

Reliability of cone beam computed tomography in scalar localization of the electrode array: a radio histological study

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Abstract Postoperative imaging plays a growing role in clinical studies concerning prognostic factors in cochlear implantation. Indeed, intracochlear position of the cochlear implant has recently been identified as a contributor in functional outcomes and radiological tools must be accurate enough to determine the final placement of the electrode array. The aim of our study was to validate cone beam computed tomography as a reliable technique for scalar localization of the electrode array. We performed therefore a temporal bone study on ten specimens that were implanted with a perimodiolar implant prototype. Cone beam reconstructions were performed and images were analyzed by two physicians both experienced in cochlear implant imaging, who determined the scalar localization of the implant. Temporal bones then underwent histological control to document this scalar localization and hypothetical intracochlear lesions. In four cases, a dislocation from

scala tympani to scala vestibuli was suspected on cone beam reconstructions of the ascending part of the basal turn. In three of these four specimens, dislocation in pars ascendens was confirmed histologically. In the remaining temporal bone, histological analysis revealed an elevation with rupture of the basilar membrane. Histological assessment revealed spiral ligament tearing in another bone. We conclude that cone beam is a reliable tool to assess scalar localization of the electrode array and may be used in future clinical studies.

Keywords Cochlear implant · Cone beam computed tomography · Dislocation · Temporal bone histology

Introduction

Cochlear implants can restore excellent speech recognition, but variability in outcomes remains a constant feature especially in post-lingually deafened adults [1–4]. Among factors accounting for this variability, duration of deafness is probably the most critical one [1, 3, 4]. Experience with CI is also reported as an important contributor in patients' outcomes, with a potential improvement of performance up to 3.5 years after implantation [3]. Other variables, such as age for post-lingually deafened implanted adults or cause of deafness (meningitis) also contribute to the variability in CI users' outcomes [3].

More recently, scalar localization of the electrode array and its consequences on hearing performance has also been investigated [5, 6]. Indeed, as soft surgery has been more and more promoted through the past 10 years, intracochlear placement of the electrode array has been the focus of increasing interest. Scala tympani is the optimal place for electrode array insertion, as terminal sensorineural

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structures and spiral ganglia are more likely to be damaged in a scala vestibuli placement [7]. Aschendorff and colleagues [5] first assessed speech recognition scores as a function of scalar localization and found poorer results in patients where the electrode array was inserted in the scala vestibuli or dislocated from scala tympani to scala vestibuli as compared to patients where the electrode array remained in the scala tympani, for similar deafness durations. Negative impact of dislocation or scala vestibuli insertion was also highlighted in Finley et al. study [6] using a linear regression analysis among CNC words recognition among 14 subjects. Although histological control was not provided in these studies, Lecerf et al. validated high-resolution CT scan (HRCT) midmodiolar reconstructions showing a high radio anatomic concordance after microdissection of implanted temporal bones [8].

Cone beam computed tomography has recently been recognized a valuable tool for morphologic assessment of the temporal bone. Its increased spatial resolution as compared to HRCT scan [9] might enhance the quality of cochlear implant imaging. Cushing et al. [10] demonstrated its ability to detect the number of electrodes inserted in the cochlea and a kinking in the electrode array. In their study, one dislocation from scala tympani to scala vestibuli was correctly identified on cone beam computed tomography reconstructions. We focused our interest on the latter parameter; namely, its capacity to evaluate the precise position of the electrode array inside the cochlea. Therefore, our study aimed at assessing the reliability of cone beam computed tomography in determining the scalar localization of the implant. We used cone beam reconstructions of implanted temporal bones to assess electrode location, which were subsequently histologically sectioned to verify the results of the cone beam reconstructions.

Materials and methods

Ten fresh temporal bones without any otological pathology were provided by the anatomy laboratory and were implanted with a perimodiolar electrode array. After insertion, cone beam computed tomography was performed and scalar localization of the electrode array was determined by both an otologist (MM) and a neuroradiologist (BE). Histological analysis was performed at Cochlear Limited (Sydney Australia).

Surgical procedure

In each temporal bone, an antromastoidectomy and a posterior tympanotomy were performed. The round window area was prepared with careful drilling of the bony overhangs that surround the round window membrane itself. In each bone, a single experienced surgeon (BF)

inserted a pre-curved prototype perimodiolar electrode array, currently under evaluation by Cochlear Ltd. This prototype was an early version of the modiolar research array (MRA) [11], which is pre-curved and held straight prior to insertion by an external sheath. Its diameters are 0.3 mm at its apical tip and 0.5 mm at the basal end. The external sheath (diameter 0.65 mm) is removed after insertion. In all specimens, the intended site for insertion was scala tympani. In four bones, the electrode array was inserted through the round window after an incision of the membrane performed with a micro-hook. In the six other bones, the insertion was performed using an extended round window approach. Thus, the round window membrane was incised at its anteroinferior ridge and the crista fenestra was curetted. The electrode array was then secured by application of histoacryl glue to the proximal electrode cable at the facial recess level.

Radiologic evaluation

The system used was a vertical NewTom VGI (NewTom, Verona, Italy). The temporal bones were immobilized using polystyrene boards and a high-resolution protocol was implemented. The system used a 200 × 25 mm flat panel detector at 650 mm from the radiation source. The 360° rotation of the X-ray tube took 18 s. Tube voltage was 110 kV, with a 19 mA charge at the terminals. Total filtrations were 2 mm and pitch 125 μm, with field of view corresponding to a 12 × 7.5 cm diameter cylinder. Acquisition began frontal and lateral to the temporal bone and lasted 18 s. Images were reconstructed in 125 μm isometric voxels and obtained in axial, coronal and sagittal planes, using the software provided by NewTom.

Then, sagittal oblique reconstructions were performed to obtain slices perpendicular to the axis of the basal turn. A 3D referential was positioned in the middle of the modiulus, with the *x* axis in the direction of the basal turn of the cochlea and the *y* axis in the direction of the modiulus. The *z* axis determined the image perpendicular to the axis of the basal turn, including a series of midmodiolar reconstructions and reconstructions in the plane of the ascending part of the basal turn. Reconstructions in the pars ascendens of the basal turn allowed to visualize the electrode array trajectory in this area which is particularly at a risk for dislocation [12]. Images were then rotated ±90° to obtain reconstructions in a vertical direction.

Scalar localization of the electrode array was determined separately by an otologist and a neuroradiologist, both experienced in cochlear implants imaging and both unaware of the surgical conditions. Theoretical positions of scala tympani and scala vestibuli were determined basing on anatomical characteristics of cochlear partition. In series of midmodiolar reconstructions presented in a vertical

direction, scala tympani is localized in the inferior part of a half-turn section of the cochlea and scala vestibuli in the superior part, as described in Lecerf et al.'s study [8]. For the temporal bones, where the electrode array remained in the inferior part of the basal turn, we inferred scala tympani localization. Diagnosis of dislocation from scala tympani to scala vestibuli relied on the visualization of the change in trajectory of the electrode array, and on the identification of the implant in the inferior part of the basal turn for its proximal portion (scala tympani) and in the superior part of the basal turn for its distal tip (scala vestibuli).

Histological analysis

Histological analyses were performed after a standardized processing of temporal bones, described in several previous studies [13, 14]. In each bone, the stapes footplate was removed to allow perfusion of the fixative, dehydrating solutions and the acrylic resin throughout the cochlea. The specimens were then fixed in 10 % formalin, dehydrated in ethanol using serial concentrations progressing from 70 to 100 % and immersed in degassed epoxy resin to achieve acrylic fixation. Vacuum was applied so that the epoxy resin infiltrates the cochlea completely.

Excess portions of the temporal bone specimens within the epoxy blocks were trimmed to leave only the cochleae. After embedding the specimens were X-rayed to assess the correct mid-modiolar plane for sectioning. The cochlear specimens were then serially sectioned using a grinding technique with a section thickness of 200 μm . For each section examined, the specimen was polished and stained with toluidine blue and light microscopy and photography performed. Scalar localization of the electrode array was thus objectively documented and intra cochlear trauma was evaluated using a grading scale of 0–4, developed by Eshraghi et al. [15].

Results

Radiological evaluation

The results of sagittal oblique reconstructions, and especially mid modiolar and pars ascendens reconstructions analyses were similar between the two physicians. For both of them, the electrode array was properly inserted in the scala tympani in six of the temporal bones (TB 1, TB 2, TB 3, TB 4 and TB 10). After an initial trajectory in the scala tympani, a dislocation from scala tympani to scala vestibuli was suspected in the remaining four temporal bones (TB 5, TB 6, TB 7, and TB 9). Figure 1a clearly shows a modification in the trajectory of the electrode array in TB 6, moving from the inferior part of the basal turn in its proximal portion to the superior part at the end of pars ascendens in its distal portion. Figure 1b further illustrates the scalar localization of the electrode array, positioned in the inferior part of the first half-turn section, and then placed in the superior part of the next half-turn section. In TB 5, the dislocation was related to a tip fold over of the electrode array at the end of the ascending part of the basal turn. The four dislocations were located in pars ascendens. The insertion depth angle varied between 220° (TB 5, tip fold over) and 460° (TB 1, TB 10) with a mean value of 375°.

Histological analysis and radiohistological concordance

The results of histological analysis were reported as a function of cochlear depth in Table 1. A dislocation from scala tympani to scala vestibuli was observed in TB 5, TB 6 and TB 7. In these three bones, histological analysis revealed a disruption of the basilar membrane in pars ascendens due to the electrode array, in the 90°–135° depth section in TB 5, and in the 180°–225° depth section in TB 6

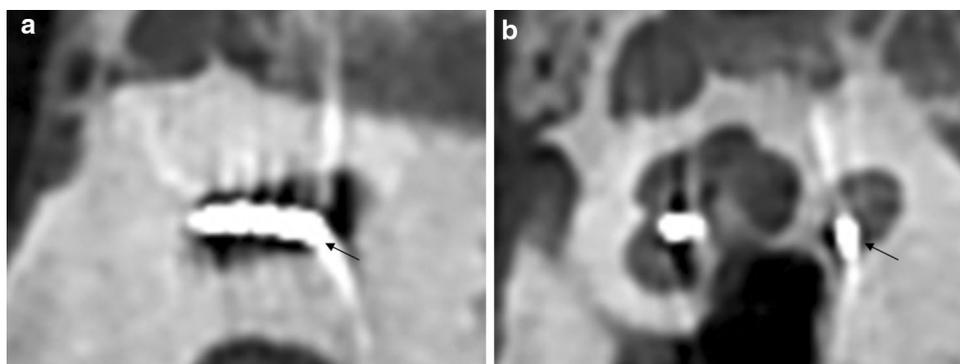


Fig. 1 Dislocation on cone beam reconstructions. **a** Electrode array is moving from inferior part of pars ascendens (scala tympani, *black arrow*) to superior part (scala vestibuli). **b** Midmodiolar reconstruction showing trajectory modification from inferior part of half-turn

section to superior part in next half-turn section. Note the limited metallic artefact and the aeric hypodensity that surrounds the electrode array

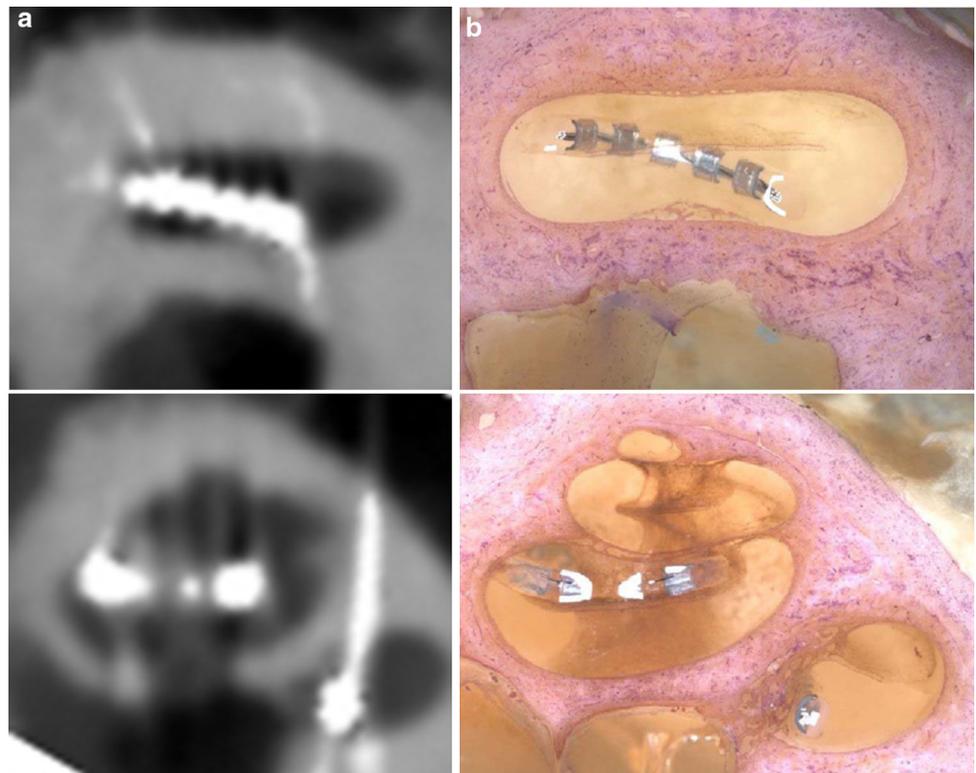
Table 1 Intra cochlear trauma in the ten temporal bones as a function of insertion depth angle

Bone <i>n</i> °	Insertion angle									
	0–45°	45–90°	90–135°	135–180°	180–225°	225–270°	270–315°	315–360°	360–405°	405–450°
TB 1	0	0	0	0	0	0	0	0	0	0
TB 2	0	0	0	0	0	1	0	0		
TB 3	0	0	0	0	0	2	2			
TB 4	0	0	0	0	0	0	0	0	0	0
TB 5	0	0	3	3	3					
TB 6	0	0	0	0	3	3	3	3	3	
TB 7	0	0	0	0	3	3	3	3		
TB 8	0	0	0	0	0	0	0	0	0	0
TB 9	0	0	0	0	0	2	2			
TB 10	0	0	0	0	0	0	0	0	0	0

Grade 0, no trauma; Grade 1, elevation of the basilar membrane; Grade 2, rupture of basilar membrane or spiral ligament; Grade 3, dislocation into scala vestibuli; Grade 4, fracture of modiolus or osseous spiral lamina

The grading scale used was Eshraghi's scale (see [15])

Fig. 2 Radio histological concordance for scala vestibuli dislocation diagnosis in TB 7. **a** Cone beam reconstructions. **b** Corresponding histological sections

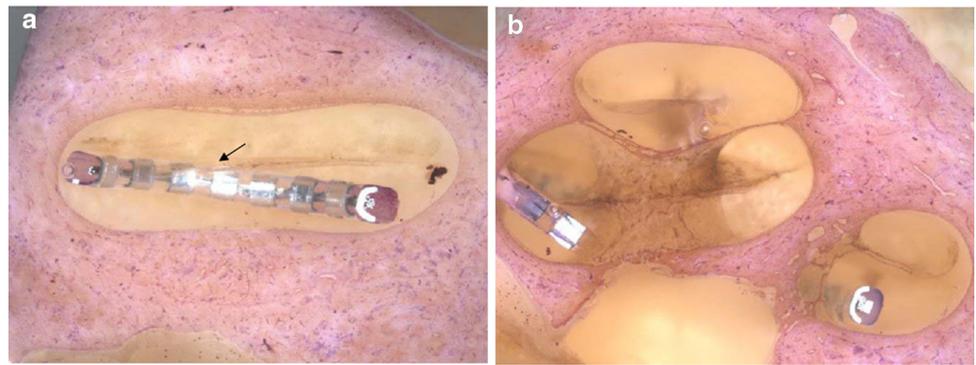


and TB 7. Besides these three dislocations, histological analysis showed more minor intra cochlear lesions in TB 2 (elevation of basilar membrane), in TB 3 and TB 9 (rupture of spiral ligament and elevation of basilar membrane). Figure 2 illustrates the concordance between radiological (a) and histological (b) findings in TB 7. The only discordance between cone beam findings and histological analysis was observed in TB 9 where both the otologist and the neuroradiologist concluded a dislocation. In this

specimen, histology revealed a significant elevation of the basilar membrane and spiral ligament rupture (see Fig. 3) but without any migration from scala tympani to scala vestibuli.

In summary, the three dislocations documented with histological analysis were previously detected on series of mid modiolar and pars ascendens reconstructions, which makes cone beam's sensitivity of 100 % in our study. In one temporal bone, we overestimated the move from

Fig. 3 Histological analysis in TB 9. **a** Elevation with rupture of the basilar membrane (*black arrow*) starting in pars ascendens. **b** Elevation with rupture of the basilar membrane and the spiral ligament by the electrode array in mid modiolar section



inferior part of the basal turn to the superior part at the end of pars ascendens and concluded to a dislocation, whereas histology showed an elevation of basilar membrane. This specimen should be considered as a false positive of the cone beam analysis of which therefore the specificity was 90 %.

Discussion

Assessing intra cochlear position of the electrode array: which radiological tools?

Several imaging techniques have been used to evaluate scalar localization of the implant [16–18]. With a particularly high-spatial resolution, micro-CT scan stands as the most precise tool for cochlear imaging. Indeed, its spatial resolution can reach up to 18 μm precision and allows a correct visualization of spiral lamina, even with the metallic artefact surrounding the electrode array [16]. However, thinner connective structures, such as basilar membrane or spiral ligament can currently not be visualized properly in micro-CT images obtained of implanted cochleae, and so therefore we still require histological evaluation to identify trauma in these cases. Micro-CT scan cannot be used as a clinical tool, as it requires a volume reduction of anatomic specimens, with dimensions approximating two centimetres long over three centimetres high. However, it has been used in several temporal bones studies to validate HRCT as a reliable method for evaluation of the implant position [16, 18].

In one temporal bone, Lane et al. [16] showed that, when compared with micro CT scan, HRCT correctly localized the cochlear implant in the scala tympani. Teymouri et al's study [18] included 16 implanted temporal bones and compared HRCT scan's accuracy for determining each electrode contact position to both micro CT and histology. A 97 % agreement was found between HRCT and micro CT and 95 % between HRCT and histological evaluation. In Lecerf et al's report [8], HRCT's

midmodiolar reconstructions provided a correct localization of the implant with high sensitivity (87.5 %) and specificity (100 %).

In our study, cone beam computed tomography reached high sensitivity (100 %) and specificity (90 %) levels. These results are comparable to HRCT's findings and provide a validation of the method that was used in Aschendorff's series [5, 19] regarding speech perception scores as a function of implant position. Cone beam offers another significant advantage regarding the radiation dose, which may be 8–22 times lower than HRCT scan [9].

Intra cochlear lesions related to cochlear implantation and their clinical consequences

In our study, dislocations from scala tympani to scala vestibuli and other cochlear damage were mainly initiated between 90° and 270° depth from the round window. This cochlear segment corresponds to the ascending part of the basal turn, i.e pars ascendens, which has been identified as a vulnerable region in several reports. In a temporal bone study by Wardrop et al. [20], the cochlear segment between 90° and 270° was systematically involved when a trauma related to implantation was observed. Stöver et al. [21] identified the 180° depth angle as the most frequent site for dislocation in their temporal bone assessment of a perimodiolar designed electrode array. Pars ascendens seems therefore to be the key region in intra cochlear trajectory of the implant. This vulnerability is probably related to the constant narrowing of the scala tympani in this area, with an average reduction of 300 μm in its diameter between 90° and 180° [12]. Orientation of the pre curved electrode arrays when inserting the implant might also have an impact on intra cochlear trauma and especially dislocations. Indeed, as the electrode array advances in basal turn, it should remain in the scala tympani axis and should not move upwards in direction of the basilar membrane.

Electrode array dislocations into scala vestibuli destroy scala media and its content, including organ of Corti remnants that may be still functional. Thus, dislocations should

absolutely be avoided in cases where residual hearing is to be preserved. Aschendorff et al. [5] also found an impact of dislocations on speech recognition in patients with short deafness duration. Dislocations into scala vestibuli might lead to an increased loss of spiral ganglion cells that may account for the poorer results obtained in these patients. Finley et al. [6] suggested the role of a cross-turn stimulation, as an electrode dislocated into scala vestibuli may excite ganglion cells in scala tympani of the current turn and but also ganglion cells in scala tympani of the upper turn, leading to a similar stimulation in both turns.

Other studies emphasized the potential damages in the hook region of the cochlea, and more specifically the secondary lesions of vestibular end organs [22, 23]. For instance, Handzel et al. [22] found a collapsed saccule and a hydropic scala media in 10 of the 17 implanted temporal bones of their series. These lesions might be due to the basal trauma after round window or promontory electrode insertion, responsible for an injury of the ductus reuniens. From a clinical point of view, Todt et al. [24] showed an increased loss of saccular function and post operative vertigo when the electrode array was inserted through an anterior cochleostomy compared to a round window insertion.

Conclusion

Cone beam allows determining the scalar localization of the electrode array with a high sensitivity (100 %) and specificity (90 %). It is therefore valid to use this tool in clinical studies that assess the impact of implant position on speech recognition. Imaging and histology identified the ascending part of the basal turn as the most critical region in implant trajectory. This localized vulnerability should be taken into account in further improvements of electrode design and mechanics.

Conflict of interest The implant prototypes were provided by Cochlear Limited. Histological evaluation was performed by Cochlear Limited.

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