The mobile 3D C-arm Ziehm Vision RFD 3D – A well-suited tool for intraoperative imaging in cochlear implantation

More than 5% of the world's population – 360 million people – suffer from hearing loss in the inner ear greater than 40 dB in adults and 30 dB in children[1]. Of those 360 million people, 328 million are adults (90%) and 32 million are children (10%). This figure implies that the proportion of people experiencing hearing loss is much higher than those who suffer from other common diseases like depression, migraine or diabetes mellitus[2].

People with hearing impairment can benefit from hearing aids, cochlear implants and other assistive devices[1]. According to a study by the Food and Drug Administration (FDA), around 324 people with severe to profound hearing loss had been provided with a cochlear implant by the end of 2012[3].

With the development of a new cochlear X-ray 3D visualization technique based on a mobile C-arm, the Ziehm Vision RFD 3D represents an innovative way to conduct intraoperative imaging during cochlear implantation. This procedure becomes more and more important as far as quality control is concerned. This paper briefly summarizes the results of initial clinical evaluation in terms of their practicability and image quality for 40 patients, who were consecutively implanted with different implants. The radiation exposure levels were compared in an extra study that used a phantom applying the same common settings for the applications used by a CT and the Ziehm Vision RFD 3D.

General information

As technology progresses and information on the financial aspects become more readily available, the number of potential patients who could wear a cochlear implant rises within all age groups. Radiological imaging plays a vital role in the planning, implementation, control and therefore the success of a cochlear implant. With the Ziehm Vision RFD 3D, Ziehm Imaging offers an alternative to current gold-standard methods in the clinical routine of cochlear implantation.

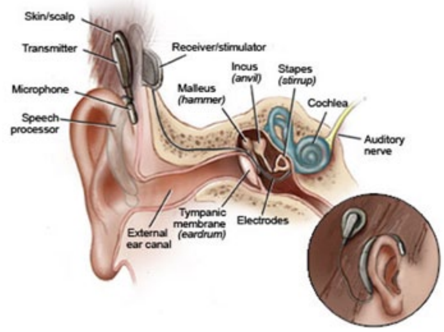

Fig. 1: Visual illustration of inner ear including a CI (Fig. 1)

The cochlear implant (CI) is an inner ear prosthesis that rehabilitates severe to profound sensorineural hearing loss in patients who haven't benefited from conventional sound-amplification hearing aids. The inserted electrode array stimulates the auditory nerve fibers electrically to bypass damaged hair cells. The hearing outcome is highly successful and provides a return to a regular everyday life[4]. One likely reason for a complication is electrode misplacement[5].

At the moment, final electrode position is mainly determined by the visual definition of typical anatomical landmarks, intraoperatively performed electrophysiological measurements and postoperative imaging. The postoperative control, meanwhile, is established for computed tomography (CT) or cochlear view (CV).

Intraoperative imaging is of particular importance in patients with anatomical malformations and for an optimal electrode placement in general to provide an optimal hearing outcome. To gain in-situ control of implant position and therefore prevent a potential revision surgery, an intraoperative solution is of substantial interest. So far the only known intraoperative approach is digital volume tomography (DVT) but it does not allow working under sterile conditions. Due to its innovative technology, the mobile C-arm Ziehm Vision RFD 3D provides an excellent opportunity for intraoperative imaging of electrode position, even under aseptic conditions, combined with high imaging information that has never before been available on a conventional 2D C-arm.

Intraoperative 3D imaging improves the clinical workflow, may shorten hospital stays and therefore improves patient outcomes by, among other things, enhancing result quality. Not only does the mobile C-arm deliver an imaging technique with highest precision for detecting even the smallest anatomical structures; it also facilitates the opportunity for intraoperative control of results at the same time. This reduces the need for postoperative CT scans and may minimize the need for revision surgeries as has already been proven in ortho, trauma and spine procedures.

Clinical Workflow

Cochlear implantation has become a routine procedure over the past few years. The 60- to 75-minute procedure is routinely performed on an inpatient basis in both adults and children. For exact evaluation of the petrous bone, a preoperative CT scan provides information about anatomical structures, any normal variants and post-traumatic or congenital deformities. The surgery itself proceeds the same way, including either a mobile C-arm or a postoperative CT scan. Intraoperative electrophysiological measurements are performed to evaluate the electrode position. For these measurements, the stapedius reflex is triggered under visual control, including for impedance measurements.

However, these measurements do not produce absolute certainty in correct implant position. Imaging techniques, which are conventionally performed on the first day post-operation, tend to shed light on the actual electrode position. The Ziehm Vision RFD 3D offers the advantage of already verifying the electrode layer intraoperatively in the sterile environment, which makes it possible to react immediately during the procedure in the case of suboptimal electrode placement. The evaluation can take place immediately after the electrophysiological measurements and can be performed several times if a malposition is detected and needs replacement during the same surgical procedure. This way, there is no need to close the patient and wait for the CT diagnosis first. The advantage of correcting the electrode column accordingly and thus preventing a revision surgery outweigh the temporal overhead during a roughly five-minute procedure. The postoperative CT scan can therefore be avoided and reduction of dose exposure can be obtained. The additional sedation or anesthesia that is often necessary for very young children can be prevented as well.

Clinical evaluation of 10 cm x 10 cm x 10 cm volume

With 16 cm x 16 cm x 16 cm volume the Ziehm Vision RFD 3D provides 320^3 voxels as standard. Benefitting from latest Ziehm Imaging innovations, a 10 cm x 10 cm x 10 cm volume can be achieved with 320^3 voxels by adapting the cubic volume reconstruction. Thus, a resolution of 0.31 mm was reached in human temporal bone.

This high resolution allows for accurate representation of even the smallest anatomical structures in the inner ear without having to take images of the less-relevant regions and the orbital.

In 40 patients, the previously placed electrode (AB MidScala n = 5, Cochlear 522 n = 17, Cochlear 512 n = 15, Medel / Flex 28 n = 3) was controlled intraoperatively with regards to its intracochlear position.

In addition to the clinical evaluation, a further dose comparison has been done to show the dose savings of this clinical approach. For more details on this approach, please refer to the Dose-comparison study chapter.

The position of the electrode array could be verified in the sagittal, coronal and axial cut position (Fig. 2 a - h). In case there is a need for the clinicians, the evaluation software even makes it possible to reconstruct any other plane.

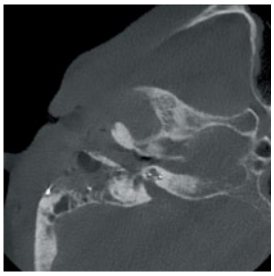

Fig. 2a: Midscala, axial

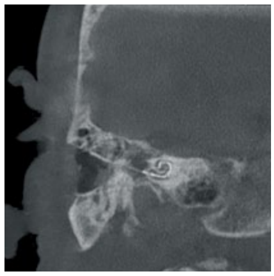

Fig. 2b: Midscala, coronal

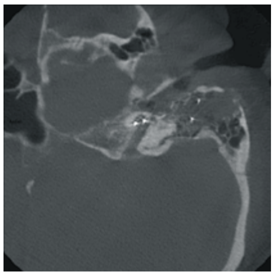

Fig. 2c: CI512, axial

Fig. 2d: CI512, coronal

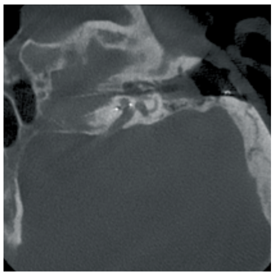

Fig. 2e: CI522, axial

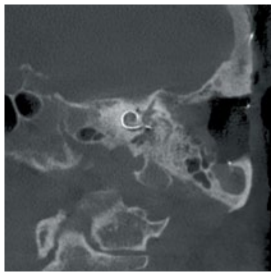

Fig. 2f: CI522, coronal

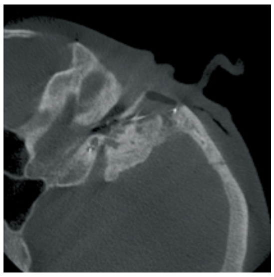

Fig. 2g: Medel Flex 28, axial

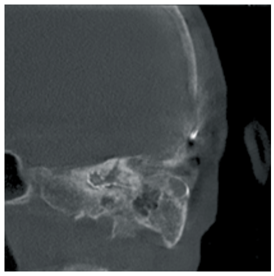

Fig. 2h: Medel Flex 28, coronal

Fig. 2 a-h: Visualization of different electrodes intrachochlear in axial and coronal view

Clinical examples

The following pages deal with a report on two of the 40 clinical cases that illustrate the initial results of using the Ziehm Vision RFD 3D for visualization and control during implantation. The clinical study was performed in the department of Otorhinolaryngology at the University Hospital Duisburg-Essen, Germany.

Patient 1

Adult patients eligible for implantation have a broad variety of indications such as slowly progressive hearing loss that starts in childhood, viral-induced sudden hearing loss, ototoxicity, otosclerosis, or bacterial infections[6]. This 52-year-old male patient presented deafness due to Meniere's disease and was implanted on the right-hand side.

After following the typical surgical workflow, the implant was finally inserted with the round window approach. To control the correct position of the cochlear implant, the Ziehm Vision RFD 3D was used.

Figure 3 shows the sagittal view, Figure 4 the coronal view. The characteristic cochlear structure is clearly visible.

Benefitting from the three-dimensional visualization, the surgeon can clearly verify the implant position. In coronal view, the characteristic cochlear structure illustrates the correct position of the implant. The full length of the stimulating electrode is positioned intracochlearly. The electrode is adapted to the outer circumference, which is characteristic for this special type (CI522).

Incorrect insertions result from, for example, a tip fold over or positioning into the vestibule or inner auditory canal. The vestibule and the inner auditory canal are clearly visible, so that misplacements can be clearly identified. Misplacement can be excluded here.

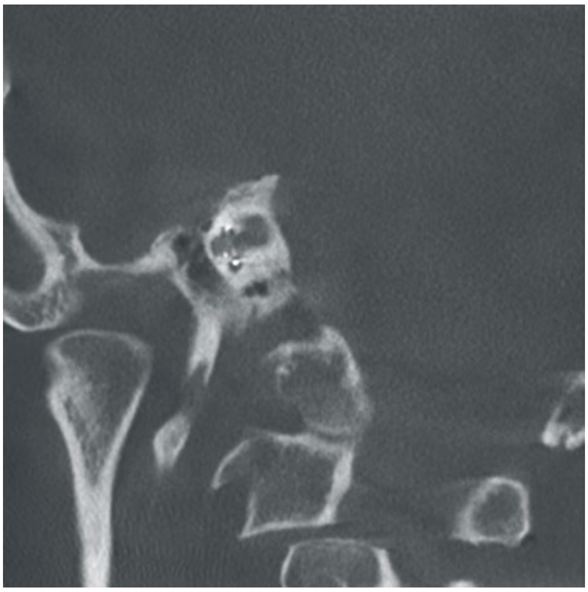

Fig. 3: Patient 1, male, 52-year-old, sagittal view, University Hospital Duisburg-Essen, Germany

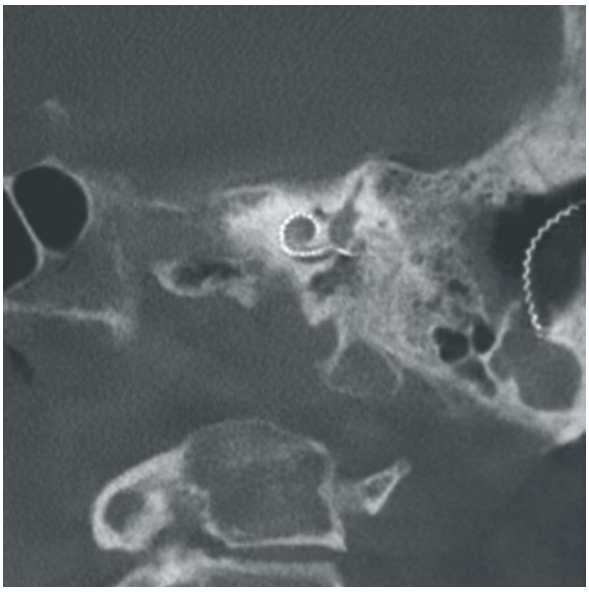

Fig. 4: Patient 1, male, 52-year-old, coronal view, University Hospital Duisburg-Essen, Germany

Patient 2

As with adult patients, the eligibility for cochlear implants in pediatric patients can have various origins.

This 7-year-old male patient suffered from bilateral progressive hearing loss related to antibiotic therapy for newborn sepsis. Cochlear implantation on the contralateral side was performed a couple of years prior.

One of these innovative features, the low dose mode, reduces mA and optimizes kV by using the imaging system to enhance images and lower dose to the patient.

The Figures 5 sagittal view and 6 coronal view for this pediatric patient were acquired using the low dose mode.

Nonetheless, the image quality is more than suitable to show precisely the right position for the cochlear implant (CI512) and therefore helps the clinician control the placement intraoperatively and avoid unnecessary revision surgeries. With that, the Ziehm Vision RFD 3D helps to improve accuracy in the OR and enhances patient outcomes by lowering exposure rates.

Apart from placing the CI and checking the position intraoperatively to avoid unnecessary postoperative CT scans and potentially reduce the need for revision surgeries, the most important goal was to reduce dose to the lowest level possible. The innovative features of SmartDose reduce the dose for children of all ages and stages of development and in other dose-sensitive procedures.

Fig. 5: Patient 2, male, 7-year-old, sagittal view, University Hospital Duisburg-Essen, Germany

Fig. 6: Patient 2, male, 7-year-old, coronal view, University Hospital Duisburg-Essen, Germany

Dose-comparison study

The measurements for radiation exposure were done at the Institute for Diagnostic Radiology and Interventional Neuroradiology at the University Hospital Duisburg-Essen in Germany. Using the industry-standard IBA phantom (cylindrical PMMA phantom with 16 cm diameter), the dose-length product was measured over 10 cm at five different points. The measurements were done on the Ziehm Vision RFD 3D and the SOMATOM Force (Siemens Healthcare GmbH, Erlangen), which is usually available for postoperative CT scans after cochlear implantation.

To achieve comparable situations between the CT and mobile C-arm, both systems used the applications' standard settings for this test to control the position of the cochlear implant. Finally, the CDTI value was calculated from the dose-length product.

Both the values of the dose-length product and the CTDI (Computed Tomography Dose Index) were up to six times higher for the conventional CT than were recorded with the Ziehm Vision RFD 3D (Tab. 1).

These measurements can be extrapolated to clinical practice, because standard clinical procedure dictates that one control scan is performed either by the Ziehm Vision RFD 3D or with the CT.

Fig. 7: IBA CDTI phantom

Dose-length product mGy

Position	Siemens SOMATOM Force	Ziehm Vision RFD 3D (Standard)	Ziehm Vision RFD 3D (Low Dose)
Center	125.0	16.0	12.0
Top	140.0	5.0	6.5
Right	130.0	20.0	10.0
Bottom	120.0	30.0	20.0
Left	120.0	26.0	16.0
CTDIW (mGy)	12.7	1.9	1.2

Tab 1: Comparison between Ziehm Vision RFD 3D and CT

Conclusion

The Ziehm Vision RFD 3D provides surgeons with the possibility to visualize even the smallest anatomical structures in the middle and inner ear. The new 10 cm x 10 cm x 10 cm volume specially tailored to cochlear applications provides a new method for evaluating the position of the cochlear implant intraoperatively. It therefore provides immediate quality control of the operation result for surgeon and patient. Considering that the additional intraoperative time expended is roughly five minutes, this method is time-saving compared to a post-operative transport into an imaging device outside the operating room.

It is of enormous clinical advantage that the Ziehm Vision RFD 3D technology makes it possible to see a clear image for a successful insertion during an operation with substantially less radiation compared to CT. Neither the increased scan time (+ 15 seconds) nor the slightly lower resolution (0.31 mm vs. 0.30 mm) usually achieved with gold-standard method DVT negatively affects the surgeon's ability to clinically evaluate the implant position in situ.

In summary, the initial evaluation for this indication area suggests that the Ziehm Vision RFD 3D C-arm is very well suited for intraoperative position control of CI even under sterile conditions. This new and innovative procedure may have the potential to change the clinical procedure of CI implantation, achieving more accuracy for the placement while still in the OR.

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Picture credits

Fig. 1
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