

ORIGINAL ARTICLE

Combining perimodiolar electrode placement and atraumatic insertion properties in cochlear implantation – fact or fantasy?

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Abstract

Conclusions. Except for basal cochlear traumatization, all specimens implanted into scala tympani showed atraumatic insertion properties and good perimodiolar electrode positioning. Cochleostomy preparation and placement can have a significant impact on levels of basal cochlear trauma. **Objective.** In the past, perimodiolar cochlear implant electrodes increased the risk for intracochlear traumatization when compared to free-fitting arrays. Recently, however, clinical evidence for atraumatic perimodiolar implantations with preservation of residual hearing has been described. The aim of this paper was to histologically evaluate a perimodiolar cochlear implant array for its insertion properties in cadaver human temporal bones. Surgical and electrode factors, as well as preparation artifacts influencing intracochlear trauma, were considered in the evaluation. **Materials and methods.** Sixteen human temporal bones were harvested up to 24 hours post mortem and implanted immediately with the Nucleus 24 Contour Advance cochlear implant electrode array. Implantations were either performed using a regular caudal approach cochleostomy or through the round window membrane. After implantation, all bones underwent special histological processing, which allowed sectioning of undecalcified bone. Insertion properties were evaluated according to a grading system. **Results.** Fourteen specimens were implanted into scala tympani and only two exhibited basal trauma attributable to electrode insertion characteristics. Two bones were implanted into scala vestibuli after causing trauma in the region of the cochleostomy. Insertion depths ranged from 180° to 400°. All bones showed good perimodiolar electrode positioning. Basal trauma due to surgical issues and histological artifacts was present in 10 of 16 bones.

Keywords: Cochlear implant, perimodiolar electrode, intracochlear trauma, hearing preservation, electric acoustic stimulation

Introduction

With the expansion of candidacy criteria for cochlear implantation to patients with substantial residual hearing, atraumatic implantation has become a great topic of interest. The development of specific surgical procedures and shorter, free-fitting electrode arrays resulted in at least partial preservation of pure tone audiometric thresholds in >90% of patients [1]. Postoperatively, remaining ipsilateral acoustic hearing was combined with a cochlear implant to provide simultaneous electric acoustic stimulation (EAS) of the auditory system – a principle first described by von Ilberg in 1999 [2]. The combination of electric and acoustic stimuli on the same ear leads to markedly improved speech perception scores in noise. This additional benefit,

however, depends on the amount of residual acoustic hearing and therefore on an atraumatic electrode implantation.

Since the introduction of EAS, several principles of realizing this method have been described [3–6]. For each way, candidates should exhibit substantial low frequency hearing with profound to complete hearing loss in the high frequency portions of the cochlea. This allows electrode insertions into the basal, high frequency regions and preservation of remaining, apical, deep frequency portions of the cochlea that are left without an array. The aim of EAS implantations therefore is to provide electric stimulation of high frequencies to approximately 1000 Hz – an area corresponding to 360° (18–22 mm using a free-fitting array)

intracochlear length measured from the round window membrane [7].

Recently, results from EAS implant recipients who were implanted with an improved electrode (Nucleus 24 Contour AdvanceTM, Cochlear Corp., Melbourne, Australia) were presented [8]. This electrode combines insertions of about one full cochlear turn and perimodiolar array placement. In the past several years, multiple perimodiolar electrode designs have been developed. Reports on initial designs demonstrated markedly increased traumatization of intracochlear structures [9,10]. However, since energy-saving properties and improved channel separation were postulated for such implants, manufacturers have focused on the design and development of atraumatic but perimodiolar electrode placement [11,12].

Preliminary data from the clinical study mentioned above – using the perimodiolar Nucleus 24[®] Contour AdvanceTM electrode – showed at least partial preservation of residual hearing in all five patients [8]. The purpose of this investigation therefore was to assess the intracochlear insertion properties of the Nucleus[®] 24 Contour AdvanceTM in human cadaver temporal bones. Histological parameters were related to surgical factors, electrode design, and preparation artifacts and conclusions were drawn regarding possible hearing preservation in routine cochlear implant surgeries.

Materials and methods

Sixteen human temporal bones were harvested maximally 24 hours post mortem and implanted with a Nucleus[®] 24 Contour AdvanceTM cochlear implant electrode array. This array features a modified tip that should facilitate atraumatic implantations. A perimodiolar electrode positioning is achieved via the preformed intracochlear portion, which is 19 mm long – from the very tip to the space between the second and third blind ring right outside of the cochlea. The array features 22 platinum contacts that are located on the modiolar surface of the electrode body. The electrode diameter reduces from 0.8 mm basally to 0.5 mm at the most apical electrode contact. Prior to insertion, the array is straightened with a stylet, which is placed into the central lumen of the electrode's silicon body (factory configuration). The array is first inserted until the marker ring, which is placed 8.5 mm from the very tip of the electrode, reaches the cochleostomy. Then, the insertion is continued while the stylet at the basal end of the electrode body is held in place. This gradually retracts the stylet out of the electrode body, and the advancement of the array is performed along the inner wall of the cochlea. With proper handling,

no direct force is directed against the outer wall of the cochlea and a perimodiolar position is achieved. This special implantation technique was described as the Advance OffstyletTM (AOS) technique [13].

All specimens were implanted using a regular cochlear implant approach using a mastoidectomy and posterior tympanotomy. Twelve of the 16 bones were implanted through a caudal approach cochleostomy. Here, great emphasis was placed on the location of the cochleostomy onto the promontory bone and the angle of electrode insertion. The anterior inferior bony overhang over the round window niche was removed and an inferior approach cochleostomy was carefully drilled. An insertion angle parallel to the anticipated outer wall of the basal cochlear turn was chosen. This was performed to reduce basal cochlear traumatization observed in prior histological reports [14,15]. All implantations were then conducted according to the AOS technique described above. Structures not necessary for implantation were removed prior to further histological processing.

Four bones were implanted through the round window membrane. Here, the anterior inferior part of the bony overhang covering the round window niche was removed first using a 1 mm diamond burr. The annulus of the round window membrane was visualized and an incision was made in the lateral portion of the membrane. Electrode implantations were then performed through the round window membrane along the outer wall of the basal cochlear turn and the AOS technique was applied during all four insertions in this group [16].

After implantation, all bones were relayed to histological processing. First, each specimen underwent fixation via perilymphatic perfusion of buffered formalin solution and dehydration with an ascending series of alcohol (70–100% ethanol). Then, each bone was slowly embedded with polymethylmethacrylate at 20°C for about 4 weeks to avoid air bubbles. After embedding was completed, a conventional X-ray of each specimen was performed to determine the radiological insertion depth in terms of degrees around the modiolus and the correct plane for sectioning (orthogonal to the axis of the basal cochlear turn). Radiological insertion depths were evaluated according to Xu et al. [17,18].

All bones then underwent serial sectioning using a special sawing-grinding-polishing technique developed by Plenk [19]. Specimens were stained with Giemsa.

After histological processing, all implanted bones were evaluated independently by two of the authors (O.A. and M.H.U.). Representative results were documented photographically.

Each specimen was analyzed according to a standardized protocol already used in prior reports [15,16]. This protocol includes evaluation of electrode position within the cochlea, and grading of cochlear trauma according to a grading scheme (Table I) established by Eshraghi et al. [20], and evaluation of the cochleostomy region. Additionally, all electrode diameters were measured to provide information about swelling artifacts due to the histological embedding procedure. Distances perpendicular to the longitudinal axis of the electrode were measured with an integrated measuring tool (Carl Zeiss, Goettingen, Germany) at the site of the cochleostomy and at 360° (or at the site of the last visible electrode contact if an insertion depth of <360° was accomplished).

To distinguish the mechanisms of basal traumatization, the cochleostomy site was analyzed and basal cochlear traumatization was classified into buckling, swelling, or drilling. Buckling referred to bulging of the basal end of the electrode into the basilar membrane or the osseous spiral lamina, where the drilling cone of the cochleostomy itself did not interfere with intracochlear structures. Drilling referred to traumatization of basal cochlear structures through the drilling of the cochleostomy itself, and swelling described basal traumatization due to a swelling artifact, where the electrode tended to become scala filling and the osseous spiral lamina altered from a straight structure into one that exhibited a curved morphology [12].

Results

Using the described histological processing technique, insertion properties including the exact location of the electrode within each temporal bone and the resulting trauma could be clearly evaluated. Also, thorough evaluations of the site of the cochleostomy were possible in every specimen. Basal cochlear trauma could be ascribed to one mechanism (buckling, drilling, or swelling) in all specimens where it was observed (Tables II and III). Surgically, all bones were fully implanted (the second blind ring remains outside the cochlea) using the AOS technique, which proved to be easy to handle.

Table I. Grading scheme for classification of cochlear trauma [20].

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

Also, all X-rays provided clear and detailed information about radiological insertion depths and section planes for serial sectioning. Of the 16 bones, 8 were right ears and 8 were left bones. Radiological insertion depths ranged from 180° to 400°. The average for the cochleostomy group was 336.3° (from 180° to 400°) and the mean value for the round window membrane insertions was 337.5° (from 270° to 360°). Data regarding histologic insertion depths correlated well with the radiological findings – mean values were 358.3° (from 180° to 400°) and 355.0° (from 300° to 400°) for the cochleostomy and the round window membrane group, respectively. One bone showed a very shallow insertion of 180° only. Further histologic evaluation of this specimen revealed a slightly malformed and large basal cochlear turn.

Basal grade 4 trauma (fracture of the osseous spiral lamina) was seen in 10 of the 14 bones implanted in the scala tympani. Of the 12 specimens implanted via a caudal cochleostomy, 9 (75%) showed basal grade 4 trauma, 4 of them revealed histological signs of a swelling artifact (electrode was scala filling and osseous spiral lamina alters to a curved shape), 1 specimen showed signs of basal electrode buckling in conjunction with slightly high cochleostomy placement, and 4 bones showed histological evidence of basal trauma due to drilling of the cochleostomy (the drilling cone of the cochleostomy pointed towards the spiral ligament and the basilar membrane). Two of the specimens that showed basal drilling trauma were primary implanted into the scala vestibuli with an overall insertion depth of 360° and 400°. In the group of specimens implanted via cochleostomy, basal trauma was present over an average length of 80.0° (from 30° to 90°, if present). In one of the specimens (no. 4), no trauma was found from 180° to 300°; however, a slight lifting of the basilar membrane from 300° to 400° insertion depth (grade 1) was observed. All other bones implanted through a cochleostomy approach showed no further intracochlear trauma (grade 0) over the entire remaining apical length of insertion apart from the basal trauma described above.

Three of the four (75%) bones implanted via the round window membrane showed a grade 4 basal trauma over an average length of 35.0° (from 30° to 45°). One bone (no. 15, 25%) was completely atraumatic over the entire implanted length of the array. In the three remaining specimens implanted through the round window membrane, no further apical trauma was observed (grade 0). Two bones showed traumatization of basal cochlear structures through buckling of the electrode and one bone

Table II. Insertion data for temporal bones implanted via caudal approach cochleostomy.

Specimen no.	Electrode	Side	Insertion depth (°)			Extent of cochlear trauma*					Basal trauma†	Array diameter‡	
			Surgery	Histology	Radiology	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4		Basal	360°
1	Contour Softip	Left	Full	360	330	0–360					No	1007	666
2	Contour Softip	Right	Full	400	360	0–30, 90–400				30–90	Buckling	884	627
3	Contour Softip	Right	Full	360	400				90–360	0–90	Drilling	1046	747
4	Contour Softip	Right	Full	400	375	180–300	300–400			0–180	Swelling	1006	569
5	Contour Softip	Right	Full	180	180	45–180				0–45	Swelling	1075	736
6	Contour Softip	Left	Full	360	330	30–360				0–30	Drilling	1024	669
7	Contour Softip	Left	Full	400	400				90–400	0–90	Drilling	860	714
8	Contour Softip	Right	Full	400	400	45–400				0–45	Drilling	866	702
9	Contour Softip	Left	Full	360	300	90–360				0–90	Swelling	1060	568
10	Contour Softip	Right	Full	360	360	90–360				0–90	Swelling	1041	674
11	Contour Softip	Links	Full	360	270	0–360					No	1239	488
12	Contour Softip	Right	Full	360	330	0–360					No	1171	593
Min				180°	180°							860 µm	488 µm
Max				400°	400°							1239 µm	747 µm
Mean				358.3°	336.3°							1023.2 µm	646.1 µm
Median				360.0°	345.0°							1032.5 µm	667.5 µm

Basal cochlear trauma was evaluated according to the presence or absence of direct traumatization through the drilling cone of the cochleostomy or indirect basal buckling of the array into the basilar membrane and adjacent structures [14].

*From–to values in degrees around the modiolus, trauma classification according to Eshraghi et al. [20].

†Classification of basal cochlear trauma refers to different mechanisms of basal cochlear traumatization. Drilling refers to basal cochlear traumatization due to the surgical drilling procedure. Buckling refers to an indirect traumatization due to a basal buckling of the array into the basilar membrane and the osseous spiral lamina.

‡Array diameter refers to measurements of the diameters (perpendicular to the axis) of the embedded electrodes (in µm). Basal refers to measurements at the basal end of the electrode at the site of the cochleostomy, whereas 360° refers to measurements at one full turn from the round window membrane (if insertion depths were less than one full turn, measurements were performed at the site of the most apical electrode contact). Normal electrode diameters 800 µm at the basal end and 500 µm at 360°.

Table III. Insertion data for specimens implanted through the round window membrane.

Specimen no.	Electrode	Side	Insertion depth (°)				Extent of cochlear trauma*				Array diameter†	
			Surgery	Histology	Radiology	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Basal trauma†	Basal
13	Contour Softip	Left	Full	400	360	30-400			0-30	Buckling	909	758
14	Contour Softip	Left	Full	360	360	45-360			0-45	Swelling	1098	671
15	Contour Softip	Right	Full	360	360	0-360				No	896	615
16	Contour Softip	Left	Full	300	270	30-300			0-30	Buckling	1010	523
Min				300°	270°						896 µm	523 µm
Max				400°	360°						1098 µm	758 µm
Mean				355°	337.5°						978.25 µm	641.75 µm
Median				360°	360°						959.5 µm	643 µm

Results show basal traumatization in three of four bones (75%) via indirect trauma mechanism (basal buckling) [14].

*In degrees around the modiolus, trauma classification according to Eshraghi et al. [20].

†Classification of basal cochlear trauma refers to different mechanisms of basal cochlear traumatization. Buckling refers to an indirect traumatization due to a basal buckling of the array into the basilar membrane and the osseous spiral lamina.

‡Array diameter refers to measurements of the diameters (perpendicular to the axis) of the embedded electrodes (in µm). Basal refers to measurements at the basal end of the electrode at the site of the cochleostomy, whereas 360° refers to measurements at one full turn from the round window membrane (if insertion depths were less than one full turn, measurements were performed at the site of the most apical electrode contact).

revealed histological evidence of basal traumatization due to swelling of the electrode array.

In summary, of the 16 bones in the study, there were 14 scala tympani insertions and 2 scala vestibuli insertions. Of the 14 scala tympani insertions, basal trauma due to electrode buckling or due to drilling of the cochleostomy was seen in 5 specimens. Slight apical trauma (grade 1) due to the electrode was observed in one sample.

Also, no fractures of the bony modiolar wall occurred in any specimen implanted in this study. Furthermore, all electrodes showed good perimodiolar placement and no apical kinking could be observed. Detailed data on all temporal bones implanted via cochleostomy approach are compiled in Table II and Figure 1, and data on bones implanted through the round window membrane are shown in Table III and Figure 2. Data on electrode swellings due to the long exposure (>2 weeks to avoid bubbling) of the silicone body to polymethylmethacrylate during histological processing are included in Tables II and III. Examples of histologic images of intracochlear electrode placement and associated trauma are shown in Figures 3-6.

Discussion

In this report, we could clearly evaluate intracochlear trauma and electrode positions after implantation of a perimodiolar cochlear implant array in human cadaver temporal bones. All specimens clearly demonstrated consistent perimodiolar electrode positioning and minimal apical trauma. Avoiding electrode misplacements and extensive basal cochlear destruction was the main intent during all surgical implantations performed by experienced cochlear implant surgeons. Four of 16 bones (25%) exhibited no histological evidence of intracochlear trauma. Significant basal trauma was observed in 12 of 16 bones (75%). Only 2 of the 12 bones (13%) resulted in intracochlear trauma attributable to electrode insertion characteristics alone; both were round window insertions. Five (42%) of these 12 bones showed clear histological evidence of a swelling artifact [12]. Also, 2 of the 12 bones (17%) were unintentionally implanted into the scala vestibuli of the cochlea as a result of cochleostomy drilling [21]. A high risk for damaging basal cochlear structures during drilling of a promontory cochleostomy has already been described in previous reports [14,15,21]. Compared with other reports, this study shows a very high likelihood of basal cochlear trauma using the Nucleus 24® Contour Advance™ electrode carrier. In another study, intracochlear trauma was successfully minimized using electrode insertions through the round window

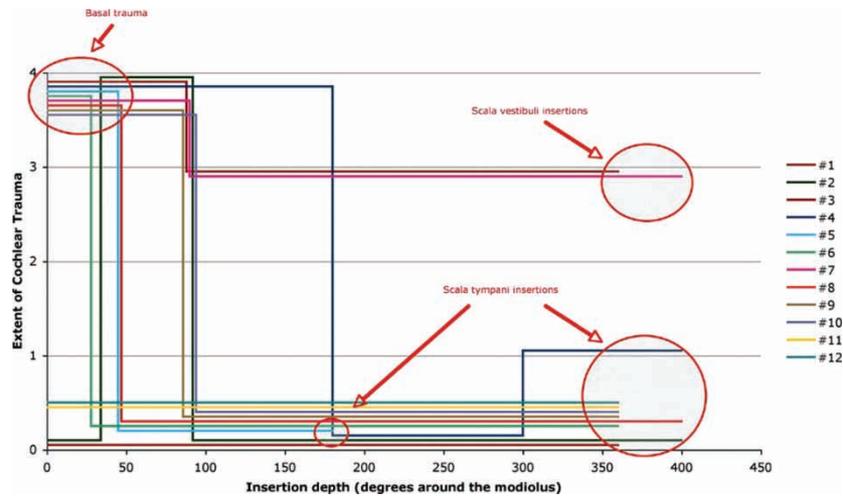


Figure 1. Insertion graph of 12 specimens implanted via caudal approach cochleostomy. Location and grading [20] of cochlear traumatization are visualized. Basal trauma was present in 9 of 12 bones (75%). One bone (8%) shows a slight apical elevation of the basilar membrane. All other bones (92%) show no trauma in the apical portions of the electrode. Two bones (17%) were implanted into the scala vestibuli of the cochlea.

membrane [16]. However, this could not be observed in the present study, since the risk of destruction of basal cochlear structures was similar in both groups. This could be due to the greater stiffness of the Nucleus 24[®] Contour Advance[™] electrode (with the stylet still in situ during the initial phase of the insertion process) compared with the MED-EL array tested in the previous study.

One possible drawback of the grading scheme used in this and other publications to standardize trauma reporting is that grade 4 trauma is not further distinguished. This leads to grade 4 classifications in this report, where only slight fractures of the osseous spiral lamina without further damage are seen. Although such trauma certainly affects hearing performance in this cochlear region, fluid hemody-

namics and ion gradients should not be disturbed. Grade 2 trauma on the other hand includes membrane ruptures, which presumably lead to more widespread intracochlear damage. Even though 75% of the specimens observed in this paper present with a basal grade 4 trauma, widespread apical hearing loss is not likely. In fact, no bone implanted into the scala tympani during this study shows membrane ruptures. However, scala vestibuli insertions need to be prevented, since ruptures of Reissner’s membrane are a logical consequence, as has been shown in previous literature [21].

Although early perimodiolar electrode designs resulted in marked increase of intracochlear trauma, potential psychophysical benefits and energy-saving properties led to further developments in this field.

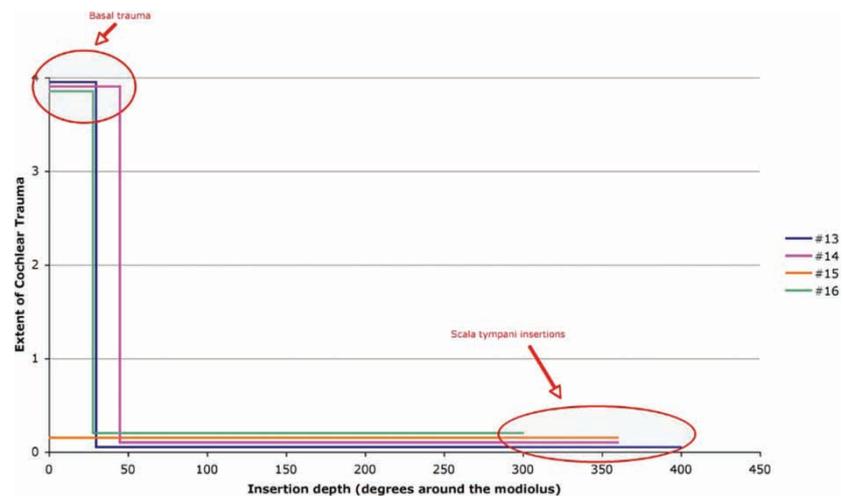


Figure 2. Insertion graph of four bones implanted through the round window membrane. Location and grading [20] of cochlear trauma are displayed. One bone (25%) shows no basal trauma, three bones (75%) produce a basal grade 4 trauma (fracture of the osseous spiral lamina). All electrodes lie against the modiolar wall of the scala tympani causing no further apical trauma.

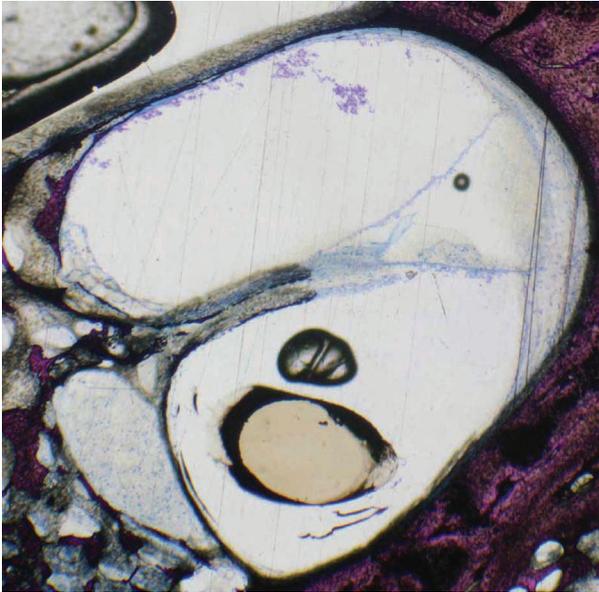


Figure 3. Histologic image of temporal bone no. 9; electrode tip in the scala tympani in middle cochlear turn. No visible cochlear trauma, 360° insertion.

Perimodiolar arrays for, example, led to statistically significant decreases in EABR wave V thresholds and increased suprathreshold wave V amplitudes – at least for some electrode contacts, as was discussed in one report comparing perimodiolar and free fitting cochlear implant arrays [22]. Furthermore, placement of perimodiolar electrodes resulted in less electrical current necessary to stimulate the auditory system [10,22].

The main issue in cochlear implantation with hearing preservation still remains the surgical ingress into the scala tympani. Advanced preoperative imaging with navigation-assisted surgeries might help to solve this problem. Basal trauma, in addition to many other factors, might also be responsible for

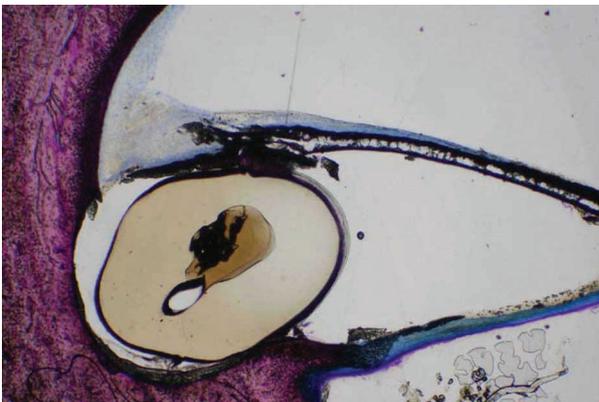


Figure 4. Histologic image of temporal bone no. 1; site of the cochleostomy – the drilling cone can be seen on the left side of the picture; the array was inserted into the scala tympani causing no visible basal cochlear trauma. Round window membrane on the bottom of the picture.

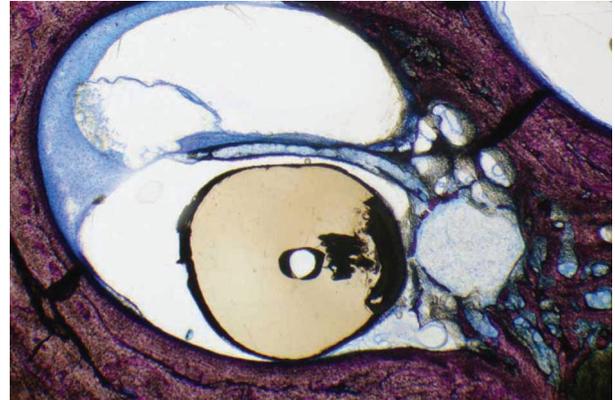


Figure 5. Histologic image of specimen no. 8; electrode in the end of the basal cochlear turn, no visible intracochlear traumatization, the electrode lies close to the modiolar wall resuming a perimodiolar positioning throughout the implanted length. Slight swelling of the silicone body (< 20%).

the varying degrees of hearing preservation observed in patients in our clinical EAS trial [1,23,24].

Conclusion

Implantations in human cadaver temporal bones with the Nucleus 24[®] Contour Advance[™] electrode carrier resulted in perimodiolar and apically atrau-

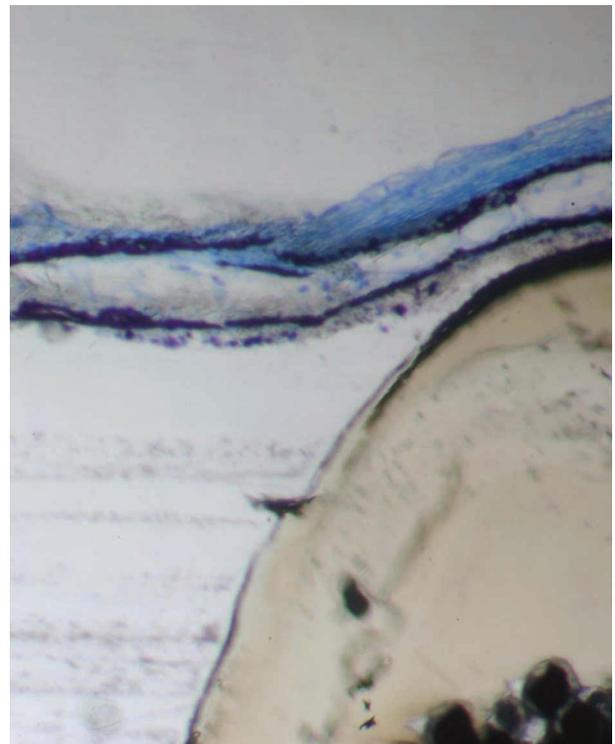


Figure 6. Temporal bone no. 10; fracture of the osseous spiral lamina in the basal cochlear turn caused by buckling of the electrode. Although graded as severe intracochlear destruction (grade 4 [20]), no ion disturbances are expected, because no membrane leaks are evident.

matic electrode insertions. Also, insertions through the round window membrane were not less traumatic than cochleostomy insertions with this electrode. Although basal traumatization was present in some specimens, hearing preservation is likely in most cases, as judged by morphological criteria. Further investigations examining the exact mechanisms of basal cochlear damage should be conducted.

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