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Original Article

A New Application of CBCT Image Fusion in Temporal Bone Studies

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OBJECTIVES: Temporal bone (TB) studies are essential during the development of new arrays. Postoperative cochlear histology is still regarded as golden standard for the assessment of electrode localization and trauma though it is time consuming, expensive and technically very demanding. The aim of this study is to investigate whether pre-operative evacuation of perilymph improve the assessment of electrode localization and insertion trauma in TBs applying fusion imaging. The results were compared to a prior validated image fusion technique based on the quantification of the electrode placement.

MATERIALS and METHODS: 12 prototype electrodes were implanted in fresh frozen TBs. The perilymph was evacuated from the scale prior to pre-operative cone-beam computer tomography (CBCT). The TB were then immersed in Ringer solution to rehydrated both scalae. After electrode insertion post-operative CBCT were obtained. 3D fusions of the pre- and postoperative registration were reconstructed. The electrode localization with respect to the basilar membrane was visually assessed.

RESULTS: The visualization of the BM on the pre-operative scans was achieved beyond the second turn in all TBs. The visual assessment was found to be as accurate as the previously validated fusion technique. There was no statistically significant difference between the methods (p=0.564). The image reconstructions and evaluations, however, were faster to perform and the insertion results are immediately available.

CONCLUSION: CBCT in combination with pre- and postoperative image fusion is an accurate method for the post-operative assessment of insertion trauma in TBs. This new application facilitates the identification of the BM and allows for a visual assessment of insertion trauma.

KEYWORDS: Cochlear implant, cochlear trauma, fusion imaging, temporal bone

INTRODUCTION

Today, cochlear implantation (CI) is a routine therapy for patients with severe to profound hearing loss. More recently, CI has been reported to be beneficial also in less severe hearing loss, especially in patients whose residual hearing could be preserved during surgery. Therefore, preservation of the delicate intracochlear structures is a central focus of the new electrode design [1-3]. Temporal bone (TB) studies are essential during the development of new arrays to study their insertion characteristics and dynamics as well as insertional trauma [4-10]. Post-insertional cochlear histology is still regarded as golden standard to assess electrode localization and trauma. Histologic examinations are also compulsory in the regulative processes of medical devices. Histologic processing of the cochlea is time- and cost-intensive and involves considerable manipulation of the specimen, so that electrode movements during this process are common. Overall, cochlea histology demands considerable knowledge and experience to be concise and reliable [10].

As compared to the conventional spiral computed tomography technique, cone beam computed tomography (CB-CT) evolved to become the preferred modality for postoperative cochlear implant imaging because of reduced electrode [11, 12]. Recent electrode studies in TBs increasingly utilize CBCT imaging in addition to histology [8-10, 13]. CB-CT often allows for a reliable assessment of insertion depth and scalar localization in the basal turn. However, depending on the type of electrode and scalar anatomy, an accu-

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rate assessment of the scalar localization is mostly not possible after 270–360 degrees of insertion depth angle (IDA) [14, 15]. We can achieve significantly improved accuracy with image fusion, at which the electrode from the postoperative registrations is reconstructed (based on Hounsfield units (HU)) and fused into the preoperative data set. The application of the image fusion technique provides artefact-free image and facilitates the assessment of array localization [7-10]. Earlier studies conducted by our group have validated this technique against histology for several types of electrodes [9, 10]. The most important limitation was related to the fact that the basilar membrane (BM) could not be identified, which decreased the reliability of these methods.

Mirco-computed tomography studies showed BM visualization when removing the perilymph from the scalae [16]. If the BM could be clearly visualized in the preoperative registration, the fusion technique would enable to accurately estimate the electrode localization in relation to the BM, thus making trauma assessment more reliable. That kind of technique would potentially represent a very cost-effective method for pre-clinical studies of electrode arrays in TBs as well as for educational applications.

This study aimed to investigate whether preoperative evacuation of perilymph improves the assessment of electrode localization and insertion trauma in TBs applying fusion imaging. We compared the results to a prior validated image fusion technique based on the quantification of the electrode placement.

MATERIALS AND METHODS

We implanted 12 freshly frozen TBs with prototype lateral wall electrodes. This study had an institutional approval and fulfilled the Helsinki Declaration for ethical use of human material. Ethical committee statement 538/2017 was granted for the study. Cortical mastoidectomies and posterior tympanotomy were performed under operating microscope. After exposing the middle ear through the facial recess, we visualized the round window membrane (RWM) and the stapes. We carefully removed the stapes superstructure and the footplate. The lateral semicircular canal (LSC) lumen was also opened by using a small diamond burr. We carefully removed the perilymph with a suction at LSC opening and the oval window. Finally, the rest of the perilymph was evacuated at the RWM opening (Figure 1) before CBCT imaging (ProMax 3D Max, Planmeca Oy, Helsinki, Finland). Thereafter, we immersed the TBs in Ringer solution for an hour to refill the cochlea before the insertion of the electrode array. Postoperative imaging was immediately performed after surgery.

For pre-insertion scanning, the used parameters were 80 kV, 16 mA, 15 s, and FOV 50×55 mm. The post-insertion scan parameters were 96 kV, 7 mA, and 15 s. The dose area products of the pre- and post-insertion scans were 1007 and 899 mGycm2. We used the Planmeca Romexis™ (Planmeca Oy, Helsinki, Finland) software to reconstruct the axial, sagittal, and coronal slices with 100 µm isometric voxel. For the post-insertion images, we used a metal artefact removal algorithm (ARA by Romexis™, Helsinki, Finland).

Two different lateral wall electrode prototypes were used for this study: a short 20-mm long electrode array that was used in 10 TBs, and 30 mm arrays in 2 TBs. Both prototypes were iterations of clinically used electrode arrays. Two CI surgeons performed all insertions through the RWM up to a minimum IDA of 360 degrees or to the point of resistance.

To determine the IDA, the images were evaluated with RomexisTM viewer before image fusion. Descriptive cochlea measures (A and B) were taken from the preoperative imaging. From postoperative CB-CTs, the radiologist specialized in neuroradiology (AL) carried out trauma evaluation. We used commercially available fusion software (iPlan Net 3.6.0 Build 77, BrainLab AG, Munich, Germany) for image fusion. HU units were used to determine electrode location. The preoperative and postoperative scans with image fusion are shown in Figure 2. Electrode reconstruction was made by using HU values for automatic reconstruction and then manually removing obvious artefacts as described by Iso-Mustajärvi et al. [9] and Sipari et al. [10]. In both the 3D-fusion and CB-CT, the trauma was evaluated at five points: 90, 180, 270, 360 degrees and in tip region of electrode array. Trauma grading from image fusion scans was made with two different methods. 1) This method, described by Sipari et al. [10], is based on data obtained by 20 temporal bones to model the average location of the BM. The electrode's location is quantified in relation with the total height of cochlea´s cross-section. This method is referred as quantitative evaluation (QE). 2) This method, referred to as visual trauma evaluation (VE), is based on the visual detection of the BM obtained by the preoperative imaging. After the fusion reconstruction, the electrode array's placement can be visually determined in relation to the BM.

Trauma evaluations from postoperative CB-CT scans were made using simplified trauma classification: electrode either in scala vestibuli or in scala tympani. The application of a more detailed grading (e.g. lifting of the BM) was not possible due the artefact, which may represent the individual contacts appear over 50% larger than its actual size. For the VE and QE method, we used an adapted Eshragi trauma evaluation, which also takes lifting/rupture of the BM into account (0=no trauma, 1=lifting of basillar membrane, 2=rupture of basillar membrane, 3=dislocation).

For statistical tests, we used the Friedman´s test. Specificity and sensitivity were also tested between two image fusion evaluation methods.

RESULTS

All 12 cochlea were adequately depleted of perilymph for preoperative imaging, and the BM could be clearly detected in most cases beyond the second turn (mean 632 degrees, range 497–685 degrees). There was no additional trauma to cochlea observed in preoperative CB-CT scans or under microscopic evaluation because of removal of the perilymph. Embedding the TBs in Ringer solution adequately replenished the cochlea with fluid so that we detected only minor air inclusions in postoperative CB-CT scans. The insertions could be normally carried out, and there were no apparent differences in the insertion characteristic of the electrodes in TBs with or without perilymph suction. Figure 2 illustrates the image fusion. Table 1 and 2 summarize the preoperative and postoperative measurements.

In TB 11, trauma rating with VE was not possible in the very apical part because of the deep insertion (IDA 678). The BM was visible up to 540 degrees, and VE was not used in the tip region in TB 11. The VE evaluation would not provide any additional value due the absent BM in preoperative scanning. CB-CT and QE was used also in tip region of TB 11.

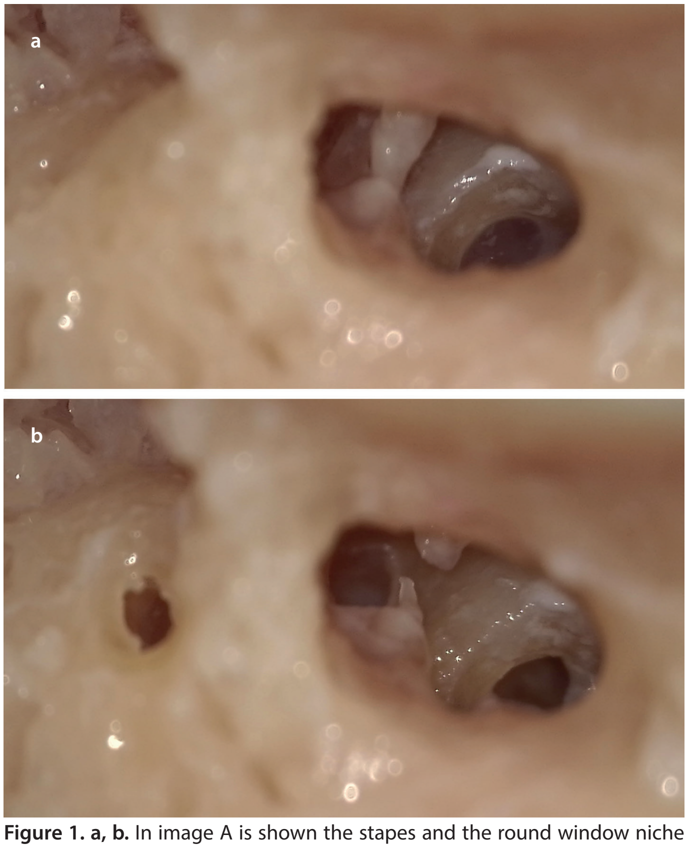

Figure 1. a, b. In image A is shown the stapes and the round window niche with the membrane. In image B, the lateral semicircular canal and round window are opened and the stapes is removed. Perilymph has been suctioned, and the specimen is ready for preoperative scanning.

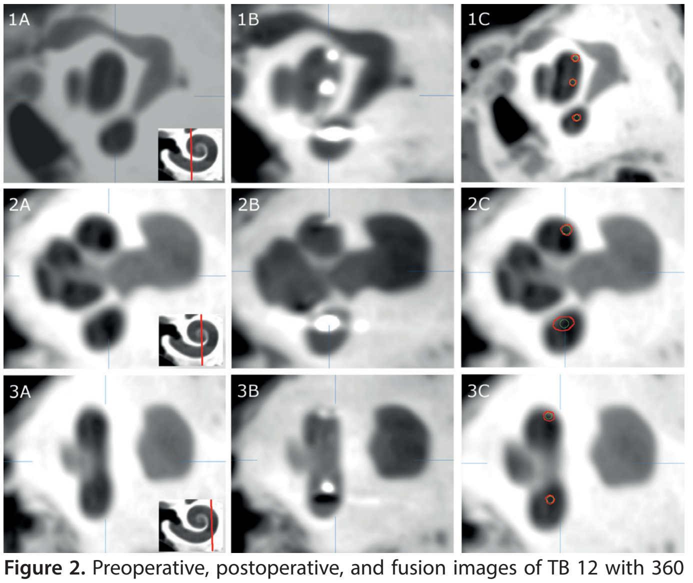

Figure 2. Preoperative, postoperative, and fusion images of TB 12 with 360 IDA. Images 1, 2, and 3 are on different planes of TB 12. A shows preoperative scans after removal of perilymph. B shows postoperative scans after refilling the inner ear with ringer solution and insertion of the electrode. C shows image fusion where the red borders resemble the artefact after processing, and the green borders resemble reconstructed electrode.

Postoperative CB-CT revealed three scala translocations from scala tympani to scala vestibuli (TB 10, 11, and 12). In TB 10, we detected dislocation at IDA 90 degrees, but otherwise the electrode was in scala tympani. In TB 11, we detected two independent translocations, first at 180 degrees from ST to SV and then the electrode returned to ST. Second translocation in TB 11 occurred from ST to SV at tip region (678 IDA). Third dislocation occurred in TB 12 at IDA 360 degrees.

According to QE, scala dislocation occurred in TB 11. In TB 11, the electrode was interpreted to be in SV at 180 IDA, 360 IDA, and in tip region by QE method. At 90 degrees, the Eshragi grading for QE method was 0 and grade 2 for trauma at 270 IDA. In TB 10, the Eshragi grade 2 trauma occurred at 90 IDA; but deeper in cochlea, no trauma was detected in QE method.

VE method revealed dislocations in two TBs (TB 10 and TB 11). In TB 10, grade 3 trauma occurred at 90 IDA. Deeper in cochlea, the electrode was in ST without any suspicion of trauma. In TB 11, the Eshragi grade 3 was interpreted at 180 IDA and 270 IDA; 90 IDA was interpreted as Eshragi grade 0 and at 360 IDA VE method suggested trauma grade 2.

Both QE and VE method interpreted no trauma for rest of the TBs. No statistical significance was observed between QE and VE (p=0.564). Sensitivity was 71.43% (95% CI 29.04 % to 96.33%), and specificity

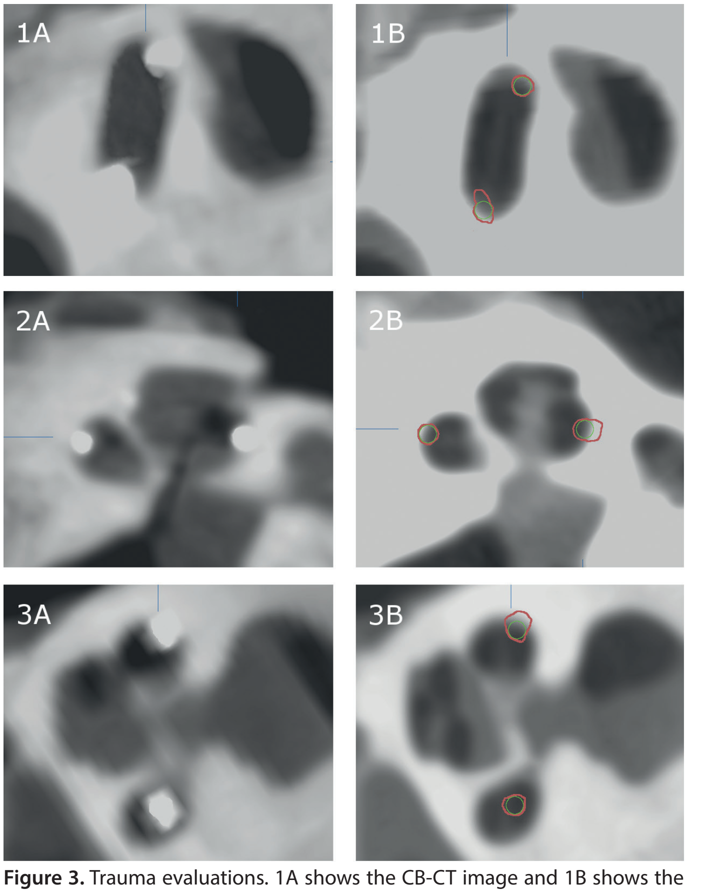

Figure 3. Trauma evaluations. 1A shows the CB-CT image and 1B shows the fusion image of TB 10, insertion traumas as Eshragi 3 in degrees 90 and 0 in 180 degrees and dislocation in CB-CT at 90 degrees. 2A shows CB-CT image with dislocation basal parts and scala tympani location approximately in 270 degrees. 2B is Eshragi grade 3 in basal part and grade 2 at 270 degree. 3A is scala tympani insertion and 3B are Eshragi grade 1 in TB 3 at 90 degrees and grade 0 deeper in cochlea.

was 97.67% (95% CI 87.71 % to 99.94%) for VE method compared to QE method. Figure 3 demonstrates advances of image fusion compared to CB-CT. The trauma gradings of all three methods are summarized in Table 2.

In TB 10, VE interpreted "dislocation" at 90 degrees and QE a rupture of BM. In CB-CT scan, the dislocation were conducted at 180 degrees, and 90 degrees area was interpreted in scala tympani. After re-evaluation, we concluded that this difference was caused by separation in IDA angles between investigators (Figure 3).

The evaluation process of the insertion results from surgery (mastoidectomy and insertion of electrode) to trauma estimates took approximately 24 h of working time.

Table 1. The cochlea measurements of 12 TBs

Bone	A-measure	B-measure	IDA	Electrode
1	10.5	7.9	280	20 mm
2	9.5	7.1	333	20 mm
3	9.9	7.2	300	20 mm
4	9.9	7.0	260	20 mm
5	9.6	6.6	370	20 mm
6	9.3	7.1	294	20 mm
7	9.4	6.4	360	20 mm
8	8.3	6.5	273	20 mm
9	9.2	6.8	340	20 mm
10	9.0	6.8	380	20 mm
11	9.4	6.8	678	30 mm
12	9.5	6.6	360	30 mm

DISCUSSION

Modern imaging modalities have significantly improved the postoperative CI evaluation for clinics and for research applications. Although the CB-CT technique has improved imaging quality, artefacts generated by the electrode array still impair accuracy, especially in the second turn and in the apical regions of the cochlea. With the image fusion technique, it is possible to reconstruct artefact-free images that allow for a much more precise trauma assessment than post-op CB-CT alone [7-10, 19]. However, the electrode array's localization in relation to the BM, which constitutes the basis of the trauma classification by Eshragi, can only be empirically assessed by cochlear modelling [17]. The accurate assessment of insertion trauma with the fusion technique is still very challenging whenever the electrode lies near the BM. Possible insertion trauma such as lifting or even rupture of the BM may go undetected.

This study showed the feasibility of CB-CT to depict the BM in TBs cleared from perilymph prior to the preoperative imaging. In comparison to former studies that classified trauma according to the electrode placement in relation to the empirically modelled localization of the BM, this study shows that the BM can be actually visualized even beyond the second turn [8-10]. The visualization of the BM allows for a visual assessment, in which the electrode's placement can be depicted in relation to the BM. Therefore, it takes the individual anatomical variations of the BM location into account, which increases the accuracy and reliability of trauma assessment.

For electrode insertion studies, histology is considered the most reliable method for the trauma evaluation. However, also histology is not unerring since electrode movements and displacements may happen during the multistage processing of the specimen. Here, the radiologic evaluation methods are superior because they do not involve any manipulation of the electrode after insertion. Additionally, histologic sections can be processed only in one plane whereas

Table 2. The trauma grading used in this study. CB-CT estimation is made whether the electrode is in scala tympani (T) or scala vestibule (V). VE is a visual based evaluation from image fusion and is graded according to adapted Eshragi scaling. QE is a quantitative evaluation measurement and based on the technique explained by Sipari et al. 10 Degree of BM visualization is the point where the BM can be seen on CB-CT and IDA is insertion depth angle

Bone	90 degrees			180 degrees			270 degrees			360 degrees			tip				
	CB-CT	VE	QE	CB-CT	VE	QE	CB-CT	VE	QE	CB-CT	VE	QE	CB-CT	VE	QE	Degree of BM visualization	IDA
1	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	526	280
2	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	685	333
3	T	1	1	T	0	0	T	0	0	-	-	-	T	0	0	660	300
4	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	534	260
5	T	0	0	T	0	0	T	0	0	T	0	0	T	0	0	539	370
6	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	497	294
7	T	0	0	T	0	0	T	0	0	T	0	0	T	0	0	631	360
8	T	0	0	T	0	0	T	0	0	-	-	-	T	0	0	512	273
9	T	0	0	T	1	1	T	0	0	T	0	0	T	0	0	543	340
10	T	3	2	V	1	1	T	0	0	T	0	0	T	0	0	619	380
11	T	0	0	V	3	3	T	3	2	T	2	3	V	n.a	3	540	678
12	T	0	0	T	0	0	T	0	0	T	0	0	V	0	0	679	360

radiology provides sections in all three planes. Radiology may also provide immediate feedback of the insertion results without waiting for months for the histologic results.

Even though it is possible to evaluate the trauma related to the BM, the differentiation of Eshragi grades 2 and 3 is still challenging with either fusion imaging method. In this study, QE and VE were not able to distinguish between grade 2 and grade 3 trauma at only three measurement points (TB10: 90 degrees; TB11: 270 and 360 degrees). For these measurement points, histology would probably have been beneficial to differentiate whether BM rupture, or minor dislocation is present.

The most significant limitation of this study is that no histologic data were available, which would have validated the presented imaging method in more detail. However, previous studies have investigated the QE fusion imaging technique and showed its accuracy compared to histology [9, 10]. The VE image fusion methods provide adequate visualization of the BM so that the individual variation of cochlear anatomy can be considered. Therefore, the VE image fusion technique may well represent the most accurate technique to detect insertion trauma. This technique is feasible for TB studies and can be applied, for example, for pre-clinical electrode studies or for training of new surgeons. Obviously, this technique cannot be applied clinically. Unfortunately, CB-CT or HRCT devices cannot yet depict the BM. However, heavy weighted T2-sequences of cochlear magnetic resonance imaging (MRI) can show the BM at least in the basal turn. Thus, image fusion of preoperative MRI with postoperative CB-CT may present a possibility to achieve better accuracy in the assessment of insertion trauma in the clinical setting [19].

CONCLUSION

To date, preoperative and postoperative CB-CT imaging with the application of fusion imaging may represent the most accurate radiologic method for electrode placement and the assessment of insertion trauma. Enhanced accuracy can be obtained when the scalae of the cochlea are cleared from perilymph for the preoperative imaging, which allows for the visualization the BM and enables for a more precise trauma classification. This method is feasible only for experimental TB work but provides accurate trauma assessment. The main applications are surgery training and electrode research and development.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Hospital District of Northern Savo.

Informed Consent: N/A.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.I.M., A.D; Design - M.I.M., H.L., A.D.; Supervision - M.I.M., H.L., A.D.; Resource - M.I.M., S.S., A.L., J.T., H.L., A.D.; Materials - M.I.M., S.S., A.L., J.T., A.D.; Data Collection and/or Processing - M.I.M., S.S., A.L., J.T., H.L., A.D.; Analysis and/or Interpretation - M.I.M., S.S., A.L., J.T., H.L., A.D.; Literature Search - M.I.M., A.D.; Writing - M.I.M., S.S., H.L., A.D.; Critical Reviews - M.I.M., S.S., A.L., J.T., H.L., A.D.

Conflict of Interest: The authors have no conflict of interest to declare.

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