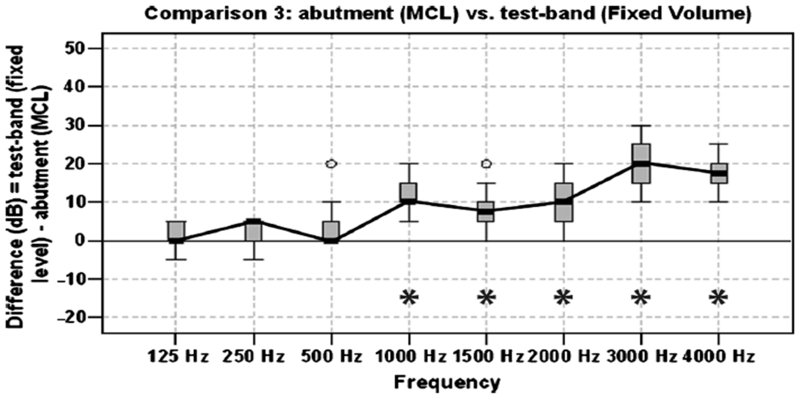

Figure 15: Difference between abutment and testband measurements for 10 patients. The plot is taken from Verstraeten et al. [40].

Håkansson et al. 1986 ’The mechanical point impedance of the human head, with and without skin penetration’

In 1986, Dr. Bo Håkansson, Peder Carlsson and Anders Tjellström conducted a study, aiming to investigate the mechanical point impedance of the mastoid portion of the human head, both with and without skin penetration [41]. In the study, the mechanical point impedance was measured on seven patients, 5 females and 2 males (ages 16-73 years). All measurements were performed using a Brüel & Kjær 8001 impedance head, which is the same as the one available at Cochlear. Thus, the data seen in Figure 16 is relevant as clinical reference data when comparing the mechanical point impedance of potential scalp materials.

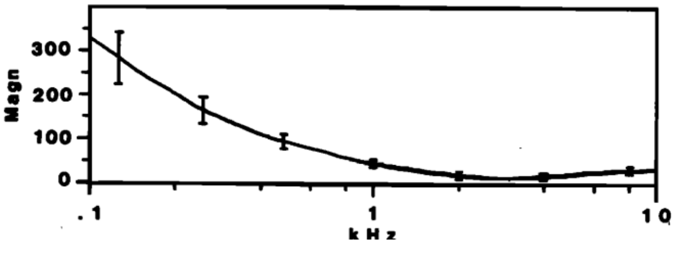

Figure 16: The average magnitude response of the skin impedance without penetration, based on seven patients. The plot is taken from Håkansson et al. 1986 [41].

Nie et al. 2022 'Measurement and modeling of the mechanical impedance of human mastoid and condyle'

In 2022, Dr. Yafei Nie and eight co-authors conducted a study aimed at characterizing the mechanical point impedance of the human mastoid and condyle regions [37]. The primary objective was to investigate how individual factors, specifically age, gender, and body mass index (BMI), influence mechanical point impedance. An additional aim was to explore whether differences in mechanical point impedance affect the output performance in bone conduction hearing devices. The study included 50 males and 50 females (ages 22-67 years) with various BMI scores. The mechanical point impedance was measured on all participants on top of the skin overlying the mastoid bone, and the results can be seen in figure 17.

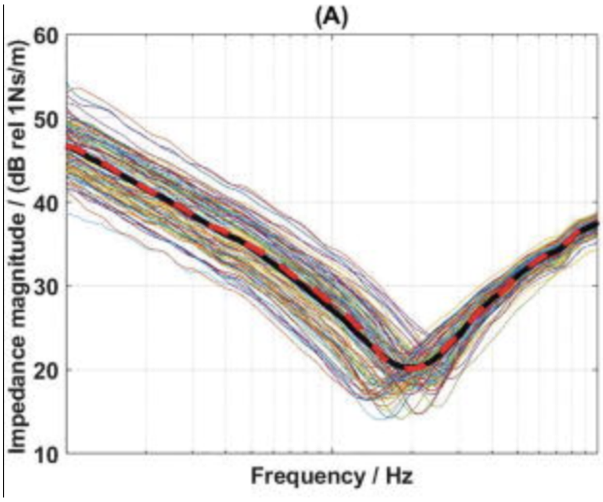

Figure 17: The magnitude response in dB of the skin impedance, based on 100 patients. The plot is taken from Nie et al. 2022 [37].

Emmanuel Mylanus et al. 2020 'Multicenter Clinical Investigation of a New Active Osseointegrated Steady-State Implant System'

In 2020, Dr. Emmanuel Mylanus and six co-authors conducted the first clinical investigation that demonstrated the clinical performance, safety, and benefit of the new active osseointegrated steady-state implant system (OSI) [42]. The investigation included 51 subjects, 37 with mixed hearing loss and 14 with conductive hearing loss, and all subjects had the implant surgically placed. As part of the study, acoustic feedback measurements were taken from all subjects and the data can be seen in Figure 18.

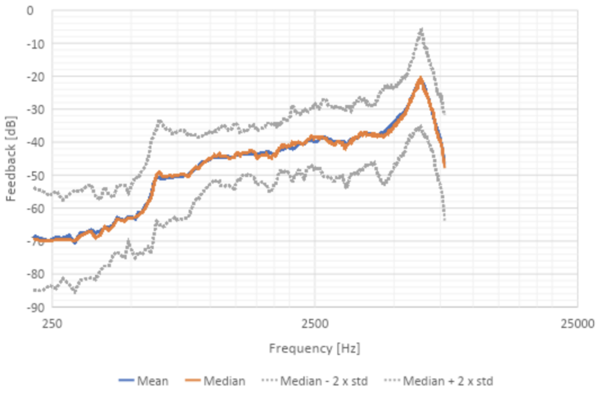

Figure 18: The mean and median from acoustic feedback measurements taken on 51 subjects. The plot is taken from Mylanus et al. [42].

3 Method

The methodology of this thesis involves an iterative process including research, measurements, visualization, analysis, and modifications. Mechanical point impedance and attenuation measurements are performed on all available materials in order to distinguish the materials that most accurately replicate the mechanical properties of the human scalp. Only the most promising materials, those that demonstrate close similarity in impedance and attenuation, are selected for further evaluation through acoustic feedback measurements.

All measurements are conducted using a round head simulator called HeadSim1. Designed to closely mimic the mechanical properties of the human skull and brain, this simulator serves as a reliable foundation for testing scalp replicas. For both mechanical point impedance and attenuation measurements, the scalp material is secured using a headband with a snap connection, called a Softband. To maintain consistency, the Softband is applied with a contact force of 2 N every time (unless anything else is stated), representing the average force typically used by patients [41]. A dynamometer is used to verify the contact force before each measurement. MATLAB is utilized for all visualization and analysis throughout the thesis work, further described in 3.6.

3.1 Materials and Fabrication

Cochlear's existing artificial scalps have been ordered from a local special effects artist, Makeup Effects Lars Carlsson AB, who created all of the existing scalps from various materials and compositions. In this thesis, additional scalps were crafted both in-house using available silicones and ordered from the same special effects artist.

3.1.1 Cochlear's existing scalps

Ecoflex is a brand of soft, flexible silicone rubbers [43]. These types of silicone rubbers are robust to tearing and can withstand pressure and careless usage. Ecoflex carries a line of different hardness levels, ranging from Ecoflex 0010 (softest) to Ecoflex 0050 (hardest). These materials have variable applications, most commonly used for creating fake skin for special effects in films and prosthetic appliances, due to their skin-safe properties. They can be colored as desired, for example to resemble human skin. As seen in Figure 19, Cochlear has three variations of Ecoflex scalps from previous orders, made from Ecoflex 0010, Ecoflex 0020 and Ecoflex 0030. Each scalp is a 4 mm thick square of size 13x13 cm.

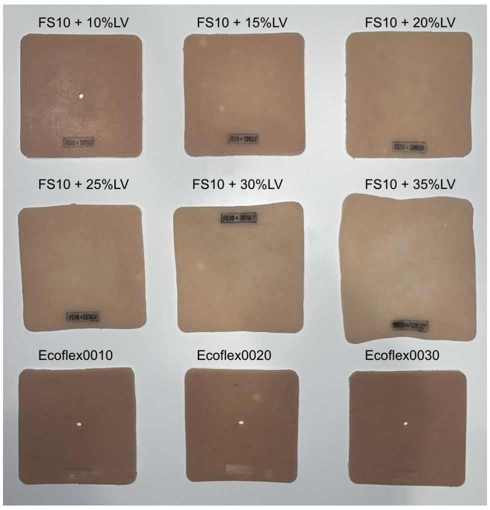

Figure 19: Cochlear's existing artificial scalps.

Platsil FS-10 is a fast setting two component silicone rubber, mixed in a liquid 1:1 ratio before curing [44]. It can be thickened using PlatThix Liquid Thickener or softened using LV softener. The rubber itself is sturdy and can withstand high pressure and tearing, however, the softener may leak, causing deformation. Platsil FS-10 is most commonly used for industrial purposes, but has in this case been used to create some of Cochlear's artificial scalps, using different percentages of softener, ranging from 0% softener to 35% softener, with a 5% increase between each scalp. Each scalp originally had a thickness of 4 mm and was square shaped, measuring to 13x13 cm. However, since the softener reduces durability, all of the scalps containing softener have shifted in both thickness and size over time.

3.1.2 Crafted silicone scalps

The crafted scalps were created in-house using silicones available at Cochlear. Two different compositions were created: one with 5% SYLGARD 184 (a harder silicone) and 95% SYLGARD 527 (a softer silicone) for a softer scalp, and one with 10% SYLGARD 184 and 90% SYLGARD 527 for a slightly firmer scalp. Two samples of each composition were made, with thickness of 3 mm and 4 mm (see Figure 20).

SYLGARD 527 is a soft silicone, created by mixing equal parts of SYLGARD 527 Silicone Dielectric Gel Part A and Part B. SYLGARD 184 is a harder silicone, created by mixing 10 parts SYLGARD 184 Silicone Elastomer Base with 1 part SYLGARD 184 Silicone Elastomer Curing Agent.

To prepare the soft silicone mixture, 50 grams of SYLGARD 527 Part A was mixed with 50 grams of Part B to achieve a 1:1 ratio. For the harder silicone mixture, 50 grams of SYLGARD 184 Base was mixed with 5 grams of Curing Agent to achieve a 10:1 ratio. Both mixtures were stirred slowly and continuously for 8 minutes to prevent air bubbles.

To create the softer silicone mixture, 47.5 grams of SYLGARD 527 was combined with 2,5 grams of SYLGARD 184. For the harder silicone mixture, 45 grams of SYLGARD 527 was mixed with 5 grams of SYLGARD 184. Both mixtures were stirred for 8 minutes and then poured into round petri dishes with a diameter of 9 cm. The final samples have thicknesses of 3 mm and 4 mm.

The four petri dishes were placed in an oven at 60°C for 11 hours, followed by 12 hours of curing at room temperature. Once cured, all silicone scalps were removed from the petri dishes. However, the softest 3 mm thick sample was too fragile and fell apart upon removal due to its thinness and material composition.

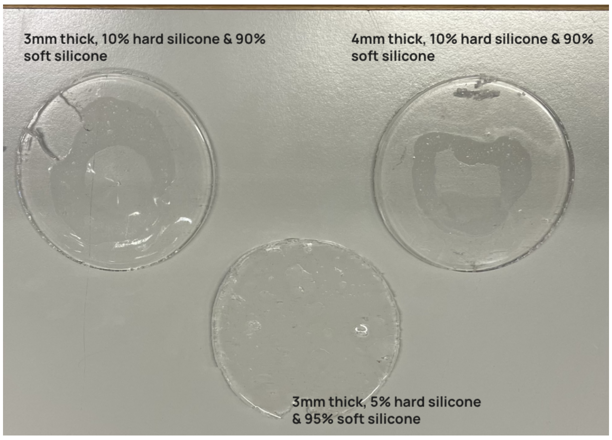

Figure 20: Crafted silicone scalps with different thickness.

3.1.3 Adapted made-to-order scalps

Ecoflex0010, the material identified as most accurately replicating the mechanical properties of human scalp based on attenuation and impedance measurements, was further modified to achieve a better fit with HeadSim1. A better fit is desired for enhanced usability and reduction of air gaps between the skull and the scalp. To accomplish this, a custom mold was designed and 3D-printed to match the specific dimensions and spherical shape of HeadSim1. Due to constrains of the available 3D printer, the diameter of each scalp is limited to 15 cm. The new molded Ecoflex0010 scalps, that can be seen in Figure 21, were also ordered from Makeup Effects Lars Carlsson AB. Details about the material can be found in 3.1.1.

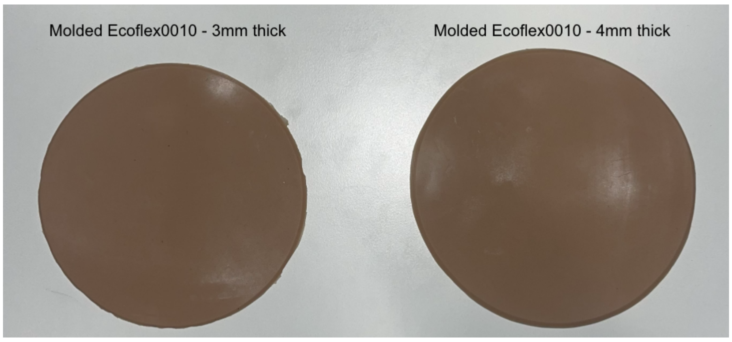

Figure 21: Molded Ecoflex0010 scalps with different thickness.

3.2 Data collection

When comparing the mechanical point impedance measurements obtained from the artificial scalps to available clinical reference data, a significant difference in characteristics was observed at higher frequencies. Thus, additional measurements were performed on ourselves in order to investigate whether the differences were related to the materials or the measurement setup and equipment. The different characteristics remained, which suggested that the measurement setup or equipment might be contributing to the inconsistencies compared to clinical reference data. The most significant difference between our setup and that used in the clinical reference data was the use of a newer version of the Softband, specifically the snap connection component. This raised the hypothesis that the snap connection could be influencing the measurement results. Thus, it was decided to collect new reference data under identical conditions to those used for testing the artificial scalps. This approach ensures direct comparability by eliminating variability introduced by different measurement setups and equipment.

To proceed, a market investigation at the company was conducted. A market investigation plan including a risk assessment was developed and can be seen in Appendix A. The plan and risk assessment was reviewed and modified according to feedback from the Clinical Affairs department, who then approved it. Following approval, an open invitation was sent out to all employees at Cochlear's Gothenburg site, offering the opportunity to voluntarily sign up for a time slot to participate in letting us collect mechanical point impedance data from the scalp overlying the mastoid bone. The invitation provided a clear explanation of the procedure and can be seen in Appendix B.

Two days were scheduled for data collection, with different time slots for each participant. Prior to each measurement, each participant received clear verbal instructions and necessary information, and were then asked to sign a Case Report Form (CRF), confirming that they understood the procedure and were aware of their right to withdraw at any time (see Appendix C). For each participant, two measurements were performed on the scalp overlying the mastoid bone (behind the ear) using the exact same equipment and measurement setup as the artificial material measurements. The setup and measurement position are seen in Figure 22, following the exact same procedure as other mechanical point impedance measurements described in Section 3.4. Data was successfully collected from a total of 19 volunteers, including the two of us. Two measurements were performed on each subject. The resulting dataset was averaged to create a new reference curve, which serves as a directly comparable mechanical point impedance reference for all artificial materials.

Figure 22: Mechanical point impedance measurement setup for data collection on test persons.

3.3 Attenuation Measurements

Attenuation is measured using the Actuator Characterization Tool (ACT), which determines sensitivity via the built in accelerometer in the head simulator. Measurements were conducted by attaching a vibrator to the HeadSim, through a snap connection to the Softband (see Figure 23).

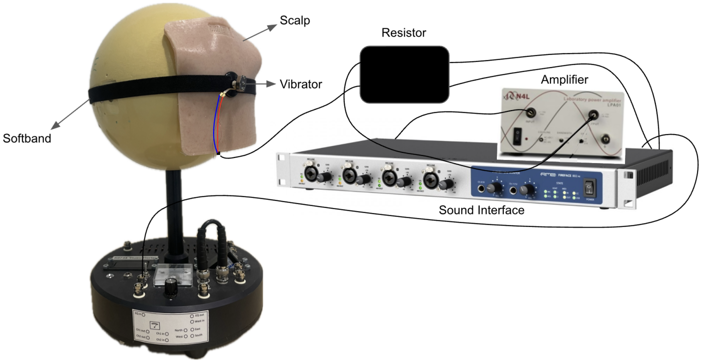

Figure 23: Attenuation measurement setup with an Ecoflex0010 scalp.

During each attenuation measurement, a signal is generated by the ACT and sent to the vibrator. The vibrator then delivers mechanical vibrations to the HeadSim (via either the abutment or the Softband). The built-in accelerometer in the HeadSim detects the resulting vibrations, which are transmitted through a resistor placed between the vibrator and the computer. The resistor enables current measurement during testing. The vibration signals are then sent to an RME Fireface 802 sound interface, amplified using the Newtons4th Ltd LPA 01 Laboratory Power Amplifier and finally analyzed by the ACT.

To obtain a reference measurement without the scalp, an abutment was attached to the HeadSim, with the vibrator placed directly on top to transmit and receive signals from the accelerometer. For scalp measurements, the scalps were placed directly on the HeadSim without any abutment and secured using a Softband, to which the vibrator was attached using a snap connection.

The attenuation was calculated for each scalp by subtracting the scalp measurement data from the abutment data. This subtraction normalized the influence of the HeadSim, ensuring that only the attenuation caused by the scalps is represented in the final results.

Attenuation measurements were performed on existing scalps, in-house crafted silicone scalps, and the newly developed molded scalps. Each scalp was measured five times on different occasions in order to produce an average attenuation curve for each scalp. Additionally, measurements with the use of different contact forces and voltages were also conducted for comparison.

3.4 Mechanical Point Impedance Measurements

The mechanical point impedance of the different materials is measured using a Dynamic Signal Analyzer (DT9837) serving as the signal source, transmitting force and acceleration to an impedance head equipped with a built-in accelerometer. The signal is amplified using an LPA01 Laboratory Power Amplifier, which is a wide bandwidth DC amplifier. The Brüel & Kjær impedance head, model 8001, has two piezoelectric crystals whereas one is sensitive to force and the other to acceleration at the point of attachment. The corresponding voltage signals $Vforce$ & $Vacceleration$ are accessible through connector ports on the sides of the head, as seen in 24. The mechanical point impedance can then be calculated from $\frac{Vforce}{Vacceleration}$. An A1 vibrator, commonly used in bone conduction hearing device testing, is attached to one side of the impedance head. The other side of the impedance head is secured to a Softband positioned around the head simulator, with the scalp material placed between the Softband and the head simulator. In case of data collection, the Softband is placed around a human head. The impedance head needs to be placed in an upright position, allowing for equal force distribution at the measurement point. Therefore, the position of the measurement object (either a head simulator or a human head) shall allow this positioning of the impedance head. This setup enables impedance measurements across a range of frequencies. Each measurement is directly depicted in graphs using MATLAB.

Before conducting any measurements, the impedance head and adapter were calibrated in combination with the Softband. This calibration was performed to compensate for the mass of these components. The calibration setup followed the same configuration as the main experiment, except the impedance head, adapters, and Softband were suspended from a circular foam, as shown in Figure 24. The measured mass was then accounted for in the MATLAB code.

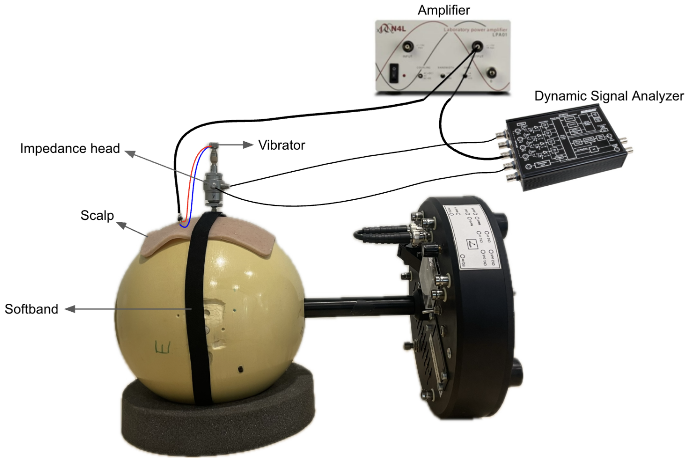

Figure 24: Mechanical point impedance measurement setup with an Ecoflex0010 scalp.

Mechanical point impedance measurements were conducted on volunteers, individual existing scalps, in-house crafted silicone scalps, and ultimately on the newly developed modified scalps to evaluate their mechanical properties compared to the human scalp. All measurements on the artificial materials were conducted across five separate sessions on different days, with the entire setup being disassembled and reassembled between each session. Measurements with the use of different contact forces were also conducted for comparison.

3.4.1 Artificial Mastoid Measurements

Mechanical point impedance measurements were also conducted on a Brüel & Kjær Artificial Mastoid, model 4930, following the exact procedure described previously in 3.4. The same measurement setup and equipment were used (the setup can be seen in Figure 25), with the only difference being that the impedance head was placed directly on the artificial mastoid rather than on an artificial scalp secured with a Softband on a head simulator. The measurements on the artificial mastoid were conducted to serve as a reference, as it is designed to replicate the properties of the human scalp overlying the mastoid bone.

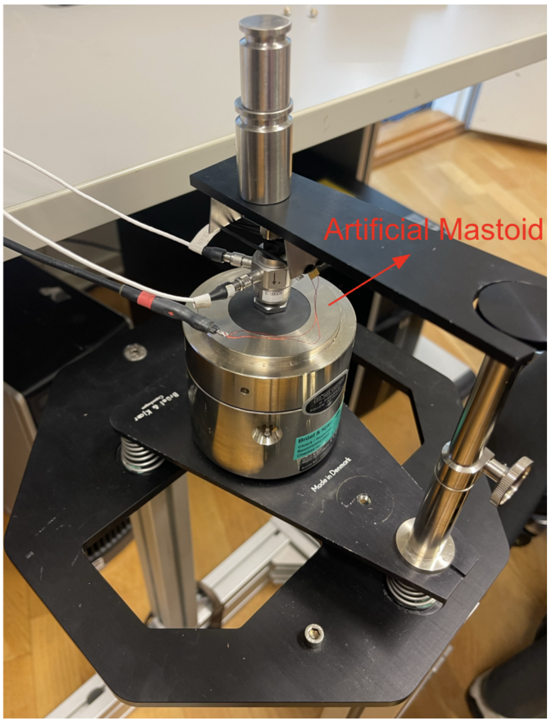

Figure 25: Mechanical point impedance measurement setup for the Artificial Mastoid, including weights corresponding to 2 N of applied force.

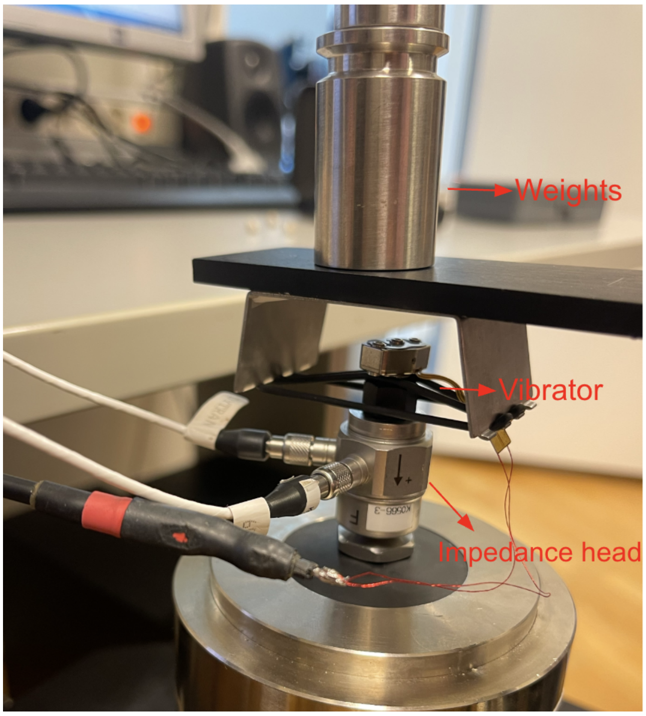

Figure 26: A close-up of the measurement setup.

To achieve a contact force of 2 N, comparable to that used in previous measurements, the weight from the arm of the stand had to be accounted for. Using a dynamometer, the force applied by the arm was measured to be 0.5 N. To reach the desired contact force of 2 N, an additional 150 g of weights were added on top of the arm. In order to ensure proper alignment and even weight distribution, small rubber bands were used to secure the impedance head to the arm as seen in Figure 26. The impedance head was placed directly onto the artificial mastoid surface, without the use of adapters or the Softband's snap connection. Therefore, additional measurements on ourselves were performed under the same conditions to isolate the effect of the snap connection. For these measurements, the impedance head was attached to the Softband using wires, allowing direct contact with the scalp overlying the mastoid bone without using the snap connection (see Figure 28). This setup enabled measurements on the human scalp with direct contact to the impedance head, thereby eliminating potential deviations caused by the snap connection interface.

Figure 27: The Softband setup used in all measurements, using the snap of the Softband as an interface between the impedance head and scalp.

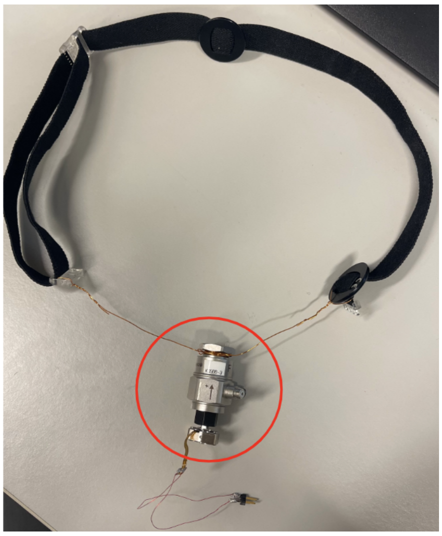

Figure 28: The Softband setup used for one comparative measurement, allowing direct contact between the impedance head and scalp.

The data obtained from these additional tests were used to create an error compensation curve. As previously mentioned in 3.2, a difference in characteristics was observed at higher frequencies when comparing our measurements to clinical reference data. In order to test the hypothesis that the snap connection might influence the measurement results, two comparisons were made:

1. The difference between measurements on ourselves with the Softband and snap connection (see Figure 27) versus those with direct contact with the impedance head (see Figure 28) was calculated to isolate the effect of the snap connection.

2. Seperately, the difference between our mechanical point impedance measurements on the artificial mastoid and the provided calibration data was determined, accounting for any error associated with the mechanical point impedance setup itself.

These two difference curves were then combined to produce a final error compensation curve. This compensation quantifies the total measurement error introduced by both the snap connection and the mechanical point impedance setup. Finally, applying this compensation curve to the averaged collected measurement data from the market investigation, enabled direct comparison to existing clinical reference data.

3.5 Acoustic Feedback Measurements

Acoustic feedback is measured using the Cochlear Osia Fitting Software version 2. During testing, an Osia implant (OSI200) is mounted onto the HeadSim, with a scalp positioned on top (see Figure 29). The scalp is secured firmly in place using tightly strapped pantyhose, fastened at the back with a bag clip. Externally, an Osia 2 sound processor is attached to the Osia implant with a magnetic connection, as shown in Figure 29. The sound processor is connected via a cable to the Hi-Pro 2, a hardware interface that enables communication between the fitting software and the hearing device. In this setup, it allows the Cochlear Osia Fitting Software to interface directly with the Osia 2 sound processor.

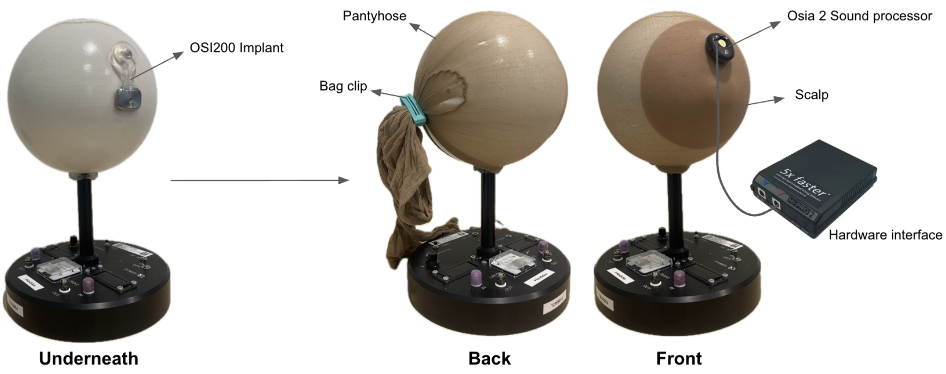

Figure 29: Acoustic feedback measurement setup with an Ecoflex0010 scalp.

To ensure accurate measurements, it is essential to reduce any air gaps between the scalp and the HeadSim1 and to maintain a silent testing environment, as noise has a significant effect on the results.

Once all components are properly connected and air gaps are minimized, a Digital Link Calibration (DLC) is performed. This process measures the distance between the implant and the external sound processor in the setup and determines the appropriate level of signal amplification required for the specific sound processor and implant combination. If DLC is not performed, the software will apply a default calibration value. The software is then switched to research mode. During the feedback analysis, the Osia sound processor generates white noise while continuously monitoring its output and internal microphones to detect feedback. The software algorithms then identify the specific frequencies at which the system is most susceptible to acoustic feedback.

Acoustic feedback measurements were conducted on the three best performing scalps, selected based on their performance in attenuation and mechanical point impedance measurements. Each acoustic feedback measurement was repeated thirty times on separate occasions, with the entire setup disassembled between the sessions. This ensured the calculation of an average acoustic feedback curve for each scalp.

3.6 Analysis & Evaluation

MATLAB was used for the visualization and comparative analysis of all measurement data. This enabled the generation of detailed plots, enabling clear and effective comparisons with existing clinical reference data. The trends observed in these plots were important in identifying necessary adjustments to material selection and design modifications. In addition to visualization, appropriate statistical methods, based on the specific type of measurement, were applied to further evaluate the data and validate the reliability of the results.

3.7 Attenuation & Mechanical Point Impedance Evaluation

All attenuation & mechanical point impedance measurements on the artificial materials were conducted across five separate sessions on different days, with the entire setup being disassembled and reassembled between each session. This approach was implemented to verify the consistency of the results and to evaluate the robustness and repeatability of the measurement setup and equipment. Thus, each material was evaluated based on the average of its five measurements.

To achieve this evaluation, the Mean Absolute Error (MAE) was calculated for each material. MAE provides a measure of the average deviation between two data sets by computing the absolute differences at each corresponding frequency point and then averaging those values. By using MAE, it was possible to rank the tested materials based on how closely their attenuation and mechanical point impedance results matched their respective reference data, providing a robust and noise tolerant method for material evaluation and selection.

3.8 Acoustic Feedback Evaluation

As mentioned previously, acoustic feedback measurements were performed on the three best performing artificial materials. These measurements are highly sensitive to external disturbances, such as background noise, which causes large and frequent oscillations in the data. To address this, the measurements were repeated 30 times for each material, with the entire setup being disassembled and reassembled between each session to simulate realistic variability. Averaging these 30 measurements produced smoother, more interpretable curves and enabled more reliable comparisons to the clinical reference data, which consists of 51 individual measurements. However, due to time constraints, it was not possible to match 51 sessions.

To assess how closely the artificial material's performance matched the clinical reference, the evaluation focuses on whether their results fall within two standard deviations of the reference data, a common method used at Cochlear. Staying in the two standard deviation interval means that the artificial material's performance is considered acceptable if it stays within the range that includes approximately 95% of the clinical reference values, assuming a normal distribution. Staying within this range suggests that the artificial materials behave similarly to the clinical standard in most typical conditions. Therefore, the results were plotted against the clinical data and its two standard deviation interval, and calculations were performed to determine the percentage of the averaged material curves that fell within this range.

4 Results

All results are presented using plots, and in some cases, rankings based on either Mean Absolute Error (MAE) or standard deviation. A result is considered acceptable if the MAE is less than 5, and if more than 95% of the acoustic feedback data falls within a two standard deviation range of the reference data. These thresholds were selected based on the observed variability in individual clinical reference measurements.

4.1 Data Collection

The market investigation at Cochlear resulted in mechanical point impedance data collected from a total of 19 volunteer subjects (ages 23-60 years), including 11 males and 8 females. Two measurements were collected from each subject, resulting in a dataset with 38 measurements in total. The data collection process proceeded without any errors or unusable results.

The average of all collected measurements is presented in Figure 30. As illustrated in the plot, the collected data deviates from both clinical reference data curves, particularly in the higher frequency range ($10^3 - 10^4 Hz$). This supports the hypothesis that the used measurement setup and equipment affects the results. The new collected data serves as a valuable comparison for other mechanical point impedance measurements on artificial materials, as it is obtained using the same measurement setup and equipment.

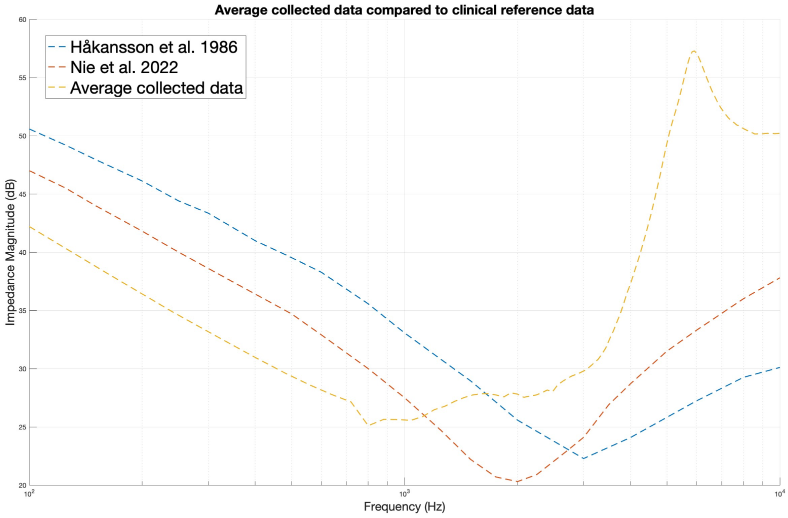

Figure 30: The average of the collected data from all test subjects compared to clinical reference data from Håkansson et al. [41] and Nie et al. [37].

4.2 Cochlear's Existing Scalps

Cochlear's Gothenburg site has access to nine different artificial scalp materials from previous orders. Among them, FS10 silicones with varying softener percentages tend to leak softener over time, leading to changes in thickness and shape. In contrast, Ecoflex silicones maintain their physical properties over time, making them a more durable and reliable choice for long term use.

4.2.1 Attenuation Measurements

Attenuation measurements were conducted on each of the nine existing materials and compared to clinical reference data, as shown in Figure 31. The reference data collected by Cuda et al. is selected for primary comparison due to its use of a similar headband and snap connection to the one employed in this thesis, making it a more appropriate comparison [39].

Performance is evaluated by calculating the Mean Absolute Error (MAE) between the attenuation curves of the artificial scalp materials and the primary clinical reference data. Based on this, the four materials that most closely replicate the attenuation characteristics of the human scalp are:

1. Ecoflex0010, with MAE = 5.4459.
2. FS10 - 35% softener, with MAE = 5.5372
3. Ecoflex0020, with MAE = 6.0135
4. FS10 - 30% softener, with MAE = 6.0239

These results are presented in Figure 32, where the attenuation curves are compared to the clinical reference. While the artificial materials generally exhibit slightly higher attenuation levels, the overall shape and characteristics of the curves are similar.

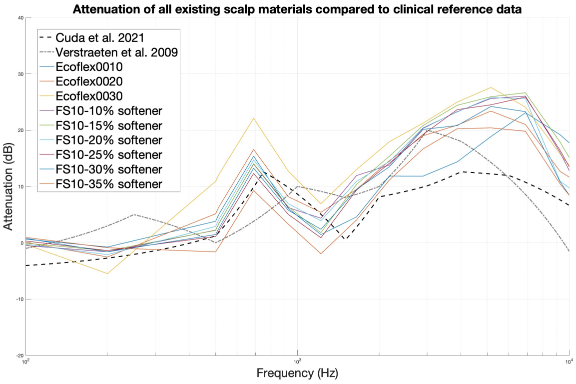

Figure 31: Average of five attenuation measurements for each existing scalp material compared to clinical data from Cuda et al. [39] and Verstraeten et al. [40].

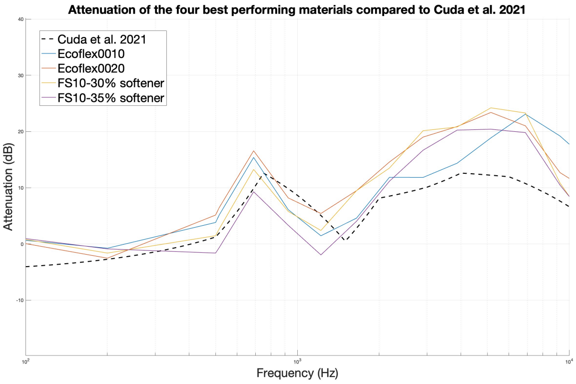

Figure 32: Average of five attenuation measurements for the four best-performing scalp materials compared to clinical data from Cuda et al. [39].

4.2.2 Mechanical Point Impedance measurements

Mechanical point impedance measurements were conducted on each of the nine existing materials and compared to both the collected data and clinical reference data, as shown in Figure 33. The collected data from the market investigation is selected for primary comparison due to its use of the exact same measurement setup and equipment, making it the most appropriate comparison. The four materials that most closely replicate the mechanical point impedance characteristics of the human scalp based on MAE are:

1. Ecoflex0010, with MAE = 1.3362
2. FS10 - 30% softener, with MAE = 1.6771
3. FS10 - 15% softener, with MAE = 1.8963
4. Ecoflex0020, with MAE = 2.0325

These results are presented in Figure 34, where the mechanical point impedance curves are compared to the data collected from the market investigation. While the artificial materials generally exhibit slightly different behavior, the overall shape, levels and characteristics of the curves are very similar.

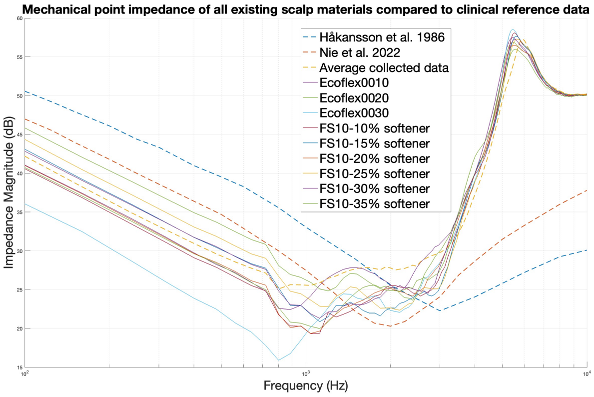

Figure 33: The average of five mechanical point impedance measurements for each existing scalp material compared to clinical data from Håkansson et al. [41], Nie et al. [37] and an average of the collected data.

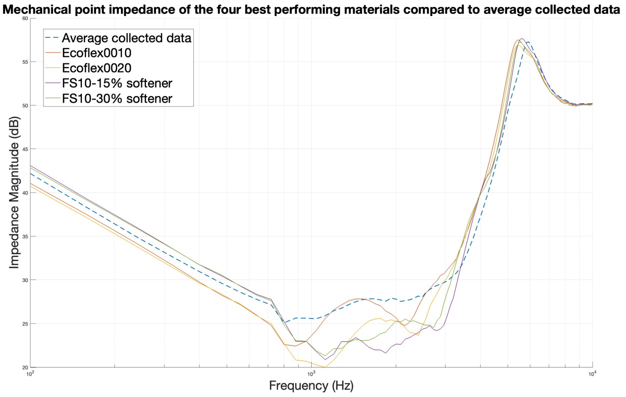

Figure 34: The average of five mechanical point impedance measurements for the four best performing scalp materials compared to an average of the collected data.

4.3 Crafted Silicone Scalps

Four versions of the crafted silicone scalps were made in-house. Two of them are composed of 90% soft silicone mixture and 10% hard silicone mixture, with thicknesses of 3 mm and 4 mm, respectively. The other two are made from a 95% soft silicone and 5% hard silicone mixture, also in 3 mm and 4 mm thicknesses. However, the 4 mm version of the latter was damaged when taken out of the mold and thereby immediately excluded from testing, as durability during handling is a crucial requirement. The remaining 3 mm soft scalp also deteriorated quite quickly due to tension from the Softband. In fact, all versions of the crafted silicone scalps experienced deformation and tearing over time due to the fragility of the material mixtures. As a result, none of these versions are considered feasible solutions.

Figure 35: The crafted silicone scalp with 10% hard silicone & 90% soft silicone, 4 mm thick, on a HeadSim1.

4.3.1 Attenuation Measurements

Attenuation measurements were conducted on each of the three crafted silicone scalps and compared to clinical reference data, as shown in Figure 36. The reference data collected by Cuda et al. is once again selected for primary comparison [39]. The order in which the crafted silicone scalps replicate the attenuation characteristics of the human scalp based on MAE are:

1. Silicone 3 mm - 5% hard silicone, with MAE = 4.3987
2. Silicone 4 mm - 10% hard silicone, with MAE = 6.0127
3. Silicone 3 mm - 10% hard silicone, with MAE = 6.3357

Once again, the artificial materials generally exhibit slightly higher attenuation levels than the clinical reference, but the overall shape and characteristics of the curves are similar, particularly for the softer silicone scalp with only 5% hard silicone.

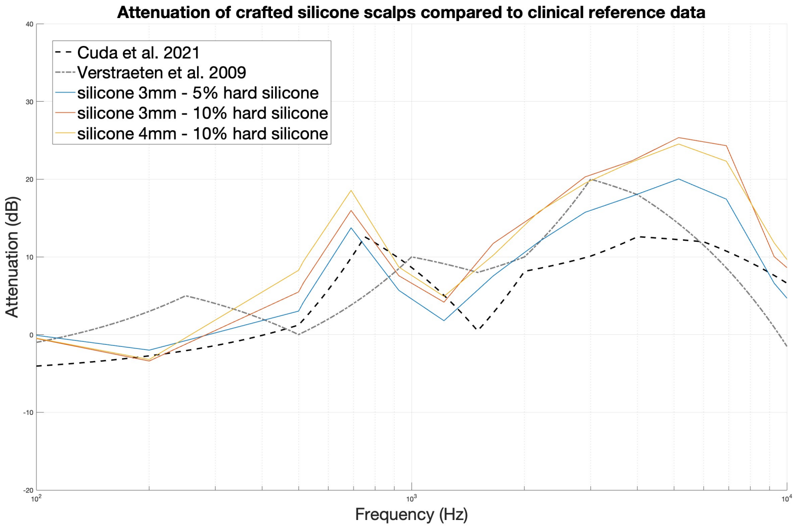

Figure 36: The average of five attenuation measurements for each crafted silicone scalp compared to clinical data from Cuda et al. [39] and Verstraeten et al. [40].

4.3.2 Mechanical Point Impedance measurements

Mechanical point impedance measurements were conducted on each of the crafted silicone compositions and compared to both the collected data and clinical reference data, as shown in Figure 37. The collected data from the market investigation is once again used for primary comparison due to its use of the exact same measurement setup and equipment, making it the most appropriate comparison. The order in which the materials most closely replicate the mechanical point impedance characteristics of the human scalp based on MAE are:

1. Silicone 3 mm - 5% hard silicone, with MAE = 1.5422
2. Silicone 3 mm - 10% hard silicone, with MAE = 3.3229
3. Silicone 4 mm - 10% hard silicone, with MAE = 3.7699

While the artificial materials generally exhibit slightly different behavior, the overall shape and characteristics of the curves are very similar. The softest silicone, with only 5% hard silicone, almost perfectly matches the collected reference data. However, as previously noted, despite the promising results, all scalps in this category ultimately proved unusable due to their fragility and are therefore not considered viable solutions.

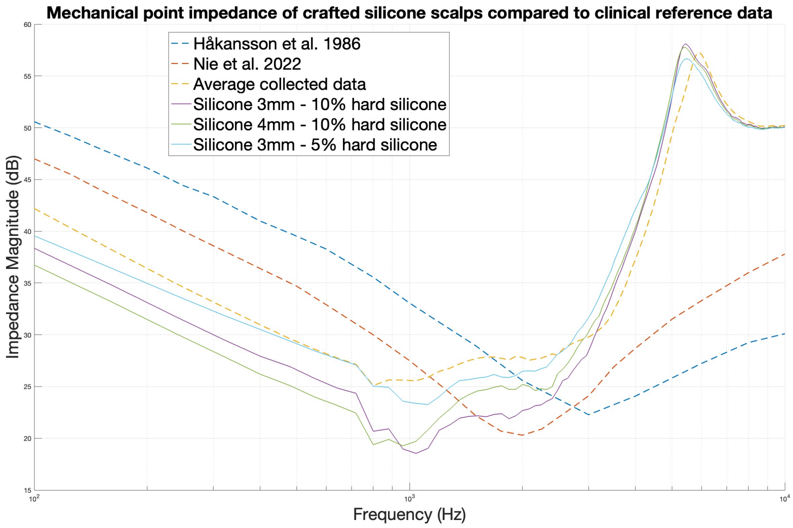

Figure 37: The average of five mechanical point impedance measurements for each crafted silicone scalp compared to clinical data from Håkansson et al. [41], Nie et al. [37] and an average of the collected data.

4.4 Adapted Made-to-order Scalps

Two versions of the molded scalps were made to order, with thicknesses of 3 mm and 4 mm. Both are made from the silicone rubber Ecoflex0010, which demonstrates superior performance in terms of durability and in replicating the attenuation and impedance properties of the human scalp. The scalps were molded using 3D-printed molds specifically designed to match the shape of HeadSim1. The 4 mm thick scalp, illustrated in Figure 38, shows no signs of wear or deformation from handling or the tension applied by the Softband. However, the 3 mm version has developed minor dents due to these factors.

Figure 38: The new molded Ecoflex0010 scalp, 4 mm thick, on a HeadSim1.

4.4.1 Attenuation Measurements

Attenuation measurements were conducted on each of the two molded Ecoflex0010 scalps and compared to clinical reference data, as shown in Figure 39. The reference data collected by Cuda et al. is once again selected for primary comparison [39]. The order in which the molded Ecoflex0010 scalps replicate the attenuation characteristics of the human scalp based on MAE are:

1. Molded Ecoflex0010 3 mm, with MAE = 4.6596

2. Molded Ecoflex0010 4 mm, with MAE = 4.8171

Once again, the artificial materials generally exhibit slightly higher attenuation levels compared to the clinical reference, but the overall shape and characteristics of the curves are similar. The 3 mm thick scalp is slightly closer to the clinical reference data, but the difference is minimal, and the performance of both scalps can be considered equivalent.

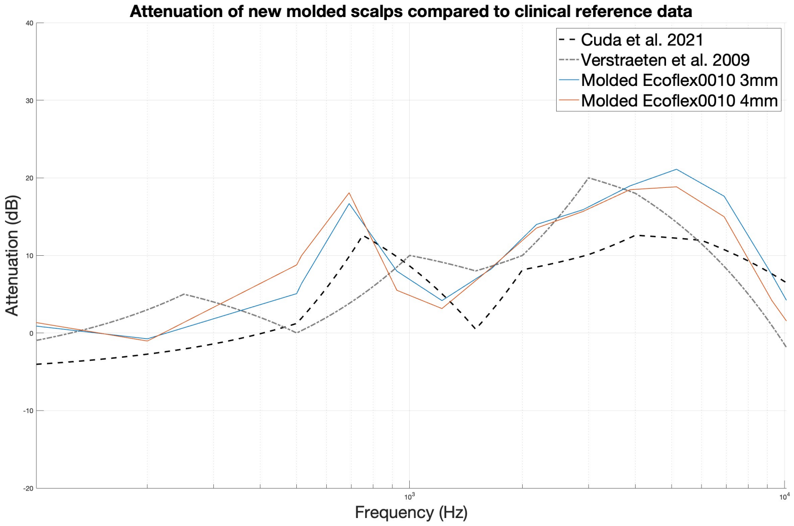

Figure 39: The average of five attenuation measurements for each new molded scalp compared to clinical data from Cuda et al. [39] and Verstraeten et al. [40].

4.4.2 Mechanical Point Impedance measurements

Mechanical point impedance measurements were conducted on each of the molded Ecoflex0010 scalps and compared to both the collected data and clinical reference data, as shown in Figure 40. The collected data from the market investigation is once again used for primary comparison due to its use of the exact same measurement setup and equipment, making it the most appropriate comparison. The order in which the scalps most closely replicate the mechanical point impedance characteristics of the human scalp based on MAE are:

1. Molded Ecoflex0010 4 mm, with MAE = 1.4492

2. Molded Ecoflex0010 3 mm, with MAE = 3.1771

While the artificial materials generally exhibit slightly different behavior, the overall shape and characteristics of the curves are very similar. The 4 mm scalp matches the collected reference data very closely, while the 3 mm scalp results in slightly lower levels.

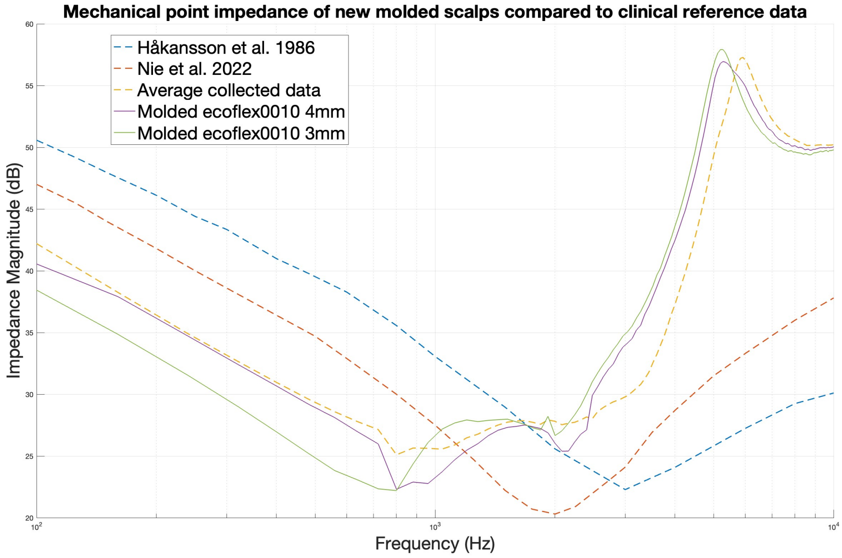

Figure 40: The average of five mechanical point impedance measurements for each new molded scalp compared to clinical data from Håkansson et al. [41], Nie et al. [37] and an average of the collected data.

4.5 Comparison

A comparative analysis of the tested artificial scalps, evaluating their performance in attenuation, mechanical point impedance, and acoustic feedback, is essential for understanding the final results and conclusions. To examine the impact of external factors such as contact force, input voltage, and variations between head simulators, the existing Ecoflex0010 scalp was used as a reference model.

4.5.1 Shape comparison

The new Ecoflex0010 scalps are molded using 3D-printed molds that are specifically designed to match the shape of HeadSim1. As shown in Figure 41, this results in a better fit and reduces air gaps that could negatively impact measurements, especially those related to acoustic feedback. The updated shape is also more user-friendly, enhancing overall usability. This is particularly important in acoustic feedback measurements, where the scalp is secured over the implant using pantyhose and a bag clip. The improved fit makes the scalp easier to handle and apply while avoiding it folding or wrinkling. As seen later in this Section, the shape has a positive effect on the acoustic feedback results.

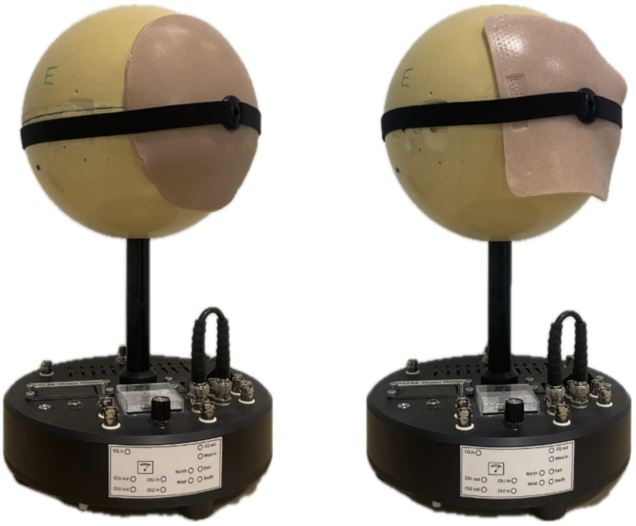

Figure 41: Side-by-side comparison of the new moldled Ecoflex0010 scalp (left) and the old existing Ecoflex0010 (right).

4.5.2 Attenuation Measurements

Attenuation comparison of different voltage amplitudes

Attenuation measurements were performed using varying signal voltages to verify the system's robustness and ensure consistent results regardless of input amplitude. The results seen in Figure 42 confirm that the attenuation remains constant across different voltage levels, indicating the absence of non-linear effects. This demonstrates that the system behaves as expected and is reliably insensitive to changes in voltage amplitude.

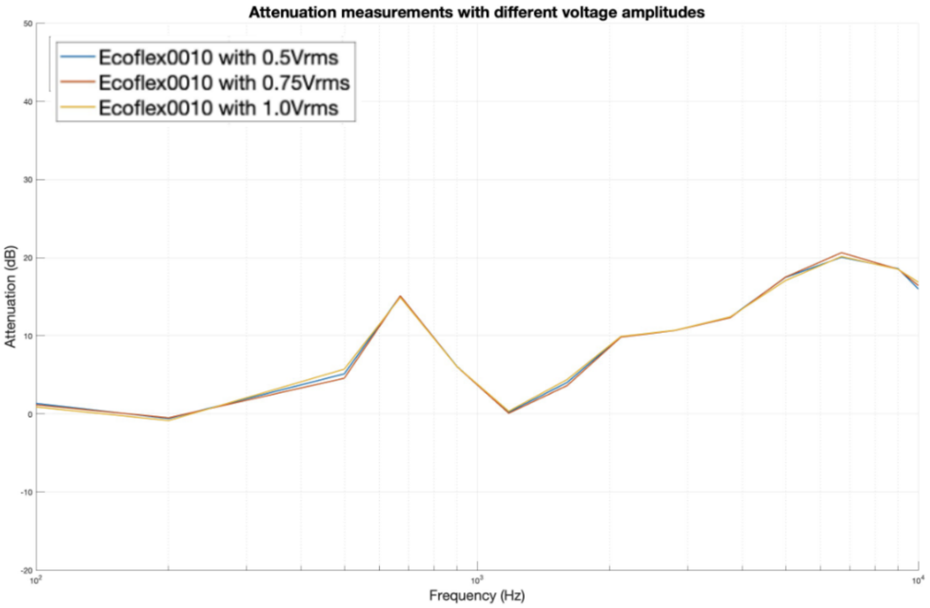

Figure 42: Attenuation measurements results for Ecoflex0010, with different voltage amplitudes sent into the vibrator.

Attenuation comparison of different contact forces

The Softband is typically fastened with a contact force of 2 N to align with clinical reference data. However, attenuation was also measured at different contact forces to assess their impact on the results. Figure 43 presents the attenuation measurements for each force level, showing how closely they replicate the clinical reference data from Cuda et al. based on MAE:

1. Contact force of 5 N, with MAE = 3.0866

2. Contact force of 4 N, with MAE = 3.4689

3. Contact force of 3 N, with MAE = 3,7299

4. Contact force of 2 N, with MAE = 4.1826

These results indicate a correlation between increased contact force and decreased attenuation, leading to improved replication of human scalp characteristics. However, higher contact forces make the Softband more difficult to handle, and only the 2 N contact force is directly comparable to clinical reference data.

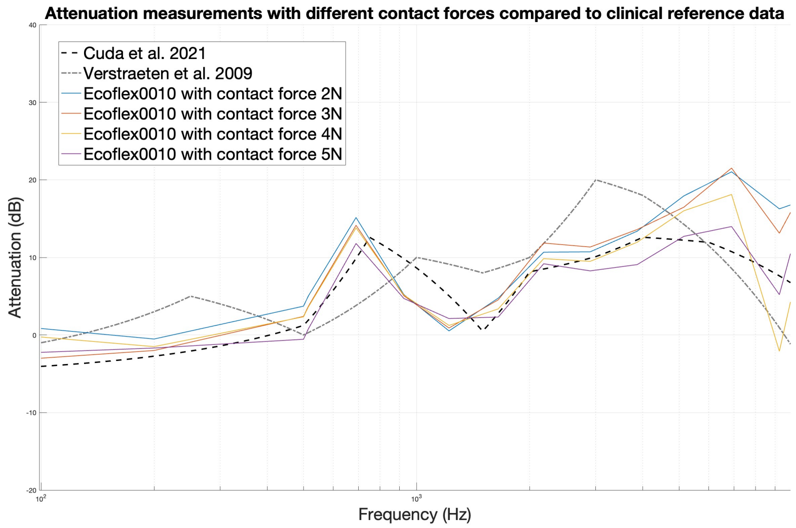

Figure 43: Attenuation measurements results for Ecoflex0010, with the Softband tightened to different contact forces. These are compared to clinical data from Cuda et al. [39] and Verstraeten et al. [40].

Attenuation comparison of different head simulators

The same attenuation measurement, using the same scalp, was performed on two different HeadSim1 referred to as ‘Helen’ and ‘Harriet’ to assess whether results are transferable across different simulators. External factors such as the condition and age of the simulators may introduce slight variations. As shown in Figure 44, the results exhibit very similar behavior and characteristics, with only minor differences in magnitude. This suggests that the choice of HeadSim1 unit does not significantly affect this type of measurement.

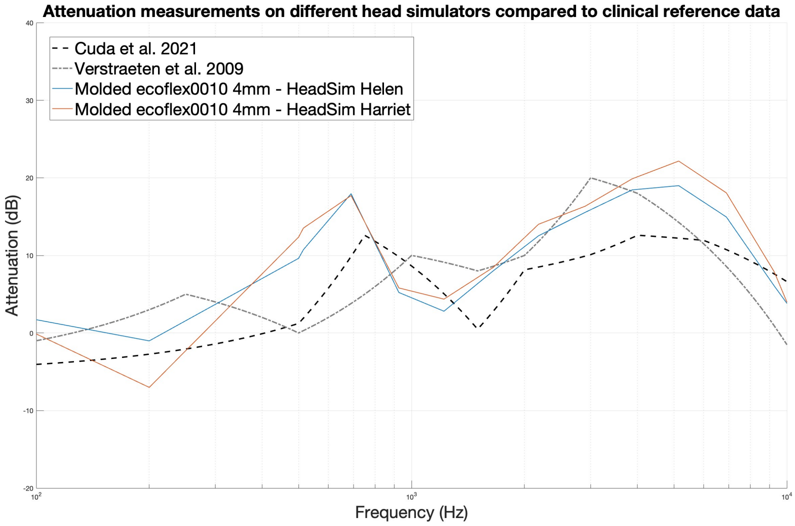

Figure 44: The average of five attenuation measurements for the 4 mm thick molded Ecoflex0010 scalp on two different Headsim1, called ’Helen’ and ’Harriet’. These are compared to clinical data from Cuda et al. [39] and Verstraeten et al. [40].

Attenuation comparison of the three best performing scalps

Attenuation measurements are compared across the existing Ecoflex0010 scalp and two molded versions of Ecoflex0010, as these materials demonstrate the best overall performance. These are in turn compared to clinical reference data, as shown in Figure 45. The reference data collected by Cuda et al. is once again selected for primary comparison. The order in which these scalps replicate the attenuation characteristics of the human scalp based on MAE are:

1. Molded Ecoflex0010 3 mm, with MAE = 4.6596

2. Molded Ecoflex0010 4 mm, with MAE = 4.8171

3. Existing Ecoflex0010 4 mm, with MAE = 5.4459

The 3 mm thick molded Ecoflex0010 matches the clinical reference data the closest in attenuation properties compared to the other two. However, the difference between the two molded scalps is very small, and since both are within the desired limit of MAE < 5, the difference is considered insignificant.

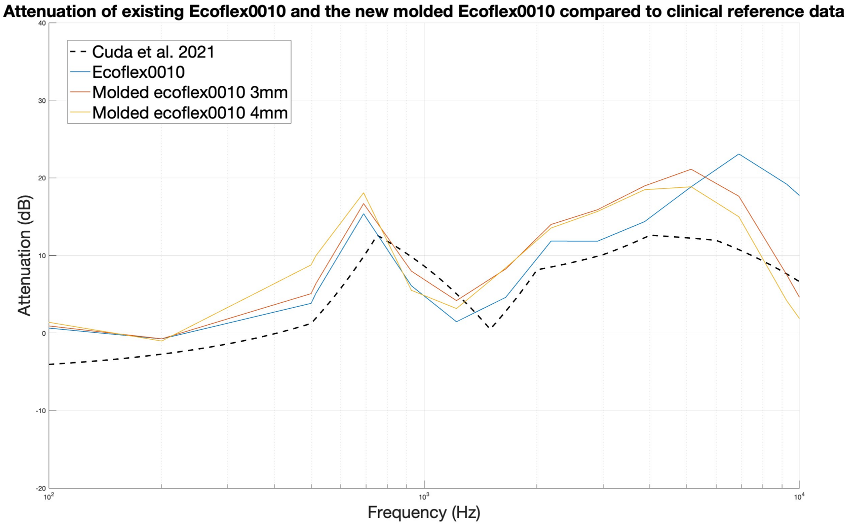

Figure 45: The average of five attenuation measurements for the three best performing scalps out of all materials, including the existing Ecoflex0010 and the two new molded Ecoflex0010 compared to clinical data from Cuda et al. [39].

4.5.3 Mechanical Point Impedance measurements

Mechanical point impedance sources of error

All mechanical point impedance measurements obtained in the thesis work display a significant difference in characteristics compared to available clinical reference data. Thus, additional measurements were performed to investigate the hypothesis that the snap connection could be influencing the measurement results. Additional measurements were also performed to further investigate the accuracy of measurement setup, by comparing measurements on the Artificial Mastoid with the current setup to its calibration data.

As seen in Figure 46, a substantial and significant difference is observed when comparing measurements with the Softband snap connection to those with direct contact to the impedance head. Thus, these deviations, particularly at higher frequencies, are confirmed to result from the snap connection. Additionally, Figure 47 confirms that the measurement setup and/or conditions introduce a slight difference when comparing Artificial Mastoid measurements with this setup to the calibration data.

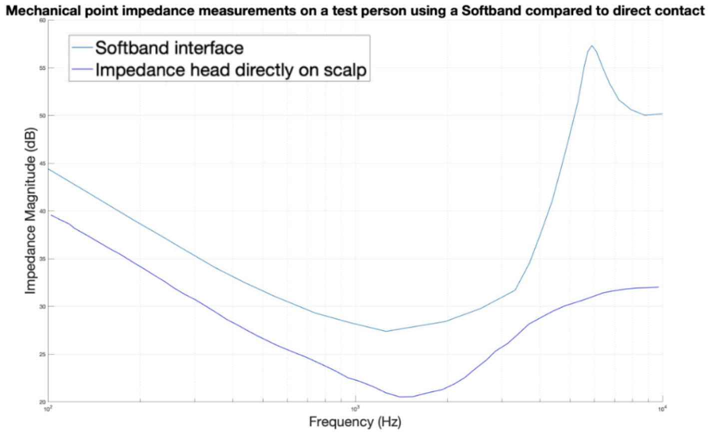

Figure 46: The mechanical point impedance on a test person using a Softband as the interface between the impedance head and the scalp of the test person, compared to direct contact between the impedance head and the test person.

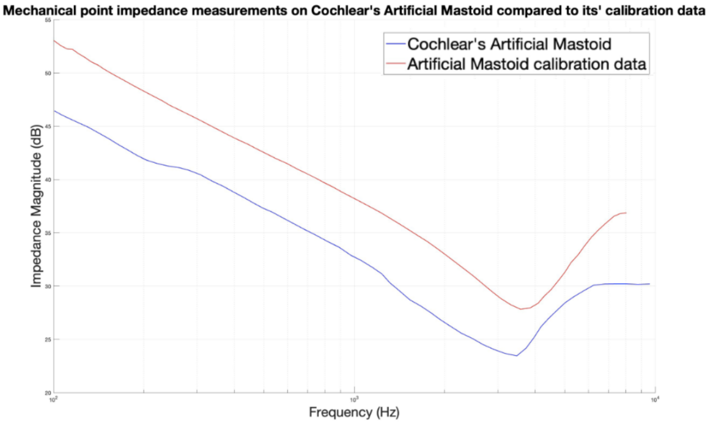

Figure 47: The mechanical point impedance of Cochlear's Artificial Mastoid compared to calibration data from RISE.

Mechanical point impedance error compensation

To account for the errors introduced by both the snap connection and the measurement setup and conditions, these sources of error were combined into an error compensation curve, shown in Figure 48. This compensation curve was then applied to the data collected during the market investigation, as illustrated in Figure 49, effectively correcting for the total measurement error. The result is a reduction in the most prominent deviations, resulting in data that more closely aligns with existing clinical reference data. Although a slight shift in the curve remains, similar variations are also observed between different clinical reference data, such as those from Håkansson et al. and Nie et al., likely due to factors like differences in vibrator resonance frequencies. Overall, the findings demonstrate that the measurements obtained in this thesis are comparable to clinical reference data, as setup and equipment-related errors can be properly compensated. This proves that there is no fundamental flaw in the setup or equipment used. Rather, they introduce specific effects on the measured signals.

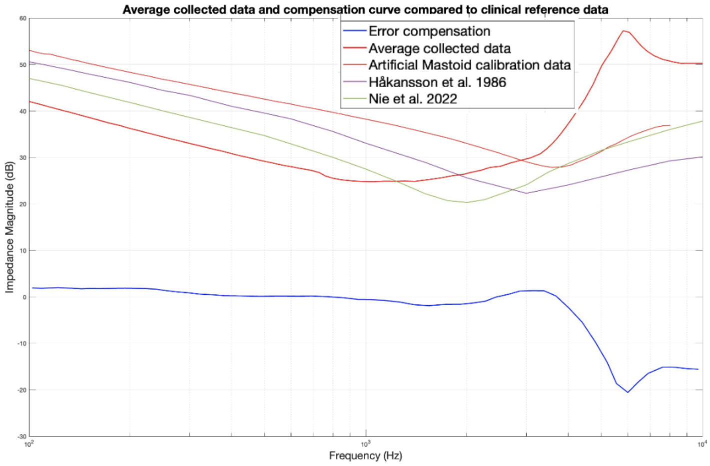

Figure 48: An average of the collected mechanical point impedance data plotted together with the error compensation curve compared to Håkansson et al. [41], Nie et al. [37] and artificial mastoid calibration data.

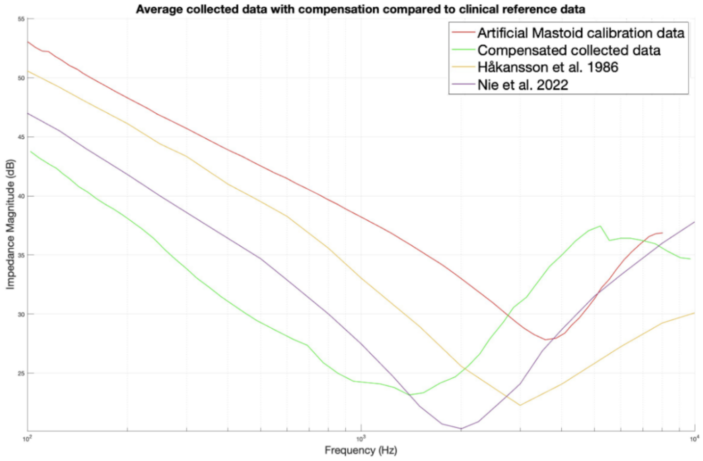

Figure 49: An average of the collected mechanical point impedance data with added compensation compared to Håkansson et al. [41], Nie et al. [37] and artificial mastoid calibration data.

Mechanical point impedance comparison of different contact forces

As previously mentioned, the Softband is typically fastened with a contact force of 2 N to align with clinical reference data. However, mechanical point impedance was also measured at different contact forces to assess their impact on the results. Figure 50 presents the mechanical point impedance measurements for each force level, showing how closely they replicate the clinical reference data from Cuda et al. based on MAE:

1. Contact force of 2 N, with MAE = 0.9780

2. Contact force of 3 N, with MAE = 1.3283

3. Contact force of 4 N, with MAE = 1.5048

4. Contact force of 5 N, with MAE = 1.8737

In contradiction to the attenuation results for different contact forces, these results indicate a correlation between decreased contact force and improved replication of human scalp characteristics. A clear correlation between contact force and mechanical point impedance can not be determined, likely due to measurement variations.

Since higher contact forces make the Softband more difficult to handle, and only the 2 N contact force is directly comparable to clinical reference data, the 2 N contact force remains the most appropriate and desirable setting.

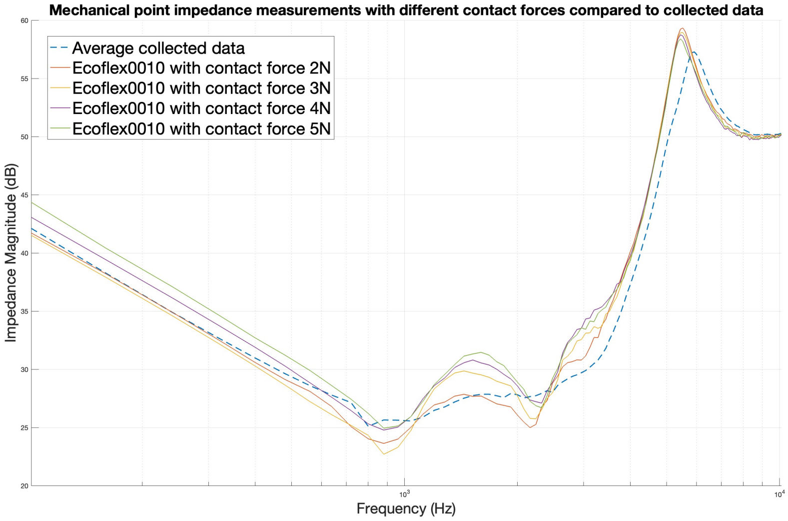

Figure 50: Mechanical point impedance measurement results for Ecoflex0010, with the Softband tightened to different contact forces. These are compared to an average of the collected data.

Mechanical point impedance comparison of different head simulators

The same mechanical point impedance measurement, using the two new molded Ecoflex0010 scalps, was performed on two different HeadSim1 referred to as 'Helen' and 'Harriet' to assess whether results are transferable across different simulators. External factors such as the condition and age of the simulators may introduce slight variations. As shown in Figure 51, the results exhibit very similar behavior and characteristics for the two different thicknesses, with nearly no differences in magnitude. This suggests that the choice of HeadSim1 unit does not significantly affect this type of measurement.

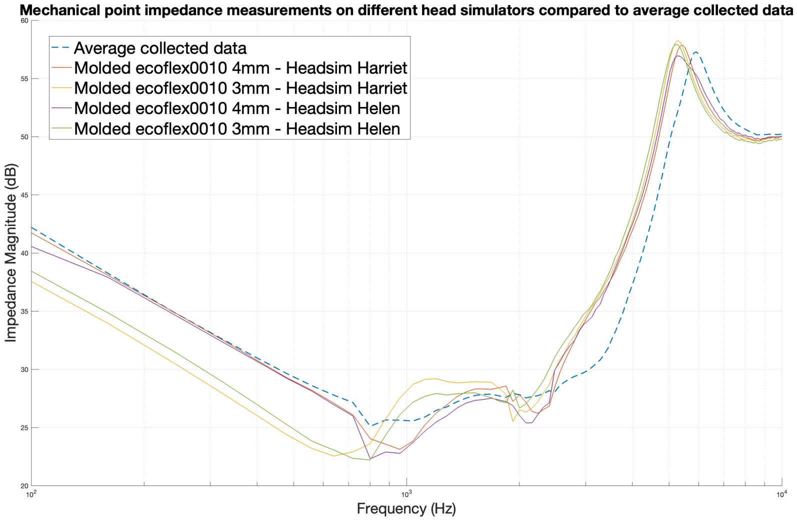

Figure 51: The average of five mechanical point impedance measurements for the two new molded Ecoflex0010, on two different HeadSim1, called 'Helen' and 'Harriet'. These are compared to an average of the collected data.

Mechanical point impedance comparison of the three best performing scalps

Mechanical point impedance measurements are compared across the existing Ecoflex0010 scalp and two molded versions of Ecoflex0010, as these materials demonstrate the best overall performance. These are in turn compared to the collected reference data from the market investigation, as shown in Figure 52. The order in which these scalps replicate the mechanical point impedance characteristics of the human scalp based on MAE are:

1. Existing Ecoflex0010 4 mm, with MAE = 1.3362
2. Molded Ecoflex0010 4 mm, with MAE = 1.4492
3. Molded Ecoflex0010 3 mm, with MAE = 3.1771

The existing Ecoflex0010 scalp matches the clinical reference data the closest in mechanical point impedance properties compared to the other two. However, the difference in MAE between the existing Ecoflex0010 and the molded 4 mm thick Ecoflex0010 is so small that it is considered insignificant. In this case, all scalps are within the desired limit of MAE < 5.

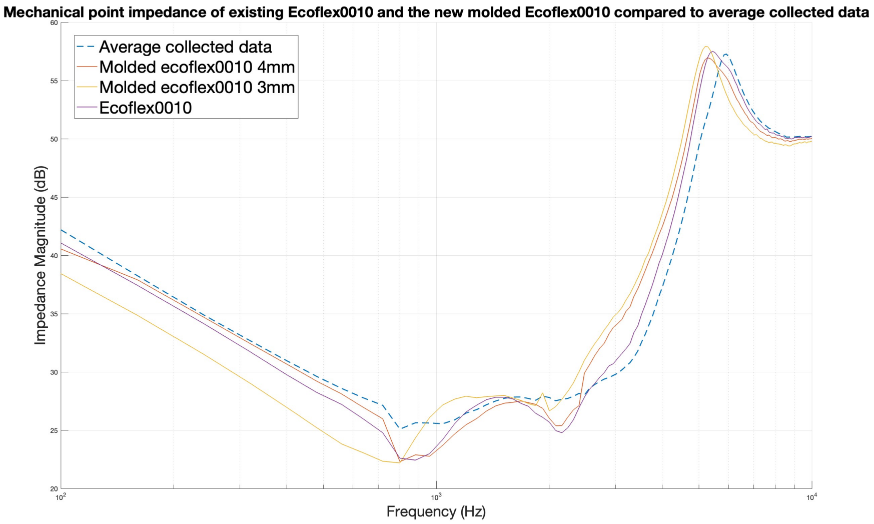

Figure 52: The average of five mechanical point impedance measurements for the three best performing scalps out of all materials, including the existing Ecoflex0010 and the two new molded Ecoflex0010 compared to an average of the collected data.

4.5.4 Acoustic Feedback Measurements

Acoustic feedback measurements are compared across the existing Ecoflex0010 scalp and two molded versions of Ecoflex0010, as these materials demonstrate the best overall performance based on the average MAE from both attenuation and mechanical point impedance (MPI) measurements:

1. Molded Ecoflex0010 4 mm - $\frac{4.8171(attenuation\ MAE)+1.4492(MPI\ MAE)}{2} = 3.13315$
2. Existing Ecoflex0010 4 mm - $\frac{5.4459(attenuation\ MAE)+1.3362(MPI\ MAE)}{2} = 3.39105$
3. Molded Ecoflex0010 3 mm - $\frac{4.6596(attenuation\ MAE)+3.1771(MPI\ MAE)}{2} = 3.91835$

These scalps are in turn compared to clinical reference data from Mylanus et al., as shown in Figure 53. Staying in the plotted two standard deviations interval means that the artificial material's performance is considered acceptable if it stays within the range that includes approximately 95% of the clinical reference values, assuming a normal distribution. Staying within this range suggests that the artificial materials behave similarly to the clinical standard in most typical conditions. The scalps are evaluated on what percentage of their respective curves stays within this range. Thus, the order in which these scalps replicate the acoustic feedback characteristics of the human scalp are:

1. Molded Ecoflex0010 4 mm - 95.77% within $\pm 2\sigma$
2. Molded Ecoflex0010 3 mm - 92.54% within $\pm 2\sigma$
3. Existing Ecoflex0010 4 mm - 91.73% within $\pm 2\sigma$

The 4 mm thick molded Ecoflex0010 scalp matches the clinical reference data the closest in acoustic feedback properties compared to the other two, with 95.77% of the data points staying within two standard deviations of clinical reference data. This reaches the desired percentage > 95%. This leaves the molded Ecoflex0010 scalp as the final result, falling within all desired performance limits.

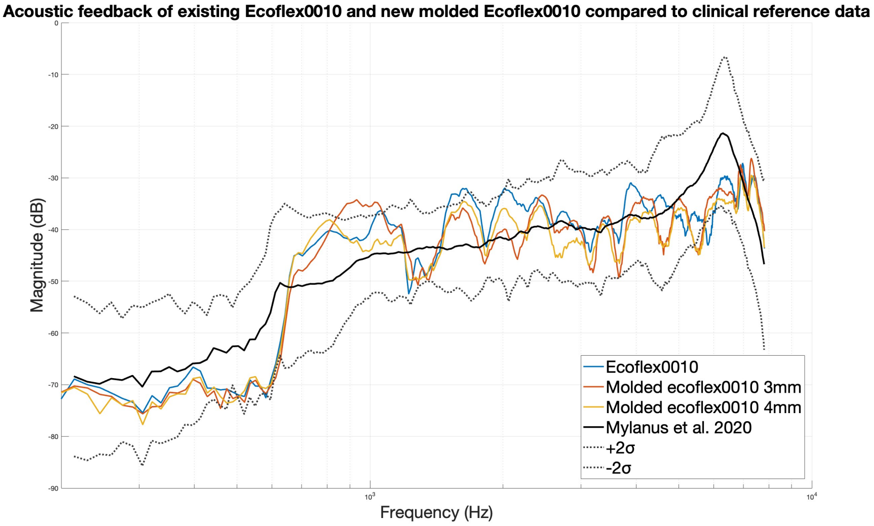

Figure 53: The average of 30 acoustic feedback measurements for the three best performing scalps out of all materials, including the existing Ecoflex0010 and the two new molded Ecoflex0010 compared to clinical data from Mylanus et al. [42].

5 Discussion

The selection of measurement and evaluation methods is discussed to provide insight into the reasoning behind the choices made in this thesis. Additionally, certain results are further interpreted and discussed, as they may be influenced by multiple factors and allow for various plausible explanations.

5.1 Choice of Measurements and Evaluation

In this thesis, the objective was to replicate the mechanical properties of the human scalp rather than its biological characteristics, such as scalp thickness. Bone conduction hearing devices function by transmitting vibrations through the skull and are therefore influenced solely by the mechanical properties of the scalp. The scalp acts as an interface and plays a significant role in damping and transmitting these vibrations. Accurate replication of the scalp's mechanical behavior is therefore essential for producing reliable test results when evaluating these devices.

One of the key evaluations was to measure the mechanical point impedance of both the human scalp and artificial materials. This property describes the scalp's resistance to motion when subjected to an external dynamic force. In other words, how much the material resists motion in response to vibrations. A higher mechanical point impedance indicates less vibration for a given input force, as described in Section 2.10. This can reduce the likelihood of acoustic feedback. In contrast, a lower mechanical point impedance permits more vibration, increasing the potential for vibrations to spread through surrounding soft tissues, thereby raising the risk of feedback loops. Thus, in order to replicate human scalp and its behavior in real life testing scenarios, the mechanical point impedance needs to be replicated as closely as possible.

Attenuation characteristics of the scalps were also analyzed, focusing on how vibrations from the device are dampened and transmitted through the scalp layer. If the artificial scalp exhibits attenuation levels that significantly deviate from human scalp levels, the performance of the bone conduction hearing device will be misrepresented. Attenuation influences the risk of acoustic feedback, which occurs when the microphone captures sound produced by the speaker and reintroduces it into the system. Lower attenuation increases this risk. Since both mechanical point impedance and attenuation affect the acoustic feedback, an inaccurate combination of these properties can increase the likelihood of unwanted feedback. Therefore, accurately replicating the mechanical point impedance and attenuation characteristics of the human scalp is essential to ensure realistic and reliable testing of bone conduction hearing devices.

To enhance the evaluation, alternative or additional testing methods could be considered. For example, applying a gel layer between the head simulator and the scalp might offer insight into changes in mechanical conductivity. Additionally, hardness tests, such as the Shore A hardness scale method, could help assess the material's resistance to deformation or indentation. While hardness and conductivity offer valuable supplementary information, they are not considered to be critical for assessing the material's suitability for the purpose at hand.

The evaluation of mechanical point impedance and attenuation results was performed using the Mean Absolute Error (MAE) to compare measurement curves against clinical reference data. Overall, the mechanical point impedance and attenuation curves had consistent shapes, though occasional spikes or outliers were observed. These anomalies were typically caused by noise or external disturbances and do not represent the actual mechanical behavior of the scalp materials. Therefore, they should not disproportionately influence the evaluation. MAE is particularly well suited in this context since it treats all deviations equally, without giving larger weights to extreme values. This makes MAE more robust against outliers and a fair method for assessing how closely each material replicates the overall behavior of the human scalp across the full frequency range.

As previously explained, scalp materials that closely replicate mechanical properties in terms of attenuation and mechanical point impedance are also expected to perform well in acoustic feedback measurements. Therefore, only the best performing scalp materials from the attenuation and mechanical point impedance evaluations, including the existing Ecoflex0010 and the two new molded Ecoflex0010, were selected for acoustic feedback testing. The evaluation focused on determining the percentage of data that fell within two standard deviations of the clinical reference data, a common method at Cochlear. Assuming a normal distribution, approximately 95% of the data should fall within two standard deviations from the reference data, indicating that the artificial scalps behave similarly to clinical reference data under most typical conditions. This approach is therefore considered a robust evaluation method for acoustic feedback measurements.

5.2 Variations in Scalp Properties

The clinical reference data and market investigation results used in this thesis are based exclusively on adult test subjects and therefore do not represent the entire target population, which includes individuals of all ages. The decision to replicate only the mechanical properties of the adult human scalp was a deliberate limitation, based on the understanding that different age groups will likely require tailored solutions. As discussed in Section 2.2.3, children under the age of seven typically have a scalp thickness between 3 and 4 mm, and even greater variation is observed in older children. Although this thesis does not replicate the biological properties such as scalp thickness, these characteristics do influence mechanical behavior. Therefore, different mechanical properties would need to be replicated for each age group since a universal solution is not feasible. To complete the work within scope, a specific age group had to be selected for replication. Given that the head simulator HeadSim1 is designed to represent the average adult skull and brain, it was logical to replicate the scalp accordingly. Replicating adult scalp properties ensures consistency within the HeadSim1 system, making it a more accurate simulator of the average mechanical properties of an adult head.

5.3 Measurement Characteristics

Across all measurement types conducted in this thesis, potential sources of error primarily stem from placement, contact force, and external disturbances such as noise and movement. To minimize such errors, diligent care was taken to ensure consistent placement and measuring point for each type of measurement respectively. This consistency is particularly important to reduce variability caused by differences in placement on the head simulator. For both attenuation and acoustic feedback measurements, the characteristics of the results are similar to clinical reference data. This alignment is largely due to the fact that the clinical reference studies selected for comparison clearly describe their measurement setups, which closely match those used in this thesis, employing similar equipment and procedures.

5.3.1 Attenuation Characteristics

While the attenuation results obtained using artificial scalps are somewhat higher in magnitude, they exhibit similar characteristics to clinical reference data. The study by Cuda et al. was chosen as the primary reference for evaluating artificial materials, as it clearly describes a setup and equipment that matches those used in this thesis. Particularly, this primary reference also used a Softband with a comparable snap connection, an interface proven to affect measurement results. This makes Cuda et al. a more suitable and reliable source for direct comparison. Another reference, Verstraeten et al., did not provide detailed setup information, though the results displayed comparable characteristics. However, a different type of vibrator was likely used, potentially explaining the observed delay in their data due to variations in resonance frequency.

5.3.2 Acoustic Feedback Characteristics

Acoustic feedback measurements are very sensitive to external factors such as background noise. Despite this, the measurement characteristics from artificial scalps still reflect those found in clinical reference data, although some variation in magnitude is observed due to the mentioned measurement sensitivity. In this case, the clinical reference data from Mylanus et al. was especially relevant, as it describes the use of a very similar setup and Softband. The study was sponsored by Cochlear, using the same OSI200 implant used in this thesis. Thereby Mylanus et al. provides a valuable basis for comparison.

However, unlike the attenuation and mechanical point impedance measurements, contact force between the scalp and HeadSim1 could not be measured for the acoustic feedback measurements. This limitation arises from the different fastening method invented at Cochlear, using pantyhose and a bag clip. Due to this method, a dynamometer could not be used to measure contact force, as there is no appropriate attachment. This trade-off was considered acceptable, as minimizing air gaps (which significantly affect results) was prioritized over precise control of contact force. Furthermore, the goal was to replicate scalp properties, not necessarily the exact measurement conditions.

5.3.3 Mechanical Point Impedance Characteristics

The mechanical point impedance measurements show significant deviations from available clinical reference data. To investigate this further, a market investigation was conducted, resulting in the same deviations. As described in Section 4.5.3, it was found that most of the differences originate from the snap connection used with the Softband. However, a small error remained from the measurement setup itself. None of the clinical references used a similar interface (the snap connection), which explains the large differences observed. Therefore, the market investigation data provided a more appropriate reference for comparison. A minor source of variation also came from the tilt of the impedance head during measurements. While artificial scalp measurements allowed the impedance head to stand straight on top of the point of measurement, the measurements conducted on human subjects required a compromise. This was because maintaining a straight position of the impedance head would have required the subject to rest their head in a rather uncomfortable posture. Thus, to ensure participant comfort and safety, the impedance head occasionally tilted slightly. This minor tilt did not significantly impact results but is acknowledged as a potential small source of error.

Overall, the findings demonstrate that the mechanical point impedance measurements obtained in this thesis are comparable to clinical reference data, as setup and equipment related errors can be properly compensated, as shown in Section 4.5.3. This proves that there is no fundamental flaw in the setup or equipment used. Rather, they introduce specific effects on the measured signals. The remaining shift is likely due to differences in vibrator models and their resonance frequencies, a factor that also explains variations between different clinical studies. Additional setup related errors, unrelated to the interface, may also contribute to the remaining differences.

5.4 Material Durability

As previously noted throughout this report, several of the tested materials exhibited inherent flaws related to durability and long term stability under typical usage conditions. These factors are critical when evaluating results, as the final solution must be robust enough to withstand its intended use.

The FS10 silicone samples, produced several years ago, have been used at Cochlear's electrical lab ever since. Although all existing scalps (FS10 and Ecoflex varieties) were originally manufactured with identical size and thickness, the FS10 scalps have since become deformed due to softener leakage. Despite the fact that FS10 with 30% and 35% softener replicate the mechanical point impedance and attenuation properties of the human scalp reasonably well, these materials were excluded from further consideration. This decision was based not only on their degraded condition but also on the fact that Ecoflex0010 outperformed them in both attenuation and mechanical point impedance replication.

The in-house crafted silicone scalps containing 5% hard silicone demonstrated the most accurate replication of the human scalp's mechanical properties. However, it proved far too fragile to withstand even the measurements conducted in this thesis. The material suffered dents and tearing from the pressure applied by the Softband, proving to be unsuitable for its intended use. Since the final solution must be durable enough to endure handling and tension during measurements, this material was also ruled out.

Among all materials tested, only the Ecoflex varieties demonstrated both long term stability and resistance to tear. However, no studies have evaluated the shelf life of this material, which forms the basis for the recommendation that it be replaced every few years. Nonetheless, Ecoflex0010 delivered the best overall performance in replicating attenuation and mechanical point impedance characteristics of the human scalp. This combination of mechanical accuracy and durability makes Ecoflex0010 the most suitable and reliable material for the intended use.

5.5 Contact force

Fastening the Softband to the artificial scalps with varying tension, and thus different contact forces, produced opposite results for attenuation and mechanical point impedance measurements. For attenuation measurements, contact forces ranging from 2 to 5 N were tested. The results revealed a clear trend, higher contact forces improved the replication of human scalp properties. Although the artificial scalps consistently show slightly higher attenuation than the clinical reference, increasing the contact force reduced this difference, bringing the values closer to those observed in clinical reference data. This is a logical outcome, as a tighter contact between the vibrator and the scalp reduces the length of the signal's transmission path, thereby decreasing attenuation. The resulting lower attenuation levels better align with those of the human scalp. However, it is important to note that these differences were relatively small.

In contrast, mechanical point impedance measurements showed the opposite correlation. Lower contact forces, specifically 2 N, result in better alignment with both clinical reference data and the data collected during the market investigation. This is because all comparable reference measurements were conducted using a Softband with a contact force of 2 N, making this value the most representative for accurate comparison.

Given that the objective is to replicate real world conditions as closely as possible, a contact force of 2 N is the most appropriate choice. It aligns well with existing clinical reference data for both attenuation and mechanical point impedance, and it simplifies the measurement process. Higher contact forces make fastening the Softband more difficult and introduce unnecessary complexity, especially since the improvement in attenuation accuracy is relatively minor. Thus, using a contact force of 2 N offers the best balance between replication of real world conditions, consistency, and practicality. However, it should be acknowledged that the method used to measure contact force, using a dynamometer, is not entirely foolproof and is susceptible to minor human errors. Assuming such errors occasionally occurred, they did not appear to significantly affect the results. However, it may be valuable to investigate this further using more precise measurement tools.

5.6 Adaption of scalps

After concluding that Ecoflex0010 provides the most accurate replication of human scalp properties, it was selected as the preferred material. However, a new hypothesis emerged suggesting that performance could be further enhanced by optimizing the shape of the scalp. To test this, a custom mold was 3D-printed to match the shape of HeadSim1, ensuring better integration between the scalp and the rest of the simulator.

Final evaluation was conducted using acoustic feedback measurements, which indicate improved performance with the newly molded 4 mm thick Ecoflex0010 scalps. While the previously used Ecoflex0010 samples have shown no visible signs of deformation or change over time, they have not undergone specific long term testing. Therefore, it can not be definitively concluded that the improved performance is solely due to the new shape. The fact that the molded scalps are freshly produced may also contribute to the results.

Nonetheless, there is strong reason to believe that the improved fit plays a significant role, particularly by reducing air gaps between the scalp and the head simulator, an issue known to affect acoustic feedback measurements. In addition to potential performance enhancement, the molded shape has also proven to be significantly easier to handle and attach across all measurement types. For these reasons, the new molded design can be considered an overall improvement.

5.7 Ethical, ecological and societal considerations

Beyond technical performance, it is essential to consider the broader implications of this work to better understand its ethical, ecological and societal impact. This perspective offers deeper insight into the project's significance and relevance from a socially responsible standpoint.

5.7.1 Ethical Considerations

Replicating the mechanical properties of human scalp and integrating them into the head simulator enhances measurement accuracy, potentially leading to a more accurate and widespread use of the head simulator. A significant ethical benefit of this advancement is the reduction in the need for testing on patients or animals. Traditional hearing implant testing may involve cadavers or live animal models, raising ethical concerns about consent, suffering, and the limitations of these models in replicating human conditions. Additionally, conducting extensive patient testing in the early stages can place a significant burden on patients. Using an accurate head simulator provides a more humane and ethically sound alternative while maintaining accuracy in testing.

Ethical responsibility extends to ensuring that the artificial scalp produces clinically relevant results. If the model fails to accurately mimic the mechanical properties of human scalp, hearing devices may be tested under unrealistic conditions, leading to suboptimal performance in real patients. Thus, validation against clinical reference data is necessary to uphold ethical research standards and protect future patients.

In addition, a market investigation was carried out as part of the thesis to collect mechanical point impedance data from volunteer participants at the company. The Clinical Affairs department played a key role in advising and overseeing the process to ensure that it was conducted ethically and in accordance with proper procedures. A proper risk assessment was conducted in advance and is available in Appendix A. All participants were fully informed of the potential risks and were made aware that their participation was entirely voluntary, with the option to withdraw at any time without the need to provide a reason.

5.7.2 Ecological Considerations

The use of head simulators offers a sustainable and resource efficient alternative to single-use methods. By reducing the reliance on physical experiments that involve cadavers, chemicals, and other disposable materials, head simulators substantially decrease waste production and environmental impact. Additionally, by minimizing the need of transportation of materials and samples, it helps reduce carbon dioxide emissions associated with logistics.

Designed for a repeated use, head simulators are far more resource efficient compared to other methods dependent on disposable materials. The initial cost of the head simulator is quickly offset by reduced costs for consumables and waste management. Furthermore, the need to handle and dispose of biological waste can have a harmful impact on the environment.

Conducting simulations in controlled environments significantly reduces energy consumption, compared to laboratories that require strict conditions to preserve biological material. This results in lower energy usage and a reduced carbon footprint.

5.7.3 Societal considerations

The ultimate societal goal of improving the head simulator is to increase the accuracy of bone conducted hearing device testing, leading to better patient outcomes. By refining device performance before clinical application, this technology has the potential to enhance the quality of life for individuals with hearing loss. Ethical decision making throughout the project should prioritize patient welfare, accessibility and fairness to ensure the greatest possible benefit to society. By improving communication and social interactions, these technologies help reduce isolation, increase participation in the workforce and promote inclusivity in education and social settings. Better hearing solutions also support cognitive health, as untreated hearing loss has been linked to cognitive decline and dementia[45].

The development of hearing devices can reduce the strain on healthcare systems by decreasing the need for frequent doctor visits, clinical interventions and treatments for complications associated with untreated hearing loss. Early and efficient treatment may also prevent the progression of related conditions, reducing long term medical costs for patients, hospitals and welfare systems. Additionally, improved hearing devices can reduce the need for audiological care, freeing up resources for other critical healthcare needs.

6 Conclusion

This thesis successfully identified and validated a material that closely replicates the mechanical properties of the human scalp, particularly for use in testing bone conduction hearing devices. Through extensive mechanical point impedance, attenuation, and acoustic feedback measurements, the 4 mm thick Ecoflex0010 emerged as the most suitable artificial scalp material. An adapted molded version was developed, which further improved accuracy and usability by minimizing air gaps and ensuring proper fit with HeadSim1. By aligning measurement conditions with clinical standards and gathering new reference data using identical setups for mechanical point impedance, this work ensured comparability and robustness of results. The implementation of this artificial scalp in test environments offers improved simulation of real world conditions and enhances the reliability of test results.

7 Future Work

The work presented in this thesis opens several opportunities for further development. Naturally, additional materials could be investigated to achieve an even closer match to clinical reference data. Similarly, the collection or identification of more comprehensive clinical datasets could enhance the validation of future scalp models. Nonetheless, some key areas for potential improvement and continued development are outlined below.

The introduction of the new molded scalp shape improved the results, prompting further interest in shape optimization. One promising direction is to develop molded designs that are adapted not only to the head simulator but also to the shape of the implant itself. This could further minimize air gaps between the artificial scalp and the simulator with the implant in place, an important factor in improving the accuracy of acoustic feedback measurements. In addition, another area worth exploring is the extent of scalp coverage, as it has not been tested. The size of the current artificial scalps is limited to the capacity of the available 3D printer. However, a full coverage scalp that surrounds the entire simulator could better replicate real world conditions and potentially influence measurement outcomes.

Additionally, the method used to fasten the artificial scalp during acoustic feedback measurements could be refined. While the current approach, using pantyhose and a bag clip, is effective, it lacks sophistication and can be difficult to use consistently. This reduces the repeatability of measurements. As such, the development of a standardized method for attaching the artificial scalp to the head simulator would greatly enhance both consistency and repeatability. Establishing a formal standard would be a significant step toward a more widespread use of simulators for testing bone conduction hearing devices.

This thesis has focused on improving HeadSim1, a simulator currently in use at Cochlear Bone Anchored Solutions. However, as described in Section 2.7, a new simulator, HeadSim 3D, is under development. Given the differences in shape, skull and brain design between HeadSim1 and HeadSim 3D, a new scalp solution tailored specifically to this model will most likely be required, presenting another opportunity for future work.

Finally, the development of artificial scalp solutions tailored to different age groups represents an important and complex area of research. Achieving this would require designing entirely new head simulators that replicate the skull, brain, and scalp properties specific to various age ranges. While this would be a considerable undertaking, it would be especially valuable, particularly for applications regarding children, where minimizing invasive testing is of great importance.

References

[1] *Deafness and hearing loss*, en, 2024. [Online]. Available: `https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss` (visited on 02/05/2025).

[2] Cochlear, *Innovate Reconciliation Action Plan*, 2023. [Online]. Available: `https://assets.cochlear.com/api/public/content/c47aa91e955e40f7825fec37829e8866?v=35a112f6`.

[3] *The Evolution of the Baha system 1977 – 2021*, en-US, Apr. 2021. [Online]. Available: `https://hearandnow.cochlear.com/hearing-solutions/bone-conduction/evolution-of-baha/` (visited on 02/05/2025).

[4] E. Talon, F. Wagner, S. Weder, L. Anschuetz, M. Caversaccio, and W. Wimmer, "Evaluating temporal bone column density for optimized bone conduction implant placement," *Frontiers in Surgery*, vol. 10, p. 1 293 616, Nov. 2023, ISSN: 2296-875X. DOI: `10.3389/fsurg.2023.1293616`. [Online]. Available: `https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10720247/` (visited on 01/28/2025).

[5] *Bone Conduction Implants: What You Need to Know*, en. [Online]. Available: `https://www.cochlear.com/us/en/home/diagnosis-and-treatment/how-cochlear-solutions-work/bone-conduction-solutions/bone-conduction-implants` (visited on 01/28/2025).

[6] *Cochlear™ Baha® System | Bone Conduction Hearing Device*, en. [Online]. Available: `https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-baha-system` (visited on 01/28/2025).

[7] N. R. Oberlies, J. E. Castaño, M. E. Freiser, J. L. McCoy, A. D. Shaffer, and N. Jabbour, "Outcomes of BAHA connect vs BAHA attract in pediatric patients," *International Journal of Pediatric Otorhinolaryngology*, vol. 135, p. 110 125, Aug. 2020, ISSN: 0165-5876. DOI: `10.1016/j.ijporl.2020.110125`. [Online]. Available: `https://www.sciencedirect.com/science/article/pii/S0165587620302688` (visited on 01/28/2025).

[8] D. Soloperto, V. Dallari, and G. Molteni, "How I do it: Cochlear Osia 2 System surgery placement," *European Archives of Oto-Rhino-Laryngology*, vol. 280, no. 2, pp. 929–933, 2023, ISSN: 0937-4477. DOI: `10.1007/s00405-022-07708-w`. [Online]. Available: `https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9849151/` (visited on 01/28/2025).

[9] *Cochlear™ Osia Hearing Implant*, en. [Online]. Available: `https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-osia-system/osia-implants` (visited on 01/28/2025).

[10] K. A. Maldonado and K. Alsayouri, "Physiology, Brain," eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK551718/` (visited on 01/31/2025).

[11] *List of regions in the human brain*, en, Page Version ID: 1271977580, Jan. 2025. [Online]. Available: `https://en.wikipedia.org/w/index.php?title=List_of_regions_in_the_human_brain&oldid=1271977580` (visited on 02/26/2025).

[12] B. W. Anderson, M. W. Kortz, A. C. Black, and K. A. Al Kharazi, "Anatomy, Head and Neck, Skull," eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK499834/` (visited on 02/04/2025).

[13] B. Bordoni, N. L. Mankowski, and D. T. Daly, "Neuroanatomy, Cranial Nerve 8 (Vestibulocochlear)," eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK537359/` (visited on 02/04/2025).

[14] *Skull base fracture, anterior*, en. [Online]. Available: `https://surgeryreference.aofoundation.org/cmf/trauma/skull-base-cranial-vault/skull-base-anterior/definition` (visited on 02/07/2025).

[15] S. Stenfelt, "Acoustic and physiologic aspects of bone conduction hearing," eng, *Advances in Oto-Rhino-Laryngology*, vol. 71, pp. 10–21, 2011, ISSN: 0065-3071. DOI: `10.1159/000323574`.

[16] A. M. Germann, Z. Jamal, and Y. Al Khalili, "Anatomy, Head and Neck, Scalp Veins," eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK540961/` (visited on 01/31/2025).

[17] *The Scalp - Layers - Innervation - Blood Supply - TeachMeAnatomy*. [Online]. Available: `https://teachmeanatomy.info/head/areas/scalp/` (visited on 02/07/2025).

[18] H. Yousef, M. Alhajj, A. O. Fakoya, and S. Sharma, “Anatomy, Skin (Integument), Epidermis,” eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK470464/` (visited on 01/31/2025).

[19] P. Dodia and M. A. Arida, “Dermatopathology Epidermis Histology,” eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK592423/` (visited on 01/31/2025).

[20] J.-H. Joo *et al.*, “Management of Scalp Biofilm in Local Dermatosis: From In Vivo Visualization to Optimal Treatments,” en, *Applied Sciences*, vol. 14, no. 21, p. 10 008, Jan. 2024, ISSN: 2076-3417. DOI: `10.3390/app142110008`. [Online]. Available: `https://www.mdpi.com/2076-3417/14/21/10008` (visited on 01/31/2025).

[21] O. J. Ungar, U. Amit, O. Cavel, Y. Oron, and O. Handzel, “Age-dependent variations of scalp thickness in the area designated for a cochlear implant receiver stimulator,” en, *Laryngoscope Investigative Otolaryngology*, vol. 3, no. 6, pp. 496–499, Dec. 2018, ISSN: 2378-8038, 2378-8038. DOI: `10.1002/lio2.218`. [Online]. Available: `https://onlinelibrary.wiley.com/doi/10.1002/lio2.218` (visited on 02/07/2025).

[22] S. D. Sharma, E. Park, P. L. Purcell, K. A. Gordon, B. C. Papsin, and S. L. Cushing, “Age-related variability in pediatric scalp thickness: Implications for auditory prostheses,” eng, *International Journal of Pediatric Otorhinolaryngology*, vol. 130, p. 109 853, Mar. 2020, ISSN: 1872-8464. DOI: `10.1016/j.ijporl.2019.109853`.

[23] D. M. Bruss and J. A. Shohet, “Neuroanatomy, Ear,” eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK551658/` (visited on 01/28/2025).

[24] *Wikimedia Commons*, en. [Online]. Available: `https://commons.wikimedia.org/wiki/Main_Page` (visited on 02/07/2025).

[25] R. A. Dobie and S. V. Hemel, “Basics of Sound, the Ear, and Hearing,” en, in *Hearing Loss: Determining Eligibility for Social Security Benefits*, National Academies Press (US), 2004. [Online]. Available: `https://www.ncbi.nlm.nih.gov/books/NBK207834/` (visited on 01/28/2025).

[26] J. P. Brandt and R. Winters, “Bone Conduction Evaluation,” eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK578177/` (visited on 01/29/2025).

[27] S. Anastasiadou and Y. Al Khalili, “Hearing Loss,” eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK542323/` (visited on 01/31/2025).

[28] T. Sooriyamoorthy and O. De Jesus, “Conductive Hearing Loss,” eng, in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2025. [Online]. Available: `http://www.ncbi.nlm.nih.gov/books/NBK563267/` (visited on 01/31/2025).

[29] E. Kay-Rivest, A. L. Irace, J. S. Golub, and M. A. Svirsky, “Prevalence of Single-Sided Deafness in the United States,” eng, *The Laryngoscope*, vol. 132, no. 8, pp. 1652–1656, Aug. 2022, ISSN: 1531-4995. DOI: `10.1002/lary.29941`.

[30] S. Prodanovic and S. Stenfelt, “Review of Whole Head Experimental Cochlear Promontory Vibration with Bone Conduction Stimulation and Investigation of Experimental Setup Effects,” *Trends in Hearing*, vol. 25, p. 23 312 165 211 052 764, Oct. 2021, ISSN: 2331-2165. DOI: `10.1177/23312165211052764`. [Online]. Available: `https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8558805/` (visited on 02/07/2025).

[31] 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,” eng, *Otology & Neurotology: Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, vol. 29, no. 8, pp. 1132–1139, Dec. 2008, ISSN: 1537-4505. DOI: `10.1097/MAO.0b013e31816fdc90`.

[32] B. Håkansson and P. Carlsson, “Skull simulator for direct bone conduction hearing devices,” eng, *Scandinavian Audiology*, vol. 18, no. 2, pp. 91–98, 1989, ISSN: 0105-0397. DOI: `10.3109/01050398909070728`.

[33] F. Woelflin, “The Mechanical Point Impedance of the Skin-penetrated Human Skull in Vivo,” M.S. thesis, Chalmers University of Technology, Department of Signals and Systems, 2011.

[34] A. Kumaar Murali Dharan, “A Pilot Study on Developing an Artificial Head for Bone Conduction Devices Testing Purposes,” Master’s thesis, Chalmers University of Technology, Department of Electrical Engineering, 2021.

[35] *Bone conduction - artificial mastoid - 4930*, en. [Online]. Available: `https://www.hbkworld.com/en/products/electroacoustics/bone-conduction/artificial-mastoid-4930` (visited on 05/06/2025).

[36] J. Song, A. L. Klibanov, J. A. Hossack, and R. J. Price, “Acoustic attenuation by contrast agent microbubbles in superficial tissue markedly diminishes petechiae bioeffects in deep tissue,” eng, *Investigative Radiology*, vol. 43, no. 5, pp. 322–329, May 2008, ISSN: 0020-9996. DOI: `10.1097/RLI.0b013e318168c715`.

[37] Y. Nie *et al.*, “Measurement and modeling of the mechanical impedance of human mastoid and condyle,” eng, *The Journal of the Acoustical Society of America*, vol. 151, no. 3, p. 1434, Mar. 2022, ISSN: 1520-8524. DOI: `10.1121/10.0009618`.

[38] 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,” *Otology & Neurotology: Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, vol. 33, no. 3, pp. 413–420, Apr. 2012, ISSN: 1537-4505. DOI: `10.1097/MAO.0b013e3182487fc8`.

[39] D. Cuda, A. Murri, P. Mochi, and A. Mainardi, “Postoperative Benefit of Bone Anchored Hearing Systems: Behavioral Performance and Self-Reported Outcomes,” *International Archives of Otorhinolaryngology*, vol. 26, no. 3, e314–e320, Oct. 2021, ISSN: 1809-9777. DOI: `10.1055/s-0040-1718959`. [Online]. Available: `https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9282944/` (visited on 04/08/2025).

[40] N. Verstraeten, A. J. Zarowski, T. Somers, D. Riff, and E. F. Offeciers, “Comparison of the audiologic results obtained with the bone-anchored hearing aid attached to the headband, the testband, and to the "snap" abutment,” eng, *Otology & Neurotology: Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, vol. 30, no. 1, pp. 70–75, Jan. 2009, ISSN: 1537-4505. DOI: `10.1097/MAO.0b013e31818be97a`.

[41] B. Håkansson, P. Carlsson, and A. Tjellström, “The mechanical point impedance of the human head, with and without skin penetration,” eng, *The Journal of the Acoustical Society of America*, vol. 80, no. 4, pp. 1065–1075, Oct. 1986, ISSN: 0001-4966. DOI: `10.1121/1.393848`.

[42] E. A. M. Mylanus *et al.*, “Multicenter Clinical Investigation of a New Active Osseointegrated Steady-State Implant System,” eng, *Otology & Neurotology: Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, vol. 41, no. 9, pp. 1249–1257, Oct. 2020, ISSN: 1537-4505. DOI: `10.1097/MAO.0000000000002794`.

[43] *Ecoflex™ Series, Super-Soft, Addition Cure Silicone Rubbers*, en. [Online]. Available: `https://www.smooth-on.com/product-line/ecoflex/` (visited on 03/07/2025).

[44] *PlatSil® FS-10 Silicone Rubber*, sv. [Online]. Available: `https://polytek.com/products/platsil-fs-10-silicone-rubber` (visited on 03/07/2025).

[45] *Hearing aids slow cognitive decline in people at high risk*, EN, Aug. 2023. [Online]. Available: `https://www.nih.gov/news-events/nih-research-matters/hearing-aids-slow-cognitive-decline-people-high-risk` (visited on 02/04/2025).

Appendix A

Investigators: Anna Fassih & Elina Sandoff
Supervisor: Dan Nyström
10 March 2025

Risk Assessment for Collecting Mechanical Point Impedance Data on Volunteers

The investigation at hand is performed as part of a master thesis at Chalmers University of Technology, in collaboration with the Technology Department at Cochlear Gothenburg Site.

The main purpose of the thesis is to investigate artificial materials that closely mimic human scalp properties. The artificial scalp is going to be used together with a head simulator that is developed to test different bone conducted hearing devices at Cochlear. The goal is to find a usable solution that enables more reliable implant testing and increases testing accuracy in the head simulator. To qualify as a suitable replica, the material should match or closely approximate the mechanical point impedance, attenuation characteristics and acoustic feedback of human scalp.

Aim of this investigation:
The aim of this investigation is to collect data in order to compare artificial scalp measurements with real measurements on people, using the exact same measurement setup. It is of high relevance since there seems to be behaviours and characteristics connected to the setup in the technology development lab at Cochlear Gothenburg. Other clinical data found in various papers does not share these characteristics and can therefore not be directly compared to our measurements.

Investigation routine:
First, the participant will state their age and gender. Then, they will get a disinfected Softband placed around their head. The contact force of the Softband will be measured to 2 Newton. After that, an impedance head connected to a vibrator will be attached to the Softband behind the ear, and the participant will get to lay their head down on a plastic covered foam. The Softband will be disinfected and the plastic cover is exchanged between every participant. Then, two impedance measurements will be performed, causing the impedance head to vibrate. During a measurement, the participant will feel slight vibrations behind their ear and each measurement will last for about 30 seconds.

Test time:

Appendix B

Hi everyone!

We are two Chalmers students who are writing our master thesis in collaboration with the Technology Department at Cochlear, with Dan Nyström as our supervisor. We are looking for volunteers who are willing to let us perform impedance measurements in order to collect data.

The data from all participants will only be used to create an average reference. Other relevant data includes age and gender. Age will only be collected and displayed as an age span of the participants and the gender will be used to showcase the distribution of genders.

Aim of this investigation:
The aim of this investigation is to collect impedance data on people in order to compare it to our artificial scalp measurements.

Investigation routine:
You will get a Softband placed around your head. After that, an impedance head connected to a vibrator will be attached to the Softband behind the ear. You will get to lay your head down on a plastic covered foam while sitting. Then, two impedance measurements will be performed, causing slight vibrations behind your ear. Each measurement will last for about 30 seconds.

Measurement position

Test time:
The estimated total time per participant is around 15 minutes, depending on if you have further questions.

Exclusion criteria:
As a participant, you must not have a wound or infection in the test area (behind your ear) at the time of the measurement. You should also be able to lay your head down on a cushion while sitting, without it causing any pain.

Risks:
A risk analysis has been performed and only minor risks were found. We will mitigate these by:
- Disinfecting the Softband between test persons.

Appendix C

Cochlear						
	Subject number	T	P	X		

Part 1

Date:							Designated time slot:
	y	y	m	m	d	d	

Demographics					
Gender	Female ☐		Male ☐		Other ☐
Age (years)	18-30 ☐	31-40 ☐	41-50 ☐	51-60 ☐	60+ ☐

Informed consent	Yes
I am aware that I always can choose if and when I want to terminate the test, without offering an explanation.	☐

Exclusion Criteria	No	Yes
Wound in the test area (behind the ear)	☐	☐
Infection in the test area (behind the ear)	☐	☐
Pain while sitting and laying the head down sideways	☐	☐

If the answer to any of the above questions is YES, the subject is NOT to be included in the study!

Part 2

Test side	Right ☐	Left ☐

Measurement 1 performed and saved	Yes ☐	No ☐
Position readjusted	Yes ☐	No ☐
Measurement 2 performed and saved	Yes ☐	No ☐

Cleaning performed before testing	
☐	Yes

DEPARTMENT OF ELECTRICAL ENGINEERING
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden
www.chalmers.se

CHALMERS
UNIVERSITY OF TECHNOLOGY