Long-Term Hearing Outcomes following Total Ossicular Reconstruction with Titanium Prostheses

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Abstract

Objective. (1) Characterize a large cohort of patients undergoing total ossicular chain reconstruction with titanium prosthesis. (2) Analyze long-term hearing outcomes of the same cohort.

Study Design. Case series with chart review.

Setting. Tertiary care center.

Subject and Methods. This study reviews patients who underwent total ossicular chain reconstruction (OCR) with titanium prostheses (TORPs) at a single tertiary care center from 2005 to 2015. Patient charts were reviewed for demographic data, diagnosis, and operative details. Patients were included in statistical analysis if length of follow-up was 2 years or more. Evaluation of hearing improvement was made by comparing preoperative air-bone gap (ABG) and ABG at follow-up at 2 years.

Results. In total, 153 patients were identified who met inclusion criteria. The mean age of included patients was 40 years (range, 6-89 years). Sixty patients (39%) had a history of OCR, and 120 patients (78%) had a diagnosis of cholesteatoma at the time of OCR. Preoperatively, the mean ABG was 36 ± 12, whereas the mean ABG at 2-year follow-up improved to 26 ± 13. This was statistically significant (P < .0001) using a Wilcoxon matched-pairs signed rank test. Twelve patients (8%) required revision OCR. Two revisions were performed due to prosthesis extrusion (<1%).

Conclusion. Titanium prostheses lead to significant improvement in hearing over long periods. The results are sustained as far out as 5 years following surgery. In addition, rates of revision surgery with titanium TORPs are low. Based on this series, there are no readily identifiable predictors for outcomes following total OCR.

Keywords

ossiculoplasty, hearing loss, cholesteatoma, outcomes

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The use of synthetic prostheses in ossicular chain reconstruction (OCR) following surgical management of chronic ear disease has been a mainstay for hearing restoration since first described by Shea¹ in 1976. A variety of materials and techniques have been used in ossiculoplasty, including autografts like incus interposition grafts and other synthetic materials such as porous polyethylene and hydroxyapatite.²,³ After their introduction, the use of synthetic materials has greatly increased in general use. The trend toward use of synthetic prostheses was seen initially in partial ossicular reconstruction but quickly followed suit in total reconstruction.⁴

The first report of the use of titanium implants for ossicular reconstruction was in 1996,⁵ and since the early 2000s, the use of titanium implants has largely supplanted other synthetic materials and autografts.⁶ Initial reports using either titanium partial ossicular reconstruction prostheses (PORPs) or total ossicular reconstruction prostheses (TORPs) revealed relative ease of use with improvement in the postoperative air-bone gap (ABG), along with subsequent low rates of prosthesis extrusion.⁶-⁹ In addition, comparison of titanium implants to other synthetic materials showed that postoperative hearing results were equivalent or better when titanium implants were used.⁹-¹² More recently, titanium TORPs have been shown to
produce superior results in reduction of ABG in patients with a mobile footplate compared to the use of autologous incus in similar patients.\textsuperscript{13} While available literature supports the use of titanium prostheses in ossicular reconstruction, most studies involve small cohorts. Furthermore, these studies typically demonstrate encouraging results with titanium prostheses early in the postoperative period, with little data pertaining to the long-term outcomes in these patients. Furthermore, most data supporting the use of titanium prostheses are found in studies evaluating the use of both titanium TORPs and PORPs, a heterogeneous population with respect to middle ear status. The following study was designed to address these limitations by evaluating ossiculoplasty in patients who underwent titanium TORP placement with a minimum follow-up of 2 years.

### Methods

After obtaining approval from Vanderbilt University Medical Center’s institutional review board, patients who underwent ossicular reconstruction were retrospectively identified using Current Procedural Terminology (CPT) codes (69632, 69633, 69636, 69637, 69642, 69644, and 69646). All patients who underwent total ossicular reconstruction at a single tertiary center between 2005 and 2015 were analyzed. Total ossicular chain reconstruction was defined as using a prosthesis spanning the tympanic membrane to the stapes footplate or oval window. Only patients who underwent ossiculoplasty with a titanium TORP were included. All patients were reconstructed using either Kurz (Dusslingen, Germany) or Grace Medical (Memphis, Tennessee) titanium implants. Operative details, including concomitant mastoidectomy and intraoperative findings, were recorded. Demographic and surgical data collected included the age of the patient at surgery, smoking history, and disease characteristics, including the presence or absence of drainage and/or cholesteatoma at the time of surgery, the status of the ossicles, and whether this was an initial or revision surgery. Disease control rates following surgery were determined based on whether further procedures were required for cholesteatoma and by clinical exam as documented in the medical record. Additional reasons for need for revision surgery such as extrusion of prosthesis or persistent conductive hearing loss without evidence of chronic otitis media with or without cholesteatoma were also identified. The Ossiculoplasty Outcome Parameter Staging (OOPS) index was calculated for each patient. Developed in 2001 by Dornhoffer and Gardner,\textsuperscript{14} this index aims to predict the likelihood of successful hearing improvement with ossicular reconstruction. The components of this index can be seen in Table 1.\textsuperscript{14} Finally, audiometric data, including preoperative and postoperative (up to 5 years postoperative) ABG, were recorded.

Patients were included in the study only if they had follow-up of at least 2 years with available audiometric data. For each patient, air and bone conduction thresholds were recorded at 0.5 kHz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz, in accordance with the guidelines from the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS).\textsuperscript{15} In instances where 3-kHz thresholds were not recorded, these were calculated by averaging the thresholds at 2 and 4 kHz as has been previously described.\textsuperscript{16} These levels were recorded at initial audiometric assessment preoperatively, in the postoperative period (typically occurring at 3 months), and then at 1 year postoperatively. Additional measurements were recorded at 12-month intervals as far out as 5 years postoperatively when available. Pure-tone averages (PTAs) were calculated based on the average of the recorded thresholds described above. ABG was determined by subtracting bone conduction PTA from air conduction PTA. Determination of long-term hearing outcome was made by comparing the preoperative ABG to postoperative ABG at 2 years.

Statistical analysis was conducted using GraphPad Prism (La Jolla, California). Features were summarized with means, medians, ranges, and standard deviations or frequency counts and percentages where applicable. Wilcoxon matched-pairs signed rank tests were used to evaluate audiometric performance over time. Secondary analysis stratifying patients based on age and history of cholesteatoma was performed using multiple \( t \) tests with correction for multiple comparisons using the Holm-Sidak method and Mann-Whitney tests. OOPS scores were correlated with postoperative ABG using a nonparametric Spearman correlation. Multivariate linear regression was used to identify risk factors or variables (including those used in the OOPS index) associated with poor hearing outcomes. \( P \) values of less than .05 were considered statistically significant.

### Table 1. Components of the Ossiculoplasty Outcome Parameter Staging Index.\textsuperscript{14}

<table>
<thead>
<tr>
<th>Variable</th>
<th>Assigned Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drainage</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>0</td>
</tr>
<tr>
<td>Present (&gt;50% of the time)</td>
<td>1</td>
</tr>
<tr>
<td>Mucosa</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>0</td>
</tr>
<tr>
<td>Fibrotic</td>
<td>2</td>
</tr>
<tr>
<td>Ossicles</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>0</td>
</tr>
<tr>
<td>Abnormal, with present malleus</td>
<td>1</td>
</tr>
<tr>
<td>Abnormal, with absent malleus</td>
<td>2</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
</tr>
<tr>
<td>No mastoidectomy</td>
<td>0</td>
</tr>
<tr>
<td>Intact canal wall procedure</td>
<td>1</td>
</tr>
<tr>
<td>Canal wall-down procedure</td>
<td>2</td>
</tr>
<tr>
<td>Revision surgery</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
</tr>
</tbody>
</table>
Results

Patient Demographics

Between 2005 and 2015, nearly 2000 ossiculoplasties were performed at a single tertiary center. Of these cases, 209 patients (11%) underwent total ossicular reconstruction. Out of the total ossicular reconstruction cases, a titanium prosthesis was used in 190 instances (91%). Ultimately, 153 patients were identified as having at least 2 years of follow-up with audiometric data. Primary preoperative diagnoses for this cohort can be seen in Table 2. The mean age was 40 years (range, 6-89 years). There were 123 nonsmokers and 30 current or former smokers. Seventy-eight percent of patients (n = 120) had a diagnosis of cholesteatoma prior to surgery. At the time of surgery, 62% of patients (n = 95) were noted to have cholesteatoma in the ear in which OCR was performed. Diagnoses other than cholesteatoma are described in Table 2. When conductive hearing loss was the primary preoperative diagnosis, the majority of these patients had either had cholesteatoma previously excised and were undergoing second-look procedures (n = 12) or cholesteatoma was incidentally encountered during the surgery (n = 1). In total, 133 patients (87%) had been treated for cholesteatoma.

Surgical Details

Table 3 summarizes operative details for this cohort. Out of all 153 patients in the study, 103 (67%) patients underwent mastoidectomy at the time of ossicular chain reconstruction, while an additional 35 (23%) had previously undergone mastoidectomy. Only 15 patients (10%) did not have a mastoidectomy on the ear in which OCR was performed at any point. For those who had mastoidectomy either concurrently with OCR or previously, 114 patients (75%) had an intact canal wall procedure and 24 (16%) had a canal wall-down procedure. Of all cases reviewed, only 3 (2%) procedures were performed totally endoscopically. Sixty cases (39%) in this series represented revision ossicular reconstruction procedures. While there is debate on the need for a staged second-look procedure for ossicular reconstruction in cases of cholesteatoma removal,¹⁷ OCR was performed as a second stage procedure in only 14 cases (9%), meaning that 91% of patients were reconstructed at the initial surgery. As is standard practice at the authors’ institution, passive total implants were used, and so the malleus was not used in reconstruction. Sixty-two patients (41%) had OOPS index scores of 5 of more, and 98 patients (64%) had scores of 4 or more.

Revision surgery was required in 12 cases. In 2 instances (1%), revision was required due to extrusion or partial extrusion of the prosthesis, and 1 of these was felt to have extruded secondary to recurrence of cholesteatoma. The remaining 10 cases requiring revision were secondary to recurrence of cholesteatoma.

Audiologic Data

All included patients had a minimum 2-year follow-up. The mean follow-up for all patients was 44 months (range, 24-98 months). The mean ABG prior to OCR was 36 ± 12 dB. At initial follow-up 3 months postoperatively, the mean ABG was 25 ± 12 dB, representing a significant improvement (P < .0001) on Wilcoxon matched-pairs signed rank test. At 2 years following OCR, the mean ABG was 26 ± 13 dB. This result represented a statistically significant (P < .0001) improvement in hearing using Wilcoxon matched-pairs signed rank test (Figure 1).

Scattergrams were developed in accordance with guidelines for presentation of hearing outcomes as recommended by the AAO-HNS.¹⁸ In total, 136 patients (89%) were able to be included in these charts as they had complete data, including pre- and posttreatment PTA and word recognition scores. Figure 2 shows the pretreatment word recognition and PTA scores, and Figure 3 shows the posttreatment scores at closest follow-up approximating 24 months. The mean PTA for the entire cohort at 2 years was 45 dB compared to a mean of 55 dB preoperatively. Thirty-nine patients (26%) had follow-up of nearly 5 years postoperatively, with a mean follow-up of 64 months (range, 55-98 months). The average preoperative ABG for this subset was 37.5 dB (range, 16-67 dB) vs a postoperative ABG of 24.9 dB (range, 4-54 dB; P = .0001) (Figure 4). At their maximum follow-up date, 54 patients (35%) had an ABG less than 20.

When secondary analyses were performed stratifying patients based on age and presence of cholesteatoma at
reconstruction, statistically significant improvements in ABG were seen as well (Figure 5). When evaluating patients’ long-term ABG at approximately 2 years, there were no statistically significant differences in outcomes based on age (greater or less than 18 years, \( P = .83 \)) or cholesteatoma (\( P = .06 \)). A 2-tailed nonparametric Spearman’s correlation test was used to determine the ability of the OOPS index to predict hearing outcomes. Overall, there was no correlation between the score on this index and ABG over the long term (\( R = 0.139, P = .09 \)).

**Predictive Factors for Poor Outcomes**

To further evaluate the applicability of the OOPS index to this patient population for predicting hearing outcomes, a multivariate linear regression was performed with the 2-year postoperative ABG representing the outcome of interest. Factors examined included variables from the OOPS index (drainage, mucosal status, status of the malleus, type of mastoidectomy, and revision vs primary surgery). Patient age, smoking status, and the preoperative ABG value were also evaluated. Finally, given the lack of use of a malleus during OCR at this institution, we included status of the stapes footplate (mobile vs absent and/or fixed) in the multivariate analysis. None of the above factors were found to be predictive of audiologic outcome on multivariate analysis.

**Discussion**

Our results are in alignment with previous studies that show statistically significant hearing improvement following total
Ossicular reconstruction with titanium implants. These results show that patients have sustained hearing improvement at 2 years. In a smaller subset of patients (n = 39), we showed that the improved hearing with titanium implants is retained at 5 years following surgery.

While many studies have reported on the results of ossicular reconstruction, these typically report hearing results in the short term following surgery. However, it is important to know how well hearing improvements are maintained over longer periods. Previous studies examining ossiculoplasty results longer than 2 years are summarized in Table 4. A study by Ilíiguez-Cuadra et al reported on hearing outcomes at 2 years for a small subset of patients. Similarly, Hess-Erga et al reported sustained hearing improvement using titanium prostheses for both total and partial ossicular reconstruction. Another study by Nevoux et al followed a pediatric population who underwent total ossicular reconstruction with titanium implants and showed good hearing improvement during lengthy follow-up (average 34 months). Whereas Nevoux et al performed OCR during a second-look procedure in all instances, OCR was only part of a second stage procedure in 14 patients in our cohort, reflecting the fact that ossicular reconstruction is most commonly performed as a single-stage procedure at the author’s institution. Our cohort showed improvement in ABG postoperatively when stratified by age (Figure 5).

Finally, O’Connell et al reported on a series of patients followed long term after undergoing either total or partial ossicular reconstruction with titanium prostheses. They also showed sustained hearing improvement in long-term follow-up periods in a relatively small cohort of patients. Their study included only patients with chronic middle ear disease, whereas other studies with long-term hearing results have included pathology other than chronic otitis media (COM). Similarly, most patients examined in the present study were being treated for cholesteatoma or conductive hearing loss resulting from COM (87%).

While this study does show statistically significant improvements in hearing both at 2 years following surgery and at 5 years following surgery in a smaller subset, it is interesting to note that the hearing improvements from the present study are not as robust as seen in other series with long-term follow-up (see Table 4). As indicated above, one reason for this less drastic hearing improvement could be due to the high percentage of patients who were treated for COM (87%). Perhaps more important, the present series of patients represents a large number of revision cases. In this study, 72% of patients (n = 110) underwent revision mastoidectomy at the time of OCR. Thirty-nine percent of patients (n = 60) underwent revision OCR. Finally, most patients in this study were noted to have scores of 5 of more on the OOPS index, reflecting a poor prognosis for hearing outcomes following ossicular reconstruction, although specific OOPS scores for each patient did not correlate with postoperative ABG in this series.

In addition to the above, the presence of underlying eustachian tube dysfunction (ETD) cannot fully be discounted as a contributor to difficult to control disease in this cohort. While tympanoplasty is at least in part aimed at producing an eardrum that is resistant to the effects of ETD, it is difficult to determine the severity of ETD in these patients preoperatively or how significantly their disease will affect their function in the late postoperative period. It is likely that continued treatment of ETD postoperatively is a significant contributor to sustained improvement in hearing following OCR. In addition, a fair number of patients had significant worsening of word recognition over the long term. Worsening word recognition has been seen in patients in other series over long terms, but the reasons for this worsening have had limited discussion. While it is difficult to determine the exact cause of this drop for individual patients, in all likelihood, this represents a progression of a sensorineural component of hearing loss present at the time of surgery. It is possible that manipulation of the oval window during surgery expedited this progression, although this cannot be proven definitively.

This study attempts to quantify long-term hearing outcomes in a complex patient population. In patients with cholesteatoma, priority is given to disease clearance, and hearing restoration assumes a secondary albeit important

![Figure 5](image)
role in surgery. In the secondary analyses performed with this cohort stratifying patients with cholesteatoma and those without, patients with cholesteatoma had statistically significant improvement in ABG postoperatively (Figure 5). Presence or absence of cholesteatoma and patient age were not shown to affect long-term outcomes in this series. The large proportion of patients undergoing revision surgery as mentioned above is another factor signaling a patient population in whom surgical control of disease has proven difficult. Titanium implants have been shown to have high rates of success even in revision OCR, although few studies have been done specifically addressing this question. During the follow-up period (mean 44 months) in this study, only 12 (8%) patients required revision surgery for any reason. This revision rate is lower than the commonly reported rate of 10% to 20% with OCR.

Only 2 patients in this series required revision surgery secondary to displacement or extrusion of the prosthesis. As seen in Table 4, the rate of extrusion is less than most studies with long-term follow-up, with the exception of the study by Nevoux et al in which there were no extrusions. There were 17 instances of displaced prosthesis in their study requiring revision surgery. In the present study, the remaining 10 cases that required revision were due to recurrence of cholesteatoma. This represents a low rate of disease recurrence, particularly in a population with long-term follow-up. As such, it can be inferred that titanium is well tolerated in the middle ear and does not contribute to recurrence of cholesteatoma or COM.

The OOPS index score did not correlate with long-term hearing results in this cohort, which is consistent with prior work validating the index. To determine which factors had an impact on hearing outcome, we analyzed each variable within the OOPS index. We included other factors such as smoking status and mobility of the stapes footplate, as these have previously been shown to be associated with hearing outcomes in OCR. Of all factors evaluated, none were found to be associated with a poorer hearing outcome. While the absence of a malleus handle has been shown to be a significant prognostic factor elsewhere, it was not a significant factor in this cohort. This could be due to the fact that this is a population of total ossicular reconstructions. Without a stapes superstructure, reconstituting a connection from the malleus to the stapes may be less meaningful. Absence of the malleus is likely an indicator of severe middle ear disease and subsequently relays important information, but the lack of significance here is likely related to the fact that the malleus is not used during OCR at the authors’ institution. Given these patients were undergoing total ossicular reconstruction, it can already be assumed that they have severe middle ear disease, and good outcomes following OCR may be difficult to achieve. The lack of identifiable risk factors in our study indicates that predicting outcomes in total ossicular reconstruction may be difficult.

This study has limitations. First, as a retrospective series, our analysis was limited by information already present within the medical record. This may have led to inclusion of fewer patients, as we limited the study to patients who had follow-up data of 2 years or more. In addition, the retrospective design prevents a priori determination of appropriate sample size to conduct the study. We feel that this is adequately addressed by the large sample size, however. Finally, we were unable to identify risk factors for poor hearing outcome in multivariate analysis. While this is a relatively large sample size, it could be that larger studies are needed to develop predictive tools for total OCR.

Conclusions
Total ossicular reconstruction with titanium implants leads to significant hearing improvement, even in difficult to treat patient populations such as the one in this study (high component of revision cases and COM). Titanium implants are well tolerated by the middle ear, as evidenced by an exceptionally low rate of prosthetic extrusion and low rate of need for revision surgery in this series. Prediction of audiological outcomes with total ossicular reconstruction is challenging, as the commonly evaluated risk factors in OCR are not significantly associated with outcomes in this patient population.

Author Contributions
C. Burton Wood, study design, data retrieval, statistical analysis, manuscript writing/editing/approval; Robert Yawn, study design, statistical analysis, manuscript writing/editing/approval; Anne Sun Lowery, data retrieval, statistical analysis, manuscript writing/editing/approval; Brendan P. O’Connell, study design, data retrieval, statistical analysis, manuscript writing/editing/approval; David Haynes, study design, data retrieval, statistical interpretation, manuscript writing/editing/approval; George B. Wanna, study design, statistical interpretation, manuscript writing/editing/approval.
Disclosures
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