Radiological and Histological Evaluation of Perimodular Electrodes: Impact on Cochlear Implant Development

ANTJE ASCHENDORFF, M.D.*, THOMAS KLENZNER, M.D.*, MONDY HAMMAD, M.D.**; RALF KUBALEK, M.D.***; BERNHARD RICHTER, M.D.* and ROLAND LASZIG, M.D.*

The Departments of Otorhinolaryngology* and Neuroradiology***, Faculty of Medicine, Freiburg University, Germany and the Otorhinolaryngology**, Faculty of Medicine, Cairo University.

Abstract

Introduction: Different Perimodiolar electrodes were developed by many cochlear implant (CI) manufacturers in the past few years. Possible advantages are lower stimulation thresholds and a better channel separation. A position close to the modiolus can be facilitated by different means: preformed electrode shape (Nucleus ContourTM electrode, Cochlear Corp., Australia), additional positioning elements like silicon in a space-filling matter (Clarion 1.2® electrode with positioner and HiFocus® electrode with positioner, Advanced Bionics Corp., USA) and additional silicon-covered wires that allow a positioning of the electrode lead by retropositioning after insertion (perimodiolar electrode, MedEl Company, Austria).

The Aim of this Work is to: Assess the position of different perimodular electrodes inside the cochlea and their impact on the fine intra-cochlear structure (insertion trauma).

Methodology: Different perimodular electrodes (Contour, Med-El, Clarion 1.2 and Clarion HiFocus II with positioner) were implanted in fresh frozen temporal bones. Assessment was carried out radiologically by digital subtraction analysis (rotational tomography) for position of electrode with regard to the modiolus, tympanic and vestibular scale. Histological preparation was focused on possible intracochlear trauma.

Results and Conclusion: All different types of electrodes may generate a design-specific kind of intracochlear damage that might be classified into minor or major damage. Major trauma may be responsible for the development of postoperative meningitis that has been recorded lately. Further developments of electrodes have to consider the specific intracochlear geometry to allow ideal positioning of electrodes with minimal intracochlear trauma.

Key Words: Cochlear implants – Perimodiolar electrodes – trauma – Histology – Rotational tomography – Meningitis.

Introduction

NEW electrode designs as perimodiolar electrode arrays, aim at improving benefit for patients in the form of reduction in the stimulation threshold and enlarged dynamic range, more functional channels may lead to better speech discrimination and lower power consumption that results in speech processor miniaturization and battery longevity [1-5]. However, in addition to providing functional improvements, modern electrode array development must also address safety aspects, because damage to the cochlear morphology (especially the osseous spiral lamina) may lead to degeneration of residual neuronal structures and bony obliteration or scarring within the cochlear ducts [6,7]. Another important risk is the likelihood development of postoperative meningitis [8].

Different designs of perimodular electrode arrays have been developed. These include a preformed electrode array shape (ContourTM electrode, Cochlear Corp., Australia), retropositioning of two components electrode array (perimodular electrode, MedEl Company, Austria) and a space filling, two components electrode system pushing the stimulating electrodes towards the modiolus (Clarion 1.2® standard electrode with positioner, and HiFocus® electrode with positioner, Advanced Bionics Corporation, USA).

Before human implantations, safety studies in temporal bone are necessary to assess potential damage to important fine intracochlear structures. Histologic examination has been the gold standard method for three-dimensional analysis of the position of the electrode inside the cochlea [9]. Other techniques have been described as surface preparation [10], frozen cuttings [11], x-ray microscopy [12], and fluoroscopy [13].

Standard CT is usually inhibited by profuse metallic artefacts, although, Wang et al. described a technique that tries to estimate the location of cochlear implant electrodes on the basis of 3D reconstruction from spiral CT data [14]. Recently, rotational tomography (RT) has been described as an alternative reliable radiological technique using the rotational digital subtraction angiography (DSA)
Aim of work:

Evaluation of electrode position and insertion trauma caused by different perimodular electrodes and the impact of this research on the technical development of cochlear implants.

Material and Methods

1- Sample and preparation for implantation:

This study was carried out in Otorhinolaryngology and neuroradiology departments of Freiburg University, Freiburg, Germany. Forty two fresh frozen temporal bones were implemented in this study. The bones were harvested within 24 hours postmortem. An electric saw was used to remove the cochlea from the deep-frozen temporal bones to facilitate the histological preparation of the samples. Four different perimodular electrodes were studied.

1- Nucleus ContourTM electrode, Cochlea Corp. Australia (24 temporal bones).
2- Med-El Perimodiolar Combi 40 Electrode (PME C40), MedEl Corp. Austria (8 temporal bones).
3- Clarion 1.2 Electrode with positioner (Advanced Bionic Corporation, USA) Clarion (5 bones).
4- Hi Focus II Electrode, Advanced Bionic Corporation, USA (5 bones).

2- The description of the electrodes:

The Nucleus ContourTM electrode is an electrode array with stylet. It has 22 intracochlear electrodes. In contrast to the standard straight electrode array, the electrodes are half-banded and designed to be oriented toward the modiolus. The electrode array is 19.3 mm long and the diameter tapers from 0.8 mm at the basal end to 0.5 mm at the tip of the array. This precurved electrode array is designed to match the curvature of an average cochlea. Before insertion, the array is held straight by platinum stylet within the center of the silicone carrier. After insertion, the stylet is removed and the electrode array assumes its precurved shape because of the recoil properties of the silicone. This positions the electrode array within the proximity to the modiolus without applying external force.

The MedEl perimodular electrode is an electrode array with 12 electrodes. It measures 31 cm long and has a diameter of 0.8 mm. It is a slightly curved electrode array with a guide positioning silicon wire (with internal stylet) attached to its tip. After insertion the wire is pushed out (Retro-positioning) that makes the electrode array curves along the modiolus.

The shape of the Clarion® 1.2 standard array mimics the curvature of the cochlea. It has a diameter of 0.64 mm at the apical end and 0.75 mm at the basal end of the silicone carrier. A special customized tool holds the electrode array straight for insertion. Once inserted into the cochlea, the silicone carrier resumes its curved shape due to the elastic nature of the material. This curving is expected to position the electrodes close to the modiolus. A recent addition to the electrode array is the partial space-filling positioner. This is a separate silicone device, 23 mm in length, which is inserted after the electrode array to push the electrode carrier further towards the modiolus and deeper into the medial turn of the cochlea. The diameter of the positioner is 0.93 mm at its apical end and 1.3 mm at its basal end.

The Hi Focus II Electrode with positioner is a space-filling two components slightly curved thin electrode of 20 mm length and 16 electrode contacts. It is inserted together with a silicone wire attached to its tip. The wire has an internal stylet and the electrode is positioned using specific insertion tool that holds the electrode straight during insertion.

3- Description of surgeries:

The cochleae were fixed for implantation using a tripod. Implantations were performed by an experienced CI surgeon. Insertion of the electrodes were performed through a cochleostomy; antero-inferior to the round window niche. Each electrode type was inserted according to the manufacture guidelines except for the Contour electrode the surgical technique was modified in 10 temporal bones where a partial 2-mm withdrawal of the stylet was employed when the electrode reached an insertion depth of at approximately 8 mm. All surgeries were performed in the presence of a staff member of the manufacture.

4- Radiological evaluation:

Radiological evaluation to verify proper placement of the electrodes included cone beam rotational tomography (RT) that was adapted for visualization of the intracochlear electrode. Principally the system is based on rotational two-dimensional digital subtraction angiography. The method is used in practice for the three-dimensional analysis of vascular architecture of intracranial vessels. However, the first CT-like applications were described by Mozo et al. beside the generation of three-dimensional views, the system provides standard axial, coronal, and sagittal slices of the investigated
object, as well as any oblique section 17. In our specimen a rotational two dimensional X-ray series was acquired using a biplane GE LCN plus (GE Medical System, Buc, France) digital subtraction angiography systems. Data acquisition was achieved at 44 projections using a 512 matrix resulting in a 7.6 cm field of view. Data were computed on an advantage Window 3.1 system (GE Medical Systems, Santa Clara, CA). From the data set, two-dimensional multiplier reformations and maximum-intensity projections (MIP) were taken.

5- Histological analysis:

Histological analysis was then carried out through fixation of the implanted bone in 4% phosphate-buffered formaldehyde. Specimens were dehydrated using an ascending series of alcohol (70%-100% ethanol) and then embedded in methacylate-based resin to permit sectioning of calcified bone with implants in situ. At the start of the study Technovit 9100 resin (Heraeus Kulzer, Wehrheim, Germany) was used. However, difficulties were encountered with these preparations during polymerization because of a chemical reaction between the silicon covering of the electrode array. Therefore, the methyIacrylate was modified to Technovit 7200 visual light curing (VLC) (Kulzer), and the swelling reaction could be minimal. Resin infiltration was initiated with a mixture (1:1) of ethanol/Technovit 7200 VLC for 1 week, followed by infiltration with pure Technovit 7200 VLC for a second week. The polymerization procedure occurred in a photopolymerization unit (EXAKT Apparatebau, Nordstedt, Germany) involving 2 hours of daily daylight exposure and another 10 hours of ultraviolet light exposure. After light polymerization, specimen were cut in 300-mm sections using a low-speed rotatory diamond saw mounted on opaque acrylic slides (3x50 x50 mm) with instant glue (loctite GmbH, Muenchin, Germany) and grounded to a final thickness of approximately 80 mm using a micro grinding system (EXAKT Kulzer). Specimens were subsequently stained in azura II and pararosaniline (Sigma-Aldrich, Deisenhofen, Germany) and examined under light microscope Axioskop (Carl Zeiss, Jenna, Germany).

6- Analysis of intracochlear structural damage:

Trauma to delicate intracochlear structures due to electrode insertion (insertion trauma) were analyzed using histological sections analogously to the RT images. Intracochlear trauma could be classified into:

- Fracture of the osseus spiral lamina (OSL).
- Fracture of the outer wall of the cochlea.

Minor trauma:

- Perforation of the basilar membrane and migration of the electrode to the scala vestibuli.
- Damage to the spiral ligament-stria vascularis (SL).

7- Interpretation of the results:

For each electrode the results were interpreted according to the following items:

A- Verification of perimodiolar position (using RT and histopathological examination findings).
B- Analysis of intracochlear structural damages.
C- Correlation of RT to histopathological examination concerning the position of the electrode.

Results

1- Contour electrode: Good perimodiolar position was confirmed by both RT and histomorphological examination with 100% correlation between both examination modes in all sections (Fig. 1).

In 13 out of 24 implanted temporal bones with Contour electrode, localized penetration of the electrode array through the BM at about 180° along the ST was detected causing the electrode array to move into the scala vestibule. Major traumas to the cochlear structures were not observed in any specimen (Fig. 2). In the ten bones where partial stylet removal was done, penetration of the BM was observed in only three bones.

2- Med-El C40 PME electrode: Could be inserted to a depth of 25-30 mm and was then retracted until the desired position was reached. The histologic and RT temporal bone sections show the position of the electrode close to the modiolus with 100% correlations in all sections. The nitinol wire was found to be located close to the spiral ligament, with major trauma in the form of fracture of OSL which was found in 6 out of 8 temporal bones (Fig. 3 A,B).

3- Clarion 1.2 standard electrode array with positioner: Although a perimodiolar position was seen in all bones, there was considerable displacement of the electrode array into the scala vestibuli in all bones with widespread fractures of the osseous spiral lamina in four specimens (Figs. 4,5). Again there were 100% correlations concerning the position of the electrode between RT and histopathology in all sections.
4- **HiFocus II electrode**: All temporal bones showed a more perimodiolar position of electrode array. However, RT and histological sections revealed the position of the electrode tip to be located in the scala vestibuli in three temporal bones with 100% correlation between both modes (Fig. 6).

Fractures of the OSL in the second part of the basal turn were found in four temporal bones. Under higher microscopic magnification (25X – 30X) opening of Rosenthal’s canal were found approximately 5 mm from the cochleostomy in two temporal bones (Fig. 7 A,B).

In one temporal bone a narrow space between the HiFocus® electrode array and positioner was observed near the cochleostomy that may in vivo not be sealed sufficiently with standardized tissue sealing. Whether this might have occurred in the remaining temporal bones remains uncertain as a technically induced (even slight) swelling of silicone materials may conceal this finding. In our data there was no correlation between ease of, or point of obstruction of insertion and the grade of intracochlear trauma, i.e. the extent of trauma was independent of the insertion mode.
Fig. (5). Histomorphological section of same specimen and in the same projection as in Fig. 4. The basal and middle turns show displacement of the array towards the scala vestibuli and fracture of the osseous spiral lamina.

Fig. (6): Rotational tomography (a) and the corresponding histological section reveals dislocation of the HiFocus electrode in the second part of the basal turn (arrows).

Fig. (7): a) Fracture of Rosenthal’s canal (circle) near to the cochleostomy possibly due to right-angled shape of the electrode array (25.X). b) Higher magnification (50.X) of the fractured region (arrows) indicating the nearness to the internal auditory canal. TS = tympanic scale; VS = vestibular scale; IAC = internal auditory canal.

**Discussion**

Perimodular position brings the active electrode as near as possible to the target excitable spiral ganglion neurons. The theoretical benefits would be decreased T and C levels, increased the dynamic range, better channel separations and less interaction with resultant possible increase in speech discrimination, and decrease battery consumption [11].

Potential benefit from the new device should exceed any negative consequences such as damage to inner ear structures resulting from insertion trauma. It is also necessary to determine whether modifications to standard surgical techniques are required to minimize this damage. Therefore, systematic insertion studies in temporal bones should be performed and the results carefully evaluated before human implantations are allowed to commence [18].
In this study, four prototypes of electrodes were evaluated that belong to the three major CI manufacturers. Regarding contour electrode, a higher rate of BM penetrations and migration to the SV was seen (54%). Damage was localized and did not include severe BM ruptures or OSL fractures. This is in contrast to Eshraghi et al., who found fractures of the osseous spiral lamina in two out of 5 bones [11].

Although considered as minor trauma, localized BM penetration resulted in movement of the electrode from ST to SV which can result in poorer postoperative performances compared to ST placement [19]. In addition a scala vestibuli insertion or dislocation from one scala to the other will probably destroy any residual hearing and is therefore unacceptable in cases where preservation of hearing is intended for electroacoustic stimulation [20-22].

Modification of the surgical technique and partial withdraw the stylet a few millimeters during insertion) significantly decreases the rate of BM penetrations and electrode dislocation from 10 out of 14 specimens (71%) to 3 of 10 specimens (30%) which is comparable to that of the Nucleus standard arrays inserted in temporal bones [23, 24].

All electrode dislocation occurred at 180° along the scala tympani (about 10 to 11 mm from the round window membrane). At that site the electrode touches the lateral wall and has to bend to continue its course in the ST. If the electrode is stiff, upwards migration can occur with perforation of the BM and dislocation into SV. Few mm withdrawal of the stylet decreased stiffness of the most distal part of the electrode and its movement away from the lateral wall of the ST, thus decrease the rate of dislocation.

In order to decrease the insertion trauma and decrease electrode dislocation rates, in 2005 Cochlear Corp. has released modified the design of its perimodular contour electrode and named it the Contour Advanced electrode. The basic design is the same as the contour electrode but with the addition of a soft silicon tip. For maximum trauma insertion, it is advised to use a modified technique for its insertion called advanced of stylet technique (AOS). In the AOS technique the electrode with the stylet is inserted in the scala tympani until a white mark that lies 10 mm from the electrode tip. This means approximately 180° insertion depth (the usual angle at which electrode dislocation has occurred). Then the stylet is grasped with a forceps and the electrode is introduced off the stylet further is the scala tympani. The soft silicon tip prevents the electrode tip from curling during insertion process. Basic temporal bone studies that have been conducted using this type of electrode showed decrease the BM penetration rate from 70% with the regular contour electrode to only 16% [19]. Hearing preservation rate in patients with residual hearing using this electrode and the AOS insertion methods can reach up to 70% [25].

Although good perimodular position was noticed with the other 3 electrodes, the rate of major trauma with fracture of OSL was higher than the contour electrode (75% in MedEl C40 PM electrode and 80% in electrode with positioned and HiFocus II perimodular electrode).

The Clarion 1.2 and HiFocus II electrodes may cause damage when the actual size of the scala tympani is smaller than expected. Therefore, if resistance is met during HiFocus II insertion, the positioner may be separated from the electrode and inserted independently at a shorter depth [26]. Similar concept can be applied in case of Clarion 1.2 electrode where the introduction of the positioner is introduced until resistance is felt [27].

Eshraghi et al. have found lower rates of major trauma with MedEl C40 PM electrode and Hifocus electrode (20% and 0% respectively). In retrospositioning for MedEl Combi40 PM, trauma was generally caused by the restraining arm. For this reason, extremely gentle pressure should be applied when retropositioning the electrode arm. So it is the design that is only responsible for the intracochlear trauma but also the method of insertion [11, 28].

Major intracochlear trauma may result in degenerations of spiral ganglion neurons. Currently, the extent to which there is a correlation between damage to fine intracochlear structures and patient performance in humans remains under debate. Signs of neuronal degeneration were found in postmortem studies of deceased cochlear implant users [29]. However, others found no correlation between speech discrimination performance and the postmortem spiral ganglion cell count. The consequences of loss of spiral ganglion cells through cochlear implant trauma warrant further investigation [9, 30].

In addition, there is currently much discussion regarding the risk of otogenic meningitis in cochlear implants recipients. In 2002 FDA has released Web Notification that Cochlear implant recipients may be at greater risk for meningitis with the surgical technique being one possible predisposing factor to post-implant meningitis [8]. The risk was much
higher in patients implanted with two components electrodes (Clarion 1.2 and Hifocus electrodes). One factor behind that is the extent on the intracochlear trauma caused by two component electrodes. With fractures of the OSL the risk of spread of infection to the cerebro-spinal fluid space is increased due to the opening of the habenula perforata and Rosenthal canals of the OSL. This has been showed clearly in Fig. (7). Another possible factor that may participate in the spread of infection is the possibility of infection spread from the middle ear to the inner through the space between the two component electrodes. Sealing of the cochleostomy with tissue is widely accepted as a closing procedure in cochlear implant surgery. Also animal trials indicated a tissue sealing of the cochleostomy to be sufficient to prevent inner-ear infection due to bacterial otitis media in single component electrode arrays [31].

It remains a matter of speculation whether the space left between the HiFocus electrode and its positioner that we observed in one temporal bone may also be a predisposing factor for infection spread inside the intracochlear spaces. As a consequence, Advanced Bionics Company voluntarily withdrew all their two component electrodes from the market and stopped their further production. Instead they introduced the Hifocus Helix electrode which is a one component preformed electrode that is introduced using an insertion tool. The MedEl Company decided not to produce their prototype C40 PME into the market [28].

Another tool that is used here for verification of electrode position is the RT. There was 100% correlation between RT images and the corresponding histological sections regarding electrode position. This makes RT a useful tool for estimation of electrode position inside the cochlea in cochlear implants patients [16,32,33].

Conclusion:
Perimodiolar electrodes are designed to place stimulating contacts close to the spiral ganglion cells, to reduce power consumption and increase stimulation selectivity and possible increase in speech discrimination. All perimodiolar electrode design produce a variable degree of intracochlear trauma that may be related to the design of the electrode or mode of insertion. It is most likely that some relationship exists between the extent of cochlear damage and resulting negative long-term effects. Therefore, new electrode array prototypes should be designed in such a way that damage to cochlear structures is minimized. This becomes more important when more candidates with residual hearing are recruited for cochlear implants where hearing preservation becomes important for combined electric-acoustic hearing. Increase incidences of dangerous complications as meningitis can be related to specific design of certain electrodes (e.g. two component electrodes) and/or the extent of intracochlear trauma. Therefore, systematic safety studies in larger samples of human temporal bones should be performed and the results carefully evaluated before human implantation can be recommended unreservedly.

References
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