Cochlear Implantation Via the Round Window Membrane Minimizes Trauma to Cochlear Structures: A Histologically Controlled Insertion Study

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Objective—To evaluate cochlear implant trauma to intracochlear structures when inserting the electrode via the round window membrane.

Material and Methods—Eight fresh human temporal bones were evaluated histologically after insertion using two types of cochlear implant array. Bones underwent a special fixation and embedding procedure that allowed sectioning of undecalcified bone with the electrode in situ. Insertions depths were evaluated radiologically and histologically.

Results—All arrays were found in the scala tympani of the cochlea. Basal trauma could be avoided in all but one specimen. The mean depth of insertion was 382.5° . Apically, only one implanted bone showed cochlear trauma exceeding lifting of the basilar membrane.

Conclusion—Insertions through the round window membrane were shown to be atraumatic, even in basal cochlear regions. This route of insertion might be very effective for combined electric and acoustic stimulation of the auditory system. *Key words: cochlear implant, hearing preservation, intracochlear trauma, round window membrane.*

INTRODUCTION

Opening of the inner ear during surgery for cholesteatoma with perilymph fistula may result in profound hearing loss through a disturbance of the endolymph and perilymph compartment of the organ of Corti. However, clinical examples of inadvertent surgical ingress into the inner ear that resulted in normal cochlear function postoperatively (1-3) and routine opening of the inner ear during surgery for otosclerosis demonstrate the feasibility of inner ear surgery without functional impairment.

For regular cochlear implantation in deaf patients, hearing preservation during surgery is not an issue. However, since the introduction of combined electric and acoustic stimulation (EAS), hearing preservation during electrode insertion has become fundamental (4-7). Here, the principles during the operation are to use smooth, atraumatic electrode carriers and adapted surgical procedures. These surgical steps are currently under discussion because of our limited knowledge of the factors responsible for hearing preservation or loss.

As seen in histologic specimens of implanted temporal bones, insertion of electrode arrays into the cochlea in principle carries the potential to cause damage to cochlear structures (8-13). The importance of smooth electrode carriers to avoid cochlear trauma has become obvious (8, 9). New prototype electrode carriers aiming to reduce intracochlear trauma have already been evaluated in human temporal bones (unpublished data). With limited insertion depths and electrode contact distribution lengths, cochlear

trauma can be largely avoided. One remaining factor is surgical ingress into the scala tympani. Despite using a caudal approach cochleostomy, which is suggested to be the least traumatic, some bones showed severe destruction of basal cochlear structures adjacent to the site of bone drilling (unpublished data from our own series). To avoid surgical trauma, insertions through the round window membrane (RWM) might be effective. This study was therefore undertaken to evaluate cochlear implant electrode insertions through the RWM in a human temporal bone model. Special emphasis was placed on basal cochlear trauma caused by the surgical approach itself.

MATERIAL AND METHODS

Eight human temporal bones were harvested 10-24 h postmortem and implanted with 2 different cochlear implant (CI) arrays. Both arrays, the standard C40+ and the Flex EAS electrode, manufactured by MED-EL (Innsbruck, Austria), consist of two-component silicon bodies. Both carriers feature 12 electrode contacts, which measure 800 μ m × 500 μ m. In the C40+ electrode, all contacts are paired and placed on opposite sides of the array. The contact spacing is 2.4 mm. Contacts are connected via wires inside the electrode bodies. These wires measure 25 µm in diameter and are made of a platinum-iridium alloy. The Flex EAS electrode was specifically designed for EAS implantations. To contribute to the limited insertion depths aimed for in combined stimulation, contact spacing is reduced to 1.9 mm. The five most apical contacts are single, resulting in enhanced

flexibility, decrease in insertion forces and reduction of the apical electrode diameter. The total intracochlear length is 31.5 and 26.0 mm for the C40+ and Flex EAS carriers, respectively. Basal electrode diameters are 0.8 mm in both electrodes. The C40+ features an apical diameter of 0.5 mm, whereas the Flex EAS has an oval apical diameter due to single contacts at the tip region.

All bones were implanted using a standard approach used for cochlear implantation. A regular mastoidectomy was performed and a posterior tympanotomy hole was drilled. When approaching the round window from the posterior tympanotomy hole, the surgeon must be aware of the conical shape of the RWM, the crista and the osseous spiral lamina hidden beneath the postero-superior overhang of the round window niche. For better visualization of the promontory region, a tympano-meatal flap was created. A simple and safe procedure is removal of the anteroinferior overhang. This step is performed prior to removal of the crista fenestrae. The round window niche is usually covered either partially or completely by mucosal folds that should not be confused with the membrane itself. When in doubt, mobilization of the ossicular chain elicits a round window reflex (14). The depth and shape of the niche can vary considerably: the membrane may be easily visible or, at times, completely covered (15). The RWM was exposed and left intact in all bones and an incision was made at the very lateral part into the membrane. Thereafter, the electrode was inserted along the outer wall of the basal turn of the cochlea with a small fork instrument assisting from endaural. In this way, insertion along the lateral wall of the basal cochlear turn was achieved in all bones. All insertions were stopped at the point of first resistance to minimize cochlear trauma. After implantation, each electrode was fixed with sutures onto the remaining temporal bone. All insertions were performed by the same surgeon (O. A.) under standardized conditions. Then, all bones were fixed and embedded as follows. A special grinding/polishing technique, which allows sectioning of undecalcified bone, was used (16). For fixation of the implanted specimens, perilymphatic perfusion of buffered formalin solution was used. Dehydration was then performed using a graded ethanol series (70-100%). Embedding was accomplished with polymethylmethacrylate at room temperature.

An X-ray examination was performed to evaluate the correct plane for sectioning and the insertion depth in degrees around the modiolus. The orientation and location of the cochlea within the implanted specimen were clearly visible. Then, serial sections were cut with a slide thickness of 100 μ m. See Plenk (16) for a detailed description of the histologic procedure.

Microscopic evaluations of all specimens were made by two of the authors (O. A. and J. K.) independently. Only concordant findings were included in the study. Positioning of the electrode within the cochlea, the location and extent of trauma and the histological insertion depth were evaluated. To standardize the extent of resulting trauma, a grading scheme, recently published by Eshraghi et al. (17), was used (see Table I). Additionally, electrode diameters were measured to exclude swelling of the implant due to histological processing.

RESULTS

Utilizing temporal bone X-ray, insertion depths in degrees around the modiolus could be clearly evaluated (mean 393.8°; range $270-540^{\circ}$). It was also possible to determine the position and orientation of the cochlea within the temporal bone and to define the correct plane for sectioning in each specimen. Using the technique mentioned above, all specimens could be evaluated histologically. Microscopic measurements of the electrode diameter showed no swelling of the array by > 20% in any bone. Histological insertion depths ranged from 270° to 540° , with a mean of 382° . Surgically, a mean insertion depth of 26.5 mm (19–30 mm) was achieved.

Histologically, neighboring structures remained intact, showing no fractures or dislocations of membranes. Trauma to cochlear structures was clearly visible when present, and grading according to the grading scheme established by Eshraghi et al. (7) was possible in all bones (Table II, Fig. 1). In one specimen (No. 2), fracture of the osseous spiral lamina (grade 4) was seen over almost the entire length of the intracochlear part of the array with the exception of the 0- 30° region adjacent to the round window. Although no swelling of the electrode carrier could be evaluated, the relation of the electrode diameter to the dimensions of the scala tympani differed to that for all other specimens. In this case, a very small cochlea was implanted and the resulting trauma was related to the fact that the electrode did not fit into the scala tympani.

Table I. Classification of cochlear trauma (17)

Grade	Histopathological changes							
0	No trauma							
1	Elevation of basilar membrane							
2	Rupture of basilar membrane or spiral ligament							
3	Dislocation into scala vestibuli							
4	Fracture of osseous spiral lamina or modiolar wall							

No.	Side	Electrode	Insertion depth			Insertion depth (°) as a function of cochlear trauma grade				
			Surgical (mm)	Histological (°)	Radiological (°)	0	1	2	3	4
1	L	C40+	27	360	330	0-330	330-360	_		
2	L	C40+	30	450	540	0-30		_		30-450
3	L	C40+	30	540	540	90-270	270 - 360	_	360-540	0-90
4	L	C40+	26	360	360	0-360		_		
5	R	C40+	29	450	450	0 - 180	180 - 450	_		
6	L	C40+	25	270	300	0 - 270		_		
7	R	C40 +	26	270	270	0 - 270		_		
8	L	Flex EAS	19	360	360	0-360	_	_	_	_
Mean Min. Max.	$6 \times L$ $2 \times R$	$7 \times C40 + 1 \times Flex EAS$	26.5 19 30	382.5 270 540	393.75 270 540	247.5 30 360	130.0 30 270	_ _ _	180.0 180 180	255.0 90 420

Table II. Data on temporal bones, insertions and cochlear damage

Significant basal trauma could be avoided in all temporal bones with one exception (No. 3). We found grade 0 trauma for electrodes Nos. 1, 2 (small scala tympani; grade 4; $30-450^{\circ}$) and 4-8 (basal cochlear parts). In two bones (Nos. 1 and 5), slight lifting of the basilar membrane (grade 1) could be seen in the middle cochlear turn. In one bone (No. 3; C40+; 540°) the array dislocated into the scala vestibuli apically. As grade 1 only represents slight dislocation of the basilar membrane, real trauma (> grade 1) was seen in only two of the eight specimens. All other temporal bones showed no destruction of cochlear

structures. Also, the bony wall of the modiolus remained intact in all specimens. Detailed data concerning the electrodes used and the resulting trauma are shown in Table II. Illustrative histological pictures are shown in Figs 2–4.

DISCUSSION

Data from our own temporal bone experiments using regular caudal approach cochleostomies showed severe basal trauma (grade 4) in almost 30% of implanted bones. This trauma is related to the surgical



Fig. 1. Insertion graph for all implanted specimens. The extent of cochlear trauma in relation to the location within the cochlea (in degrees around the modiolus, starting at 0° at the RWM) is shown. Electrodes Nos. 1-7 = C40+; Electrode No. 8 = Flex EAS.



Fig. 2. Temporal bone No. 4, C40+ standard electrode, basal cochlear turn, no trauma to cochlear structures.

approach into the cochlea, i.e. cochleostomy. Personal communications with other research groups studying CI trauma in fresh human temporal bones confirms that finding (basal trauma seen in one-third to onefifth of cases). Therefore, this study was conducted to evaluate whether or not basal trauma can be avoided using the RWM for electrode insertions. Surgically, the round window was a convenient access for electrode insertion in all specimens implanted. The creation of a tympano-meatal flap from endaural enhances the visibility of the promontory region and round window niche. Histologic data confirmed deep insertions into the scala tympani and showed details of the temporal bone anatomy. Using the grading scheme established by Eshraghi et al. (17), the extent and location of cochlear trauma were evaluated for each bone. The results showed that insertions were atraumatic, especially in the basal parts of the cochlea where surgical trauma could be avoided in all but one specimen (12.5% of cases).

Nowadays, cochlear implantations are usually performed using a cochleostomy approach, whereas,



Fig. 3. Temporal bone No. 8, Flex EAS electrode, basal cochlear turn, no trauma.



Fig. 4. Temporal bone No. 5, region of the RWM, no trauma to the osseous spiral lamina and attached structures.

in the early days of cochlear implantation, insertions through the RWM were standard (18–21). The round window itself is not round, but rather triangular (22, 23). In 541 temporal bones, the niches had a mean width of 1.66 mm (range 0.48– 2.7 mm) (24). In 460 temporal bones, the same authors measured a mean depth of 1.34 mm (range 0.69-2.28 mm). Mean values were similar for all age groups. The membrane itself has an average size of 2.3 mm × 1.87 mm (23). Although individual values varied considerably, placement of a standard CI array with a maximum diameter of 1.0–1.2 mm through the RWM should be possible in almost every case.

Avoiding basal trauma might be one of the key factors contributing to hearing preservation in cochlear implantation for combined EAS. In a recent paper (7), hearing preservation was seen in six patients implanted for combined stimulation via the RWM. In our series of 18 patients, hearing preservation was possible in all but 2 subjects when using a caudal approach cochleostomy. Additionally, nine patients showed partial loss of residual hearing after surgery. Complete or partial loss of apical cochlear function may be the result of basal trauma, even when these regions are not in direct contact with a CI array. Longitudinal flow of cochlear fluids might lead to a spread of toxic factors released by the localized trauma in the basal parts. Such a flow is usually not seen in healthy organs; however, when creating a second membrane leak (basilar membrane rupture represents the first leak) through either drilling the cochleostomy hole or a RWM incision, a pathological cochlear flow could be created (25). Because the exact mechanisms of cochlear trauma that lead to hearing loss in implantations for combined stimulation remain unclear, mechanical trauma of any kind to cochlear structures should be avoided.

Another issue in cochlear implantation, namely unintentional implantation into the scala vestibuli, has also been discussed recently (personal communication and data from our own series). These unwanted insertions were seen in almost one-fifth of temporal bones implanted, even when performing caudal cochleostomies. Unintentional as well as intentional insertions into the scala tympani result in great basal trauma, in addition to rupture of Reissner's membrane in almost every temporal bone implanted. Such insertions have to be avoided when aiming at hearing preservation. The cause of unintended scala vestibuli insertions may be related to anatomic variations in the position and orientation of the basilar membrane within the basal cochlear turn. Variations in these anatomical structures cannot be identified externally. As shown in this study, unintentional lesions to the basilar membrane can be avoided by using the round window as an exact anatomical landmark that is always in direct continuity with the scala tympani. This will be a key factor in surgery for combined stimulation with the aim of preserving hearing.

CONCLUSIONS

Smooth implantations via the RWM resulted in deep, atraumatic insertions into the scala tympani. Furthermore, the degree of basal trauma was lower when compared to bones implanted using a regular cochleostomy approach. The absence of basal cochlear trauma may be a major factor in cochlear implantation with the aim of hearing preservation. Additional anatomic studies examining the possible variances of structures lying within the cochlea should shed light on the mechanisms of basal cochlear trauma.

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