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Experimental Investigation of Rotational Tomography in Reconstructed Middle Ears with Clinical Implications

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Abstract

A large air-bone-gap after ossiculoplasty may be due to a malpositioned or displaced prosthesis. Rotational Tomography (RT) has the potential to provide high-resolution images of implants without artifacts and with less radiation dosage than CT scan.

Twenty-seven temporal bone specimens underwent measurements of middle ear transfer function using Laser-Doppler-Vibrometry (LDV) before and after placement of ossicular replacement prostheses (PORPs, TORPs) made of titanium. RT was performed on all specimens.

RT allowed 3-dimensional viewing of the temporal bone, accurate localization of implants within the reconstructed middle ear and determination of angles between the inserted prostheses and the tympanic membrane (TM) and/or the malleus handle (MH). Presence or absence of contact between the implant and the TM, malleus or stapes could be clearly visualized. Displaced prostheses were readily identified. The functional LDV measurements for TORPs showed a trend favoring coupling to the malleus handle, while for PORPs, coupling to the TM was favored. For PORPs, sound transmission was worse with increasing angles between the PORP and stapes superstructure ($p < 0.05$). Following our experimental results RT is an innovative, relevant and useful imaging technique to obtain immediate postoperative feedback after ossicular reconstruction and to precisely determine the position of middle ear implants.

Keywords

Rotational tomography; middle ear; transfer function; prostheses; imaging; inclination angle

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INTRODUCTION

Partial or total ossicular replacement prostheses (PORP/TORP) are commonly used for ossiculoplasty in cases of chronic otitis media with or without cholesteatoma (Bernal-Sprekelsen et al., 2003; Merchant et al., 1997; Vassbotn et al., 2007). Optimal positioning of a prosthesis against the tympanic membrane (TM) or the malleus handle (MH) and proper coupling to the stapes footplate or superstructure are essential in order to achieve satisfying postoperative functional results (Rosowski and Merchant, 1995; Zahnert and Huttenbrink, 2005). Successful ossiculoplasty requires surgical skills, as well as knowledge of middle ear mechanics, material properties of implants and prosthesis design. An important cause of a failed ossicular reconstruction is a prosthesis that was placed improperly or one that has migrated postoperatively (Asai et al., 1999; Huttenbrink et al., 2004; Yung, 2005). Currently, it is difficult to accurately determine the precise position and location of an ORP in the postoperative setting without resorting to exploratory tympanotomy. High resolution CT scanning can be of assistance in this situation. However, metallic prostheses create artifacts in the CT images, a limitation which is significant, especially with increasing popularity of titanium middle ear implants. Modern imaging techniques like virtual endoscopy or 3-dimensional CT may help in delineating complex middle ear anatomy, but suffer from a similar problem, as they are also based on CT data (Klingebiel et al., 2001; Martin et al., 2004; Seemann et al., 1999).

In contrast, investigations using conventional tomography have shown promise in allowing artifact-free visualization of the middle ear implants (Offergeld et al., 2007b; Offergeld et al., 2000). Rotational Tomography (RT) is an advanced type of conventional tomography that has potential to delineate the anatomy of ossicular implants in a reliable and precise manner without the problem of artifacts. RT has been used in clinical trials in patients who have undergone cochlear implantation (Aschendorff et al., 2004). We recently adapted RT to successfully visualize middle ear implants placed in cadaveric temporal bone specimens (Offergeld et al., 2007a).

In the present study, which was also carried out in temporal bone specimens, we used RT to systemically assess those anatomical features of PORPs and TORPs such as position, coupling, angulation, etc. that impact their mechanics. We found that these anatomical parameters could be determined by RT in an objective manner. We also made functional measurements of middle ear sound transmission with the inserted PORPs and TORPs using Laser-Doppler-Vibrometry (LDV). We then correlated the anatomical data obtained by RT with the functional LDV measurements. We present our results and discuss the potential utility of RT in a clinical setting.

MATERIAL AND METHODS

The study was performed using a total of 27 fresh human temporal bone specimens with intact inner ear which were obtained within 48 hours after death. The bones were kept in physiologicalringer's solution at 5°C to prevent postmortem degeneration. All specimens were immediately used and kept moist constantly during measurements. Inspection of each temporal bone (TM, middle ear) was performed by use of the operating microscope; suspicious temporal bones or those with abnormal middle ears or TM were not included, in our study 3 of 27 temporal bones were excluded due to suspicious middle ears. Two experienced otosurgeons performed all temporal bone preparations and the LDV measurements only. All PORPs and TORPs were inserted while avoiding tension on the annular ligament and consecutively controlled by direct observation using an operation microscope (Zeiss Co., Oberkochen, Germany). These observations were used for comparison with the RT findings. The first 24 specimens were divided into 2 groups: group 1 (n=12), where middle ear reconstruction was simulated using a titanium PORP and group 2 (n=12), where a titanium TORP was placed (Kurz Co.,

Dusslingen, Germany). In each group, the head of the prosthesis was attached to either the MH (n=6) or the TM (n=6). The mid-malleus region was used for all cases of MH-coupling. We used a CO₂-Laser (Heraeus Co., Hanau, Germany) for all TORP cases to remove the stapes superstructure without imparting any trauma to the stapes footplate (FP) or the annular ligament. In 3 additional specimens, clinical failure was simulated as follows: lateralization of the TM away from a PORP was achieved by bending the prosthesis head and shaft away from the TM; dislocation of a prosthesis was simulated by positioning a TORP on the promontory; and a malposition was produced by placing the foot of a TORP on the rim of the oval window.

All specimens underwent measurement of the middle ear transfer function before and after placement using LDV (Polytec OFV 3001/OFV 302; Polytec Co., Waldbronn, Germany). Figure 1 demonstrates the experimental setup for LDV-measurements. A posterior tympanotomy was performed including removal of the facial nerve in order to gain adequate access to the oval window niche and the FP. Reflective foil was placed on the distal, central and proximal part of the FP for LDV-measurements. Velocity of the stapes footplate was measured in all cases. The external ear canal (EAC) was sealed after positioning a silicone tube connected to a sound source (Praecitronic Co., Dresden, Germany). The sound source provided sound excitation of 94 dB SPL at the level of the TM for frequencies 300 Hz to 5 kHz in steps of 100 Hz. A probe microphone (Etymotic Research Inc., Elk Grove Village, IL, USA) was placed through an opening in the EAC next to the TM for reference measurements. Signal to noise ratio exceeded 1 in all tested frequencies. Noise floor was determined from the spectral power in a 200 Hz frequency band around the excitation frequency. After completion of measurements with each PORP or TORP, each implant was fixed in place using cyanoacrylate glue (Histoacryl®) to prevent dislocation, following which RT was performed on each specimen. All RT examinations were performed by one experienced radiologist.

The technique of RT is based on three-dimensional digital radiography using a DynaCT-capable angiography unit. DynaCT allows selected systems of the Axiom Artis family to create images similar to a CT scan. In our study, DynaCT was used with an Axiom Artis dTA (Siemens Co., Germany), equipped with a digital flat-panel detector. The maximum field of view was a volume scan of 24 × 24 cm with a height of 18 cm. The physical resolution of the flat panel detector was an isovolumetric voxel size of 0.4 × 0.4 × 0.4 mm. We always used this highest of possible resolutions. DynaCT utilizes the images of a single Dynavision rotational radiography. Within 5, 10 or 20 seconds, the pivoting C-arm acquires up to 495 images within a rotation of 200°, depending on the number of projections. The acquired volume set was reconstructed using an X-Leonardo workstation, which allowed various types of standard 3D-post-processing: e.g. multiplanar reformation, curved reformations, volume rendering, maximum intensity projection and surface-shaded displays. Reconstruction time for the 3-D data set was approximately 5 minutes. The radiological evaluation time (post processing) also took approximately 5 minutes. The irradiation dose for RT was determined to be a maximum of 10–15 mGy for each specimen.

RT images were used in each specimen to measure two angles defined as follows (Table 1, Figs. 2, 3): (1) The coupling angle (α) was the angle between the head of the prosthesis and the bony margins of the TM. (2) The inclination angle (β) was the angle between the shaft of the prosthesis and a line perpendicular to the FP. In each case, coupling and inclination angles were measured in the coronal plane (α_1 , β_1 respectively) and in the sagittal plane (α_2 , β_2 respectively). The following landmarks were used: the term “coronal” referred to the long axis of the FP/oval window (OW), the term “sagittal” referred to the short axis of the FP/OW. We needed two lines to define a plane (Fig. 4). The coronal and sagittal planes were oriented orthogonally (90°) to each other. Both planes were tilted in such a way, that the intersection of both planes contained the tilted prosthesis shaft and ran through the prosthesis head centrally. In cases of a TORP-reconstruction the planes intersect in the foot of the prosthesis located on

the FP/OW. After PORP-reconstruction this is not necessarily the case, depending on the angulation of the prosthesis. Nevertheless the planes were oriented along the two axes of the FP/OW. The stapes head might be contained depending on its existence and its alignment in cases of PORP reconstruction. The above measurements were used to calculate the spatial coupling angle and spatial inclination angle in each case by spatial trigonometry (Table 1). This trigonometric formula bases upon only 2 angles which have to be defined in two orthogonal planes. The intersection of both planes was defined in alignment of the prosthesis shaft and head.

In addition, RT was used in each case to assess the following, so called “surgical check list” (Table 2/Fig. 5): PORP insertion: 1) Coupling point on MH or TM; coronal plane (Fig. 5b). 2) Contact area of the prosthesis head with the TM; coronal plane (Fig. 5a). 3) Proximity of prosthesis head to the MH. 4) Coupling to stapes superstructure; coronal plane (Fig. 5e). TORP insertion: 1) Coupling point on MH or TM; coronal plane (Fig. 5d). 2) Contact area of the prosthesis head with the TM; coronal plane (Fig. 5d). 3) Proximity of prosthesis head to the MH; axial plane (Fig. 5c). 4) Position of the prosthesis foot on the stapes footplate; axial plane (Fig. 5f). The thickness of each section was 0.5 mm.

In all specimens, the TM was marked using small sponges impregnated with radiopaque contrast agent (Isovist®, Bracco Altana Co., Konstanz, Germany) introduced via the EAC. The different prosthesis angles were tested against the Pure-Tone-Average (PTA) gain in all specimens. For correlation purposes a linear regression analysis was used. Statistical analysis was done using a student's t-test with $p < 0.05$ being necessary to achieve significance.

RESULTS

RT enabled precise visualization of middle ear anatomy and location of the inserted prostheses in all specimens (Fig. 5). In addition, the stapes superstructure and footplate and the stapedia tendon were clearly visualized (Fig. 5e). The placement of radiopaque sponges in the EAC enabled indirect visualization of the TM and its contact area with the prosthesis head (Fig. 5a). 3-D post-processing allowed determination of specific anatomical structures (e.g. MH, FP, TM) and their spatial relation to the inserted prostheses. Thus, parameters noted in the “surgical check list” (e.g. contact of prosthesis head to the MH, contact between TORP and FP) could be determined in all specimens (Table 2/Fig. 5a–f). All 3 cases of simulated surgical failures (lateralized TM, dislocated TORP and malpositioned TORP) were clearly identified. The accuracy of assessment of orientation by RT was high in comparison to the gold standard of direct observation, which was obtained in all specimen by use of the microscope.

Dynamic LDV-measurements yielded an average gain in the transfer function in the range of +2 to −13 dB (post-op to pre-operative ratio of stapes velocities), depending on the frequency, the site of coupling, the reconstruction procedure and the type of prosthesis used (Fig. 6). Extreme spikes in either direction can be neglected as they are considered as a shift of resonance and antiresonance features of the middle ear transfer function between normal and reconstructed middle ears. These results represent an adequate reconstruction procedure under experimental conditions which could be assigned to clinical circumstances. With PORP-reconstructions, the average gain was between −2 and −9 dB for TM-coupling and between 0 and −13 dB for MH-coupling (Fig. 6). With TORP-reconstructions, the average gain was between 0 and −7 dB for TM-coupling and between +2 and −4 dB for MH-coupling (Fig. 6).

The functional results were further evaluated by means of the pure-tone-average (PTA) for frequencies 0.5, 1, 2, 3 kHz calculated from the transfer function gain (Fig. 7).

With TORPs, there was a trend for superior results when the MH was used for coupling, or in case of TM-coupling, when at least the malleus handle was in contact with the prosthesis head.

With PORPs, functional results were better with TM-coupling instead of MH-coupling. However, statistical significance ($p < 0.05$) was achieved only when comparing the PORP-TM group to the TORP-MH group (the latter had a better outcome; Fig. 7).

With PORPs, the spatial coupling angles were between 11° and 56° for MH-coupling and between 3° and 14° for TM-coupling. Spatial inclination angles were between 25° and 47° for MH-coupling and between 12° and 28° for TM-coupling (Table 1). There was no evidence for statistical correlation between the coupling angles and the PTA gain, regardless of the coupling site.

Notably, 2 specimens in the PORP-MH group also had large inclination angles ($> 40^\circ$) in presence of excellent middle ear transfer function, whereas the other 4 specimens showed worsening of functional results with increasing angles. No statistical significance was found between angles and PTA gain, only when excluding specimens 2 and 6 a linear fit with statistical significance ($p < 0.03$) was achieved in this group (Fig. 8).

With TORPs, spatial coupling angles were between 8° and 21° for MH-coupling and between 1° and 32° for TM-coupling. Spatial inclination angles were between 9° and 21° for MH-coupling and between 4° and 14° for TM-coupling (Table 1). Concerning coupling angles there was no correlation with PTA gain irrespective of the coupling point.

No correlation was found between angles and functional outcome in the TORP-MH group as spatial inclination angles were similar. However, a tendency for worse outcome with increasing angles was observed in the TORP-TM group ($p < 0.09$) but statistical significance was not achieved (Fig. 9).

DISCUSSION

When failure of ossiculoplasty is suspected to be the result of a displaced or improperly placed prosthesis, surgical exploration is often considered to make an accurate diagnosis (Asai et al., 1999; Zahnert and Huttenbrink, 2005). Imaging may help in such situations. CT is currently the method of choice for middle ear imaging (Ayache and Williams, 2003; Rodt et al., 2002; Schubert et al., 1996; Swartz, 1986). However, it has limitations such as a certain degree of radiation exposure for the patient (20–60 mGy) and impaired imaging (artifacts, partial volume effect) due to metallic middle ear prostheses (Offergeld et al., 2007a; Rodt et al., 2002; Schubert et al., 1996). RT has the potential to be an alternative imaging modality in such situations, with the benefits of high resolution, capacity to resolve small structures such as the ossicles, a relative low radiation dose (10–15 mGy) and negligible metallic artifact (Offergeld et al., 2007a). We found that RT can accurately determine position of middle ear prostheses and resolve anatomical factors that have functional consequences, such as coupling and inclination angles, proximity of the prosthesis head to the MH, position of the prosthesis foot on the stapes FP and the area of a prosthesis in contact with the TM.

Keeping in mind that our data are investigational, it seems nonetheless reasonable to speculate about the potential clinical use of RT, as this diagnostic tool has already been introduced in clinical otology to assess the position of cochlear implants (Aschendorff et al., 2004). The image quality after RT in a living person is expected to be somewhat different than that in a temporal bone specimen due to the additional soft tissue and bony structures of the head, but we believe that the images will be adequate to allow precise definition of metallic middle ear prostheses as already shown in cochlear implant patients. In addition to the lack of metallic artifacts, RT allows for excellent isovolumetric resolution in 3 dimensions, which, so far, cannot be realized by CT (Offergeld et al., 2007a). While some authors claim CT to be the method of choice for visualization of middle ear anatomy and prostheses, it has to be taken into account that these publications mainly refer to prostheses manufactured from

hydroxylapatite which have different attenuation values in CT and therefore do not generate artifacts (Hirsch et al., 1994; Kobayashi et al., 2002; Mukherji et al., 1994; Stone et al., 2000; Watanabé et al., 1995). As titanium prostheses are gaining increasing popularity in contemporary otology (Fisch et al., 2004; Schwager, 1998; Vassbotn et al., 2007), clinical correlation of failure or success in otosurgery using CT may become problematic (Offergeld et al., 2007a). Our temporal bone data using the combination of RT and LDV also offer insight into the mechanics of ossicular reconstructions. Our data suggested a preference for TM-coupling when using a PORP in contrast to other authors (Bance et al., 2004), and MH-coupling when using TORP (Fig. 6) in accordance with other studies (Murugasu et al., 2005; Puria et al., 2005). In our study the TORP- MH group had the best outcome (Figs. 6,7). Although the majority of our measured angles with PORPs were in the range (45° or less) recommended by other authors (Nishihara and Goode, 1994; Vlaming and Feenstra, 1986), we had 2 PORPs with very large angles that, surprisingly, had excellent transfer functions. When viewed with the microscope, both specimens showed that the inclination of the PORP was along an ideal axis towards the stapedial crurae and tendon, which probably allowed ideal transfer function towards the stapes footplate (Fig. 10). Therefore, we assume that such a special line-up will tolerate large angles, but it also requires anatomical preconditions that are probably specific to a given temporal bone.

It must be remembered that successful middle ear surgery also depends on additional factors such as anatomical and technical factors in general, tension on the annular ligament, stapes mobility or the individual geometry of the ossicular chain (De Vos et al., 2007; Morris et al., 2007; Nishihara and Goode, 1994; Yung, 2005; Zahnert and Huttenbrink, 2005). Assessment of these parameters is beyond the potential of any imaging technique thus far. Nevertheless, RT does offer the possibility of postoperative feedback regarding structural features of functional importance such as optimal positioning and coupling of middle ear implants. Regarding our experimental results inclination angles seem to have certain influence on postoperative hearing outcome. Although statistical significance for positive correlation between PTA gain and smaller inclination angles was only achieved in the reduced PORP-MH group, the TORP-TM group also demonstrated a positive trend. In contrast the coupling angles did not show any correlation, regardless of coupling point or prosthesis type. This is probably due to the fact that under experimental conditions the TM is not reconstructed unlike in real surgery. The normal TM keeps its cone shape as well as its tension and does therefore not necessarily need large contact areas for adequate transfer function. However, in regard to inclination angles our results give evidence that the angle value seems to be an important parameter which is in accordance with other authors (Vlaming and Feenstra, 1986). Based on our data we therefore conclude that inclination angles can in fact not be used as real predictive parameters but are capable of providing useful information about possible expectations concerning postoperative hearing outcome. In this sense, a postoperative RT has the potential to become a valuable tool in quality control by enabling a surgeon to develop a “surgical check list” (Table 2) to ensure that a given prosthesis is placed as optimally as possible.

Given the positive experience gained from the present experimental study, we have initiated a clinical study to evaluate the value of RT after middle ear surgery. Future technological developments may also enable RT to be used intraoperatively, thereby permitting a surgeon to confirm optimum placement of a PORP or TORP before terminating the procedure. RT also may be applicable in the future for other diagnostic issues in otology, such as visualization of stapes prostheses, inner ear malformations, superior canal dehiscence, and evaluation of other lesions affecting the temporal bone.

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List of abbreviations

RT	Rotational Tomography
LDV	Laser Doppler Vibrometry
PORP	Partial Ossicular Replacement Prosthesis
TORP	Total Ossicular Replacement Prosthesis
TM	Tympanic Membrane
MH	Malleus Handle
ORP	Ossicular Replacement Prosthesis
FP	Footplate
CO ₂	Carbon dioxide
dB	Decibel
SPL	Sound Pressure Level
Hz	Hertz
kHz	Kilohertz
EAC	External Auditory Canal
3D	3-Dimensional
mGy	Milligray
PTA	Pure Tone Average

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Figure 1. Schematic view of experimental setup for LDV measurements showing probe microphone, sound source and Laser-Doppler-Vibrometer in place.

Figure 2. Rotational tomography (RT) images of a PORP. Measurement of the coupling (α) and inclination (β) angles are illustrated in coronal (upper part) and sagittal (lower part) planes.

Figure 3. Rotational tomography (RT) images of a TORP. Measurement of the coupling (α) and inclination (β) angles are illustrated in coronal (upper part) and sagittal (lower part) planes.

Figure 4. Schematic view of orthogonal planes (coronal and sagittal). Planes are tilted so that intersection of both planes contains the tilted prosthesis' shaft and head.

Figure 5.

“Surgical check list” enabled by RT: a) Contact area between TM and the prosthesis head (PORP/coronal plane). b) and d) Determination of coupling area (MH or TM) – (TORP/coronal plane). c) Proximity of prosthesis head to MH (TORP/axial plane). e) Coupling to stapes superstructure (PORP/coronal plane). f) Central position of prosthesis foot on FP (TORP/axial plane).

Figure 6.
Mean gain (dB) of LDV measurements vs. frequency, for various subgroups of prostheses.
Best outcome for TORP-MH group.

Figure 7. Box plot comparison of various subgroups of prostheses. Significant difference ($p < 0.05$) between TORP-MH and PORP-TM groups.

Figure 8.

Linear fit of PORP-subgroups (MH, TM). No significant correlation was found between PTA gain and spatial inclination angle in both groups when including all specimens. In case of the PORP MH-group, a linear fit ($p < 0.03$) was only possible by exclusion of 2 specimens with very large angles.

Figure 9.

Linear fit of TORP-subgroups (MH, TM). No significant correlation was found between PTA gain and spatial inclination angle in both subgroups but positive trend ($p < 0.09$) for TORP-TM group.

Figure 10. Otomicroscopic view of the PORP MH specimen number 6 with large inclination angle of 47° and excellent functional result. Note that the axis of the PORP-shaft is in ideal alignment with the stapes superstructure, including the stapedial tendon.

Table 1

Calculation of spatial angles

Specimen Group (G) Subgroup (SG)	α_1	coupling angle coronal	coupling angle sagittal α_2	spatial coupling angle	inclination angle coronal β_1	inclination angle sagittal β_2	spatial inclination angle
G 1; SG 1							
PORP MH 1	12		3	12,3	25	7	25,7
PORP MH 2	32		9	32,8	38	4	38,1
PORP MH 3	20		9	21,7	25	10	26,5
PORP MH 4	54		30	56,2	36	1	36,0
PORP MH 5	11		3	11,4	25	20	30,6
PORP MH 6	40		4	40,1	46	16	47,1
G 1; SG 2							
PORP TM 1	1		4	4,1	9	22	23,5
PORP TM 2	2		3	3,6	20	6	20,7
PORP TM 3	2		5	5,4	23	19	28,7
PORP TM 4	3		14	14,3	9	8	12,0
PORP TM 5	3		2	3,6	28	6	28,5
PORP TM 6	5		8	9,4	20	18	26,0
G 2; SG 1							
TORP MH 1	6		8	10,0	4	18	18,4
TORP MH 2	7		20	21,0	10	16	18,6
TORP MH 3	10		16	18,6	3	21	21,2
TORP MH 4	2		8	8,2	2	9	9,2
TORP MH 5	15		16	21,4	3	20	20,2
TORP MH 6	12		10	15,4	0	21	21,0
G 2; SG 2							
TORP TM 1	1		1	1,4	5	2	5,4
TORP TM 2	1		14	14,0	4	1	4,1
TORP TM 3	4		19	19,4	1	14	14,0
TORP TM 4	8		32	32,6	1	8	8,1

Specimen Group (G) Subgroup (SG)	coupling angle coronal α_1	coupling angle sagittal α_2	spatial coupling angle	inclination angle coronal β_1	inclination angle sagittal β_2	spatial inclination angle
TORP TM 5	8	1	8,1	5	2	5,4
TORP TM 6	7	2	7,3	4	1	4,1

Trigonometric formula used for conversion of measured angles into spatial angles $\arctan \sqrt{\tan^2 \alpha_1 + \tan^2 \alpha_2}$ (same application of formula for β values, respectively)

Table 2

Surgical check list

PORP
1. Coupling point
2. Extension contact plane (prosthesis plate)
3. Contact malleus handle
4. Coupling angle α
5. Inclination angle β
6. Contact on stapes superstructure
TORP
1. Coupling point
2. Extension contact plane (prosthesis plate)
3. Contact malleus handle
4. Coupling angle α
5. Inclination angle β
6. Position prosthesis foot on footplate

Parameters to be checked by Rotational Tomography for different prostheses types