

OTOLOGY

# 3D curved multiplanar cone beam CT reconstruction for intracochlear position assessment of straight electrodes array. A temporal bone and clinical study

## *Ricostruzione multiplanare 3D di immagini cone beam per l'identificazione della posizione degli impianti cocleari. Studio su ossi temporali e pazienti impiantati*

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### SUMMARY

A retrospective review of post-op cone beam CT (CBCT) of 8 adult patients and 14 fresh temporal bones that underwent cochlear implantation with straight flexible electrodes array was performed to determine if the position of a long and flexible electrodes array within the cochlear scalae could be reliably assessed with CBCT. An oto-radiologist and two otologists examined the images and assessed the electrodes position. The temporal bone specimens underwent histological analysis for confirm the exact position. The position of the electrodes was rated as scala tympani, scala vestibule, or intermediate position for the electrodes at 180°, 360° and for the apical electrode. In the patient group, for the electrodes at 180° all observers agreed for scala tympani position except for 1 evaluation, while a discrepancy in 3 patients both for the 360° and for the apical electrode assessment were found. In five temporal bones the evaluations were in discrepancy for the 180° electrode, while at 360° a disagreement between raters on the scalar positioning was seen in six temporal bones. A higher discrepancy between was found in assessment of the scalar position of the apical electrode (average pairwise agreement 45.4%, Fleiss  $k = 0.13$ ). A good concordance was found between the histological results and the consensus between raters for the electrodes in the basal turn, while low agreement (Cohen's  $k = 0.31$ , pairwise agreement 50%) was found in the identification of the apical electrode position confirming the difficulty to correct identify the electrode position in the second cochlear turn in temporal bones. In conclusion, CBCT is a reliable radiologic exam to correctly evaluate the position of a lateral wall flexible array in implanted patients using the proposed imaging reconstruction method, while some artefacts impede exact evaluation of the position of the apical electrode in temporal bone and other radiological techniques should be preferred in ex vivo studies.

KEY WORDS: Cone Beam CT • Cochlear implants • Electrode position • Histology • Temporal bone

### RIASSUNTO

*Questo studio riporta un'analisi retrospettica delle immagini cone beam CT effettuate su 8 pazienti adulti sottoposti ad impianto cocleare MedEl flex 28 e su 14 ossi temporali impiantati con lo stesso tipo di array portaelettrodi. Lo scopo dello studio è di determinare l'affidabilità della metodica cone beam CT nella valutazione della posizione intracocleare degli elettrodi in impianti che si posizionano lungo la parete laterale del lume cocleare, quindi non perimodiolari la cui posizione è più facilmente identificabile. Un otoradiologo e due otologi hanno analizzato le immagini e assegnato la posizione per ciascun elettrodo localizzato nella regione dei 180° e dei 360° del primo giro cocleare e per l'elettrodo apicale scegliendo tra scala timpanica, vestibolare o posizione intermedia. L'analisi istologica ha successivamente confermato l'esatta posizione negli ossi temporali. Nel gruppo dei pazienti per l'elettrodo a 180° i tre esperti concordavano sulla posizione in scala timpanica in tutti eccetto un paziente, mentre una discordanza nella valutazione era presente in 3 pazienti per gli elettrodi a 360° e per gli elettrodi apicali. Negli ossi temporali in 5 casi era presente una discordanza per l'elettrodo a 180°, mentre a 360° sei valutazioni erano discordanti tra i valutatori. Una discordanza tra le valutazioni più elevata veniva trovata per la la posizione dell'elettrodo apicale (concordanza valutatori 45.4%, Fleiss  $k = 0.13$ ). Un buon grado di concordanza veniva trovato tra i risultati istologici e le valutazioni tra i valutatori per gli elettrodi localizzati nel giro basale; un grado più basso esisteva per la posizione degli elettrodi apicali (concordanza valutatori 50%, Cohen's  $k = 0.31$ ) confermando la difficoltà nella corretta valutazione della posizione degli elettrodi nella regione più apicale negli ossi temporali. In conclusione, le immagini cone beam postoperatorie analizzate con la metodica della ricostruzione multiplanare 3D rappresentano una metodica affidabile per lo studio della posizione intracocleare degli elettrodi a posizionamento laterale nei pazienti impiantati. La corretta identificazione del posizionamento dell'elettrodo più apicale risulta difficile su osso temporale per la presenza di un artefatto più importante o per la minore resistenza delle strutture della parete laterale della coclea (legamento spirale, membrane basilare) nel preparato istologico (osso temporale fresco/congelato) che è responsabile di un maggior numero di traslocazioni dalla rampa timpanica alla rampa vestibolare e di localizzazioni intermedie più difficilmente interpretabili.*

PAROLE CHIAVE: Cone beam CT • Impianti cocleari • Posizione elettrodi • Istologia

## Introduction

The indications for cochlear implantation during the last decades have extended including not only the severe-profound bilateral deafness, but also sensorineural hearing loss involving only medium-high frequencies or single sided deafness. The so-called soft or minimally invasive surgery and its principles are regularly applied to the standard procedures in cochlear implantation not only in hearing preservation surgeries. In this context, pre- and post-operative imaging have gained importance both for planning of surgery, choice of kind and length of the electrode array to be implanted and correct evaluation of the position of the implanted array<sup>1</sup>. The use of cone beam CT (CBCT) in otology has increased during the last years with a lower dose cross-sectional technique for visualising bony structures in the ear<sup>2</sup> providing a better resolution than multislice helical CT for the bone structure with strong density contrast<sup>3</sup>. Several studies reported the reliability to assess the scalar position of electrodes array using CBCT in isolated temporal bones<sup>4-8</sup> or whole cadaveric heads<sup>9</sup>, but the possibility to apply these results in a real clinical situation on cochlear implanted patients has not been studied in detail. The scalar position of the electrodes in implanted patients was analysed in a study including precurved and straight arrays implanted in 61 ears<sup>10</sup> but the reliability of the radiological exam was not reported. Moreover, the results might change in function of the different implanted arrays (i.e. perimodiolar or straight array). Studies in cochlear implanted temporal bones reported excellent reliability in scalar localisation of precurved perimodiolar array<sup>4-8</sup>, while for slim straight electrodes the position assessment still remains difficult in some cases<sup>6,8</sup>. Diogo et al.<sup>9</sup> reported a lower degree of cochlear implant (CI) metal artefacts in the images of the whole head in comparison with the same isolated temporal bones that present reduced soft-tissue absorption of radiation, but it was still difficult to evaluate the precise location in the more apical regions of the cochlea. Another issue to take in account is the artefact due to the movement of the patient, which is completely absent in studies on cadaveric specimens, considering the duration of the CBCT exam longer than other radiological imaging techniques of the ear. The aim of this study was to validate the 3-dimensional curved multiplanar reconstruction in CBCT images as a method for the assessment of long straight cochlear implant electrodes array scalar position in implanted adult patients and compare the results with a temporal bone radio-histologic study using the same electrode array and surgical technique.

## Materials and methods

The scalar position of two electrodes located in the basal turn of the cochlea and a third located in the second turn

in temporal bones and in adult implanted patients was assessed by an expert otoradiologist and two otologists by reviewing the CBCT reconstruction images. The scalar position and the ratings of the temporal specimens were successively confirmed by histological analysis. Each step is described in detail below.

### *Temporal bones*

Fourteen fresh temporal bones (seven left and seven right from the same subjects) were prepared with a simple mastoidectomy and posterior tympanotomy. The MedEl flex 28 arrays (Innsbruck, Austria) used for this study were provided by the manufacturer. The temporal bone was fixed to an in-house made temporal bone holder and the electrodes arrays were inserted through an extended round window approach using an in-house made motorised insertion tool<sup>11</sup>. This tool comprised a rotary actuator (RE10CLL, MDP, Miribel, France) connected to a threaded screw that pushed a blunt pin into an insertion tube loading the array. The tool was held steady by a flexible arm. The actuator speed was controlled via laboratory power supply and set at 0.8 mm/sec. The round window was irrigated with saline serum and sodium hyaluronate (Healon, Abbott Medical Optics, Abbott Park, Illinois, USA) was applied before CI insertion. A cone beam CT (CBCT) scan (NewTom 5G, QR s.r.l. Verona, Italy) was performed on the temporal bone specimens after the CI insertion.

### *Patients*

Eight adult patients (nine ears) cochlear implanted with MedEl flex 28 arrays in the cochlear implant program at a tertiary referral centre where prospectively enrolled in a study and accepted to receive a CBCT postoperatively. All patients were operated by the same experienced CI surgeon (EDS) via standard retroauricular approach followed by mastoidectomy and posterior tympanotomy, and extended round window insertion of the array. The patients were discharged at day 1 postsurgery and received a CBCT scan one to three months postimplantation; the activation of the CI was performed between 3 and 4 weeks postoperative. Patients signed a written informed consent, study was approved by the local IRB and performed in accordance with the principles of the 1983 Declaration of Helsinki.

### *Imaging*

The NewTom 5G CBCT scanner (NewTom, Verona, Italy) was used both for patients and temporal bones using the same setting. The system setup used a 200 x 25 mm flat panel detector at 650 mm from the radiation source. One 360° rotation of the x-ray tube took 36 sec. The tube voltage was 110 kV, with a 19-mA charge at the terminals. Total filtrations were 2 mm, with a pitch of 125 µm; this corresponded to a field view of 12 x 7.5 cm diameter. The

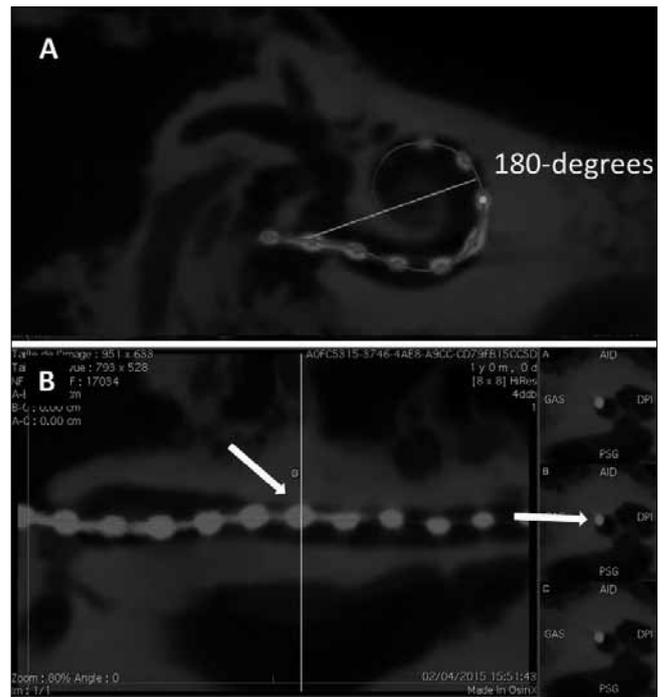
images were isometric voxel rendered from the 125  $\mu\text{m}$  sections.

#### Scalar position assessment

Two otologists and an expert otoradiologist reviewed the CBCT images and assessed the position of the electrode array within the cochlea. The DICOM (Digital Imaging and Communications in Medicine) data were analysed by Osirix program (Osirix v 4.0 64-bit; Pixmeo Sarl, Bernex, Switzerland). This program allowed the realisation of multiplanar reconstructions for the evaluation of the scalar position of the arrays was used for the measurements of the cochlear sizes. The largest cochlear diameter (distance A) going from the centre of the round window membrane to the opposite lateral wall<sup>12</sup> as well as the angular depth of insertion, were calculated on a plane perpendicular to the modiolus axis and coplanar to the basal turn<sup>13</sup>. The round window was considered as the 0° reference angle in accordance with the consensus of cochlear coordinates<sup>14</sup>. The reconstruction plane for the evaluation of the electrodes position was the midmodiolar plane obtained with the curved multiplanar reconstruction (3D curved MPR viewer in Osirix®). This plane was defined as a 3D Bezier path along the electrodes array. Once the path is defined by means of the selection of all the single electrodes the array is straightened and visible in the curved MPR viewer window. In this window the cochlear lumen and the electrodes array can be easily visualised in a dynamic series of midmodiolar section of the cochlea (Fig. 1, for a demonstration video see: <http://www.youtube.com/watch?v=aHDEISNiooU>). The raters assigned the localization scala tympani, scala vestibuli or intermediate position for each of the electrodes positioned at 180°, 360° and for the apical electrode both for the temporal bone implanted specimens and for implanted patients.

#### Histological procedures

Immediately after its insertion in temporal bones the electrode array was fixed with cyanoacrylate glue to the round window region to avoid any displacement during the successive steps. Cochlea was removed from the temporal bone and was fixed in 10% buffered formalin. The specimen was successively dehydrated in graded alcohol and casted in methyl methacrylate resin (10% Polyethylene Glycol 400, 20% Technovit 7200 VLC, Heraeus Kultzer GmbH, Germany; 70% Methylmethacrylate). The specimen was sawed (Leica SP 1660 Saw Microtome, Nussloch GmbH Germany, sawing speed 3) perpendicularly to the basal turn passing through the round window and the images under white light microscope were obtained for the two parts. The half cochlea was successively grinded to visualize the apical electrode if the first cut did not allow its visualisation.



**Fig. 1.** 3D curved multiplanar reconstruction (MPR) of the electrode array in a temporal bone. A. The electrodes were first selected with the 3D MPR tool defining a 3D Bezier path connecting all the electrodes together. B. This function permitted to straightened electrode array and follow it along its trajectory in the cochlear lumen in a dynamic way across a continuous series of midmodiolar reconstruction of the cochlea (MPR views on the right down panels). The arrow shows the translocated electrode. The between electrodes part of the array has a very limited metallic artifact thus the assessment of the electrode position results easier in this portion of the array.

#### Statistical analysis

Results are reported as means  $\pm$  SD. Inter-rater reliability was calculated using the Fleiss' kappa for three raters and the Cohen's kappa for two raters as appropriate. The averaged pairwise percent agreement among raters for each of the 3 examined electrodes was calculated. "R" statistical software (<http://www.r-project.org>) was used for statistical analysis.

## Results

Table I reports pre- and postoperative cochlear measurement in patients and temporal bones. The mean distances A were  $9 \pm 0.1$  mm and  $9 \pm 0.07$  mm in patients and temporal bones respectively. Among patients, the full insertion of the array was achieved in six ears (angular depth of insertion  $498 \pm 17$  degrees), while in three ears a partial insertion was found. In temporal bones, 8 arrays were fully inserted (angular depth of insertion  $464 \pm 20$  degrees).

#### Electrode position in implanted patients

There was an overall high agreement within raters for the

**Table I.** Preoperative and postoperative measurements in temporal bones and patients.

Patient	Distance A (mm)	Angular depth of insertion	Inserted electrodes
1	9.77	480	12
2	9.16	533	12
3	8.93	512	12
4R	8.82	422	12
4L	8.62	507	12
5	9.35	407	10
6	8.91	403	11
7	8.92	461	11
8	9.1	535	12
Temporal bones			
1R	9.07	440	12
1L	9.49	400	12
2R	8.67	270	8
2L	8.85	369	10
3R	9.52	365	11
3L	9.46	387	11
4R	9.22	412	12
4L	8.77	520	12
5R	9.13	472	12
5L	9.02	514	12
6R	8.45	404	11
6L	8.42	529	11
7R	9.48	522	12
7L	9.52	434	12

assessment of the electrodes position within the cochlea (Fig 2). The intracochlear position for the electrode at 180° in the implanted patients showed a great concordance among raters with only 1 evaluation in disagreement, one evaluator rated as inferior an electrode rated as intermediate for the other two evaluators (average pairwise agreement 92.5%, Fleiss  $k = 0.46$ ). For the electrode at 360°, three evaluations were not in agreement between raters (average pairwise agreement 88.8%, Fleiss  $k = 0.38$ ). For the position of the apical electrode the raters were more

discordant with 4 evaluations in disagreement (average pairwise agreement 70.3%, Fleiss  $k = 0.35$ ). A consensus on the position of the electrodes from the three raters was obtained after rereading the images and two arrays resulted translocated, both in the second turn (Fig. 2 B-C).

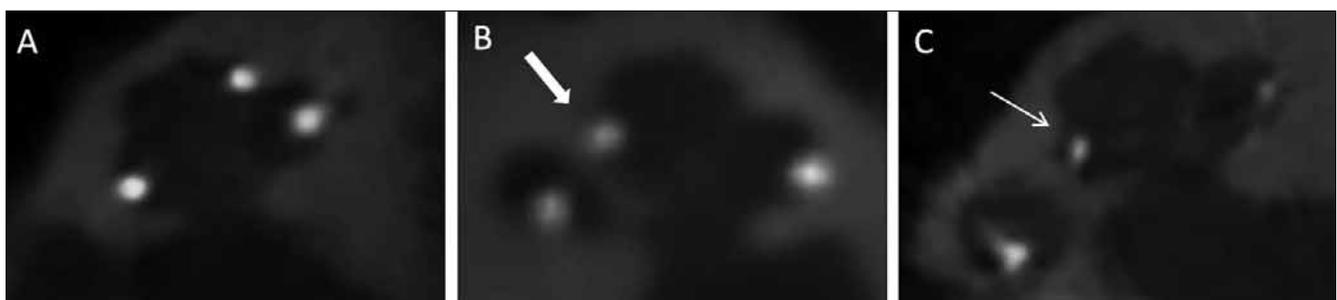
#### *Electrodes position in temporal bones*

In temporal bones, the rate of agreement was similar to that found in implanted patients for the electrode at 180° (average pairwise agreement 71.5%, Fleiss  $k = 0.48$ ) and for the electrode at 360° (average pairwise agreement 61.9%, Fleiss  $k = 0.35$ ) (Fig. 3). In five temporal bones, the evaluations were in discrepancy for the 180° electrode, while at 360° disagreement on the rating of the scalar positioning was in six temporal bones. A higher discrepancy between rater was found in assessment of the scalar position of the apical electrode (average pairwise agreement 45.4%, Fleiss  $k = 0.13$ ). In one temporal bone, the raters were in total disagreement with the same apical electrode assessed either as SV, ST or intermediate position (Fig 4). A collective statement on the position of the electrodes from the three raters was obtained after rereading the images; this statement was compared to the histological results.

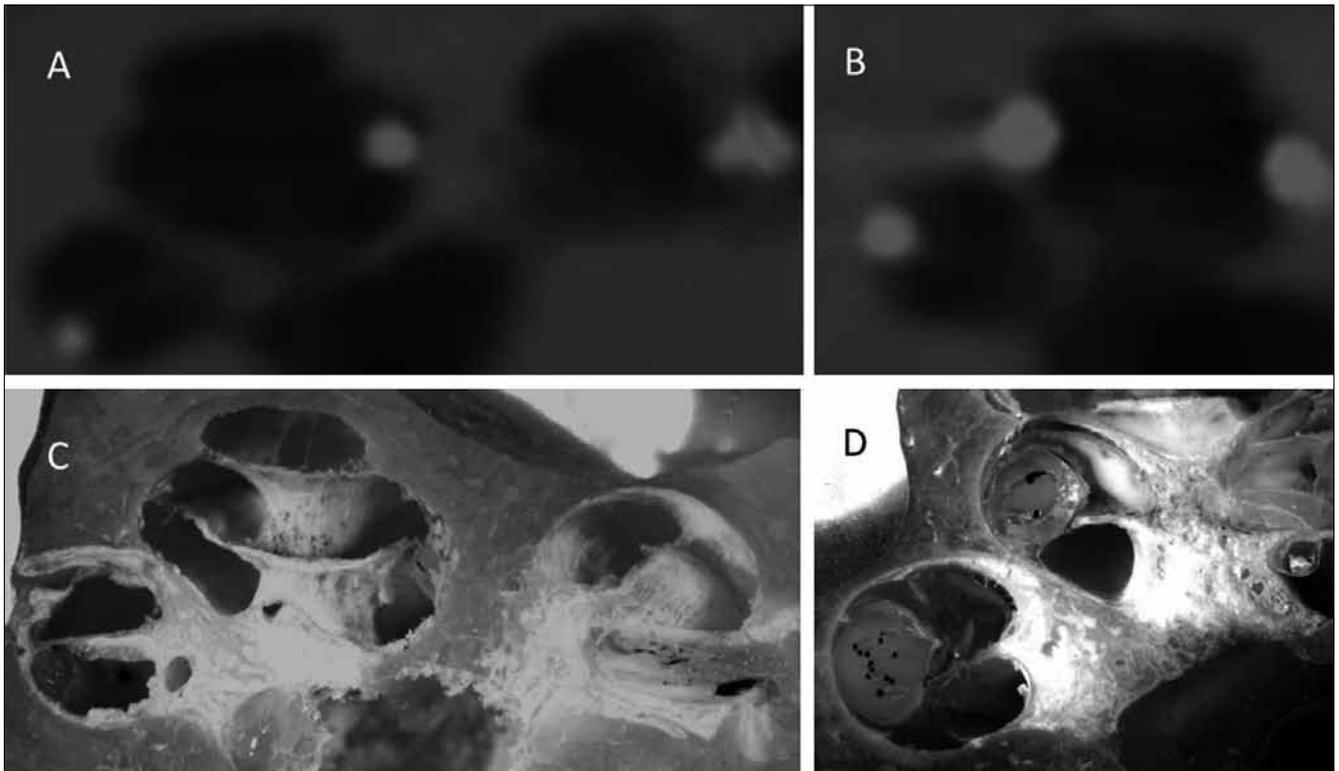
The histological analysis confirmed the localisation of the electrodes and showed a translocation between scala tympani and scala vestibuli in 6 temporal bones (42%). All the translocation occurred between 150° and 180°. A good concordance was found between the histological results and the consensus between raters for the electrodes at 180° (Cohen's  $k = 0.54$ , pairwise agreement 78.7%) and 360° (Cohen's  $k = 0.71$ , pairwise agreement 85.7%). The identification of the apical electrode position after the consensus between raters was poor (Cohen's  $k = 0.31$ , pairwise agreement 50%), highlighting the difficulty to correctly identify the electrode position in the second cochlear turn in temporal bones.

## Discussion

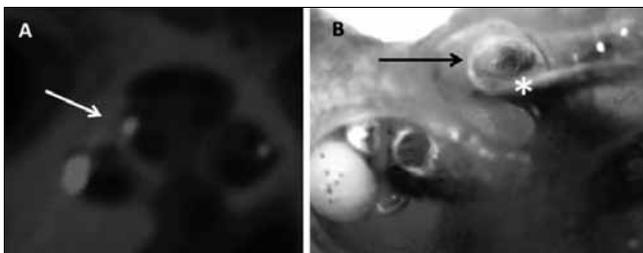
In this study, the CBCT scan was confirmed to be a reliable radiological technique for assessment of intracochle-



**Fig. 2.** Cone beam CT in cochlear implanted patients. In A, all raters indicated the three electrodes in scala tympani position. The apical electrode in B (thick arrow) was indicated by all raters as translocated. In C the apical electrode (thin arrow) was considered in intermediate position by two raters and translocated by one, and finally considered as a traumatic insertion after consensus.



**Fig. 3.** Electrode array in the scala tympani position (left) and in scala vestibuli (right) in temporal bone specimen. In these examples a full concordance on the electrode localisation on CBCT images (A, B) was obtained among the three raters and after the histological analysis that confirmed the electrode position (C, D).



**Fig. 4.** Difficulty in the assessment of the apical electrode. A. In this specimen the raters assessed the electrode (white arrow) either as scala vestibuli, scala tympani or intermediate position. B. The histology confirmed the translocation (black arrow). \* Osseous spiral lamina.

ar location of straight and flexible electrodes array in adult implanted patients. In temporal bones, the assessment of the more apical electrodes was more difficult than in patients. The 3-dimensional curved multiplanar reconstruction as a method to evaluate the electrode position helped to standardise the methodological technique among the raters and was a reliable, rapid and easy tool for intracochlear identification of electrode positions.

Several studies investigated the reliability of the CBCT on the scalar position assessment of cochlear implants. For precurved arrays, Marx et al. <sup>7</sup> reported a high sensitivity (100%) and specificity (90%) in scalar assessment locali-

sation of the array), while in another study the exact position was reviewed correctly by CBCT in 11 of 13 cases (85%) <sup>4</sup>. The position of a precurved electrode array was reported to be correctly assessed in the oblique sagittal plane <sup>15</sup> or using midmodiolar reconstruction even in multislice CT, with a radioanatomic correlation of 0.94 (0.89-0.98) after the consensus of two raters <sup>16</sup>.

The identification of electrode position could be different using different kind of electrodes array and could result easier for precurved electrodes. Indeed, the perimodiolar position of the electrode array is more consistent than that of straight electrodes <sup>8</sup>. The presence of osseous spiral lamina clearly divides the medial portion of the cochlear lumen into two compartments and the electrode is firmly held by this bony structure either in a lower or higher position i.e., tympanic or vestibular ramp. In contrast, the lateral wall of the cochlear lumen has a rounded shape and the spiral ligament being less resistant is deformed or bended by the cochlear array that can assume an intermediate position close to the midline of the cochlear lumen even without damaging the basilar membrane or the spiral ligament, thus assuming a position that sometimes is difficult to be identified. For this reason, we adopted a third “intermediate” position for array location assessment that was never used in other studies. This third position increased the number of possible choices for the raters

**Table II.** Interrater agreement for electrode positioning assessment in patients and temporal bones.

	Electrode		
	180°	360°	Apical
	% Patients		
Mean pairwise agreement	92.5%	88.8%	70.3%
Fleiss' kappa	0.46	0.38	0.35
	Temporal bones		
Mean pairwise agreement	71.5%	61.9%	45.4%
Fleiss' kappa	0.48	0.35	0.13

making more difficult a high percentage of inter-observer agreement.

Inter-observer agreement for the imaging characteristics (scala implanted, number of contacts inserted into the cochlea and presence of kinking within the electrode array) was 100% among three reviewers in a temporal bone study where a straight electrode was implanted<sup>5</sup>. In this study, the authors only evaluated the presence or not of the translocation of the array and did not evaluate the location of three electrodes with three possible positions as in our study, and the implant used was different, which might also explain the different findings. Boyer et al.<sup>10</sup> found a very low translocation rate (3%) and high agreement between raters for the correct intracochlear localisation of the MEDEL flex electrodes; even in that study, the methodology for the evaluation of the position of the electrode was different to that used in our study and the results are not completely comparable.

Studies performed in temporal bones that evaluated the same electrodes array used in the present study reported a reliable postoperative control of the intracochlear position in the basal turn, but difficulties in the evaluation of the localisation in the medial and apical turns<sup>6</sup>. Diogo et al.<sup>9</sup> found a higher metallic artefact of the electrodes in temporal bone in comparison to the whole head, probably due to the lower absorption of radiation by soft tissue determining greater surface radiation of the metal, and thus a greater artefact. The amount of the metallic artefact was not considered in this study, but the different results in the identification of the apical electrodes between temporal bones and patients may be caused by the different intensity of the artefact. Indeed, CBCT has few artefacts, but is not an artefact-free method<sup>6</sup>.

A possible drawback of the CBCT for analysis of submillimetre structures could be represented by the longer duration of the exam (18-36 sec) in comparison with MSCT (4-6 sec) that may result in possible artefacts due to the head movement<sup>17</sup>. Moreover, the higher the spatial resolution, the smaller the movement necessary to move the patient's structures out of the "correct" position. Nevertheless, in the eight CBCT images obtained from patients we did not observe any artefacts. The cone beam ma-

chine used in this study allowed the lying down position, and the use of a head holder helped to avoid artefacts.

## Conclusions

With this study we validated a technique to identify the intracochlear position of straight electrodes array in the cone beam CT images using the 3D multiplanar reconstruction method. CBCT is confirmed to be a reliable imaging technique for the identification of scalar translocation even for straight and flexible arrays in adult implanted patients. In temporal bones, probably due to higher metallic artefacts, the position of the electrodes in the apical region of the cochlea were more difficultly assessed. For this reason, we suggest the use of histologic analysis for confirmation of electrode position in temporal bone studies.

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Received: June 8, 2016 - Accepted: June 19, 2016