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# Main Articles

# Evaluation of the HiFocus® electrode array with positioner in human temporal bones

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**Abstract**
The aim of the study presented was to assess the insertion mode and possible intracochlear trauma after implantation of the HiFocus® electrode with positioner in human temporal bones. The study was performed in five freshly frozen temporal bones. The position of electrodes was evaluated using conventional X-ray analysis, rotational tomography and histomorphological analysis. Insertion of the HiFocus® electrode with positioner resulted in considerable trauma to fine cochlear structures including fracture of the osseous spiral lamina, dislocation of the electrode array from the scala tympani into the scala vestibuli and fracture of the modiolus close to the cochleostomy. The implication of the results regarding clinical outcome will be discussed.

**Key words: Cochlear Implantation; Temporal Bone; Surgical Procedures, Operative**

## Introduction

Recent designs of intracochlear electrode arrays try to achieve a perimodiolar position of the stimulating electrodes. The possible advantages are lower stimulation thresholds, better channel separation and better rehabilitation results. Different designs of perimodiolar electrode arrays have been developed: a preformed electrode array shape (Contour™ electrode, Cochlear Corp., Australia), retropositioning of a two-component electrode array (Perimodiolar electrode, MedEl Company, Austria, currently under development) and a space-filling, two component electrode system pushing the stimulating electrodes towards the modiolus (HiFocus® electrode with positioner, Advanced Bionics Corporation, USA).

These new electrode arrays may cause intracochlear trauma. Studies in human temporal bones of deceased implant users[1] as well as animal trials[2] have indicated loss of ganglion cells in regions of intracochlear damage although as yet it is not known whether this loss of ganglion cells has an adverse effect on rehabilitation results.[3] In addition, there is currently much discussion regarding the risk of otogenic meningitis in cochlear implantees[4] with the surgical technique being one possible predisposing factor to post-implant meningitis. The Contour™ electrode and HiFocus® electrode with positioner have already been used in human implantation. Different temporal bone studies indicated a risk of perforation of the basilar membrane (BM) using the Contour™electrode but with no further damage.[5,6] Regarding the HiFocus® electrode with positioner, temporal bone studies by Lenarz *et al.*[7] suggested no intracochlear trauma to fine cochlear structures.

We have performed several temporal bone studies in order to assess possible intracochlear trauma after insertion of different electrode arrays.[5,8,9] Our group[9] reported a high risk of fracture of the osseous spiral lamina (OSL) when using the Clarion 1.2® standard electrode with positioner. This paper reports the results of a temporal bone study using the HiFocus® electrode with positioner.

## Material and methods

Freshly frozen temporal bones (n = 5) were used for implantation. The labyrinth bone was isolated using an electric saw prior to implantation to ease later histomorphological processing.

A standard cochleostomy was performed anterior to the round window and the scala tympani was clearly visualized in all temporal bones. The size of cochleostomy was approximately 1 mm × 1.5 mm-1.8 mm being oval in shape to allow insertion both of the electrode array and positioner.

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TABLE I
PROCEDURE OF INSERTION, SIZE OF COCHLEOSTOMY AND INTRACOCHLEAR TRAUMA IN IMPLANTATION OF THE HI-FOCUS® ELECTRODE ARRAY WITH POSITIONER

| TB | Cochleostomy | Insertion | Histology | FX OSL | FS/FI | Others |
|---|---|---|---|---|---|---|
| 1 | 1 x 1.5 | easy, deep | Tip VS | basal complete | FI | |
| 2 | 1 x 1.5 | easy, deep | Tip VS | 2. part basal turn | FS | FX M |
| 3 | 1 x 1.8 | resistance after 2/3 Stop | El TS | – | – | FX M |
| 4 | 1 x 1.6 | resistance after 4/5 Stop | Tip VS | 2. part basal turn | FI | |
| 5a | 1 x 1.5 | Resistance after 2/3, stop of insertion, retraction of electrode and positioner, new insertion 5b | | | | |
| 5b | | easy, deep | Tip VS | 2. part basal turn | FS | |

TB = temporal bone; OSL = osseous spiral lamina; M = modiolus; TS = tympanic scale; VS = vestibular scale; EL = electrode; FX = fracture; FS = from superior; FI = from inferior

The HiFocus® electrode with positioner[7] is a slightly curved thin electrode of 20 mm length and 16 electrode contacts that is inserted together with a silicone positioner straightened with an internal stylet mounted on an insertion tool.

All cochleostomies and insertions were performed in the presence of two representatives of Advanced Bionics Corporation.

The electrode position was assessed by conventional X-ray in cochlear view position[10] and rotational tomography.[11] Subsequently, temporal bones were processed for histomorphological analysis following standard procedures as described earlier by our group.[9]

## Results

Insertions were easy to perform and complete in two of the temporal bone studies. In two other bones resistance was noticed after insertion of two thirds and of four fifths of the electrode length and insertion was stopped. In one bone resistance was again noticeable at two thirds of the electrode length, the electrode was removed and in a second step completely inserted (for details see Table I).

### *X-ray analysis*

Conventional X-ray in cochlear view projection revealed a deep insertion in three temporal bones (Figure 3(a)), a shallower insertion in two temporal bones (Figure 1(a)) and a more perimodiolar position compared to any straight electrode array, without any kinking of electrode arrays in all five bones (Figures 1(d), 2(d), 3(a)).

### *Rotational tomography*

All temporal bones showed a more perimodiolar position of electrode array in cochlear view projection. However, different transmodiolar oblique sections revealed the position of the electrode tip to be located in the scala vestibuli in three temporal bones. In four temporal bones dislocation of electrode artifact signal was seen. It was located centrally in the cochlear duct in the second half of the basal turn in four temporal bones (Figure 2(c)) indicating dislocation of the electrode array in this part of the cochlea. The

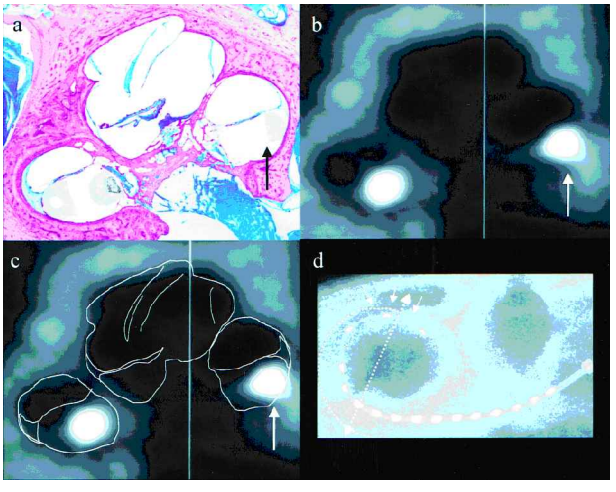


FIG. 1

Incomplete insertion (d, conventional X-ray, half-circle indicates the outer cochlear wall, double-arrow indicates position of transmodiolar sections in RT and histology) of the Hifocus® electrode with positioner with position of electrode system in the tympanic scale in histology (a) and rotational tomography (b and c with superimposed histological structures) with no trauma to OSL. However higher magnification (Figure 4) reveals fracture to the modiolus.

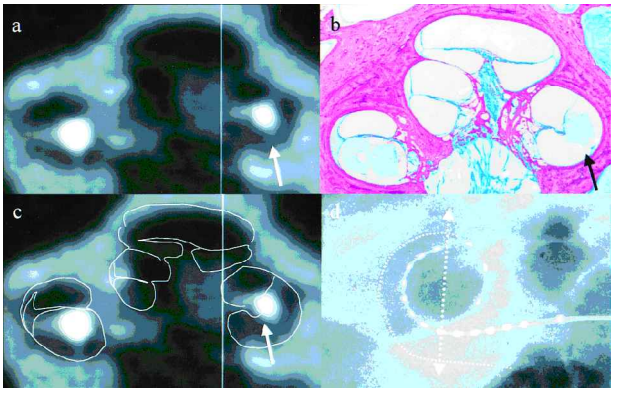


FIG. 2

Near complete insertion (c, half-circle indicates the outer cochlear wall, double-arrow indicates position of transmodiolar sections in RT and histology) of the HiFocus® electrode with positioner by conventional X-ray. Rotational tomography (a and c) and histology (b) reveals dislocation of the electrode in the second part of the basal turn (arrows) which is easier to identify if intracochlear structures are superimposed (c) to the RT-images. Note that the fracture of the OSL develops from inferior which results from an upward movement of the electrode system in the second part of the basal turn.

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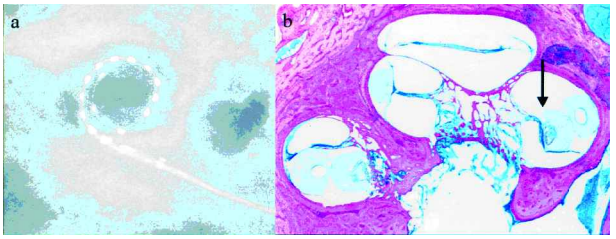



FIG. 3

Deep insertion of the HiFocus® electrode array with positioner as indicated in conventional X-ray (a). Transmodiolar histology slice (b) shows fracture of the OSL from superior indicating a dislocation of the electrode system having already occurred at approximately 180 degrees of insertion. The electrode tip is consecutively dislocated to the vestibular scale.

positioner itself could not be visualized by rotational tomography as it is manufactured from silicone.

*Histomorphological analysis*

After processing and cutting, the temporal bones were analysed microscopically to assess intracochlear trauma. In all five temporal bones the most proximal part of the electrode array was located inside the scala tympani (Figures 1(a), 2(b), 3(b)) with only a little swelling artifact caused by the silicone materials. One temporal bone with incomplete electrode insertion showed no dislocation or fracture of the OSL (Figure 1(a)) but in three temporal bones we found fracture of the OSL in the second part of the basal turn (Figure 2(b), 3(b)). In one temporal bone the OSL was dislocated and fractured over the whole basal turn. The electrode tip, which is not covered by the positioner, was located in the scala vestibuli (Figure 3(b)) in four temporal bones touching the outer cochlear wall in this region. The OSL was fractured from below due to the electrode array and positioner (Figure 2(b)) in two temporal bones suggesting an upward movement of the electrode in the second half of the basal turn. In two temporal bones, fracture of the OSL was due to movement from above (Figure 3(b)) suggesting that dislocation of the electrode into the scala vestibuli having already occurred at approximately 180 degrees of insertion.

In addition, all slices were analysed microscopically at a higher (25X–50X) magnification and fractures of the fragile modiolus bone (Figures 4(b) 4(c)) with opening of Rosenthal's canal were found approximately 5 mm from the cochleostomy in two temporal bones – one bone with deep insertion and fracture of OSL in the second part of the basal turn, and one bone with incomplete insertion that showed no further damage (Figure 1(a)).

In one temporal bone a narrow space between the HiFocus® electrode array and positioner was observed near the cochleostomy (Figure 1(a)) 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.

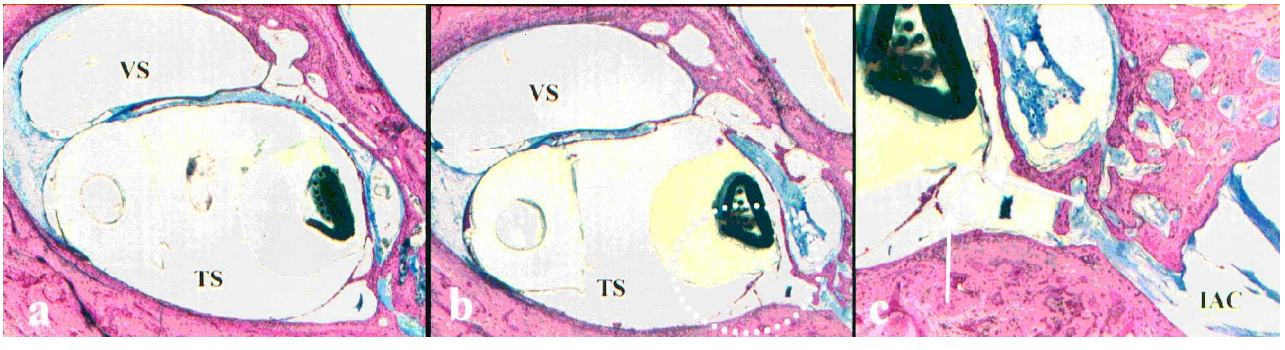
## Discussion

We found fractures of the OSL in four out of five temporal bones. One temporal bone with an incomplete electrode and positioner insertion showed no trauma to the OSL.

The Clarion 1.2® standard electrode and positioner[9] caused less trauma to the intracochlear region probably due to the modified shape of the electrode array and stable mounting of the positioner to the electrode array and no rotation of the positioner. However, fractures of the lateral part of the modiolus were found near to the cochleostomy in two out of five bones.

The surgical technique was performed consistently as all five bones indicated by both rotational tomography (RT) and histology analysis that the electrode array and positioner were placed into the scala tympani in the proximal basal turn. Intracochlear trauma was not due to the processing of temporal bones as RT, performed prior to histological processing, already revealed electrode dislocation.

Mechanics of trauma: due to the greater stiffness of the electrode array together with the positioner a




(TS = tympanic scale; VS = vestibular scale; IAC = internal auditory canal)

FIG. 4

a) The electrode array is located in touch with the tender bone of the lateral modiolus wall without fracture (25 X). b) Fracture of Rosenthal's canal (circle) near to the cochleostomy possibly due to right-angled shape of the electrode array (25 X). c) Higher magnification (50 X) of the fractured region (arrows) indicating the nearness to the internal auditory canal.

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dislocation at the pressure point (approximately 180–250 degrees after insertion where the system will touch the outer cochlear wall) may occur in case of a deep insertion with fracture of OSL in the second half of basal turn (up to the whole length of positioner) and consequent dislocation of the electrode tip into the scala vestibuli. The intended directional preponderance of the electrode array may not be sufficient to prevent this dislocation if the mechanically induced pressure of the positioner is taken into account.

- **Study aims to assess the insertion mode and possible intracochlear trauma after implantation of the HiFocus® electrode with positioner in human temporal bones**
- **The position of the electrodes was evaluated using conventional x-ray analysis, rotational tomography and histomorphological analysis**
- **The results showed considerable trauma to fine cochlear structures including fracture of the osseous spiral lamina, dislocation of the electrode array for the scala tympani into the scala vestibule and fracture of the modiolus close to the cochleostomy**
- **The implications of these findings are discussed**

The fractures in Rosenthal's canal were observed close to the cochleostomy and seemed to be due to contact with the right-angled edge of the electrode array. The shape of the electrode array may in these cases be the reason for fracturing of these fragile structures. In cases of otitis media after cochlear implant surgery this might be a predisposing weak spot that allows the spread of infection to the internal auditory canal. In cases of bacterial labyrinthitis it is imaginable that, even if fractures of the OSL occur in the second part of the basal turn only, the risk of spread of infection to the cerebro-spinal-fluid space is increased due to the opening of the *habenula perforata* of the OSL.

Sealing of the cochleostomy with tissue is widely accepted as a closing procedure in cochlear implant surgery. Also animal trials[12] 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. It remains a matter of speculation whether the space left between the HiFocus® electrode and positioner that we observed in one temporal bone may also be a predisposing factor for infection spread inside the intracochlear spaces but it seems likely that the size of the cochleostomy may influence the reliability of sealing if the electrode array and positioner are not in very close contact with a space between them.

Recent reports of human implantation using the electrode positioner show significant reduction of stimulation thresholds as intended by the design of this space-filling, two-component perimodiolar electrode.[13] So far, there is no significant change or advantage in rehabilitation outcomes.[13,14] Human temporal bone studies of Clarion electrode systems with positioner are sparse.[7,9,15,16] However, up to now two investigating groups using histological evaluation reported significant trauma to fine cochlear structures.[9,16] So it has to be discussed whether an electropphysiological advantage alone justifies the use of the positioner.

## Conclusion

The HiFocus® electrode with positioner can produce considerable intracochlear trauma which seems to result from the design-specific mechanical features of this two-component electrode system. It is the responsibility of implanting surgeons and the manufacturer to critically rate these results in temporal bones and to decide on future use and possible changes in the design of this implanted electrode system *in vivo*.

With regard to our results and in the light of the present discussion of the possible risk of otogenic spread of bacterial infection, which may cause meningitis in cochlear implant patients, we strongly recommend further debate on the extent of intracochlear trauma acceptable in cochlear implant recipients together with surgical procedue (i.e. the size of cochleostomy necessary). This might influence the use, design and further development of intracochlear electrodes to reduce any risk of intracochlear trauma.

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