Vibration transmission with a bone conduction implant (BCI) on sheep skulls in vivo

Master of Science Thesis

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Abstract

Some patients who suffer from conductive or mixed hearing loss cannot fully regain their hearing with a traditional air conduction hearing aid. Instead they are referred to a treatment based on bone conduction. For many years the Bone Anchored Hearing Aid (BAHA) has been the preferred choice.

There are some drawbacks reported with the BAHA related to the percutaneous anchoring of the transducer that require daily care and which is prone to complications. Therefore a new non-skin penetrating hearing device called the Bone Conduction Implant (BCI) is under development. This method uses a transducer that is permanently implanted under the skin.

One step in the development of the BCI is to observe how the transmission of vibrations from the BCI to the skull changes over time. This can be evaluated by measuring the mechanical point impedance and the transfer function during the surgery when the BCI is installed. This initial data is then compared with data from measurements made 6 months later.

The aim of this master's thesis was to conduct the initial measurements on three living sheep while a BCI was implanted on each side of their head. Before the measurements were made the measurement equipment was calibrated and the entire setup was tested on a dry sheep skull. During the operation half of the implants were fitted with bone dust between the implant and the skull bone and the rest were not. The reason for this was to see if healing and bone remodelling is promoted by the presence of bone dust or not. This master's thesis explains how the initial calibrations and measurements were made on the sheep and presents the mechanical point impedance and transfer response function for each implant. Mathematical models were fitted to the mechanical point impedance and the transfer response function for each implant. From these models parameters were extracted that will be used for the comparison of the transmission properties when the measurements will be repeated 6 months later.

It has been observed that the usage of bone dust during implantation has a dampening effect and lowers the mechanical point impedance compared to not using bone dust. This is assumed to the opposite after 6 months as bone dust is expected to facilitate the development of a firm and rigid connection between the implant and the skull bone.

Keywords: bone conduction implant, BCI, bone anchored hearing aid, BAHA, mechanical point impedance, vibration transmission

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1 Introduction

1.1 Background

In this chapter background about the human ear, hearing loss and bone conduction implants are presented. The aim of this study is also presented.

1.1.1 The human ear

Hearing is a vital sense for the human being. People who have a hearing impairment will experience a big handicap and have a wish to regain as much hearing sense as possible.

The human ear is made up of three parts namely the outer, middle and inner ear as seen in figure 1. These parts work together in the task of passing the sound through the ear and converting it into an electrical signal that can be interpreted by the brain. In the outer ear the pinna acts like a shell that collects the sound waves, these then pass through the ear canal and reach the eardrum that will start to vibrate. The higher frequency the sound has the faster the eardrum vibrates. The vibrations are then transferred to the middle ear where they are amplified by the ossicles that are joined together with the eardrum and then passed on to the cochlea or the inner ear. Tiny hairs inside the cochlea are set into motion by the vibrations, this will generate an electric signal that excites the auditory nerve and it varies depending on the frequency and loudness of the sound. The signal is finally transferred via the auditory nerve to the brain where it is interpreted [1].

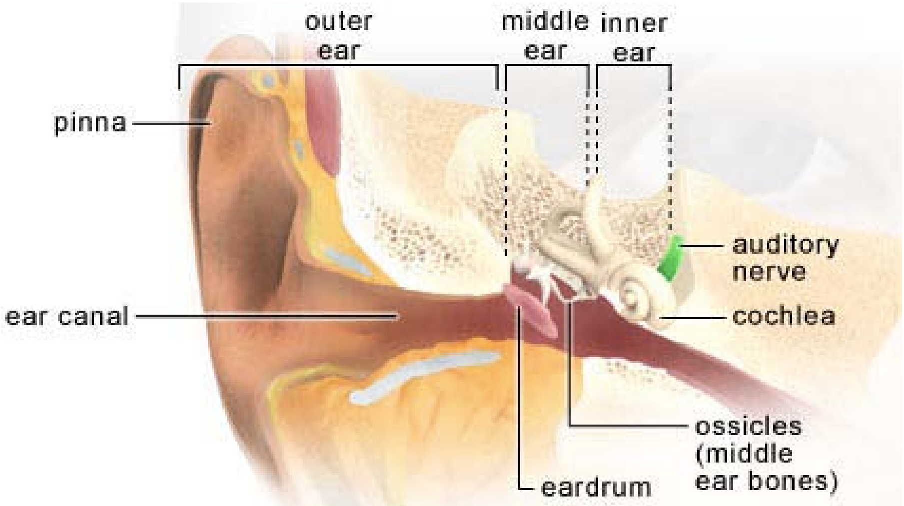

Figure 1. Anatomy of the human ear.

Sound can be perceived by the cochlea in two different ways, namely by air conduction hearing (AC) and bone conduction hearing (BC). In the case of AC, sound waves pass through the outer, middle and the inner ear. With BC, vibrations in the skull bone are transmitted directly to the inner ear and therefore bypass the outer and middle ear. One source for skull bone vibrations is through a person’s own voice.

1.1.2 Hearing loss

Hearing loss can be divided into two main types, namely conductive and sensorineural hearing loss. Conductive hearing loss occurs when there is a dysfunction in the outer or middle ear, resulting in that the sound transmission to the cochlea is impaired. Sensorineural hearing loss is an impairment that is due to damage to the inner ear or the pathway between the inner ear and the brain. A person who is suffering from both conductive and sensorineural hearing loss is said to have a mixed hearing loss.

A person can have a hearing impairment for many reasons. One of the reasons is ageing, a hearing loss progressing as a natural part of getting older. Repeated exposure to high sound levels, which is common in some occupations, can also be a reason. This is called noise induced hearing loss. The risk of obtaining a hearing loss can be minimized in these occupations with the usage of ear protection. These have not always been used which is why many people in the older generation suffer from hearing loss today.

Disease or illness can also be a cause for hearing loss. Mumps and scarlet fever are childhood infections that can destroy the eardrum and damage the ossicles causing hearing problems. Cardiovascular diseases and high blood pressure can lead to insufficient blood flow in the inner ear leading to problems with the hearing. One of the most common consequences with meningitis is considered to be hearing loss.

A baby can have an impairment of the hearing at birth. This can be a result of the genes passed on from the parents as well as the misuse of alcohol during pregnancy. In some cases premature birth is a cause for hearing loss [2].

1.1.3 The Bone Anchored Hearing Aid (BAHA)

Since the early 1980’s Chalmers has been doing research with the ear, nose and throat department at SU Sahlgrenska on bone conduction hearing aid, with focus on the bone anchored hearing aid (BAHA) system. This method involves a titanium screw that is penetrating the skin and anchored to the skull bone. An external abutment is attached to the screw and on the abutment a sound processor is attached. The sound processor will send vibrations through the titanium screw and to the skull bone. These vibrations will then propagate to the inner where they are interpreted. The BAHA device is illustrated in figure 2.

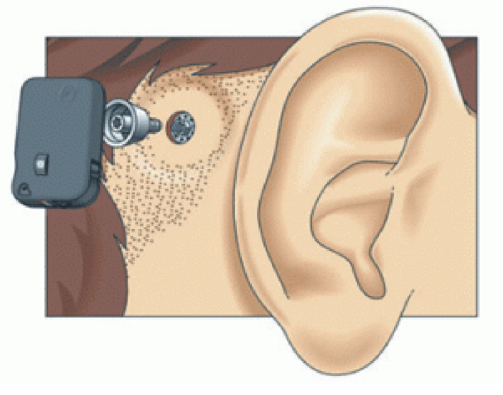

Figure 2. The BAHA device that consists of a bone anchored fixture, a skin penetrating abutment and a sound processor [3].

There have been some drawbacks reported with the BAHA. One of these is that the skin penetration requires daily care and that skin complications can occur. There is also a risk that the titanium screw will loose its connection to the skull bone if the implant is subjected to an external force. The titanium screw can also for no apparent reason become loose in some cases. Some patients are hesitant to the BAHA for aesthetic reason because of the titanium screw that will stick out of their skull bone and they are worried of what people around them might think.

1.1.4 The Bone Conduction Implant (BCI)

The drawbacks of the BAHA have lead to the research of a new non-skin penetrating hearing aid. This device called the Bone Conduction Implant (BCI) does not use a titanium screw to connect to the skull. Instead the BCI approach use a transducer that is encapsulated in a titanium chamber that is implanted under the skin and is hold in place by a titanium bar and screw. The sound signal is transmitted from a sound processor through the skin to a receiver coil using electromagnetic waves. The signal is then transferred to an implanted transducer that starts to vibrate. The function of the BCI is depicted in figure 3.

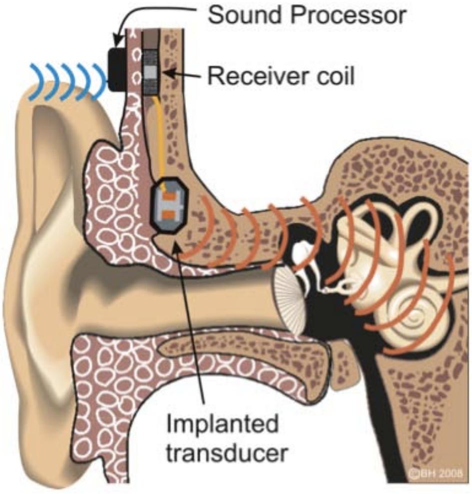

Figure 3. The BCI device comprising of a sound processor, receiver coil and an implanted transducer.

The biggest benefit of the BCI compared to the BAHA is that there is no skin penetration of the implant; this will reduce the risk of skin complications. The sound quality might also be improved with the BCI.

1.2 Aim of study

One step in the development of the BCI is to observe how the attachment in the interface between the BCI and the skull bone changes over time. This is done in an animal study that is divided into two phases. The animal model used is Gotland sheep.

During phase 1 of the animal study a BCI was implanted into each side of a total of three sheep. This gives a total of six BCI that were implanted. The transmission characteristics of the BCI will be observed by measuring the mechanical point impedance and transfer response function of the vibrations from one side of the skull to the other.

In phase 2 the sheep will be sacrificed, this occurs 6 months after phase 1.The measurements that were made in phase 1 will be repeated in the same way and compared with each other. During phase 2 a study of the implant to bone contact on a microscopic level will also be conducted.

This master’s thesis is focused on making the initial mechanical point impedance and transfer response function measurements on the sheep in phase 1. Before the measurements are made the measurement equipment was calibrated and tested on a dry sheep skull. The measurement data will be analysed and mathematical models that fit the mechanical point impedance and transfer response function will be made for each implant.

2 Theory

2.1 Mechanical point impedance

The mechanical point impedance can be described as the ability for a structure to be set into motion by an excitation force, the higher the mechanical impedance is the lower the motion is for a given force. Both the magnitude and the phase of the mechanical impedance is of interest as they both give important information. It is also necessary to do the measurements over a wide frequency range. The mechanical impedance is defined according to equation 1 where Z(jω) is the complex mechanical impedance, F(jω) is the excitation force and v(jω) is the responding velocity.

—— (1)

Instead of measuring the responding velocity it is also possible to measure the acceleration. The measured acceleration can be converted to velocity with a multiplication by jω as shown in equation 2.

—— (2)

In this study the acceleration will be measured and therefore equation 2 will be used [4].

2.2 Transfer response function

The transfer response function describes how vibrations transfer from one side of a skull to the other side. Different ways of defining the transfer response function can be made, in this study the transfer response function is defined as the acceleration at the contralateral side of the skull divided by the force at the ipsilateral side according to equation 3. Both the magnitude and phase of the transfer response function is needed for a complete measurement.

—— (3)

3 Materials

3.1 Gotland sheep

For the study a few different animal models were considered. One of the reasons why sheep was chosen is because of its relative large skull, which makes for an easier fitting of the implant. This also avoids the problems of having to scale down the experiment, which would happen with animals with smaller skulls. An important aspect was also that there was a need of getting hold of fresh and dry skulls of the animal for practicing purposes, for the implantation of the BCI and the measurements respectively. As these were relatively easy to get hold of it strengthened the choice of sheep as animal model.

The sheep chosen for this study were of the breed Gotland sheep that is shown in figure 4. All of them were female and around 3 years old when phase 1 of the study began in March 2011. Table 1 shows facts about the sheep that were used for the study.

Table 1: Sheep data.

Sheep	Chip id	Date of birth	Weight [kg]
1	499-08001	4 April 2008	74
2	103-08029	1 May 2008	66
3	216-08024	22 April 2008	67

Figure 4. One of the Gotland sheep used for the animal study.

3.2 Implant

The implant used was made out of titanium and was a so-called dummy containing no electrical components. It had the same size as the real implant. To make it possible to connect the impedance head to the implant an M2-threaded screw was attached to the top surface of the implant. After the measurements were done the m2-threaded screw was covered with a plastic cap to protect the sheep from unwanted irritation. The implant was hold into place with a slight pressure using craniofacial reconstruction components (bar and screws). These were manufactured by stryker and were made of titanium. In figure 5 the implant with the bar attached is depicted.

Figure 5. The BCI implant with bar attached.

4 Method

4.1 Setup

For mechanical point impedance measurements the impedance head was connected to the titanium implant by using an M2-threaded screw. A transducer was then connected to the top of the impedance head that received a signal generated by an Agilent signal analyzer. The Agilent used a swept sine signal from 100 to 10 kHz, with fixed amplitude voltages for each level over the whole spectrum.

Vibrations from the transducer excited the impedance head and the implant attached to the skull. The force and acceleration from gauges within the impedance head was measured during this time and the mechanical point impedance was calculated according to equation 2.

For the transfer response function an accelerometer was connected to the implant of the contralateral side. Same setup was used for the ipsilateral side measurements as with the point impedance measurements. Since both of the measurements use the same signal and the Agilent have four channels both of the measurements could be obtained during the same sweep. The entire measurement setup is illustrated in figure 6.

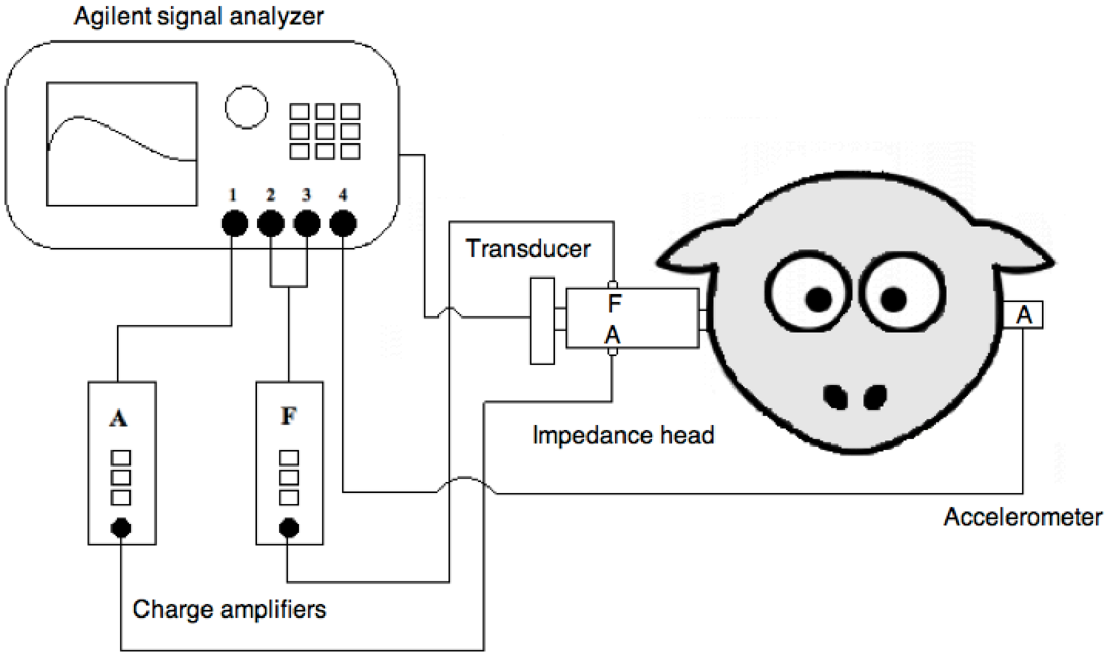

Figure 6. The measurement setup is composed of a signal analyzer, two charge amplifiers, a transducer, an impedance head and an accelerometer.

4.1.1 Agilent 35670A dynamic signal analyzer

The Agilent 35670A 4 channel FFT Dynamic signal analyzer seen in figure 6 was used to collect measurement data and also for generating the excitation signal. For the measurements the Agilent was used in swept sine mode, which gives the possibility to keep the signal constant over frequencies. There is also the possibility to use fast Fourier transform (FFT), which is faster than swept sine. The difference in time between swept sine and FFT mode was not an issue for us.

Measured data can be analyzed directly on the display of the Agilent. This way of analyzing wasn't used much instead the data was transferred to a computer and analyzed in Matlab.
The Agilent 35670A have many more features, for a full list and details visit the manufactures homepage [5].

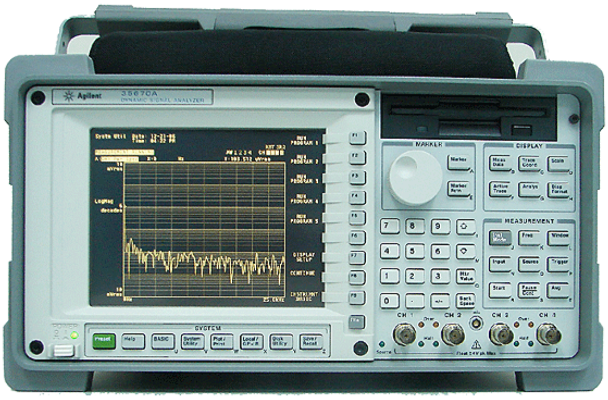

Figure 6. The Agilent 35670A – a powerful dynamic signal analyzer [5].

4.1.2 Impedance head

An impedance head type 8001 from Bruel & Kjær (B&K) was used to measure force and acceleration. The impedance head and its construction is shown in figure 7.
To measure the force and the acceleration at a single point the impedance head uses piezoelectric discs that are connected to known masses.

The principal of measuring the acceleration is that a seismic mass is connected to a first piezoelectric disc that measures the acceleration. A force that is proportional to the built-in seismic mass times the acceleration will be generated when the accelerometer is subjected to vibrations. The piezoelectric disc will thus give an output in form of a voltage that is proportional to this excitation acceleration force. A second piezoelectric disc is placed in series with the driving platform and thus this disc give an output that is proportional to the excitation force [6].

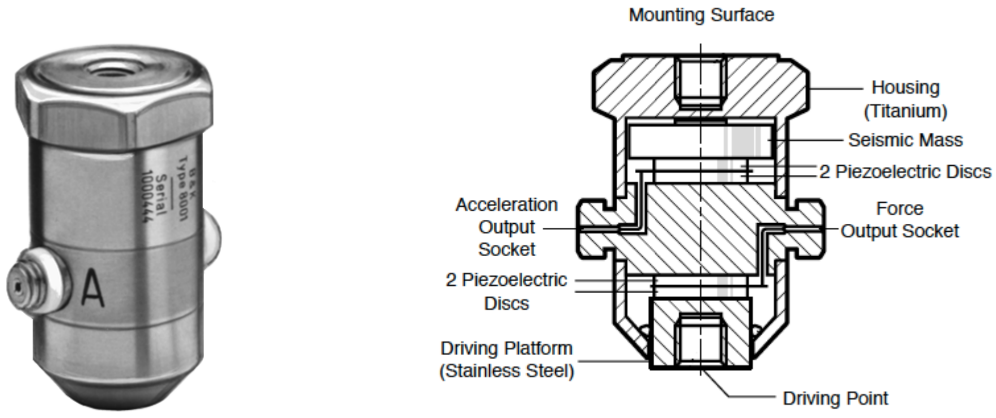

Figure 7. Overview of the B&K type 8001 impedance head [6].

4.1.3 Accelerometer

An accelerometer type 4518-003 from B&K depicted in figure 8 was used when the transfer response function was measured. The accelerometer has a built-in preamplifier that can be powered by ICP from the Agilent Signal Analyzer. This eliminates the need of a charge amplifier between the accelerometer and the Agilent [7].

Figure 8. The B&K type 4518-003 accelerometer used for measuring the transfer response function [7].

4.1.4 Charge amplifiers

To eliminate the influence of any stray capacitances between the impedance head and the Agilent charge amplifiers were used, one for each output of the impedance head. For the acceleration output a B&K Charge Amplifier Type 2651 was used and for the force output a type 2635 from the same manufacturer was used. Both the charge amplifiers are shown in figure 9.

Figure 9. Charge amplifier from B&K type 2651 used for the acceleration signal and type 2635 was used for the force signal.

4.1.5 Transducer

A transducers task is to convert an electrical signal into mechanical vibrations without distorting it [8]. For all of the measurements made a BEST designed by Bo Håkansson that is depicted in figure 10 was used. Two transducers were used in this master's thesis; they were labelled 813-15 and 813-17.

Figure 10. The BEST transducer is used to generate the exciting vibrations.

4.1.6 Dry sheep skull

A dry skull from a Gotland sheep was used for the purpose of calibrating the measurement equipment. It was also used for testing the measurement setup and practicing the measurement procedure of the phase 1 animal study measurements. A picture of the skull used with the accelerometer, impedance head and transducer attached can be seen in figure 11.

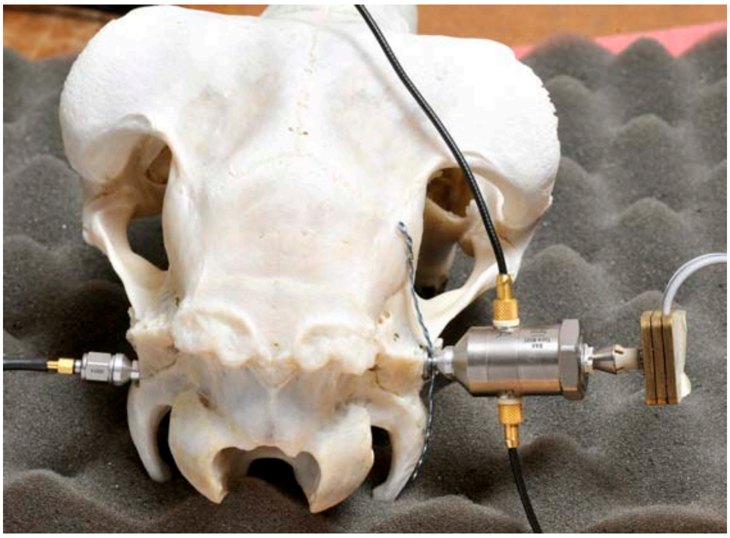

Figure 11. Dry sheep skull with the impedance head attached via the implant on one side of the skull and the response accelerometer attached on the other side.

4.1.7 Skull simulator

To measure the force output from the transducers a skull simulator TU-1000 shown in figure 12 was used. The skull simulator mimics the load properties of the human skull and gives a voltage output that is proportional to the force given by the transducer. The skull simulator has external power connected and is also connected to the Agilent which reads the output.

Figure 12: The skull simulator to the right and its external power to the left.

4.2 Calibration

4.2.1 Impedance head

For calibration of the impedance head a solid brass mass with a known weight was used. The weight was fastened with a rigid connection to the impedance head and a transducer was attached to the top of the impedance head. The force and acceleration was measured with a swept sine signal from 100 to 10 000 Hz. The force was then divided with the acceleration. When properly calibrated the measurement shows the weight of the brass mass as seen in figure 13. According to the second law by Newton the mass multiplied with the acceleration equals force; this was used to calculate the calibration constant according to equation 4. For lower frequencies the frequency response behaves like an ideal mass. The non-ideal mass behavior at higher frequencies is due to that the force piezoelectric disc compliance forms a resonance with the load mass giving a resonance frequency of approximately 9.4 kHz.

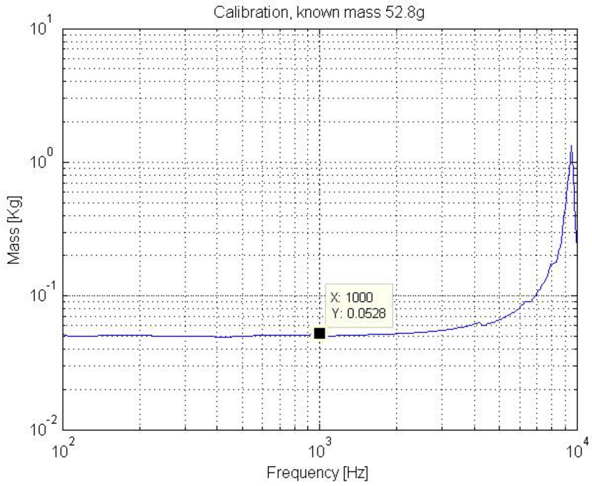

Figure 13. Graph obtained with a known mass connected to the impedance head. The calibration was made at 1 kHz.

– (4)

In equation 4, m is the mass below the force gauge, – is the measured data and is the calibration constant. The calibration constant was calculated to be 0.00929. This constant was applied to all our mechanical point impedance measurements.

There is a small mass attached to the impedance head below the force gauge that cannot be removed, this mass have to be subtracted when measurements are made. Figure 14 shows the force divided by the acceleration when the impedance head had no mass attached.

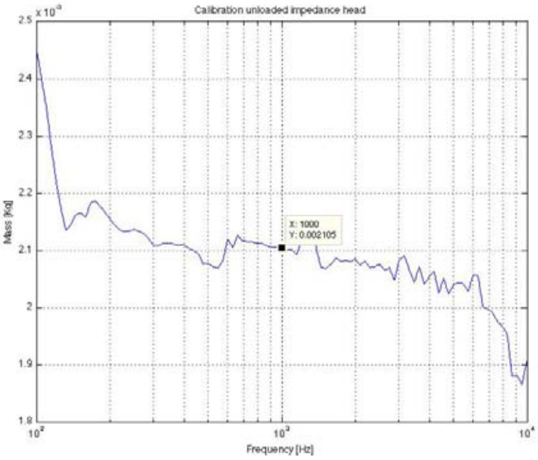

Figure 14. Resulting graph when no mass was attached to the impedance head.

The magnitude at 1 kHz was subtracted from all of the mechanical point impedance measurements, as seen in figure 14 the magnitude is 2.1 gram.

4.2.2 Accelerometer

The accelerometer was calibrated by connecting it to the impedance head and comparing the two accelerometers. Because the acceleration measured by the impedance head and the acceleration measured by the accelerometer should give the same result, the constant was set to give 1 at the reference point as in equation 5 below. 1 kHz was again used as reference point. For the transfer response function measurements, the force output of the impedance head was used and to get a correct value equation 7 was derived out of equation 5 and 6.

— — (5)

— — (6)

— = — — (7)

is the acceleration of the accelerometer, is the voltage of the accelerometer, and is the acceleration divided with the force at the impedance head, and is the voltage for the accelerometer divided with the force gauge at the impedance head, are the calibration contstants.

The calibrated graph of the measurement made can be seen in figure 15, notice that the magnitude is 1 at 1 kHz.

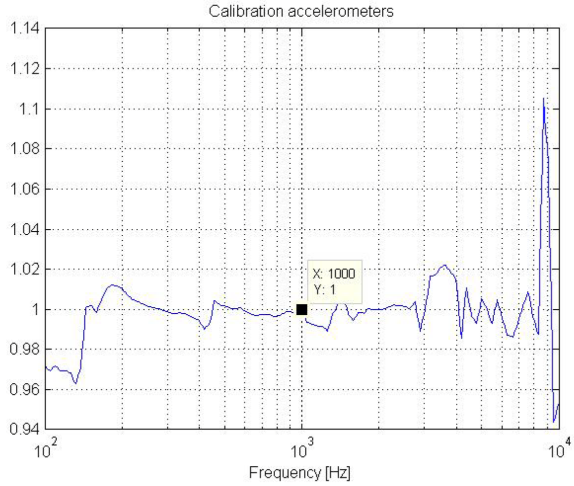

Figure 15. Calibrated graph of the accelerometer attached to the impedance head.

4.2.3 Input voltage to the transducers

One objective for this master's thesis was to do the measurements at three different levels; 40, 60 and 80 dB HL. It was soon realized that 80 dB HL was too high for our transducer when driving such low mass as the sheep head. Therefore the levels were changed to 40, 50 and 60 dB HL. Since dB HL changes with frequency it was decided to use 1 kHz as reference point. According to [9] 0 dB HL is 45.5 dB above 1 µN at 1 kHz. It was decided to use 46 dB instead, because it gives an amplification of roughly 200 times and is easier to do calculations with.

According to the data sheet of the impedance head the force gauge has a sensitivity of 391 — and the charge amplifier was set to —. Which set the reference point for 0 dB HL to µV.

The dry sheep skull was used to find the correct voltage levels for each transducer. It was done by looking at the force output of the impedance head and changing the voltage of the transducer until desired force output was reached for each level. Table 2 shows the results for the two transducers and corresponding voltage for the force output on the impedance head.

Table 2: Voltage setting for the transducers.

Level [dB HL]	Voltage from force gauge [mV]	Transducer 813-15 [mVrms]	Transducer 813-17 [mVrms]
40	7.82	40.0617	41.4989
50	24.7	123.7782	127.5508
60	78.2	377.2629	391.6348

4.3 Surgery – implant installation

The surgery to fit the implants was done by Dr Måns Eeg Petterson and Dr Anders Tjellström. The original plan was to install all of the implants into the three sheep during the course of a day. Because the installation of the implants on the first sheep took longer than expected there was only time to finish two sheep on this day. The third sheep was therefore fitted with implants on a different day a couple of weeks later. Implants were installed on both sides of the sheep skulls, which gave a total of six implants. It is important that the implants on the two different sides of the sheep skull are not mixed up with each other. Therefore it was decided to name the implants left and right as seen in figure 16.

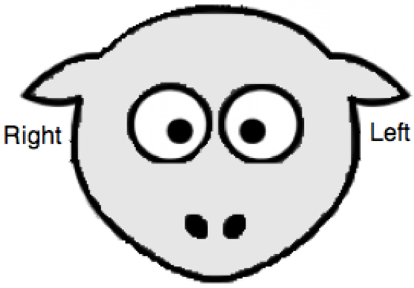

Figure 16. The two sides of the sheep skull.

Half of the implants were installed with bone dust in the implant to skull bone interface. The reason for doing this is to see if there is a difference in the two surgical methods and how it changes over time. Which implants were installed with bone dust and the day of the operation can be seen in table 3 below.

Table 3: Implant information.

Implant	Bone dust	Date of installation
Sheep 1 Left	No	23 February 2011
Sheep 1 Right	Yes	23 February 2011
Sheep 2 Left	Yes	23 February 2011
Sheep 2 Right	No	23 February 2011
Sheep 3 Left	Yes	6 April 2011
Sheep 3 Right	No	6 April 2011

Figure 17 shows one of the implants after it has been fastened to a sheep skull with the use of a titanium bar and screw. The surgeon made the estimation that the force that held the implant in place was at least 1 N.

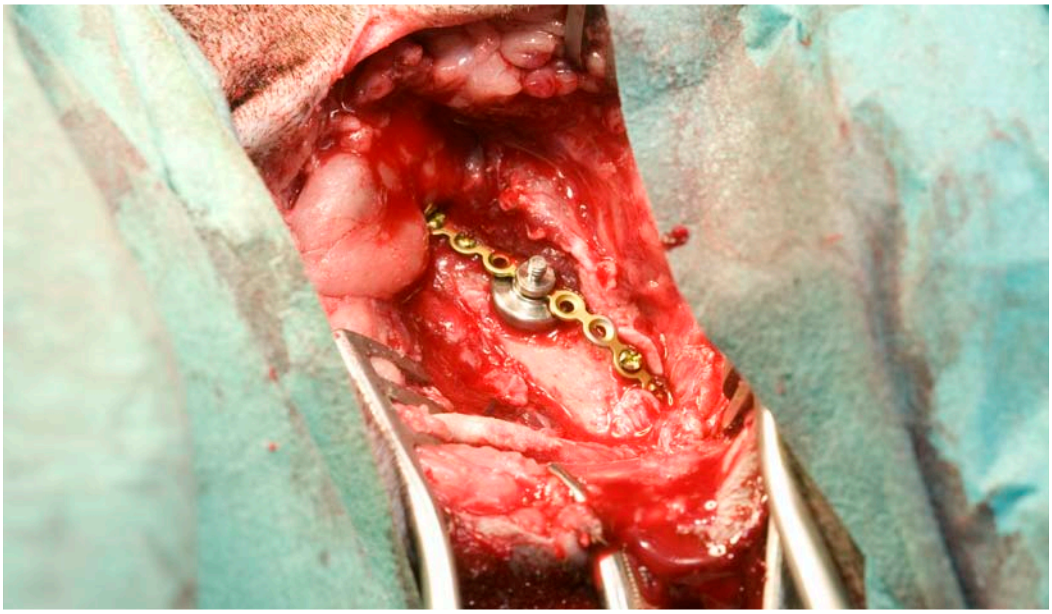

Figure 17. Implant attached to the sheep skull with the use of titanium bar and screw.

During the measurements the incision was held open with the use of surgical equipment as seen in figure 18 below.

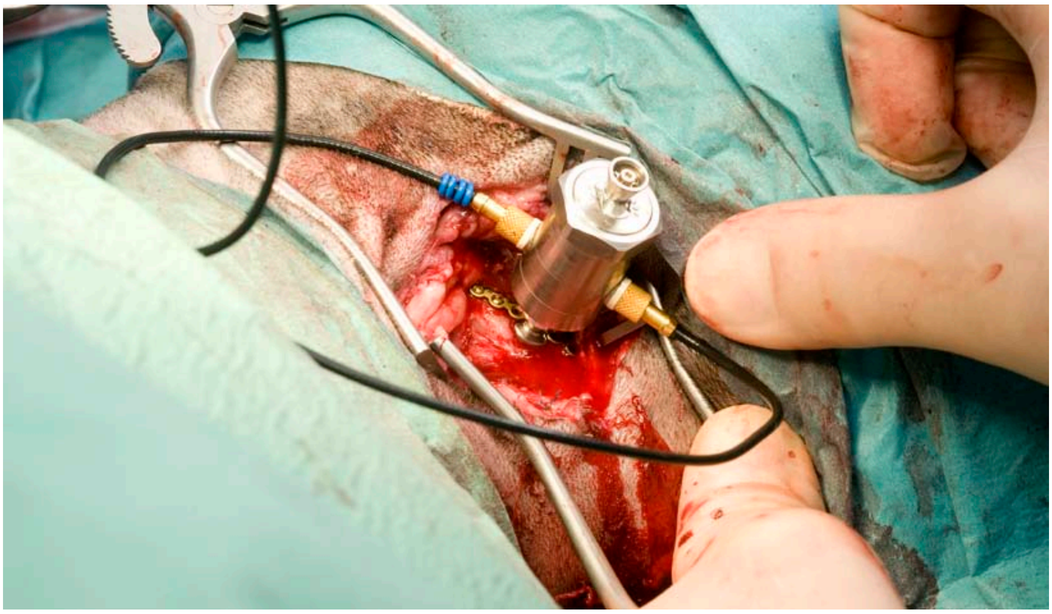

Figure 18. The impedance head attached to the implant with cables connected to its force and acceleration output.

5 Results

5.1 Excitation force level

Figure 19 shows the excitation force for three different input voltage levels. It can be clearly seen that there are three different levels that are 10 dB apart, which was the intention. The curves also have the same amplitude shape versus frequency.

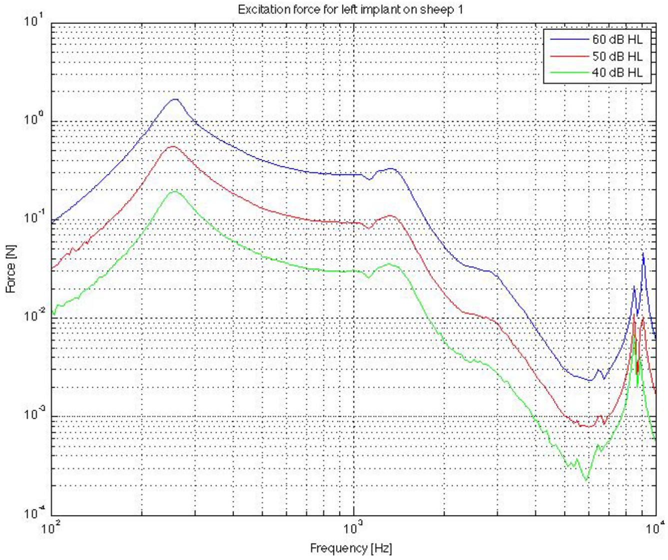

Figure 19. Excitation force at one of the implants for three levels.

There was almost identical force applied to the implants at lower frequencies. For frequencies above 600 Hz the difference is more noticeable as seen in figure 20.

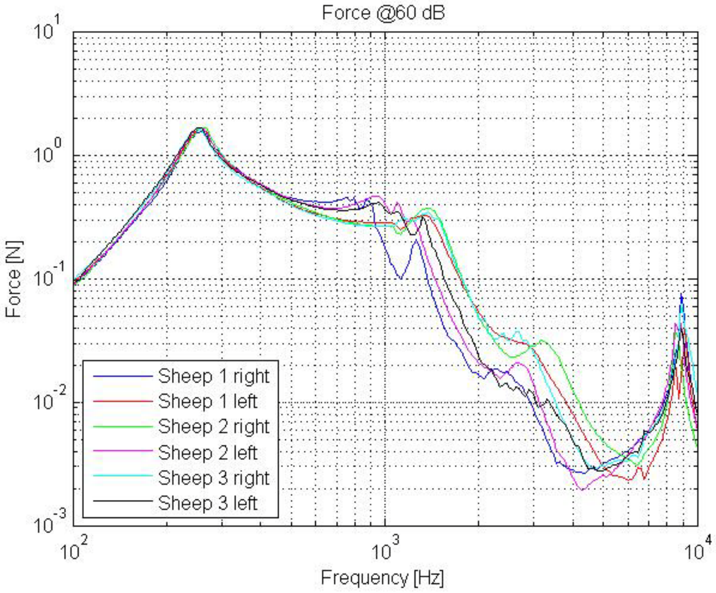

Figure 20. Excitation force levels for all implants at same input voltage level (60 dB HL).

5.2 Mechanical point impedance

The mechanical point impedance at the three different input levels is presented in figure 21. Using a lower force level yields a result that has more noise in the lower frequency compared tor using a higher input force. Therefore the 60 dB level was used for modeling and comparison purposes.

Figure 21. The mechanical point impedance for one implant at three different input levels.

In figure 22 the mechanical point impedance for all of the implants at 60 dB are shown. There are differences between the different implants; this is to be expected because the connection to the skull, mass of skull and the compliance of the bone differ from sheep to sheep. The general shape of the curves is the same and shows typical mechanical point impedance behaviour for a skull. Two different groups can be distinguished, one with lower magnitude and one with higher magnitude at 1 kHz. The three curves that belong to the group with the lower magnitude correspond to the implants that were installed with bone dust. Thus the bone dust has an initial dampening effect.

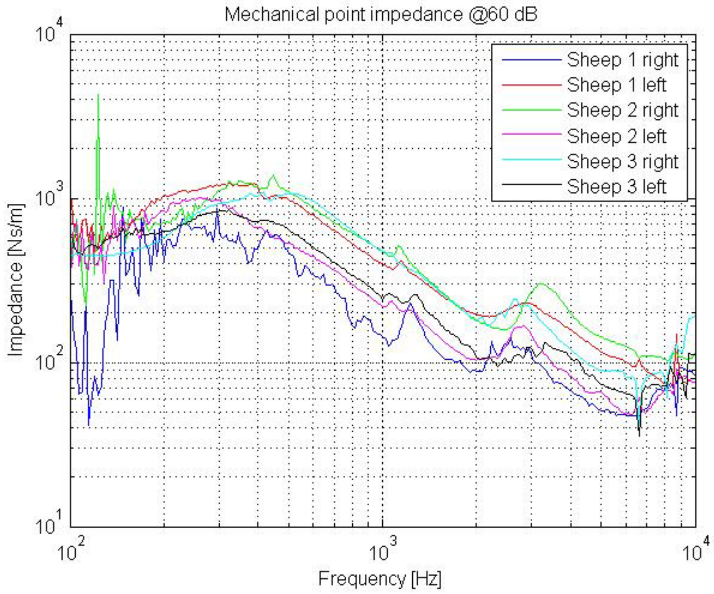

Figure 22. Mechanical point impedance magnitude for all implants.

The corresponding phase for the mechanical point impedance measurements are shown in figure 23. In the ideal case the phase should be between -90 and 90 degrees. The ideal case holds for all of the curves above 200 Hz.

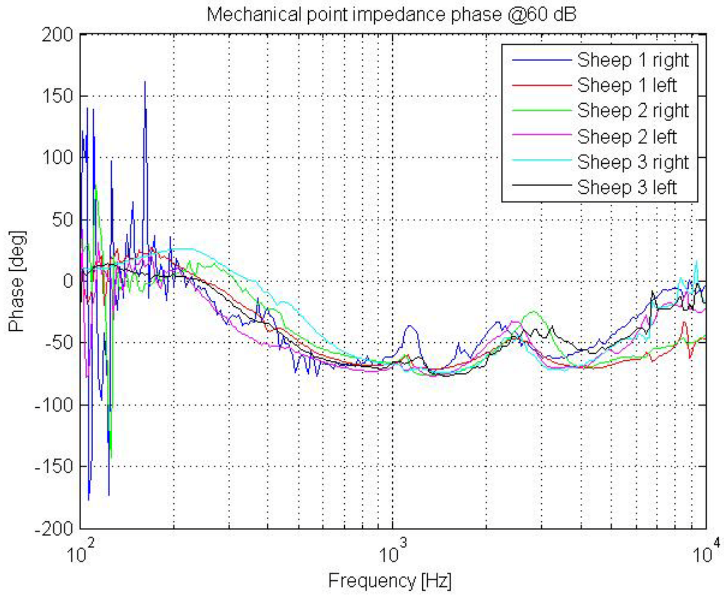

Figure 23. Mechanical point impedance phase for all implants.

5.3 Transfer response function

The magnitude of the transfer response function for all of the implants can be seen in figure 24. The behaviour of the transfer response function is similar for all of the implants, especially for frequencies below 2 kHz.

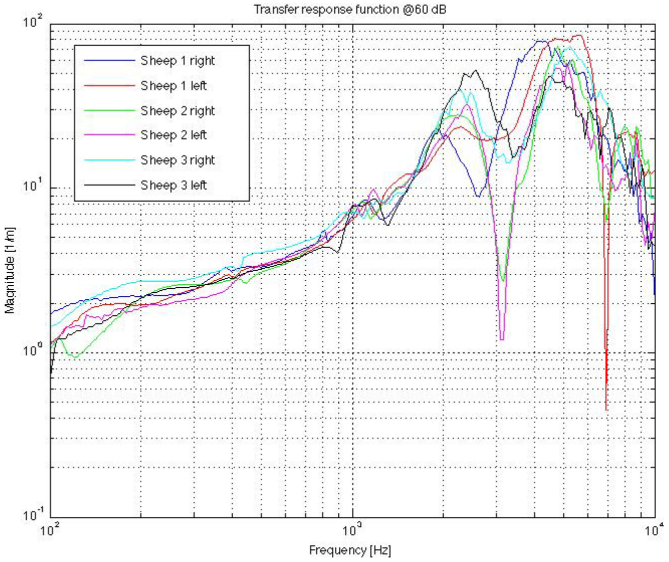

Figure 24. Magnitude of the transfer response function for all implants.

The main behaviour of the phase of the transfer response function presented in figure 25 is that it decreases, as the frequency gets higher. Although at frequencies around 3 kHz the phase has a sudden increase.

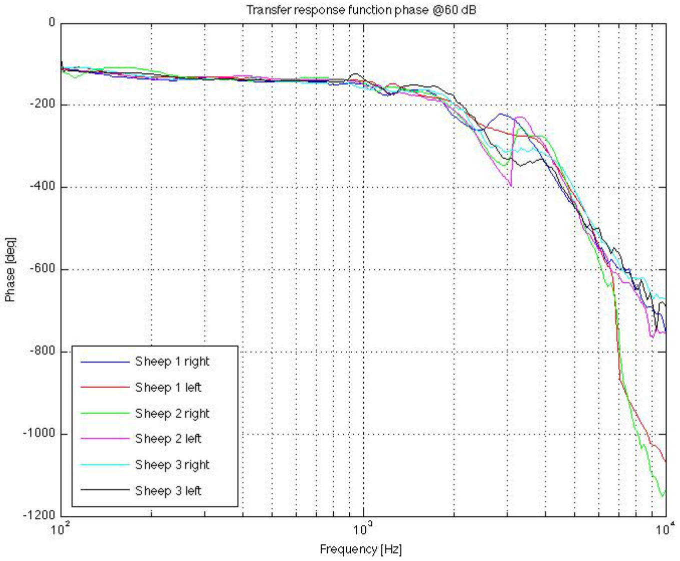

Figure 25. Phase of the transfer response function for all implants.

6 Discussion

6.1 Modeling

The modeling of the mechanical point impedance and transfer response function was done in Matlab using iterating prediction-error minimization (pem) method. The pem function creates a model by using an iterative nonlinear least square algorithm to minimize a cost function.
The reason for making models of the mechanical point impedance and transfer response function is that it is possible to calculate exact parameter values for comparison between phase 1 and 2 measurements in an objective and constant way. The models also give a better understanding of the vibration transmission.

6.1.1 Mechanical point impedance

For the mechanical point impedance measurements a model of second order was used according to equation 8, where A, B, C and D are constants and s is the Laplace operator.

$$\frac{\qquad}{\qquad} \qquad (8)$$

The peak in the lower frequency range is the feature of the mechanical point impedance that is of most interest. Therefore it is important that the model makes a good approximation of it. Figure 26 shows how well the model fits the measured data for one of the implants. It can be seen that model estimates the measured data satisfactory at low frequencies while the other parts are less accurate. The model could be made more accurate by using a model of higher order.

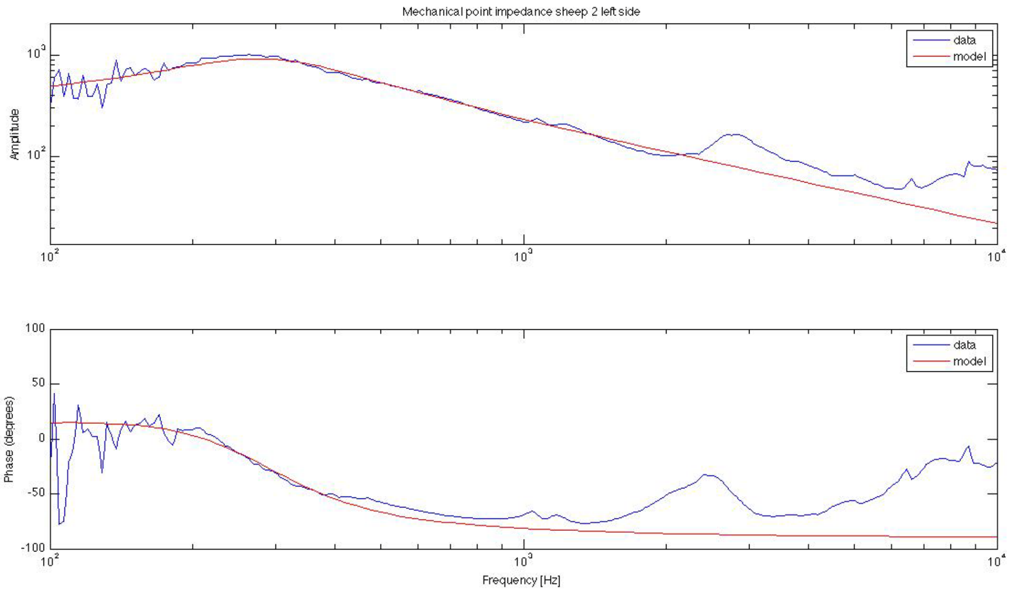

Figure 26. Mechanical point impedance model compared with measured data for an implant.

Parameters were extracted from the model to achieve an objective measure which should be used for the comparison when the study is terminated in phase 2. Most importantly the magnitude and the frequency of the peak in the lower frequency range was extracted. Also dc gain, which is the magnitude of the model at 0 Hz was extracted. Table 4 shows the values of the model parameters extracted for all implants and the mean value for each parameter. As pointed out before the implants that were fitted with bone dust have a smaller peak magnitude. The peak is also positioned at a lower frequency.

Table 4: Mechanical point impedance model parameters.

Implant	Peak magnitude [Ns/m]	Peak frequency [Hz]	Dc gain	Bone dust
1 left	1200	327	467	
1 right	593	282	154	X
2 left	918	275	382	X
2 right	1167	417	538	
3 left	797	324	410	X
3 right	1069	442	360	
Mean value	**957**	**345**	**385**	

When comparing the model parameters extracted from the phase 1 with the phase 2 parameters it is of interest to see how the peak of the mechanical point impedance changes. A higher peak magnitude indicates a connection to the skull that is stiffer and better. A more detailed description of the models created can be found in Appendix.

6.1.2 Transfer response function

The modeling of the transfer response function requires a more complex model compared to the one used for the mechanical point impedance. The main reason for this is that there are two peaks in the higher frequency range that need to be modelled accurately. Therefore a model of sixth order according to equation 9 had to be used to model the most important characteristics of the measured data.

(9)

With the transfer response function measurements both of the implants on the sheep skull are used simultaneously, one is used as input and the other for measuring the response. The transfer response function can be characterised by its two peaks in the higher frequency range. Figure 27 shows the model response based on one of the measured transfer response functions. It can be seen that the model fits the two peaks accurateley but is less accurate in the lower and higher frequency ranges.

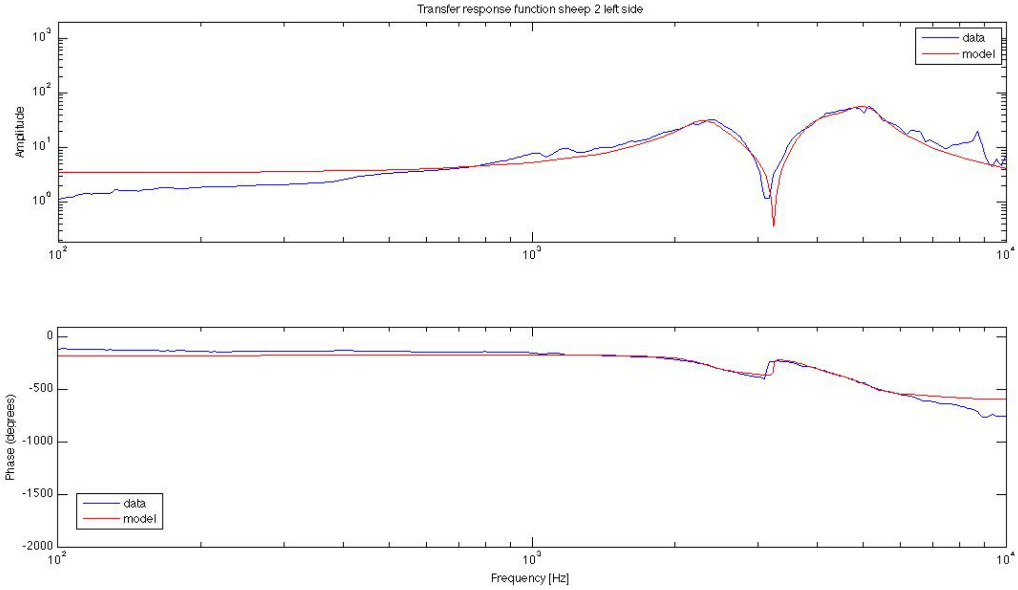

Figure 27. Transfer response model compared with measured data for an implant.

The model parameters that were extracted from the models are shown in table 5. For the left implant on the first sheep it was not possible to extract magnitude and frequency for the first peak. The reason for this was because the peak was too small to be detected.

Table 5: Transfer response function model parameters.

Implant	Peak 1 magnitude [1/m]	Peak 1 frequency [Hz]	Peak 2 magnitude [1/m]	Peak 2 frequency [Hz]	Dc gain
1 left	-	-	88	5623	-1.8
1 right	21	1820	80	4074	5.2
2 left	31	2291	57	4955	-3.5
2 right	29	2090	71	4677	-3.6
3 left	51	2399	47	4842	-2.5
3 right	38	2213	74	5189	-3.2
Mean value	**34**	**2163**	**70**	**4893**	**-1.6**

In the phase 2 measurements of the animal study it will be of interest to compare the two peaks with the phase 1 measurements and see how the magnitude and frequency changes. In Appendix A more detailed information about the mathematical models can be found.

6.2 Error analysis

The decibel calibrations are done on a dry skull, this yield slightly different results than on the living sheep skull. If the force graphs from the measurements are studied it is obvious that the force is slightly higher than desired. This is something that the people redoing the measurements have to take into account. If the same equipment is used the next time this shouldn't be a problem.

The point impedance measurement is well analysed by Bo Håkansson in [10].
He concludes that the impedance head can be used to do accurate point impedance measurements when calibrated correctly. We can expect to have the same error sources as in the article; the force crystal compliance, the mass in front of the force crystal and acceleration crystal compliance.

Since our measurements are done during surgery there is chance that other instruments such as the clamps holding the incision open or the doctor's hands effect the measurements.

The transfer response functions major source for errors is the fact that both implants are used for each measurement. If things turnout as expected and the implants with bone dust gain a better connection after 6 months, effects of this will show up on the transfer response function measurements for both implants of the sheep.

The calibrations are all made at 1000 Hz as reference point and then applied to the whole frequency spectrum. Since the magnitude of the error changes with frequency, this error is in general small.

7 Conclusions

It seems that the mechanical point impedance and transfer response function are good measures of the vibration transmission. The measurements and the models that have been made should be reliable enough to make good enough analysis of what has happened to the implants during the 6 months.

It was calculated that the average peak magnitude of the mechanical point impedance was 957 Ns/m and that it was located at the average frequency of 345 Hz.

The usage of bone dust has an initial dampening effect but may promote bone remodelling over time.

8 Future work

The future measurements in 6 months time will show how well this type of connection works. Then it will also be possible to study how the bone has healed and if the body has accepted the implant.

There are different ways to hold the implant in place using a titanium bar and relying on the flex is not the only way. When redoing the measurements it is also possible to see how well this bar has worked.

In this report the implant had an almost flat surface connecting to the skull. This might not be optimal. Therefore a study with different surfaces of the implant could give an implant that yield better end result. Doing the same studies on humans is also a must before commercialization of the BCI can begin.

9 References

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10 Appendix

Mathematical model coefficients

Mechanical point impedance

Implant	A	B	C	D
1 left	2626e3	2132e6	2348	4567e3
1 right	1039e3	5022e5	1815	3251e3
2 left	1400e3	1259e6	1710	3298e3
2 right	2624e3	4112e6	2603	7648e3
3 left	1732e3	1972e6	2468	4808e3
3 right	2794e3	2944e6	2789	8182e3

Transfer response function

Implant	A	B	C	D	E	F
1 left	-90960	-7033e5	2025e10	-2163e14	-1037e20	-2872e23
1 right	-161300	1877e5	2268e10	-323e16	-2481e19	-3467e23
2 left	-189400	3949e6	-1741e11	5573e14	-4007e19	-4427e23
2 right	-71640	-4124e5	-423e11	-1089e15	-4771e19	-6263e23
3 left	-16900	-1755e6	-8836e10	6374e15	-1763e20	-1167e24
3 right	-17410	5177e6	1127e11	2102e14	-1167e20	-1132e24

Implant	G	H	I	J	K	L
1 left	18940	2388e6	3051e10	1475e15	1003e19	1613e23
1 right	16020	2031e6	1795e10	1015e15	3409e18	9282e22
2 left	14050	1876e6	1609e10	9715e14	3671e18	1273e23
2 right	10600	2263e6	1481e10	1398e15	4072e18	1754e23
3 left	18550	3491e6	3695e10	2879e15	1191e19	4628e23
3 right	2197	3165e6	3711e10	2502e15	1063e19	3555e23