High resolution micro-CT scanning as an innovatory tool for evaluation of the surgical positioning of cochlear implant electrodes

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Abstract
X-ray microtomography (micro-CT) is a new technique allowing for visualization of the internal structure of opaque specimens with a quasi-histological quality. Among multiple potential applications, the use of this technique in otology is very promising. Micro-CT appears to be ideally suited for in vitro visualization of the inner ear tissues as well as for evaluation of the electrode damage and/or surgical insertion trauma during implantation of the cochlear implant electrodes. This technique can greatly aid in design and development of new cochlear implant electrodes and is applicable for temporal bone studies. The main advantage of micro-CT is the practically artefact-free preparation of the samples and the possibility of evaluation of the interesting parameters along the whole insertion depth of the electrode. This paper presents the results of the first application of micro-CT for visualization of the inner ear structures in human temporal bones and for evaluation of the surgical positioning of the cochlear implant electrodes relative to the intracochlear soft tissues.

Keywords: Cochlear implants, micro-CT, three-dimensional imaging, surgical trauma, insertion trauma

Introduction
X-ray microtomography (micro-CT) is increasingly attracting attention in biomedical research. Micro-CT is a powerful technique that allows visualization of the internal structure of opaque preparations [1,2]. The major advantage of micro-CT is that visualization is completely non-invasive. In biomedical research, micro-CT has not only been applied to the study of bones and calcified tissues [3–6] but also to the imaging of soft tissues such as lung tumors [7]. One of the potential new applications of micro-CT is visualization of the inner ear tissues and evaluation of the surgical aspects of newly developed cochlear implant electrodes.

A cochlear implant (CI) is an electronic implantable device replacing the human hearing organ by direct electrical stimulation of the auditory nerve. The stimulation pulses are delivered by a multi-channel electrode implanted into the cochlea (acoustic part of the inner ear). In the 1990s CIs became clinically routine, with almost 10,000 patients implanted worldwide. When applied in young children, CIs give realistic chances of normal or quasi-normal speech and language development and for speech understanding without additional clues, such as lip-reading [8]. However, understanding in difficult conditions (e.g. party noise), as well as musical perception, is still very difficult or impossible to achieve for a vast majority of implanted patients. To overcome these limitations new developments in electronics, speech-coding and micromechanics are necessary. Since the current trends in CI development are aimed at the application of more and more sophisticated electrodes with ever increasing numbers of stimulating contacts, the surgical difficulty of implantation of such electrodes and thus the risk for insertion trauma dramatically increases.

Concurrently, the results obtained in implanted patients are so good that CIs are also indicated for patients with significant residual hearing. In such patients the hearing preservation during cochlear

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implantation is of paramount importance. In order to obtain this, the newly developed electrodes must be as atraumatic as possible. For ethical reasons the implantation safety, effectiveness and atraumaticity of CI electrodes must already be sufficiently proven during the developmental phase. Adequate visualization of the electrode in the scala tympani, its orientation, insertion depth and positioning of the contacts together with evaluation of possible electrode damage and/or surgical trauma to the basilar membrane and to the lateral and medial cochlear walls are major challenges in electrode development.

In the present report, we describe the first results obtained with micro-CT imaging of human temporal bones implanted with cochlear implant electrodes.

**State of the art**

The main objectives for evaluation of the CI electrode designs are the following: (1) visualization of the electrode in the scala tympani; (2) evaluation of the insertion depth and positioning of the contacts; (3) evaluation of the electrode status after insertion; (4) evaluation of damage to the basilar membrane and to the lateral and medial cochlear walls.

The first three goals can be realized by standard plain Rx imaging. Obtaining the fourth goal requires development of innovatory solutions, as the standard techniques appear to be insufficient. For example, common histological slicing and staining techniques proved to be unsuitable for bones implanted with electrodes containing metallic wires, because the sectioning knives cannot reliably cut through them. Cutting through the wires not only leads to destruction of the knife blade but also introduces significant artefacts in the tissues soften in the decalcification process – these tissues become damaged by the wires stretched on the cutting knives.

An alternative histological technique of grinding and polishing [9,10] has an advantage that it can be utilized on non-decalcified bone specimens and also on bones containing metallic electrodes and wires. However, extensive sample preparation and embedding in acrylic resins applied in this technique as well as replacement of the cochlear fluids by resins greatly increase the risk of introducing preparation artefacts to the examined sections. The presence of such artefacts would always raise the question whether observed damage was caused by the electrode properties and the surgical implantation or was due merely to sample preparation. Similar remarks and deficiencies are inherent for another technique of evaluation of the insertion trauma, i.e. direct visual inspection of the intracochlear tissues under operating microscope. In this method, after electrode insertion into the cochlea, the inner ear is drilled out in a block and isolated from the temporal bone. The bony shell covering the cochlea is gradually thinned with a surgical burr until the cochlear turns are “blue-lined”, showing a shadow of the scala vestibuli through a very thin bony shell. Then the thin bone covering the scala vestibuli is microfractured and consecutively removed together with the internal endosteal lining. By doing so a very good direct view of the basilar membrane and of the electrode lying beneath is created, allowing for detailed visual inspection of the status of the basilar membrane and of the lateral cochlear wall. Unfortunately this technique also requires major sample preparation and even for experienced surgeons it is sometimes very difficult to distinguish real damage from artefacts.

An ideal evaluation technique would thus require none or very minimal sample preparation. Therefore various radiological techniques have been proposed for this purpose. They include plain conventional radiography in various projections, e.g. “cochlear view” [11], fluoroscopy [12,13], and phase contrast radiography [14]. However, the conventional radiographic techniques produce only two-dimensional superposition images and have a very low contrast between various tissues. Therefore plain radiographs are completely unsuitable for examination of the relation of the implanted electrodes to the endocochlear structures. Various clinical CT techniques have also been proposed [15–18], but the current clinical CT machines (even the modern spiral CT devices) still do not have sufficient resolution for visualization of the inner ear details and relation of the implanted electrode to the endocochlear tissues. Also, image distortion caused by the presence of metallic elements cannot be adequately removed. Techniques of pooling consecutive sections [19] or rotational tomography [20] improve visualization of the electrode in the scala tympani, but are still unable to show the details of the soft tissues.

In contrast to the above-mentioned techniques, the micro-CT technique proposed here requires only minimal sample preparation and can supply artefact-free images. At the same time it supplies sections in any chosen plane and with nearly histological quality.

**Methods**

**Preparation of the temporal bones**

Cylindrical blocks of human temporal bones containing the inner ears were used for this study. Two bones were preserved in formol and the third was freshly prelevated, i.e. within 48 h after the patient’s
were reduced in volume to approximately 2–3 ml (preserving the above-mentioned surgical landmarks and an intact bony labyrinth). In order to demonstrate the current possibilities of micro-CT, three different approaches were applied in further preparation of each of the temporal bone samples.

In the first bone sample the next step was insertion of the cochlear implant electrode, which was performed via cochleostomy, antero-inferior to the round window. The electrode used for implantation of this bone was a dummy electrode, i.e. it contained no metallic elements (contacts or lead wires). This dummy electrode was used to prevent reconstruction artefacts generated by metallic elements in the CT field. After insertion, the cochleostomy was sealed with a piece of connective tissue and histo-acrylic glue. The electrode was then cut at the level of the posterior tympanotomy; the electrode’s stump was fixed with a suture to a hole drilled through the facial nerve canal. Afterwards the bone specimen underwent quick decalcification in inorganic acids (hydrochloric and nitric acids solution) to increase the contrast on the CT images. After decalcification the bone was scanned with micro-CT.

The second and the third bone were not decalcified. In these bones standard commercial CI electrodes containing Pt-Ir contacts and lead wires (AB Corporation) were used but a different approach was applied to increase the CT image contrast and to remove the “star” artefacts caused by metal parts. Therefore, the second and the third bone were scanned twice, before and after insertion of the electrode, to allow digital image subtraction (see below). In these bones, before electrode insertion, three reference points were placed at three different locations on the specimen: at the centre of the stapes footplate, at the ganglion geniculi and in the internal auditory canal within the acoustic-vestibular nerve bundle. The marking points were platinum balls with a diameter of approximately 100 μm; they were glued at the above-mentioned locations with histo-acrylic glue.

In the third (fresh) bone, an additional preparation stage was performed before the electrode insertion. In this bone, beside cochleostomy, a second micro-opening was made in the stapes footplate. The perilymph contained in the scala vestibuli and the scala tympani was very slowly and gently suctioned out through these two holes, introducing air into the scala tympani and vestibuli. In this way the baseline micro-CT scan was carried out under conditions of a much higher contrast between the now air-filled cochlear scalae and the spiral lamina, the basilar membrane comprising the organ of Corti and the spiral ligament. After the baseline micro-CT scanning, the fluid in the cochlear scalae was replaced. This was done by placing the bone specimen under slight pressure created by a vacuum pump; in this manner the air contained in the scala vestibuli and the scala tympani was gradually sucked out and replaced by physiological fluid. After insertion of a CI electrode (as described above) both openings (cochleostomy and the opening in the stapes footplate) were sealed with a piece of connective tissue and histo-acrylic glue.

After the procedures described above, bones two and three, containing implanted electrodes, were scanned a second time to obtain the second set of data for digital subtraction/superposition.

### Characteristics of the electrodes

In bone specimen one, only a model (dummy) electrode was used. This model contained no Pt-Ir wires and no electrode Pt-contacts and was composed of only the silicone carrier with dimensions corresponding to the dimensions of an Advanced Bionics Corporation Hi-Focus II cochlear implant electrode. To increase the contrast between the silicone carrier and the surrounding tissues the electrode shaft was sputtered with a very thin layer of gold.

In bone specimens two and three, standard Advanced Bionics Corporation Hi-Focus II electrode, without positioner, comprising 16 contacts, was inserted.

### Scanning procedure

For X-ray micro-CT investigations a new in vivo scanner (Skyscan-1076, Aartselaar, Belgium) was used. This scanner looks like a reduced model of a medical CT, where the investigated object is kept still and the X-ray source and detector are rotated around it. The reduced field of view (up to 68 mm in diameter and 200 mm long) is compensated by the high resolution (up to 9 μm) and this resolution is not related to the object size. Resolution is limited by the pixel size of the detector (9 μm), while the diameter of the air-cooled X-ray source is 5 μm. A 2.3 × 4 K 14-bit CCD camera is used as a detector, providing cross-section up to 4000 × 4000 pixels. The two-dimensional detector reduces the scanning time dramatically compared with linear detectors. Isotropic datasets that allowed visualization of any arbitrary cross-section in any orientation were obtained.
Technical details about the scanner have been published elsewhere (www.skyscan.be).

In the present study, 9, 18 and 35 μ pixel size modes were applied. A titanium filter was the most suitable for visualization of the membrane while an aluminium filter was used for the investigations of the electrode position. Imaging of the membrane with 9 μ resolution required extra long scanning times (from 2 to 20 h).

Acquired projections were reconstructed as virtual slices using the Feldkamp algorithm [21]. Three-dimensional models were built from the obtained cross-sections using Skyscan software packages.

There were two main difficulties while visualizing the electrode in the inner ear. Firstly, there is the low density of the membrane that absorbs very few X-ray photons compared with the bone. Secondly, the total absorption in the platinum electrode blurred surrounding details so that no membranes could be seen.

To overcome these problems, temporal bone specimens two and three were scanned twice: before and after the insertion of the electrode. The initial scan was performed with low energies in order to visualize the cochlear walls together with non-calcified membranes. The second scan with the electrode inserted was acquired only to detect the position of the electrode relative to the three reference points. At that time high energy photons were used to transmit platinum wires. Finally, both datasets were registered in three-dimensional space and the picture of the electrode was “imported” into the artefact-free low energy scan.

Registration of two datasets and recalculation of the dataset in the orientation required was performed manually using the Skyscan software for three-dimensional modelling.

Results

In Figure 1 a virtual cross-section obtained by micro-CT (panel B) is compared to a histological cross-section of the cochlea (panel A). In the CT picture scala tympani and scala vestibuli can be distinguished as well as the bony lamina spiralis, the basilar membrane and the spiral ligament that separate them. The Reisner’s membrane separating the scala media from the scala vestibuli is extremely thin (a few micrometres) so that it is not readily visible, but its position between the scala media and the scala vestibuli can be easily established in the third bone sample where the air contrast has been used (see Figure 5).

A decalcified bone was used to improve visualization of the bone together with the electrode and the membranes. Figure 2 illustrates these experiments in the decalcified ear with silicone electrode without platinum inside. The cross-section represented in panel B visualizes both membranes and electrode in an ideal situation. Unfortunately, the same quality of the picture cannot be obtained in the untreated preparation.

A major difficulty in visualizing the electrodes in the bone is the fact that due to the high attenuation of the platinum electrode contact and the lead wires the picture becomes blurred around the metal parts. This is illustrated in Figure 3A. To avoid these artefacts two scans were made: one with electrode and another one without electrode. Both scans were superimposed. This resulted in an image without blurring and distinct shapes of the inserted electrode, soft tissues and the bony parts. This is shown in Figure 3B.

The whole set of cross-sections similar to the one represented in Figure 3B made it possible to build three-dimensional models where the spatial orientation of the electrode in the human temporal bone could be imaged. Figure 4 shows such a model. The model of the bony structure is made semitransparent (panel A) to visualize the whole length of the electrode.

In panel B the position of the electrode in relation to the bony wall of the cochlea can be clearly seen. This particular electrode has a lateral position through the whole insertion length.

Finally, a three-dimensional model was built where damage to the basilar membrane by the inserted electrode can be detected. This is illustrated in Figure 5: the spatial position of the electrode relative to the cochlear walls and basilar membrane can be seen. Slight damage to the membrane is also noticeable.

Discussion and conclusions

In this study, first attempts were made to use high resolution micro-CT for the evaluation of the position of the cochlear implant electrodes in human temporal bones. Good visualization of the intracochlear soft tissues was achieved owing to a voxel size of only 9 μm, the use of a titanium filter and extra-long scanning times. These high resolution scans reach nearly histological quality. Basic elements of the cochlea can be visualized and used for evaluation of the electrode position. The cross-section presented in Figure 1 allows study of the anatomical structures of the inner ear in detail, creating virtual cross-sections in any orientation.

A major challenge for micro-CT is the simultaneous visualization of the endocochlear soft tissues, silicone electrode carrier of the implanted electrode and platinum electrode contacts and lead wires. The
range of differences in attenuation coefficients is very wide: from almost total absorption in platinum and the leads to virtually no absorption in thin membranes. The scan of the decalcified ear with implanted dummy electrode (Figure 2) demonstrated nicely the ideal situation: the bone and the electrodes have been made transparent.

In the real situation we have more absorption that contains no useful information. Bony parts reduce the amount of signal that is necessary to illuminate the membrane and hence the scanning time should be increased to obtain the same signal-to-noise ratio. Metal parts introduce a new type of artifact that is based on almost total absorption of X-rays. This is even more deleterious for image quality because shadow projections lack data about the parts of the object that are behind the electrode. As a result, reconstructions are not valid in the area around these electrodes. To overcome this problem, we need to increase the energy of the X-ray photons to be transmitted through heavy metals, but the higher the energy used, the lower the contrast between soft tissues becomes. To solve this problem two different scans with two energies were used. Digital superposition/subtraction techniques were applied to remove the scattering caused by the metallic electrode contacts. In this manner, scatter-free images could be obtained and the electrode inserted into the bony structures of the inner ear could be visualized well, together with the endocochlear soft tissues. The

**Figure 1.** Comparison of the results of the micro-CT technique and classical histological cross-sections. On both images the anatomical details such as the scala tympani, scala vestibuli, Rosenthal's canal, modiolus, and basilar membrane are clearly visible. (A) Cross-section obtained with classical histological technique. (B) Virtual cross-section of the cochlea obtained by micro-CT.
relation of the electrode to the basilar membrane and the lateral cochlear wall is especially interesting in view of detection of the surgical insertion trauma.

In contrast to histological and other techniques described above, imaging by micro-CT requires minimal sample manipulation, and consequently no artefacts are created by staining and slicing.

By this means it is possible to obtain isotropic three-dimensional information about the situation with the sample remaining intact, allowing the use of other destructive techniques afterwards. Equal resolution in all directions allows the creation of virtual cross-section of the preparation in any given orientation, not just the one in which it was scanned. This fact was used while matching two datasets with and without electrode.

Three-dimensional orientation of the electrode relative to the membrane and the cochlear walls is of key importance in evaluating the quality of implantation. Micro-CT can provide this information (Figures 4 and 5), providing an opportunity for feedback to the developers of new electrodes. Advantages or hidden drawbacks of electrodes can be clearly visualized.

Another interesting feature of micro-CT is that it allows a step-by-step “film-strip” following of the electrode along the whole insertion depth. Such an approach is much more reliable in detection and distinction of the real electrode insertion damage than examination of multiple single sections as offered by standard histological techniques.
In addition, the electronic data obtained by micro-CT are a very rich source of raw data for electrical and mechanical modelling the properties of the inner ear. This is also potentially interesting for future research on determining the normative data for the anatomical and topographical variability of the inner ear.

In conclusion, micro-CT proves to be a promising non-invasive technique for visualization of cochlear implants.

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