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SINI SIPARI

COCHLEAR IMPLANTATION: POST-OPERATIVE ASSESSMENT WITH IMAGE FUSION

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ABSTRACT

Cochlear implantation has become the standard of care for moderate-to-profound hearing loss during the last three decades. Advances in electrode design and surgical techniques have expanded the indications such that they now include also patients with residual hearing and single sided deafness. Safeguarding the inner ear structures and preserving the residual hearing of the implanted ear have been shown to improve the postoperative hearing results. Both the surgical features of the electrode and its location in the cochlea are important factors contributing to hearing outcomes.

Postoperative imaging is essential for the assessment of insertion trauma, quality control and documentation of surgical outcomes. It also aids in the individual programming of the sound processor. Cone-beam computed tomography (CBCT) has become the modality of choice for post-implant imaging. Metallic artefacts, however, impair the image quality, complicating a reliable assessment.

The aim of our first study was to evaluate the surgical insertion results of a new straight electrode array (EVO®) in fresh-frozen temporal bones (TB) with image fusion technique and validate this technique against histology. The second study investigated the clinical application of the fusion technique and the insertion results in patients implanted with a mid-scala electrode (HFms™). The image data of a consecutive patient sample was re-evaluated and compared with the results obtained with the image fusion of the pre-op MRI and post-op CBCT scans. The aim of the third study was to investigate the possible benefits of the image fusion technique with six different commercially available array types. The findings of the image fusion and the post-operative CBCT were compared.

There were atraumatic insertions with the EVO electrode in fourteen out of twenty (70%) TBs, which is comparable to the results reported for other long lateral wall electrodes. It was found that the sensitivity and specifity for the image fusion technique were 88% and 97%. In the second study, image fusion revealed 5 dislocations out of 28 electrodes (18%) which had not been previously diagnosed by CBCT. In the third study, we found that image fusion enhanced the accuracy of the assessment of insertion trauma, especially in deep insertions. Image fusion improved the trauma assessment by 20% in the basal turn and by 52% when the measurement points exceeded 360°. Altogether, in 15 out of 30 cases (50%) image fusion improved the assessment. Although different electrodes showed specific radiologic characteristics, there was no significant difference in the benefit of image fusion between the electrodes.

In summary, both of the electrodes that were evaluated with respect to the insertion results were found to be feasible for atraumatic insertion. The image fusion technique was validated for postimplant evaluation against histology in a temporal bone study; it was found to be an accurate method for electrode location assessment also in clinical patients. A new MRI image fusion technique was introduced. We found that it enhanced the trauma assessment and therefore we recommend adopting this technique for the postoperative evaluation of electrode location in ambiguous cases, i.e. when CBCT alone is not sufficient. Correlation with the clinical outcomes needs further research.

Keywords: Cochlear implant, hearing loss, electrode, imaging, magnetic resonance imaging, computed tomography, cone beam computed tomography, image fusion, insertion trauma, hearing preservation.

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TIIVISTELMÄ

Sisäkorvaistutteesta on tullut kolmen vuosikymmenen kuluessa vaikean ja keskivaikean kuulonaleneman vakiintunut hoitomuoto. Elektrodien ja kirurgisten tekniikoiden kehittymisen myötä hoidon indikaatiot ovat laajentuneet koskemaan myös potilaita, joilla on toispuolinen kuurous tai merkittävää jäännöskuuloa. Tutkitusti paremmat kuulotulokset saavutetaan, kun sisäkorvan simpukan rakenteet välttyvät toimenpiteen aikaisilta vaurioilta ja jäännöskuulo saadaan säästettyä. Sekä elektrodin kirurgiset ominaisuudet että sen sijainti sisäkorvan sisällä vaikuttavat leikkauksen jälkeisiin kuulotuloksiin.

Postoperatiivinen kuvantaminen on tärkeää toimenpiteen aiheuttamien vaurioiden arvioimiseksi, laadun valvomiseksi sekä tulosten dokumentoimiseksi. Lisäksi se auttaa istutteen yksillöllisessä ohjelmoinnissa. Vaikka kartiokeilatietokonetomografiasta (KKTT) on tullut keskeisin kuvantamismenetelmä tulosten arvioinnissa, istutteen aiheuttamat metalliartefaktat heikentävät edelleen kuvan laatua ja vaikeuttavat elektrodin tarkan sijainnin määrittämistä.

Ensimmäisen tutkimuksemme tavoitteena oli arvioida uuden suoran sisäkorvaelektrodin (EVO^R^) kirurgisia tuloksia ohimoluissa kuvafuusiotekniikalla ja validoida kuvantamismenetelmä histologialla. Toisessa työssä tavoiteenamme oli arvioida perimodiolaarisen sisäkorvaelektrodin (HFms™) kirurgisia tuloksia kliinisillä potilailla kuvafuusion perusteella ja esitellä uusi MRI-kuvafuusiomenetelmä sisäkorvaistutteiden postoperatiivisessa arvioinnissa. Kolmannessa työssä tutkimme kuvafuusiomenetelmän hyötyjä kuudella eri kliinisessä käytössä olevalla elektrodityypillä ja vertasimme tuloksia KKTT:llä saavutettuihin.

Suoran elektrodin insertioista 70%:lla ei todettu sisäkorvavaurioita, mikä vastaa muiden täyspitkien suorien elektrodien insertiotuloksia. Kuvafuusiomenetelmän sensitiivisyys sisäkorvavaurion osoittamisesssa oli 88% ja spesifisyys 97%. Perimodiolaarinen elektrodi osoittautui kirurgisilta ominasuuksiltaan atraumaattiseksi ja pitäytyi keskimodiolaarisessa sijainnissa, jollaiseksi se on suunniteltu. Perimodiolaarisella elektrodilla havaitsimme kuvafuusiolla 5 dislokaatiota (18%), joita ei ollut diagnosoitu pelkällä KKTT:llä arvioitaessa. Kuvafuusiomenetelmän havaittiin tarkentavan elektrodin sijainnin määritystä etenkin syvissä insertioissa. Sen hyöty basaalikierteen mittauspisteissä oli 20% ja sen ylittävissä mittauspisteissä (>360°) 52%. Kaikkiaan 50%:lla 30 tapauksesta kuvafuusion todettiin tarkentavan arviota. Vaikka eri elektrodeilla todettiin olevan tyypilliset radiologiset piirteensä, ei kuvafuusion hyödyllisyydessä havaittu eroja elektrodien välillä.

Molemmat insertiotulosten osalta arvioiduista elektrodeista todettiin soveltuviksi atraumaattiseen insertioon. Kuvafuusiotekniikka validoitiin histologialla ja todettiin tähän asti tarkimmaksi kliiniseen käyttöön soveltuvaksi elektrodinpaikannusmenetelmäksi. Uusi MRI-kuvafuusiometelmä esiteltiin ja sen todettiin tarkentavan trauma-arviota kaikilla elektrodityypeillä, etenkin syvissä insertioissa. Näin ollen voimme suositella kuvafuusiota postoperatiivisen arvion työkaluksi sekä tutkimustyössä että kliinisessä käytössä. Lisää tutkimusta tarvitaan kliinisten kuulotulosten korrelaatiosta havaintoihin.

Avainsanat: Sisäkorvaistute, kuulonalenema, elektrodi, kuvantaminen, magneettikuvaus, tietokonetomografia, kartiokeilatietokonetomografia, kuvafuusio, insertiotrauma, kuulonsäästäminen.

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Kuopio, March 2020

Sini Sipari

“The Universe is made of twelve particles of matter and four forces of nature.
That’s a wonderful and significant story.”

Brian Cox

LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following original publications:

I Sipari S, Iso-Mustajärvi M, Matikka H, Tervaniemi J, Koistinen A, Aarnisalo A, Sinkkonen ST, Löppönen H, Dietz A. Cochlear Implantation With a Novel Long Straight Electrode: the Insertion Results Evaluated by Imaging and Histology in Human Temporal Bones. Otol Neurotol. 2018 Oct;39(9):e784-e793.

II Sipari S, Iso-Mustajärvi M, Löppönen H, Dietz A. The Insertion Results of a Mid-scala Electrode Assessed by MRI and CBCT Image Fusion. Otol Neurotol. 2018 Dec;39(10):e1019-e1025.

III Sipari S, Iso-Mustajärvi M, Könönen M, Löppönen H, Dietz A. The Image fusion technique for cochlear implant imaging: A study of its application for different electrode arrays. Otol Neurotol. 2020 Feb;41(2):e216-e222.

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CONTENTS

ABBREVIATIONS

BM	Basilar membrane
CI	Cochlear implantation
CISS	constructive interference in steady state
CT	Computed tomography
CBCT	Cone beam computed tomography
dB	decibel
ECAP	electrically evoked compound action potential
EI	electrode impedance
EVO	The EVO[R] electrode
FIESTA	fast imaging employing steady-state acquisition
HFms	HiFocus™ Mid-Scala electrode
HRCT	High resolution computed tomography
HU	Hounsfield unit
LWE	Lateral wall electrode
MRI	Magnetic resonance imaging
PME	Peri-modiolar electrode
SOE	spread of excitation
TB	Temporal bone
3D	Three dimensional

1 INTRODUCTION

Cochlear implantation has emerged as the standard treatment for severe and profound hearing loss. However, there are extensive variations in speech perception outcomes, the reasons for this are numerous and partly unknown. There are several studies demonstrating that the duration of hearing loss, age at implantation, age at onset of hearing loss, etiology and duration of cochlear implant experience are predictive factors for speech perception outcomes, but these account for only a fraction of the variation (Blamey, Artieres et al. 2013, Lazard, Vincent et al. 2012).

It has been shown that electrode array placement is an important factor predicting the hearing outcomes. Better postoperative speech perception performance can be accomplished by the preservation of the inner ear structures in cochlear implant surgery. Today, due to the advances in electrode design and surgical techniques, the indications for cochlear implantation have widened to include patients with substantial residual hearing. For optimal outcomes, the electrode should be inserted into the scala tympani without damaging the cochlear structures and preserving the possible preoperative residual hearing (Finley, Holden et al. 2008a, Carlson, Driscoll et al. 2011, Holden, Finley et al. 2013a, Gifford, Dorman et al. 2013a).

There is a wide selection of electrode arrays available. They can be divided into two main categories: straight lateral wall electrodes (LWE) and pre-curved or perimodiolar electrodes (PME). A variety of different lengths of straight electrodes are available, allowing insertion across alternative stimulation ranges and different sized cochleae, whereas precurved electrodes mainly cover the basal turn, but are positioned closer to the neural tissue of the modiolus (Dhanasingh, Jolly 2017). The length of the electrode and, more importantly, its insertion depth angle into the cochlea, determine the electrical coverage of the neurons across the cochlea. This contributes significantly to the speech perception performance, especially for speech recognition in noise (Büchner, Illg et al. 2017, Suhling, Majdani et al. 2016).

Cone-beam computed tomography (CBCT) has recently become the modality of choice for postoperative cochlear implant imaging. In clinical settings, CBCT is a rapid, low cost and low radiation dose technique, providing an accurate evaluation of the insertion trauma and electrode location (Razafindranaly, Truy et al. 2016, Ruivo, Mermuys et al. 2009, Kennedy, Connell et al. 2016, Theunisse, Joemai et al. 2015). Despite the advantages of CBCT, electrode artifacts can impair the image quality, limiting the accurate location assessment to the basal turn (Guldner, Weiss et al. 2012, Güldner, Wiegand et al. 2012, De Seta, Mancini et al. 2016). Better accuracy can be obtained by utilizing both the pre- and postoperative scans with the image fusion technique, which substantially reduces electrode artifacts (Dietz, Gazibegovic et al. 2016, Iso-Mustajärvi, Matikka et al. 2017, Dees, van Hoof et al. 2016) .

In the image fusion technique, the electrode is reconstructed on the postoperative imaging using HU (Hounsfield Unit) segmentation and then fused onto preoperative registrations, eliminating disturbing artifacts and thus enhancing the image quality and postinsertion trauma assessment.

The present study evaluates the surgical results of a new straight electrode in temporal bones assessed with postoperative imaging, image fusion technique and histology. The image fusion technique is validated against histology. The study also examines the surgical results of a mid-scala electrode in clinical patients assessed with image fusion of the preoperative (CT and MRI) imaging and the postoperative (CBCT) imaging. In the final part of the work, the benefits of the image fusion tecnique are studied for six different types of electrode arrays by comparing this new technique to postoperative CBCT imaging.

2 REVIEW OF THE LITERATURE

2.1 HEARING LOSS

2.1.1 General

Around 5% of the world's population, in other words 470 million people, suffer from a disabling hearing loss, referring to threshold levels greater than 40 decibels (dB) in the better ear in adults and 30 dB in children. The causes for hearing loss can be either congenital or acquired. The loss of cochlear function may result from genetic causes, certain infectious diseases affecting the inner ear, chronic ear infections, use of ototoxic drugs, exposure to noise, head injury, and ageing (WHO 2015).

2.1.2 Impact

The major consequence of hearing loss is an impaired ability to communicate. The development of spoken language is often delayed in children with unaddressed hearing loss and difficulties in communication can have a significantly adverse effect on their academic performance. Exclusion from communication has a negative impact on the quality of life and, in the elderly, on cognitive performance. Hearing loss has been shown to be a significant risk factor for dementia, especially if it becomes manifested during middle-age (Livingston, Sommerlad et al. 2017). Hearing loss is associated with higher unemployment rates and increased risk of early retirement (Helvik, Krokstad et al. 2013, Svinndal, Solheim et al. 2018, M. E. Fischer, Cruickshanks et al. 2014). It is estimated that unaddressed hearing loss has an annual global cost of US$ 750 billion including societal and health sector costs, costs of educational support and loss of productivity (WHO 2015).

Treatment of hearing loss has been found to be cost effective for the society, and it is associated with a significant improvement of the individual's quality of life (Olze, Szczepek et al. 2011, Foteff, Kennedy et al. 2016, Knopke, Gräbel et al. 2016, Contrera, Betz et al. 2016, Cheng, Rubin et al. 2000, World Health Organization 2017).

2.2 COCHLEAR IMPLANTATION

2.2.1 General

A cochlear implant is an electronic device that restores hearing to a person with severe-to-profound sensorineural hearing loss. Whereas a hearing aid amplifies the sound signal, a cochlear implant bypasses the dysfunctional inner ear which is unable to benefit from amplification, and provides an electrical input directly to the spiral ganglion cells of the auditory nerve. This nerve transmits the signal to the auditory cortex of the brain, where it is interpreted as sound. Speech reception and speech understanding develop gradually after cochlear implantation (Lenarz, Pau et al. 2013).

2.2.2 Indications

Candidacy criteria for cochlear implants vary between different countries and it is primarily regulated by each country's reimbursment and social welfare funding capacity. Even within the developed countries, the indications vary due to different reimbursment schemes. Therefore, although treatment decisions should be based on the need and audiological requirements, they also can be significantly guided by short-term economic considerations. Cochlear implantation is generally always indicated in patients with severe-to-profound sensorineural hearing loss, in whom hearing aids are not able to restore adequate speech perception and communication, and who are motivated toward CI rehabilitation. CI is also indicated for newborns diagnosed with profound-to-severe hearing loss. It has been demonstrated that children implanted before the age of one year have improved linguistic and hearing outcomes than children receiving implantation later (Miyamoto, Hay-McCutcheon et al. 2008, Valencia, Rimell et al. 2008). In a growing number of institutions, the indications for CI have expanded during recent years to include patients with moderate and unilateral hearing loss (von Ilberg, Kiefer et al. 1999, Gantz, Turner et al. 2005, Gifford, Dorman et al. 2013b, Härkönen, Kivekäs et al. 2015). Electro-acoustic stimulation, EAS, can be utilized in patients with substantial low frequency residual hearing by electrically stimulating the lost high frequencies and amplifying the residual lower frequencies with a hearing aid in the same ear. A cochlear implant is not indicated in individuals with absent cochlear development or deafness due to defects in the acoustic nerve or central auditory pathways.

Auditory brainstem implant is indicated in deaf patients with bilateral auditory nerve disorder but no no impairment of the central auditory nervous system. It attempts to restore hearing through direct stimulation of the brainstem (Nakatomi, Miyawaki et al. 2016).

2.2.3 Device

The cochlear implant consists of an external sound processor placed behind the outer ear and an internal part that is surgically placed on the surface of the skull. The microphones of the external part capture sound signals to be processed in the sound processor. The sound processing strategies modify the signal to achieve optimal speech perception. The processed sound signals are transmitted through the headpiece to the internal device, the implant, by radio-frequency transmission. A receiver/stimulator receives signals and converts them into electrical impulses. An electrode array placed in the cochlea delivers the signal to the auditory nerve, stimulating the different frequency sensitive areas. Each sound processor is individually programmed to meet the needs of the cochlea and the patient in order to achieve the optimal hearing outcome (Lenarz, Pau et al. 2013).

2.2.4 Surgery

The electrode insertion is an invasive procedure which carries a high risk for damaging the delicate anatomical structures of the inner ear. The concept of soft surgery consists of surgical techniques aiming to preserve the delicate cochlear structures. It has been shown to correlate with more favorable postimplant hearing outcomes (Carlson, Driscoll et al. 2011, Friedland, Runge-Samuelson 2009).

The most common surgical procedure used for implanting the device is the trans-mastoid posterior tympanotomy approach. Mastoidectomy refers to the procedure to remove the mastoid cells to create an access to the facial recess, the narrow bony passage between the facial and the corda tympani nerves. The round window (RW) of the cochlea can usually be approached through the facial recess once it has been drilled open. Usually the bony ridge surrounding the RW has to be removed to make the insertion window accessible for the electrode.

Insertion through the RW into the scala tympani is recommended whenever possible, since it is the least traumatic to the cochlear structures and contributes to the postoperative hearing outcomes according to some studies (Sikka, Kairo, Singh, Roy et al. 2017a, Snels, IntHout et al. 2019, O. F. Adunka, Buss et al. 2008, Causon, Verschuur et al. 2015, Wanna, O'Connell et al. 2018). If the RW or extended RW approach are not possible due to obliteration of the RW or an unfavorable insertion trajectory, then the cochleostomy approach may be required. The literature still has an ambivalent view whether the choice of approach, RW or cochleostomy, has an impact on the postoperative residual hearing outcomes. Recent review articles found no significant difference between the approaches (Nguyen, Cloutier et al. 2016, Havenith, Lammers et al. 2013). Furthermore, intracochlear trauma may provoke fibrosis and neo-ossification, making revision surgery more complicated (Li, Peter M. M. C., Somdas et al. 2007, Kamakura, Nadol 2016, Somdas, Li, Peter M. M. C. et al. 2007). Therefore, atraumatic surgical techniques designed to preserve cochlear structures and to allow for easy access for re-implantation are recommended. Structure preservation is all the more important in children, who are more likely to require repeated re-implantation (Ramsden, Gordon et al. 2012).

2.2.5 Outcomes

Cochlear implantation has been found to be cost-efective in all age groups (Smulders, van Zon et al. 2016, Foteff, Kennedy et al. 2016). The majority of the implanted patients achieve hearing-based communication without the support of lip-reading

(Dettman, Dowell et al. 2016, Budenz, Cosetti et al. 2011). Nonetheless, there is still extensive variation in the hearing outcomes between individuals. Several studies have reported that etiology, duration of deafness, age at onset of hearing loss, age at implantation, and duration of cochlear implant (CI) experience account for some of the variance in outcomes. Electrode design and the electrode-neural interface are other factors affecting the hearing results. The preservation of the delicate inner ear structures and the scalar location of the electrode are considerable factors in achieving optimal outcomes. Studies suggest that the electrode should locate entirely in the ST for better audiological outcomes (O'Connell, Hunter et al. 2016, Wanna, Noble et al. 2014). Electrode array design and surgical technique, in turn, contribute to recidual hearing preservation (O'Connell, Hunter et al. 2017, Zanetti, Nassif et al. 2015, Jurawitz, Büchner et al. 2014).

2.3 ELECTRODES

2.3.1 Elecrode Array Design

Electrode array design is essential for inner ear structure preservation. There is a wide selection of array types from which to choose (Dhanasingh, Jolly 2017). There are two main designs: straight lateral wall electrodes (LWE) and perimodiolar electrodes (PME) (figures 2-3). The selection of the array should be based on individual factors, such as cochlear anatomy and size and the amount of residual hearing. The surgeon must be also familiar with the electrode.

Electrode arrays can be described by their specific characteristics: length, shape (perimodiolar and straight), stiffness and thickness. The length of the array and the insertion depth angle (IDA) into the cochlea, are factors affecting the electrical coverage of the neural tissue (figure 1). There are studies indicating that better speech perception outcomes can be achieved with longer electrodes which provide better electrical coverage of the neural population than shorter electrodes (O'Connell, Hunter et al. 2017, Hamzavi, Arnoldner 2006, Buchman et al. 2014a). Nonetheless, there is also evidence claiming that full cochlear coverage does not confer any significant benefit over incomplete coverage (Doubi, Almuhawas et al. 2019). Even though deep insertions are not necessarily associated with more trauma, the hearing preservation rates are reportedly lower than for short electrodes. Deeder IDA has been shown to correlate with poorer word recognition and low frequency hearing threshold level shifts (Finley, Holden et al. 2008a, O'Connell, Hunter et al. 2017).

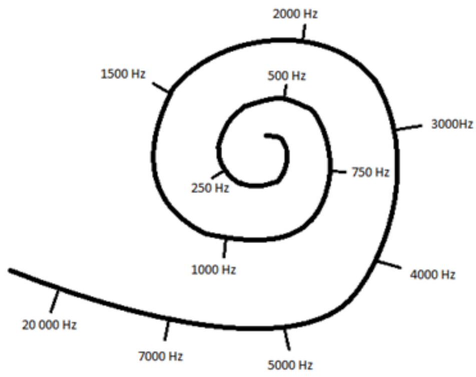

Figure 1. Tonotopic frequency distribution of the cochlea.

2.3.2 Straight Lateral Wall Electrodes

Straight electrode arrays are available in different lengths allowing for personalized implantation for different sized cochleae. The latest generation of short lateral wall electrodes has shown the most consistent results for hearing preservation (Wanna, O'Connell et al. 2018, Mady, Sukato et al. 2017, Fabie, Keller et al. 2018). Long arrays, in turn, may offer better pitch perception and speech performance as they provide better cochlear coverage (O'Connell, Cakir et al. 2016, Buchman et al. 2014b)(figure 1). However, these electrodes are positioned near to the lateral wall of the cochlea stimulating the modiolar neural tissue from a further distance than is the case with PMEs. Straight electrodes carry lower risk than PMEs for insertion trauma (Dhanasingh, Jolly 2019).

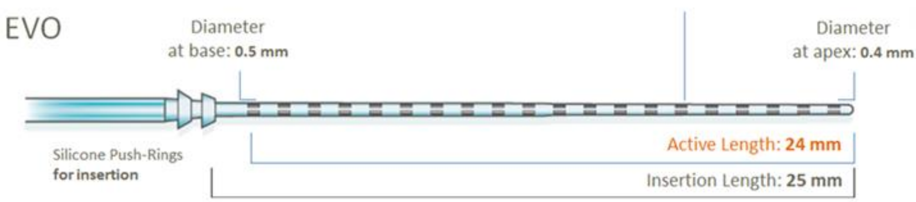

Figure 2. The EVO[R], as an example of a typical straight lateral wall CI electrode (Oticon Medical, Copenhagen, Denmark).

2.3.3 Perimodiolar Electrodes

PMEs are pre-curved and, when correctly inserted, can be positioned closer to the modiolus and the presumed target neural tissue than straight electrodes. Theoretically, the PMEs have the advantage of a better focus of the electrical current toward the ganglion cells. Electrophysiological studies have demonstrated lower thresholds and less spread of excitation with the PMEs, but there is no convincing data these benefits have an impact on the outcomes (O'Connell, Hunter et al. 2017, Shepherd, Hatsushika et al. 1993, Davis, Zhang et al. 2016).

PMEs are usually stiffer than LWEs and need a stylet or a sheath for insertion and therefore carry a potentially higher risk for insertion trauma (Boyer, Karkas et al. 2015). Several research groups have explored the scalar locations of different electrode array types by CBCT, and found that PME arrays are associated with the highest incidence of scalar translocation (Wanna, Noble et al. 2014, Wanna, Noble et al. 2011, Hassepass, Bulla et al. 2014, Lane, Witte et al. 2007, Holden, Finley et al. 2013b, Boyer, Karkas et al. 2015, O'Connell, Cakir et al. 2016, Dietz, Gazibegovic et al. 2016, Aschendorff, Klenzner et al. 2011, N. Fischer, Pinggera, Weichbold, Dejaco, Schmutzhard, and Widmann 2015a).

While the spiral ganglion cells extend to around 630 degrees in the cochlea, perimodiloar electrodes can usually provide direct stimulus covering around 400 degrees, leaving a substantial part of the ganglion cells without direct stimulation. PMEs are available to cover just beyond the basal turn of the cochlea, whereas the spiral ganglion cells extend into 1.75 turns (630°) of the cochlea (Dhanasingh, Jolly 2017, Rask-Andersen, Liu et al. 2012) However, the effect of the cochlear coverage on the hearing outcomes remains controversial (Hamzavi, Arnoldner 2006, O'Connell, Hunter et al. 2017, Doubi, Almuhawas et al. 2019, Buchman et al. 2014a).

Figure 3. The HiFocus™ Mid-Scala, as an example of a typical perimodiolar CI electrode (Advanced Bionics, Valencia, USA).

2.4 INSERTION TRAUMA

2.4.1 Assessment

The assessment of electrode placement is important not only for quality control, documentation and assessing electrode placement but it also helps in the individual programming of the sound processor. The electrode location can be evaluated with postoperative radiologic imaging. There are several available approaches which can be exploited to assess the electrode placement and function of the device intra-operatively; electrically evoked compound action potential (ECAP), electrode impedance (EI), spread of excitation (SOE) and radiologic imaging modalities of intraoperative computed tomography (CT), plain X-ray radiograph and 3-dimensional rotational x-ray. Each technique has its own clinical value. CT aplications are the only modalities capable of evaluating the scalar location of the electrode.

2.4.2 Anatomy

Mechanical trauma to various intracochlear structures plays an important role in implant surgery associated hearing loss (Gifford, Dorman et al. 2013a, Carlson, Driscoll et al. 2011). Certain structures are particularly vulnerable to insertion injury e.g. basilar membrane (BM), osseus spiral lamina, Rosenthal’s canal, soft tissues of the lateral wall of the scalae, the modiolus, and the scala tympani associated blood vessels (Figure 4). The length of the Rosenthal's canal is analogous to the legth of the ST ranging from 510 to 615°. The mean length of the cochlea (A-measure) is 9.2mm SD 0.4 and width (B-measure) 7.0mm SD 0.3 (Avci, Nauwelaers et al. 2014).

Different types of BM trauma have been reported in association with electrode array placement in the scalae. The electrode can penetrate through the BM and enter scala media or scala vestibule. When staying within scala tympani, the electrode may still elevate the BM or fracture the osseous spiral lamina (Sikka, Kairo, Singh, Roy et al. 2017b, De Seta, Torres et al. 2017, Dietz, Iso-Mustajärvi et al. 2018). An electrode translocation damaging the scala media allows the perilymph and the endolymph to become mixed, resulting in the disappearance of the intra-cochlear potential, which may result in a loss of residual hearing (Bas, Goncalves et al. 2015). It has been shown that trauma to the BM can provoke neo-ossification and formation of fibrous tissue, which can reduce hearing performance and complicate a possible re-implantation (Li, Peter M. M. C., Somdas et al. 2007, Kamakura, Nadol 2016).

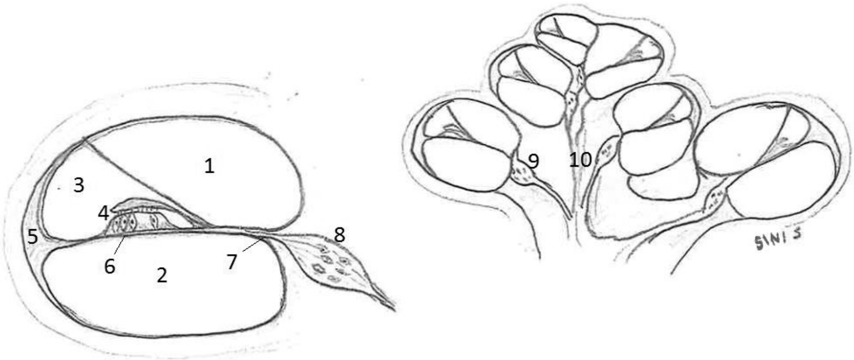

Figure 4. Schematic cross-section of the human cochlea.
1. scala vestibuli, 2. scala tympani, 3. scala media, 4. organ of Corti, 5. stria vascularis, 6. basilar membrane, 7. osseus spiral lamina, 8. spiral ganglions, 9. Rosenthal's canal, 10. modiolus.

2.4.3 Risk

The insertion of an electrode carries a high risk of inner ear damage. The risk for intracochlear damage is multifactorial. It has been stated that the surgical approach, insertion trajectory, insertion speed and force in combination with the electrode design with its mechanical characteristics all exert an impact on the risk of insertion trauma (Carlson, Driscoll et al. 2011, R. J. Briggs, Tykocinski et al. 2001, Verberne, Risi et al. 2017, Iso-Mustajärvi, Matikka et al. 2017). Electrode design is a major factor contributing to the risk of insertion trauma. A recent review article described an overall occurrence rate of 32% for scalar deviation with PCEs whereas it was much lower, 6.7%, for straight electrodes (Dhanasingh, Jolly 2019).

The round window approach and cochlear structure preservation appear to decrease the risk for the loss of residual hearing as well as minimizing damage to vestibular function (Nordfalk, Rasmussen et al. 2014, Wanna, Noble et al. 2011, Todt, Basta et al. 2008, Friedland, Runge-Samuelson 2009). Insertion through the RW/ERW is associated with lower rates of the electrode locating outside the ST, and electrodes locating inside the ST were associated with better hearing outcomes (Wanna, Noble et al. 2014, O'Connell, Hunter et al. 2016). Insertion into the scala vestibule and breakage of the basilar membrane or osseus spiral lamina have been reported to highly correlate with vestibular damage in histologic studies, yet its clinical significance has not been established (Tien, Linthicum 2002, Handzel, Burgess et al. 2006).

Deep insertions do not appear to be associated with higher rates of scala dislocations, but they have been linked with an increased loss of residual hearing (Finley, Holden et al. 2008b, Büchner, Illg et al. 2017, O. Adunka, Kiefer 2006).

2.4.4 Classification

Trauma classification following CI implantation is based on postoperative imaging, which is the only modality that can be used to visualize the electrode scalar position in living patients. Histology is considered as the golden standard in cadaver TB studies. Electrode-induced trauma can be histologically categorized according to Eshragi et al. 2003: grade 0: no trauma; grade 1: elevation of the basilar membrane; grade 2: rupture of the basilar membrane; grade 3: dislocation of the electrode array from the scala tympani to the scala vestibuli; and grade 4: severe trauma such as fracture of the osseous spiral lamina or modiolus (Eshraghi, Yang et al. 2003). However, this classification applies only for histological evaluations whereas imaging studies tend to describe the electrode location rather than tissue trauma of the cochlea.

2.5 IMAGING

2.5.1 Preoperative Imaging

Precise candidate selection for cochlear implantation is dependent on preoperative radiological investigations. MRI and CT are considered as a standard not only to rule out cochlear malformation and retrocochlear pathology but also to detect temporal bone abnormalities that may alter the surgical approach. Although the side of the implantation is basicly selected based on preoperative hearing, there can be anatomical factors, such as cochlear fibrosis, affecting the choise. A preoperative imaging assessment helps to choose the best ear for implantation, select the right approach and to avoid potential hazards. An effective radiological evaluation is important when planning cochlear implant surgery. Both CT and MRI modalities should be used for preoperative planning as they delineate, in different manners, anatomical variations in the cochlear, retrocochlear and middle ear structures (Aschendorff 2011, Alam-Eldeen, Rashad et al. 2017, Connor 2018, Digge, Solanki et al. 2016, Young, Ryan et al. 2014). However, in postlingually deafened adults with symmetrical sensoryneural hearing loss, imaging is unlikely to affect surgical decision making (Tamplen, Schwalje et al. 2016). Preoperative imaging is predominantly concidered as a standard for children, but for adults there remains a controversial view in the literature (Abdullah, Mahmud et al. 2003, Tamplen, Schwalje et al. 2016, Schwartz, Chen 2014, Choi, Kaylie 2017, Roberts, Bush et al. 2014).

2.5.2 Postoperative Imaging

An accurate postoperative radiological evaluation of cochlear electrodes is essential for the determination of the electrode location in the scalae, and thus for the development of devices and surgical techniques. In the clinic, it serves as quality control and documentation of the surgical results, as well as helping in device programming as it reveals the electrode contacts outside the cochlea and, for instance, tip fold-over. Postoperative imaging can be exploited for identifying possible electrode tip folding, migration, bulging and scala translocation. The necessary countermeasures for the optimal outcomes can be taken based on the image findings (Dietz, Wennström et al. 2016, Aschendorff 2011).

2.5.3 Magnetic Resonance Imaging

MRI is considered as a standard approach for pre-implant evaluation. It is the only modality that can detect vestibulocochlear nerve bundles and the associated pathologies, such as the absence of the nerve (Digge, Solanki et al. 2016). The CISS-sequence (the constructive interference in steady state, Siemens), or FIESTA (fast imaging employing steady-state acquisition, GE), is a strong T2 weighted gradient echo sequence and it provides a good contrast between cerebrospinal fluid and other structures, allowing visualization of the membranous labyrinth of the inner ear (Jiang, Odiase et al. 2014, Connor 2018, Young, Ryan et al. 2014). Furthermore, the liquid-filled cochlear turns, cochlear fibrosis and obliteration, and in numerous cases even the BM, can be visualized. MRI carries no radiation risk.

2.5.4 Stenver's Projection

Stenvers projection is a plain oblique X-ray radiograph view of the skull establishing the position of the cochlear implant after surgery. It can be used to achieve an approximation of IDA as well as the detection of tip-folding, but the scalar location cannot be assessed by this technique (Dirr, Hempel et al. 2013). Stenver's projection can be taken in the operating room and is used in some institutions primarily for children under general anesthasia taking advantage of their immobility. It has been mainly replaced by intra-operative CBCT.

2.5.5 Computed Tomography

CT is used both for pre- and post-implant evaluation as it is able to provide submillimeter 3D positional information as well as offering excellent contrast for different tissue types, especially bony structures. It is necessary for surgical planning and the identification of crucial structures, such as the course of the facial nerve canal, width of the facial recess, location of the tegmen, sigmoid sinus and jugular bulb. CT imaging is also beneficial in detecting malformations. It is used for measuring the cochlear dimensions and hence it helps in selecting the most appropriate electrode (Aschendorff 2011).

CT together with CBCT are the modality of choice for post-implant evaluation as they can be utilized with the implant device in place and they provide a 3D illustration of the electrode location in relation to the surrounding structures. However, cochlear implants tend to be problematic for CT imaging, demanding high spatial resolution and avoidance of the artifacts created by the metallic electrode contacts and the dense cochlear capsule bone (Güldner, Wiegand et al. 2012).

The normally formed cochlea is variable in size. Variations in cochlear size produce even 5.0 mm variation in the length of the lateral wall within the basal turn, in IDA range of 360 degrees (Escudé, James et al. 2006) . Size of the cochlea can be measured in the preoperative images using the A-length, the B-length and the basal turn length to approximate the electrode length for sufficient cochlear coverage and to avoid insertion trauma. Gender and racial differences have also been found. A recent study measured the mean A legth as 9.17mm in males and 8.97mm in females (Thong, Low et al. 2017).

2.5.6 Cone-Beam Computed Tomography

CBCT is an X-ray based volume acquisition method that provides 3D images. It has emerged in cochlear implant imaging, both in preoperative planning and postoperative quality control as it has several advantages over conventional CT, such as low radiation dose and fast execution. In Kuopio University Hospital imaging protocol the radiation dose for temporal HRCT is approximately 0.5mSv and for temporal CBCT 0.075mSv, the HRCT dose being roughly 5-10 fold. Metallic artefacts are less pronounced in CBCT as compared to conventional CT, making it the modality of choice for postoperative cochlear implant imaging. The spatial resolution of CBCT equals or exceeds that of CT, varying according to material, but with a much lower radiation intensity. (Ruivo, Mermuys et al. 2009, Kennedy, Connell et al. 2016, Razafindranaly, Truy et al. 2016, Theunisse, Joemai et al. 2015) CBCT is able to provide accurate information of the scalar location of an electrode array (Saeed, Selvadurai et al. 2014, Razafindranaly, Truy et al. 2016, Ruivo, Mermuys et al. 2009, Mosnier, Célérier et al. 2017, Marx, Risi et al. 2014). However, the accurate location assessment within the submillimeter cochlear structures is primarily limited to the basal turn (Güldner, Wiegand et al. 2012, Guldner, Weiss et al. 2012, De Seta, Mancini et al. 2016, Saeed, Selvadurai et al. 2014, Marx, Risi et al. 2014).

Both the X-ray tube and the plane detector turn around the patient during X-ray emission. The images are processed to obtain a cylindrical numeric volume, which is used to reconstruct three series in perpendicular planes. Each voxel, within the numeric cylinder, is cubic in shape, i.e. isotropic. This results in identical spatial resolution irrespective of the slice orientation within the volume. This is an important feature, when the cochlea is observed in different orientations in order to locate the electrode array within the scalae. CT, on the other hand, reconstructs volume by superimposition of thicker slices and the voxels are rarely cubic. When the voxels are anisotropic, the spatial resolution varies with respect to slice orientation. With small size isotropic voxels, CBCT can provide 3D images of good resolution in all spatial directions, especially with regards to the bone structures. Due to the low radiation intensity and high scattering, it does not discriminate soft-tissue density as accurately as CT. It has a lower signal-to-noise ratio and poorer density resolution than CT, which restricts its indications. For postoperative cochlear implant imaging, however, CBCT can achieve a superior image quality. The possible motion artefact, in devices where the patient is positioned sitting up, can be minimized with the head steadied in a frame. In devices where the patient is lying down, the motion artefact can be further minimized to the level of other CT devices (Miracle, Mukherji 2009).

2.5.7 Artefact

The metallic electrode contacts of the array are responsible for artefacts in the postoperative imaging. Although metallic artefacts can be reduced with CBCT, they still impair the image quality and limit the accurate assessment of trauma to the basal turn (Güldner, Wiegand et al. 2012, De Seta, Mancini et al. 2016, Guldner, Weiss et al. 2012). Variation of the imaging parameters has not led to any significant reduction of the artefacts despite of metallic artefact reduction (MAR) algorithms (Güldner, Wiegand et al. 2012).

2.5.8 Image Fusion

The image fusion technique is a new method for postoperative cochlear implant imaging (figure 5). It has previously been reported that an improved accuracy in electrode location assessment can be achieved by the fusion of pre- and postoperative images (Iso-Mustajärvi, Matikka et al. 2017). 3-Dimensional (3D) models of the electrode images can be created from the post-operative CBCT by HU (Hounsfield Units) thresholding. The reconstructed electrode is then overlaid onto the preoperative MRI and/or CT registrations by image fusion software. The technique achieves a substantial reduction of electrode artefacts and thus significantly enhances the accuracy of the assessment of the electrode's location. The technique has been validated against histology with reliable results in the assessment of insertion trauma for a perimodiolar electrode (Iso-Mustajärvi, Matikka et al. 2017).

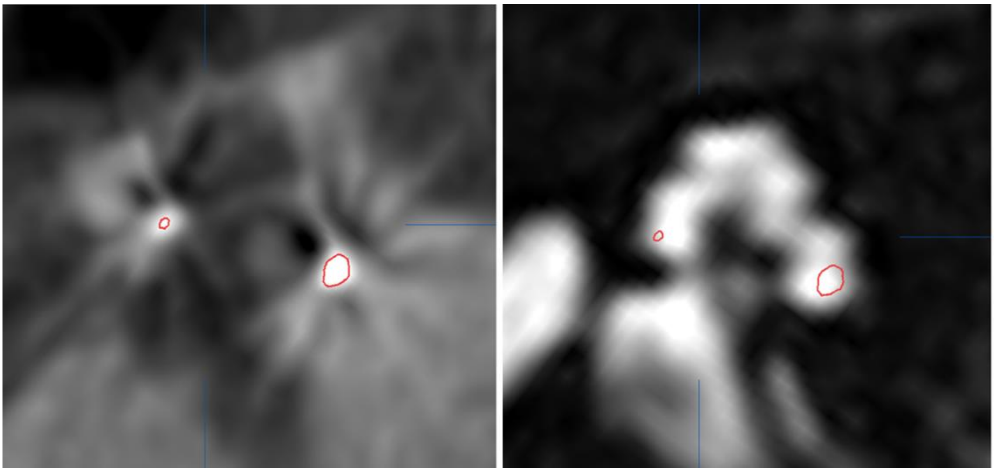

Figure 5. Electrode reconstructions (red) on postoperative CBCT (left) and preoperative MRI image fusion (right). The cochlear topography can be better defined on the MRI image fusion reconstruction and hence the electrode location in the scalae can be assessed more accurately.

3 AIMS OF THE STUDY

3.1 AIMS OF THE STUDY

The aims of the study were:

1. To evaluate the insertion characteristics and insertion trauma of a new straight electrode, EVO, in 20 temporal bones as assessed by image fusion of the pre- and postoperative CBCT and postoperative histology, and to validate the image fusion technique against histology.

2. To examine the surgical insertion results of 31 HFms™ insertions in 26 consecutive recipients and to explore the new MRI image fusion technique in a clinical setting.

3. To evaluate the possible benefits of the image fusion technique for the assessment of electrode location for six different commercially available electrode arrays, and to compare the results with those obtained by CBCT alone.

4 METHODS

In the temporal bone study (I) twenty TBs were implanted with the EVO electrode. Pre- and postoperative CBCT scans were fused to create artefact-free images. The vertical position of the electrode was quantified in relation to the BM. The TBs underwent histologic examination. Trauma was classified according to adapted Eshraghis trauma scale.

In the second study (II) the imaging data of 26 patients (31 insertions) implanted with the HFms was re-evaluated for insertion trauma by the image fusion technique validated in the first study. Electrode reconstructions from postoperative CBCT were overlaid onto preoperative MRI scans to create artefact-free reconstructions of the electrodes. The intracochlear position of the electrode was again quantified in relation to the BM. The results of the visual assessment of the postoperative CBCT were compared to the ones obtained with the image fusion technique.

In the third study (III) imaging data of 30 patients implanted with six different commercially available electrode array types was analyzed. Electrode reconstructions from postoperative CBCT were overlaid onto preoperative MRI and/or HRCT scans to create artefact-free reconstructions. Intracochlear position of each electrode was analyzed with the image fusion reconstructions and compared with the results obtained by CBCT alone. The electrode location was classified according to its position in relation to the BM.

5 RESULTS

With the EVO electrode atraumatic insertions were accomplished in 14 out of 20 TBs (70%). There were three apical translocations. Two basal translocations were caused by electrode bulging. One TB had multiple translocations. The sensitivity and specificity of image fusion for detecting insertion trauma was 87.5% and 97.3.0% (I).

Consistent peri- to mid-modiolar placement was found with the HFms. The mean insertion depth angle was 376 degrees. The visual examination of the postoperative CBCT had revealed no scala dislocations according to the medical records. When assessed by the image fusion technique, five scala dislocations (17.8 %) were found. One tip fold-over was detected on the postoperative CBCT which was not evident in intraoperative measurements (II).

The final study showed that in 40 out of 151 measurement points (26.5 %), the location grading obtained by CBCT changed after the assessment of the image fusion reconstructions. A significant association was found between deep insertions over 360 degrees and the effectiveness of image fusion (p=0.019). The difference between the impact of the image fusion technique on the location assessment for the basal turn versus the apical cochlea was highly significant (p=0.001). There was no significant difference between the effectiveness of the image fusion and the different electrode types (III).

6 GENERAL DISCUSSION

6.1 GENERAL DISCUSSION

6.1.1 Electrode Array Design

At present, there is a wide range of different electrode designs available, differing extensively in their physical and surgical characteristics. Design, dimension and flexibility will affect the insertion characteristics and dynamics. In theory, the optimal electrode array design, although still only a theoretical concept, would allow for easy atraumatic insertion by the surgeon and reliable placement in the scala tympani. Furthermore, it would allow for the adjustment of the insertion depth, with the option to move it forward i.e. deeper, if residual hearing is lost. Eventually, neural tissue and synapses grow onto the electrode and in this way, create an optimal electrode-neural interface. The current electrodes are still far from these requirements and manufacturers have to make significant compromises in favor or against some of the aforementioned optimal features.

Electrode array length and cochlear duct length are the two main factors determining the angular insertion depth and the cochlear frequency coverage (Rask-Andersen, Liu et al. 2012).

6.1.2 Features of the LWE

Straight electrode arrays are available in different lengths, making it possible to choose the most suitable array according to each individual cochlea size for optimal coverage. Electrodes from different manufacturers and of various lengths may differ substantially in their insertion characteristics, and the operation technique has to be adjusted for any given array. In general, straight arrays can be handled without a stylet, which allows a more favorable insertion angle and a significantly reduced rate of insertion trauma (Boyer, Karkas et al. 2015, Wanna, Noble et al. 2014, Wanna, Noble et al. 2015, O'Connell, Hunter et al. 2017, O'Connell, Hunter et al. 2016).

A recent review article describes a prevalence of 32% for scalar translocations with PMEs and 6.7% with straight electrodes in clinical patients (Dhanasingh, Jolly 2019). In our TB study, atraumatic insertions with the straight EVO electrode (EVO) (figure 3) were achieved in 70% of the cases (14 of 20). The rate is comparable to another TB study with the EVO which reported that 68% of the insertions were atraumatic (17 out of 25) (Martins, Graziela de Souza Queiroz, Brito Neto et al. 2015). Additionally, surgical experience appeared to be important for atraumatic insertions; the trauma rate for an expert surgeon was 18% (2 of 11) whereas for a trainee surgeon, it was much higher, 44% (4 of 9). Due to the limited number of insertions, the difference was not statistically significant. The surgical behavior of the EVO was found to be very different from the other straight arrays. In comparison to the other LWE, the proximal part of the EVO is very thin and flexible which increases the risk for bulging and compression of the array at the proximal end. Therefore, specific training with any new electrode array is essential before performing clinical insertions in order to become acquainted with the individual surgical behavior of the array and to avoid insertion trauma.

The insertion trajectory of the tip of a straight electrode is mainly determined by the cochlear microanatomy, especially with a round window approach. In addition to the narrowing apical structures, the surgeon has no control over the trajectory of the distal part of the electrode beyond the basal turn. Therefore, deep insertions carry a considerable risk for apical trauma which can be prevented by shallower insertions. We found a weak positive correlation between IDA and insertion trauma with EVO. We detected four tip translocations, of these, three could have been prevented by limiting the IDA to 360 degrees. The risk for increased trauma rate should be considered when seeking a balance between partial vs. full insertion for long LWEs. Deep insertion allows for better electrical coverage over the frequency distribution of the cochlea, but is more likely to cause insertion trauma and have a negative impact on the hearing outcomes.

The literature provides an ambivalent view regarding the relationship between user performance and insertion depth, although a stronger correlation has been shown between deep insertion and better hearing performance. Especially better speech recognition in noise has been associated with deeper IDA (Buchman et al. 2014b, O'Connell, Cakir et al. 2016, O'Connell, Hunter et al. 2017, Nayak, Panda et al. 2016, Roy, Penninger et al. 2016). Therefore deeper insertion could be advisable for patients with no residual hearing. Deep insertions in subjects with residual hearing provide the opportunity to turn off apical contacts where they do not provide any benefit to electrical hearing and turn them on again if the hearing loss progresses later on. It also provides fibrous encapsulation to the apical cochlea, which may help with possible re-implantation.

6.1.3 Features of the PME

The perimodiolar electrode design is associated with relatively high trauma rates (Boyer, Karkas et al. 2015, Mittmann, Rademacher et al. 2015, Hassepass, Bulla et al. 2014, Lane, Witte et al. 2007, Holden, Finley et al. 2013a, Aschendorff, Klenzner et al. 2011, Wanna, Noble et al. 2014). During insertion, the electrode array is stiff with the stylet wire inside, which may cause damage to the spiral ligament and provoke a scala translocation at the insertion depth of 180°. Accordingly, we observed scala translocations with the precurved Advanced Bionics Hires Mid-Scala electrode (HFms) (figure 2) at corresponding locations in 18% of the cases (5 out of 28), all occurring at 90°-180°. The same phenomenon has been described in the study of Briggs et al. 2011: even in the hands of experienced surgeons and with the application of the advance off-stylet technique (AOS), translocation cannot be completely prevented (R. J. S. Briggs, Tykocinski et al. 2011). With the AOS technique, the stylet should be withdrawn at an insertion depth of 8 mm, corresponding to around 90 to 110 degrees IDA. We found no correlation between growing IDA and insertion trauma. The IDAs varied from 350° to 454° (median 365°, mean 376°) and were normally distributed.

Scala vestibuli insertions are reportedly rather common with PMEs, which is probably due to the fact that they are often inserted via a cochleostomy approach. Reported rates for ST location range between 10-74% for PMEs and 89-97% for LWEs (O'Connell, Hunter et al. 2016, Boyer, Karkas et al. 2015, Aschendorff, Kromeier et al. 2007, Wanna, Noble et al. 2014, N. Fischer, Pinggera, Weichbold, Dejaco, Schmutzhard, and Widmann 2015b, Connor, Holland et al. 2012). Our study shows that the HFms can be inserted through the RW or an extended RW in the most cases, which provides the most reliable access to the scala tympani with practically no risk of scala vestibuli insertion. We detected no scala vestibuli insertions with the HFms.

The organ of Corti extends to the whole length of the cochlea (Greenwood 1990), whereas the spiral ganglion cells in the Rosenthal's canal extend into 1.75 turns of the cochlea, which is equivalent to an insertion angle of 660° (Rask-Andersen, Liu et al. 2012, Locher, de Groot, John C. M. J. et al. 2014). Currently, there are no commercial PMEs, which can reach such depths, because it is technically impossible to insert deeper with a stylet or a sheath type array. The maximum insertion depth with a pre-curved electrode is 390°- 450° (Frisch, Carlson et al. 2015, R. J. S. Briggs, Tykocinski et al. 2011, Dietz, Gazibegovic et al. 2016, Iso-Mustajärvi, Matikka et al. 2017). For an average size cochlea, an insertion depth of 420° would cover up to 500 Hz in the low end of the frequency range (Figure 1).

The precurved HFms is designed to be positioned in the middle of the scala tympani, avoiding contact with the surrounding structures but with closer proximity to the modiolus than LWEs, yet, not touching it as is the case with other perimodiolar designs. TB studies have shown that the HFms is located mostly in the desired midscalar position (Frisch, Carlson et al. 2015, Dietz, Gazibegovic et al. 2016). In our study, 82% of the electrode contacts were positioned in a peri- to mid-modiolar location, which confirms the desired functionality of the design also in the clinical setting.

PMEs are designed to position closer to the modiolus and its ganglion cells than straight electrodes with the intention of providing more focused electrical stimuli. However, the literature provides a controversial view about the placement of the electrode contacts closer to the modiolar wall in terms of user performance and threshold levels (Doshi, Johnson et al. 2015, Saunders, Cohen et al. 2002, Fitzgerald, Shapiro et al. 2007). Furthermore, the defined curvature geometry may not always match the coiling patterns of different sizes and shapes of cochleae. As a result, the pre-curved electrode may not settle around the modiolus along its whole length, thus losing the original purpose of the perimodiolar design (Frisch, Carlson et al. 2015, Holden, Finley et al. 2013b). The mismatch between the individual cochlear anatomy and the standardized array geometry may be one reason for the high risk of translocations during insertion. In contrast to LWEs, PMEs are less prone to electrode migration due to their modiolus-embracing design (Mittmann, Rademacher et al. 2015). However, the diameter of the modiolus in the second turn is very thin (Avci, Nauwelaers et al. 2014) and extraction of the perimodiolar array could theoretically pose a risk for trauma. Nonetheless, the literature shows good re-implantation hearing outcomes with both the PME and LWE. Cochlear fibrosis or osteoneogenesis was associated with postmeningitis reimplantation, but not with the type of the array. (Côté, Ferron et al. 2007, Marlowe, Chinnici et al. 2010, Yeung, Griffin et al. 2018).

Cochlear electrodes have constantly developed toward more delicate designs to help to reduce insertion trauma and improve hearing outcomes. Unfortunately, as electrodes become slimmer, the tendency for tip fold-over appears to increase. Tip fold-overs can occur with both electrode types, but the rate is higher with perimodiolar electrodes due to the pre-curved geometry of the array (Zuniga, Rivas et al. 2017, Garaycochea, Manrique-Huarte et al. 2017). In a recent review article, the overall incidence rate for tip fold-over was 4.7% for PMEs in comparison to 0.80% for straight electrodes (Dhanasingh, Jolly 2019). Our findings with the HFms are in line with that proposal: out of the 31 insertions, we detected one (3%) tip fold-over on the postoperative CBCT. This reveals the limited predictive value of intraoperative measurements for identifying tip fold-over. These findings highlight the necessity of performing postoperative imaging after cochlear implantation.

In the clinical setting tip fold-over has led to reimplantations and deactivation of the overlapping electrodes because offor facial nerve costimulation, vertigo and compromiset speech performance (Sabban, Parodi et al. 2018, Zuniga, Rivas et al. 2017, Gabrielpillai, Burck et al. 2018). In the study by Zuniga et al. 3 out of 6 tip fold-overs (50%) underwent deactivation of the overlapping electrodes. There was marked audiological improvement in two cases (Zuniga, Rivas et al. 2017). In the rewiev article study by Gabrielpillai et al. 11 out of 15 tip fold-overs undervent reimplantation which improved their speech perception outcomes. The review suggests revision surgery should be offered to each tip fold-over, since it is likely to enhance speech performance and reduce side effects (Gabrielpillai, Burck et al. 2018).

6.1.4 Postoperative Imaging and Image Fusion

Accurate postoperative radiological evaluation is essential for the assessment of insertion results and possible trauma. Imaging is necessary for the detection of possible scala translocation, tip fold-over and migration as well as for the development of new electrode arrays and surgical techniques (Aschendorff 2011, Dietz, Wennström et al. 2016).

In the TB study we validated the image fusion technique against histology: the sensitivity and specifity for the image fusion technique were 88% and 97%. Imaging revealed 7 traumatic insertions, but histology confirmed only five (71%) of them.

Image fusion technique misdiagnosed insertion trauma in this sample, probably due to scalar variation described in the histologic findings. Histology is still the golden standard for insertion trauma assessment, yet accessible only in TB studies.

Interestingly, in the HFms study, a visual assessment with CBCT alone found evidence of the tip fold-over but detected no scala dislocations. We identified the five dislocations with the image fusion technique, i.e. these could not be diagnosed by CBCT alone. We have validated the image fusion technique against histology for straight electrodes in the EVO study and, in an earlier study, also for precurved electrodes (Iso-Mustajärvi, Matikka et al. 2017).

In the present work, we have applied the image fusion technique in both TB specimens and in clinical patients, utilizing preoperative CBCT and CT, as well as MRI registrations. All modifications have improved the results for detection of trauma. In clinical studies, we used mostly the MRI fusions for the final evaluation as it supplied the most accurate data. The advantage of preoperative MRI and postoperative CBCT fusion is that it mostly provides a clearer depiction of the apical cochlear topography than can be obtained with CT and CBCT fusions. In addition, the basilar membrane can often be identified by the novel technique, which is beneficial for a reliable interpretation.

An accurate assessment of electrode location with CBCT alone is often limited to the basal turn (Guldner, Weiss et al. 2012, Saeed, Selvadurai et al. 2014, De Seta, Mancini et al. 2016, Güldner, Wiegand et al. 2012). An important finding of this study is that image fusion can significantly improve the assessment of electrode placement in deep insertions beyond the basal turn. With insertions deeper than 360° (IDA > 360 degrees), the fusions exerted a significant impact on location assessment in 52% of the cases, whereas for the basal turn (IDA < 360°) insertions, the impact was less, 20%. Additionally, for cases in which there were profuse artefacts that blur the cochlear structures, image fusion reconstructions achieved a better, more precise electrode location assessment within the cochlea and the benefits were also evident in the basal turn region. Insertion trauma between the different electrodes in the final study were not compared, as the small sample size would not have provided significant outcomes.

Some electrodes can generate asymmetrical artefacts, which makes the accurate determination of the center of the electrode difficult. We used Hounsfield segmentation in the electrode reconstructions. The Hounsfield unit (HU) is a quantitative value describing radiodensity in CT imaging. It provides a specific density for each substance and is therefore used for the identification of different tissue types and substances in the region of interest. An electrode contact can be defined within the larger artefact by the HU segmentation with better accuracy than by visual assessment alone. The effect of the size and shape of the artefact can be reduced and electrode reconstructions can be made by autosegmentation. The method was found to be feasible for the electrode reconstruction based on the postoperative CBCT.

Image fusion is a rapid and mostly fully automatic procedure with CT and CBCT modalities. Both of these techniques sharply visualize bony structures allowing the automatic script to combine the scans accurately. With Brainlab software a single fusion took only seconds once the images had been downloaded to the software. While the differences between the MRI and CT modalities result in more manual manipulation, they can still be fused semi-automatically. All fusions were visually checked for accuracy. Our experience in TB studies suggests that CBCT image fusion is the quickest, fully automated procedure, which generates reconstructions with adequate resolutions. CBCT images, as well as their fusions, can maintain the optimal resolution in every spatial direction due to the isotropic voxels.

We could not utilize the optimal image resolution in the reconstructions, since the raw data of the preoperative imaging was no longer available for fusion. Better image quality and fusion reconstructions could be obtained by using the raw data and using thinner CT slices. The adoption of CBCT in the preoperative study instead of HRCT would be one way to further improve the image quality, but it would require a device in which the patient could be scanned in a supine position to eliminate motion artefacts. The study is retrospective and does not include clinical outcomes. Further prospective research is needed to investigate the short and long term hearing outcomes and the correlation with the imageing findings. Research on the correlation of intracochlear trauma and hearing outcomes is needed. Small sample sizes and several variables, such as etiology and age, complicate the approach.

The present study shows that visual assessment based on postoperative imaging alone is not necessarily sufficient for the identification of insertion trauma. This study shows that the image fusion technique is an accurate and valid method for achieving a reliable evaluation of electrode location and insertion trauma. As perioperative imaging with MRI, HRCT or CBCT have become standard protocols for cochlear implantation in an increasing number of institutions, it is recommended to upgrade these modalities to obtain the benefits conferred by the image fusion technique. We consider this novel technique to be a worthy supplement for ambiguous cases, both in research and clinical work.

7 CONCLUSIONS

7.1 CONCLUSIONS

1. Atraumatic insertions with the EVO electrode can be reliably accomplished by an experienced surgeon. Insertion trauma can be most often prevented by meticulous insertion techniques and by limiting the IDA to 360 degrees. Any attempt to insert the electrodes further while experiencing resistance increases the risk of apical or basal trauma. The image fusion provides accurate assessment of intracochlear electrode placement and is feasible for grading the extent of insertion trauma.

2. The HFms electrode possessed mostly atraumatic insertion characteristics and achieved a consistent mid-modiolar placement. Postoperative imaging is recommended for identifying tip fold-over. The MRI image fusion technique enhances the accuracy of the insertion trauma assessment.

3. With the application of image fusion technique, it is possible to achieve a more accurate evaluation of electrode location with all electrode types due to elimination of the metallic artefacts. Fusion images were especially helpful for the assessment of electrode location with deeper insertions (> 360 degrees).

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SINI SIPARI

Preserving the inner ear structures during cochlear implantation improves the postoperative hearing results. The surgical features of the electrode and its location in the cochlea contribute to hearing outcomes.

In this study we evaluated the insertion results of a straight electrode in temporal bones and of a mid-scala electrode in clinical patients. We validated the new image fusion technique and evaluated its benefits in post-operative location assessment.

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