Clinical applications

Cochlear implantation with the BV Pulsera with 3D rotational X-ray

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A cochlear implant is a surgically implantable electronic device which can help to provide a sense of sound to a person who is profoundly deaf or severely hard of hearing. As of today approximately 100,000 people around the world have received either one or two cochlear implants. Unlike hearing aids, the cochlear implant does not amplify sound, but converts sound to electrical impulses that directly stimulate a functioning auditory nerve inside the cochlea. The auditory nerve of cochlear implant candidates must be intact, which is the case in most patients who are deaf due to meningitis, otosclerosis or induced or congenital hearing impairment. The cochlear implant consists of two parts: an external speech processor and an internal part with a multi-electrode array which is inserted by surgery. Parallel to the ear canal a hole is drilled towards the cochlea. The multi-electrode array with guide wire (stylet) is inserted through a small drilled hole in the cochlea (cochleostomy). Subsequently, the guide wire is removed and the tip of the array curls around the winding of the cochlea. The 24 or 16 electrodes, depending on the brand, stimulate the auditory nerve.

However, the procedure is, at times, difficult due to anatomical variations of the ear. Incomplete insertion and incorrect insertion of the multi-electrode array has been recognized as a major complication [1]. From the series of Hoffman et al. it is known that only 1.2% of all performed implantations are incorrectly inserted. Moreover, from the literature, it is clear that in cochlear implantation revision surgery, 17 - 33% of revisions are due to positioning failure of the multi-electrode array [2-5]. Furthermore, of all incorrectly inserted multi-electrode arrays, 94% require re-intervention [6]. In addition, the indication for cochlear implantation has also broadened considerably in the last decade with congenital malformed ears, extensive cochlear otosclerosis and revision surgery becoming more frequent. Consequently, the surgical challenge has increased [2]. Proops et al. showed that cases with meningitis and otosclerosis in particular can cause difficulties with insertion of the multi-electrode array in respectively 39% and 38% of their patients [7].

After the electrode placement, impedance and signal measurements are carried out by the audiologist to assess whether the device is working and connected to the nerve. These measurements, however, are not conclusive for the precise position of the array. In the case of a foldover (curled array) inside the cochlea the measurements can still be normal. Computed tomography (CT) imaging after the operation is currently used to provide an assessment about the proper placement of the electrode. Until now, peri-operative visual control of the multi-electrode position has been carried out with a conventional mobile C-arm image obtained in the modified Stenver’s view [8]. However, the C-arm based fluoroscopic images have low definition and are two-dimensional (2D) whereas 3D would be preferred. Three-dimensional rotational X-ray (3D-RX) imaging can help the surgeon to obtain and confirm proper placement of the electrode during the operation, and may avoid the need for re-operation.

This article describes a new technique in which an investigational modified C-arm system is used for intra-operative checking of the multi-electrode array position in the cochlea. The advantage of this technique is the high definition 3D images, which can help to confirm the positioning of the multi-electrode array.

Scanning technique

The BV Pulsera with 3D-RX system is a mobile digital X-ray C-arm (Philips Healthcare, Best, the Netherlands), modified for motorized movement (Figure 1). A series of projection images are taken during rotation of the C-arm in 30 s. These scans are reconstructed with a Philips Xtravision workstation into a 3D dataset [9]. The X-ray dose of each image in this scanning run is dynamically adjusted to obtain a low X-ray dose and the best image quality.
Figure 1. Intra-operative scanning.

Figure 2. Intra-operative 3D-RX scans of a cochlear implantation, the images are approximate coronal slices in a 45 by 45 mm field of view. Left: coronal slice of the first 3D-RX dataset. The multi-electrode array is inserted up to the white marking of the array (stylet in place). Center: coronal slice of the incorrectly placed multi-electrode array in the cochlea (second scan); although fully inserted the multi-electrode array curved in the first winding. Right: coronal slice of the first 3D-RX dataset. The cochlear implantation was performed by two senior ear, nose, throat (ENT) surgeons of the University Hospital Amsterdam as part of the Cochlear Implantation Amsterdam group. Once adequate exposure of the stapes, round window and basal cochlear turn is achieved the cochleostomy is performed. The multi-electrode array (Nucleus 24 Contour, Cochlear) was partially inserted into the cochlea. In the more difficult operations, such as in the case of extensive otosclerosis and anomalies, a 3D-RX scan was performed as a first step in the procedure. If the correct position of the array was confirmed with the 3D-RX scan (Figure 2 left panel), the stylet was removed from the cochlear implant and full insertion into the cochlea was achieved. In all cases a 3D-RX scan was made to check proper positioning in the cochlea after full insertion (Figure 2 center and right panel). The procedure was finalized by the audiologist with neurophysiological assessment. CT imaging after the operation was used to assess proper placement of the electrode.

Table 1. Overview of the patient population of this study.

<table>
<thead>
<tr>
<th>Surgery characteristics</th>
<th>32.2 years (1-82)</th>
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<tbody>
<tr>
<td>Age at implant (min-max)</td>
<td>30</td>
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<tr>
<td>Sex</td>
<td>34</td>
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<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<td>Progressive hearing loss</td>
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<td>Pregnancy rubella</td>
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<tr>
<td>Meningitis</td>
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<tr>
<td>Otosclerosis</td>
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</tr>
<tr>
<td>Other</td>
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<tr>
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<tr>
<td>Left</td>
<td>26</td>
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<tr>
<td>Right</td>
<td>30</td>
</tr>
<tr>
<td>Bilateral</td>
<td>8</td>
</tr>
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</table>

For inner ear imaging 450 images were acquired over 200° with the highest magnification. The reconstructed data set is a sphere with a diameter of 9 cm and 0.36 mm voxels. An earlier cadaver study showed that 450 projection images are optimal for the small anatomy of interest. The patient’s head was placed on a radiolucent rest such as a carbon fiber surgery table in order to allow rotational imaging. For all scans, the system was aligned with external lasers pointing at the isocenter of the rotation.

Procedure
The cochlear implantation was performed by two senior ear, nose, throat (ENT) surgeons of the University Hospital Amsterdam as part of the Cochlear Implantation Amsterdam group. Once adequate exposure of the stapes, round window and basal cochlear turn is achieved the cochleostomy is performed. The multi-electrode array (Nucleus 24 Contour, Cochlear) was partially inserted into the cochlea. In the more difficult operations, such as in the case of extensive otosclerosis and anomalies, a 3D-RX scan was performed as a first step in the procedure. If the correct position of the array was confirmed with the 3D-RX scan (Figure 2 left panel), the stylet was removed from the cochlear implant and full insertion into the cochlea was achieved. In all cases a 3D-RX scan was made to check proper positioning in the cochlea after full insertion (Figure 2 center and right panel). The procedure was finalized by the audiologist with neurophysiological assessment. CT imaging after the operation was used to assess proper placement of the electrode.
Results
The 3D-RX scanning system has been used in the University Hospital Amsterdam in every cochlear implantation since February 2005. Sixty-four patients have been scanned according to the procedure described above (Table 1).

Figure 2 shows a series of 3D-RX scans in a post-meningitis patient. The images show good bone and implant detail, allowing the surgeon to assess the position of the implant in the cochlea. In a patient with meningitis, intra-operative 3D-RX assisted with the correction of the incorrect multi-electrode array position, and may have therefore avoided the need for revision surgery at a later date (Figure 2 center). From the literature, it is known that cochlear implantation in post-meningitis patients has an increased failure rate, most likely due to small intra-cochlear obstructions [7]. The post-operative Neural Response Telemetry (NRT) measurements showed no damage to the device.

Figure 3a is an approximate Stenver’s view, and Figure 3b is a pre-operative coronal slice in the same patient showing the potentially difficult route to the cochlea.

Figure 3d is an intra-operative 3D-RX image of a patient with otosclerosis, with the multi-electrode array in the right position before removing the stylet. Especially in these cases, intra-operative 3D-RX images help to verify proper implantation.

Figure 4 shows another case of proper positioning of the electrode, which would have been very difficult without the aid of 3D-RX.

The presence of artifacts arising from metal is low due to optimal system properties. The effective X-ray dose of one scan series is 0.07 mSv (CT-scan ear 0.6–3 mSv) [10, 11]. The low X-ray dose is mostly as a result of the small region scanned and the low kV used (≤70 kV). Xu et al. used 80 mAs to create a modified Stenver’s view radiograph and for the 3D-RX system a total of 270 mAs [8].

Discussion
Intra-operative 3D-RX scanning and reconstruction provide high-quality images of the cochlea and the cochlear implant. They provide supplemental information since they indicate the position of the multi-electrode array in the cochlea. This technique helps the surgeon to obtain and confirm proper placement of the multi-electrode array, while using only a low X-ray dose. It contributes only a relatively small extra amount of time to the overall operation time, and may avoid the need for re-operation.

Insertion failures occasionally occur, but in otosclerosis, congenital malformed cochleas, and post-meningitis patients the failure rate is
Verifying the correct position of the multi-electrode array can reduce revision surgery.

It is believed that this system has the potential to lessen revision surgery, since the correct position of the multi-electrode is verified during surgery. The X-ray dose is estimated, from simulations, to be one eighth of a regular CT-scan of the ear and four times a modified Stenver’s view X-ray [13, 14].

References


