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USE OF ASSR IN ESTIMATION OF HEARING THRESHOLDS FOR COCHLEAR IMPLANT USERS

Master's Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Technology.

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HELSINKI UNIVERSITY OF TECHNOLOGY	ABSTRACT OF THE MASTER'S THESIS

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A cochlear implant is a surgically implanted electronic device that bypasses damaged inner ear and provides a sense of sound to a person who is profoundly deaf or severely hard of hearing. It produces an electrical stimulus, which bypasses the damaged or missing hair cells and stimulates the remaining auditory neurons directly.

Hearing testing by traditional methods is subjective and is based on the sound perception that patient reports. From children or difficult-to-test patients this kind of feedback is not possible to receive. To define the patient's hearing ability without active participation or cooperation, objective hearing tests can be applied. Since the worldwide introduction of hearing screening in newborns, the need for objective audiometric techniques to quantify hearing thresholds has increased.

Auditory steady state response (ASSR) is a new research method for determining brainstem or cortical responses caused by sound stimuli. With the ASSR method it may be possible to record responses elicited by sound stimuli given through the cochlear implant. This could offer an opportunity to objectively determine an implanted patient's hearing threshold. The purpose of this research was to study ASSR responses with cochlear implant patients and to determine how ASSR can help in programming implant processor with difficult-to-test patients and children who cannot report their auditory perception.

The results of this study strongly suggest that ASSR parameters measured using stimulation through cochlear implant can be used in estimation of patient's audiogram. With further study it might be used in determining the parameters for the programming of the implant processor.

Keywords: cochlear implant, auditory steady-state response, objective diagnosis methods for hearing loss

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Sisäkorvaistute on osittain kirurgisella toimenpiteellä korvaan asetettu elektroninen laite. Sen avulla ohitetaan vahingoittunut sisäkorva ja voidaan tuottaa kuurolle tai vakavasti kuulovammaiselle henkilölle ääniaistimuksia. Se tuottaa sähköisen ärsykkeen, joka ohittaa vahingoittuneet tai puuttuvat simpukan karvasolut ja stimuloi suoraan kuulohermoja.

Kuulon testaus perinteisillä menetelmillä perustuu potilaan antamaan subjektiiviseen palautteeseen. Lapsilta ja vaikeasti testattavilta potilailta tällaisen palautteen saaminen on mahdotonta. Kuulon mittaus ilman potilaan aktiivista osallistumista ja yhteistyötä on mahdollista objektiivisia kuulonmittausmenetelmiä käyttäen. Objektiivisten kuulonmittausmenetelmien tarve on kasvanut maailmanlaajuisen vastasyntyneiden kuulon tutkimuksen myötä.

Auditory steady-state response (ASSR) on uusi tutkimusmenetelmä, jolla voidaan mitata ääniärsykkeen tuottamia aivorunko- tai kortikaalivasteita. Sen avulla on mahdollista objektiivisesti arvioida potilaan kuulokynnys taajuusspesifisti. ASSR:n avulla ärsykkeet voidaan antaa suoraan sisäkorvaistutteen kautta, joka mahdollistaa sisäkorvaistutepotilaiden objektiivisen kuulonmittauksen. Tämän tutkimuksen tarkoituksena oli tutkia ASSR-vasteita sisäkorvaistutepotilailta ja selvittää voiko näitä vasteita käyttää apuna lasten ja vaikeasti testattavien potilaiden istutteen säätämisessä.

Tutkimuksen tulokset viittaavat vahvasti siihen, että sisäkorvaistutteen kautta stimuloituja ASSR-vasteiden parametreja voidaan käyttää potilaan audiogrammin estimointiin. Jatkotutkimuksien myötä voi olla mahdollista, että niitä voidaan käyttää hyväksi sisäkorvaistutteen prosessorin parametrien ohjelmoinnissa.

Avainsanat: sisäkorvaistute, auditory steady-state response, objektiivinen kuulonmittausmenetelmä

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I wish to thank also Ph.D. Riitta Korpela, who encouraged me to contact the department of othorhinolaryngology back in 2005, when I became interested in cochlear implants in the first place. Thanks to all test patients for their time and cooperation.

Finally, I want to thank my parents for their support throughout my studies.

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Johannes Hautamäki

Contents

Abbreviations

ABR	Auditory Brainstem Response
ACE	Advanced Combination Encoders
AD	Analog to Digital
AEP	Auditory Evoked Potentials
AGC	Automatic Gain Control
AM	Amplitude Modulation
ASSR	Auditory Steady-State Response
CIS	Continuous Interleaved Sampling
DA	Digital to Analog
DIB	Diagnostic Interface Box
EEG	Electroencephalogram
FDA	US Food and Drug Administration
FFT	Fast Fourier Transform
FM	Frequency Modulation
HL	Hearing Level
MCL	Most Comfortable Level
MM	Mixed Modulation
RMS	Root Mean Square
SAM	Sinusoidally Amplitude Modulated
SAS	Simultaneous Analog Stimulation
SNR	Signal to Noise Ratio
SPEAK	Spectral peak

1 Introduction

For centuries people believed that the hearing system couldn't be restored to the deaf. It wasn't until forty years ago that scientists tried for the first time to restore hearing by stimulating the auditory nerve. At first, results were not so encouraging when patients reported that speech was unintelligible. In spite of all, scientists kept on researching and developing different methods for delivering electrical stimulus to the auditory nerve, and the auditory sensations gradually came closer to sounding more like normal speech.

Nowadays, a prosthetic device called cochlear implant can be implanted in the inner ear and part of hearing can be restored to profoundly deaf people. Some individuals can communicate without lip-reading and signing and for some children a cochlear implant can make it possible to go to school with children with normal hearing. This result can be attributed to efforts of scientist from various fields including otolaryngology, physiology, bioengineering, speech processing and signal processing.

Cochlear implants were some time ago still a quite controversial topic but are now a generally accepted form of rehabilitation for carefully selected deaf individuals. Though there is still some controversy, it is not anymore about should humans be implanted or not but what kind of implant is applicable to different patients. Cochlear implants haven't merely become an accepted treatment for sensory deafness, they have come of age.

The purpose of this research is to study Auditory steady-state responses (ASSR) responses with cochlear implant patients and to determine how ASSR can help in programming implants with difficult-to-test patients and children who cannot report their auditory perception. In order to understand what is a cochlear implant and how does it work, this document first gives an overview on the basis of human speech production and hearing system. Then the basic principles and characteristics of a cochlear implant are introduced and further to whom and how the implantation can be done.

After the basic knowledge of cochlear implants has been presented, the basis for the present research is introduced concentrating on the objective assessment methods for frequency specific hearing thresholds. Then the study is being introduced and we present the procedure, results and conclusions of different measurements and finally sum up all the results and make the final conclusions based on them.

2 Background

2.1 Speech production

Scientists designing cochlear implants need to understand what information speech signal carries and what part of it is perceptually most important. This information has to be preserved in order to maintain the intelligibility of the speech signal. In biology, the components of speech are produced in the vocal organs (see Figure 1). As speech signal has reached the listener's ear it goes through a multi-phased analysis until, at best, the linguistic and conceptual reconstruction of information is reached by the recipient. This section reviews some basic concepts of speech communication from the viewpoint of phonetics and Finnish language.

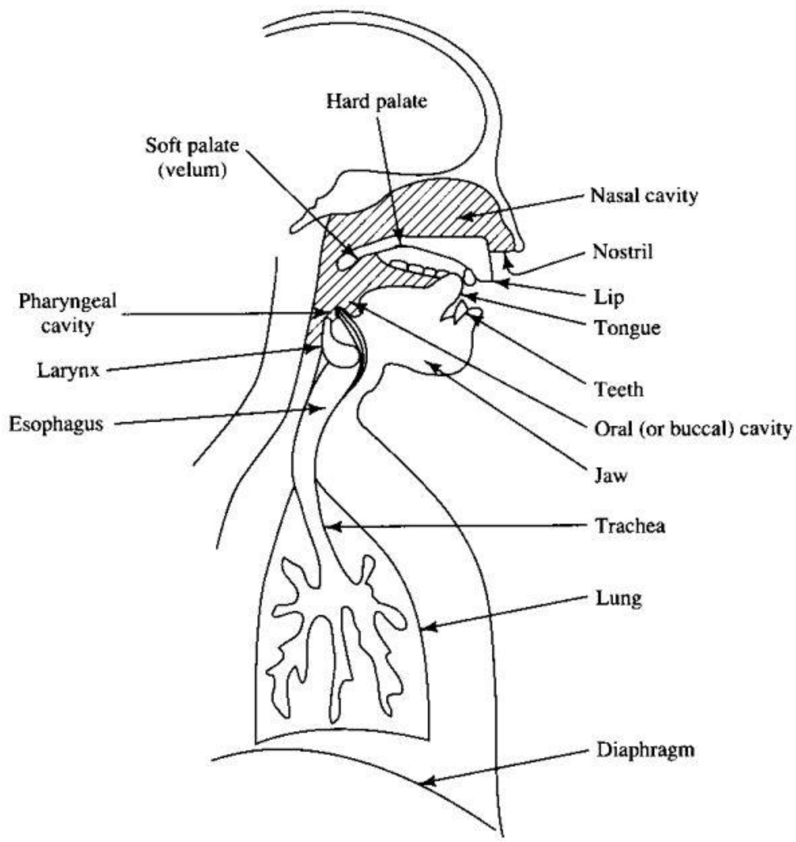

Figure 1. Cross sectional view of human speech production mechanism. The lungs and the associated muscles act as the source of air for exciting the vocal mechanism. Airflow from the lungs causes vocal cords to oscillate creating phonation. The sound is modulated in spectrum in passing through the throat, the oral cavity, and possibly nasal cavity [62].

2.1.1 Human vocal organs

Vocal cords, phonation

Voiced sounds consist of fundamental frequency (F0) and its harmonic components produced by vocal cords in the larynx. Vocal cords are two horizontal and elastic vocal ligaments that are movable by muscles. The opening between vocal cords is called glottis. The back ends of the vocal cords are attached to the arytenoid cartilages, by which the size of the opening can be varied. The opening is largest during the normal breath and almost closed when vocalizing. When air flow from the lungs is enforced to go through the opening the resulting air pressure on the surface of the vocal cords moves them into the first cycle of the motion. If airflow continues, the vocal cords will continue to oscillate in and out creating phonation. Oscillating frequency represents the fundamental frequency of speech which is approximately 120 Hz with men, 200 Hz with women and with children even higher.

Vocal and nasal tract, articulation

Before pressure pulses from the vocal cords become audible, the shape of the pharynx and the oral and nasal cavity, and especially if these tracts are open or not, interact with the sound substantially. The effect of these organs is called articulation.

The larynx, pharynx and oral cavity constitute a 17 cm long acoustic pipe that is called the vocal tract. A nasal cavity diverged behind the velum is called a nasal tract. When vocalizing nasal phonemes the velum lowers to the front, opening this tract. Thus, the vocal and the nasal tract process the glottal excitation. The vocal tract is a variable acoustic signal filter that produces a number of moving resonance spots, the formants. The measurements of the tract and particularly its cross-sectional area define the characteristics of this filter. The position of the tongue and its movements affect most significantly to the shape of the profile. The butt of the tongue can change the cross-sectional area of the pharynx and the lead may narrow or close the front of the tract. Also movements of lips and chin participate in adjusting the profile and the acoustic properties of the vocal tract.

The effect of the measures and the physical properties of a vocal tract to its acoustic transfer function is very complex. The tract is so called distributed system where the essential parameters and variables are continuous by nature, distributed over the whole tract. Thus, only a few parameters of the tract can directly affect to parameters of the transfer function alone and certain transfer function is constituted by the entire vocal tract. On the other hand, quite different vocal tract profiles may produce similar transfer characteristics.

When the vocal cords are tensed the airflow causes them to vibrate producing voiced sounds like /a/ and /o/ (see Figure 2). When the vocal cords are relaxed, in order to produce a sound, the airflow must pass through a constriction in the vocal tract and thereby become turbulent, producing unvoiced sounds like /f/ or /s/ (see Figure 3), or it can build up pressure behind a point of total closure within the vocal tract, and then when the closure is opened, the pressure is suddenly and abruptly released causing a brief transient sound like /k/ or /p/.

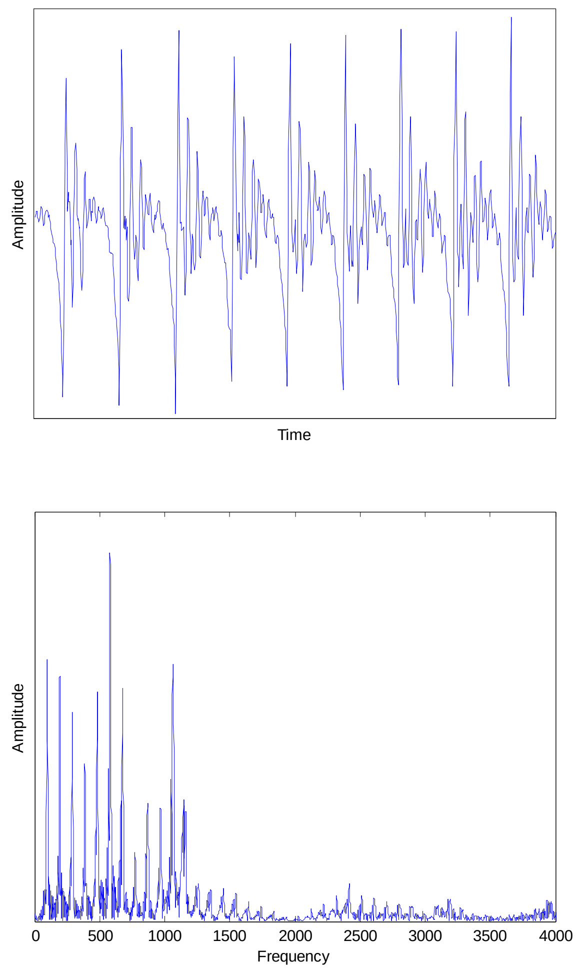

Figure 2. Diagrammatic representation of voiced sound /a/ in the time domain (upper) and the frequency domain (lower). The periodicity is easily found in the time domain representation. In the frequency domain it can be seen that the signal energy has concentrated at lower frequencies.

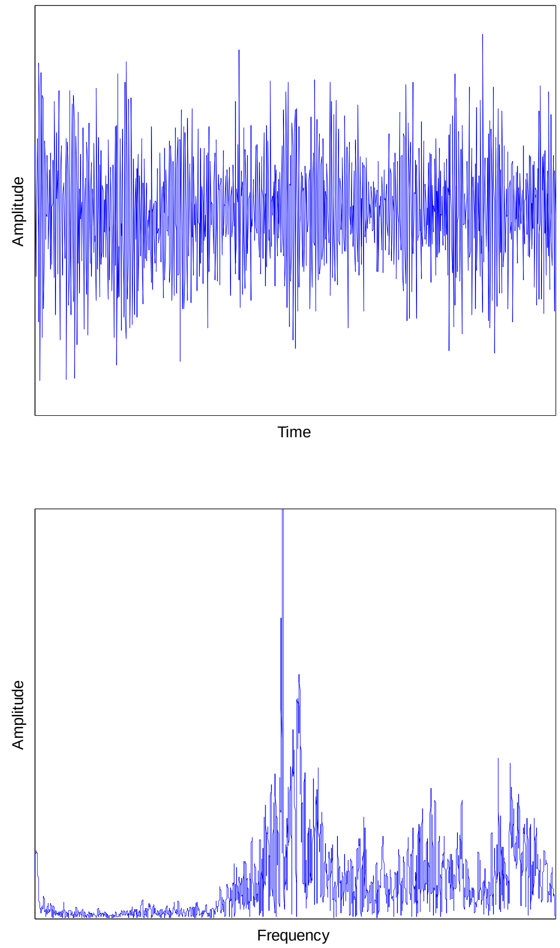

Figure 3. Diagrammatic representation of unvoiced sound /s/ in the time domain (upper) and the frequency domain (lower). In the time domain representation no periodicity can be found and signal can be interpreted as noise. In the frequency domain it can be seen that the signal energy has concentrated at higher frequencies.

3 Ear anatomy

Although the structure and the function of the human hearing system are suggestive of hearing system of many animal species, the human hearing system has a unique task and ability to analyze and recognize the speech sound. The main function of an ear is to receive a sound wave traveling in the air and to mediate it to the auditory nerves in order to be analyzed. The advantage of two ears instead of one is better directional hearing and on the other hand better reliability since damaging one ear does not make the whole hearing system disabled. The ear can be divided into three parts: outer, middle and inner ear, that all have their own function and way of action (see Figure 4).

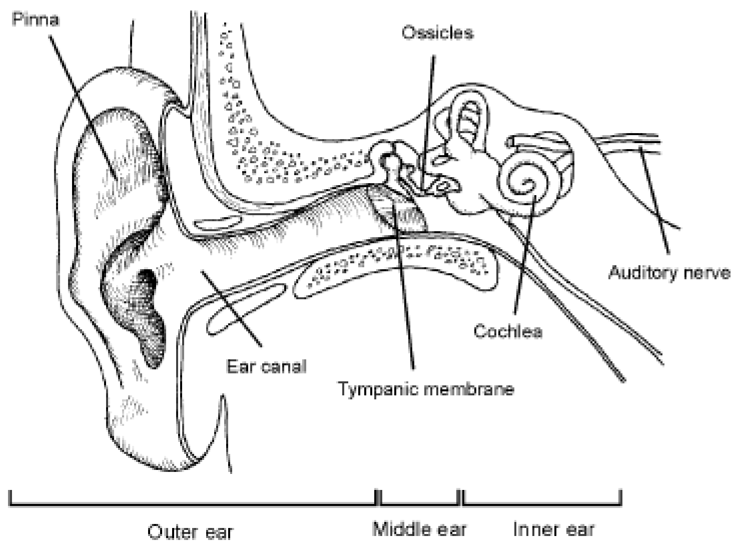

Figure 4. Simplified diagram of human ear. [51]

3.1 Outer ear

The parts of an outer ear are the pinna and the ear canal. An interface between the outer and middle ear is the tympanic membrane (eardrum). The outer ear is a passive and linear system where the behavior of a sound follows perfectly the laws of acoustics. Thus, the outer ear does not react to the sound in any way or analyze it, but only mediates and filters the sound to the middle ear.

The effect of the pinna is important in high frequencies. If the pinna was missing and the head was a regular ball, it would not be possible to tell apart sounds coming from obliquely forward (e.g. 45 degrees) and symmetrically from the behind (e.g. 135 degrees). The pinna causes different responses for sounds coming from the front and behind and thus improves the directional hearing.

The ear canal can be approximated with an acoustic pipe, with the average length 22.5 mm, diameter 7.5 mm and volume 1 cm^3. The acoustic transmission line ends with the acoustic impedance of the tympanic membrane. The lowest resonance frequency of the ear canal is approximately at 3-4 kHz. As a consequence this frequency range is emphasized in the real ear about 10 dB. With the acoustic waveguide theory it can be proved that up to 20 kHz frequency only the lowest waveform, so called (0,0) – form, propagates in the ear cavity. It is a plane wave that propagates parallel with the cavity. Thus, the difference in the sound pressure level between the opening in the ear and the eardrum is independent from how and where the sound comes to the outer ear. Furthermore, the ear cavity does not have an effect on directional hearing. Only the pinna and the diffraction of the head produce the differences of the signals between ears that make directional and spatial hearing possible.

The tympanic membrane transforms the waves traveling in the air into a mechanical vibration to the auditory ossicles. The tympanic membrane vibrates easily though its acoustic impedance is not matched to the impedance of the ear cavity. In the frequency range 600 Hz – 8 kHz the absolute value of the impedance of the tympanic membrane is approximately 2-4 times the acoustic impedance of the ear cavity. In the low frequencies the reactive part of the impedance grows deeply.

3.2 Middle ear

The middle ear begins from the tympanic membrane and reaches to the oval window. The main parts are the auditory ossicles: malleus, incus and stapes. The purpose of the middle ear is the impedance matching between the air in the outer ear and the fluid in the inner ear. The characteristic impedance of the fluid is approximately 4000-fold to the one of the air. The ossicles act as an impedance transformer that transforms the low pressure and high particle velocity in the air to the high pressure and low particle velocity in the fluid. The malleus and the incus do not move compared to each other except in case of very powerful and low sounds.

The function of the middle ear as a transformer is based on the fact that the square area of the stapes (approximately 3mm^2) is considerably smaller than the square area of the tympanic membrane (65 mm^2). However, the tympanic membrane does not vibrate like a piston so the equivalent area is much smaller than the physical one. The auditory ossicles act also as a lever, whose lever ratio is approximately 1.3. The total transformation ratio of the middle ear is approximately 18. Without the growth of the pressure in the oval window caused by the middle ear, the oval and the round window would have the same pressure. Thus the amount of the sound energy mediated to the inner ear would be very small.

The tube between the middle ear and the pharynx is called Eustachian tube. Its function is to compensate the static pressure difference between the outer and the middle ear for example in case of swallowing, internal otitis or flying. The pressure difference deviates the tympanic membrane so that the impedance of the tightened membrane increases and because of the impedance matching the sensitivity of the hearing decreases especially at low frequencies.

Stapedius reflex is an involuntary contraction of the stapedius muscle that occurs in the middle ear when a high intensity sound is presented to the ear. The contraction occurs with tens or hundreds of milliseconds delay. The reflex stiffens the chain of the ossicles and thus decreases the transmission of vibrational energy to the inner ear. The sensitivity of the hearing decreases mainly at low frequencies. The purpose of the stapedius reflex is probably to protect the ear. However, the protective effect is quite insignicant because high-frequency sounds do not attenuate and in case of impulse the reflex works not until the sound has already propagated to the inner ear.

3.3 Inner ear

The essential part of the inner ear for hearing system is called cochlea. The cochlea is filled with fluid and is connected to the middle ear through the oval and the round window. The oval window is covered by the stapes and the round window by an elastic membrane. The cochlea is a spiral organ that has approximately 2.7 rounds and is about 35 mm long.

The movement of the stapes makes the fluid to vibrate so that also the basilar membrane inside the cochlea begins to vibrate as well. At the side of the basilar membrane is the organ of Corti. It has several rows of hair cells that are vibration-sensitive receptors. Hair cells convert the movement information into nerve impulses in the auditory nerves. In total there are approximately 20 000-30 000 hair cells nearly at a regular density along the basilar membrane.

The cochlea is a very complex and sensitive organ. In addition to the basilar membrane there is also tectorial membrane and Reissner’s membrane in the cochlea. The fluids in the different chambers bounded by the membranes have different chemical compositions that create electric potential differences between the chambers. At the head of the hair cells there are capilliform fibers with certain bending stiffnesses that create tassels which are in touch to the tectorial membrane. When the fluid vibrates and the basilar membrane moves, it causes lateral movement between the basilar and the tectorial membrane, which furthermore bends fibers of the hair cells, producing activity in the hair cells. In consequence they send impulses to the auditory nerve fibers signaling information to upper levels about the place and amplitude of the vibration on the basilar membrane. The activity of the hair cells is not merely receptor activity but the outer hair cells have to be understood also as effectors.

3.3.1 Basilar membrane

The basilar membrane is a long and narrow membrane whose mass and flexibility properties change along the membrane. At the window end it is narrow and light whereas at the apical end it is wider, more flexible and more massive. It acts as a mechanical transmission line whose mechanical impedance and the propagation velocity of the wave changes as a function of place. When sound coming from the middle ear moves the stapes and causes a pressure wave to the fluid of the cochlea it produces a traveling wave on the basilar membrane. A traveling wave propagates from the window end towards helicotrema. Because the properties of the basilar membrane change as a function of the place, each part of the membrane reacts differently to the sounds with different frequency. At high frequencies the traveling wave resonates at the window end of the membrane and then attenuates quickly. At centre frequencies the maximum amplitude of the vibration is about at the middle of the membrane and at low frequencies at the apical end. If the input signal is composed of various frequencies, the traveling wave will create maximum displacements at different points on the basilar membrane. Thus the cochlea works like a spectrum analyzer decomposing signal to its frequency components. The hair cells bent because of the displacement in the membrane stimulate the auditory nerve fibers, which are arranged according to the frequency they are most sensitive at, so each point of the cochlea is therefore responding best to a certain frequency. This principle is called the place theory.(see Figure 5)

Békésy's traveling wave model for describing the operational principle of the basilar membrane was qualitatively right but problems occurred because the frequency selectivity measured from the auditory nerve was far better than when measured from the basilar membrane. Later on it has turned out that also on the basilar membrane the frequency selectivity is good. The problems of the early measurings were that due to the extremely difficult conditions the measured ear was not physiologically functioning anymore.

There are still different explanations for the increased selectivity but it is evident that the outer hair cells participate actively in the movement of the basilar membrane and in the producing the resonance that increases selectivity. This can be understood for example by means of feedback. There is also a nonlinearity that increases the feedback when the signal level lowers, resulting in the growth of intensification and increased selectivity. As the signal level increases, the feedback decreases in which case also selectivity decreases, e.g. the band widens.

As a whole the phenomena in the cochlea are very complex and there are still details or their meanings that are still unknown. One interesting phenomenon is otoacoustic emission, i.e. an active echo from the inner ear. When a narrow-band tone burst is sent from the outer ear, it is possible to register an echo that can not be mechanical or acoustic reflection based on the duration of the delay. Apparently the effector character of the hair cells explains this echo as a response for the control from the neural level.

Another interesting phenomenon is so called hearing of missing fundamental that can not be explained by the place theory. If e.g. two or three lowest harmonics are removed from a harmonic tone complex, we can still hear the original pitch though the timbre has changed. The hearing of the missing fundamental is an example of virtual pitch, a.k.a. residual pitch. It can be explained among others by the non-linearity of an ear, especially the half-wave rectification performed by the hair cells. If more than one pure tones fall within the same critical band, this non-linearity causes sum and difference frequencies. The difference frequency of the harmonics is after all same than the fundamental frequency. It appears in the concerned critical band channel as a amplitude envelope curve and in the auditory nerve as actually affecting periodicity.

3.4 Deafness

The basilar membrane and hair cells are responsible for translating physical vibrations into neural information. While the acoustic pressure waves traveled through the outer ear, middle ear and inner ear, the information never makes it to the brain if hair cells are damaged. Such auditory system has no way to transform sound waves to neural information and that leads to hearing impairment. The hair cells can be damaged by many causes: certain diseases, congenital disorders, certain drug treatments and many others. Damaged hair cells might subsequently lead to degeneration of adjacent auditory neurons and if a number of hair cells and neurons are damaged, the person with this kind of loss is diagnosed profoundly deaf. According to research [2] the most common reason for deafness is damaged hair cells rather than degeneration of auditory neurons.

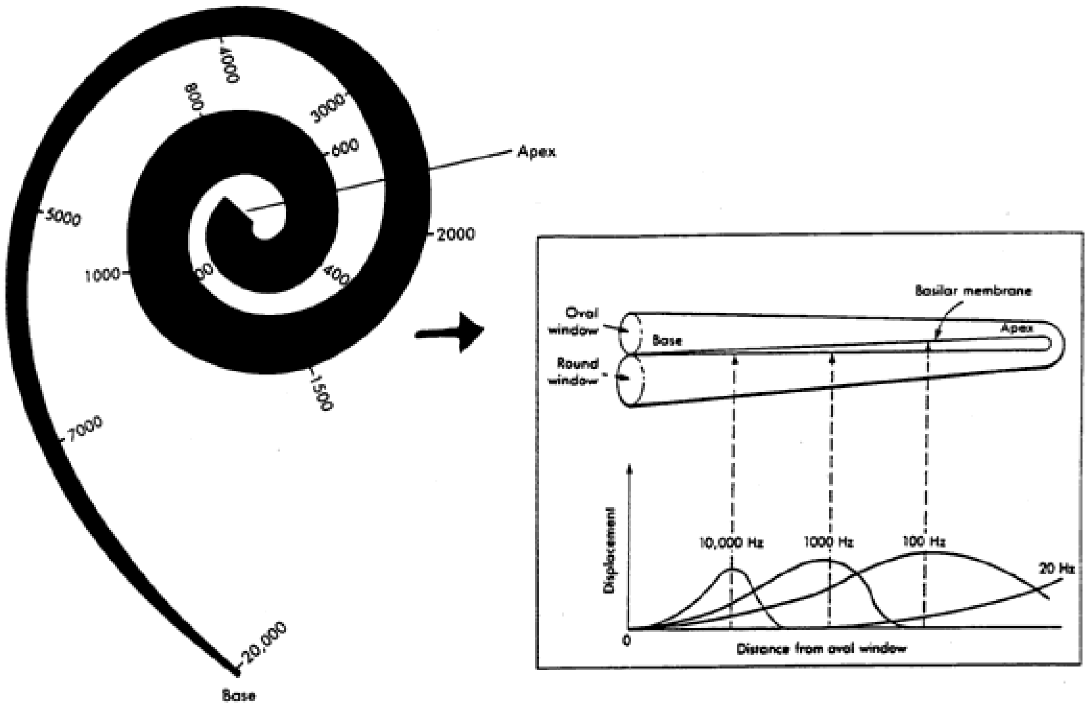

Figure 5. Frequency sensitivity along the basilar membrane.[63]

4 Cochlear implants

A cochlear implant is an electronic hearing device, which is meant for deaf persons or persons with difficult hearing impairment to whom a conventional hearing aid can’t provide sufficient help. The cochlear implant stimulates the auditory nerve through the inner ear and thus creates sound sensations. A conventional hearing aid device amplifies the sound which is then directed to the outer auditory canal whereas a cochlear implant does not amplify the sound but transforms it to an electrical signal. [1]

In 1960s cochlear implants were tested with deaf adults in USA and Europe still quite rarely. Later on from 1970s implantations have been done as routine clinical work in many countries. The number of people that have a cochlear implant has increased rapidly. By the end of 2007, the total number of cochlear implant recipients has grown to an estimated 120000 worldwide. In Finland the first ten patients were implanted in 1984-85. At the moment, the number of implant users in Finland is around 450.

There are mainly four large cochlear implant system manufacturers in the world. All of them offer both pocket type processors and ear level type processors. Also all of the new devices are nowadays multichannel and multielectrode systems. However, single-electrode systems are still manufactured and used successfully.

Figure 6. On the left the behind-the-ear microphone, implant processor and the transceiver (outer part). On the right the implanted part of the cochlear implant device (inner part). [64]

4.1 Basic principles

The cochlear implant is an electronic device, which is partially implanted in the ear in a surgical procedure (see Figure 6 and Figure 7). The external part of the device is worn in the same way as a hearing-aid. The cochlear implant is based on the idea of bypassing the normal hearing mechanism from outer ear to the inner ear including the hair cells. It produces an electrical stimulus, which bypasses the damaged or missing hair cells in profound sensorineural hearing loss and stimulates the remaining auditory neurons directly.

Over the years a variety of cochlear implant devices have been developed. However, all the implant devices have the same basic components in common. A microphone picks up the sound and sends it as an electrical signal to a signal processor. The processor modifies the signal depending on the processing scheme in use and sends the processed signal to an external transmitter from where it is transmitted through the skin to an implanted electrode or electrodes. This is usually done by using electromagnetic induction or radio-frequency transmission to an internal receiver. One way is also to use direct connection via a percutaneous plug. Electric current flows between one or more active electrodes and return electrodes, creating the sensation of sound by stimulating the auditory nerve.

Figure 7. Ear with the cochlear implant.[65]

In single-channel implants only one electrode is used, but in multi-channel implants an electrode array is inserted in to the cochlea. Using an electrode array, different auditory nerves can be stimulated at different places in the cochlea exploiting the place mechanism for frequency coding, so different electrodes are stimulating depending on the signal frequency. In order to make this happen, input signal has to be decomposed to its frequency components, like in a healthy cochlea. This is done in the signal processor of the implant device.

The main requirement of using a cochlear implant is that there have to be viable auditory nerve fibers left in the nearness of the electrodes. When stimulating nerve fibers they fire and provide neural impulses, which the brain finally interprets as sound. Sensation of loudness depends on the number of nerve fibers activated and their firing rate. The more fibers are activated, the louder the sound is perceived. Alike if only a small number of fibers are activated the sound is experienced as soft. Loudness can therefore be controlled by adjusting the amplitude of the stimulus current. Stimulating an electrode near the apex causes a sensation of low pitch and near the oval window high pitch sensation. Thus a cochlear implant can effectively send loudness and pitch information of the input signal to the brain.

4.2 Characteristics of cochlear implants

4.2.1 Electrodes and channels

A cochlear implant can have one or more electrode pairs, which represent the positive and negative polarity contacts that electric current passes. The stimuli pass through the electrodes and activate the nerve fibers. If the implant device has several electrodes they are usually placed along the cochlea enabling the stimulation of the different neurons. The number of channels describes the number of electrode pairs which supply different stimulus waveforms. Usually, the number of channels equals to that of electrodes in use but in some cases some electrodes can carry the same waveform.

4.2.2 Single and multiple channels

It is possible to differentiate between single- and multielectrode systems, and between single- and multichannel systems. A single-electrode system can only be a single channel system and has certain limitation because of that. If an implant device is a multielectrode system it doesn’t necessarily mean that it is also a multichannel system. With more electrodes than channels some selection can be made when choosing the electrode to use. For example Hochmair and Hochmair-Desoyer (1985) used a four-electrode device with only one channel by choosing the best electrode for the particular stimulation. Ineraid device [67] used six electrodes from which four were selected for stimulation. With multichannel systems the separation of frequency components and differential excitation of neurons, normally done in a healthy ear, becomes possible.

4.2.3 Placement of the electrode array

The electrodes can be placed in the cochlea (intracochlear) or outside the cochlea (extracochlear). Early researchers were divided by the best location for placing the electrode array for stimulation of the auditory nerve. At the present moment, the four major implant manufacturers have designed their implants for placing in the scala tympani, inside the cochlea, since it brings the electrodes in close vicinity with auditory neurons along the cochlea making it possible to retain the place mechanism used in a healthy ear. It also needs less current to stimulate the neurons. There has been some concern that placing the electrodes inside the cochlea might cause bone growth and damage nerve fibers. However, many patients have used a cochlear implant already over 20 years and no clear decrement in performance has been perceived.

Placing the electrodes central to the cochlea has the disadvantage that orderly alignment of neural “best-frequency” is not straightforward to the electrode position. The mapping of an electrode to pitch has to be determined for each patient separately and is very difficult to do for young children. Other stimulation sites like in the auditory nerve, cochlear nucleus or brain are possible.

4.2.4 Localization of the current

The current must be localized to separate groups of auditory nerve fibers in order to use place coding with multiple-channel devices. In implants, stimulation can be done in three ways: bipolar, monopolar and common ground. In bipolar electrode configuration the active and ground electrodes are placed close to each other. Bipolar electrodes have been shown to produce more localized stimulation than monopolar ones [4][5]. Bipolar stimulation also activates neurons from more restricted place which is desirable if the goal is to stimulate different fibers with different stimulus. In common ground stimulation current flows between one electrode and all of the other electrodes in the array that have been connected together electronically. It also localizes current to separate groups of auditory nerve [14].

In monopolar electrode configuration current flows between one electrode in the array and one or more other electrodes placed outside the cochlea. With animal experiments is has been demonstrated that monopolar stimulation is not as localized as bipolar or common ground stimulation. Anyway, psychophysical studies showed that users could scale pitch just as well with monopolar stimulation as with the other two modes [68].

4.2.5 Analogue and pulsatile

When stimulating auditory nerve fibers, information can be presented either in a continuous analogue waveform or a series of pulses. An analogue waveform can carry all the information of input signal. In multichannel implants the acoustic waveform is bandpass filtered and the filtered waveforms are presented simultaneously to all electrodes. In this way the nervous system can sort out and exploit all the information contained in the original raw acoustic waveforms. A drawback of analog simulation is that simultaneous stimulations can cause channel interaction.

In pulsatile stimulation, series of pulses represents a digitized sample of the original acoustic waveform. This usually results in a synchronous neural discharge corresponding to the pulse onset. The advantage of this type of simulation is that channel interactions can be reduced by delivering pulses in a non-overlapping (non-simultaneous) way. Increasing pulse amplitude and width usually results in an increased perceived loudness.

4.2.6 Transcutaneous vs percutaneous

There are two general ways to provide the stimulus and data from the speech processor to the electrode. In a percutaneous system the signal is transmitted through the skin via a wire connection between the processor and a plug inserted in the skull. In this system there are no other implanted electronics than the electrodes. The advantage of this system is that less power is needed, new signal processing techniques are easy to test and the internal impedance can be checked easily. The disadvantage of this system is that the external plug is susceptible to dirt, moisture and mechanical damage, thus providing an external entrance for infection.

In a transcutaneous system the stimuli are transmitted through a radio frequency link. An external transmitter encodes the information of stimulus for radio frequency transmission from an external coil to an implanted coil. Then the internal receiver decodes the signal and passes the stimuli to the electrodes. The transmitter and the receiver are held in alignment by a magnet. The advantage of this system is that the skin is closed after the operation, thus avoiding possible infections. The disadvantage is that the implanted electronics may fail (i.e. receiver circuitry) causing another surgery for replacing them.

4.3 Sound processing and stimulation strategies

4.3.1 Strategy based on continuous sampling and sequential stimulation, CIS

At the moment the most common speech processing method is based on so called CIS – strategy (Continuous Interleaved Sampling) or its variations. Basically it means that the stimulation pulses are presented to the electrodes in turn so that only one electrode is active at a time. Speech signal is bandpass filtered to more than one channels and every channel has its own defined electrode. The samples are taken from each channel in very short intervals by turns. Channel-specific activity is monitored with the envelope curve of the signal, which gives a good picture of the amplitude changes of e.g. speech signal. Channel-specific loudness at the sampling moment defines the intensity of the current to be sent to the electrode. Sampling interval is short: each electrode is stimulated even 1500 times per second. Sampling frequency varies depending on the system in use. (see Figure 8)

In the individual programming of the signal processor it is defined, which electrodes are connected to which channels, as well as the refreshing order of the electrodes. Normally the electrodes near to the apex are connected to the low frequency channels and electrodes near to the round window to the high frequency channels following the normal frequency-specific behavior of the cochlea. Electrodes may be stimulated sequentially or so that the distance between the two sequential electrodes in the time domain is as long as possible. In one typical variation of the conventional CIS two electrodes are stimulating at the same time. With this kind of method it is possible to attain twice as fast neural stimulating rate than in the conventional one. CIS gives a good picture of the temporal features of the audio signal due to its high refreshing rate.

4.3.2 Strategies based on the spectral content of sound, N-of-M and SPEAK

The CIS-strategy defines the amplitudes of the stimulation pulses based on the temporary channel-specific loudness value. Another method that differs from it is based on the thorough frequency analysis of the input signal. Different manufacturers have implemented it a bit differently and that is why it exists in different names, SPEAK (Spectral peak) and N-of-M. The basic principle is that all electrodes are not stimulated in turn but from the number of electrodes in use (M) a subset of electrodes (N) is picked that participate in the particular stimulation cycle. The basis for this operation is the Fast Fourier Transformation (FFT). Due to its quite high resolution, spectrum analysis gives more energy peaks than the available number of channels. Therefore adjacent energy information has to be gathered to the single channel-specific energy information. (see Figure 9)

Also in this method there is one electrode for one channel. After the analysis the number of energy peaks corresponding to that of the electrodes to be stimulated (N) are picked from the number of the channels (M). The electrodes of these channels are stimulated during the stimulation cycle by turns. After the cycle the same procedure is repeated and the channels containing energy peaks in the new sampling moment define the electrodes to be stimulated. The best feature of the methods using frequency analysis is considered to be the possibility to provide specific spectral information of the audio signal.

The signal processing strategies have developed a lot in 1990s giving better possibilities to separate the temporal features of the speech signal. As an example of this are ACE and SAS strategies. ACE (Advanced Combination Encoders) works basically so that the number of electrodes in each stimulation cycle is smaller than in CIS but greater than in SPEAK. Refreshing rate is however approaching that of CIS. This way the ACE method exploits the benefits of both previously described strategies: temporal accuracy of CIS and spectral accuracy of SPEAK.

Simultaneous Analog Stimulation (SAS) is a method by which it is possible to simultaneously stimulate all electrode pairs in use. In reality this method is pulsatile but there are no breaks between pulses. Thanks to the high refreshing rate the wave shapes formed by pulses are getting quite similar to those of continuous analog signals.

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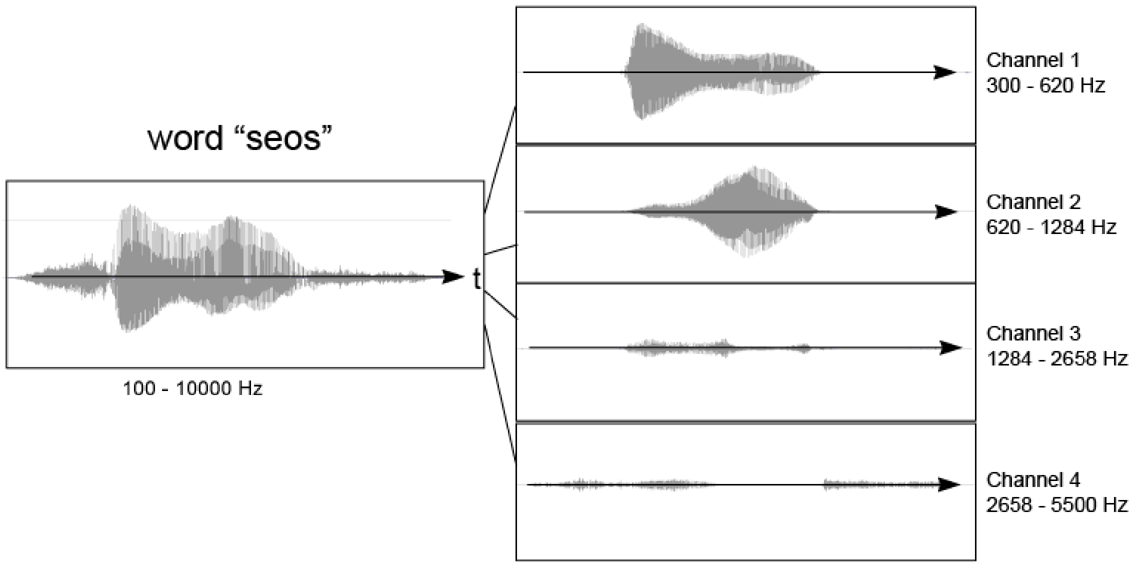

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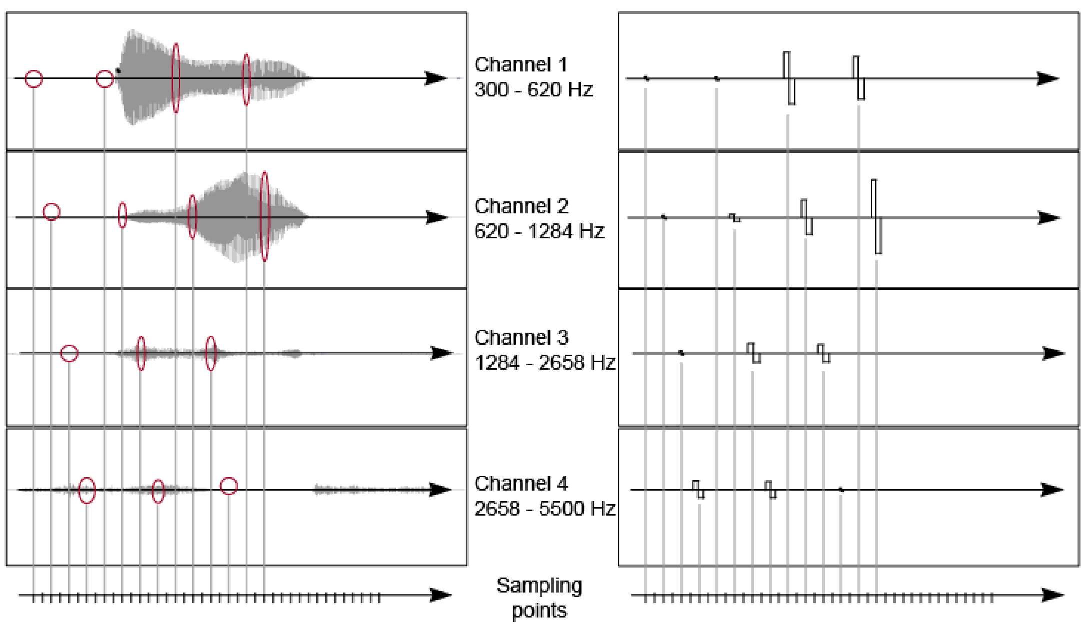


Figure 8. The basic principle of the CIS-strategy. The finnish word "seos" is first bandpass filtered to four different channels (upper). Horizontal axis represents time and vertical axis amplitude. Channel-specific loudness at the sampling point defines the amplitude of the stimulation pulse of the channel-specific electrode. [21]

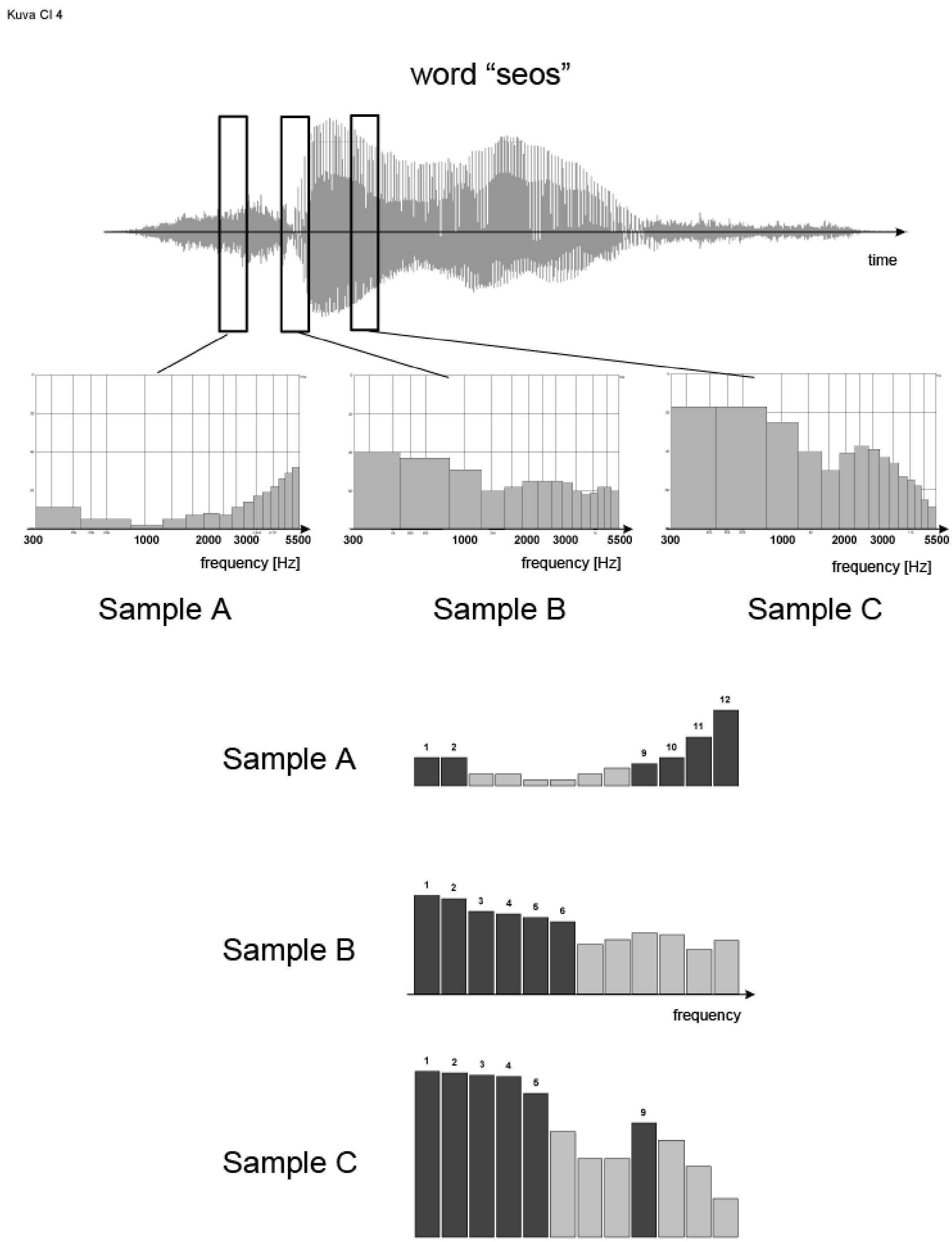


Figure 9. Basic principle of N-of-M and SPEAK strategies. In this example N is 6 and M is 12. Samples A, B and C direct the stimulation pulses to the electrodes of the channels that have the highest energy level (A => 1, 2, 9-12; B => 1-6; C => 1-5, 9). [21]

5 Implantation process

5.1 Patient selection

Original FDA (US Food and Drug Administration) guidelines for selecting patients for cochlear implantation contained specifications of audiologic, medical, radiologic, psychologic and cognitive criteria. Guidelines have now been loosened as more information is acquired about benefits provided by cochlear implants. Originally cochlear implants were limited only for postlingually deafened adults who got no benefit from conventional hearing aids and had no possibility of worsening hearing. There is no upper age limit in the selection procedure. As long as other criteria are met and patient’s general health status will allow a general anesthetic, the cochlear implantation is appropriate.

Nowadays the entry criteria have been broadened to include also patients with residual hearing. Adult selection criteria include postlingual, profound bilateral sensorineural hearing impairment more than 95 dB pure tone average, little or no benefit from hearing aids and psychological and motivational suitability. The candidate should not have word discrimination scores more than 30% or speech detection threshold of 70 dB sound pressure level.

Pediatric cochlear implant candidate selection is a complex process that requires careful consideration of many factors. A child has to be at least two years old (for anatomical reasons), has to have bilateral, severe or profound hearing loss with pure tone averages of 90 dB or greater in better ear and no medical contraindications to surgery. Before the implantation it has to be made sure that even with adequate experience and training (3 to 6 months trial), a hearing aid cannot provide the same level of auditory benefit as expected from an implant. Also parents have to be highly motivated and appropriate expectations have to be well explained.

5.2 Surgery for multichannel cochlear implantation

5.2.1 Surgical anatomy

For implant surgery it is very important to understand the relevant anatomy of an ear. Especially, it is absolutely necessary to be familiar with the anatomy of the basal turn and round window of the cochlea through which the electrode array is taken in. Firstly, a bony overhang anteriorly and inferiorly may block the round window membrane in its niche. To provide a satisfactory exposure of the round window the bony overhang may have to be drilled away. Sometimes a fold of mucous membrane may extend across superficial to the round window membrane. In case of failure to distinguish this false membrane from the right one may lead to the impact of the electrode and the true membrane possibly causing a traumatic insertion. Also, it is important to understand that the round window membrane is conical and it is attached superiorly to the osseous spiral lamina. If drilling is done posterosuperiorly it can lead to damage of the spiral lamina [12]. Directly inferior to the round window may be hypotympanic cell which can be mistaken for the round window. The orientation and direction of the basal turn of the cochlea must be perfectly understood since the line for the electrode insertion has to be provided. Inside the round window the scala tympani is tapered by an anteroinferior ridge. If this ridge is remarkable it should be drilled away before inserting the electrode.

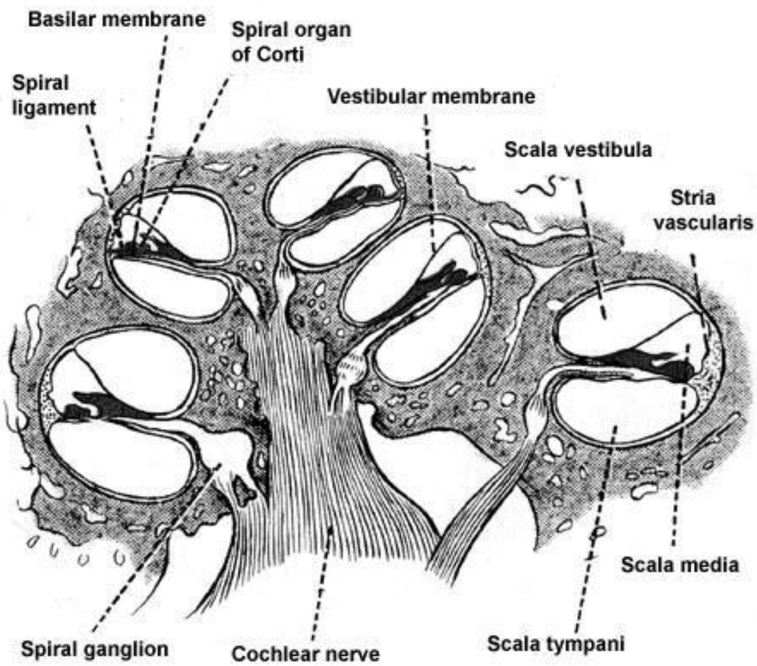
When implanting young children with multichannel implants, it is important to take into account the effect of the skull growth because it can cause the electrode array being dislodged. Dislodging can be avoided for example by using lead wire designs that will accommodate to these changes.

5.2.2 Applied biophysics and physiology

Multichannel cochlear implants require electric current to be localized to discrete groups of residual auditory nerve dendrities or spiral ganglion cells. Studies concerning intracochlear stimulation with electrode array in the scala tympani of the basal turn (see Figure 10 and Figure 11) show that current localization is best with bipolar stimulation. In that case the current falls away at approximately 3-8 dB/mm [13][14]. Also with common ground stimulation the satisfactory localization can be achieved but with monopolar stimulation the localization is poor [14][15].

For maximal current localization with bipolar stimulation the placement and orientation of the electrodes is crucial. In case of peripheral processes still remain intact a moulded electrode array is used to keep electrodes just beneath the basilar membrane and the spiral lamina for the best current localization. However, many profoundly or totally deaf people do not have residual peripheral processes and thus an electrode array should not be merely designed to localize current to the peripheral processes. In order to provide the maximal current localization to the spiral ganglion cells the electrode array has to be placed as close to the modiolus (a conical shaped central axis in the cochlea) as possible.

There are number of other aspects that have to be taken into consideration. When the charge density is high there is a possibility of platinum corrosion and still the surface area should be as large as possible. Because of this a banded electrode array was developed. It minimizes the charge density and maximizes the surface area because it is circumferential. A banded electrode array is also free fitting, smooth and tapered so that it can be inserted with minimal trauma. These characteristics are also very important if the electrode array needs to be explanted and another reinserted.



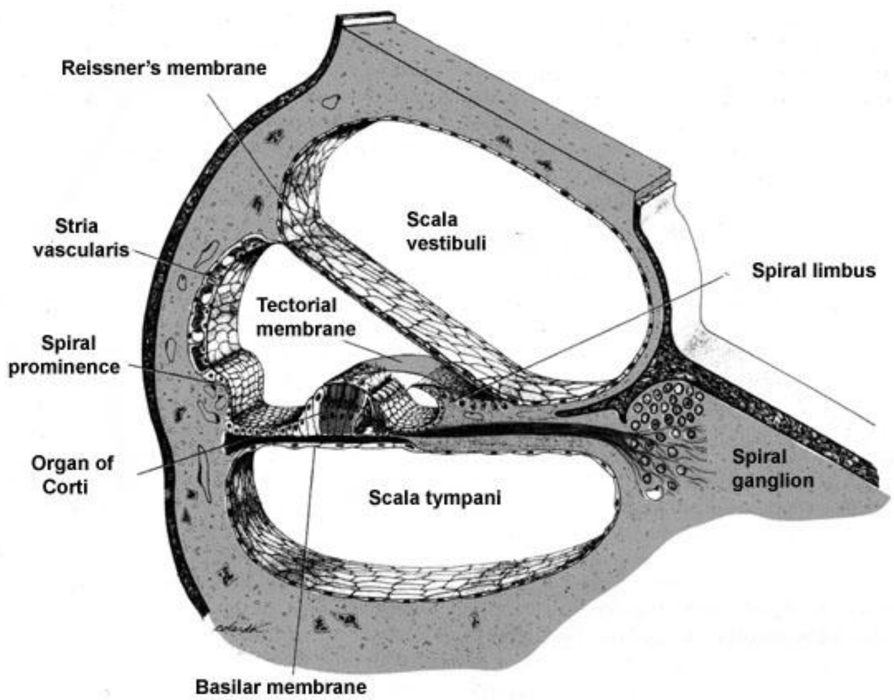


Figure 10. Schematic cross-section of the cochlea. At present, all major implant manufacturers have designed their products for placing in the scala tympani of the cochlea. Due to the spiral shape of the cochlea electrodes tend to lie along the outer wall of the cochlea near the spiral ligament, as far away as they can from the spiral ganglion and any peripheral processes that might be left.

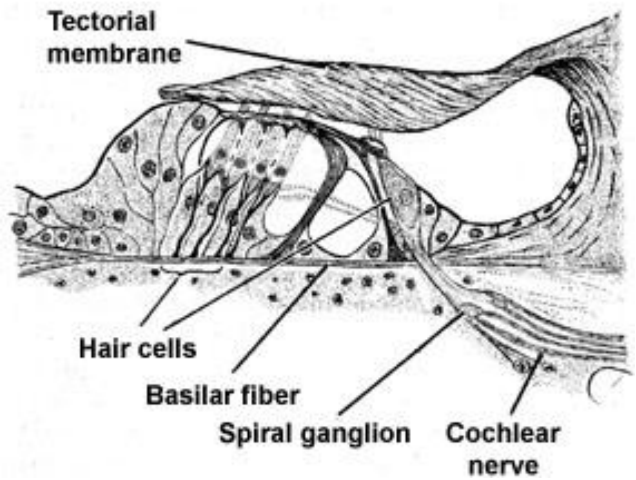


Figure 11. The organ of Corti.

5.2.3 Biocompatibility and pathology

It is important to ascertain that materials used for the cochlea implant device are biocompatible. To do this, candidate materials are implanted in the subcutaneous tissue and muscle of the experimental animal and in the case of an electrode array to the cochlea. Also the certain materials being used in fabricating devices should be tested because the composition may differ. The electrode array should be atraumatic and it should not cause any significant loss of neural elements. Also tissue reactions like new bone growth should be minimized because they can present reduced performance over time.

A multielectrode array has been inserted in human temporal bones to study the presence of any trauma. Histological study of the bones showed that a tear of the spiral ligament occurred typically at a point approximately 10 mm from the round window [16]. This was probably caused by a shearing force produced as the electrode passed around the outside of the basal turn. However, histopathological studies have proved that this would not cause a loss of spiral ganglion cells or an adverse tissue reaction [17]. Another study using surface preparation techniques [18][19][20] made similar findings and they verified that the smooth, tapered, free-fitting array manufactured by Cochlear could be inserted with minimal trauma in case of insertion stopped when resistance was felt. Further studies found that rotating electrode array would direct the tip of the electrode down and away from the basilar membrane avoiding a possible trauma. (see Figure 12)

Figure 12. Banded electrode array to be implanted

5.3 Speech processor fitting for cochlear implants

5.3.1 Logistics and preparation

After the surgical operation the patient is required to wait until the wound has healed before the external part of the implant device can be fitted. Suggested waiting time for healing varies from 10 days to six weeks depending on the surgical procedure used. Systems using transcutaneous transmission of speech information are quite demanding with the distance between external transmitting coil and the internal receiver coil. For example the Nucleus device requires that distance is no longer than 6 mm and any greater distance can cause some loss of information and power. That is why it is very important to wait until the postoperative swelling has subsided.

The waiting time before the processor is switched on can be very difficult for the patient. Therefore some implant teams favor an early fitting of the device reassuring the patient that the device really works. Some preliminary measurements can be made for example one week after the operation where the patient can report sound sensations from their implant but is not allowed to take the processor outside the clinic before the fitting is completed. At the early stage sessions it is very important to remind the patient and family that these are the first of many fitting sessions where audiologists will progressively determine the optimal settings for the speech processor.

5.3.2 Determining the dynamic range

The most critical task in fitting of all implant speech processors is to adjust the patient's dynamic range for electrical stimulation. Dynamic range means the difference between the threshold for electrical stimulation and the maximum loudness level the patient accepts from the stimulating current. Though methods for determining these levels varies with different implants the basic premise for finding the dynamic range is the same for all systems. With some psychophysical measurements the implant device can be set within the comfortable loudness range for the patient so that speech and other sounds will be audible but not too loud.

5.3.3 Threshold measurements

In traditional pure-tone audiometry we begin testing the patient delivering a stimulus that is above patient's threshold and then descending to a level that is nearer to the threshold. When obtaining threshold for a cochlea implant an use ascending approach is used. This is because it is practically impossible to set some starting level from which to descend due to the varying sensitivity to electrical stimulus among patients. Using the ascending approach, overstimulating the patient is avoided.

The amount of the current delivered to the implant is gradually increased and the patient is instructed to notify when something is first heard. First thresholds tend to be a little bit higher than they really are because the patients are not sure what they should be hearing. Threshold measurements may be done at different frequencies or different sites of stimulation of the cochlea depending on the type of the implant system being used.

5.3.4 Comfort level measurements

The implant devices need to be set to have the maximum output level, the most comfortable level (MCL) which is still comfortable for the listener. Finding this comfort level may require testing for a comfortable level, a maximum comfortable level or an uncomfortable loudness level. Determining this setting is very critical in providing a well-fitted device because a patient experiencing stimulations exceeding the comfortable level may feel some anxiety and unwillingness to use the device.

Loudness growth to electrical stimulation is not straightforward and there is often a rapid increase in loudness at the top of the dynamic range. Without exception the patient will experience uncomfortable loudness level until the suitable comfort level can be attained. This level is also obtained with ascending approach. With multichannel devices it is vital to use an ascending approach to obtain comfort levels for each channel because adjacent electrodes may be stimulating areas of the cochlea with very different nerve survival. On one channel a stimulus can be perceived as soft but on another channel it might well be perceived as uncomfortable.

5.3.5 Dynamic range values and performance

There is number of factors that affect to the true values of dynamic range measurements. These are for instance stimulus waveform, repetition rate of the stimulus, electrode configuration and placement, stimulus frequency and neural density and distribution. Generally the dynamic range for electrical stimulation is considered as rather narrow, somewhere between the region of 2 and 15 dB throughout the receptive region [6]. The units used in measuring the dynamic range vary between different systems. Anyway, when measuring the dynamic range, the electrode and electrode-nerve interface are really assessed. Low thresholds and large dynamic ranges have been associated with a greater percentage of surviving neural elements [7].

Patients who have achieved good results with their implants seem to have a wide dynamic range [8]. Some clinical observations have shown that the patients who have recently become deaf have much wider dynamic range than those who have long duration of deafness. Especially prelingually deafened adults have been seen to have very small ranges for electrical stimulation [9]. Therefore it seems that the previous auditory experience may affect a lot to dynamic range values. During the first few months of programming after the surgery, threshold and comfort levels tend to vary considerably, but when patient's auditory experience increases it usually tends to settle.

5.3.6 Loudness balance

The second critical step in fitting of the implant device after the determination of the dynamic range is to balance the perceived loudness of stimulation. Loudness judgements are made according to the pitch of the stimulus and pitch judgements are influenced by the loudness of the signal [10]. The patient should be able to confirm his or her loudness judgement by relating it to other adjacent electrodes (multichannel devices) or to a sound of a similar frequency (singlechannel devices). When the loudness balance is obtained across the frequency range, speech perception should be better.

In multichannel implant fitting the patient has to make judgements about the comparative loudness of different channels along the electrode array. This can be done either by presenting a certain stimulus level to each electrode by turns or presenting a same-different loudness judgement to two adjacent electrodes. The latter method is more accurate but more time-consuming.

5.3.7 Performance relative to number of stimulating channels

On average it is accepted that patients with multichannel cochlear implants are more potential to have better speech understanding without lipreading compared to the single-channel ones. Also patients with intracochlear devices have better speech understanding than patients with extracochlear devices. However, the number of channels is not the main factor affecting to the results but the coding technique used. For example patients with a 4-channel analogue device may achieve comparable results to the 22-channel pulsatile device [11].

5.4 Experiences of using implants

Cochlear implantation has become a standard rehabilitative procedure for profoundly deaf people who don't benefit sufficiently from hearing aids. Although there are a number of different implant systems available, none can provide normal hearing. Several factors, including age at onset of deafness, age at implant surgery, duration of deafness, status of remaining auditory nerve fibers, training, educational setting and type of implant affect the benefit a patient receives from a cochlear implant. The variability of outcomes with cochlear implants is thought to depend mainly on patient factors. The primary goal of cochlear implantation is improved speech perception.

The people who have learned the speech and language prior to becoming deaf adapt to cochlear implants more quickly and achieve open-set speech discrimination earlier than people who have not learned speech and language. Therefore postlingually deafened patients succeed better with their implants than prelingually deafened. However, prelingually deafened children continue to improve over a period of 2 to 5 years. During that time their results become closer to those of postlingually deafened children. There have been many well documented studies that demonstrate the fact that prelingually deafened children who receive their cochlear implants at an early age and are educated in aural-oral settings achieve open-set word recognition. For example, Myamoto and associates at Indiana University reported on 55 children who were born deaf or acquired hearing impairment before age three. The average child in this group achieved 63% open-set speech understanding. In Iowa University in study of 54 children, Gantz and colleagues showed that after four years of use of an implant 82% prelingually deafened children achieved open-set word understanding. Also Lusk and his associates in Washington University showed that all of the 25 congenitally deaf children implanted before age of five achieved open-set speech understanding after 36 months of the surgery. This proves that the earlier the profound hearing impairment is recognized and the child is given an implant, the better results are achieved.

Cochlear implants are not anymore experimental. They have become an important and valuable sensory aid for carefully selected patients. Continuing research will develop new processors with better sound processing techniques providing sensation of hearing to severely or profoundly deaf people to be more and more realistic.

6 Objective diagnosis methods for hearing loss

Objective hearing tests are typically related to a physiological response. Auditory evoked potentials (AEP) are based on recordings of brain activity associated with auditory stimulation (see Figure 13). The central nervous system generates spontaneous, random electrical activity in the absence of sensory stimulation, which can be recorded with surface electrodes from the scalp in the electroencephalogram (EEG). The recording of auditory evoked potentials is based on the assumption that there is an exact temporal relationship between the presentation of auditory stimuli and the resulting neural response patterns [66]. The amplitude of the AEP is related to the intensity of the stimulus.

The facilities needed for AEP testing is composed of two main parts: an auditory stimulator for providing the necessary sounds to evoke the response that is picked up with surface electrodes on the scalp, and a signal amplifier and processor for recording and displaying the response [60]. Applying technical manipulations, the neural activity related to the auditory stimulus can be extracted from the EEG, which contains many unwanted potentials, for example muscle activity, internal instrumentation noise and spontaneous EEG. Because the AEP signal is much smaller than the noise, the signal to noise ratio (SNR) has to be enhanced by amplification, differential recording, filtering, artifact rejection and averaging techniques.

6.1 The click-evoked auditory brainstem response

With young infants and difficult-to-test patients the most widely used objective technique to assess hearing thresholds in clinical practice has been the click-evoked auditory brainstem response (ABR). This method is based on recordings of EEG-signals of synchronously firing auditory neurons as a response to acoustical clicks. Click stimuli provide a sufficiently short rise time to ensure a synchronous neural burst from the auditory system [24].

The major advantage of ABR is a relatively short testing time when estimating the degree of hearing loss. Yet, this method has a few drawbacks. First, there is lack of frequency specificity over the auditory spectrum. The rapid onset and the broad frequency spectral content of the click stimulus result in activation of a wide area of the basilar membrane in the cochlea [25][26]. Thus, detailed information concerning the type and degree of hearing loss frequency-specifically cannot be provided. ABR correlates best with hearing sensitivity in the 2000-4000 Hz region. However, the responses to clicks receive contributions to the response from a wide area of the basilar membrane and could be misinterpreted when a hearing-impairment is restricted to a particular frequency region.

The loss will often be missed or the degree of the loss will be substantially underestimated [26].

6.2 Frequency-specific auditory brainstem response

A number of variations have been developed for retrieving frequency-specific information from the ABR including different stimulus paradigms and different signal processing techniques. The most straightforward approach is the use of brief tones or tone bursts [28][29][30][31][32]. As shown in Figure 13, clicks produced by passing a 100-μs square wave through an earphone, have a broad frequency spectrum. In contrast, tone bursts have their concentration of energy at the nominal frequency of the tone and sidebands of energy at lower and higher frequencies.

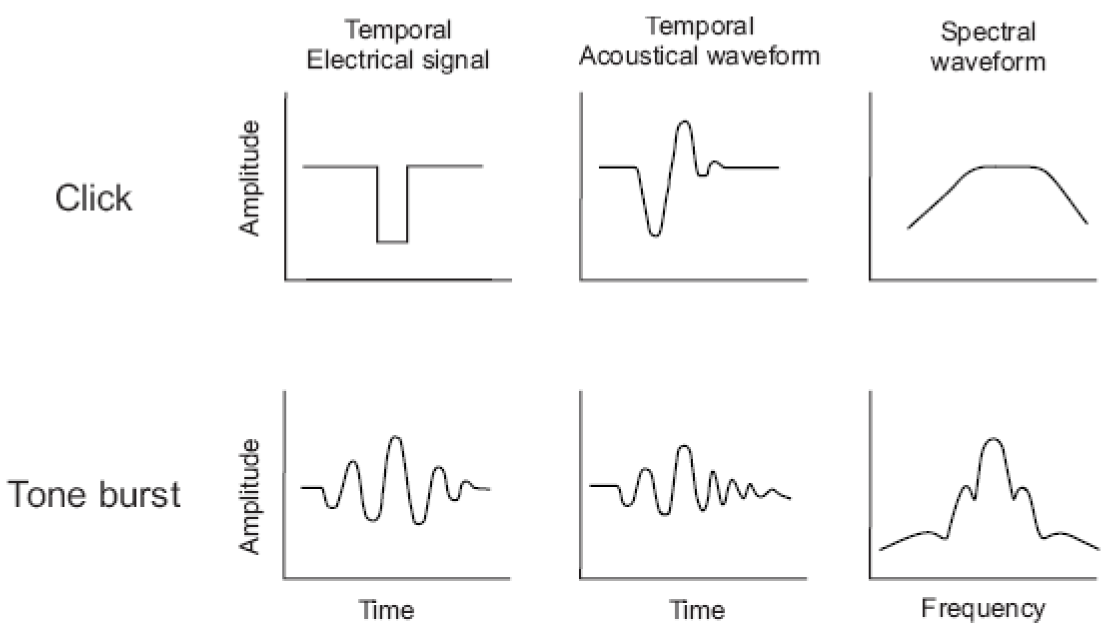


Figure 13. Representation of click and tone burst stimuli used in AEP measurement. The temporal electrical signal, the temporal waveform of the acoustical signal and the spectrum are shown diagrammatically. [27]

Noise masking techniques have been suggested to improve the frequency specificity and place specificity of the response. The noise, which is presented simultaneously with the click or tone burst, restricts the regions of the basilar membrane that are capable of contributing to the ABR by selectively masking certain regions that are outside the region to be stimulated.

6.3 Auditory steady-state response

Over the last few years, auditory steady-state responses (ASSR) have been studied as a possible technique for objective evaluation of frequency-specific hearing thresholds. ASSRs are periodic electrical responses of the brain to continuous auditory stimuli [33][34]. The frequency components of ASSRs remain stable in amplitude and phase over time [35]. The potentials can be evoked by amplitude- and/or frequency modulated pure tones or noise. The resulting EEG signal contains a component at the modulation frequency.

In order to understand how ASSR works, we have to consider how the cochlear transducer works. The transfer function of the hair cell and the auditory nerve fiber can be considered as compressive rectification of the signal waveform [36][37]. An AM tone has energy at the carrier frequency and at two sidebands separated from the carrier by the modulation frequency. The spectrum of the stimulus does not contain any frequency component at the modulation frequency. When the ear captures this sound, frequency place analysis is performed in the cochlea. Lower frequencies activate the basilar membrane near the apex and higher frequencies near the oval window. The hairs on the inner hair cells bend producing polarization and depolarization of the hair cells. Only depolarization causes the auditory nerve fibers to transmit action potentials. Thus, the output of the cochlea contains a rectified version of the acoustic AM stimulus which has a frequency component at the modulation frequency. This component can be used to detect the response of the cochlea to the carrier. The signal is not merely rectified, it is also compressed. Larger depolarization of the inner hair cells causes faster firing rates in the auditory nerve fibers. (Though, the transfer function is non-linear and saturates with high levels of depolarization of the inner hair cell.)

ASSR can be elicited by a variety of stimuli like clicks, tone bursts and sinusoidally amplitude and/or frequency modulated tones. The advantage of modulated tones compared to clicks and bursts is a narrower spectrum that is centered around the carrier frequency. The parameters, related to modulated tones, that can vary are the carrier frequency, the modulation rate and the depth of the amplitude and/or frequency modulation. The carrier frequency defines which part of the basilar membrane is activated. All octave frequencies that are usually used in audiometric tests (125 – 8000 Hz) can be used for the recording ASSR.

6.3.1 Modulation frequency

The modulation frequency of the stimuli is a defining characteristic of the ASSR. In many studies ASSR has been tested with a wide range of rates between 2 and 450 Hz [38][39][40]. When ASSR appears in the EEG (electroenchephalogram), the amplitude of ASSR (the amplitude at the modulation rate) is the sum of the signal amplitude and the residual EEG noise. Usually the ASSR amplitude decreases when modulation rate increases (see Figure 14). However, in region between 40 – 90 Hz there is an enhancement of the response above the general decline.

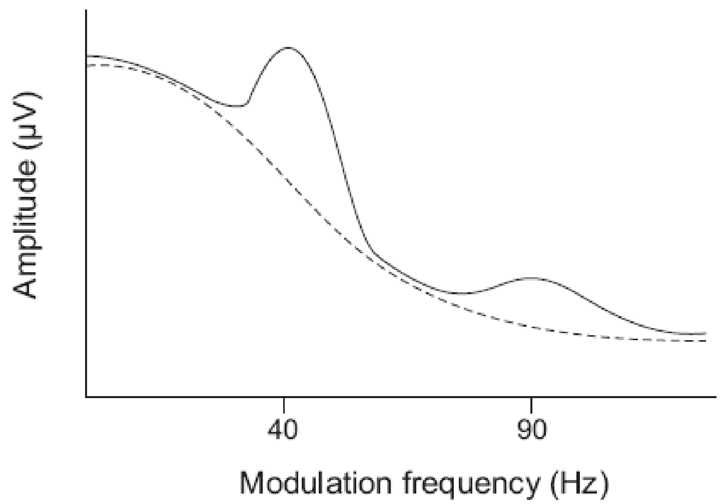


Figure 14. Schematic representation of the amplitude of the auditory steady-state response (solid line) and the noise level (dashed line) as a function of modulation frequency for amplitude-modulated tones. [41]

The detectability of the ASSR depends on the characteristics of the EEG. EEG signals consist of several simultaneous oscillations which have traditionally been divided into frequency bands e.g. delta (1-3 Hz), theta (4-8 Hz), alpha (8-12 Hz), beta (14-30 Hz) and gamma (around 40 Hz). The brain signals are associated to alertness, degree of mental effort and level of attention. When EEG is recorded from the scalp it is intermixed with other electrical activity from the scalp muscles, the eyes, the skin and the tongue. The amount of EEG activity decreases with increasing modulation frequency and the activity is most prominent at frequencies below 25 Hz. Thus, although the response amplitude decreases with increasing modulation rate, the signal-to-noise ratio may well increase [42]. In order to determine hearing thresholds with ASSR, the responses should be recognizable at intensity levels just above threshold.

6.3.2 Amplitude and/or frequency modulation

The most common stimuli used to evoke ASSRs are sinusoidally amplitude modulated (SAM) tones. The advantage of this kind of stimuli is the simple spectrum. It contains frequency components only at the carrier frequency and carrier frequency plus and minus modulation frequency. The depth of modulation is defined as the ratio of the difference between maximum and minimum amplitude of the signal to the sum of the maximum and minimum amplitudes. The spectral energy at the carrier frequency decreases and at the sideband increases when the depth of modulation is increased. When the depth is 100%, the amplitude at the sidebands is a half of carrier frequency amplitude. As depth of modulation increases, the amplitude of the ASSR increases (see Figure 15).

Also frequency-modulated (FM) tones can evoke ASSRs [38][34]. The depth of frequency-modulation is defined as the difference between maximum and minimum frequencies divided by the carrier frequency. The amplitude of the response increases as the depth increases. However, the frequency specificity of the stimulus decreases as the FM depth increases.

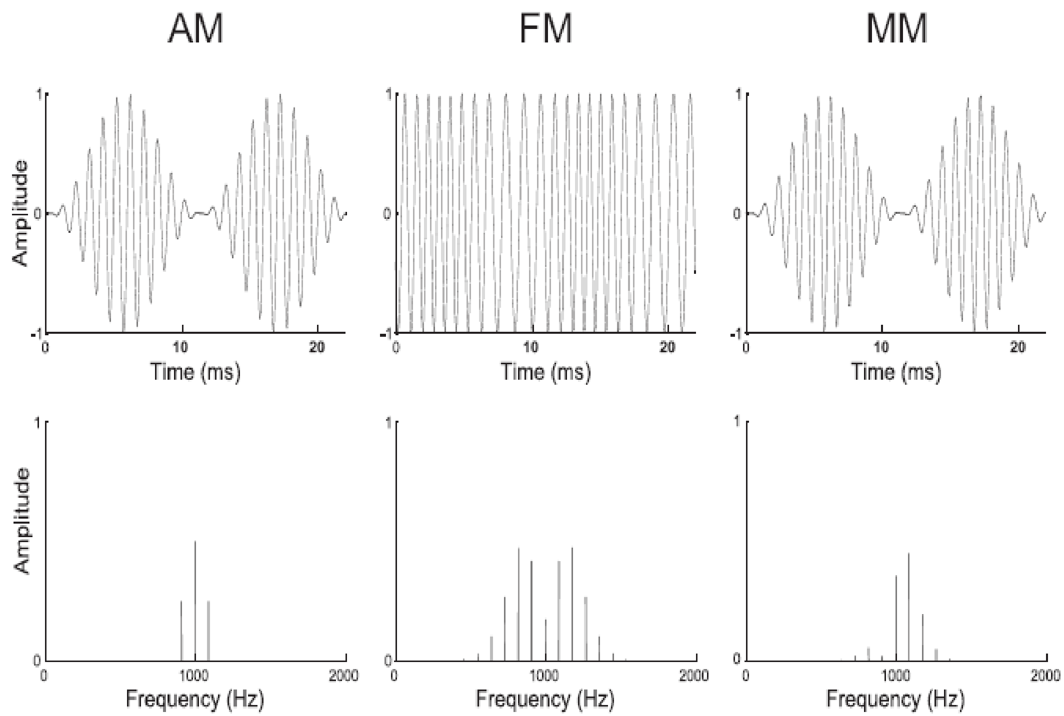


Figure 15. Stimuli used to evoke auditory steady-state responses. The stimuli are presented in the time domain (upper part) and in the frequency domain (lower part). Three types of sinusoidally modulated tones are shown: an amplitude-modulated tone (AM) with a depth of modulation of 100%, a frequency- modulated tone (FM) with a depth of modulation of 50% and a mixed-modulated tone (MM) that is modulated in amplitude (100%) as well as in frequency (20%). All signals consist of a carrier frequency of 1000 Hz that is modulated at a rate of 90 Hz. [41]

Mixed modulation (MM), a combination on FM and AM, evokes larger responses than simple FM or AM tones. In MM both frequency and amplitude of the carrier change at the same modulation rate. It seems apparent that FM and AM components elicit independent responses which add together. If phase of FM is delayed 90° the stimulus reaches the maximum amplitude and frequency at the same time [43]. This type of stimulus is often used with ASSR in audiometric purposes. The FM depth is kept limited, usually between 10% and 25%, in order to keep the stimulus still quite frequency-specific and within one critical band.

6.3.3 Recording and response detection

Time and frequency domains

ASSRs are the most detectable it the frequency domain. In the frequency domain responses are measured as the amplitude and phase at a particular frequency and objective response detection methods can be utilized. Thus, ASSRs are double objective. The patient does not have to respond subjectively so the response generation is objective. Secondly, the clinician does not have to judge the presence of a response subjectively. Therefore also response detection is objective. The recorded EEG activity is transformed from time domain to frequency domain with Fast Fourier Transform (FFT).

SNR

Like in other evoked potential applications, also ASSRs are recorded with other EEG activity and noise. Thus, the SNR has to be considered as an important aspect. The SNR can be improved by averaging the data in the time domain or using the data to increase the duration of the recorded measurement which will be submitted to FFT analysis [47]. Averaging together repeated recordings reduces the level of activity in the recording which is not time-locked to the stimuli. Increasing the duration of the activity submitted to the FFT increases the frequency resolution of the analysis. Averaging process can also be improved by rejecting prior to averaging recordings in which the noise level is excessively high.

Objective response detection methods

A steady-state response is characterized by its amplitude and phase and both of them can be used to assess whether the response is present or not. A detection algorithm can be based on the similarity of a measurement across replications or based on the difference between a measurement at the frequency of stimulation and other measurements (noise) in the spectrum [44]. The two most common methods are phase coherence and the F-technique. Phase coherence evaluates similarity in phase across replications. It calculates the probability that the set of response angles could appear in the absence of a response at any time during the recording. A response is considered reliable if its phase remains stable over time rather than varying randomly [45][46]. The F-technique assesses whether the amplitude and phase of the response at the stimulation frequency are different from the noise at adjacent frequencies [36].

6.3.4 Neural sources

The generators of ASSRs are still not perfectly understood. Nonetheless, separate generators have been suggested for ASSRs evoked by low (25 – 55 Hz) and high (80 – 400 Hz) modulation frequencies because of different dependence on the state of arousal and different latencies. At high modulation frequencies ASSRs are not depended on the state of arousal [48][49]. Low frequency ASSR amplitudes are however sensitive to the subject's behavioral state [39]. During sleep or sedation the amplitude decreases dramatically. This suggests a cortical generator. ASSRs evoked at high modulation frequencies have a short latency (7-9 ms) while at low modulation frequencies latency is about 30 ms. This indicates that the source which generates the high-frequency ASSRs presumably resides in the brainstem, and the source which generates the response at low modulation frequencies is probably cortical.

Studies [39][50] suggest that different generators respond selectively to different modulation frequencies. A possible neural basis for this selectivity is provided by the responses of auditory neurons to amplitude-modulated tones. Animal studies of locally recorded evoked potentials or single-unit studies show that the higher structures in the auditory system the lower rates of modulation are preferred by neurons [39]. If patients are tested using ASSRs to 70-100 Hz modulated AM tones, the results would suggest normal auditory function up to the level of the brainstem. In case of malfunction further along the auditory pathway it would not be noticed unless lower modulation rates are used [50].

6.3.5 Frequency specificity

The frequency specificity of the ASSR is not merely related to stimulus characteristics but also to the response pattern of peripheral and central auditory structures. Frequency specificity can be divided into acoustics specificity, place specificity and neural specificity [42].

The acoustic specificity defines how well the stimulus energy is concentrated within certain frequencies in the spectrum. Place specificity is related to an activation pattern of the basilar membrane caused by a traveling wave. The point of maximal activation is considered as the specific place for that certain tonal frequency. However, the activation can be spread to regions on the basilar membrane other than the specific place. In a normal healthy ear the tuning curve of the auditory nerve shows a narrow tip at the characteristic frequency (see Figure 16). In case of cochlear hearing impairment, the tuning curve looks quite different. Its tip may be attenuated and distorted, which leads to reduced neural specificity. Thus, the threshold of auditory nerve to fire at the characteristic frequency and at other frequencies decreases.

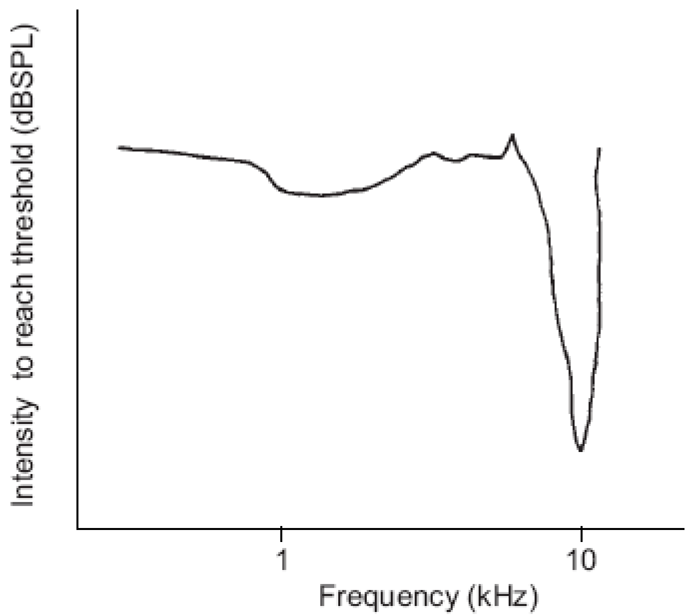


Figure 16. Schematic representation of a physiological tuning curve of an auditory nerve fiber. The frequency at which the threshold of the fiber is lowest is called the characteristic frequency. [51]

6.3.6 Electromagnetic artifacts

In recording ASSRs, some electromagnetic problems might occur [52]. When electric currents are converted into sound by an acoustic transducer, some electromagnetic fields are generated. These fields may be picked up by the EEG recording electrodes. When stimulus and response overlap in time, the aliased stimulus energy might be interpreted as a response. In case of a linear transducer, its electromagnetic field contains only frequencies that are present in the signal. Since the response frequency is different from the stimulus frequency, it should not cause much problems. A sinusoidal AM-modulated stimulus contains energy only at its carrier frequency and its nearness, not at the modulation frequency which is used in response detection. Anyway, because of the aliasing effect [52] and non-linearities in transducers and the recording system, problems may occur with high-intensity air-conducted stimuli or moderate-intensity bone-conducted stimuli [53][54].

Aliasing occurs if sampling frequency is lower than twice the signal frequency. When ASSRs are recorded with an AD-conversion at sampling rate 800 Hz, the frequencies above 400 Hz alias into the spectrum. For example, if a 1600 Hz carrier modulated at 80 Hz is presented, there will be aliased frequency component in the spectrum at 0 Hz. The sidebands, however, will be aliased exactly at the modulation frequency, which is used in response detection.

The fact that a recording system is not a perfectly linear system can directly incur artifactual energy at the modulation frequency. The occurrence and size are dependent on intensity and frequency of stimulus, the distance between recording circuits and transducer, the geometry of the electromagnetic field and recording circuits, and electrode montage and other factors. Bone conduction transducers cause more artifacts than air-conducted transducers, and earphones more than insert phones [52].

There is a number of solutions to try to avoid electromagnetic artifacts. The easiest solution is to change the sampling rate. When the sampling rate is not an integer multiple of the carrier, the stimulus energy is not aliased at the modulation frequency and thus will not disturb the response detection [52.] It is important that the AD and DA buffers have the same duration and remain synchronized during the recording. Thus the number of appropriate sampling rates is limited. Another way to avoid electromagnetic artifacts is to use a stimulus with spectrum that does not alias back to the response frequencies, such as beats or SAM tones with alternating stimulus polarity [52][54]. Also shielding of cables and transducer can reduce the electromagnetic interference.

6.3.7 Multiple-stimulus ASSR

In 1970, it was demonstrated that steady-state responses to simultaneous visual stimuli can be analyzed independently if each stimulus is modulated at different frequency [55]. Later the possibility of using multiple auditory steady-state responses to evaluate hearing at different frequencies in both ears was introduced in 1995 [56].

In order to assess hearing with multiple frequencies in both ears simultaneously, multiple carrier frequencies have to be presented. Each carrier has to be modulated at a different frequency so that carriers activate different regions on the basilar membrane (see Figure 17). When evaluating the responses to each carrier frequency, responses can be separated by assessing the spectral component at the modulation frequency specific to the certain carrier. Thus, modulation frequencies act as labels to carrier frequencies [57]. Modulation frequencies for each carrier can be very close to each other if Fourier analysis used has enough resolving power. Separating the frequencies only by 1.3 Hz does not attenuate the response [58].

If carrier signals that form the combined stimulus are separated by one octave or more there is a slight overlap of the activated regions on a basilar membrane, at least at the low and moderate intensities. Thus, at the low frequencies the response is specifically mediated by hair cells and nerve fibers in one region of the basilar membrane. However, at high intensities the interaction is greater because the bandwidth of the cochlear filter enlarges with increasing sound pressure level [55][57].

The multiple-stimulus approach can increase the efficiency of steady-state audiometry by decreasing the test duration compared to the single-stimulus approach. However, the decrement in amplitude of the response caused by the simultaneous stimulation has to be less than the EEG noise decrement provided by the increased time available for recording the responses [47]. The decrement in amplitude could be a result of interactions between simultaneous stimuli due to overlap of activated regions on the basilar membrane [42] or neural interactions in the central nervous system [55]. Another limitation of the multiple-stimulus approach can be the attenuation of the envelope response of the low-frequency carrier caused by the high-frequency one. Also responses to high-frequency carriers might be enhanced if they are presented together with low-frequency stimuli [59]. The multiple stimulus approach would be the most efficient if the amplitudes of the responses were equal. It takes longer to determine that the response is absent than it takes in case of present response.

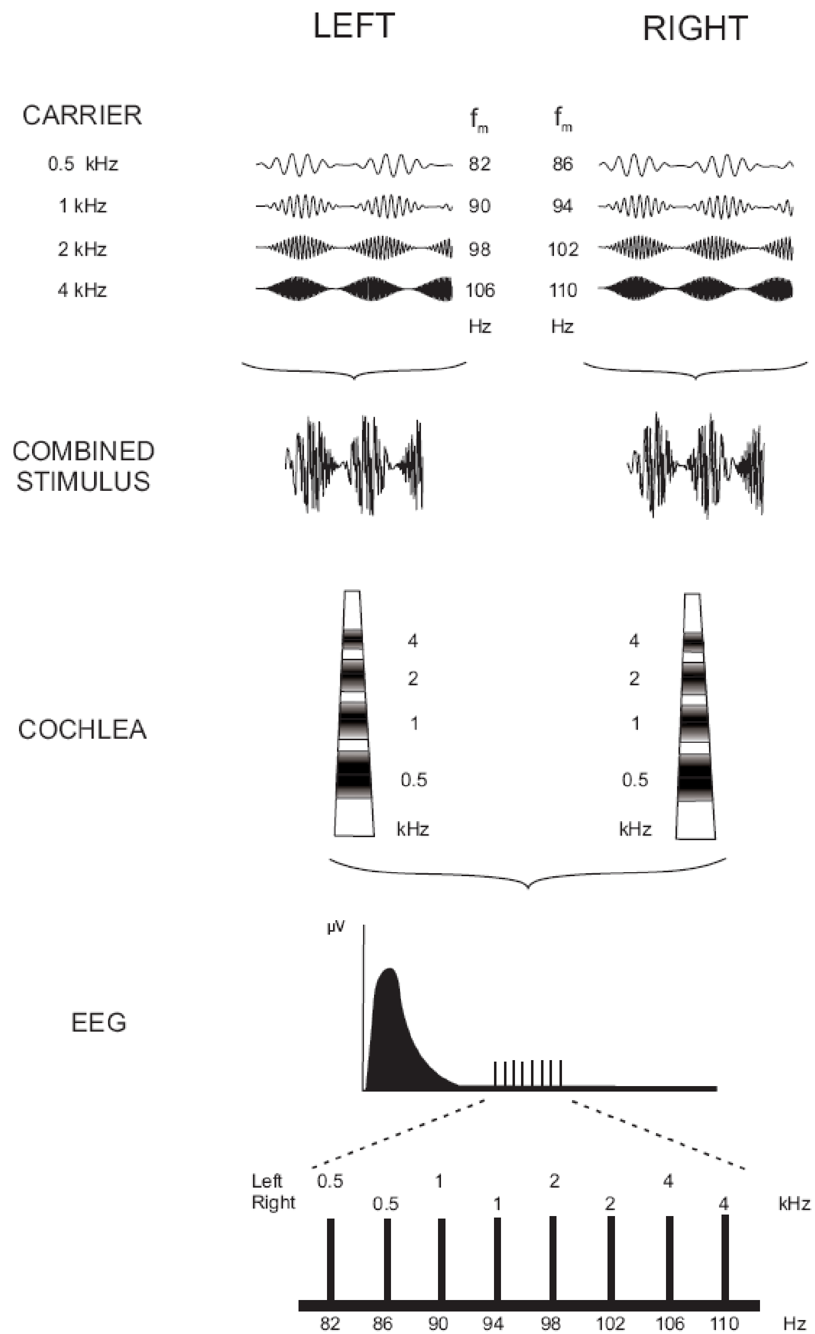


Figure 17. Principle of dichotic multiple-stimulus auditory steady-state responses. A combined stimulus that consists of four carrier frequencies, each modulated at a different modulation frequency is presented to each ear. On both basilar membranes, only the regions around the carrier frequency are stimulated, since the presented signals do not contain spectral energy at the modulation frequencies. As a result of the compressive rectification process, the neural response does contain energy at the modulation frequencies. Moreover, the response to each carrier can be separated in the frequency domain, since it occurs exactly at the modulation frequency. [41]

7 Objective assessment of frequency specific hearing thresholds in cochlear implant patients using ASSR

The purpose of the present research was to study ASSR responses with cochlear implant patients and to determine how ASSR can help in programming implants with difficult-to-test patients and children who cannot report their auditory perception. The main interest was to find out whether the hearing threshold measured with ASSR corresponds to the threshold measured in an acoustic field with the same speech processor programming parameters, and can this objective information be used in programming a cochlear implant speech processor. In addition an extra study was performed on perception of AM and FM with only one electrode in use.

7.1 Methods

7.1.1 Patients

All testees were adult cochlear implant patients managing well with their implants. Another selection criteria was that these patients had to be known as good listeners who could evaluate and describe their sound sensation clearly and accurately. We ran our test procedure with five patients. The first, third and fourth patients had implant on the right side, the second and fifth on the left side.

7.1.2 Experimental design

Our test procedures changed a bit as the research proceeded and our knowledge and experience increased. Our original plan was to start with defining the normal hearing level and threshold based on the subjective evaluation from the patient. We ran the tests at three different frequencies, 500 Hz, 1500 Hz and 4000 Hz, that were planned to be also the ASSR test frequencies. However, we dropped the test after third patient since we reassessed the value of the information the test gave. In addition we thought that the short testing time period we had was more valuable when determining the thresholds in sound field, for which we did not have time at the first two test sessions. Also the FM – AM comparison tests were dropped after the third patient since the results were as obvious as we expected nor did they bring any additional value to this research.

We used a pocket model processor[1] for testing in order not to have to program patients' own processors again. With each patient we built three different programs into the processor so that one was similar to the patients' own program for communication and two

[1] MedEl Combi 40+

programs for testing. With patient 1 another two programs we used were MCL 530 with all electrodes in use and MCL 530 with only electrodes 2, 5 and 9 in use. With patient 2 we had MCL 595 with all electrodes in use and MCL 595 with electrodes 3, 7 and 11 in use. With patient 3 and 4 we had MCL 105 and MCL 205 also with electrodes 3, 7 and 11 in use (see Figure 18). In case of patient 5 we used only one MCL 515 program with electrodes 3, 7 and 11 in use. In all programs with only three electrodes in use the center frequencies for the three channels in use were adjusted to 500Hz, 1500Hz and 4000Hz for electrodes 3, 7 and 11 (in case of patient 1 for electrodes 2, 5 and 9) respectively. The idea of choosing only three electrodes on three channels was that they had to be far enough from each other to avoid interference. In this case it implicates that when stimulating one chosen channel, the signal should not be detectable on either of the other two channels. This was verified using implant simulator[2]. Three stimuli on the chosen frequencies were given, one at a time, while listening the output of the electrodes corresponding to the other two channels. No signal was detected, and thus the channel end electrode selection proved to be useful.

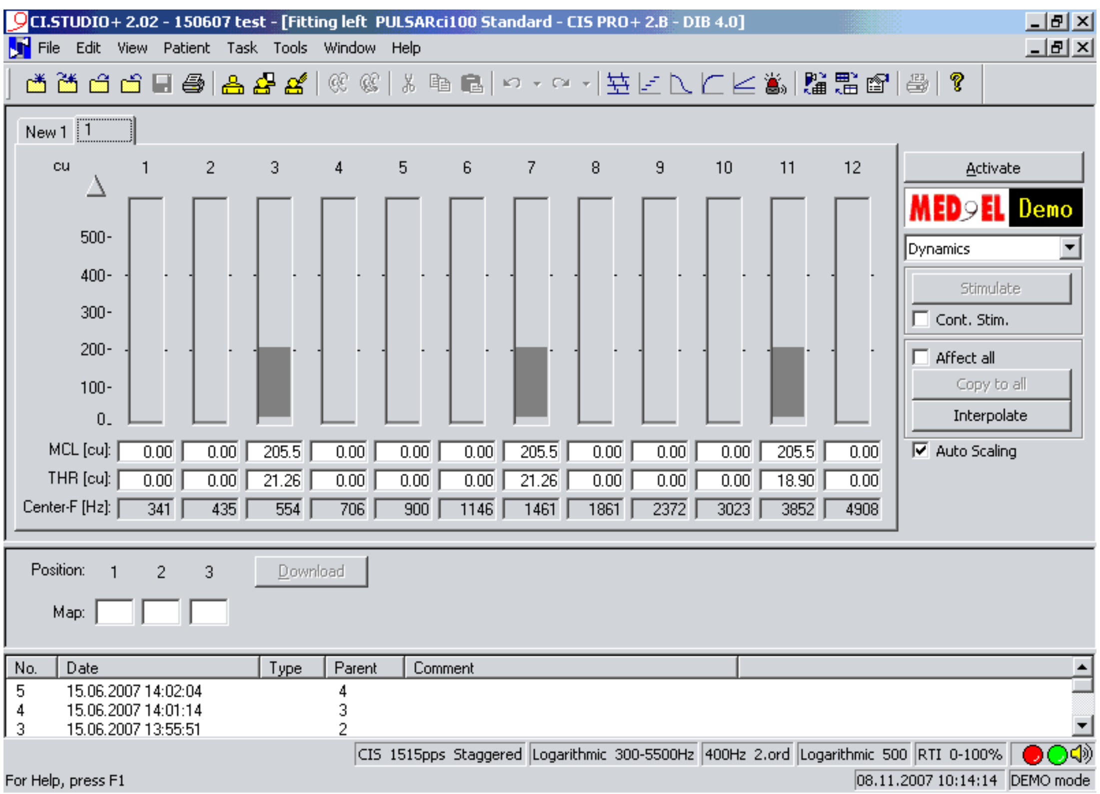


Figure 18. A screenshot of adjusting the test parameters for patient 4 (program 1) in CI.Studio+ 2.02 implant processor fitting program. Only electrodes 3, 7 and 11 are set up at MCL 205 cu (current units). Other electrodes are off. Center frequencies are adjusted as close as possible to the stimulating frequencies 500Hz, 1500Hz and 4000Hz. After adjusting the testing parameters, test program was downloaded to the processor through MedEl Diagnostic Interface Box (DIB).

[2] MedEl CIS Pro+ Detector12 implant simulator

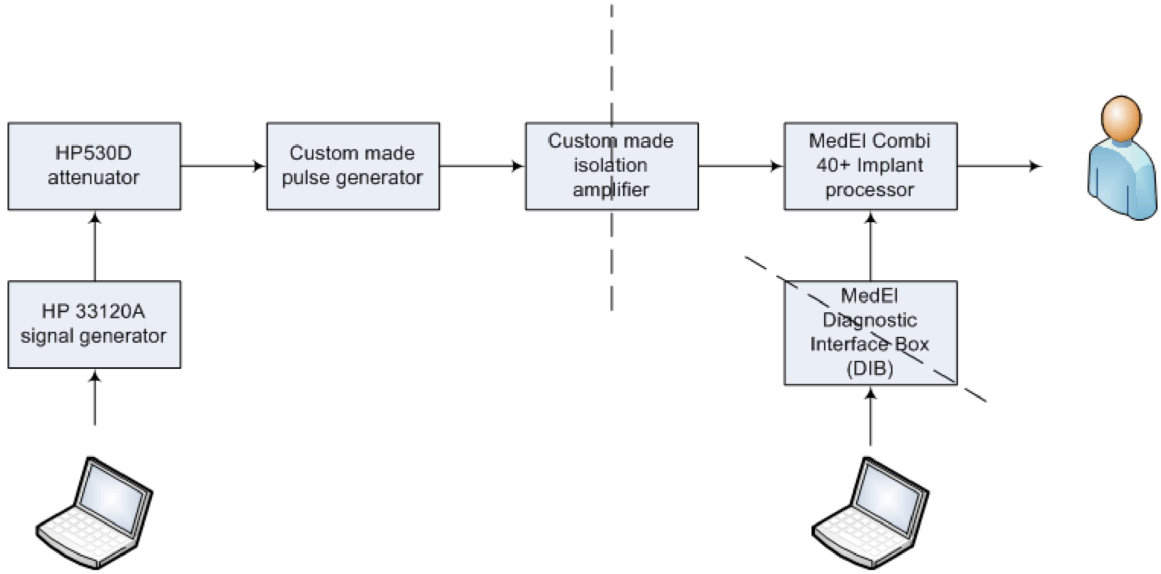


Figure 19. Schematic view of experimental arrangement of hearing level determination. Signal from the HP signal generator was given through attenuator and pulse generator to the isolation amplifier that isolates patient from the mains current. From that the signal was mediated to the implant processor that was programmed according to our test parameters. Test programs were downloaded to the processor through diagnostic interface box.

7.2 Hearing level determination

We wanted to find the normal loudness level and the threshold at three different frequencies, 500Hz, 1500Hz and 4000Hz by giving the pure tone stimuli straight to the cochlear implant speech processor (see Figure 19). Testing started at well audible level and then proceeded by descending manner until the patient could not report any sound sensation. Then the loudness level was increased to the audible level and again decreased in smaller steps until the threshold was found. After every stimulation the patient was asked to point out the loudness level on the Med-El loudness chart. The normal loudness level was determined in the same manner than the threshold.

7.3 FM-AM comparison

The purpose of this measurement was to study how frequency and amplitude modulation can be detected when stimulating an electrode with its center frequency and if there is no adjacent electrodes in use.

7.3.1 Procedure

We made the comparison using pure tone, frequency modulated tone and amplitude modulated tone. Frequency deviation was 10 %, modulation depth 100% with AM and modulation frequency 81 Hz with both cases. Signals were continuous and given at normal loudness level that we had defined before testing for each patient. We started with pure tone – frequency modulated tone comparison and asked the patient to tell if signals were same or different. Then the comparison was made to pure tone – amplitude modulated and finally to frequency modulated – amplitude modulated signals. The same cycle was repeated for 500 Hz, 1500 Hz and 4000 Hz signals. The first test round was run with three electrode program. Then we repeated the whole procedure and made the comparisons using the program with all electrodes in use.

7.3.2 Results

The results of FM – AM comparison are presented in Table 1. The comparisons were made with three first patients at three different frequencies (500 Hz, 1500 Hz, 4000 Hz) using program with only three electrodes in use. In the table the x-symbol describes when the patient heard the difference between signals. The results show that patients are not able to recognize the difference between pure tone and frequency modulated signals. The comparisons were also made using the program with all electrodes in use and in that case patients could hear the difference in all test cases.

Table 1. Results of FM – AM comparison. x-symbol describes when the patient heard the difference between signals.

	No Mod - FM			FM - AM			No mod - AM		
	Patient			Patient			Patient		
	1	2	3	1	2	3	1	2	3
500 Hz				x	x	x	x	x	x
1500 Hz	x			x	x	x	x	x	
4000 Hz			x	x	x		x	x	

7.3.3 Discussion

The measurements gave the results we expected. When measuring with only three electrodes in use, the patients should not hear the difference between pure tone and frequency modulated, and they did not. The stimulation signals were adjusted to be the same than the center frequencies for each electrode, and because there were no adjacent electrodes in use, the frequency variation could not be detected. When we took all electrodes in use, the frequency modulation could be heard and the difference between pure tone and frequency modulated signals was reported every time.

In case of amplitude modulation the patients were able to tell the difference between pure tone and amplitude modulated, and between frequency modulated and amplitude modulated signals. This result was also as we expected. The variation in amplitude could be detected without adjacent electrodes since it affects only to the voltage amplitude of the simulation signal.

7.3.4 Conclusions

Frequency modulation cannot be detected with only one electrode if no adjacent electrodes are in use when stimulating with the center frequency of the electrode.

7.4 ASSR measurements

7.4.1 ASSR stimulation and recording parameters

The ASSR was recorded with GSI Audera auditory steady state audiometer. Stimuli were presented one at a time at three carrier frequencies, 500 Hz, 1500 Hz and 4000 Hz. The stimuli were 100% amplitude modulated and 10% frequency modulated. Simultaneous modulation in both amplitude and frequency results in larger responses compared to simple amplitude modulation [61]. The angle between FM and AM was 0 degrees. Modulation frequencies were 81 Hz at every carrier frequency. Stimulus levels ranged between 10 and 100 dB HL depending on the patients' dynamic range. (see Table 2)

Noise criteria level determines if the result is considered a noise result or a random result. We kept it at the default -140 dB. Five tests were required before Audera's algorithm started to calculate probabilities and the maximum number of tests was limited to 55. Stimulus level resolution was 5 dB and programmatic upper and lower limits were 0 and 130 dB HL respectively. (see Table 2)

7.4.2 ASSR testing procedure

ASSR measurements were made in neck supported sitting position. Patients were asked to stay relaxed and as still as possible to avoid unwanted potentials in EEG. Electrodes were attached to the left and right mastoids, high forehead and common electrode under the chin (see Figure 21). We wanted the contact impedance to be under 2.5 kohm. If impedance was too high we cleaned the contact spot on the skin a bit with soft sand paper and used contact gel on the skin. We ran tests using three different frequencies, 500 Hz, 1500 Hz and 4000 Hz. First at 1500 Hz, then 500 Hz and finally 4000 Hz since many patients find the highest frequency the most difficult and annoying to listen. With each patient the measurements were ran with both of their test programs except in case of patient 5 with only one. The experimental arrangement is presented in Figure 20.

Table 2. ASSR stimulation and recording parameter for testing frequencies 500Hz, 1500Hz and 4000Hz.

Carrier frequency	500 Hz	1500 Hz	4000 Hz
Stimulus level	0 to 100 dB HL	0 to 100 dB HL	0 to 100 dB HL
Modulation frequency	81 Hz	81 Hz	81 Hz
AM modulation	100 %	100 %	100 %
FM deviation	50 Hz	150 Hz	400 Hz
Relative AM/FM angle	0 degrees	0 degrees	0 degrees
Stimulus type	AM/FM	AM/FM	AM/FM
Noise criteria level	-140 dB	-140 dB	-140 dB
Resolution	5 dB	5 dB	5 dB
Lower limit	0 dB HL	0 dB HL	0 dB HL
Start level	65 dB HL	65 dB HL	65 dB HL
Upper limit	130 dB HL	130 dB HL	130 dB HL
Tests required	5	5	5
Total tests	55	55	55

The measurement started at well audible level, 75 dB HL – 100 dB HL depending on the patient's normal hearing level. After every test the patient was asked to give subjective feedback on the sound sensation, but not until the particular ASSR measurement was finished. This was done by pointing out the perceived loudness level on the loudness chart. The stimulus level was decreased with 10 dB HL if the previous response had been very clear and phase locked almost immediately. If the response was not that clear, we used 5 dB decrease in stimulation level. We decreased the stimulation level until the phase did not lock. If the phase did not lock but the patient however reported a sound sensation, we decreased the level until the subjective threshold was found. This same procedure was repeated at all three frequencies.

7.4.3 Results

Results of ASSR measurements are shown in
Table 3-Table 6. In total 158 measurements were carried out of which 115 are presented here. Some measurements were repeated if the results appeared to be somehow inconsistent with other measurements and thus are not shown here. Also the results of patient number 3 are not shown here since the results were completely inconsistent due to some unexplained electromagnetic interference and thus do not bring any value to our research.

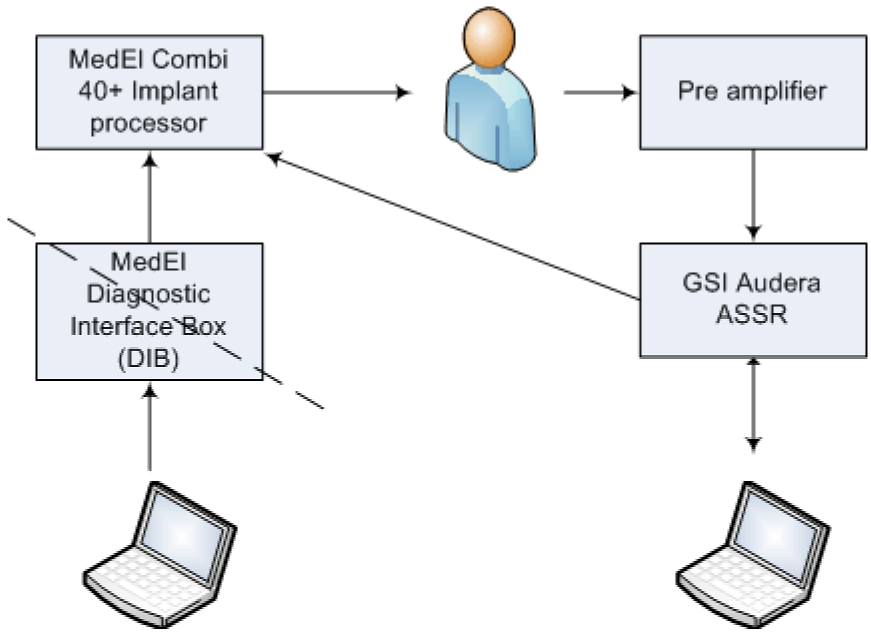


Figure 20. Schematic view of experimental arrangement for ASSR measurements. Testing program is first downloaded to the implant processor through diagnostic interface box. Then the stimulus is given from the Audera straight to the implant processor and at the same time Audera measures the patient's ASSR responses that are registered by the electrodes attached to the patient's head, and mediated to the Audera through the preamplifier.

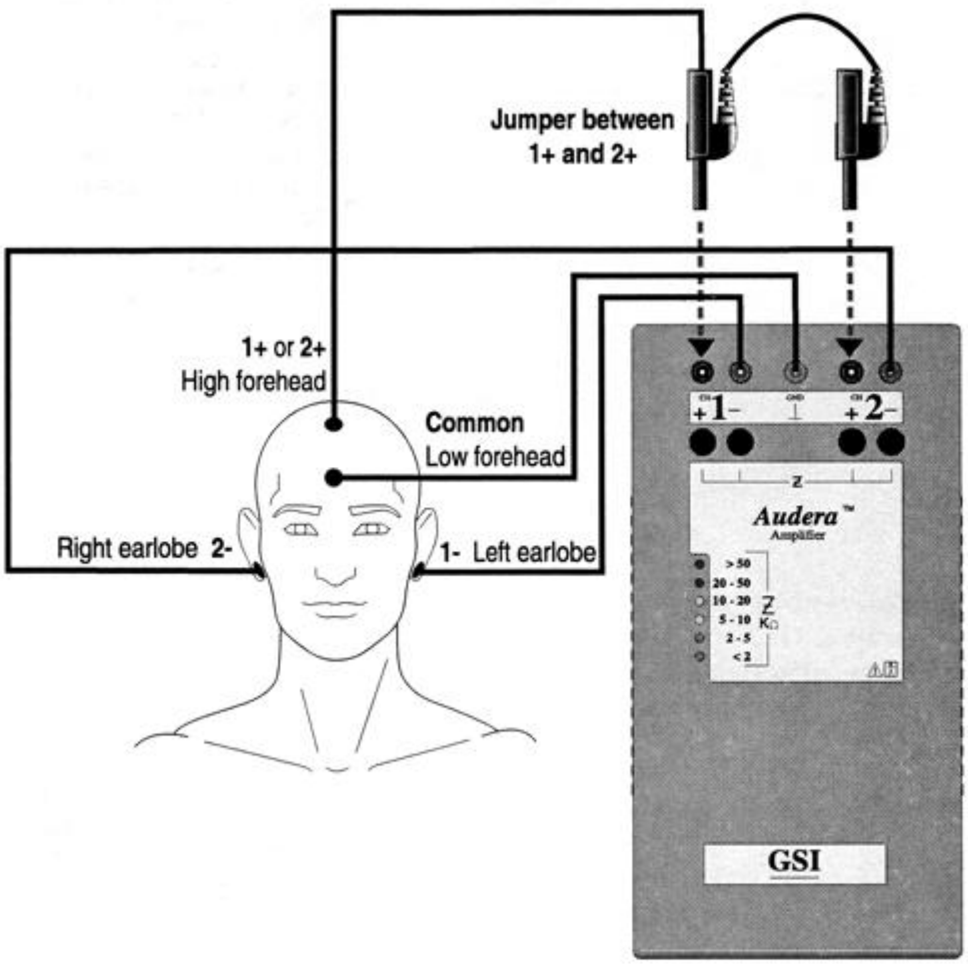


Figure 21. Schematic representation of placing the electrodes for ASSR measurements and connecting them to the preamplifier. 2- and 1- electrodes can be attached either to the left and right mastoids or earlobes. Electrodes 1+ or 1- to the high forehead. Common electrode can be attached either to the low forehead or under the chin. Picture adapted from GSI Audera manual.

Table 3. Patient 1. The results of ASSR measurements. For parameters, see text.

Freq [Hz]	El nr	MCL [cu]	ASSR level [dB HL]	Lock / Random	N	Duration [s]	Vect spread [deg]	Main angle [deg]	Length [uV RMS]	Subjective perception
program 1										
500	2	530	60	Lock	17	35	45	-265	1,8	normal
			50	Lock	17	35	31	-291	1,21	very quiet
			45	Random	44		315	-275	0,45	none
1500	5	530	85	Lock	17	35	46	-99	1,35	normal-strong
			80	Lock	16	33	21	-220	1,89	normal-strong
			65	Lock	16	33	17	-223	2,04	normal-strong
			60	Lock	17	35	30	-223	1,23	normal
			55	Lock	28	50	224	-218	0,88	very quiet
			50	Lock	47	76	241	-208	0,6	none
			40	Lock	58	91	310	-48	0,38	none
4000	9	530	60	Lock	18	36	55	-40	0,95	very quiet
			50	Lock	45	73	235	-76	0,59	none
			45	Lock	56	88	300	-23	0,44	none
program 2 (flat)										
500	2	530	60	Lock	17	35	43	-271	1,78	normal
			50	Lock	18	36	61	-286	1,05	very quiet
			40	Lock						none
1500	5	530	80	Lock	17	35	40	-87	1,58	normal
			60	Lock	17	35	22	-220	3,07	normal
			50	Lock	28	50	180	-230	0,55	very quiet
			40	Lock	34	58	165	-43	0,53	none
4000	9	530	60	Lock	18	36	63	-12	1,61	very quiet
			50	Lock	26	47	121	-38	0,58	none
			40	Random	60		300	-30	0,77	none

Table 4. Patient 2. The results of ASSR measurements. For parameters, see text.

Freq [Hz]	El nr	MCL [cu]	ASSR level [dB HL]	Lock / Random	N	Duration [s]	Vect spread [deg]	Main angle [deg]	Length [uV RMS]	Subjective perception
program 1										
500	3	595	70	Lock	16	33	5	-91	5,92	strong
			50	Lock	17	35	28	-202	1,86	normal
			40	Lock	16	33	15	-203	1,79	quiet
			30	Lock	17	35	35	-201	1,39	none
			20	Lock	28	50	217	-224	0,34	none
			10	Random	40		330	-172	0,19	none
1500	7	595	70	Lock	16	33	15	-104	3,1	normal
			50	Lock	18	36	75	-125	0,74	very quiet
			45	Lock	42	69	285	-217	0,28	none
			40	Lock	24	44	137	-251	0,43	none
			35	Random	57		270	-232	0,2	none
4000	11	595	80	Lock	17	35	25	-68	3,03	normal
			70	Lock	16	33	10	-72	3,78	strong
			50	Lock	17	35	38	-63	2,84	normal
			40	Lock	17	35	22	-77	2,4	very quiet
			35	Random	45		325	191	2,1	none
program 2 (flat)										
500	3	595	60	Lock	16	33	9	-187	4,96	strong
			50	Lock	16	33	10	-202	3,01	quiet
			45	Lock	17	35	35	-208	1,52	very quiet
			40	Lock	36	61	270	-273	0,22	none
1500	7	595	50	Lock	17	35	40	-244	0,82	very quiet
			45	Lock	18	36	90	-247	0,6	none
			40	Lock	24	44	120	-243	0,36	none
			35	Random	52		270	-226	0,22	none
4000	11	595	70	Lock	16	33	15	-213	0,86	quiet

Table 5. Patient 4. The results of ASSR measurements. For parameters, see text.

Freq [Hz]	El nr	MCL [cu]	ASSR level [dB HL]	Lock / Random	N	Duration [s]	Vect spread [deg]	Main angle [deg]	Length [uV RMS]	Subjective perception
program 2										
500	3	105	65	Lock	16	33	20	-43	1,7	normal
			35	Lock	22	41	105	-138	0,42	quiet
			25	Lock	17	35	50	-157	0,44	very quiet
			20	Lock	20	39	82	-151	0,48	none
			15	Lock	62	96	310	-143	0,33	none
			10	Random	43		320	-103	0,25	none
1500	7	105	65	Lock	17	35	30	-51	1,02	quiet
			35	Lock	17	35	40	-65	0,55	very quiet
			30	Lock	25	46	145	-67	0,4	very quiet
			25	Lock	29	51	151	-73	0,5	none
			20	Lock	23	43	108	-51	0,36	none
			15	Lock	45	73	290	-70	0,36	none
			10	Random	46		306	-6	0,35	none
4000	11	105	65	Lock	18	36	53	-56	0,68	quiet
			60	Lock	18	36	75	-28	0,61	very quiet
			55	Lock	17	35	35	-28	0,83	very quiet
			50	Lock	19	37	61	-36	0,93	very quiet
			45	Lock	17	35	44	-29	1,04	very quiet
			40	Lock	17	35	33	-36	0,9	very quiet
			35	Lock	18	36	55	-40	1,24	none
			30	Lock	17	35	48	-32	0,82	very quiet
			25	Lock	19	37	73	-37	0,57	very quiet
			20	Lock	44	71	292	-62	0,68	very quiet
			15	Random	61		310	-13	0,27	none
program 1										
500	3	205	65	Lock	16	33	15	-37	1,95	normal
			55	Lock	21	40	70	-51	0,31	normal
			45	Lock	23	43	141	-158	0,39	quiet
			35	Lock	20	39	91	-160	0,68	quiet
			25	Lock	17	35	45	-155	0,75	very quiet
			20	Lock	18	36	50	-166	0,53	very quiet
			15	Lock	33	56	283	-185	0,46	none
			10	Random	50		320	-187	0,31	none
1500	7	205	65	Lock	18	36	55	-60	0,87	normal
			55	Lock	16	33	15	-28	1,42	normal
			45	Lock	21	40	100	-42	0,63	normal
			35	Lock	17	35	58	-61	0,83	quiet
			25	Lock	17	35	41	-39	0,7	very quiet
			20	Lock	18	36	69	-79	0,83	very quiet
			15	Lock	25	46	150	-69	0,3	none
			10	Lock	27	48	158	-35	0,4	none
			5	Random	45		320	-112	0,22	none

4000	11	205	65	Lock	17	35	31	-108	0,79	normal
			60	Random	37		315	-355	0,61	very quiet

Table 6. Patient 5. The results of ASSR measurements. For parameters, see text.

Freq Hz	**El nr**	**MCL [cu]**	**ASSR level [dB HL]**	**Lock / Random**	**N**	**Duration [s]**	**Vect spread [deg]**	**Main angle [deg]**	**Length dBV**	**Subjective perception**
500	3	515	70	Lock	16		10	-227	-106,08	strong
			65	Lock	16		8	-231	-105,15	strong
			60	Lock	16		5	-237	-105,17	strong
			55	Lock	19		85	-276	-126,17	normal
			50	Lock	17		30	-349	-123,2	quiet
			45	Lock	17		30	-350	-120,28	quiet
			40	Lock	17		45	-335	-117,7	quiet
			35	Lock	17		25	-345	-115,95	very quiet
			30	Lock	17		32	-338	-116,11	very quiet
			25	Lock	17		32	-340	-116,4	very quiet
			20	Lock	17		40	-349	-121,7	none
			15	Lock	32		240	-34	-131,07	none
			10	Random	42		320	-124	-133,11	none
1500	7	515	60	Lock	16		15	-214	-133,11	normal
			55	Lock	16					quiet
			50	Lock	17		32	-241	-116,41	quiet
			45	Lock	17		20	-245	-117,05	quiet
			40	Lock	16		20	-239	-113,05	quiet
			35	Lock	17		27	-239	-111,5	very quiet
			30	Lock	16		5	-245	-112,34	very quiet
			25	Lock	16		20	-244	-114,72	very quiet
			20	Lock	16		10	-240	-116,83	very quiet
			15	Lock	18		75	-265	-126,95	none
			10	Random	43		330	-181	-128,08	none

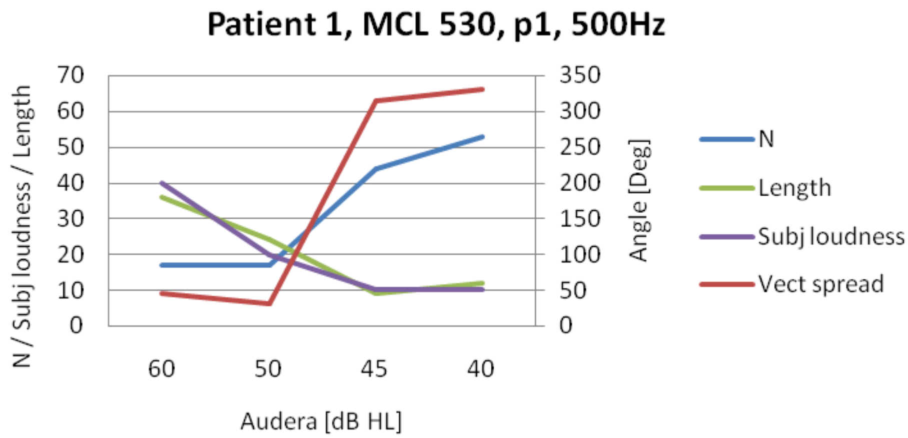
In the ASSR result tables we have first stimulation frequency, then the electrode stimulated, the most comfortable level of the program used and the ASSR stimulus level in dB HL. The "Lock/Random" column describes if the Audera found the response or not. Columns "N" and "Duration" describe how many samples were needed for Audera to lock the response and how many seconds this took. Column "Vector spread" gives the angle the vector drew until it locked (see Figure 22) to some angle that is given in the column Main angle. Angle varies between 0 – 360 degrees. The column "Length" describes the RMS-length of the response. Basically it tells the strength of the response. Finally, the subjective perception is feedback the patient gave on each measurement.

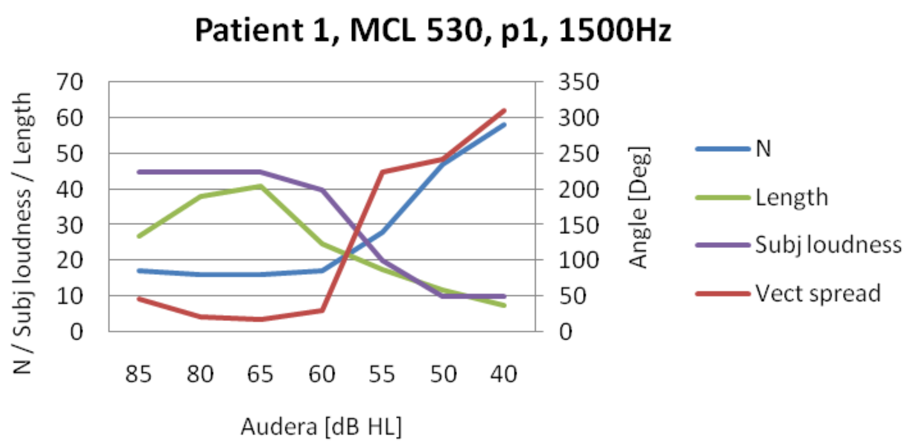
In Figure 23-Figure 29. the number of samples, vector spread, vector length and patient's subjective perception are presented in diagrammatic form. In case of patient 5 the main angle difference to the previous measurement is presented instead of vector length. The values of vector length and main angle difference have been scaled up to make the diagram more readable. The values of subjective perception have been formulated from 10 to 50 as follows:

Table 7. Subjective perception on the scale 10 to 50.

strong	50
normal	40
quiet	30
very quiet	20
none	10

Figure 22. Three screenshots of part of the ASSR recording view. In the left upper corner is a really good and clear response. The vector spread is small. In the right upper corner the stimulus level has been lowered and the vector spread is already started to widen. In the lower screenshot the stimulus level was so low that vector rotated around the circle. Thus, Audera interpreted the response as noise.





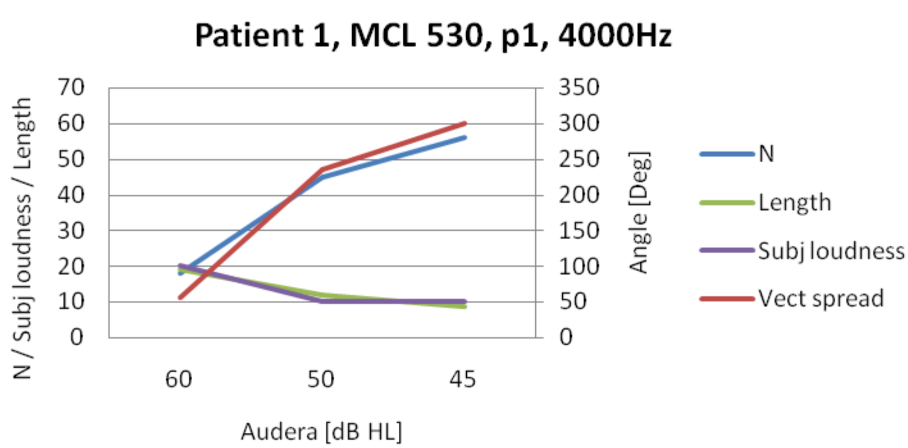
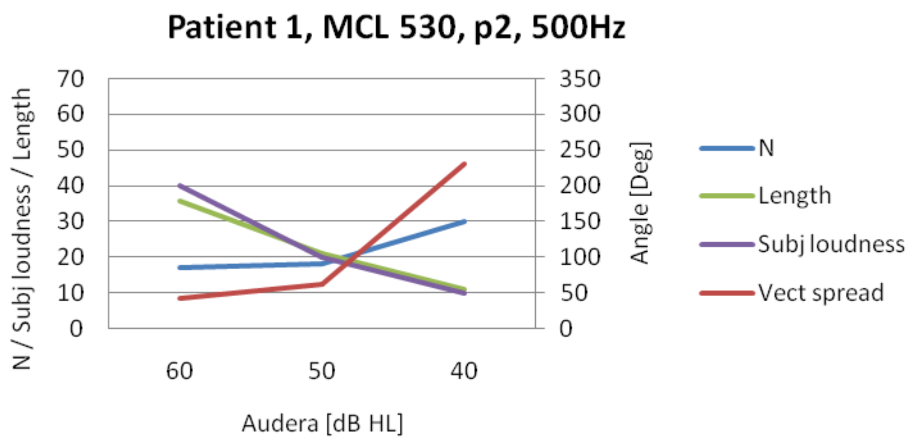
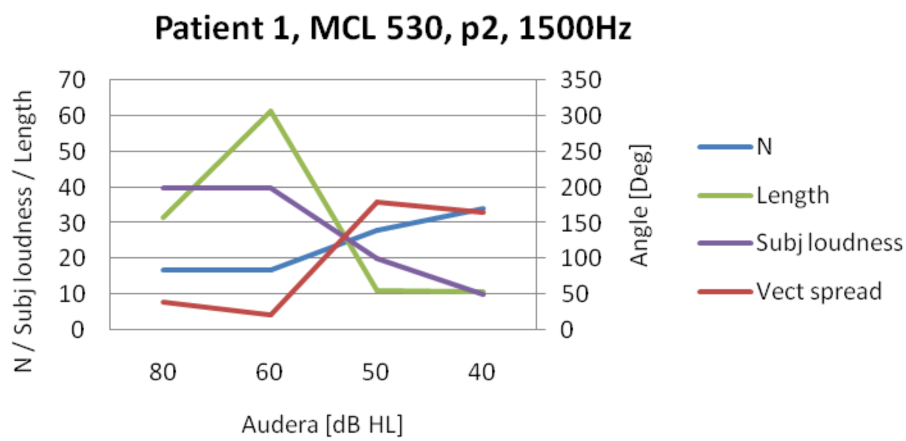


Figure 23. Diagrammatic representation of ASSR measurement results of patient 1, program 1. Number of samples (N), Length and Subjective loudness are on the left vertical axis and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 530 cu. Electrodes 2, 5 and 9 are in use. Stimulus frequencies are 500 Hz, 1500 Hz and 4000 Hz respectively.





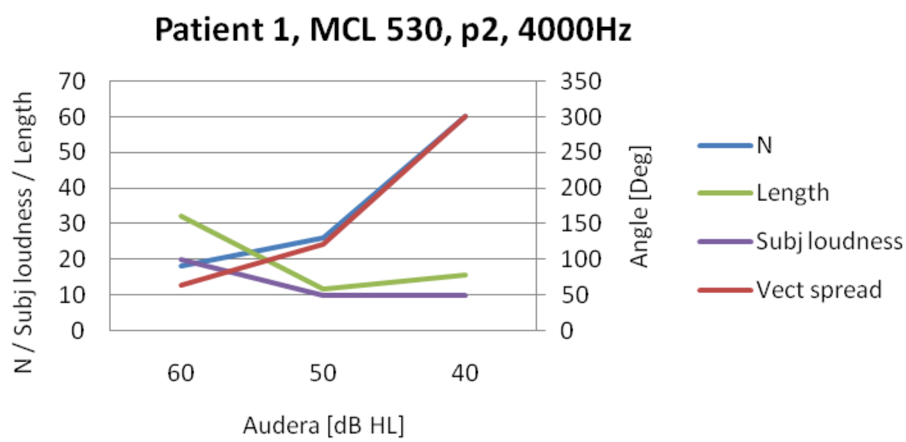
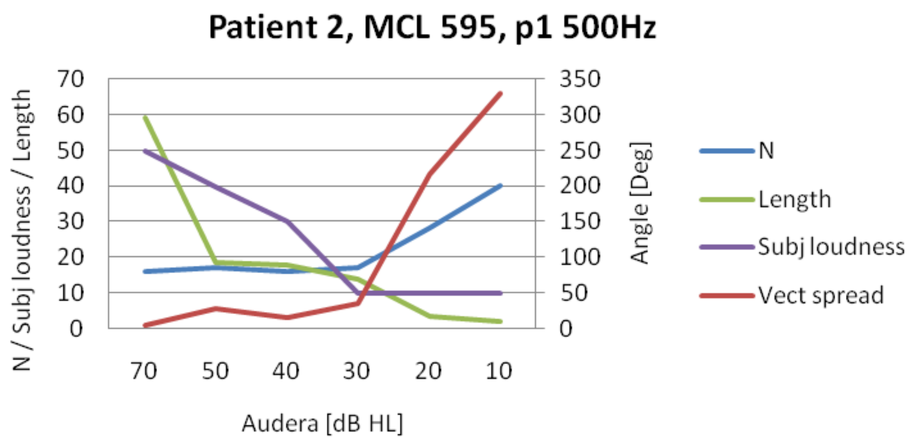
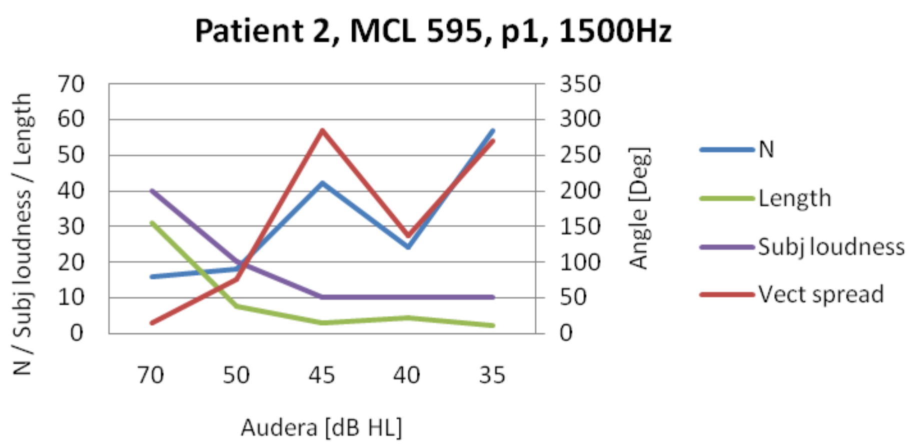


Figure 24. Diagrammatic representation of ASSR measurement results of patient 1, program 2. Number of samples (N), Length and Subjective loudness are on the left vertical axis and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 530 cu. All electrodes are in use. Stimulus frequencies are 500 Hz, 1500 Hz and 4000 Hz.





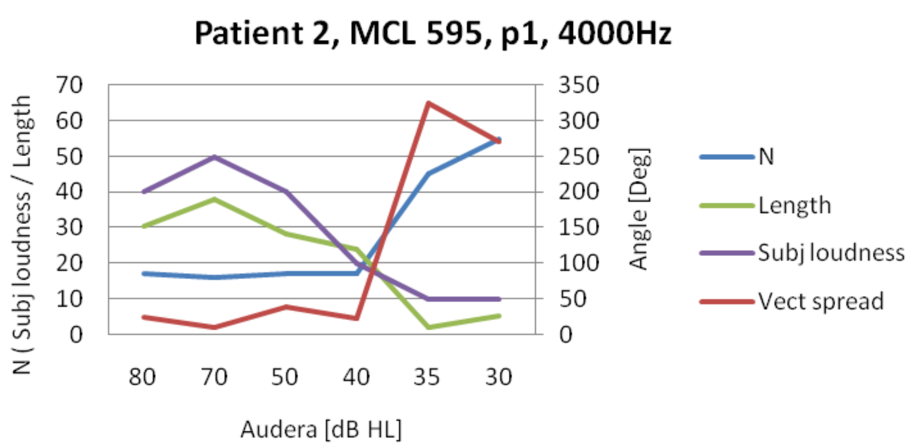
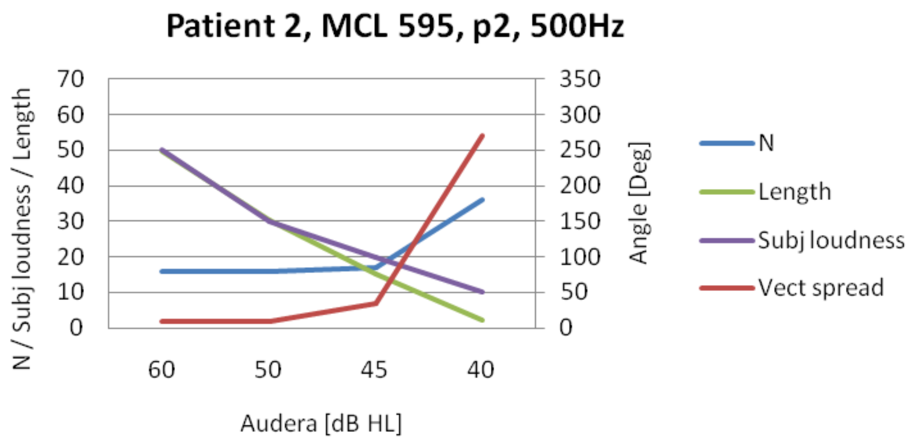


Figure 25. Diagrammatic representation of ASSR measurement results of patient 2, program 1. Number of samples (N), Length and Subjective loudness are on the left vertical axis and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 595 cu. Electrodes 3, 7 and 11 are in use. Stimulus frequencies are 500 Hz, 1500 Hz and 4000 Hz respectively.



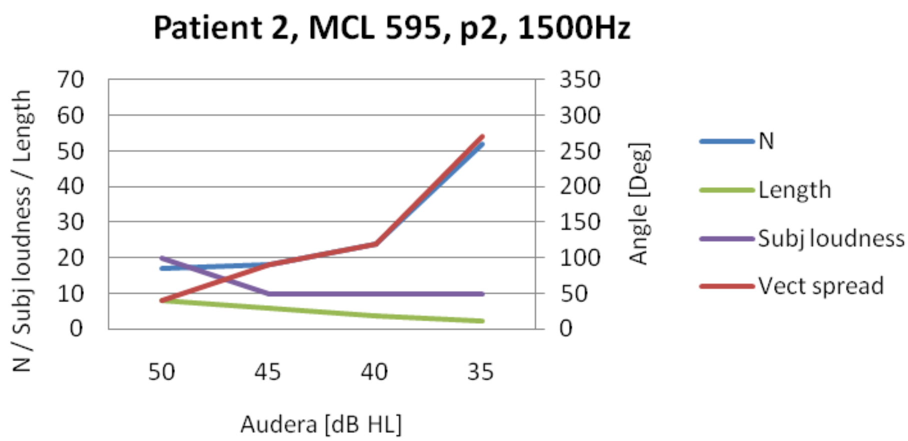


Figure 26. Diagrammatic representation of ASSR measurement results of patient 2, program 2. Number of samples (N), Length and Subjective loudness are on the left vertical axis and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 595 cu. All electrodes are in use. Stimulus frequencies are 500 Hz, 1500 Hz

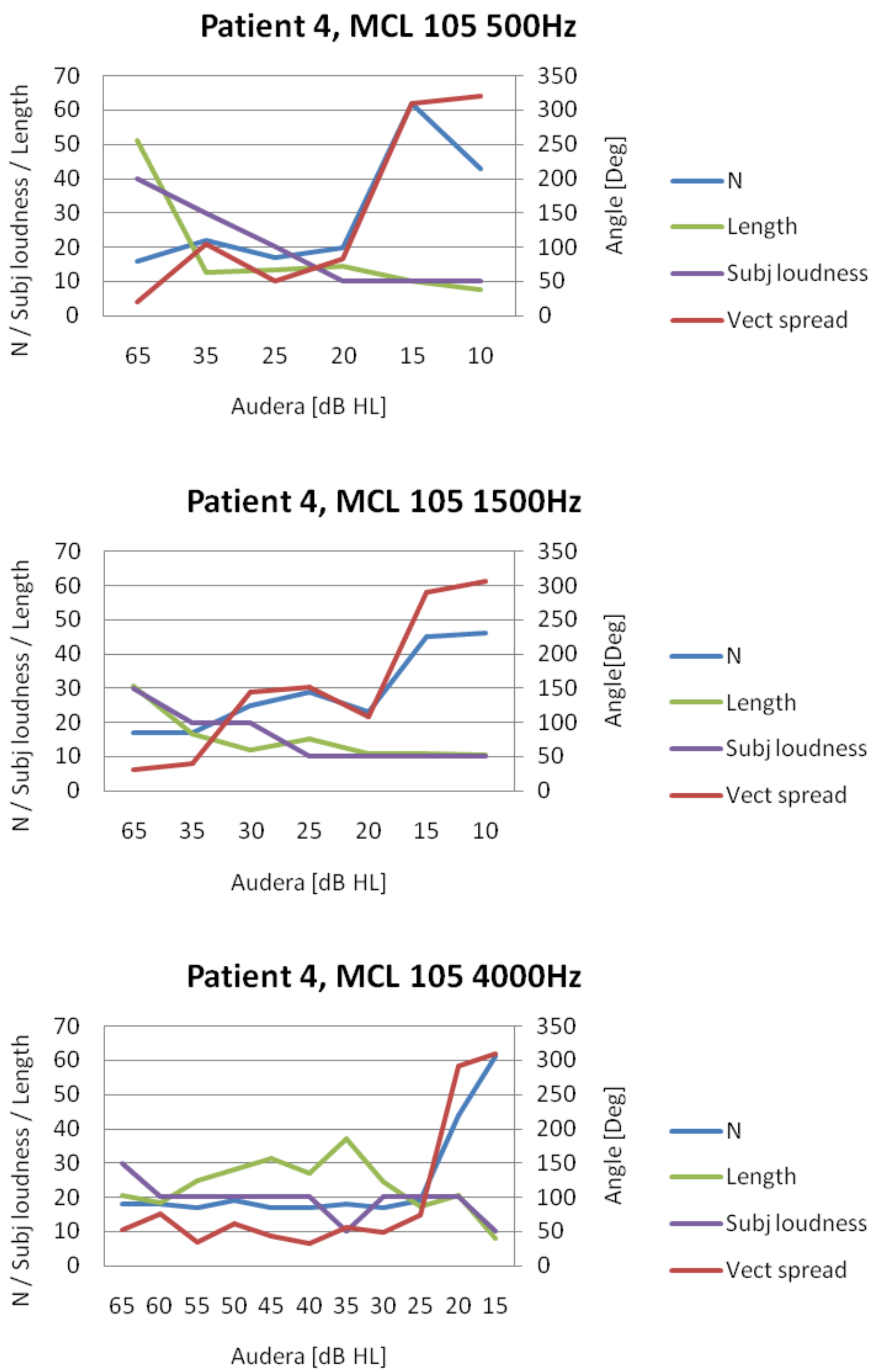
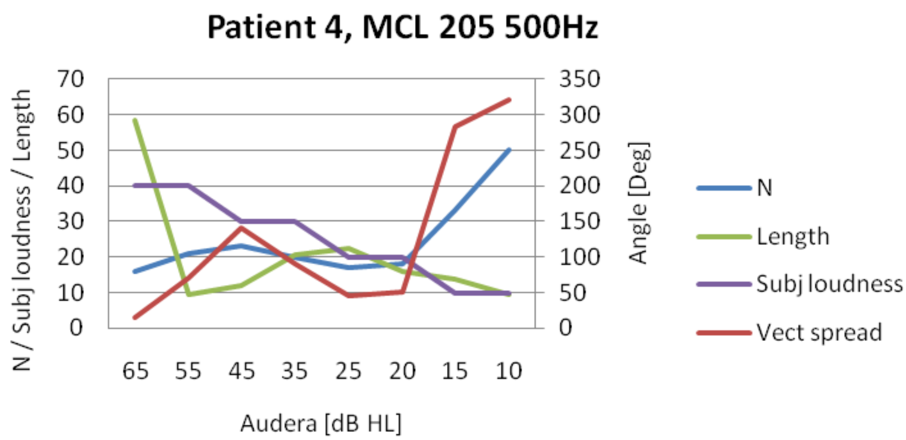
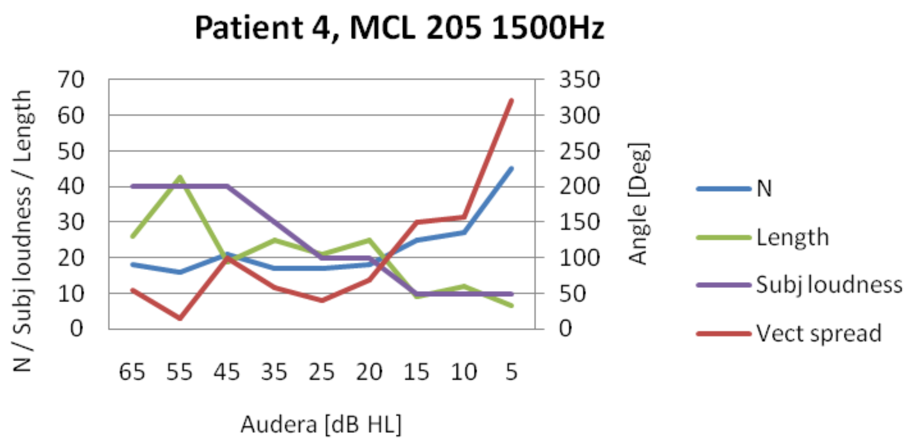


Figure 27. Diagrammatic representation of ASSR measurement results of patient 4, program 2. Number of samples (N), Length and Subjective loudness are on the left vertical axis and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 105 cu. Electrodes 3, 7 and 11 are in use. Stimulus frequencies are 500 Hz, 1500 Hz and 4000 Hz respectively.





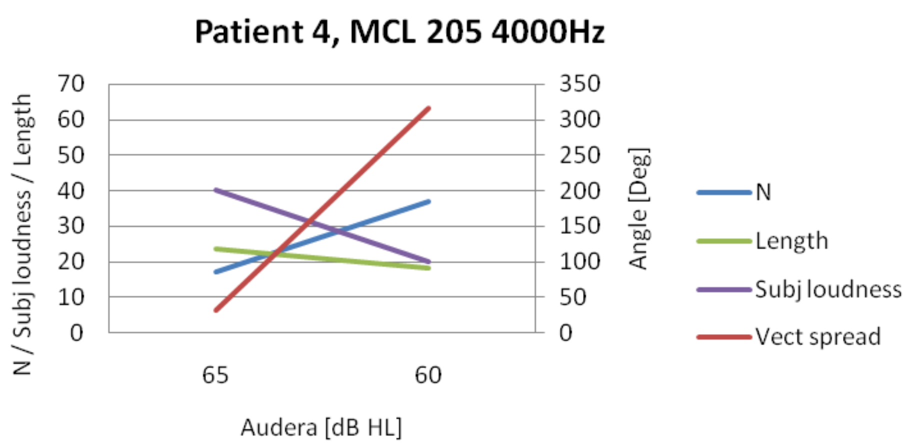
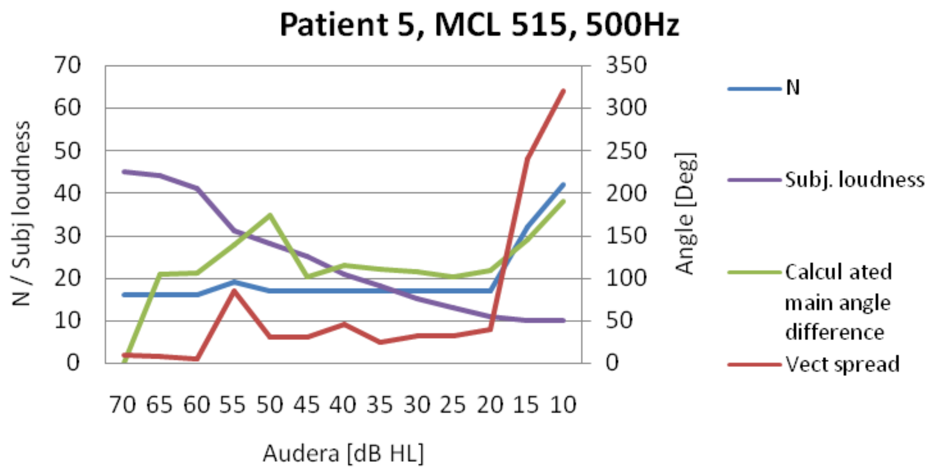


Figure 28. Diagrammatic representation of ASSR measurement results of patient 4, program 1. Number of samples (N), Length and Subjective loudness are on the left vertical axis and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 205 cu. Electrodes 3, 7 and 11 are in use. Stimulus frequencies are 500 Hz, 1500 Hz and 4000Hz respectively.



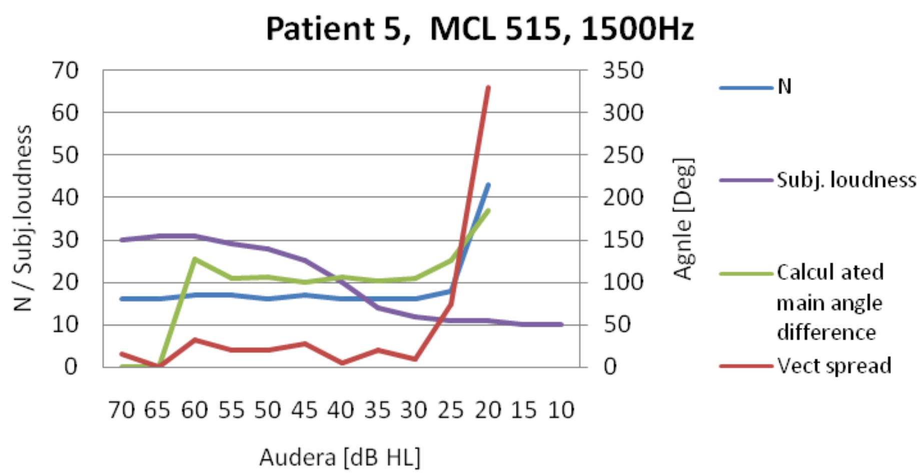


Figure 29. Diagrammatic representation of ASSR measurement results of patient 5. Number of samples (N) and Subjective loudness are on the left vertical axis and Calculated main angle difference and Vector spread on the right axis. Horizontal axis is the Audera's stimulus level in [dB HL]. MCL level is 515 cu. Electrodes 3, 7 are in use. Stimulus frequencies are 500 Hz, 1500 Hz respectively.

7.4.4 Discussion

The diagrams of patient 1 seem to behave quite similarly though the third, fourth and sixth of them have measurements at only three stimulus levels. However, there is clearly a section where all diagrams intersect. At this point the number of the samples and the subjective perception decreases and at the same time the vector spread and the number of the samples start growing rapidly.

This same section can be easily found also from the diagrams of the patient 2. In the second diagram of patient 2, the sudden decrease in the number of the samples and vector spread can be explained by the fact that the patient did not hear anything anymore at this point, and thus the ASSR-response could be interpreted faster merely as noise.

In case of patient 4, the diagrams behave a little less consistently but still same kind of rapid increase in vector spread and the number of samples can be found when the patient's subjective perception is very quiet or none.

In the diagrams of patient 5 the value-graph has been replaced by the calculated main angle difference to the previous measurement. It's behavior seems to be in line with patient's subjective perception as well. The calculated main angle difference starts to increase at the same time when the number of samples and vector spread begin to increase. At this point, the subjective perception is very quiet or none. Around 50-55 dB HL at 500 Hz and 60 dB HL at 1500 Hz there is a notable increment in vector spread and main angle difference. The patient really reported these changes and told that the sound was somehow different in that point. For the meantime, the reason that caused this remains unsolved.

7.4.5 Conclusions

The results suggest that the rapid increase in the vector spread and the number of the samples implicates the patients hearing threshold. However, due to the methods and equipment used, a strict threshold value cannot be estimated.

7.5 Determination of ASSR voltage levels

The purpose of this measurement was to specify the real voltage levels that stimulate the auditory nerves from the implant.

7.5.1 Procedure

ASSR voltage levels were measured with the same ASSR parameters that were used when determining ASSR thresholds. We used programs with three electrodes and MCL-levels 105 cu, 205 cu, 515 cu and 595 cu. Voltage levels were determined at the same three frequencies than before, 500 Hz, 1500 Hz and 4000 Hz. ASSR stimulus level was increased to the level were output level was saturated. Instead of surgically implanted cochlear implant, the MedEl CIS PRO+ Detector implant simulator was used. ASSR stimuli were given to the implant speech processor and thence further to the implant simulator through the tranceiver. The voltage levels were measured from the output of the implant simulator. Readings were made visually from the oscilloscope screen. Implant simulator was loaded with an external 10 kohm resistor in order to simulate the impedance normally caused by the tissue. (see Figure 30)

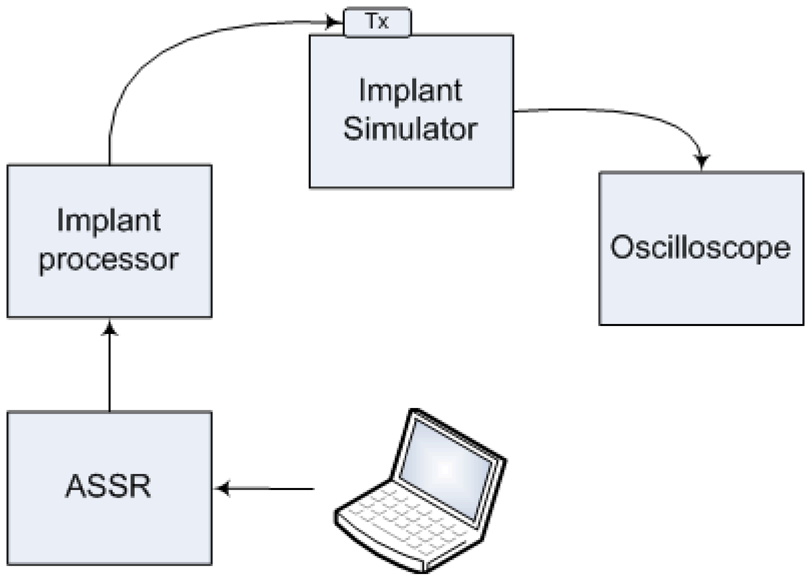


Figure 30. Schematic representation of experimental arrangement of ASSR voltage level determination. ASSR stimulus is given straight to the implant processor, from which the signal is mediated to the implant simulator. The voltage level is measured from the output of the simulator with an oscilloscope. Simulator is loaded with an external 10 kohm resistor to simulate the impedance of the skin.

7.5.2 Results

The results of the ASSR voltage level measurements are presented in Figure 31. It shows clearly that the higher the MCL-value the higher is the output voltage level. Also increasing the ASSR stimulus level upraises the output voltage. The output voltage levels seem to behave same way despite the stimulus frequency.

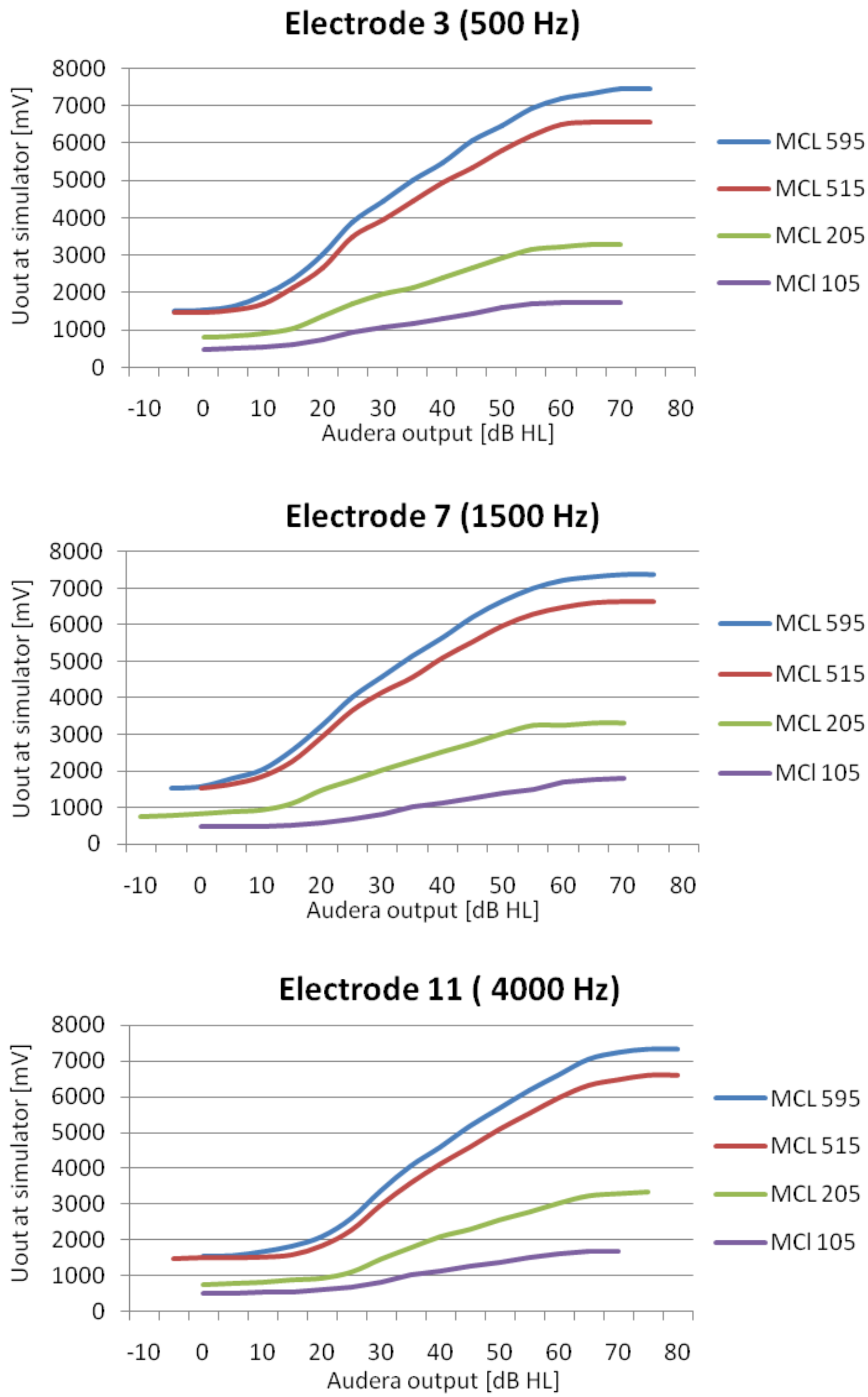


Figure 31. Diagrammatic representation of the results of ASSR voltage levels determination. On the vertical axis is the voltage level in [mV] and on the horizontal axis the Audera stimulus level in [dB HL]. In topmost diagram are the results of electrode 3 (500 Hz), in the middle electrode 7 (1500 Hz) and in the lowest electrode 11 (4000 Hz). Levels were measured with four different MCL: 595 cu, 515 cu, 205 cu and 105cu.

7.5.3 Discussion

Voltage output seems to increase in a non-linear manner. The saturation of the diagrams can be explained by the automatic gain control (AGC) that is used in the implant processor. However, from 25-30 dB to 50-55 dB, a section that behaves fairly linearly can be found.

7.5.4 Conclusions

The voltage level diagrams behave similarly although the stimulation frequency and the electrode being stimulated are changed.

7.6 Sound field threshold measurements

7.6.1 Procedure

For determining sound field thresholds we used audiometric room and Hughson-Westlake ISO 8253-1 [22] audiometry method. The calibration of audiometric equipment was made according to ISO 389 [23]. Thresholds were determined at three different frequencies, 500 Hz, 1500 Hz and 4000 Hz. We used Madsen OB822 Audiometer to control the stimuli signals. Sounds were picked by behind-the-ear microphone from which they were mediated to the implant signal processor[3] and further to the implant (see Figure 33 and Figure 34).). In case of sound sensation, patients reported their sound perception by pushing the signaling button that could be read from the audiometer. We used the ascending method, with bracketing around threshold (10 dB decrement and 5 dB increment). The threshold was accepted after the third similar round.We performed these measurements for patient 4 and 5 during our research and the measurements were carried out with two of the three-channel programs for patient 4 and MCL 515 program for patient 5.

7.6.2 Results

The results of sound field measurements are presented in Figure 32. In case of patient 4, program 1, the thresholds were found on the sound field level 40 dB HL at 500 Hz and 1500 Hz. At 4000 Hz the threshold was found on 60 dB HL. With program 2, the thresholds were on 45 dB HL at 500 Hz and 1500 Hz, at 4000 Hz on the sound field level 60 dB HL. In case of patient 5, the thresholds were found on 45 dB HL at 500 Hz, 35 dB HL at 1500 Hz and on 50 dB HL at 4000 Hz.

[3] MedEl Combi 40+ implant signal processor

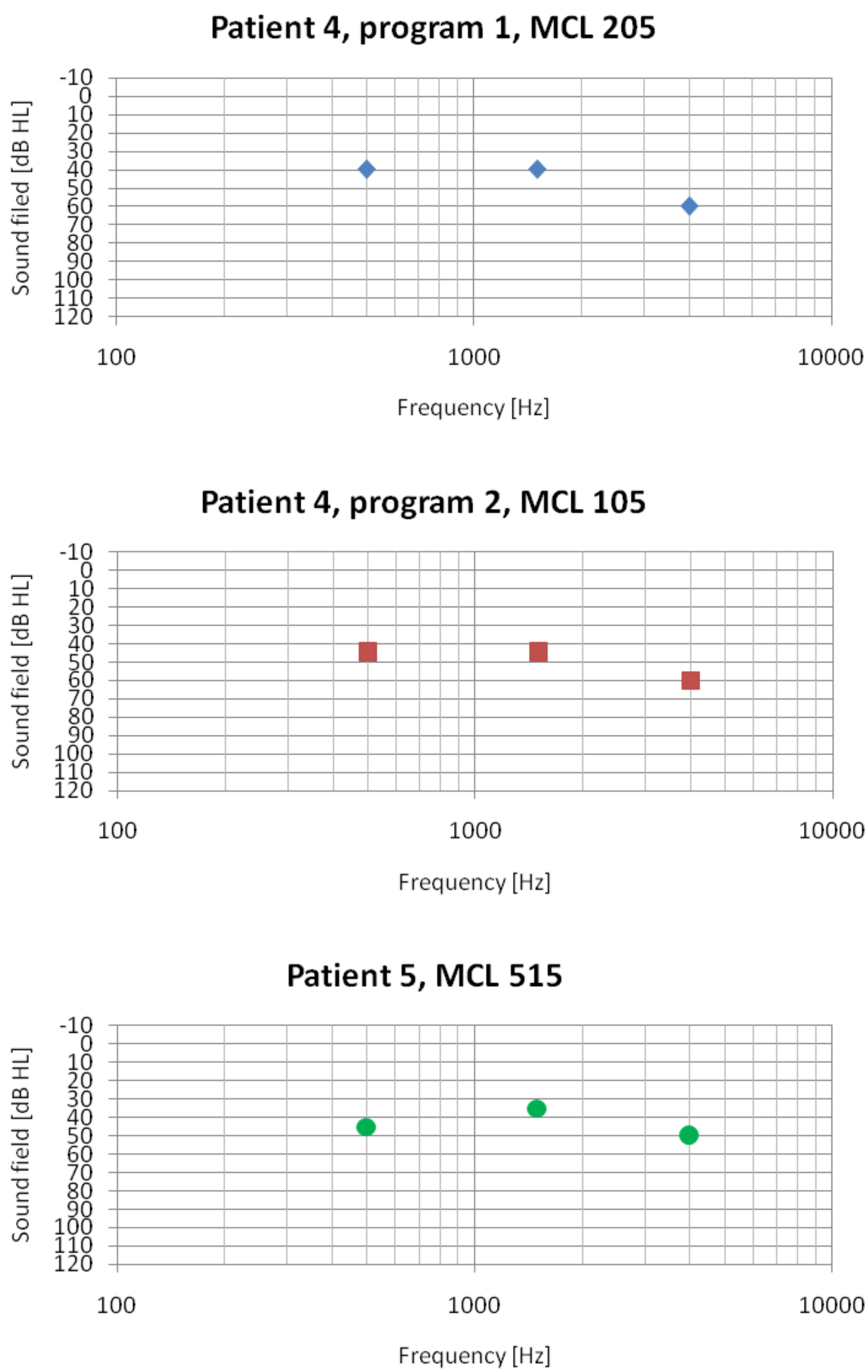


Figure 32. Diagrammatic representation of the results of the sound field threshold determination. On the vertical axis is the sound field level in [dB HL] and on the horizontal axis the sound field frequency in [Hz]. At the topmost are the results of patient 4, program 1. In the middle the results of patient 4, program 2. The results of patient 5 are presented in the lowest diagram.

7.6.3 Discussion

The results of sound field threshold measurements show the fact that for cochlear implant patients high frequency sounds are not easy to listen. At 4000 Hz the thresholds are higher and more uncertain than at the lower frequencies.

7.7 Determination of sound field voltage levels

The purpose of this measurement was to specify the real voltage levels that stimulate the auditory nerves from the implant in sound field.

7.7.1 Procedure

The procedure for determining voltage levels from the implant in case of acoustic stimulation was made with similar experimental arrangement than sound field threshold determination (see Figure 33 and Figure 34). We used the Kemar torso in patient's stead to simulate the diffractions caused by human head and body. The implant simulator was loaded with 10 kohm external resistor. The voltage levels were measured from the implant simulator's output with digital oscilloscope and readings were made visually from oscilloscope screen.

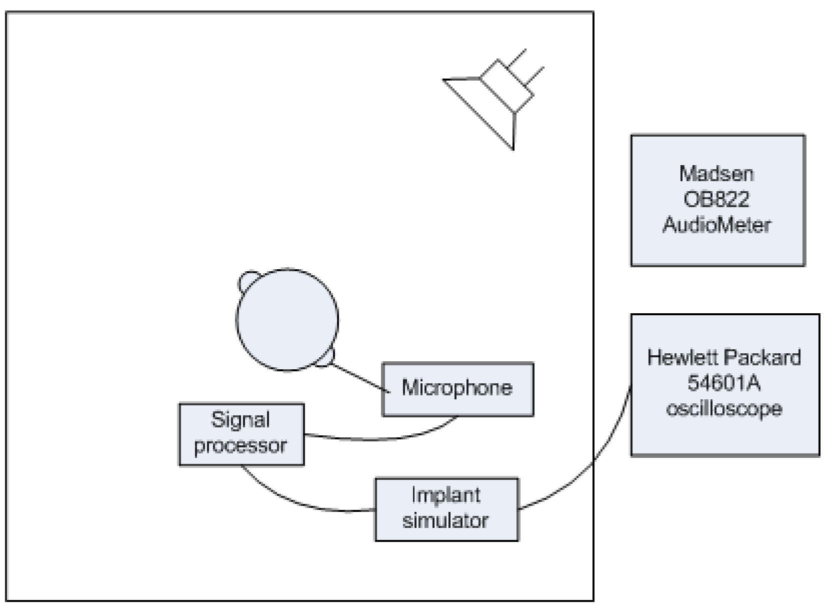


Figure 33. Schematic representation from above of experimental arrangement for sound field threshold measurements and determination of sound field voltage levels. Stimuli signals were controlled with Madsen OB822 Audiometer. Sounds were picked by the behind-the-ear microphone that was worn by the patient or Kemar torso. Then the signal was mediated to the implant processor and further to the implant simulator. The voltage levels were measured from the output of the simulator with the Hewlett-Packard 54601A digital oscilloscope

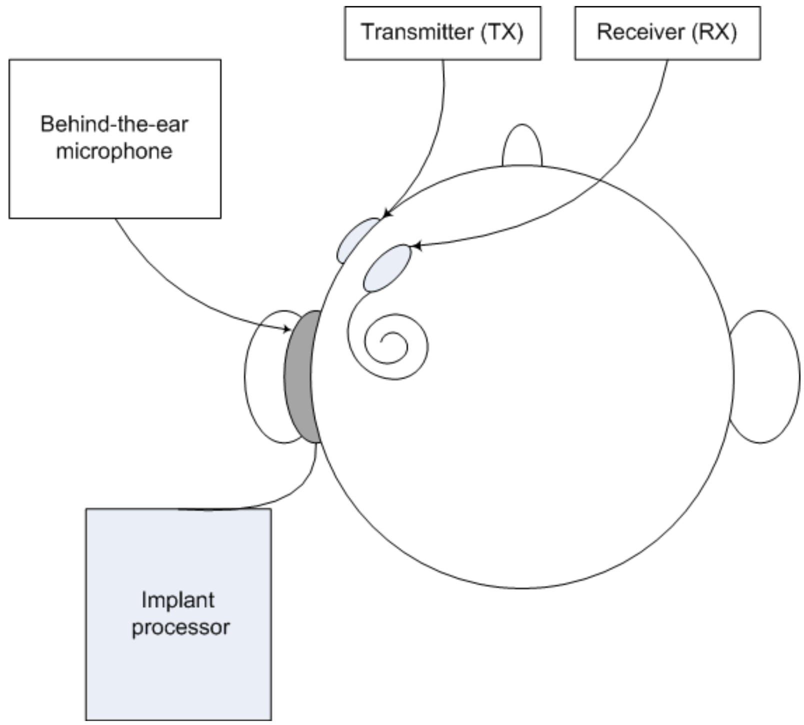


Figure 34. A more detailed schematic representation from above of experimental arrangement for sound field measurements. A behind-the-ear microphone picks the sounds and mediates them to the implant processor. From the processor the signal is passed to the transmitter, which passes them transcutaneously to the receiver from which the stimulus is passed to the electrode array placed in the cochlea.

7.7.2 Results

The results of voltage ouput measurements are presented in Figure 35. Output voltage level increases when sound pressure level is upraised. Also the higher the MCL-value the higher is the output voltage. The output voltage levels seem to behave in quite same way when stimulating different electrodes with different stimulation frequency.

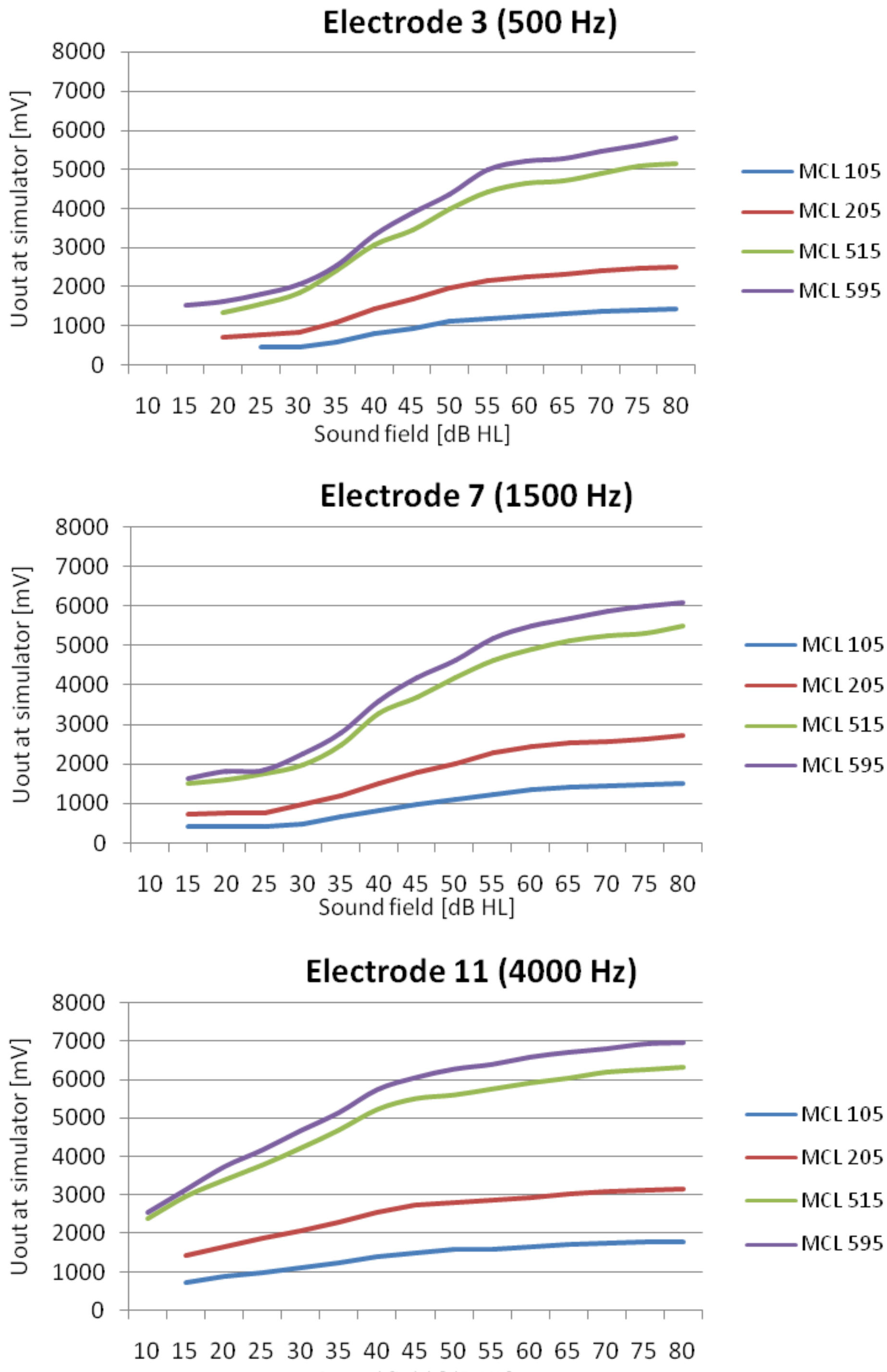


Figure 35. Diagrammatic representation of the results of sound field voltage level determination. On the vertical axis is the output voltage in [mV] and on the horizontal axis the sound field level in [dB HL]. At the topmost are the results from the measurements with electrode 3 (500 Hz), in the middle from the electrode 7 (1500 Hz) and at lowest the results from measurements with electrode 11 (4000 Hz).

7.7.3 Discussion

When stimulating an implant with an acoustic signal, the same nonlinearity can be found in voltage level diagrams as in ASSR stimulated voltage diagrams. This is of course obvious since the behavior of the implant processor is not conditional on the stimulus source. The automatic gain control (ACG) and the background noise attenuation system have the same effect on the stimulator ouput as before. The only main difference between the results is that when stimulating with an acoustic signal, the saturation of the voltage levels does not come up as fast than when stimulating with Audera output

7.7.4 Conclusions

The results from the implant output voltage level measurements (Audera stimulated and sound field stimulated) show that the behavior of the implant output voltage levels does not depend on the stimulation source. The results also indicate that the Audera's stimulus level cannot be compared directly to the acoustic sound pressure level.

8 Summary and conclusions

The purpose of this research was to study whether it is possible to estimate a patient's audiogram based on ASSR measurements or not. First, with patient 1 and 2 the main goal was to study how well the ASSR results correspond to the patient's subjective perception. Patient 4 and 5 were also taken to the sound field measurements in order to collect data for audiogram estimation.

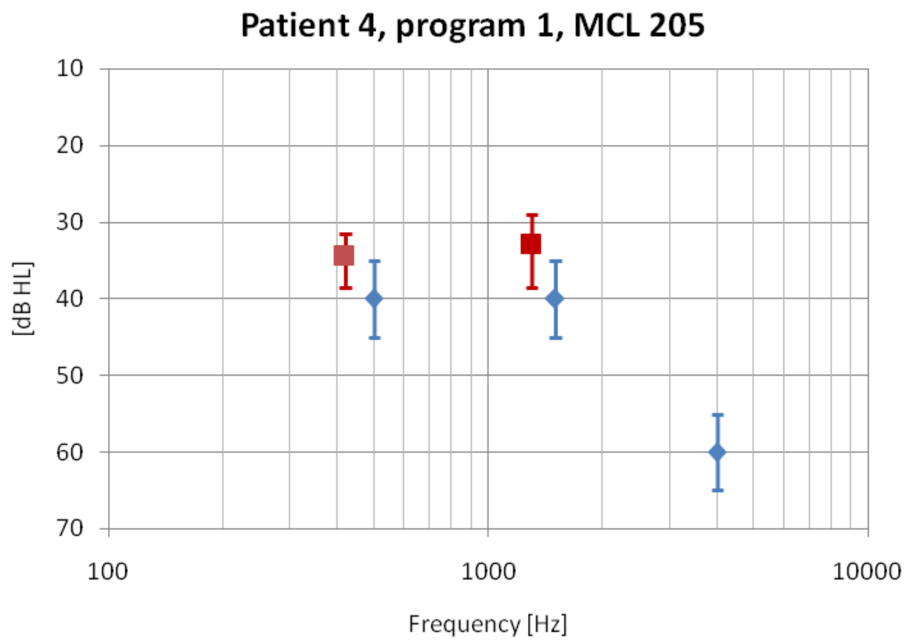
8.1 Estimation method

Audiogram estimates are constituted based on patients' subjective ASSR thresholds, Audera stimulated voltage levels and free field stimulated voltage levels. First, we determined the real voltage output at subjective ASSR threshold (see Table 5, Table 6 and Figure 31). Then we specified the loudness level in sound field that gives the same voltage ouput (see Figure 35). The maximum and minimum margins of error for audiogram estimates are specified in the same way according to the ASSR threshold margin of error ±5 dB HL.

8.2 Results

The summary audiograms of patients 4 and 5 are presented in Figure 36 and Figure 37. Blue audiograms are patients' subjective audiograms and red ones the estimated audiograms. In case of patient 4, program 1, we did not have the subjective threshold at 4000 Hz and in case of patient 5 Audera measurements were only carried out at 500 Hz and 1500 Hz since the electrode 11 was not in use in the patient's electrode array. The estimated audiograms are moved a little to the left in Figures 36 and 37 in order to make the comparison of the audiograms easier.

At frequencies 500 Hz and 1500 Hz the estimated audiograms seem to correspond well with the subjective audiograms. In case of patient 4, program 2, at 4000 Hz the estimated audiogram is not even close to the subjective one.



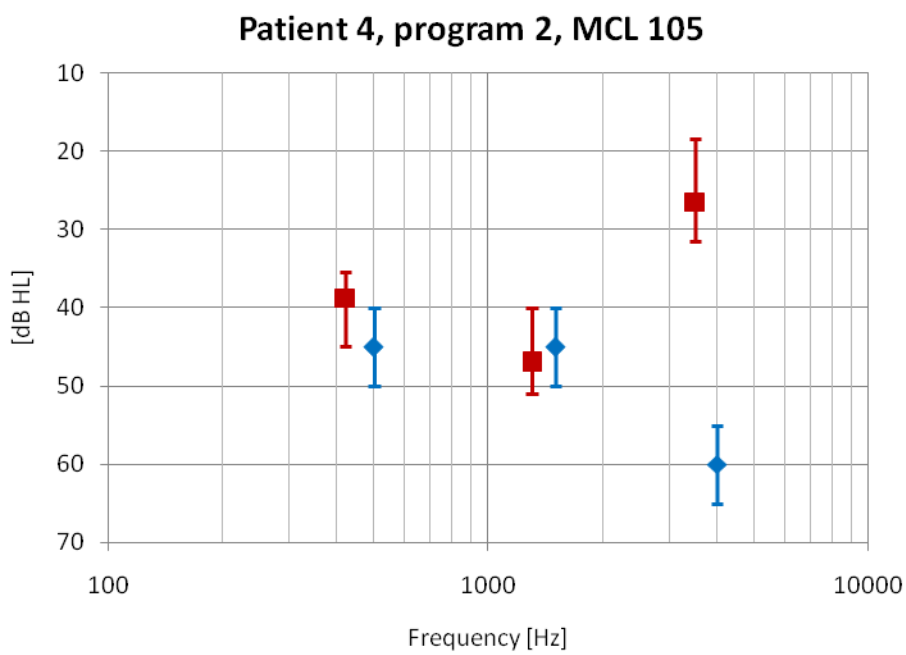


Figure 36. Diagrammatic representation of the summary results for patient 4. On the vertical axis is the sound field level in [dB HL] and on the horizontal axis the stimulus frequency on a logarithmic scale in [Hz]. The blue bars are the results of patient's subjective thresholds and the red bars the estimated ones. In the upper diagram are the results with program 1 and in the lower one with program 2.

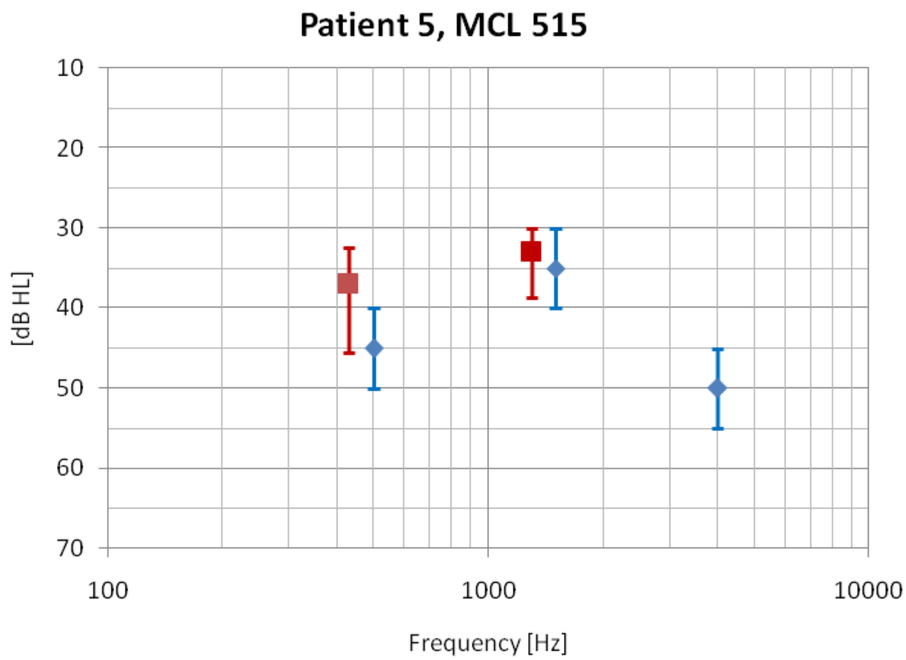


Figure 37. Diagrammatic representation of the summary results for patient 5. On the vertical axis is the sound field level in [dB HL] and on the horizontal axis the stimulus frequency on a logarithmic scale in [Hz]. The blue bars are the results of patient's subjective thresholds and the red bars the estimated ones.

8.3 Discussion

The estimated audiograms give us the result we wanted. They correspond fairly well with subjective audiograms and thus show that ASSR results could be used in the implant processor programming process with difficult-to-test patients. The difference at 4000 Hz can be explained by the fact that many of the cochlear implant patients have tinnitus that really complicates their perception for example at 4000 Hz. This was the case also with our test patients.

In order to develop this method the next step of the research would be to computationally determine the voltage outputs of the implant processor. For the programming of the processor the current and charge units needed should be calculated. Also a statistical analysis for ASSR result parameters could be carried out. This way, we could examine which of the parameters best correlates with the subjective threshold. In our present method the audiogram estimates are based on approximate visual interpretation.

8.4 Final conclusion

The results of our study strongly suggest that ASSR parameters measured using stimulation through cochlear implant can be used in estimation of patient's audiogram. With further study it might be used in determining the parameters for the programming of the implant processor.

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