Evaluation of functional results of CWD surgery with ossicular replacement prosthesis due to cholesteatoma using computed tomography

Selcuk Ucar · Mete Iseri · Murat Ozturk

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Abstract With the use of high-resolution computed tomography, this retrospective clinical study evaluated the factors affecting hearing in patients who were operated on due to chronic otitis media with cholesteatoma and underwent ossiculoplasty with titanium total ossicular replacement prosthesis (TORP). Fifteen patients with postoperative hearing results of 20 dB or less air-bone gap, and thirteen patients with postoperative hearing results of 21 dB or more air-bone gap were the subjects of this study. All patients were operated on due to chronic otitis media and underwent ossiculoplasty with titanium TORP. High-Resolution Computed Tomography (HRCT) and pure-tone audiometry were performed on each patient after an average of 17 months, postoperatively. Three-dimensional oblique CT cross-sections were analyzed with Vitrea 2® software. The presence of soft tissue in the middle ear and contact between the prosthesis head plate and the bone had an adverse effect on hearing \( (p < 0.05) \). The angle between the TORP and the oval window did not seem to affect the hearing results \( (p > 0.05) \). The study results indicate that an examination of the patients with poor postoperative hearing with HRCT may help find the possible cause and allow for the determination of the prosthesis location.

Keywords Tympanoplasty · Ossicular replacement · Spiral computed tomography

Introduction

In chronic otitis media (COM) surgery, ossicular chain defects may be observed in the malleus, incus, or stapes. After cleaning the cholesteatoma, partial ossicular replacement prosthesis (PORP) or total ossicular replacement prosthesis (TORP) can be applied [1]. Ossiculoplasty-related post-operative hearing results were previously reported [1–9]. In those studies, PORP and TORP made by various materials were used. When the hearing results were evaluated, results obtained from TORP studies were less promising than the results obtained from PORP studies. The reason for the less promising results might be that it is not currently possible to create a more stable fixed platform for TORPs compared to PORPs and the preferred use of TORP in advanced middle ear pathologies. The most important reason for the failure of ossicular reconstruction is the displacement or malposition of the prosthesis during the post-operative period [10]. In such cases, it is difficult to determine the position and the location of the ossicular replacement prosthesis without performing exploratory tympanotomy [10, 11]. Some studies suggested that HRCT might be helpful in such cases [12, 13]. In this study, factors affecting hearing during the postoperative period were evaluated in patients who were operated on due to COM and in whom ossiculoplasty was performed with titanium TORP. In contrast to the previous studies, the angles between prosthesis and the oval window and the tympanic membrane (TM) were evaluated three dimensionally by HRCT.
Materials and methods

The human research ethics committee approval of Kocaeli University and informed consent of all patients were obtained. Thirty-one patients who applied to our university’s department of otorhinolaryngology between March 2007 and April 2010 were the subjects of this study. The patients had a canal wall down (CWD) mastoidectomy surgery due to COM with cholesteatoma. A titanium TORP was used for reconstruction of the ossicular chain. During their checkup, the patients displayed intact graft and no recurrence. In all cases, cholesteatoma was observed preoperatively. All patients were classified using the Austin-Kartush ossicular status index. The aspect of middle ear mucosa of all patients were analyzed and noted during the surgery.

Surgical procedure

The temporalis muscle fascia and the shaped conchal cartilage flap were laid under in order. The simultaneously prepared TORP (TTP-VARIO; Heinz Kurz GmbH Medicotechnik, Germany) (0.2 × 3.0–7.0 mm) was placed in a manner that it touched the cartilage island graft and had a 90-degree perpendicular angle to the oval window and was supported by a surrounding sponge layer. In two of the ten patients who had hypertrophic middle ear mucosa, absorbable silastic sheeting was placed in the reformed middle ear cavities. For the remaining patients, non-absorbable silastic sheeting was similarly placed in the external ear canal, and the graft was supported by sponges laterally. Meatoplasty was performed in all patients. The surgery wounds were dressed every other day during the first postoperative week and the sutures were removed at the end of the first week. On the 21st day, cavity cleaning was performed and the silastic sheet on the graft was removed.

Audiometric assessment

Postoperative hearing tests were performed within an average of 17 months (between 8 and 37 months). Each patient’s postoperative pure tone air and bone conduction measurements were calculated by averaging the hearing levels measured at 0.5, 1, and 2 kHz frequencies. Differences observed among the measurements were recorded as air bone gap (ABG) values. ABG values of 20 dB or below were considered as successful and ABG values of 21 dB or above were considered as failed.

HRCT data acquisition

HRCT was conducted on all patients at the 17th month on average (between 8 and 37th months) during the postoperative period to evaluate the success of hearing and the condition of the prosthesis. High-resolution temporal bone screening was performed with multi-detector helical computer tomography (Toshiba® Aquilion 64, Japan). The screening parameters used were 120 kV, 200mAS/section, 64 × 0.5 mm collimation, 0.641 pitch, 0.5 s rotation speed, 180–220 mm field of view (FOV) image thickness, 0.3 mm reconstruction interval, and an average of 200–300 mGycm radiation intensity. The patients were kept in the supine position during screening with their heads in a neutral position and parallel to the hard palate.

Post-processing of the data

Axial bone algorithm was used for screening the collected data. The data were transferred to Vitrea 2® software version 4.1.8.0 for rendering. Three-dimensional images were generated from the axial, coronal, and sagittal sections. The list given below was generated by examining the predefined dots.

- The presence of soft tissue in the middle ear and around the prosthesis: Patients with the presence of soft tissue in their middle ear and/or around the prosthesis were registered after screening of respective volumes.
- Contact between prosthesis head plate and the bone: Axial volumes belonging to the patients were screened and the contact between the TORP head plate and promontorium/facial ridge were determined and recorded.
- The angle between TORP axis and the oval window (stapes footplate): An axis is defined as the line connecting two points. A flat surface formed by at least three cross-cutting lines is called a plane. A plane makes an angle when it intersects with another axis or a plane. In light of the current knowledge, it may be said that it is necessary to measure the angle between a plane and an oval window to evaluate the relationship between the prosthesis and the oval window. A plane, which was parallel to the oval window, was formed by reformatting with Vitrea software and labeled as the X plane. Three-dimensional Y and Z planes were created perpendicular to the X plane. The Z plane, from where one can see the whole length of the prosthesis, was formed by reformatting the Y plane (Fig. 1a). On the Z plane, the angle X formed between the TORP axis and the oval window was measured and recorded (Fig. 1b).
- The angle between the oval window and the TM: Because the TM and the oval window planes are two different planes, it is necessary to measure the angle in two different perpendicular axes to evaluate the relationship between the oval window and the TM. By considering the X axis as a base, which was created parallel to the oval window by oblique reformatting, the angles between the oval window and the TM were measured on the Y and
Z planes. For each patient, the angle on the Y plane ($\beta_1$, oblique coronal) and the angle on the Z plane ($\beta_2$, oblique axial) were measured and recorded (Fig. 2). During measurement of the TM plane, the contact points were examined.

The position of the prosthesis head plate relative to the oval window: On the X plane that was parallel to the oval window, the oval window was divided into four quadrants with planes passing through the long and the short axes: anterior–superior, anterior–inferior, posterior–superior, and posterior–inferior (Fig. 3a). Then, the quadrants that carried the prosthesis head plate were determined and recorded for each patient (Fig. 3b).

**Statistical analysis**

The postoperative ABG results were evaluated under two groups: Group I 20 dB or below (satisfactory

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**Fig. 1** a Three-dimensional schematic representation of the relationship of TORP with the X plane, which is parallel to the oval window, and the Y and Z planes that were formed by considering the X plane as the base. Green lines represent the X axis, which is parallel to the X plane and TORP axis. Notice the $\alpha$ angles in between the green lines. b The oblique coronal axial cross section (the Z plane) from where the full TORP length can be seen. The blue line represents the X plane that is parallel to the oval window, the green line represents the Y plane, and the red line represents the TORP axis. The yellow brackets were used to display the TORP length. The $\alpha$ sign was used to represent the angle between TORP axis and the X axis

**Fig. 2** a The oblique axial sagittal cross section (the Y plane) perpendicular to the X plane that was parallel to the oval window. The blue line represents the X plane that passes by the lower border of the oval window and the red line represents the Z plane. The yellow line represents the TM axis (passes through the TM's attachment site). The $\beta_1$ sign was used to represent the angle between the X plane and TM on the Y plane. b The oblique coronal axial cross section (the Z plane) that was perpendicular to the X plane that was parallel to the oval window. The blue line represents the X plane that passes by the lower border of the oval window and the green line represents the Y plane. The yellow line represents the TM axis (passes through the TM's attachment site). The $\beta_2$ sign was used to represent the angle between the X plane and TM on the Z plane
performance), and Group II 21 dB or above (unsatisfactory performance). The presence or absence of bone contact with the head of the prosthesis, the presence of soft tissue in middle ear, and existing malleus remnant were evaluated as existing or non-existing. The angle of the prosthesis longitudinal axis with stapes footplate was evaluated under two groups (Group I 70° or below, and Group II 71° or above), and these groups were compared with the audiometric groups (successful or failed). The Statistical Package for Social Sciences (SPSS) 16.0 was used for statistical analysis of the data. Two independent sample (Mann–Whitney U-test), K independent sample (Kruskal–Wallis), and Chi square tests were used for data analysis.

Results

The study began with 31 patients. Twenty-eight of these patients were of primary surgery and three were revision surgery patients. The three patients on whom revision surgery was performed were excluded from the study and the results of the remaining 28 patients were evaluated. Thirteen of the patients that were included the study were females, and 15 of the patients were males. The mean age was 31.4 (18–56) years. HRCT was conducted on the patients at the 17th month (8–37) on average after the surgery.

When preoperative and postoperative air born gap (ABG) results were evaluated, 15 patients had a level of 20 dB or below (Group I) and 13 patients had a level of 21 dB or above (Group II). In Group I, eight of the fifteen patients were females, whereas seven were males. In Group II, five of the thirteen patients were females, whereas eight were males.

In 16 patients, ossicular chain status was Austin-Kartush group B (malleus positive, and incus, and stapes negative), and in 12 patients ossicular chain status was Austin-Kartush group D (malleus, incus, and stapes negative).

Perioperative mucosal pathology (severe hypertrophic mucosa and granulation tissue) was observed under an operation microscope for ten of 28 cases (35.48 %). CT scan results revealed that seven of these ten patients had soft tissue in their middle ears. The relationship between preoperatively observed mucosal pathology and the presence of soft tissue in the middle ear by HRCT was not statistically significant (p > 0.05) (Table 1).

The presence of soft tissue in the middle ear was observed in 15 of 28 cases (50.57 %) by HRCT (Fig. 4) (Table 1). In ten of these 14 cases, postoperative pure tone audiometry ABG was found to be above 21 dB (Table 2).

There was a significant relationship between the presence

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<th>Table 1</th>
<th>Comparison of mucosal pathology and the presence of soft tissue in middle ear by HRCT</th>
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| HRCT high-resolution computed tomography |

![Fig. 3](image)
of soft tissue in the middle ear and the failure of hearing test results \( (p < 0.05) \).

In 14 of the 28 cases (50 %), the head plate of prosthesis was touching the surrounding bone tissue (eight cases to the promontorium and six cases to the facial ridge). In ten of these 14 cases, the postoperative pure-tone audiometry air-bone gap measurements were above 21 dB (Table 3). There was a statistically significant difference between the hearing results of the groups in which the prosthesis head plate was in contact with the bone compared with the prosthesis head plate that was not in contact with the bone \( (p < 0.05) \).

For all cases, the average value for the angle \( \alpha \), which is between the oval window and the TORP, was 66.25 ± 12°. When the \( \alpha \) angle for Groups I (71° or above) and II (70° or below) were compared with postoperative ABG values, there was no statistically significant difference \( (p > 0.05) \) (In Group I, the postoperative average ABG value was 15.4 dB for ten cases and in Group II, the postoperative average ABG value was 15.55 for 18 cases). The average value for angle \( \alpha \) in 15 cases where the postoperative ABG value was 20 dB or below was 66.06° ± 10.87°, whereas in 13 cases where the postoperative ABG value was 21 dB or above was 73.91° ± 14.62°. There was no statistically significant difference between the \( \alpha \) angles of successful postoperative hearing results and failed postoperative hearing results \( (p > 0.05) \).

The angles between the oval window and the TM were approximately 11.17° ± 4.74° for \( \beta^1 \) in the Y plane (oblique coronal) and 10.60° ± 5.47° for \( \beta^2 \) in the Z plane (oblique axial). There was not a statistically significant difference when \( \beta^1 \) and \( \beta^2 \) angles were compared with groups that had either successful or failed hearing test results \( (p > 0.05) \).

TORP head plate position was determined relative to the oval window for six cases in Group I (anterior–superior), for seven cases in Group II (anterior–inferior), for six cases in Group III (posterior–superior), and for nine cases in group IV (posterior–inferior). When these groups were compared with the groups formed by considering the successful and unsuccessful postoperative hearing test results, there was no statistically significant relationship \( (p > 0.05) \).

Data belonging to all patients are presented in Table 4.

### Table 2

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<th>Soft tissue is present in postoperative HRCT</th>
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<td>Postoperative ABG 21 dB or above</td>
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**HRCT** high-resolution computed tomography, **ABG** air bone gap

### Table 3

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<th>Bone contact is present</th>
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<td>ABG above 21 dB</td>
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**ABG** air bone gap

### Discussion

Various methods and various prostheses are described in the literature on tympano-ossiculoplasty to obtain better
prognostic results. Classifications described in the literature on this subject include Bellucci’s classification based on ear discharge [14], Austin’s classification of ossicular chain status [15], Kartush’s middle ear risk index (MERI) [16], and Dornhoffer and Gardner’s ossiculoplasty outcome parameter staging index (OOPSI) [17].

The middle ear mucosa pathology that was classified as a high-risk factor in Dornhoffer and Gardner’s OOPSI adversely affects hearing. Shinnabe measured aeration around the stapes on coronal and axial computed tomographic sections at 1 year after ossiculoplasty and investigated the correlation between postoperative aeration around the stapes and postoperative air-bone gap at 1 year after ossiculoplasty, and found that aeration around the stapes contributes to better hearing outcome [18]. In the current study, middle ear soft tissue was detected by postoperative HRCT in 14 of 28 cases. Perioperative mucosal pathology was detected in only six of these 14 cases. In eight cases, despite the preoperative absence of mucosal pathology, the presence of soft tissue was detected by HRCT. The reason for this is thought to be tubal dysfunction or the development of granulated tissue due to silastic or sponge, or individual differences in each patient’s recovery abilities, or adhesive otitis ground.

When postoperative hearing results were compared, the presence of middle ear soft tissue had an adverse effect on

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Mean value

| | 66.25 | 11.17 | 10.60 |

Standard deviation

±12 ±4.74 ±5.47

HRCT: high-resolution computed tomography; dB: decibel; ABG: air bone gap; (+): present; (−): not present; AS: Anterior–Superior; AI: Anterior–Inferior; PS: Posterior–Superior; PI: Posterior–Inferior
hearing results that were statistically significant. The presence of soft tissue was demonstrated in six of ten cases with mucosal disease by performing HRCT. Soft tissue might also be detectable in patients without perioperative mucosal pathology by HRCT, which is statistically significant in explaining hearing failure. These findings led us to think that other factors beyond mucosal pathology may be important.

In the current study, in 14 cases, the TORP head plate was in contact with the surrounding bone tissue as determined by HRCT and postoperative hearing results of ten of these cases were found to be unsuccessful. Based on this statistically significant result, the contact of the TORP head plate with the surrounding tissue adversely affected the postoperative functional outcomes. This result seems to prove that the sound energy that originates from TM loses its intensity due to bone contact before it reaches the oval window.

It is important that TORP, along with the TM or the malleus handle, has stable contact in the oval window so that good sound energy transfer to the inner ear can occur [19, 20]. In ossiculoplasty, the prosthesis, ossicular remnant, and TM should vibrate as a single unit [19]. To fully transfer the force to a surface, the force should be applied to the surface at a 90-degree angle. For this reason, the ideal anatomy in TORPs is to place the prosthesis against the oval window and the TM at a 90-degree angle. To achieve this, in his study, Vincent relocated the malleus to the posterior by his malleus relocation technique to place both the TORP and the PORP [21]. In this way, Vincent was able to achieve better sound transmission using a plane perpendicular to the plane of the stapes. In an ideal sound transmission, the oval window and TM are required to be parallel to each other. However, this is not often the case in otological surgeries [22].

In Herkenhoff’s study [22], ten temporal bones were used and the average angle between the TM and the stapes was 25.87° ± 7.5° along the transverse axis relative to the oval window and 24.55° ± 5.7° along the longitudinal axis. Again in Herkenhoff’s study, the CWU procedure was used and measurements were recorded using a plane in between the contact places of TM in manubrium mallei at the anterior and external ear canal wall at the posterior [23]. In the current study, measurements between the TM and the oval window were recorded based on the plane that was created between the contact places (anterior annulus and posterior facial ridge) of the TM. This method was selected instead of using the manubrium mallei as a landmark because in otological surgery, especially in COM with cholesteatoma, the manubrium malleus is not monitored at all times and may be removed. Thus, a standard measurement cannot be provided through the manubrium mallei in all cases. In such cases, measurement of the contact places of TM may help standardization and was used in our study.

In the current study, the measured \( \beta_1 \) and \( \beta_2 \) angles between the TM and the oval window for the \( Y \) and \( Z \) planes were 11.17 ± 4.74° and 10.60° ± 5.47°, respectively. The causes for the differences in obtained angles could be due to (1) the variation of the attachment site of the TM to the posterior wall because of the CWD surgery, and (2) change of the anterior attachment site from the manubrium mallei to the annulus.

Herkenhoff [22] suggested that the TORP head plate should be placed parallel to the TM and the foot piece should be placed perpendicular to the oval window, and the head plate should be bent 25° caudally and ventrally. In the current study, in patients in whom CWD was applied, there was a decrease in the angle between the TM and the oval window due to the change of the attachment site of the TM to the posterior site, which made them relatively more parallel to each other. Based on these findings, providing an incline to the TORP does not create better functional results and seems to be unnecessary.

In Offergeld’s study, the angles that formed between TORP and the oval windows were measured. For the measurements, the oval window was considered to be a plane and two other planes perpendicular to the oval window plane were considered. The angles were then measured between the oval window and these two perpendicular planes [23]. In our opinion, a TORP applies a vector force to the oval window from a single point. Therefore, the angle between the TORP and the oval window should be measured in an oblique section from where the full TORP length is seen. This type of measurement can standardize and ease the measuring procedure.

In the current study, the \( z \) angle between the TORP axis and the oval window plane was measured from a section where the full TORP length could be seen. When the measured \( z \) angles were compared with postoperative successful and failed hearing results, there was no statistical significance. Furthermore, there was no statistically significant difference between the postoperative hearing results of the subjects and the \( z \) angle degree of 70 or below and the \( z \) angle degree of 71 or above. These findings contradict the classic laws of physics and state that being close to 90°, the angle between TORP and the oval window does not contribute much to hearing.

Additionally, the angle of the TORP that was placed perpendicular to the preoperative stapes footplate did change in postoperative HRCT images. This type of change was considered to be due to the changes in the middle ear pressure during recovery from anesthesia, dressing factors, individual healing rates, the pull effect of mucosal bridges during postoperative mucosal healing, and gravity.
the quadrants on which the TORP head plate was located was determined, no statistically significant difference was observed when compared with successful and failed hearing results groups. This finding could very well be such in reality, but it is also possible that this could be due to the inadequate number of cases in the groups. Future studies with more cases might shed some light on this subject and guide the surgeon.

Conclusions

When an overall evaluation of this study was performed, it was realized that the angle between the TM and the oval window decreased due to the changes in attachment site of the TM in the CWD procedure. An evaluation of the postoperative hearing results highlighted the fact that the angle that was formed between the titanium TORP and the oval window or the TM was not that significant. The presence of contact between the prosthesis and its surrounding tissue and the presence of soft tissue in middle ear are more important and statistically more significant. Therefore, performing HRCT on patients who have failed postoperative hearing results and have no pathologic findings in their otomicroscopic examinations may be useful in revealing the presence of newly developing soft tissue and the contact with the bones, and shed light on the cause of failure. If the prosthesis is seen in its place in HRCT images, and soft tissue is observed in the middle ear by HRCT again, exploratory tympanotomy may be performed after intratympanic steroids or similar treatments. Such an approach may be an alternative to the classic revision surgery. Studies that will be carried out by improved imaging techniques and greater number of subjects will contribute to the development of alternative approaches and treatment strategies, especially in cases with poor hearing.

Conflict of interest None.

References