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INSERTION CHARACTERISTICS OF DIFFERENT COCHLEAR IMPLANT ELECTRODES: A CLINICAL, RADIOLOGICAL AND HISTOLOGICAL STUDY

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Matti Iso-Mustajärvi

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ABSTRACT

Cochlear implantation is currently the only routinely used treatment to restore the function of a sense organ. Cochlear implantation was first introduced in 1961 but it was only with the advent of multichannel devices in the early 1990s, that it has gained an established place for the treatment of severe to profound hearing loss.

There are multiple positive and negative factors predicting the hearing outcomes after implantation. One of the most significant negative predictive factors is possible inner ear trauma induced by the surgery. There are mainly two mechanical factors which determine the occurrence of inner ear trauma: electrode design and the insertion technique.

The cone-beam computed-tomography (CB-CT) has recently become a more popular modality in the postoperative evaluation of the results of electrode insertion. The insertion depth, extracochlear electrode contacts, electrode tip fold overs and gross trauma can be easily detected with CB-CT. Even though CB-CT can also quite reliably recognize scala dislocation up to the second turn of the cochlea, a more detailed evaluation of trauma such as elevations or ruptures of the basilar membrane is not possible. Fusion imaging has emerged as a promising modality for achieving a more precise evaluation of electrode positioning and trauma assessment after cochlear implantation.

In the first two studies of this thesis, the insertion results of two newly introduced electrodes were evaluated in freshly frozen temporal bones. The first study was a radiological and histological study that evaluated the Slim Modiolar electrode ™ (Cochlear corporation, Sydney, Australia) (SME) which represents a completely new design of a modiolar (precurved) electrode. It was designed to have a more reliable structure and to achieve better hearing preservation than its predecessor, a stylet-type modiolar electrode. In this evaluation study, we detected one scala dislocation in 20 temporal bones inserted with SME. The image fusion with pre- and postoperative CB-CT was performed in all of the 20 TBs. The image fusion proved to be an accurate method in the evaluation of electrode placement inside cochlea.

The second study investigated the insertion characteristics of a new lateral wall electrode, the SlimJ –electrode (Advanced Bionics, Valencia, USA) in 11 freshly frozen temporal bones. In this study, we found one scala dislocation in postoperative fusion imaging. These results are comparable to other temporal bone studies with modern straight electrodes. SlimJ is reasonably predictable with respect to the insertion results, however the final evaluation of insertion properties will require clinical verification.

In the third study, we retrospectively analyzed hearing preservation results with SME in 17 clinical patients (18 ears) with low frequency residual hearing. The preliminary results (mean follow-up 582 days) showed a good hearing preservation rate. There were no total hearing losses and seven patients could use electric-acoustic stimulation (EAS). This study revealed significantly more favorable hearing preservation rates than reported for other stylet-type modiolar electrodes.

Fusion imaging was validated with histological samples in the first temporal bone study made with SME. The fusion imaging provided a fast and accurate method for the evaluation of the electrode placement. We observed no significant difference between histologic or fusion imaging measurements.

The fourth study investigated a new fusion imaging technique which may enable better visualization of the basilar membrane. Visualization was conducted in twelwe temporal bones. The perilymph was evacuated from the scalae prior to pre-operative CB-CT. The frozen temporal bone (TB) was initially immersed in Ringer solution to rehydrate both scalae. Insertion was made after rehydration followed by post-operative CB-CT imaging. With the application of this technique, it was easier to detect the individual anatomy of the basilar membrane and a reliable trauma assessment was possible beyond the second turn of the cochlear partition.

The new studied electrode designs provide not only more atraumatic but also more predictable insertion results. The fusion imaging is an accurate method making possible a more detailed electrode placement evaluation as compared to postoperative CB-CT alone. It also represents a fast and cost-effective method for evaluating insertion results in temporal bone studies.

Keywords: Cochlear Implant, Insertion trauma, Electro-acoustic stimulation, Cone-Beam Computed Tomography, Fusion imaging

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TIIVISTELMÄ

Sisäkorvaistutehoito on ainut lääketieteellinen hoito, jolla voidaan palauttaa aistielimen toimintaa. Sisäkorvaistutehoitoa kokeiltiin ensimmäisen kerran 1961, jonka jälkeen se on vakiinnuttanut asemansa vaikeiden kuulovikojen kuntoutuksessa.

Sisäkorvaistutehoidon kuulotuloksiin vaikuttaa useita ennustetekijöitä, joista yksi merkittävimpiä leikkaukseen liittyviä negatiivisia ennustetekijöitä on mahdollinen elektrodin aiheuttama sisäkorvan simpukan vaurio. Suurimmat tekijät vaurion taustalla ovat käytetty leikkaustekniikka ja elektrodin ominaisuudet.

Leikkauksen jälkeisen sisäkorvan vaurion, insertiosyvyyden ja mahdollisten komplikaatioden toteamiseksi paras tulos suhteessa säderasitukseen saadaan korvan kartiokeila-tietokonetomografialla (KK-TT). Vaikka KK-TT onkin tarkka havaitsemaan scala dislokaation aina simpukan toiseen käänteeseen/kierteeseen saakka, ei tarkemman vaurion analyysi sillä ole mahdollista. Lupaava uusi menetelmä tarkempaan vaurion analysointiin on fuusio kuvantaminen.

Tämän väitöskirjan kahdessa ensimmäisessä osatyössä tutkittiin kahden uuden elektrodin leikkaustuloksia käyttäen tuoreita pakastettuja ohimoluita. Uusi Slim Modiolar –elektrodi (SME) edustaa uutta simpukan muotoon esimuotoiltua elektrodia ja on suunniteltu olemaan edeltäjiään vähemmän simpukan vauriota aiheuttava. Tutkimuksessa 20 ohimoluuhun tehdyissä leikkauksissa havaittiin yksi elektrodin scala dislokaatio. SME:n insertio syvyys ei korreloinut simpukan koon kanssa. Kuvafuusiomenetelmä osoittautui tarkaksi elektrodin sijainnin ja mahdollisen simpukan trauman arvioinnissa.

Toisessa osatyössä tutkittiin uuden suoran elektrodin, SlimJ, leikkausominaisuuksia 10 ohimoluussa. Tutkimuksessa todettiin yksi scala dislokaatio postoperatiivisella fuusiokuvantamisella. Insertiosyvyyden keskiarvo oli 368° (arvoalue/vaihteluväli 330°–430°). Tulokset ovat verrannolliset myös muilla suorilla sisäkorvaistutteilla tehtyihin ohimoluututkimuksiin. SlimJ:lla saavutettava tulos on hyvin ennustettava elektrodin insertio syvyyden ja vaurion suhteen, tosin tulokset vaativat vielä lisäksi kliinistä arvioita varmentuakseen.

Kolmannessa osatyössä arvioitiin SMEn leikkaustuloksia potilailla, joilla oli vielä merkittävää matalien taajuuksien jäännöskuuloa ennen leikkausta. 17 potilasta (18 korvaa) täytti tutkimuskriteerit. Yhdelläkään potilaista ei todettu leikkauksen jälkeistä kuulonmenetystä. 7 potilasta (8 korvaa) päätyi käyttämään elektro-akustista stimulaatiota. Tulokset jäännöskuulon osalta ovat SME:llä paremmat kuin on raportoitu aikaisemmilla premodiolaarisilla elektrodeilla. Tulokset osoittavat myös sen, että SME:llä on jopa mahdollista hyödyntää elektro-akustista stimulaatiota. SME:n etuna on myös riittävän syvä insertiosyvyys tarjotakseen hyvän taajuuspeiton myös pelkälle sähköiselle stimulaatiolle, mikäli jäännöskuulo joko leikkauksen yhteydessä tai kuulovian edetessä menetetään.

Fuusiokuvantamisen validaatio tehtiin ensimmäisessä osatyössä vertaamalla kuvaustulosta ohimoluista kerättyihin histologisiin leikkeisiin. Fuusiokuvantaminen tarjoaa nopean ja tarkan menetelmän elektrodin sijainnin arvioimiseen. Tutkimuksessa ei löytynyt tilastollisesti merkittävää eroa histologian tai fuusiokuvantamisen välillä.

Neljännessä osatyössä pyrittiin visualisoimaan basilaarimembraani simpukan sisällä kahdessatoista ohimoluussa. Perilymfa poistettiin simpukasta ennen preoperatiivista KK-TT -kuvausta, jonka jälkeen simpukka täytettiin Ringerin liuoksella. Elektrodi vietiin tämän jälkeen simpukkaan ja näyte kuvattiin uudelleen. Fuusiokuvantamisella saatiin yksilöllinen basillaarimembraanin anatomia näkyviin suhteessa elektrodin sijaintiin.

Uudet tutkitut elektrodimallit tarjoavat turvallisen sisäkorvaistuteleikkauksen ja tuovat lisää vaihtoehtoja yksilöllisempään sisäkorvaistukuntoutukseen potilaalle. Fuusiokuvantaminen on KK-TT:tä tarkempi menetelmä elektrodin sijainnin arvioon sisäkorvassa. Se tarjoaa myös nopean ja kustannustehokkaan mahdollisuuden ohimoluilla tehtäviin elektroditutkimuksiin.

Avainsanat: Sisäkorvaistute, Insertio trauma, electro-akustinen stimulaatio, kartiokeila tietokonetomografia, fuusio kuvantaminen

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Kuopio, October 2020
Matti Iso-Mustajärvi

“I have no fear of death. More important, I don’t fear life”

- Steven Seagal

LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following original publications:

I Iso-Mustajärvi M, Matikka H, Risi F, Sipari S, Koski T, Willberg T, Lehtimäki A, Tervaniemi J, Löppönen H, Dietz A. A New Slim Modiolar Electrode Array for Cochlear Implantation: A Radiological and Histological Study. Otol Neurotol. 2017 Oct;38(9):e327-e334. doi:10.1097/MAO.0000000000001542.

II Iso-Mustajärvi M, Sipari S, Löppönen H, Dietz A. Preservation of residual hearing after cochlear implant surgery with slim modiolar electrode. Eur Arch Otorhinolaryngol. 2020 Feb;277(2):367-375. doi: 10.1007/s00405-019-05708-x. Epub 2019 Oct 31.

III Dietz A, Iso-Mustajärvi M, Sipari S, Tervaniemi J, Gazibegovic D. Evaluation of a new slim lateral wall electrode for cochlear implantation: an imaging study in human temporal bones. Eur Arch Otorhinolaryngol. 2018 Jul;275(7):1723-1729. doi: 10.1007/s00405-018-5004-6. Epub 2018 May 24.

IV Iso-Mustajärvi M, Sipari S, Lehtimäki A, Tervaniemi J, Löppönen H, Dietz A. A New Application of CBCT Image Fusion in Temporal Bone Studies. J Int Adv Otol. 2019 Dec;15(3):431-435. doi: 10.5152/iao.2019.7365.

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CONTENTS

ABBREVIATIONS

1 CI	Cochlear implant
2 TM	Tympanic membrane
3 SSC	Superior semicircular canal
4 LSC	Lateral semi circular´canal
5 PSC	Posterior semi circular´canal
6 CIS	Continuous interval sampling
7 RF	Radiofrequency
8 CA	Compressed analogue
9 HiRes	HiResolutionTM
10 SPEAK	Spectral peak
11 ACE	Advanced combined encoder
12 SNHL	Senorineural hearing loss
13 EAS	Electric and acoustic stimulation
14 CNS	Central nervous system
15 SSD	Single sided deafness
16 LWE	Lateral wall electrodes
17 IDA	Insertion depth angle
18 AOS	Advance of a stylet insertion technique
19 CNC	Consonant-nucleus-consonant
20 RWM	Round window membrane
21 CB-CT	Cone-beam computed-tomography
22 MRI	Magnetic resonance image
23 CT	Computed tomography
24 PET-CT	Positron emission computed tomography
25 SMA	Slim modiolar array

1 INTRODUCTION

Cochlear implantation has become a routine treatment for the rehabilitation of severe to profound hearing loss. Cochlear implant (CI) is a medical device including an electrode that is surgically implanted into the inner ear (figure 1). A CI can restore hearing by bypassing the defective inner ear hair cells and making direct electric stimulation of the neural cochlear tissue and auditory nerve fibers. At present, a CI is the only treatment in routine clinical use which can restore the function of a human sense.

Even though the outcomes of cochlear implant users are most commonly favorable, recipients still experience difficulties with speech recognition if there is background noise and reverberation as well as with music perception.

This dissertation aims to provide insights into the surgical properties of two new electrode designs. The fusion imaging technique for visualizing the cochlear implant electrode location has been validated and developed.

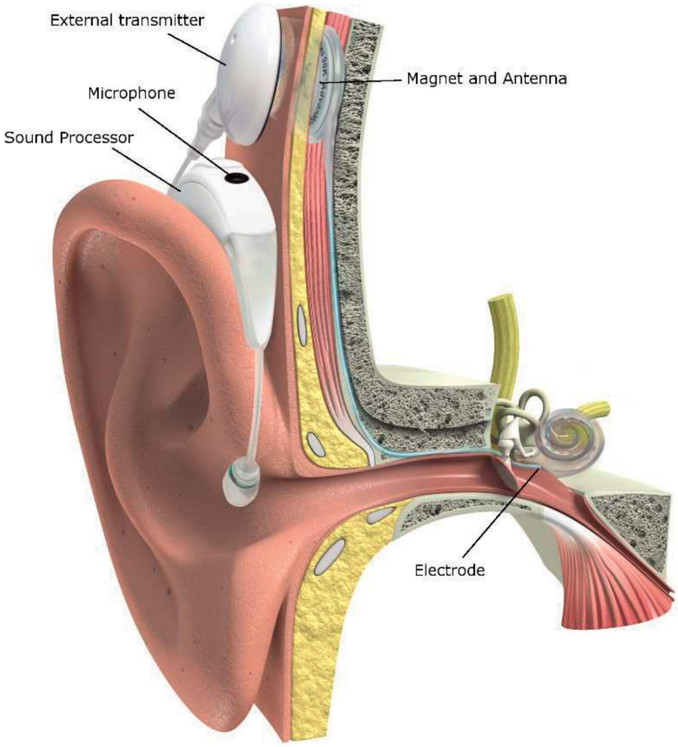


Figure 1. Cochlear implant system. With courtesy of Advanced Bionics.

2 REVIEW OF THE LITERATURE

2.1 ANATOMY OF THE EAR AND PHYSIOLOGY OF HEARING

2.1.1 Anatomy of ear

The ear is an organ dedicated to ensuring hearing and balance. The outer ear is composed of the pinna and the outer ear canal (1). The tympanic membrane divides the ear to the outer ear in a lateral direction and the middle ear medially. The middle ear is a small cavity inside the temporal bone, where the auditory ossicles (malleus, incus and stapes) are located. The middle ear communicates with the air cells of the mastoid cavity via the aditus, which leads to the antrum (largest single air cell) in the mastoid cavity. The volume of the mastoid cavity varies extensively between individuals (2). The facial nerve passes through the middle ear and mastoid cavity until it passes out from the stylomastoid foramen at the lateral skull base (1). The oval and the round window are located in the mesotympanum of the middle ear. The stapes footplate is attached to the oval window, which connects the auditory ossicles to the inner ear. The round window opening is covered by a membrane which closes the scala tympani of the cochlear partition. The promontorium of the cochlea forms a part of the medial wall of the middle ear. A cross-section of middle ear is presented in figure 2.

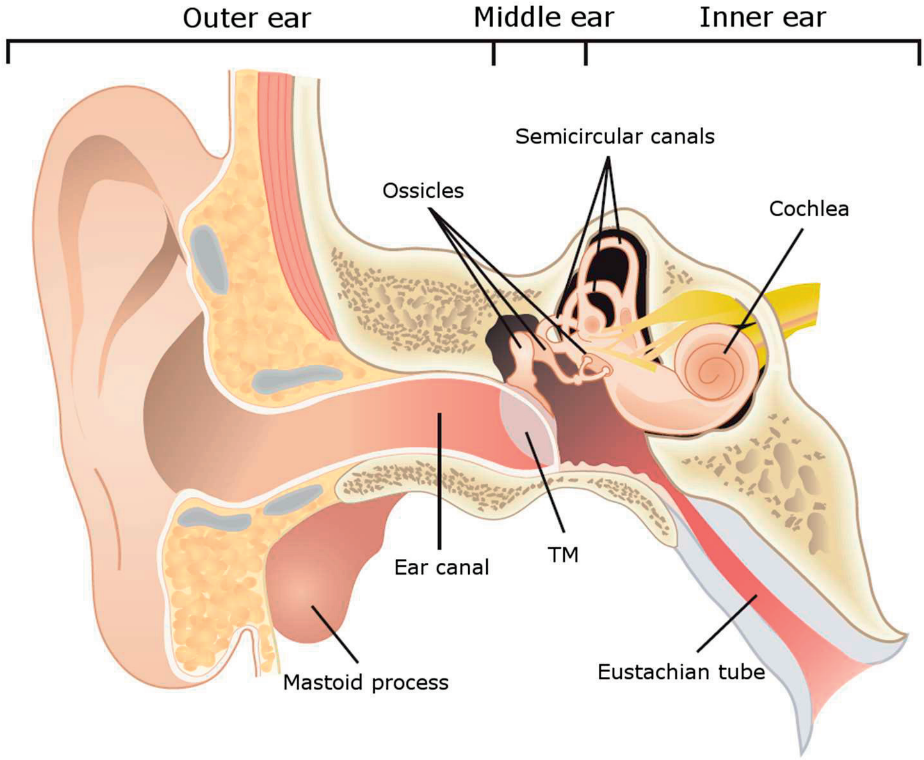


Figure 2. Anatomy of ear. TM= tympanic membrane. With courtesy of Korvatieto OY.

The inner ear includes the semicircular canals, vestibulum and cochlea.The inner ear can also be divided in membranous and bony labyrinth as presented in figure 1. The semicircular canals and the vestibulum make up the vestibular system, where the balance receptors are located (sacculus, utriculus, ampullas of semicircular canals). The vestibulum includes two different vestibular end organs: sacculus and utriculus. The vestibular system is filled with perilymph and it is connected to the fluid space of the cochlea via the vestibulum. The cochlea is located inside the otic capsule. The human cochlea is a shell-like structure inside the otic capsule. The average cochlea makes approximately two and a half turns and ends blindly at the apex (also called the helicotrema). The dimension of cochlea partition gradually diminishes towards the helicotrema. The average length of the cochlear duct is 37.6 mm and it is generally longer in males than in females (3). The shape of the cochlea's curvature and its fine structure varies substantially (4). The cochlear duct is divided by the osseus spiral lamina and the basilar membrane and forms three different spaces. The basillar membrane is fibrous tissue, which is medially attached to the osseus spiral lamina of the modiolus (center of cochlea) and laterally to the spiral ligament of the outer wall of bony cochlea. The basillar membrane divides the cochlea into two parts; scala tympani and scala vestibuli. Scala tympani and scala vestibuli communicates in the apex of the cochlea through a small opening called the helicotrema. The scala vestibuli ends at the oval window and the scala tympani is located behind the round window. A smaller space called scala media is located between the scala vestibuli and the scala tympani. It is separated from the scala tympani by the basilar membrane and from the scala vestibuli by Reissner´s membrane. The organ of Corti is inside the scala media, over the basilar membrane. The hair cells are part of the organ of Corti. The hair cells are further divided into outer hair cells and inner hair cells. The outer hair cells are located closer to the lateral wall of cochlea and are organized in three rows. The outer hair cells amplify the vibrations of the basillar membrane. The inner hair cells are located in a single row closer to the modiolus of cochlea and they form synapses with the spiral ganglion cells. Most of the outer wall of scala media is formed by the stria vascularis, which is a dense layer of blood vessels and specialized cells. The stria vascularis is responsible for producing the endolymph of the scala media. It also supplies the cochlea with oxygen and energy for metabolism. The scala vestibulum and the scala tympani are filled with perilymph, and there is a concentration difference of potassium and sodium ions between the endo- and perilymph (5). The anatomy of the inner ear and the cross-section of the cochlea is illustrated in Figure 3.

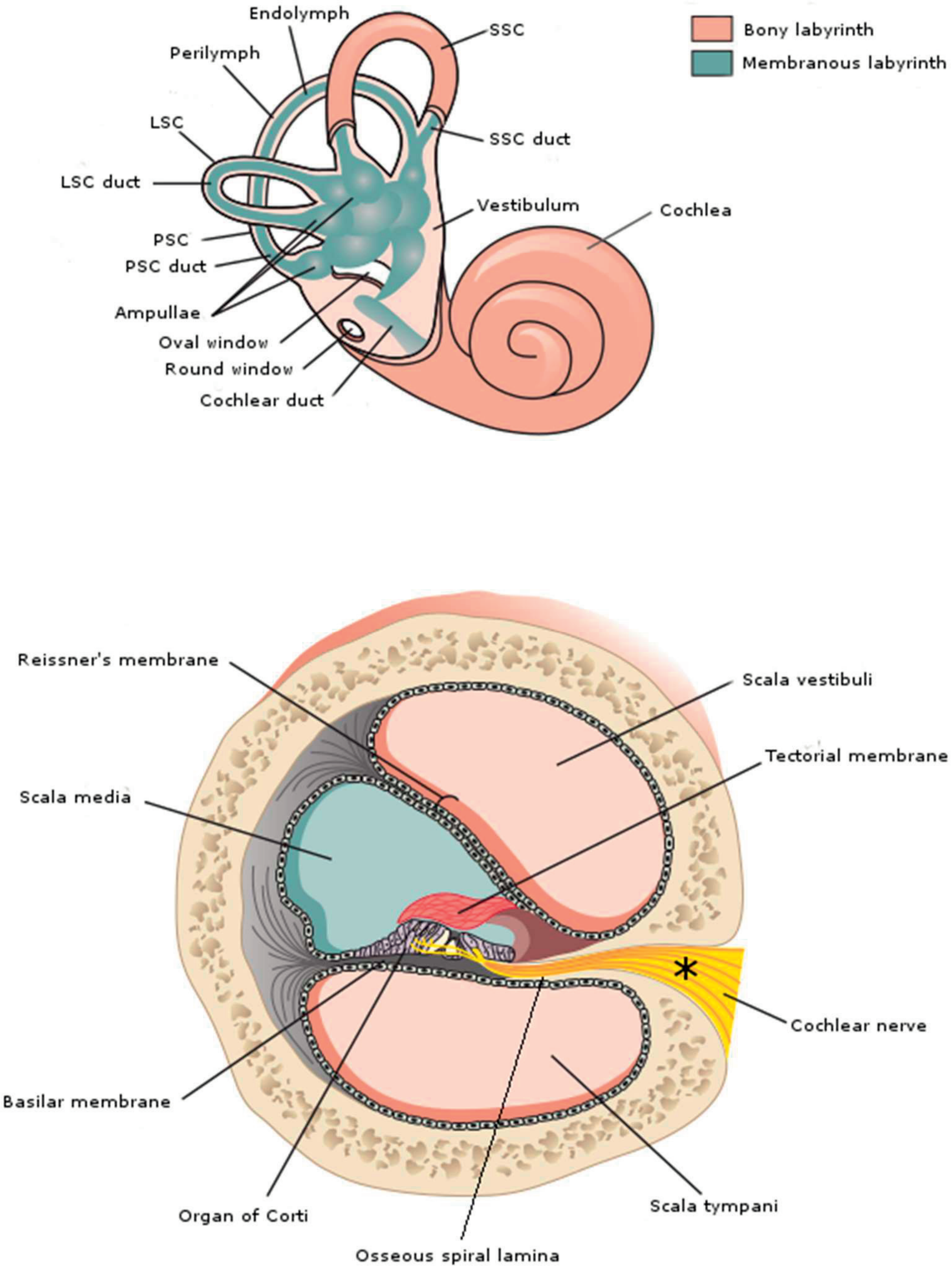


Figure 3: Anatomy of inner ear and cross-section of cochlea. SSC = superior semicircular canal, LSC = lateral semicircular canal, PSC = posterior semicircular canal and ✻ = rosenthal canal. With courtesy of Korvatieto OY.

2.1.2 Physiology of hearing

The sound waves travel via the outer ear canal to the tympanic membrane (TM). The vibration in the TM and the ossicles is transmitted to the cochlea via the oval window. The sound wave then advances inside the scala vestibulum and induces vibration in the basillar membrane. The location of maximal vibration depends on frequency of the sound, e.g. low frequency travels deeper inside cochlea and high frequency causes vibration near to the basilar portions of the cochlea. The cochlea can be considered to be organized in a tonotopical order. The basic function for estimating a certain frequency´s location was presented by Greenwood in 1961 (6) (illustrated in figure 4). A deeper understanding of the cochlear physiology was provided by the research of Békésy. He was awarded by the Nobel Prize for his research in 1961. The research of cochlear physiology and function of hair cells was then carried out by several researchers such as Russell and Sellick, who conducted the first in vivo recordings of hair cells in 1978 (7).

The vibrations of the basilar membrane causes the hair cells to move against the tectorial membrane which then bends the hair cells. The outer hair cells are responsible for the amplification of soft sounds and the inner hair cells form synapses with the spiral ganglion cells. Damage to the inner hair cells causes a more profound hearing loss as the damage to the outer hair cells causes elevation in the hearing threshold and difficulties in frequency separation. Bending of the inner hair cells causes an opening of their electrolyte channels and a subsequent depolarization of the cochlear cells. These electrical pulses are then transformed into a neural signal transmitted through spiral ganglion cells to auditory nerve and then via brainstem to the auditory cortex at the superior temporal gyrus of the brain (8, 9).

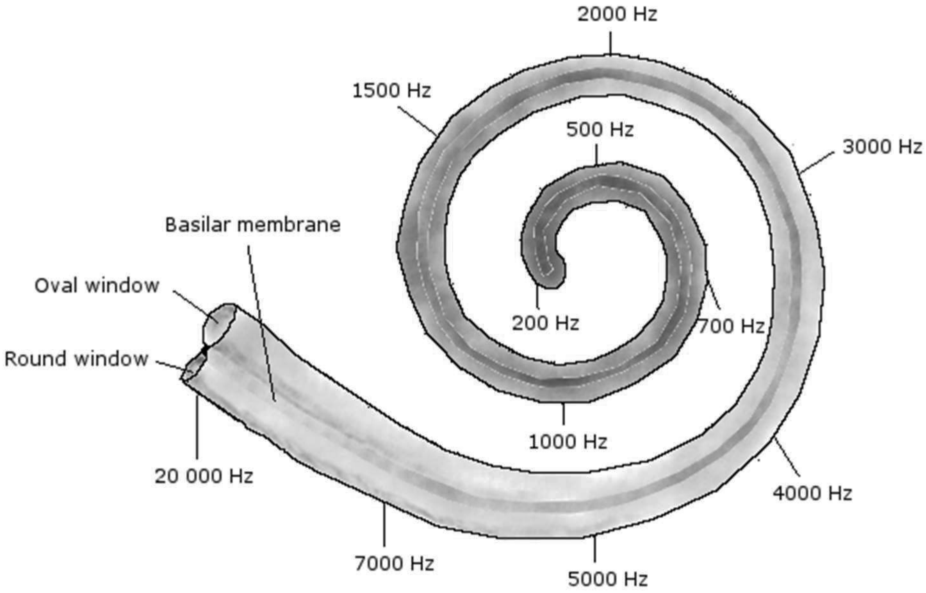


Figure 4. Illustration of Greenwood map.

2.2 COCHLEAR IMPLANT

A cochlear implant (CI) is an implantable medical device which restores hearing by providing a direct electrical stimulation of the spiral ganglion cell of the auditory nerve.

2.2.1 History

The use of electric stimulation to generate a hearing sensation was first described by Alexander Volta (1745-1826) in his experiment with two 50-volt batteries placed in contact to his ear. This led to "crackling and boiling" sensations and this is considered as the first documented auditory sensation caused by an electric current (Volta 1800). The next advances occurred 150 years after Volta´s experiment; they were made by S.S. Stevens and his colleagues from Harvard, U.S. who investigated the "electrophonic hearing" by stimulating the inner ear through the skin (10). Djourno was the first investigator to report hearing sensations evoked by electric current in deaf patients in 1957 (11, 12). This finding increased the research interest in hearing restoration by an electrical current, and in the year 1961 William House implanted two deaf patients with silicon coated single electrode into cochlea (13). The development of multichannel implant systems was carried out by several groups: Graeme Clark in Australia, Ingenborg and Erwin Hochmair in Austria, Chouard in France and Eddington in Utah, USA. Blake Wilson developed the continuous interval sampling (CIS) strategy exploited in multichannel implant systems. Clark, Hochmair and Wilson were awarded with the Laskin Prize for their achievements in the field of cochlear implant research.

In 1988, the National Institutes of Health issued a consensus statement (14) regarding cochlear implants, when they concluded that "multichannel implants may have some superior features in adults when compared with the single-channel type". Subsequently, multichannel cochlear implants have become widely used in hearing rehabilitation.

In 2018, there were 320 000 patients worldwide who had been treated with a cochlear implant. Currently there are four companies manufacturing the multichannel cochlear implants on the market.

2.2.2 Cochlear Implant

Cochlear implant system can be divided into two parts: sound processor (figure 1) and the implant (figure 5). The sound processor contains the battery-pack and speech processor with an external transmitter and microphones for sound detection. The implant is surgically implantable and consists of the following parts: the receiver/stimulator, lead wire and electrode array also known as the electrode. External transmitter creates the contact with the receiver stimulator by coupling with its own magnet to the magnet in the receiver/stimulator. The sound processor converts the acoustic signals into electric signals, which are encoded into a radiofrequency (RF) signal. The RF-signal is transferred to the implant by induction via an antenna (9). Modern cochlear implant arrays have 12-22 stimulation contacts, which transfer the electrical signal into the cochlea (9, 15, 16).

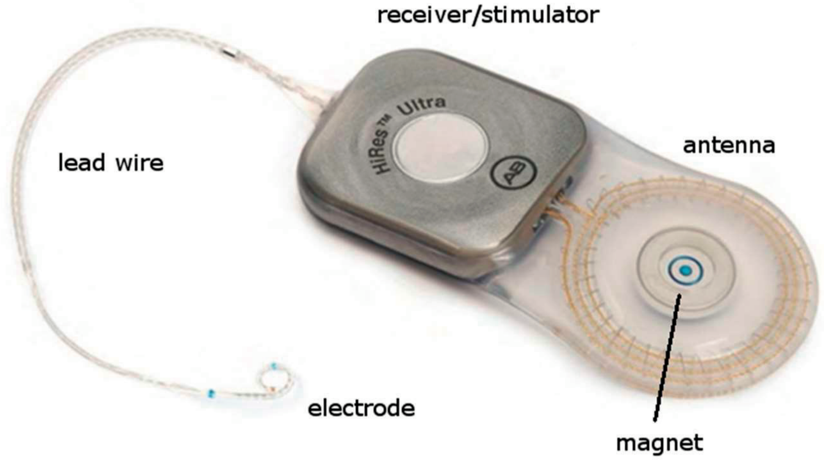


Figure 5. Cochlear implant (with courtesy of Advanced Bionics)

2.2.3 Cochlear Implant Surgery

The cochlear implant is operated through an incision behind the ear above the mastoid process. The air cells of the mastoid are eradicated with an otologic drill under an operating microscope. Access to the cochlea is made by opening the facial recess, which is the space between the posterior bony ear canal, the chorda tympani and the facial nerve. The electrode is inserted into the cochlea, preferably into the scala tympani through the round window membrane or via cochleostomy. The cochleostomy is drilled inferior and slightly anterior to the round window in order to reach the scala tympani. If the array is positioned into the scala tympani, the electrode contacts lie closer to the spiral ganglion cells than when positioned in the scala vestibuli (9, 16). The electrode insertion is made very slowly and the insertion trajectory should be tangential to the basal turn. An implant bed is made for the receiver/stimulator by drilling a recess into the pars parietal of the temporal bone.

2.2.4 Electric stimulation

The main target tissues for the electrical stimulation are presumably the spiral ganglion cells. Electric current causes depolarization in these cells which leads to an activation of the auditory nerve with the signal being conveyed via the brainstem to the auditory cortex, where sound sensations are generated. The stimulation of cochlea exploits the tonotopic organization of the neural elements as the individual electrodes in the cochlea stimulate different spiral ganglion population depending the site of each electrode contact. (17). Basically this means that basal electrodes produce high frequency sounds and contacts deeper in cochlea to aid in the detection of lower frequency sounds. The aim is to provide a maximized number of nonoverlapping electrode contacts in terms of neural stimulation inside the cochlea. The sound information can be divided also into two components, the envelope and the temporal sound, also known as the fine structure (FS) (9, 18). The CIS strategy represented a distinct improvement in the electrical stimulation of the cochlea and achieved significantly more favorable hearing outcomes as compared with earlier strategies (19). In the CIS approach, the sounds are divided into bands of frequencies by filters and the stimulation is sent as brief biphasic pulses to each electrode in the corresponding tonotopical site as a fast, non-overlapping sequence. Previous strategies, called compressed analogue (CA), utilized analogue waveforms which were presented to all electrodes. Usually CI patients can identify up to 8 individiual activation sites (20-23). The spread of the electrical current is the limiting factor for channel distribution. There are several different speech coding strategies used in commercial cochlear implants: HiResolution™ (HiRes), spectral peak (SPEAK), advanced combination encoder (ACE) (24-26). All these stimulation strategies have been developed on the basis of the CIS strategy.

The HiRes strategy is very similar to the CIS strategy. It uses a high rate of stimulation and cutoff ranges for envelope detectors.

SPEAK and ACE use a channel selection strategy that detects the highest amplitude of sound in different channels (i.e. corresponding to each individual electrode) and stimulate the corresponding electrode. The deletion of low-amplitude sounds and associated stimuli may reduce the overlapping stimulus regions in cochlea (9).

Current systems provide good information about higher frequencys, which are more tonotopically oriented. In the low frequency areas, the timing of the sound and fine structure are more important. The CIS strategy and its successors exploit the sound envelope which is provided to the cochlea. Currently the FSP (fine structure processing) strategy, where the deepest electrode contacts (tonotopically responsible for low frequencies) are stimulated at a very high rate of stimulus in order to transmit FS of the sound. The intention is to provide better low frequency hearing, although the amount of provided FS is still unclear (9, 18). Tonotopically the coverage for electric stimulation for lower frequency areas is also more problematic due their deeper localization (18). Thus, generally the cochlear implant systems tend to stimulate higher frequencies better than the lower frequencies.

2.3 INDICATIONS

Cochlear implants are used for both adult and child patients with severe or profound hearing loss. WHO hearing classification designates 26 to 40 dBHL$_{(0.5\text{-}4\ kHz)}$ as mild, 41 to 60 dBHL$_{(0.5\text{-}4\ kHz)}$ as moderate, 61 to 80 dBHL$_{(0.5\text{-}4\ kHz)}$ as severe and 81 dBHL$_{(0.5\text{-}4\ kHz)}$ or more as profound hearing loss (27). There are no guidelines for cochlear implantation in Finland, but when a patient suffers from hearing problems in everyday life even with an satisfactorily fitted hearing aid, then a consultation for possible cochlear implantation is recommended (15). Part of the patient examination is the Finnish speech in noise test, which evaluates better the patient's hearing from a functional aspect when compared with the Finnish word test. This test reports the results as the signal to noise ratio (SNR). In the normal hearing group, the average is -10.1 dB SNR (28). For comparison, in the average Finnish unilateral cochlear implant user, the result is -3.5 dB SNR, though there is extensive variation between patients (29). Cochlear implantation should be considered when other methods of hearing rehabilitation have failed to provide satisfying results. The evaluation of candidancy for cochlear implantation demands a detailed clinical multifactorial and interdisciplinary evaluation of the patient.

2.3.1 Sensorineural hearing loss

The etiology of sensorineural hearing loss (SNHL) can be congenital or acquired; the former can include the following causes: genetic, infectous diseases passed from mother to child (e.g. rubella), lack of oxygen at birth, maternal diabetes or prematurity. The etiology behind acquired SNHL includes a large variety of causes e.g. aging, exposure to excessively high levels of noise, infections, head or acoustic trauma, tumors and ototoxic medications (Holden ear hear 2013, Moberly AC, Otol Neurotol. 2018 Dec;39(10):e1010-e1018. Wilson BS, Dorman MF J Rehabil Res Dev. 2008, Deep J Neurol Surg B Skull Base. 2019, Lenarz, GMS Curr Top Otorhinolaryngol Head Neck Surg. 2017; Ear Hear 2007, Lin, Chien; Medicine (Baltimore) 2012))

Congenital hearing loss is a frequent chronic condition in children (30). The most common cause for nonsyndromatic SNHL is a mutation of GJB2 gene; this can be detected in 10-20 % of cases in Caucasian childrens (30). The prevalence of moderate or severe SNHL is approximately 1.33 /1 000 at birth and increases to 2.83 /1 000 by the age of 7 to 9 (31-33). In the year 2000, Bradham and Jones (34) estimated that in the United States, there were 12 861 children (age between 12 months to 6 year) with severe to profound SNHL suitable for cochlear implantation but only approximately 55 % these children had been treated with a cochlear implant.

Hearing impairments are rather common in the adult population in Finland i.e. approximately 37 % of people (aged 54-66 years) (35). The prevalence of hearing loss increases according to the age group: 7% among 45-year-olds, 16% among 55-year-olds, 37% among 65-year-olds and 65% among 75-year-olds (36). Claeson and Ringdal (37) conducted a study in Sweden, where they estimated that 18.6 /100 000 post-lingually deaf adult patients with SNHL would fulfill the criteria to receive a cochlear implant.

2.3.2 Hearing preservation and electro-acoustic stimulation

In most types of sensorineural hearing loss such as age-related hearing loss, the hair cells of the high frequency range (1000 Hz – 8000 Hz) are commonly more severely affected than the hair cells responding to the low frequencies (125 Hz – 500 Hz). This results in a very distinct cochlear attenuation profile, in which there is relatively good residual hearing in the low frequencies with significantly more severe attenuation (up to complete deafness) in the high frequencies. Hearing of low frequencies (125-500 Hz) may remain quite good. In extreme cases of high frequency hearing loss or partial deafness, modern hearing aids may provide only marginal help for hearing in normal life situations. (38, 39). In these cases, the best option would be to provide an electrical stimulus to the cochlea's deaf regions while maintaining the residual hearing. By combining the electric and acoustic stimulation (EAS), patients may acquire the most optimal outcomes with CIs.

The improvements in electrode design towards more flexible and smaller electrode arrays and surgical techniques have expanded implantation criteria so that they now encompass patients with considerable functional low frequency hearing in the 125-500 Hz range. Patients with significant functional hearing in the lower frequencies may benefit from cochlear implantation involving combined electric – acoustic stimulation (EAS), provided that their residual hearing can be preserved in surgery. Better sound quality, music listening ability and speech recognition in noise have been shown to be the benefits of EAS as compared to exclusive electric stimulation (40-45). Though the patient's hearing has a tendency to deteriorate with time, it is still considered to be a slow deterioration, even after implantation in many cases (46, 47).

According to AAO-HNS criteria (48), considerable functional hearing is present when average unaided hearing is better than 80 dB HL at 125, 250 and 500 Hz. Even though the 80 dB HL is still within the limits of current EAS-processors amplification limits (49), realistically for the fitting of EAS-processor, the hearing criteria are 70 dB HL or better (50).

2.3.3 Specific indications

Improvements in the cochlear implant technology have an influence on expanding of the criteria for cochlear implantation.

More recently, implantation after skull base surgery has become an area of interest. Implantation after removal of the vestibular schwannoma has given reasonable hearing results in some cases when the auditory nerve could be preserved (51, 52). Furthermore, in cases where the schwannoma is left in place but is not growing, the cochlear implantation could be nonetheless achieve significant benefits in hearing rehabilitation (53, 54). Implantation may also provide hearing after removal of intralabyrinthal schwannoma (55, 56)

Cochlear implantation has been considered as one rehabilitation option for hearing in several other retrocochlear disorders (hemosiderosis of the central nervous system (CNS), auditory neuropathy, other CNS tumors) (57-59). The results in these cases show more variation and should be taken in consideration when planning cochlear implantation for these patients.

Cochlear implant treatment for single sided deafness (SSD), has become an indication for implantation during recent years. SSD is defined as a condition where a patient has no functional hearing in one ear and receives no clinical benefit from amplification in that ear, with the contralateral ear possessing normal function. However, this is still not standard of care in most Western countries. SSD has been shown to have a negative effect on the patient's quality of life, speech discrimination in noise, sound localisation and tinnitus (60-65). Significant tinnitus is present in 54-84 % of SSD patients (66, 67). SSD seems also to cause increased activation of the brain areas involved in the processing of a diminished input (68). SSD also has psychological comorbidities such as anxiety and depression (69).

There are studies showing an improvement in speech discrimination in noise, sound localization and tinnitus after cochlear implantation in SSD patients (60-62, 69). Rehabilitation of SSD with a cochlear implant seems also to improve the quality of life and reduce cognitive stress of the patient (69).

2.3.4 Contraindications

In fact, although some of the contraindications to implantation are only relative and nowadays more patients may benefit from cochlear implant, there are still situations when a cochlear implant should not be considered. Major anomalies (Complete labyrinthine aplasia, rudimentary otocyst and cochlear aplasia) i.e. when there are not any structures resembling a cochlea, then the use of conventional cochlear implant is not possible (70). In situations in which the cochlear or vestibulocochlear nerve is missing or cut, cochlear implantation is contraindicated since no auditory sensations can be transmitted (71). However, in cases of congenital auditory nerve hypoplasia or aplasia, there is still a possibility of auditory stimulation with cochlear implants (72). The resolution of magnetic resonance imaging, even with 3 Tesla devices, may be too low to detect the presence of the nerve fiber entering the modiolus. Therefore, CI treatment is usually recommended since some children might benefit from the CI (70).

The patient's own motivation and support from his/her social environment is essential in order to achieve optimal hearing outcomes with CIs. It is important that the candidate understands the limitations of CI rehabilitation. There is extensive variation in the adaptation to electrical hearing with a similar variety in outcomes. In fact, CI rehabilitation represents a lifelong commitment to the particular device chosen. Contraindications for general anesthesia have been considered to prevent cochlear implantation. Cochlear implantation under local anesthesia has expanded the treatment also for these patients to allow them to gain the benefits of a cochlear implant (73, 74).

2.4 ELECTRODE DESIGN

Electrodes can be categorized in two distinct designs: lateral wall electrodes (LWE) and precurved electrodes. Precurved electrodes are also known as modiolar or perimodiolar electrodes. There are variations in the designs of electrodes between different manufacturers, but the basic principles are similar. Electrode design exerts a significant influence on surgical properties and thus can also have an influence on outcomes (75-81).

2.4.1 Lateral wall electrodes (LWE)

All companies serving the EU market have at least one design of an LWE in their portfolio. The LWE are usually inserted through a round window membrane. Another option is to insert a LWE through a cochleostomy. The LWE is positioned most often at the lateral wall of the scala tympani. Depending on the manufacturer and design, the standard length of the LWE may vary between 20 mm and 31.5 mm with 12 to 22 contacts (79). LWEs may preserve the intracochlear integrity quite well, with good preservation of low frequency residual hearing ranging from 54% to 88% for shorter LWEs and from 11% to 77%% for long electrodes (41, 71, 77, 82-93). Most LWEs today are designed to have maximum atraumaticity, thus they are mostly thin and flexible. The LWEs carry a risk for gradual electrode migration out of the cochlea (94) and therefore different surgical techniques have been developed including fixation clips to prevent migration. A tip fold over is also possible with LWEs. The study of Zuniga (95) found 1 (0,8%) tip fold over in 124 cases implanted with LWE.

Short LWEs electrodes are designed for patients with significant low frequency residual hearing and who are candidates for electro-acoustic stimulation. These electrodes range in length from 14.5 mm to 20 mm (79). The insertion depth with these short electrodes varies from 270 to 360 degrees, thus providing electrical stimulus only to the basal turn of the cochlea. Studies have shown that better hearing outcomes can be achieved with deeper insertions, in which the so-called cochlear coverage is more optimal. However, there have been reports that in very deep insertions beyond the second turn, the most apical electrode contacts may not provide accurate pitch perception. There are large datasets indicating that there is indeed an optimal insertion depth angle (IDA), which varies from about 450 to 630 degrees, that seems to provide the best possible outcome with electric stimulation (96). A insertion depth of less than 360 degrees is therefore not optimal for electric-only stimulation (83, 97, 98). It has been reported that residual hearing tends to deteriorate during a longer follow-up time leading to a loss of the benefits of electro-acoustic stimulation (88, 99). However, short electrodes minimize the possibility of trauma in the deeper parts of the cochlea where the low frequency areas are located (41, 100). According to several studies, about 54 to 96 % of the candidates for electro-acoustic hearing are reported to gain benefits from electro-acoustic stimulation post-operatively (41-43, 88). If the hearing deteriorates after surgery, and the patient does not adapt to the electric stimulation with a concurrent deterioration of his/her speech recognition, then a revision might be necessary to replace a short array with a longer one to achieve better cochlear coverage (41). Fortunately, especially younger patients, can still adapt to a short electrode and its pitch-place mismatch i.e. they may obtain favourable results with a short electrode.

2.4.2 Modiolar electrodes

Modiolar electrodes are designed to be accommodated into the spiral of the cochlea. In this position, the electrode's contacts are closer to the neural structures intended to be stimulated. Currently two manufacturers offer modiolar electrodes (Cochlear, Sydney, Australia and Advanced Bionics, Valencia, CA, USA). In theory, the closer position of the electrode to the modiolus could provide lower electric current levels, less spread of excitation and lower energy consumption. Lower threshold levels theoretically cause less spread of excitation which could lead to better pitch resolution. Some studies have shown improvements of psychoelectric measures, channel separation and a greater dynamic range with modiolar electrodes (101-107). Even though the improvements in different measures have been reported, the clinical benefits are still somewhat uncertain (108-112). The perimodial electrodes are significantly stiffer and have a larger volume in comparison with the second generation LWE´s (79, 113, 114).

The modiolar electrodes are precurved electrodes which are usually made straight prior to insertion with an internal stylet. Modiolar electrodes are more prone than the LWEs to inflict intracochlear trauma. The introduction of the advanced technique of stylet insertion (AOS) represents an attempt to avoid intracochlear trauma during insertion of the modiolar electrodes (77, 80, 82, 83, 97, 115, 116). The modiolar electrode may not accommodate all varying shapes of the cochlea, which makes it also more prone to trauma (4, 117). Dislocation from scala tympani to scala vestibuli (a dislocation represents a significant trauma) with perimodiolar electrodes has been reported to occur from 15.8 to 52.3 % of the cases (75, 83, 93, 97, 118, 119).

A new, second generation modiolar electrode, the so-called Slim Modiolar electrode (Cochlear, Sydney, Australia) was launched in 2017. It is significantly smaller in size than the conventional modiolar electrodes, making it more flexible (113, 120). The stylet has been replaced with a thin sheath, which keeps the electrode straight prior to insertion. At the beginning of this dissertation work, there were no data available about the final version of this SME. Recently published results with the Slim Modiolar electrode are promising, although the sheath requires some changes in surgical techniques during electrode insertion (121-123). The slim modiolar electrode is more prone to tip fold over than the conventional modiolar or LWE´s (95, 122).

Figure 6. Four different electrode arrays of the Cochlear company from top to bottom: Slim Modiolar electrode, Contour Advance, Slim Straight electrode and straight electrode (with courtesy of Cochlear Company).

2.5 PROGNOSTIC FACTORS RELATED TO HEARING OUTCOMES

2.5.1 Patient specific

There are many patient related factors that affect the post-operative hearing result. There are several predictors for better outcomes e.g. young age at implantation, short duration of hearing loss, short duration of hearing aid use before implantation and education level of the patient (75, 106, 124). The cognitive capacity influences the hearing result and residual hearing at the time of implantation (106, 124). In patients with SSD there have been reports describing changes in the brain's gray matter areas that are responsible for hearing corresponding to the deaf side (68, 125, 126). This finding explains why the duration of deafness can influence the results of cochlear implantation i.e. the brain needs to accommodate again to an incoming signal from the cochlea. Cardon and Sharma used EEG and detected significant hearing related changes in age-related hearing loss when compared to normal hearing reference in controls (127).

2.5.2 Insertion related

2.5.2.1 Intracochlear trauma

Electrode insertion to the scala tympani has been shown to provide the best hearing outcomes (75, 83, 106, 128, 129). Trauma to the basilar membrane, spiral lamina, compression or tears in the vascular structures and translocation from the scala tympani to the scala vestibuli cause trauma-related cellular apoptosis and fibrosis and a degeneration of the neural tissue. (130, 131). Therefore, the preservation of the delicate cochlear structures plays a significant role in the hearing outcomes with a cochlear implant (109). Trauma to the cochlea has been shown to induce reduction the spiral ganglion cell population (132). Postmortem studies have revealed a direct correlation of the density of the spiral ganglion cell population with the hearing outcomes. (133, 134). In clinical studies, electrode scala translocations have been shown to be an independent and relevant factor for hearing results in cochlear implant users (75, 81, 83, 97, 106, 135). O´Connell et al. (97) found a 12 % decrease in CNC (consonant- nucleus-consonant) scores in cases where the electrodes had become dislocated. Similarly, Wanna et al (83) found a 12.8 % decrease of post-operative CNC scores if the electrodes were located in scala vestibule as compared with scala tympani localization.

Insertion technique and electrode design are the most significant factors influencing the risk of cochlear trauma (see above in chapter about electrode design). Individual temporal bone anatomy may also predispose some patients to trauma; in these individuals the insertion trajectory may force the electrode towards basillar membrane (136). Insertion via the round window membrane has been associated with full scala tympani insertion more often when compared to cochleostomy insertion (83, 97, 137). Adunka et al. found (138) trauma in 48 % of temporal bones after insertion through a cochleostomy, as compared to 15 % when insertion was conducted through RWM with the conventional straight electrodes. Drilling of the cochleostomy itself may already cause trauma to the basillar membrane (138). Insertion speed influences the risk of trauma, as a low insertion speed decreases the insertion force and pressure changes which further achieves better insertion results (139, 140). De Seta et al. (141) detected a significant correlation with increased insertion forces and scalar dislocation in a temporal bone study. Pressure changes during insertion have also been related to the dimensions and design of the electrode (78, 142). Moving of the electrode after insertion causes also pressure changes inside the cochlea, which may have an impact on possible residual hearing (143).

2.5.2.2 Insertion depth and distance from the modiolus

The assumption is that a deeper electrode insertion enables a better coverage of different frequencies, as demonstrated in the model suggested by Greenwood. Recent clinical studies have found that the deeper electrode insertion seems to provide better hearing results (97, 98, 118). O`Connell et al (118) found that a 0.6 % increase in CNC test was achieved with a 10 degree addition to the insertion depth angle. Buchner et al (144) studied three different length LWEs and found significant higher scores in favor of the longest electrode at 3 months after implantation. These differences diminished in the 6 month follow-up, indicating brain plasticity to adapt to the frequency mismatch. In the studies made by Holden et al.(106) and by van de Marel et al (145), there was no correlation found between insertion depth and better speech perception in quiet situations. There are theories that an overly deep insertion causes apical frequency pitch confusion and may potentially reduce the stimulation of the basal area of the cochlea (129, 146).

A closer modiolar position of the electrode has been suspected to improve sound resolution due the closer proximity of the electrode contacts to the spiral ganglion cells. It is believed that the threshold levels are lower when the contacts are the nearer to ganglion cells since this should result in less spreading of the current to adjacent contact sites. Therefore, a modiolar localization of the electrode may be one way to provide a more accurate pitch perception with smaller thresholds. (104, 109, 110, 121, 147). Holden et al. found a clinical correlation with closer modiolar proximity in their study (106). However, several other clinical studies have not been able to demonstrate these benefits. On the contrary, more favorable speech perception outcomes have been reported for LWEs (101-112).

As discussed above, the current systems do not provide as good hearing of the lower frequencies as they do for higher frequencies. Although this is at least partly related to physiology of hearing, also the insertion depth may be too shallow to allow the stimulation of lower regions (18).

2.6 HEARING OUTCOMES

An average cochlear implant patient can usually understand speech in a noiseless environment and gain significant improvement in his/her hearing as compared with the preoperative condition. When assessed with audiometry, hearing thresholds of the cochlear implant patient are around 25 dBHL, depending on the fitting of the cochlear implant. The speech open set sentence recognition score with cochlear implant patient is around 75 % (16).

A patient's hearing with the cochlear implant is considered as adequate if it allows him/her to manage in a normal listening and conversation situation without the need for lip reading, although this can vary between patients. In challenging hearing situations (e.g. significant background noise), the hearing capacity of the cochlear implant patient is significantly lower than that of a person with normal hearing.

Patients with EAS often gain better sound quality and music listening ability as compared with electric-only stimulation (40-44).

2.7 TEMPORAL BONE STUDIES IN PRECLINICAL TESTING

Before there can be any clinical use, electrodes must be tested for safety, surgical handling and interactions; this testing is conducted by the manufacturing companies who are obliged to meet the official medical requirements for the approval of a medical device. Artificial insertion models are used with several iterations of the electrode under development. The final studies with the ultimate electrode design are conducted in cadaver temporal bones (TB) (113, 114, 138, 148-151). In TB studies, the operation should be simulated to resemble very closely that of a real operation. The temporal bone studies are conducted usually with the latest iteration prototypes or the final version of the electrode. A golden standard for intracochlear evaluation after insertion has traditionally been histology, which is neither time nor cost-effective. It also involves a considerable amount of manipulation of the specimen (151).

Imaging with a cone-beam computed-tomography (CB-CT) has become more widely used in TB studies because it is a fast and readily available imaging method and it interprets dislocation precisely at the second turn of cochlea (150-153). Although imaging with the CB-CT is faster and cheaper when compared to histology, its accuracy for trauma evaluation is far lower (154, 155). Nonetheless, imaging does represent a rapid method to identify design flaws, if they are present.

2.8 COCHLEAR IMPLANT IMAGING

2.8.1 Pre-operative planning

In the pre-operative evaluation, two modalities of imaging are usually used, magnetic resonance image (MRI) and high-resolution computed tomography (CT) (71). These are taken to evaluate the implantation requirements and to achieve better operation planning. CT shows accurately the bony anatomy of TB whereas MRI is better when neural structures such as auditory nerve and liquid-filled spaces (inner ear) are being evaluated.

2.8.2 Postoperative imaging

Post-operative imaging allows for an assessment of electrode position and to reveal possible complications e.g. tip fold over (95, 156). Postoperative imaging is an important quality control and it provides valuable information for surgeon as feedback about the surgery. Traditionally, a plain x-ray image (Stenvers view) with a cochlear view has been used to verify the post-operative insertion results (157). Although this does provide a rough estimate of electrode positioning, it does not allow any approximation for scalar location. CB-CT has proven to be a safe, low dose imaging modality with respect to radiation exposure and more informative than can be obtained with only a cochlear view (153-155). It enables an evaluation of the electrode's location in three planes with less artefact from the electrode's metallic components as compared with conventional CT. Most of the CB-CT devices take images with the patient in the sitting position, which may cause more movement artefacts in the images than with conventional CT.

2.8.3 Image fusion

The image fusion concept in general means overlying two different images to gain additional information exploiting the strengths of both modalities. One approach in routine clinical practice utilizes an image fusion technique involving positron emission computed tomography (PET-CT). In terms of cochlear implantation, image fusion can be used in order to minimize the effect of artefact caused by the electrode inside the cochlea (158). This provides an evaluation of the exact electrode location in relation to the bony borders of the cochlea.

In 3D image fusion, the pre-operative images are overlaid with postoperative images. The utilized image modalities are usually CT, CB-CT or MRI (148, 151, 158, 159). Image fusion softwares are exploited to align the images in planes where the entropy between the overlaid images is at its lowest. The electrode is reconstructed as a 3D model based on Hounsfield Units (HU, the Hounsfield Units describes the radiodensity of the imaged tissue or material) in postoperative images and then overlaid onto the fused pre-operative image.

With the fusion technique, it is possible to conduct a trauma evaluation beyond cochlea's second turn and to use more precise trauma scaling in the evaluation (151). There have been several methods for simulations of electrode reconstruction with image fusion using either imaging data or rendered cochlear models in the evaluation (106, 129, 148). There are several different commercial programs and also free software is available for undertaking image fusion.

2.9 STUDY CONCEPT AND PURPOSE

Independent research provides information for CI-surgeons about the advances and pitfalls of these rather new electrode designs. Even though the preclinical study settings do not completely correspond to in vivo surgery, the information is useful and guarantees that the devices can be safely handled during surgery. Currently, the best known method for testing these new electrode designs is to use temporal bones harvested from cadavers. With temporal bones, the CI surgery can be simulated rather realistically.

Clinical follow-up of CI-patients also provides further information of these new electrode designs in actual surgery and hearing rehabilitation and is thus as important as preclinical studies.

Fusion imaging is a promising innovation, which uses already existing technology and programs. In cochlear implantation, it has not been widely used, but it seems to be a promising tool to allow a more detailed trauma evaluation. When implementing new tools for patient work and research, both a thorough investigation and a validation of these tools are necessary.

A weakness of these studies is the number of cases in both preclinical and clinical studies. With larger samples, the reliability of the studies could have been improved. The clinical follow-up would have been preferable if the design and execution would have utilized a prospective protocol.

This dissertation provides information about the surgical properties and handling of two rather new electrode designs. It also provides a validated method to allow a more detailed evaluation of the intracochlear location and possible trauma in CI surgery in both preclinical and clinical settings.

3 AIMS OF THE STUDY

The aims of this dissertation project are

1. To test the insertion properties of the new Slim Modiolar Electrode.
2. To evaluate the slim modiolar electrode insertion properties in hearing preservation surgery.
3. To evaluate the insertion properties of the new straight SlimJ electrode.
4. To validate and further improve the image fusion method.

4.2 STUDY 2: PRESERVATION OF RESIDUAL HEARING AFTER COCHLEAR IMPLANT SURGERY WITH SLIM MODIOLAR ELECTRODE

4.2.1 Abstract

Purpose

To evaluate the insertion results and hearing preservation of a novel slim modiolar electrode (SME) in patients with residual hearing.

Methods

We retrospectively collected the data from the medical files of 17 patients (18 ears) implanted with a SME. All patients had functional low frequency hearing (PTA (0.125-0.5 kHz) ≤ 80 dB HL). The insertion results were re-examined from the postoperative cone-beam computed tomography scans. Postoperative thresholds were obtained at the time of switch-on of the sound processors (mean 43 days) and at latest follow-up (mean 582 days). The speech recognition in noise was measured with the Finnish matrix sentence test preoperatively and at follow-up.

Results

The mean insertion depth angle (IDA) was 395 degrees. Neither scala dislocations nor tip fold over were detected. There were no total hearing losses. Functional low frequency hearing was preserved in 15/18 (83 %) ears at switch-on and in 14/17 (82 %) ears at follow-up. According to HEARRING classification, 55 % (10/18) had complete HP at switch-on and 41 % (7/17) still at follow-up. Thirteen patients (14 ears) were initially fitted with electric-acoustic stimulation and 7 patients (8 ears) continued to use it after follow-up.

Conclusions

The preliminary hearing preservation results with the SME were more favorable than reported for other perimodiolar electrodes. The results show that the array may also be feasible for electro-acoustic stimulation; it is beneficial in that it provides adequate cochlear coverage for pure electrical stimulation in the event of postoperative or progressive hearing loss.

4.2.2 Introduction

The preservation of the delicate inner ear structures has become a major consideration in cochlear implant surgery as intracochlear trauma has been shown to negatively affect the post-implant hearing results (75, 97, 106, 129, 135). Due to the more advanced surgical techniques and more delicate electrode arrays, post-operative results have improved during recent years. This has led to an expansion of the use of these devices, now including also patients with functional residual hearing. Patients with substantial residual hearing in the lower frequencies may benefit from cochlear implantation by combined electric – acoustic stimulation (EAS), provided that their hearing can be preserved at surgery. First described by von Ilberg et al.(173), the physiological acoustic stimulation in the low frequencies combined with the electric stimulation by the cochlear implant has been shown to enhance the post-operative hearing results in terms of better sound quality, improved music listening abilities and better speech recognition against background noise (40-44) Although residual hearing can be preserved with longer lateral wall electrodes (LWE), much more favorable results have been reported for shorter LWE. For short electrodes (≤ 20 mm active length), the hearing preservation rates vary from 54 % to 88 %, depending on the classification (41, 43, 84, 88, 89). The disadvantage of short arrays is that in the event of a total postoperative hearing loss, the incomplete cochlear coverage may compromise the outcome with pure electrical stimulation. For electric hearing, deeper insertion angles have been shown to provide significantly better speech perception results (93, 97, 98). The hearing preservation results for these standard length LWEs (i.e. > 20 mm active length) vary from 11.3 % up to 77.7 % (88, 90-92, 174).

Conventional (i.e. stylet type) perimodiolar electrodes (PME) are reported to cause more trauma as compared to lateral wall electrodes (LWE) (76, 93, 164). Thus, the use of PMEs for hearing preservation surgery is seldom justified. Due to the closer proximity to the modiolus and the spiral neurons, PMEs may provide electro-physiological advantages, such as lower current consumptions and possibly more localized stimulation. However, there is no convincing data that these potential benefits are related to better clinical outcomes (104, 106, 109, 110).

A new PME, the slim modiolar electrode (SME) (Cochlear Company, Sydney, Australia) was recently designed for atraumatic insertion. The aim of this study was to analyze the clinical insertion and hearing preservation results of the SME.

4.2.3 Material and methods

We retrospectively collected the data from the medical files of 17 patients (18 ears) implanted with the SME. Patients with relevant functional hearing, defined as preoperative low-frequency PTA (0.125-0.5 kHz) ≤ 80 dB (HL) were included in this study (48). Patients with vestibulo-cochlear anomalies or cochlear fibrosis and/or ossification were excluded. The study had institutional approval (No. 5551850). Preoperative hearing thresholds were available from all patients and results from the Finnish Matrix Sentence Test (FMST) in sixteen patients. Speech recognition was measured with the novel FMST, the standard speech-in-noise test was used in adult CI recipients to measure hearing performance (28, 29). Randomized 20-sentence test lists and a non-fluctuating speech-spectrum shaped noise at a constant level of 65 dB SPL were used as speech and noise signals. The speech reception threshold (SRT), i.e. the signal-to-noise ratio at which 50 % of the test items are correctly recognized, was determined in an adaptive test measurement procedure. One child was an immigrant with insufficient language skills and the other child had mild autism spectrum disorder (cases 4 and 7) and could not perform the FMST. All measurements were performed in the best-aided condition.

All patients underwent routine pre-operative magnetic resonance imaging (MRI) and high-resolution computed tomography (HRCT) to rule out cochlear malformation or retrocochlear pathology. All patients had normal temporal bone and labyrinthine anatomy.

The SME is a new generation PME, whose volume is approximately 40 % smaller than the Contour array. The internal stylet was replaced by an external sheath in order to keep the electrode straight prior to its insertion. The SME has a diameter of 0.35 x 0.4 mm at the tip and 0.45 mm x 0.5 mm at the base.

All patients underwent cochlear implantation via a trans-mastoid posterior tympanotomy approach under general anesthesia according to the institution’s hearing preservation protocol. The patients were given cefuroxime 1.5 g and dexamethasone 7.5 - 10 mg intravenously during induction. Weight equivalent doses were administered to the pediatric patients. The bony overhang over the round window (RW) was carefully drilled down to largely expose the round window membrane (RWM). A Spongostan (Ferrosan, Copenhagen, Denmark) soaked with dexamethasone 10 mg/ml was placed into the RWM for the time of implant bed drilling. The RWM was incised in the anterior part and lifted posteriorly with a short hook to open the anterior half of the round window. A hyaluronic acid – dexamethasone mixture (50:50 ratio) was then applied onto the RW area. Prior to loading the electrode, the hyaluronic acid - dexamethasone mixture was applied onto the array to ensure smooth gliding of the sheath during insertion. During insertion, special attention was paid to the appropriate orientation of the wing. The insertion and the removal of the sheath were performed as slowly as possible. The final position of the array was finally adjusted, with the distal marker inside the cochlea and the proximal marker outside. The white triangle was locked between the chorda-facial angle and was secured with bone paste and fibrin glue for stabilization. Finally, a tiny piece of temporal fascia was prepared and placed around the array in order to seal the RW.

On the first post-operative day, a cone-beam computed tomography (CBCT) was taken to assess the insertion results. The insertion depth angle (IDA) was measured and the scalar placement was evaluated (Figure 1). All patients were discharged from the hospital on the first post-operative day. The patients did not receive any postoperative corticosteroid and/or antibiotic therapy.

The first postoperative hearing thresholds were mostly measured at the time of switch-on of the sound processor. Thresholds were measured routinely in the follow-up visits at approximately 6 and 12 months after activation.

The hearing preservation results are presented according to the following classifications used in the literature: The hearing thresholds were analyzed for PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$, PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$ and for HEARRING classification (S) [S= 1-((PTApost-PTApre)/(PTAmax-PTApre))*100%] as described by Skarzynski et al. [31]. In the HEARRING classification, complete preservation was achieved whenever S >75 %, partial S= 75% - 25 % and loss when S <25 %. For PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ and PTA $_{(0.125\text{-}1\mathrm{kHz})}$, complete hearing preservation was achieved when the mean pre- and postoperative threshold deterioration was ≤ 15 dB (HL) and partial hearing preservation when the threshold shift was ≤ 30 dB (HL). A postoperative threshold deterioration > 30 dB (HL) was classified as minimal preservation.

Data were analyzed with Statistical Packages for the Social Sciences (SPSS) for Windows version 25 (SPSS Inc., Chigaco, IL, USA). Wilcoxon signed rank test was used in the statistical analysis when comparing hearing results. The Pearson test was used as a correlation test.

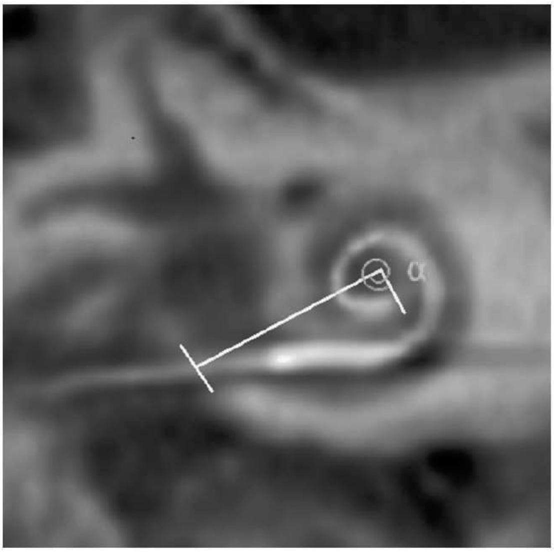


Figure 1. Method for the insertion depth angle (IDA) measurement. Starting point for the first line is the level of RWM in middle of electrode, reaching to modiolus. Second line of the angle is drawn from modiolus to tip of electrode.

4.2.4 Results

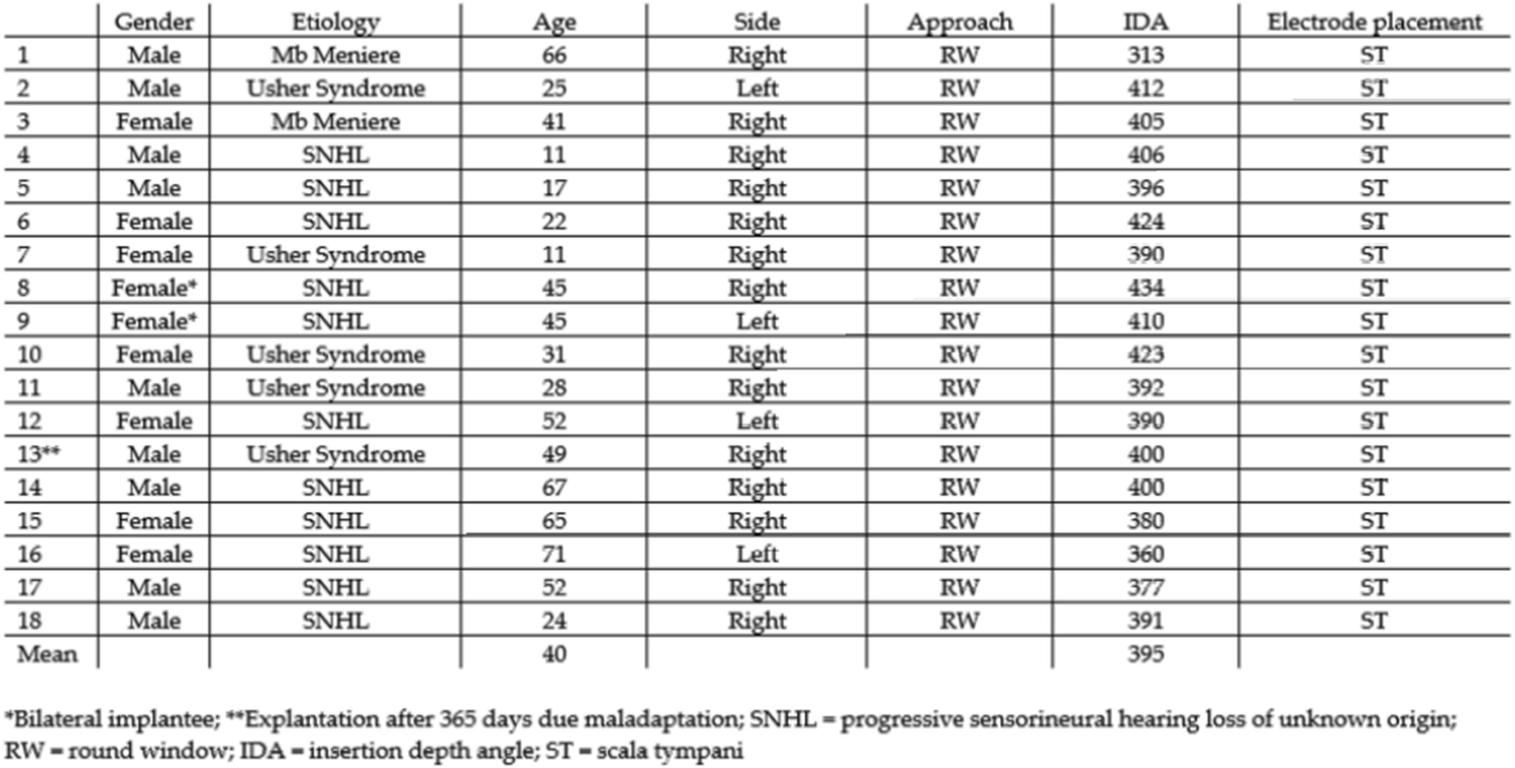
All eighteen insertions could be performed through the RWM without any need to drill an extension. All insertions were carried out slowly, over one minute. There were no post-operative complications. In the post-operative CBCT, the mean IDA was 395 degrees (range 313-434 degrees). All electrodes were fully inserted without any tip fold-over or scala translocations. The SME was located in close proximity to the modiolus in all but one ear. Information regarding the patient demographics and insertion results is summarized in Table 1. One patient with a psychiatric disorder (No. 13) insisted on the removal of the device after three months. Removal of cochlear implant was done 356 after implantation. This patient has been excluded from end point results because data from a longer follow-up was not available.

The mean time between surgery and the first postoperative threshold measurements was 43 days (range 3- 93, median 31). The mean follow-up time for all ears was 582 days (range 229-1041, median 482).

There were no total hearing losses. Functional low frequency hearing (PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ $\leq$ 80 dB (HL)) was preserved in 14 out of 17 ears (82 %). The mean postoperative deterioration in the PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ was 11 dB (HL). At end of the follow-up, complete hearing preservation was achieved in 14 out of 17 ears (82.4 %) for PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ and in 13 out of 17 ears (76.5 %)) for PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$. Partial preservation was achieved in 1/17 (5.8 %) and 3/17 (17.6 %) and minimal preservation occurred in 2/17 (11.8 %) for PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ and in 1/17 (5.8 %)) for PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$. The corresponding rates for earlier threshold measurements at 3 to 93 days after surgery, showed a complete preservation rate in 15 out of 18 ears (80.3%) for both PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ and PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$. According to the HEARRING classification, 7 out of 17 ears (41 %) had complete hearing preservation and 10 out of 17 ears (59 %) had partial preservation. According to the earlier threshold measurements, complete hearing preservation was present in 55 % of the ears and partial preservation in the remaining 45 % when applying the HEARRING classification. The hearing preservation results according to the different classifications conducted in the early postoperative period and the final follow-up are summarized in Table 2a and 2b. The overall hearing results are illustrated in Figure 2.

We found a moderate correlation between the patient's age and the deterioration of the residual hearing at the final follow-up. The correlation coefficients were r=0.603 (p=0.01) for PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ and r=0.613 (p=0.009) for PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$. There was no correlation between the baseline hearing and the preservation after surgery. For PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$, the correlation coefficient was $r = -0.341$ ($p = 0.180$); for PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$ the value of r was -0.417 ($p = 0.096$). We did not detect any significant differences between etiologies and the deterioration of residual hearing at the end of follow-up (PTA $_{(0.125\text{-}0.5\ \mathrm{kHz})}$ $p = 0.768$ and for PTA $_{(0.125\text{-}1\ \mathrm{kHz})}$ Hz $p = 0.649$).

Table 1. Patient demographics and insertion results



	Gender	Etiology	Age	Side	Approach	IDA	Electrode placement
1	Male	Mb Meniere	66	Right	RW	313	ST
2	Male	Usher Syndrome	25	Left	RW	412	ST
3	Female	Mb Meniere	41	Right	RW	405	ST
4	Male	SNHL	11	Right	RW	406	ST
5	Male	SNHL	17	Right	RW	396	ST
6	Female	SNHL	22	Right	RW	424	ST
7	Female	Usher Syndrome	11	Right	RW	390	ST
8	Female*	SNHL	45	Right	RW	434	ST
9	Female*	SNHL	45	Left	RW	410	ST
10	Female	Usher Syndrome	31	Right	RW	423	ST
11	Male	Usher Syndrome	28	Right	RW	392	ST
12	Female	SNHL	52	Left	RW	390	ST
13**	Male	Usher Syndrome	49	Right	RW	400	ST
14	Male	SNHL	67	Right	RW	400	ST
15	Female	SNHL	65	Right	RW	380	ST
16	Female	SNHL	71	Left	RW	360	ST
17	Male	SNHL	52	Right	RW	377	ST
18	Male	SNHL	24	Right	RW	391	ST
Mean			40			395	

*Bilateral implantee; **Explantation after 365 days due maladaptation; SNHL = progressive sensorineural hearing loss of unknown origin; RW = round window; IDA = insertion depth angle; ST = scala tympani

There were 14 ears (78 %) eligible for possible EAS and the vast majority, i.e. 13 ears (72 %) were primarily fitted with EAS. Subsequently, eight patients (nine ears) continued to use EAS. Two patients did not experience any subjective benefit from simultaneous acoustic stimulation and three patients preferred an open ear canal to the EAS strategy. The patient with bilateral SMEs used an EAS strategy in both of her ears.

The mean preoperative SRT was -1.2 dB (SNR) (range -6.8 to +10.0 dB (SNR)). The postoperative SRT improved significantly and was -5.2 dB (SNR) (range -8.5 to -0.7 dB (SNR)). The improvement of Δ -4.0 dB (SNR) with the Finnish matrix sentence was statistically significant (p=0.01) and in the clinically expected magnitude. We found a significant (negative) correlation between IDA and post-operative speech test results (r=-0.617; p=0.014), i.e. better post-operative speech test results with deeper IDA. No correlations were detected for the pre- and postoperative SRT values (r=0.251; p=0.367).

Figure 2 Mean hearing thresholds with minimum and maximum. a) preoperative b) early postoperative c) final follow-up

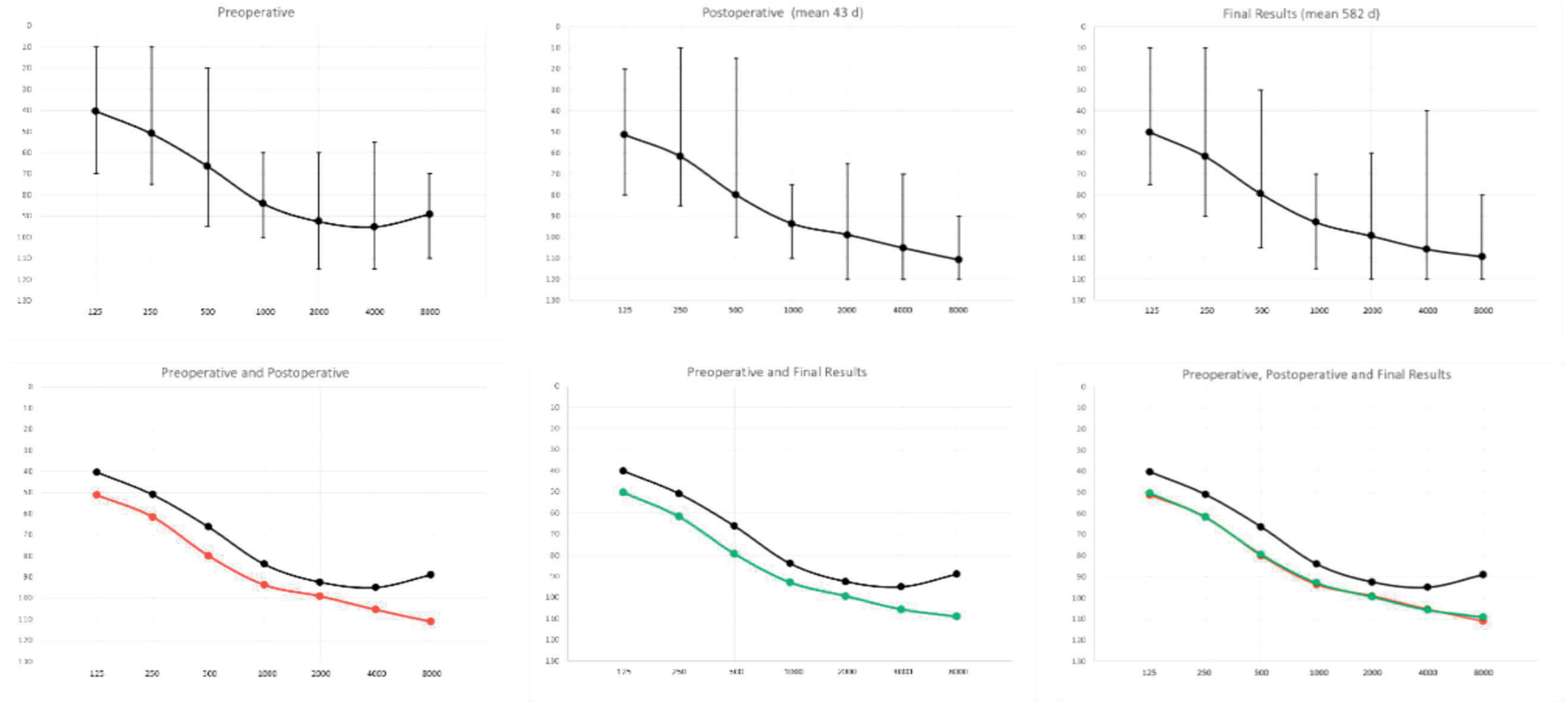


Table 2 Summary of hearing preservation results according to PTA 125 -500 Hz, PTA 125 -1000 Hz and HEARRING criteria described by Skarzynski et al. (2013). a) early postoperative b) final follow-up.

Ears	Preop PTA$_{125\text{-}}$ 500 Hz dB (HL)	Postop PTA$_{125\text{-}}$ 500 Hz dB (HL)	Δ PTA $_{125\text{-}}$ 500 Hz dB (HL)	Hearing preservation	Preop PTA 0.125-1 kHz dB (HL)	Postop PTA 0.125-1 kHz dB (HL)	Δ PTA 0.125-1 kHz dB (HL)	Hearing preservation	HEARRING (%)	HEARRING	Postoperative audiogram (d)
1	48	60	12	Complete	51	64	13	Complete	94	Complete	93
2	73	87	14	Complete	78	90	12	Complete	55	Partial	41
3	60	73	13	Complete	61	76	15	Complete	90	Complete	3
4	65	80	15	Complete	69	84	15	Complete	64	Partial	62
5	52	62	10	Complete	61	71	10	Complete	83	Complete	48
6	73	83	10	Complete	80	90	10	Complete	55	Partial	27
7	77	87	10	Complete	78	89	11	Complete	58	Partial	89
8*	40	53	13	Complete	49	63	14	Complete	69	Partial	57
9*	42	53	11	Complete	56	64	8	Complete	90	Complete	83
10	73	75	2	Complete	80	83	3	Complete	82	Complete	31
11	68	75	7	Complete	73	80	7	Complete	79	Complete	37
12	13	15	2	Complete	31	33	2	Complete	98	Complete	30
13	43	77	34	Minimal	56	83	27	Partial	47	Partial	29
14	33	42	9	Complete	44	51	7	Complete	92	Complete	28
15	27	43	16	Partial	39	56	17	Partial	78	Complete	27
16	57	62	5	Complete	59	65	6	Complete	88	Complete	28
17	70	80	10	Complete	71	84	13	Complete	66	Partial	30
18	28	45	17	Partial	39	56	17	Partial	74	Partial	30
MEAN	**52**	**64**	**12**	**15/18**	**60**	**71**	**12**	**15/18**	**76**	**10/18**	**43**

*Bilateral implantee; Hearing preservation: Complete Δ PTA ≤15 dB (HL); Partial Δ PTA ≤30 dB (HL); Minimal Δ PTA > 30 dB (HL) but reliably measurable

Ears	Preop PTA_{125-} 500 Hz dB (HL)	Final PTA_{125-} 500 Hz dB (HL)	Δ PTA $_{125-}$ 500 Hz dB (HL)	Hearing preservation	PTA 0.125-1 kHz dB (HL)	Final PTA 0.125-1 kHz dB (HL)	Δ PTA 0.125-1 kHz dB (HL)	Hearing preservation	HEARRING (%)	HEARRING	Follow-up (d)
1	48	87	39	Minimal	51	90	39	Minimal	29	Partial	779
2	73	73	0	Complete	78	79	1	Complete	55	Partial	434
3	60	62	2	Complete	61	64	3	Complete	95	Complete	854
4	65	67	2	Complete	69	70	1	Complete	64	Partial	436
5	52	60	8	Complete	61	70	9	Complete	87	Complete	784
6	73	87	14	Complete	80	93	13	Complete	42	Partial	587
7	77	85	8	Complete	78	88	10	Complete	63	Partial	482
8*	40	55	15	Complete	49	64	15	Complete	69	Partial	229
9*	42	50	8	Complete	56	66	10	Complete	69	Partial	363
10	73	78	5	Complete	80	85	5	Complete	90	Complete	660
11	68	73	5	Complete	73	78	4	Complete	74	Partial	608
12	13	17	3	Complete	31	35	4	Complete	95	Complete	388
13**	43	n/a	n/a	n/a	56	n/a	n/a	n/a	n/a	n/a	29
14	33	67	34	Minimal	44	70	26	Partial	62	Partial	969
15	27	50	23	Partial	39	65	26	Partial	63	Partial	462
16	57	65	8	Complete	59	69	10	Complete	76	Complete	403
17	70	77	7	Complete	71	79	24	Partial	100	Complete	1041
18	28	33	5	Complete	39	46	8	Complete	90	Complete	413
MEAN	52	64	11	14/17	60	71	12	13/17	72	7/17	582

*Bilateral implantee; ** Explantation after 356 days due to maladaptation; Hearing preservation: Complete Δ PTA ≤15 dB (HL); Partial Δ PTA ≤30 dB (HL); Minimal Δ PTA > 30 dB (HL) but reliably measurable

4.2.5 Discussion

The SME was originally developed to achieve less traumatic insertions through either the round window or via a cochleostomy. Our pre-clinical study revealed very consistent insertion results and one scala translocation out of twenty insertions in fresh frozen temporal bones (120). Although the SME was not originally designed for hearing preservation, we observed good preservation of the residual hearing in our first clinical patients. Encouraged by these results, we started to use the SME also in patients with better hearing thresholds and ultimately even in patients eligible for EAS fitting. This study describes the SME's clinical results with an emphasis on hearing preservation in 17 consecutive patients (18 ears) with meaningful residual hearing.

Similar to the temporal bone study, the overall surgical handling was reasonably good. However, in patients with a narrow facial recess, the visibility to the round window may be obstructed by the bulky array-sheath assembly and in two cases, this compelled us to switch devices in favor of a slim LWE. Aschendorff et al. (123) also reported difficulties in the overall access to the round window area in some cases. Impaired visibility may easily lead to surgical inadequacies or even errors. Another surgical issue is that the inferior lip of the silicone sheath occasionally becomes stuck at the inferior border of the crista fenestra, complicating the introduction of the sheath into the cochlea. Upon loading of the array, the tip of the silicone sheath may open and spread which aggravates the aforementioned issue. Cuda and Murri (175) reported problems in 2 out of 61 insertions; in these two cases, several reloads and insertion attempts were required to achieve adequate insertion.

The insertion results with SME appear to be rather consistent. All insertions were performed through the RWM without any need for drilling an inferior extension. The mean IDA in our clinical series was 395 degrees, which is almost identical to the IDA found in a temporal bone study and also similar to that reported in other studies (113, 120, 123). Therefore, the cochlear coverage appears to be adequate for pure electrical stimulation.

Current publications have reported significantly higher rates of tip fold-over for the SME (4.5 – 7.7 %), compared to other LWE's (approx. 1 %) or stylet-type PME's (approx. 2-3 %) (95, 122, 123, 176-178). McJunkin et al. (122) reported about 9 tip fold-overs out of 117 insertions (7.7%), Gomes et al. (177) about two out 40 insertions (5%) and Friedmann et al. (176) about 11 out of 237 insertions (4.6 %). In a multicenter study, Aschendorff et al. (123) reported two tip fold-overs out of 44 insertions (4.5 %), which they attributed to surgical error. Unfortunately, they did not provide any detailed description of the specific error other than noting that the surgeon was not sufficiently experienced. Nevertheless, these reports demonstrate that postoperative imaging and/or specific electrophysiological measurements are necessary to exclude tip fold-over with this array.

In our cohort of patients, we found no scala translocation on the CBCT images and all electrodes were in the scala tympani. McJunkin et al. (122) described scala translocation in 3 out of 23 insertions (13%), whereas Aschendorff et al (123) reported of no scala translocations. In summary, the translocation rates of the SME appear to be considerably lower than those reported for stylet-type PMEs, in the publications, their translocation rates have varied from 15.8 % up to 52.3 % (83, 93, 97, 119, 129, 156).

There are many different classifications for defining postoperative hearing preservation. We chose to present our data according to the most common definitions used in the literature. The hearing preservation rates achieved with the SME appear to be superior to other stylet-type PMEs (121, 164, 179). The majority of patients (72 %) were initially fitted with an EAS strategy and 44 % experienced benefits with the acoustic stimulation and continued to use the device. Roland et al. (41) reported on 50 patients eligible for EAS who were implanted with short 16 mm LWE; of these, 33 (66 %) were postoperatively fitted with an EAS processor and 23 patients were still benefiting from EAS five years after surgery (99). Although the overall hearing preservation results of the SME appear to be inferior to those reported for a shorter 16 mm LWE, the SME has the clear advantage of providing adequate cochlear coverage for pure electric stimulation should the residual hearing deteriorate. Therefore, it eliminates the possible need for re-implantation with a longer electrode. Roland et al. (41) reported the need for five revision surgeries out of 50 EAS patients (10%) in which the 16 mm LWE had to be replaced with a longer array to provide adequate hearing performance with electric stimulation. In our study, the mean postoperative threshold deterioration for PTA $_{(0.125\text{-}1\text{kHz})}$ was 12 dB (HL), which is comparable to the value reported by Gantz et al. (40), who found a mean threshold decline of 9 dB (HL) with a 16 mm LWE. Ramos et al. (121) compared the hearing preservation results of the SME with a 20 mm slim LWE and stylet-type PME. The hearing preservation (PTA $_{(0.125\text{-}0.750\text{ kHz})}$ < 15 dB (HL)) results with the SME (50 %) and the slim LWE (43 %) were similar to our series, whereas very poor hearing preservation (0 %) was encountered with the stylet-type PMEs.

When comparing the results according to the HEARRING classification, complete preservation was observed in 47 % of ears. In pediatric patients, Manjaly et al. [45] reported complete hearing preservation in 55 % for 20 mm and 28 mm LWEs. There is another report of complete hearing preservation in nine out 25 patients (35 %) with LWEs of different lengths after one year (180).

LWEs are reported to achieve low frequency hearing preservation in a wide range from 11.3 % to 77.7 % (88, 90-92). Our results were 82.4 % for PTA $_{(0.125\text{-}0.5\text{ kHz})}$ and 76.5 % for PTA $_{(0.125\text{-}1\text{ kHz})}$. Although there is some variation in the methods of assessing low frequency preservation between different studies, we have achieved comparable short-term preservation results with the SME as reported for LWE. We were not able to measure the thresholds immediately after surgery, which raises the question of whether the threshold shift was due to direct insertion trauma or to postoperative inflammation.

We found an age-related effect on the postoperative hearing preservation. Zanetti et al. (181) reported better hearing preservation rates with children as compared to adults, but this difference was not statistically significant. In the systematic review conducted by Causon et al. (182), age was not a significant factor for hearing preservation. Thus, it is uncertain whether age is a contributing factor behind hearing preservation. We found no correlation between the baseline residual hearing with the preservation rates.

We found a significant improvement in the speech recognition in noise as measured with the FMST. The mean improvement of the speech reception threshold in noise after implantation of 4.0 dB (SRN) was clinically most significant and in the range of the desired and expected improvement (29). One interesting finding was that the postoperative SRT correlated significantly with the insertion depth (i.e. the deeper the insertion, the better the postoperative SRT). There is published data which has revealed a correlation between deeper insertion angles with better postoperative hearing outcomes (83, 97, 98). This correlation is all the more surprising, since in our series there were seven patients (eight ears) with EAS for whom the IDA is not considered to be critical. However, caution is necessary in the interpretation of this correlation due to the small number of patients.

The limitations of this study are inherent in its retrospective nature. The statistical power of the analysis is weakened by the small size and heterogeneity of the cohort. Additionally, our finding should be regarded as preliminary, since a longer follow-up will be needed to evaluate the long-term hearing preservation results.

4.2.6 Conclusion

The hearing preservation results with the SME were superior to those reported for stylet type PMEs. In several cases, residual hearing was well preserved which enabled patients to use EAS stimulation. Although the hearing preservation rate of the SME was inferior to that achieved with short LWEs, it provided deeper insertions and better cochlear coverage for pure electrical stimulation in the event of post-operative or progressive hearing loss. This may have obviated the need for re-implantation with a longer electrode in the event of postoperative or progressive hearing loss

4.4 STUDY 4: A NEW APPLICATION OF CBCT IMAGE FUSION IN TEMPORAL BONE STUDIES

4.4.1 Abstract

Objectives:

Temporal bone (TB) studies are essential during the development of new arrays. Postoperative cochlear histology is still regarded as golden standard for the assessment of electrode localization and trauma though it is time consuming, expensive and technically very demanding. The aim of this study is to investigate whether pre-operative evacuation of perilymph improve the assessment of electrode localization and insertion trauma in TBs applying fusion imaging. The results were compared to a prior validated image fusion technique based on the quantification of the electrode placement.

Materials and Methods:

12 prototype electrodes were implanted in fresh frozen TBs. The perilymph was evacuated from the scale prior to pre-operative cone-beam computer tomography (CBCT). The TB were then immersed in Ringer solution to rehydrated both scalae. After electrode insertion post-operative CBCT were obtained. 3D fusions of the pre- and postoperative registration were reconstructed. The electrode localization with respect to the basilar membrane was visually assessed.

Results:

The visualization of the BM on the pre-operative scans was achieved beyond the second turn in all TBs. The visual assessment was found to be as accurate as the previously validated fusion technique. There was no statistically significant difference between the methods (p=0,564). The image reconstructions and evaluations, however, were faster to perform and the insertion results are immediately available.

Conclusion:

CBCT in combination with pre- and postoperative image fusion is an accurate method for the post-operative assessment of insertion trauma in TBs. This new application facilitates the identification of the BM and allows for a visual assessment of insertion trauma.

4.4.2 Introduction

Today, cochlear implantation (CI) is a routine therapy for patients with severe to profound hearing loss. More recently, CI has been reported to be beneficial also in less severe hearing loss, especially in patients whose residual hearing could be preserved during surgery. Therefore, preservation of the delicate intracochlear structures is a central focus of the new electrode design (129, 135, 156). Temporal bone (TB) studies are essential during the development of new arrays to study their insertion characteristics and dynamics as well as insertional trauma (113, 120, 148, 151, 165, 200, 201). Post-insertional cochlear histology is still regarded as golden standard to assess electrode localization and trauma. Histologic examinations are also compulsory in the regulative processes of medical devices. Histologic processing of the cochlea is time- and cost-intensive and involves considerable manipulation of the specimen, so that electrode movements during this process are common. Overall, cochlea histology demands considerable knowledge and experience to be concise and reliable (151).

As compared to the conventional spiral computed tomography technique, cone beam computed tomography (CB-CT) evolved to become the preferred modality for postoperative cochlear implant imaging because of reduced electrode (152, 153). Recent electrode studies in TBs increasingly utilize CBCT imaging in addition to histology (120, 150, 151, 201). CB-CT often allows for a reliable assessment of insertion depth and scalar localization in the basal turn. However, depending on the type of electrode and scalar anatomy, an accurate assessment of the scalar localization is mostly not possible after 270–360 degrees of insertion depth angle (IDA) (154, 155). We can achieve significantly improved accuracy with image fusion, at which the electrode from the postoperative registrations is reconstructed (based on Hounsfield units (HU)) and fused into the preoperative data set. The application of the image fusion technique provides artefact-free image and facilitates the assessment of array localization (120, 148, 151, 201). Earlier studies conducted by our group have validated this technique against histology for several types of electrodes (120, 151). The most important limitation was related to the fact that the basilar membrane (BM) could not be identified, which decreased the reliability of these methods.

Mirco-computed tomography studies showed BM visualization when removing the perilymph from the scalae (202). If the BM could be clearly visualized in the preoperative registration, the fusion technique would enable to accurately estimate the electrode localization in relation to the BM, thus making trauma assessment more reliable. That kind of technique would potentially represent a very cost-effective method for pre-clinical studies of electrode arrays in TBs as well as for educational applications.

This study aimed to investigate whether preoperative evacuation of perilymph improves the assessment of electrode localization and insertion trauma in TBs applying fusion imaging. We compared the results to a prior validated image fusion technique based on the quantification of the electrode placement.

4.4.3 Material and Methods

We implanted 12 freshly frozen TBs with prototype lateral wall electrodes. This study had an institutional approval and fulfilled the Helsinki Declaration for ethical use of human material. Ethical committee statement 538/2017 was granted for the study. Cortical mastoidectomies and posterior tympanotomy were performed under operating microscope. After exposing the middle ear through the facial recess, we visualized the round window membrane (RWM) and the stapes. We carefully removed the stapes superstructure and the footplate. The lateral semicircular canal (LSC) lumen was also opened by using a small diamond burr. We carefully removed the perilymph with a suction at LSC opening and the oval window. Finally, the rest of the perilymph was evacuated at the RWM opening (Figure 1) before CBCT imaging (ProMax 3D Max, Planmeca Oy, Helsinki, Finland). Thereafter, we immersed the TBs in Ringer solution for an hour to refill the cochlea before the insertion of the electrode array. Postoperative imaging was immediately performed after surgery.

For pre-insertion scanning, the used parameters were 80 kV, 16 mA, 15 s, and FOV 50×55 mm. The post-insertion scan parameters were 96 kV, 7 mA, and 15 s. The dose area products of the pre- and post-insertion scans were 1007 and 899 mGycm2. We used the Planmeca Romexis™ (Planmeca Oy, Helsinki, Finland) software to reconstruct the axial, sagittal, and coronal slices with 100 μm isometric voxel. For the post-insertion images, we used a metal artefact removal algorithm (ARA by Romexis™, Helsinki, Finland).

Two different lateral wall electrode prototypes were used for this study: a short 20-mm long electrode array that was used in 10 TBs, and 30 mm arrays in 2 TBs. Both prototypes were iterations of clinically used electrode arrays. Two CI surgeons performed all insertions through the RWM up to a minimum IDA of 360 degrees or to the point of resistance.

To determine the IDA, the images were evaluated with RomexisTM viewer before image fusion. Descriptive cochlea measures (A and B) were taken from the preoperative imaging. From postoperative CB-CTs, the radiologist specialized in neuroradiology (AL) carried out trauma evaluation. We used commercially available fusion software (iPlan Net 3.6.0 Build 77, BrainLab AG, Munich, Germany) for image fusion. HU units were used to determine electrode location. The preoperative and postoperative scans with image fusion are shown in Figure 2. Electrode reconstruction was made by using HU values for automatic reconstruction and then manually removing obvious artefacts as described by Iso-Mustajärvi et al (120) and Sipari et al 10. In both the 3D-fusion and CB-CT, the trauma was evaluated at five points: 90, 180, 270, 360 degrees and in tip region of electrode array. Trauma grading from image fusion scans was made with two different methods. 1) This method, described by Sipari et al. (151), is based on data obtained by 20 temporal bones to model the average location of the BM. The electrode's location is quantified in relation with the total height of cochlea´s cross-section. This method is referred as quantitative evaluation (QE). 2) This method, referred to as visual trauma evaluation (VE), is based on the visual detection of the BM obtained by the preoperative imaging. After the fusion reconstruction, the electrode array's placement can be visually determined in relation to the BM.

Trauma evaluations from postoperative CB-CT scans were made using simplified trauma classification: electrode either in scala vestibuli or in scala tympani. The application of a more detailed grading (e.g. lifting of the BM) was not possible due the artefact, which may represent the individual contacts appear over 50% larger than its actual size. For the VE and QE method, we used an adapted Eshragi trauma evaluation, which also takes lifting/rupture of the BM into account (0 = no trauma, 1 = lifting of basillar membrane, 2=rupture of basillar membrane, 3=dislocation).

For statistical tests, we used the Friedman´s test. Specificity and sensitivity were also tested between two image fusion evaluation methods.

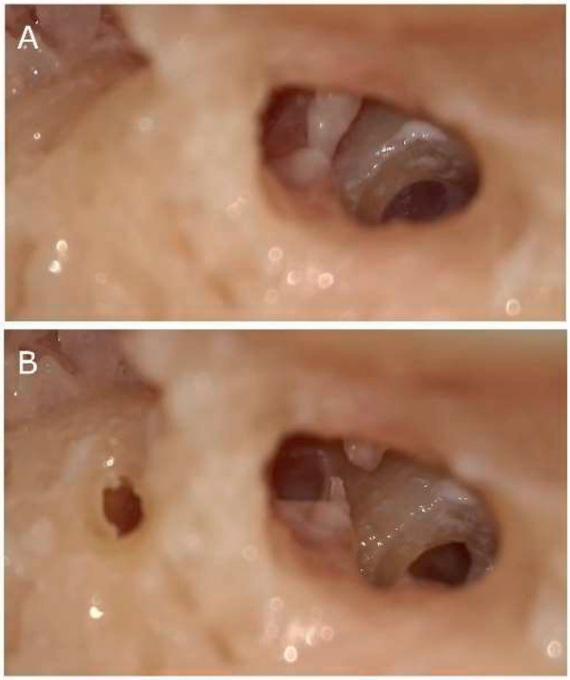


Image 1. In image A is shown the stapes and the round window niche with the membrane. In image B the lateral semicircular canal and round window are opened and the stapes is removed. Perilymph has been suctioned and the specimen is ready for pre-operative scanning.

4.4.4 Results

All 12 cochlea were adequately depleted of perilymph for preoperative imaging, and the BM could be clearly detected in most cases beyond the second turn (mean 632 degrees, range 497–685 degrees). There was no additional trauma to cochlea observed in preoperative CB-CT scans or under microscopic evaluation because of removal of the perilymph. Embedding the TBs in Ringer solution adequately replenished the cochlea with fluid so that we detected only minor air inclusions in postoperative CB-CT scans. The insertions could be normally carried out, and there were no apparent differences in the insertion characteristic of the electrodes in TBs with or without perilymph suction. Figure 2 illustrates the image fusion. Table 1 and 2 summarize the preoperative and postoperative measurements.

In TB 11, trauma rating with VE was not possible in the very apical part because of the deep insertion (IDA 678). The BM was visible up to 540 degrees, and VE was not used in the tip region in TB 11. The VE evaluation would not provide any additional value due the absent BM in preoperative scanning. CB-CT and QE was used also in tip region of TB 11.

Postoperative CB-CT revealed three scala translocations from scala tympani to scala vestibuli (TB 10, 11, and 12). In TB 10, we detected dislocation at IDA 90 degrees, but otherwise the electrode was in scala tympani. In TB 11, we detected two independent translocations, first at 180 degrees from ST to SV and then the electrode returned to ST. Second translocation in TB 11 occurred from ST to SV at tip region (678 IDA). Third dislocation occurred in TB 12 at IDA 360 degrees.

According to QE, scala dislocation occurred in TB 11. In TB 11, the electrode was interpreted to be in SV at 180 IDA, 360 IDA, and in tip region by QE method. At 90 degrees, the Eshragi grading for QE method was 0 and grade 2 for trauma at 270 IDA. In TB 10, the Eshragi grade 2 trauma occurred at 90 IDA; but deeper in cochlea, no trauma was detected in QE method.

VE method revealed dislocations in two TBs (TB 10 and TB 11). In TB 10, grade 3 trauma occurred at 90 IDA. Deeper in cochlea, the electrode was in ST without any suspicion of trauma. In TB 11, the Eshragi grade 3 was interpreted at 180 IDA and 270 IDA; 90 IDA was interpreted as Eshragi grade 0 and at 360 IDA VE method suggested trauma grade 2.

Both QE and VE method interpreted no trauma for rest of the TBs. No statistical significance was observed between QE and VE ($p = 0.564$). Sensitivity was 71.43% (95% CI 29.04 % to 96.33%), and specificity was 97.67% (95% CI 87.71 % to 99.94%) for VE method compared to QE method. Figure 3 demonstrates advances of image fusion compared to CB-CT. The trauma gradings of all three methods are summarized in Table 2.

In TB 10, VE interpreted “dislocation” at 90 degrees and QE a rupture of BM. In CB-CT scan, the dislocation were conducted at 180 degrees, and 90 degrees area was interpreted in scala tympani. After re-evaluation, we concluded that this difference was caused by separation in IDA angles between investigators (Figure 3).

The evaluation process of the insertion results from surgery (mastoidectomy and insertion of electrode) to trauma estimates took approximately 24 h of working time.

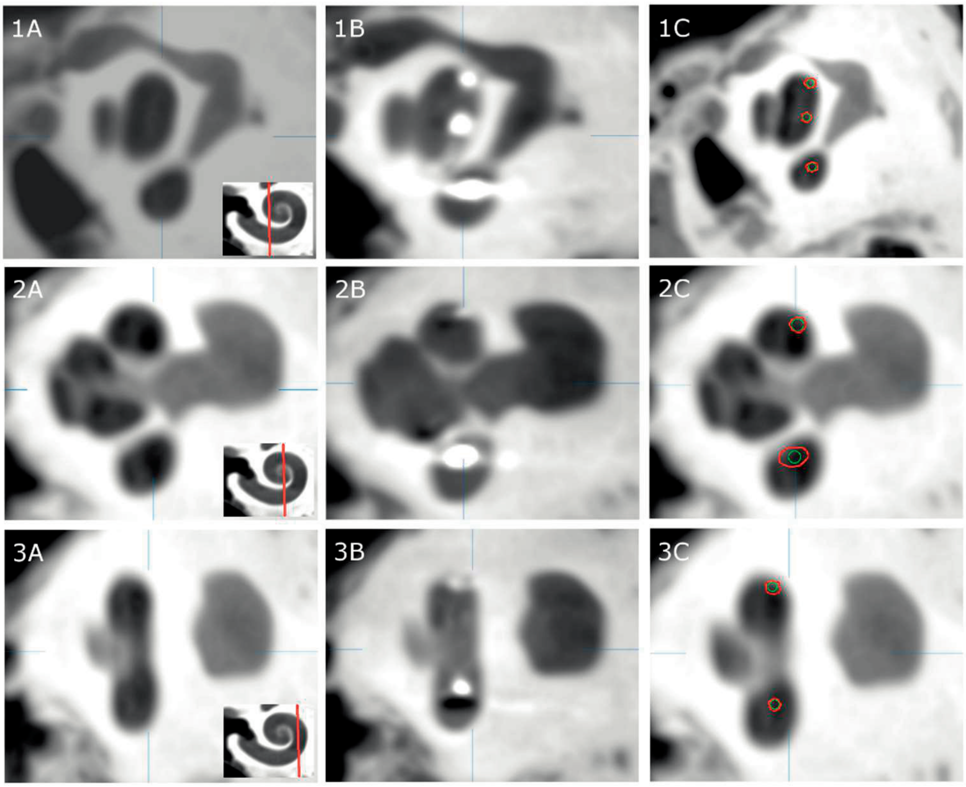


Figure 2. Preoperative, postoperative, and fusion images of TB 12 with 360 IDA. Images 1, 2, and 3 are on different planes of TB 12. A shows preoperative scans after removal of perilymph. B shows postoperative scans after refilling the inner ear with ringer solution and insertion of the electrode. C shows image fusion where the red borders resemble the artefact after processing, and the green borders resemble reconstructed electrode.

4.4.5 Discussion

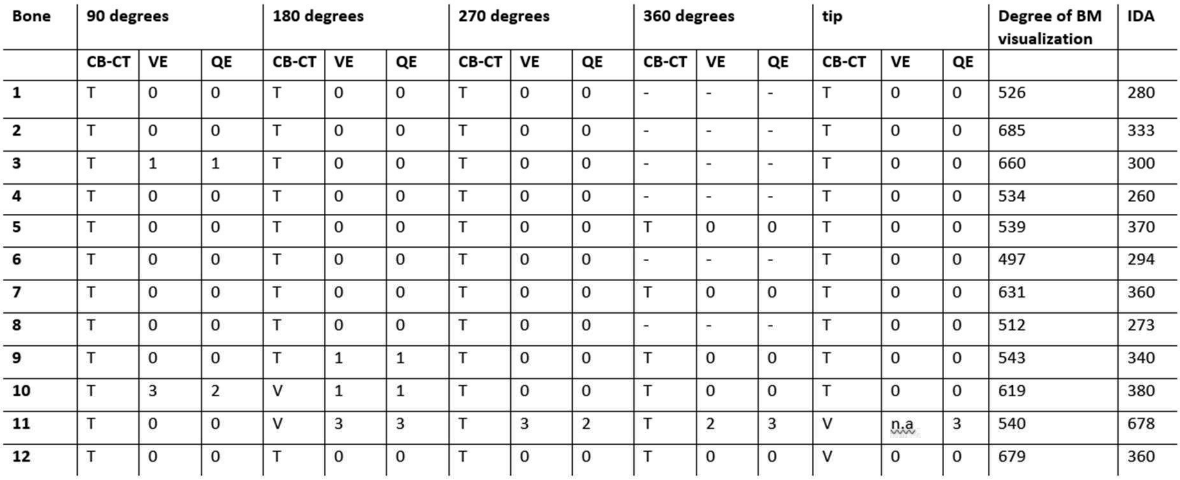
Modern imaging modalities have significantly improved the postoperative CI evaluation for clinics and for research applications. Although the CB-CT technique has improved imaging quality, artefacts generated by the electrode array still impair accuracy, especially in the second turn and in the apical regions of the cochlea. With the image fusion technique, it is possible to reconstruct artefact-free images that allow for a much more precise trauma assessment than post-op CB-CT alone (120, 148, 151, 201). However, the electrode array's localization in relation to the BM, which constitutes the basis of the trauma classification by Eshragi, can only be empirically assessed by cochlear modelling (170). The accurate assessment of insertion trauma with the fusion technique is still very challenging whenever the electrode lies near the BM. Possible insertion trauma such as lifting or even rupture of the BM may go undetected.

Bone	A- measure	B- measure	IDA	Electrode
1	10,5	7,9	280	20 mm
2	9,5	7,1	333	20 mm
3	9,9	7,2	300	20 mm
4	9,9	7,0	260	20 mm
5	9,6	6,6	370	20 mm
6	9,3	7,1	294	20 mm
7	9,4	6,4	360	20 mm
8	8,3	6,5	273	20 mm
9	9,2	6,8	340	20 mm
10	9,0	6,8	380	20 mm
11	9,4	6,8	678	30 mm
12	9,5	6,6	360	30 mm

Table 1. The cochlea measurements of 12 TBs

This study showed the feasibility of CB-CT to depict the BM in TBs cleared from perilymph prior to the preoperative imaging. In comparison to former studies that classified trauma according to the electrode placement in relation to the empirically modelled localization of the BM, this study shows that the BM can be actually visualized even beyond the second turn (120, 151, 201). The visualization of the BM allows for a visual assessment, in which the electrode's placement can be depicted in relation to the BM. Therefore, it takes the individual anatomical variations of the BM location into account, which increases the accuracy and reliability of trauma assessment.

For electrode insertion studies, histology is considered the most reliable method for the trauma evaluation. However, also histology is not unerring since electrode movements and displacements may happen during the multistage processing of the specimen. Here, the radiologic evaluation methods are superior because they do not involve any manipulation of the electrode after insertion. Additionally, histologic sections can be processed only in one plane whereas radiology provides sections in all three planes. Radiology may also provide immediate feedback of the insertion results without waiting for months for the histologic results.



Bone	90 degrees			180 degrees			270 degrees			360 degrees			tip			Degree of BM visualization	IDA
	CB-CT	VE	QE	CB-CT	VE	QE	CB-CT	VE	QE	CB-CT	VE	QE	CB-CT	VE	QE		
1	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	526	280
2	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	685	333
3	T	1	1	T	0	0	T	0	0	-	-	-	T	0	0	660	300
4	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	534	260
5	T	0	0	T	0	0	T	0	0	T	0	0	T	0	0	539	370
6	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	497	294
7	T	0	0	T	0	0	T	0	0	T	0	0	T	0	0	631	360
8	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	512	273
9	T	0	0	T	1	1	T	0	0	T	0	0	T	0	0	543	340
10	T	3	2	V	1	1	T	0	0	T	0	0	T	0	0	619	380
11	T	0	0	V	3	3	T	3	2	T	2	3	V	n.a	3	540	678
12	T	0	0	T	0	0	T	0	0	T	0	0	V	0	0	679	360

Table 2. The trauma grading used in this study. CB-CT estimation is made whether the electrode is in scala tympani (T) or scala vestibule (V). VE is a visual based evaluation from image fusion and is graded according to adapted Eshragi scaling. QE is a quantitative evaluation measurement and based on the technique explained by Sipari et al. (139) Degree of BM visualization is the point where the BM can be seen on CB-CT and IDA is insertion depth angle

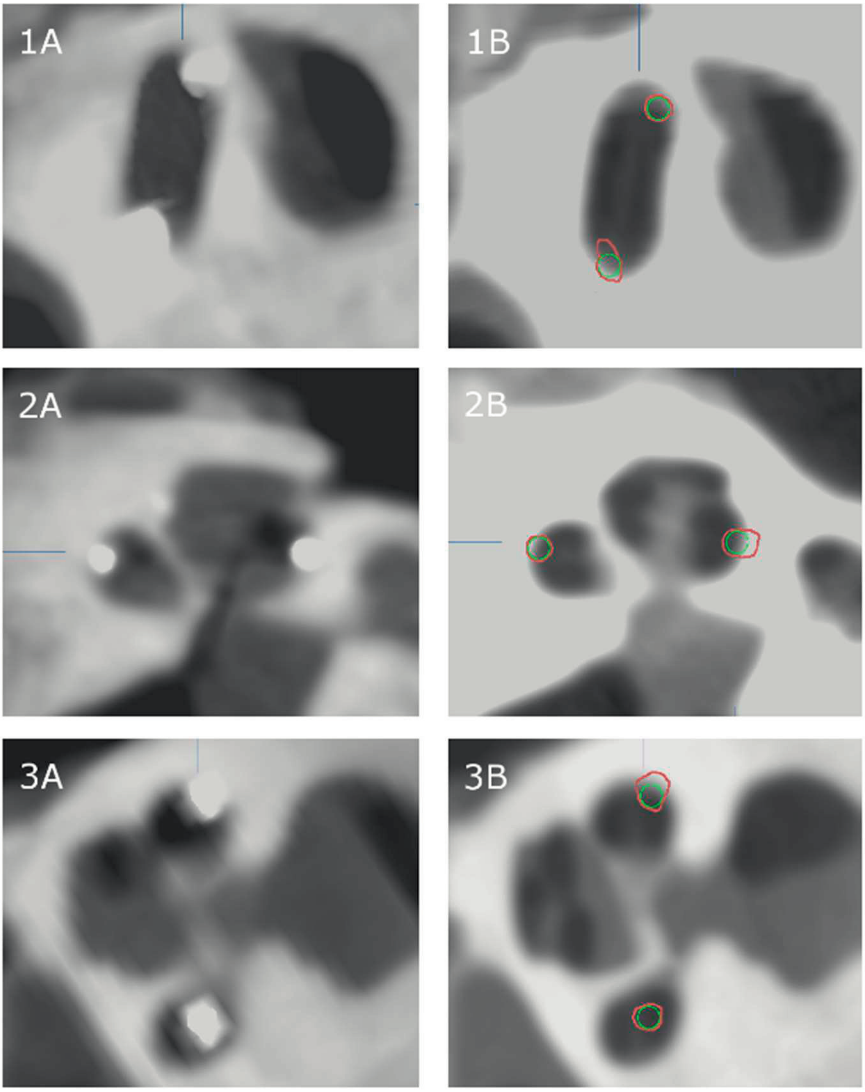


Image 3. Trauma evaluations. 1A shows the CB-CT image and 1B shows the fusion image of TB 10, insertion traumas as Eshragi 3 in degrees 90 and 0 in 180 degrees and dislocation in CB-CT at 90 degrees. 2A shows CB-CT image with dislocation basal parts and scala tympani location approximately in 270 degrees. 2B is Eshragi grade 3 in basal part and grade 2 at 270 degree. 3A is scala tympani insertion and 3B are Eshragi grade 1 in TB 3 at 90 degrees and grade 0 deeper in cochlea.

Even though it is possible to evaluate the trauma related to the BM, the differentiation of Eshragi grades 2 and 3 is still challenging with either fusion imaging method. In this study, QE and VE were not able to distinguish between grade 2 and grade 3 trauma at only three measurement points (TB10: 90 degrees; TB11: 270 and 360 degrees). For these measurement points, histology would probably have been beneficial to differentiate whether BM rupture, or minor dislocation is present.

The most significant limitation of this study is that no histologic data were available, which would have validated the presented imaging method in more detail. However, previous studies have investigated the QE fusion imaging technique and showed its accuracy compared to histology (120, 151). The VE image fusion methods provide adequate visualization of the BM so that the individual variation of cochlear anatomy can be considered. Therefore, the VE image fusion technique may well represent the most accurate technique to detect insertion trauma. This technique is feasible for TB studies and can be applied, for example, for pre-clinical electrode studies or for training of new surgeons. Obviously, this technique cannot be applied clinically. Unfortunately, CB-CT or HRCT devices cannot yet depict the BM. However, heavy weighted T2-sequences of cochlear magnetic resonance imaging (MRI) can show the BM at least in the basal turn. Thus, image fusion of preoperative MRI with postoperative CB-CT may present a possibility to achieve better accuracy in the assessment of insertion trauma in the clinical setting (119).

4.4.6 Conclusion

To date, preoperative and postoperative CB-CT imaging with the application of fusion imaging may represent the most accurate radiologic method for electrode placement and the assessment of insertion trauma. Enhanced accuracy can be obtained when the scalae of the cochlea are cleared from perilymph for the preoperative imaging, which allows for the visualization the BM and enables for a more precise trauma classification. This method is feasible only for experimental TB work but provides accurate trauma assessment. The main applications are surgery training and electrode research and development

5 DISCUSSION

5.1 MODERN ELECTRODE DESIGN

The current trend in the design of electrode arrays is to make it more flexible and as atraumatic as possible. The modiolar electrodes have a significantly greater tendency to cause inner ear trauma as compared to the LWEs (77, 80, 82, 83, 97, 115, 116). The conventional modiolar electrodes are held straight prior to insertion with an internal stylet, which is removed as the electrode is advanced inside the cochlea. The silicon cover over the electrode is larger in order to accommodate the stylet in modiolar electrodes and thus requires a larger volume compared to the LWEs. The larger volume of the electrode makes it stiffer and therefore, it may be more likely to induce trauma in the delicate structures of the inner ear. Due to its larger volume, it potentially causes also greater pressure changes than dimensionally smaller electrodes.

The modiolar proximity of the electrode has been thought to offer several advantages as compared to the straight electrodes. Smaller electric thresholds may activate the auditory nerve at lower current levels. Some studies have found a better pitch perception; this has been correlated to the array's modiolar proximity (104, 109, 110, 121, 147). Clinically this rather small advantage has not been unequivocally demonstrated (101-112).

An insertion depth angle of approximately at 450-630 degrees is considered to be a sufficient insertion depth for electric-only stimulation (96, 203). Deeper insertion has been shown to relate with better speech perception scores (97, 98). However, the the diameter of the scala tympani decreases considerably after approximately 450 degrees, which increases the possibility for trauma in very deep insertions. Deep insertion may also reduce the time required for adaptation to electric stimulus (203). Ideally, the electrodes should achieve an insertion depth around 400 degrees to be able to provide good cochlear coverage for electric stimulation.

For the new SME, the replacement of the stylet by an external sheath has reduced the dimensions by 60 % as compared to the former perimodiolar electrode, the Contour Advance. The dimensions of the SME are comparable to the second generation LWEs (79). On the one hand, a smaller diameter is associated with better atraumatic properties in terms of increased flexibility; on the other hand, the electrode is more prone to a tip fold over in comparison to the conventional perimodiolar electrodes (95, 122, 123, 176, 177).

5.1.1 Temporal bone study with the SME

In the temporal bone study with the SME, only one scala dislocation was found out of 20 insertions (5 %), which is a substantial improvement compared to previous modiolar electrode designs (69, 77, 87, 89, 110, 111). The results are similar when compared to studies with LWEs (3% -13% scala dislocation)(80, 93, 118, 204, 205). Briggs et al. (113) studied the final prototype of this SME and found a slightly better outcome in insertions via cochleostomy in terms of tip fold overs. In our study, all but one insertion was conducted via the round window without any significant problems. This indicates that the SME is suitable for both insertion routes. The SME seems to achieve consistent insertion results in terms of modiolar placement and insertion depth. The SME mean IDA value was 400 degrees (270-449). The IDAs for the SME have been surprisingly similar in all currently available studies (113, 122, 123, 176, 177). Most of the variation between the electrode and modiolar distance occurred in the basal part of the cochlea. This was attributable to anatomical variations in the round window area. Otherwise, it seems that the SME is located just under the osseus spiral lamina near to the modiolus. The SME seems to be very versatile in terms of both the insertion route and the size of the cochlea, as well as still ensuring predictable insertions properties. Due to the sheath assembly, the SME requires space in posterior tympanotomy for visualization of the round window. The insertion technique and alignment of the electrode demand training and skill rom the surgeon in order to avoid tip fold overs. Not all unfavourable results are the result of inappropriate insertion technique, but the incidence could be lower with adequate training (113, 122, 123, 176, 177). The sheath itself did not seem to increase the tendency for trauma in the basal region of cochlea. Briggs et al (113) found also no trauma inflicted by the sheath itself.

5.1.2 The SME in residual hearing preservation

Soft surgery in terms of preserving the cochlear structures was first described by Lehnhardt (160). The concept of EAS was then described by von Ilberg in 1999 (173). Currently, the most favorable results have been achieved with short LWEs (≤ 20 mm active length), with the aim for best possible preservation of residual hearing and EAS strategy (43, 84, 88, 186). If an unavoidable loss of residual hearing occurs, some of these patients might benefit from revision surgery in order to provide deeper cochlear coverage for electric stimulation. In the study of Rolands et al. (186), it was reported that revision with a longer electrode had to be conducted in 5 cases (10 %) because of the loss of residual hearing after surgery with a short array.

As discussed above, the SME provides adequate IDA for electric only stimulation and has promising, atraumatic insertion properties in temporal bone studies. In our clinical series of 18 ears with significant functional residual hearing, the SME performed surprisingly well; no scala dislocations, or loss of residual hearing occurred during the follow-up period. The majority of cases had their residual hearing within 15 dBHL of their preoperative hearing at the end of follow-up. These levels of hearing preservation results are similar with the standard length straight electrodes (86, 121, 180). When compared to conventional perimodiolar electrodes the SME was superior (164).

In our study, 44 % of the patients considered that the EAS strategy was beneficial and they remained as EAS users at the end of the follow-up. This is a poorer result compared to the patients with short electrodes (55-87 %) (88, 89, 113, 186). The SME was not originally intended to perform as an EAS electrode, but in certain cases it may provide the possibility for EAS. In this series of patients, no tip fold-over occurred. One must take into account the small number of patients in this study when judging the absence of tip fold over i.e. no firm conclusions regarding this matter can be made.

5.1.3 The SlimJ electrode

The SlimJ has asymmetric properties which influence its flexibility. The electrode is flexible in the vertical plain but somewhat stiffer in the horizontal plain. According to the manufacturer, the electrode design aims to avoid the migration problem while still providing better handling during insertion.

In our temporal bone study, there was only one SlimJ electrode which had a scala dislocation out of 11 insertions performed. In two cases, there was a suspicion of lifting or rupture of the basilar membrane. The mean IDA in our study was 368 degrees. Lenarz et al (206) did not detect any scala dislocations with the SlimJ electrode in 10 temporal bones. They had a deeper mean insertion angle of 432 degrees in their study.

Even though the frozen temporal bones differ with regard to insertion properties when compared in vivo insertions (141, 196, 207), the overall results with the SlimJ are promising. The findings in this study confirm the SlimJ electrode’s suitability for atraumatic surgery, although more studies regarding clinical performance are needed before it will be possible to make a final evaluation.

5.2 FUSION IMAGING

CB-CT is the currently increasing imaging method for the clinical evaluation after cochlear implantation. It involves a considerably lower radiation dose as compared to CT (effective dose in HR-CT is roughly 0.5 mSv for CB-CT it is 0.075 mSv and for plain x-ray 0.03 mSv). According to temporal bone studies, information regarding possible electrode scala dislocation can be evaluated up to the second turn of the cochlea (154, 155). In clinical settings, the movement artefact may harm the image quality in CB-CT when the patient is in a sitting postion, but the fusion can usually still be carried out without problems (119, 159).The electrode studies with the TBs are also being increasingly utilized in CB-CT imaging in addition to histology (150, 151). Nonetheless, artefacts originating from the electrodes limit the possibility of trauma detection of scala dislocation. A more detailed trauma grading is not practical from CB-CT images.

Fusing the electrode from the postoperative images into the preoperative images allow evaluation without an artefact interfering with the bony margins of the cochlea. Fusion imaging method has been used in our study with the perimodiolar electrode (148). As far as we are aware, this is the first time when image fusion was validated in evaluating the temporal bone after insertion of a SME. Compared to postoperative histology, we found no statistically significant difference in the location of the electrode. The method was further validated in the study of Sipari et al (151) with a straight electrode. When using a modified Eshragi trauma grading, the specificity and sensitivity were 97.3% and 87.5% respectively as compared to histology (151, 170).

After this kind of method validation, image fusion has also been used in clinical studies by our research group (119, 159). It does seem that the combination of postoperative CB-CT and preoperative MRI imaging make it possible to visualize the basillar membrane in relation to the electrode (119).

In temporal bone studies, histology is still considered as a golden standard for the evaluation of trauma inside the cochlea. While it is true that histology provides an accurate evaluation in terms of Eshragi trauma grading, on the other hand, a histological evaluation is expensive, time consuming and it may pose a risk that the electrode will make additional movements or even cause trauma. In the fourth study of this dissertation, we combined two techniques to achieve a fast and more precise method to evaluate electrode location with respect to the basilar membrane with CB-CT. The results of our experiment were very promising, in terms of basilar membrane visualization and trauma evaluation. This new method represents a fast and cost-effective way to evaluate the results of the insertion into the temporal bones.

6 CONCLUSIONS

1. The new Slim Modiolar Electrode provides favourable and atraumatic insertion in most cases
2. The new Slim Modiolar Electrode is suitable for hearing preservation surgery. The results with Slim Modiolar Electrode are comparable to previous publifications with the standard length, straight electrodes.
3. The SlimJ electrode is surgically favourable to insert due to its asymmetric stiffness properties, and it allows atraumatic insertion in most cases.
4. The image fusion technique provides an accurate method for electrode location inside the cochlea both in temporal bone laboratory and clinical settings.

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MATTI ISO-MUSTAJÄRVI

Cochlear implantation is currently the only routinely used treatment that restores the function of a sense organ. Atraumatic cochlear implant surgery ensures the optimal hearing rehabilitation results. Mainly two mechanical factors predict the occurrence of inner ear trauma: the electrode design and the insertion technique. This Thesis investigates two novel cochlear implant electrode designs and associated imaging techniques, and reports on preclinical and clinical results.

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