Hearing Outcomes after Ossicular Reconstruction with Removal of the Malleus

Rex S. Haberman II, MD1,2 and Anna M. Salapatas, MS3

Abstract

Objectives. (1) Evaluate hearing outcomes of patients after planned malleus removal during ossicular chain reconstruction. (2) Analyze hearing results for titanium (Ti) and hydroxyapatite (HA) total ossicular prostheses (TOPs) and partial ossicular prostheses (POPs). (3) Compare Ti and HA partial prostheses.

Study Design. Retrospective case series with chart review.

Setting. Tertiary health care organization.

Subjects and Methods. A chart review was conducted of 139 consecutive patients who presented with chronic otitis media with perforation (with or without cholesteatoma) and were treated with initial-stage tympanoplasty (with or without mastoidectomy) and managed with TOP (n = 22) or POP (n = 117) between July 2010 and July 2015. The malleus was completely removed in all cases. Hearing was assessed via bone and air conduction pretone averages (0.5, 1, 2 kHz) pre- and postoperatively. Air-bone gap (ABG) and change in ABG (ΔABG) were analyzed. Pre- and postoperative values were compared.

Results. The overall mean ABG decreased from 29.4 ± 12.3 dB to 18.2 ± 11.4 dB postoperatively (P < .001) with a mean ΔABG of 14.5 dB (95% CI, 12.793-16.203). Overall success was achieved by 69.1%. The POP group achieved higher success (70.9%) than the TOP group (59.1%; P = .0001). Mean ABG decreased significantly within surgical groups (TOP and POP) and prosthesis material groups (Ti and HA; all P < .001). Ti had statistically higher success than HA in both techniques: POP (P = .0478) and TOP (P = .0251). There was a 98% graft take rate.

Conclusion. Planned malleus removal during ossicular chain reconstruction, regardless of disease extent, allows for simpler reconstruction and comparable favorable results to preservation of the malleus and should be considered during surgical planning.

Keywords
tympanoplasty, mastoidectomy, ossicular reconstruction, malleus, removal, hearing

The primary goal of ossicular chain reconstruction (OCR) is hearing restoration. To optimize OCR outcomes, extensive surgical literature is available of studies comparing materials, surgical methods, and patient factors. However, a consensus is far from established. The ear surgeon is essentially striving for 2 main outcomes: improved acoustic results and stability of the reconstructed ear. These goals can often be mutually exclusive, and different surgical perspectives should be considered.

It is widely accepted that to achieve optimum hearing during OCR, the malleus must be preserved.1-3 Furthermore, it is believed that malleus preservation will prevent tympanic membrane (TM) lateralization during the healing phase if some ligamentous attachments are preserved.4 Given these principles, otologists strive to preserve the malleus (except for the malleus head)—including, most important, the anterior malleolar ligament (AML) attachment and, of less significance, the tensor tympani attachment during tympanoplasty.

The AML is known to stabilize the TM while maintaining it at the level of the annulus, conceptually preventing lateralization. The presence of the malleus with an intact AML is considered to offer improved prosthesis stability by allowing precise length adjustments and ultimate fit, leading to optimal hearing results. Nevertheless, because anterior and anterior-superior mesotympanic and epitympanic cholesteatoma and granulations are common in chronic ear surgery, the risk of complications may increase when preservation of the malleus and retention of the intact AML are made a priority. Also, frequently encountered anterior and anterior-superior TM retraction associated with or
without medialization of the malleus further compromises the AML benefit, and this leads to more difficulty in the placement of the prosthesis and thus jeopardizes its stability.

Reports in the literature have failed to produce a consensus of various prosthetic materials that lead to best practice for OCR. A meta-analysis by Zhang et al.\(^5\) reported no significant difference between the titanium (Ti) and non-Ti groups in the rehabilitation of conductive hearing loss. Although Ti has similar weight to the ossicle, practical advantages for intraoperative manipulations and stability, and hypothetical advantages in speech frequencies performance,\(^6,7\) no definitive conclusion about the superiority of Ti over hydroxyapatite (HA) has yet been drawn.\(^5,6,8-11\)

The purpose of this research is to introduce an alternative surgical technique for OCR with intentional removal of the malleus in all studied patients. Functional results of OCR are also compared with either HA or Ti for partial ossicular prosthesis (POP) and total ossicular prosthesis (TOP) at a 6-month follow-up. Pre- and postoperative air-bone gaps (ABGs) are compared as a function of frequencies.

**Methods**

**Patient Selection**

Institutional review board (Allina Health, Minneapolis, Minnesota) approved this case series and chart review with exempted informed consent and a Health Insurance Portability and Accountability Act waiver. Cases from a total of 225 consecutive patients who underwent planned malleus removal during OCR between July 2010 and July 2015 were included in this retrospective case series. All cases were performed by the senior author (R.S.H.), and only primary cases were included (no revisions). Silastic was not used in any cases. Cartilage was used when Ti prostheses were used. No cartilage was used with HA prostheses. The following inclusion criteria were used for this study: (1) diagnosis of chronic suppurative otitis media with and without cholesteatoma, (2) minimum follow-up of 6 months, and (3) complete pre- and postoperative audiometric data.

Congenital malformations and traumatic displacements were excluded. In addition, patients whose charts did not have adequate postoperative information for complete data collection were eliminated (n = 86). Otherwise, all patients were included in the study for data analysis. Of the 225 patients who underwent OCR with malleus removal, 139 met our inclusion criteria and were the basis of this study.

**Surgical Technique**

Tympanoplasty and ossiculoplasty with or without mastoidectomy were performed on patients presenting with chronic otitis media with perforation (with or without cholesteatoma; Figure 1). In all cases, the malleus was intentionally removed, and the AML was cut (Figure 2) because the surgeon determined intraoperatively that malleus involvement by cholesteatoma or malleus medialization precluded preservation. Once the malleus is removed and the AML is cut, graft and prosthesis placement with a standard underlay technique becomes clear and simple (Figure 3), albeit now with no impeding malleus to finesse or AML to circumvent.

The ossicular chain was reconstructed with Grace Medical (Memphis, Tennessee) HA POPs and TOPs and Grace Medical Ti and Olympus Micron Ti (Olympus Gyrus Middle Ear Implants, Cardiff, United Kingdom) POPs and TOPs. An appropriate length needed for insertion of the prosthesis was measured. All HA prostheses placed were adjustable. The HA prosthesis shafts were trimmed to length by a wire cutter, which removed excess wire to be flush with the surface. Ti prostheses were presized or else sized to length at the time of surgery. There were no selective criteria for the choice of type of prosthesis, which was left to the preference of the surgeon at the time of surgery.

**Data Collection**

Data included demographic, clinical, disease-related, and audiologic information. The demographic information collected included age and sex. Clinical data included diagnosis, surgical technique used (POP, TOP), type of material used for reconstruction (Ti, HA), postoperative findings (eg, extrusion), hearing, and follow-up period.

The main outcome criteria were functional results (ABG) and 6-month postoperative anatomic condition (ie, recurrence of cholesteatoma or retraction pocket and extrusion or displacement of the prosthesis). All patients underwent an audiogram preoperatively and at least 6 months postoperatively. Audiologic data were analyzed and reported according to the 1995 guidelines of the American Academy of Otolaryngology—Head and Neck Surgery.\(^12\) Hearing results were reported with a 3-frequency pure-tone average ABG (0.5, 1, 2 kHz). Mean ABG and change in ABG (ΔABG) were also recorded. A successful functional result was defined as a postoperative ABG ≤20 dB for all POPs and a postoperative ABG ≤30 dB for all TOPs. Graft take rates and hearing results were recorded and analyzed.

**Mortality and Morbidity**

The graft take rate was at a 98.6%, with no lateralizations and no cholesteatoma recurrence to date. There was no mortality. No major complications were observed, such as facial paralysis, cerebrospinal fluid leak, vertigo requiring admission, or vascular injury. There were no infections or hematomas. Operations were conducted in an outpatient setting unless institutional requirements for overnight observation were imposed. No readmissions were identified.

**Statistical Analysis**

All statistical analyses were performed with SAS 9.4 (SAS Institute Inc, Cary, North Carolina). Continuous data are displayed as mean ± SD and categorical data as n (%). Mean change in ABG (ΔABG) is reported as mean (95% CI). Paired t tests were used to compare pre- and postoperative differences for hearing results. Chi-square tests were used to test the association between categorical variables.
when analyzing the POP and TOP groups. Fisher’s exact tests were used to test the association between HA and Ti for the POP and TOP groups, since >20% of the expected cell frequencies were <5. Pearson r correlations were calculated to determine relationships and strong interactions between variables and as a preliminary test for multicollinearity. To calculate factors predictive of surgical outcomes, logistic regression was utilized to obtain the odds ratios (ORs) and 95% CIs and a receiver operating characteristic (ROC) analysis. An area under the curve >0.70 was considered satisfactory. For the ROC analysis, the point with the largest sum of sensitivity and specificity was chosen as a threshold. The Shapiro-Wilk test, the skewness and kurtosis values, and the Q-Q plots suggest normality of data.

Figure 1. Cholesteatoma and medialization of malleus. A, A cholesteatoma (shaded area) eroding into the malleus. Also, canal incisions are made from 12 to 6 o’clock, with lateral incisions creating a flap to be retracted anteriorly with the auricle if a postauricular approach is utilized. B, Here the malleus is medialized and adherent to the middle ear, precluding preservation.
Validation of results was done with a holdout sample taken from the original data. All variables with a $P$ value $> .05$ in the univariate analysis were included in the multivariate analysis. Statistical significance was accepted for $P < .05$.

**Results**

Data from a total of 139 patients were included in this analysis: 117 were implanted with POP and 22 with TOP. The median age at the time of surgery was 43 years (range, 7-78 years), and the median follow-up time was 13 months (range, 6-45 months). A total of 110 patients received Ti prosthesis (91 POP and 19 TOP), and 29 received HA prosthesis (26 POP and 3 TOP).

The overall mean ABG decreased significantly from 29.4 ± 12.3 dB to 18.2 ± 11.4 dB postoperatively ($P < .0001$). The mean ABG decreased from 27.8 ± 12.0 dB to 16.4 ± 9.9 dB in the POP group ($P < .0001$) and from 38.0 ± 10.4 dB to 27.9 ± 14.0 dB in the TOP group ($P = .0030$). The mean ABG decreased from 31.4 ± 11.5 dB to 21.5 ± 12.6 dB in the HA group ($P < .0001$) and from 28.9 ± 12.6 to 17.4 ± 10.9 in the Ti group ($P < .0001$).

The overall $\Delta$ABG is 14.5 dB (95% CI, 12.793-16.203). The mean improvement in ABG was 6.7 dB (95% CI, 7.676-21.009) for HA TOP, 14.2 dB (95% CI, 8.576-19.792) for Ti TOP, 14.4 dB (95% CI, 10.006-18.794) for HA POP, and 14.8 dB (95% CI, 12.813-16.886) for Ti POP. The overall success was achieved by 69.1% of cases, with “surgical success” being defined as a postoperative ABG ≤ 20 dB for all POPs and a postoperative ABG ≤ 30 dB for all TOPs. Success was achieved in 0.0% of HA and 68.4% of Ti TOP cases ($P = .0251$) and 57.7% of HA and 74.7% of Ti POP cases ($P = .0478$). Ti is statistically more successful in both POP and TOP techniques. The POP group achieved higher success (70.9%) than the TOP group (59.1%, $P = .0001$; Table 1).

Logistic regression was performed with a stepwise variable selection technique to determine the likelihood of surgical success. Overall, there were no substantial indicators of multicollinearity between predictor variables ($r < 0.19$). Results indicate that surgical success is more likely to occur in patients who underwent POP ossiculoplasty (OR, 2.70; 95% CI, 3.89-5.980; $P = .0058$) with Ti prosthesis (OR, 1.37; 95% CI, 1.076-1.873; $P = .0133$) and lower preoperative audiologic results for the 2-kHz frequency (OR, 2.11; 95% CI, 0.137-0.202; $P < .0001$). The Hosmer and Lemeshow goodness-of-fit test implies that the data fit this model ($\chi^2 = 19.8, P = .063$). Area under the model ROC curve is 0.791 (95% CI, 0.581-0.921; $P = .0045$). Sensitivity and specificity of the model are 75.8% and 69.5%, respectively.

A software-generated randomly selected sample (n = 87) from the original data was used as a holdout sample to validate the results. There were no statistical differences between the data obtained from the holdout sample and the full original data set, suggesting that this study is a good representation of this group of patients. Additionally, the holdout sample was used to verify our regression model. The classification accuracy rate of the holdout sample was within 10% of the remaining sample, indicating that our model is valid.

**Discussion**

Classical thinking has led many surgeons to believe that the preservation of the malleus during OCR is the most reliable method to optimize hearing results. It is believed that an intact malleus plays a role in concentrating energy and stabilizing the new TM. This is said to improve malleus-cartilage couple transmission at the head of the prosthesis because of the absence of lateralization and the improved middle ear aeration from the maintenance of the new drum in an optimal position. Nevertheless, lateralizations and other complications do occur.

This study illustrates a surgical technique for OCR that includes the intentional removal of the malleus, where the AML is cut. The results of this study show an overall $\Delta$ABG of 14.5 dB (95% CI, 12.793-16.203), with a statistically significant mean improvement in ABG for each of the subgroups: HA TOP, Ti TOP, HA POP, and Ti POP. The results are comparable to similar studies where the malleus and AML are intact.

In a meta-analysis that studied individual ossicle status, Blom et al concluded that only malleus condition influenced postoperative hearing outcomes; however, just 2 case-control studies were included in this assessment. Bared and Angeli reported a significant difference between patients with intact and absent malleus handle; however, Redaelli and Goode did not find the presence of the malleus handle to have clinically significant results. Additionally, previous studies that included malleus status in regression analysis concluded that a present malleus was a significant predictor.
Nevertheless, the results of the surgical procedure performed in this study are comparable to their favorable group. In the studies by Dornhoffer and Gardner, Mardassi et al., and De Vos et al., the mean change in ABG for their malleus-intact group is not statistically different from the result of this study ($n = 126$, $\Delta ABG = 11.6 \, dB$, $P = .0724$; $n = 70$, $\Delta ABG = 12.7 \, dB$, $P = .3165$; and $n = 69$, $\Delta ABG = 16.7$, $P = .1407$, respectively). Although, Bared and Angeli did not provide a standard deviation to their mean $\Delta ABG$ of 13.1 dB and it cannot
be statistically compared with this study, their result is comparable.

Another important outcome of this study is the statistical superiority of Ti versus HA in both POP and TOP techniques. Previous literature has failed to produce a definitive conclusion of Ti over HA for best practice of OCR.\textsuperscript{5,6,8-11} Although theories of Ti’s superiority have been made,\textsuperscript{6,7} this study is the first in the literature that shows this result statistically.

This study has limitations, with the most obvious being the retrospective nature and heterogeneity of patients included, as well as the lack of a control group. A prospective study comparing these 2 groups would add information about the benefit of this proposed surgery. This type of study would be extremely difficult to perform. The lead author also performs OCR with the malleus left in place, but the decision to remove or retain is made at surgery and is dictated by the pathologies present. Thus, prospective groups would not be similar in their underlying pathologies. Specifically, the intact-malleus group may have less ossicular pathology and better-expected results.

Although a longer follow-up period would have been more desirable in demonstrating longer-term results of the surgery, the extent of the available data allowed us a follow-up range of 6 to 45 months. Since our median follow-up was 13 months, more than half of the patients had >1-year follow-up. Longer-term data were not available for the remaining patients. A subset analysis on those patients with >1-year data did not differ significantly from the shorter term. We concluded that at least 6 months was a reasonable time frame. Future studies may help look at longer-term results of this surgery.

An additional limitation was the small HA TOP sample. To account for this, we used Fisher’s exact test in our categorical analysis of the prosthesis groups. Ideally, an equal number of patients would be included in each group; however, this was unattainable in the time frame that our data were collected. Nevertheless, this group is important to the results and the study.

Eighty-six patients were excluded due to incomplete postoperative follow-up information, primarily absence of a postoperative audiogram assessment. It is possible that patients who experience elimination of symptoms may be reluctant or deem it unnecessary to undergo a second audiogram. Alternatively, patients with no change or worsening of their symptomatology may not complete a follow-up for separate reasons. If anything, exclusion of these patients had a negative effect on success rate. This can lead to under- or overestimation of surgical outcomes that are truly unknown. Nevertheless, the normality tests performed prior to any other analysis suggest that this sample of cases is statistically a normal representation of our population. To further analyze this, a holdout sample of 87 randomly selected cases of the original data set was used to validate our study’s results. These 87 random cases demonstrated similar outcomes to the full data set. The results of these tests statistically imply that the outcomes of this study can be generalized.

### Conclusion

After removal of malleus and incus, tympanoplasty and OCR with POP/TOP are simplified and facilitate placement of cartilage and fascia grafts. This method has shown to have a high graft take rate, no lateralization concerns, and improved hearing results.

### Author Contributions

Rex S. Haberman II, lead surgeon, study design, acquisition of data, interpretation of data, drafting and critical revision of manuscript, final approval; Anna M. Salapatas, study design, acquisition of data, interpretation of data, drafting and critical revision of manuscript.

### Disclosures

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### References

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