Prognostic Factors in Ossiculoplasty: A Statistical Staging System

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Objective: To determine factors that predict hearing results using a standard prosthesis system.
Study Design: Retrospective chart review.
Setting: Tertiary referral center.
Patients: All patients undergoing ossiculoplasty with the Dornhoffer HAPEX partial and total ossicular replacement prostheses (PORP and TORP) from February 1995 to May 1999 who had documented postoperative follow-up and no congenital atresia or stapes fixation. A total of 185 patients (200 ears), 105 men and 80 women, were evaluated.
Interventions: Ossiculoplasty with the Dornhoffer prostheses.
Main Outcome Measures: Hearing results using a four-frequency pure-tone average air–bone gap (PTA-ABG). Multivariate statistical analysis determined the effect of mucosal status, ossicular chain status, and type of reconstruction techniques on hearing.

Results: The PTA-ABGs were 13.4 ± 8.1 dB and 14.0 ± 8.4 dB for the PORPs (n = 115) and TORPs (n = 86), respectively, which was not statistically different. When the malleus handle was present (n = 126), the PTA-ABG was 11.6 ± 6.2 dB, compared with 16.9 ± 10.1 dB when it was absent (n = 74), which was statistically significant (p < 0.05). Mucosal fibrosis, drainage, revision ear surgery, and type of surgical procedure had a significant detrimental impact on hearing. The type of pathologic process (perforation vs. cholesteatoma) had no significant impact on hearing results.

Conclusions: The revised staging system, the Ossiculoplasty Outcome Parameter Staging Index, more adequately predicts hearing outcome in this series of 200 cases.

Key Words: Ossiculoplasty—Outcomes—Staging system.
tients undergoing ossicular reconstruction with identical prostheses (the Dornhoffer PORP or TORP) and standardized surgical technique. A multivariate analysis was used to determine which factors influenced hearing results. Directed by these findings, a more appropriate and simplified grading system is introduced.

MATERIALS AND METHODS

A computerized otologic database was used to identify all patients undergoing ossiculoplastic procedures from February 1995 through May 1999, which, during this time frame, used the Dornhoffer TORP and PORP exclusively. The surgeries were performed by the senior author and residents under direct supervision at the University of Arkansas for Medical Sciences (UAMS) and Arkansas Children’s Hospital (Little Rock, AR, U.S.A.). The following were reasons for exclusion from the study: no postoperative follow-up or audiogram, inaccessible records, congenital atresia, and stapes fixation. Congenital atresia cases were excluded because this group of patients, in our experience, has significantly worse hearing results for reasons that appear to be unrelated to middle ear status. Stapes fixation cases were excluded because these were managed using a staged stapedotomy or malleovestibulopexy, which used a different prosthesis in most cases.

After inclusion in the study, the following information about patients was extracted from the database, which had been completed immediately after the surgical procedure: preoperative audiogram, ossicular status and type of prosthesis used (PORP or TORP), primary versus revision surgery, type of surgery (tymanomastoidectomy canal wall up, tympanomastoidectomy canal wall down, tympanoplasty with ossicular reconstruction, or exploratory tympanotomy with ossicular reconstruction), indication for surgery (audiologic, cholesteatoma, atelectasis, or perforation), and Bellucci classification (1 through 4). Hearing results were reported using a four-frequency (500, 1000, 2000, 3000 Hz) pure-tone average air–bone gap (PTA-ABG) (5). The following information was obtained from the patient’s chart: postoperative audiogram, mucosal status (normal, thickened, fibrotic), and frequency of drainage. Because of the way the data were obtained for this study, reviewer bias was prevented (i.e., preoperative data could not influence or be influenced by postoperative hearing results because the former had been recorded separately in the database).

The postoperative bone conduction scores were used to compute the results. The best postoperative audiogram was used in the data analysis, which was usually the 6-month or 1-year audiogram. The reason for this selection was that it was found that approximately 20% of patients experience persistent effusion immediately after surgery, a factor reflected in the first postoperative audiogram. If the effusion persists for >3 months despite nasal steroids and autoinsufflation, the ear is intubated. In these cases, the hearing improves after intubation, and this audiogram was used in the computation.

A one-way analysis of variance (ANOVA) was performed to determine statistically which factors influenced hearing outcome. In terms of variable-to-variable interaction, the data were analyzed for multicollinearity, and a correlation matrix was created. None of the values in the correlation matrix exceeded 0.4, and the model found no multicollinearity.

A multivariate linear regression was then used to determine a relative weight for each significant variable. This was performed by determining a regression coefficient for each significant factor, and then dividing each coefficient with the smallest coefficient. This normalized score was then rounded to the nearest whole number to develop the staging system.

RESULTS

Between February 1995 and May 1999, a total of 327 ossiculoplasties were performed using the Dornhoffer prostheses. Of these, 200 ears (185 patients, 105 male, 80 female) were included for study. Twenty-six cases were excluded for congenital atresia, but the predominant reason for exclusion was lack of appropriate follow-up. Because the surgeries were performed at a tertiary referral center, many patients, especially those living a great distance away, requested follow-up with their local ear, nose, and throat specialist; thus, postoperative audiograms were not available. Of the 200 ears available for analysis, 114 were implanted with a PORP and 86 with a TORP. The average patient age was 29.3 years (range, 4–73 years). The average follow-up was 11.6 months (range, 4 months to 5 years). The indications for surgery were cholesteatoma in 98 cases, atelectasis in 48, chronic otitis media with perforation in 46, and purely audiologic in 8. Purely audiologic indications were those cases in which the tympanic membrane appeared normal on physical examination but conductive hearing loss was demonstrated. These included four cases of incus necrosis with an intact tympanic membrane, two cases of incus dislocation after temporal bone fracture, and two cases of malleus head fixation. The ANOVA showed the following categories significantly to influence hearing outcome: ossicular chain status, mucosal status, drainage, type of surgery, and revision surgery.

With regard to the status of the ossicular chain, the average PTA-ABG for the PORP (stapes superstructure present) was 13.4 ± 8.1 dB, whereas that for the TORP (stapes superstructure absent) was 14.0 ± 8.4 dB. This difference was not statistically significant (p > 0.05), indicating that the effect of the stapes superstructure on hearing outcome was not significant. The malleus handle was incorporated in the reconstruction in 126 cases, and, in this group, the postoperative PTA-ABG was 11.6 ± 6.2 dB. The malleus handle was not used in the reconstruction in 74 cases, and the postoperative PTA-ABG was 16.9 ± 10.1 dB in this group. This difference was statistically different (p < 0.05), indicating the importance of the malleus in the reconstruction. Breaking these findings down further according to the Austin classification system gave the postoperative PTA-ABG data shown in Table 1. The regression coefficient for the malleus-absent situation was 1.72, which was rounded to 2 for the staging system.

The status of the middle ear mucosa was likewise found to influence the hearing results. On the otologic database, mucosa was described as normal (n = 65), thickened (n = 64), or fibrotic (n = 71), with fibrotic defined as significant adhesions, scar bands, or denuding of the mucosa during surgery. The postoperative PTA-
TABLE 1. Hearing results based on ossicular status

<table>
<thead>
<tr>
<th>Stapes</th>
<th>Malleus</th>
<th>N</th>
<th>PTA-AGB (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>+</td>
<td>80</td>
<td>11.5 ± 6.2</td>
</tr>
<tr>
<td>+</td>
<td>−</td>
<td>34</td>
<td>17.7 ± 10.3</td>
</tr>
<tr>
<td>−</td>
<td>+</td>
<td>46</td>
<td>11.9 ± 6.2</td>
</tr>
<tr>
<td>−</td>
<td>−</td>
<td>40</td>
<td>16.3 ± 10.0</td>
</tr>
</tbody>
</table>

PTA-AGB, pure-tone average air–bone gap.

ABGs for these types of middle ear mucosa were 10.7 ± 5.7, 11.8 ± 6.6, and 18.0 ± 9.7 dB, respectively. Although there was a trend toward worse hearing results with mucosal thickening, only fibrosis was statistically significant in predicting a worse outcome (p < 0.05). The regression coefficient for fibrosis was 2.1, which was rounded to 2 for staging purposes.

The Bellucci classification was not statistically significant overall (p = 0.06); however, there was a clear trend toward worse results with Bellucci classifications 1, 2, and 3 (11.6 ± 6.3, 14.4 ± 8.6, and 15.3 ± 9.6 dB, respectively). Bellucci classification 4, which involves an association with cleft palate or choanal atresia, deviated from this trend with a PTA-ABG of 12.3 ± 5.1 dB, which skewed the data. When the analysis was changed to assess ears with no drainage (Bellucci type 1) versus drainage at least 50% of the time (Bellucci type 3), and excluding type 4, the results were significant (p < 0.05). The frequency of drainage was obtained from the patient’s chart and had been determined during the initial evaluation by patient response to the following: drainage occurs never, some of the time, most of the time, or all of the time. The latter two responses were considered to represent drainage at least 50% of the time. The presence of drainage was associated with a regression coefficient of 1.06, which was rounded to 1.

The type of surgery affected the results in a negative way when mastoidectomy was a component of the surgical procedure, with removal of the canal wall more significantly affecting outcome. Ossiculoplasty without mastoidectomy was performed 73 times, yielding an average PTA-ABG of 10.8 ± 7.5 dB in this group. Canal-wall-up mastoidectomy, including canal wall reconstruction with the retrograde technique (6), was performed 87 times, yielding a PTA-ABG of 13.8 ± 6.5 dB. Canal-wall-down techniques were used 40 times, with a resulting average PTA-ABG of 18.3 ± 10.6 dB. Both the inclusion of mastoidectomy as part of the procedure and removal of the canal wall were associated with worse hearing results that reached statistical significance (p < 0.05), compared with cases with no mastoidectomy. Likewise, in a comparison between canal-wall-up versus canal-wall-down techniques, the latter was found to yield significantly worse results (p < 0.05). The regression coefficient was 1.01 for the performance of a mastoidectomy and 2.1 for a canal-wall-down procedure. These were rounded to 1 and 2, respectively, for the staging system.

Revision surgery was performed 101 times, resulting in an average postoperative PTA-ABG of 16.3 ± 8.9 dB in this group compared with 10.9 ± 6.5 dB in the group that had no previous otologic reconstruction (n = 99). This difference was statistically significant (p < 0.05). The regression coefficient for revision surgery was 1.62, which was rounded to 2.

Based on these results, Table 2 provides our grading system, termed the Ossiculoplasty Outcome Parameter Staging (OOPS) Index. To our knowledge, this is the first staging system for ossiculoplasty that incorporates statistical analysis of a large series of patients treated in a standard fashion (i.e., same surgeon, surgical technique, prosthesis). Figure 1, which shows the best-fit curve plotting risk score versus the PTA-ABG of our series, illustrates the adequacy of this staging system for predicting hearing outcome. The curve shows a fairly linear function with a coefficient of correlation of 0.8.

DISCUSSION

Success in ossiculoplasty is determined by technical ability and, to a large extent, case selection. One of the most challenging aspects of training ear surgeons in a residency program is the instruction of when and when not to operate in a given situation based on the patient’s hearing level, history, and presentation. Likewise, much of the variability in the literature concerning hearing results after ossiculoplasty is due to a lack of understanding and uniform reporting of those middle ear factors that influence the results. A good example can be appreciated by analyzing the initial results for ossiculoplasty reported from this institution, which showed surgery with PORPs to have an average postoperative PTA-ABG of approximately 10 dB (1). Although the prosthesis, technique, and surgeon are the same, the current results with the

TABLE 2. Ossiculoplasty outcome parameter staging index

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Risk value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle ear factors</td>
<td></td>
</tr>
<tr>
<td>Drainage</td>
<td>0</td>
</tr>
<tr>
<td>Present &gt;50% of time</td>
<td>1</td>
</tr>
<tr>
<td>Mucosa</td>
<td>0</td>
</tr>
<tr>
<td>Normal</td>
<td>2</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>Malleus +</td>
<td>1</td>
</tr>
<tr>
<td>Malleus −</td>
<td>2</td>
</tr>
<tr>
<td>Surgical factors</td>
<td></td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
</tr>
<tr>
<td>No mastoidectomy</td>
<td>0</td>
</tr>
<tr>
<td>Canal-wall-up mastoidectomy</td>
<td>1</td>
</tr>
<tr>
<td>Canal-wall-down mastoidectomy</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>

PORP are 20% worse because more severely diseased ears are being reconstructed under our expanded indications. The importance of a middle ear grading system that is reliable and simple to use cannot be overemphasized.

Valid attempts have been made to elucidate prognostic factors in tympanoplasty, each contributing significantly to our understanding of middle ear disease and its affect on hearing results with ossiculoplasty. Black reported his SPIITE method of assessment, which divided prognostic factors into surgical, prosthetic, infection, tissue, and eustachian (7). Bellucci’s classification has four groups, which helps separate cases with good and poor prognoses based on degree and duration of drainage and associated craniofacial abnormalities (3). Austin’s classification is based on the status of the ossicular chain as a determinant of success (4). Albu and colleagues’ work, although not a grading system as such, was a well performed statistical analysis of a variety of middle ear and ossicular factors and their impact on results in tympanoplasty (8). Kartush’s MER index is a logical culmination of several of the aforementioned systems (2). This index initially adapted well to the computerized otologic database used at our institution and has been used for several years (2). The current study offers the possibility of statistically analyzing this system using standardized techniques and one prosthesis line, the lack of this type of standardization being a criticism of many previous attempts.

The status of the ossicular chain as a determinant of hearing results has been somewhat controversial in the literature. In the current study, only the malleus manubrium was found to be significant, whereas the stapes superstructure contributed little. Theoretically, the stapes superstructure should contribute little or nothing to the acoustic gain of the middle ear mechanism, whereas the malleus actually may be significant acoustically through its action as a cantenary lever and impedance matcher (9). In the past, the poor performance of TORPs compared with PORPs was probably reflected in the increased stability afforded by the stapes superstructure in the latter situation. In the design of the Dornhoffer TORP, a large emphasis was placed on the design of the head to incorporate the malleus and shift the center of gravity over the shaft for increased stability. This increased stability has allowed a more equal comparison between the PORP and TORP, thus shifting attention to the importance of the malleus, as evidenced by the results of this study. Albu et al. (8) also showed the statistical contribution of the malleus, and others, such as Fisch (10), Austin (4), and Black (7), have emphasized its importance in successful ossiculoplasty. Others, however, have found the malleus to be less relevant (11,12). Interestingly, although not quite statistically significant with the multivariate analysis, the presence of the stapes superstructure was found to be a detriment in cases involving more severe mucosal fibrosis, which has been noted by others (13). As is shown in Table 1, worse hearing results occurred in those cases where the stapes was present and the malleus was absent. In the milieu of severe fibrosis, consideration is now being given to removal of the superstructure with the laser in an attempt to improve results in this situation.

The pathologic condition of the middle ear as a predictor of outcome is a very confusing issue in the literature (7,8,11). Albu et al. found significance in dividing simple otitis media, granulating otitis media, and cholesteatoma in relation to worsening results (8), although others have found no significance (11). In the current study, the pathologic condition associated with the surgical indication was not significant. The statistical analysis was performed in such a way as to determine which factors in a given situation were most predictive of outcome, and the mucosal status and presence of drainage

![Risk score versus the postoperative pure-tone average air–bone gap for the patient series, illustrating adequacy of the Ossiculoplasty Outcome Parameter Staging Index. Coefficient of correlation = 0.8.](image-url)
were more significant than the pathologic conditions initiating the surgical procedure. In other words, some epitympanic cholesteatomas were associated with no drainage or mucosal disease in the middle ear cleft and resulted in excellent outcomes, whereas others showed severe mucosal fibrosis and drainage and were associated with poor outcomes. It was not the presence of cholesteatoma, but the associated middle ear disease, that was found to be significant.

As in other studies (7,8), the condition of the middle ear mucosa was found to correlate significantly with outcome, demonstrating a standardized regression coefficient of 2 in this study. In the database used at this university, an attempt is made to differentiate between mucosal thickening, which is potentially reversible, and fibrosis, which may not be. Included in the fibrosis category are those cases associated with significant denuding of the mucosa during surgical manipulation, as well as scarring between adjacent structures in the middle ear at time of surgery. Interestingly, mucosal thickening, when not associated with fibrosis, was not a significant risk factor in this study. The entire issue of mucosal disease, reversibility, and tubal function is beyond the scope of this analysis, but the importance of preserving the mucosa is underscored by the present statistical analysis. Although assessment of tubal function is very difficult and not currently included in the database, every attempt is made at this institution to improve eustachian tube function in the preoperative and postoperative period. The patient is instructed to perform autoinsufflation three times daily after surgery, and if unable to insufflate the ear by 3 months, the ear in intubated. Using this protocol, it does appear that mucosal thickening is at least in part reversible, and good results can be obtained.

The type or complexity of the surgical procedure had a significant impact on the hearing results, both in the performance of a mastoidectomy with the surgical procedure and, more important, in the removal of the canal wall. This is in agreement with Albu et al., who showed a detrimental association with the performance of a mastoidectomy (8). Likewise, Black demonstrated a negative impact when complex surgeries involving major scutum repairs were performed (7). The issue of the importance of the canal wall in hearing results has been very controversial and was shown in this study and others to affect outcome significantly (7,8). The detrimental impact of removing the canal wall has not, however, been universally shown (11). Conceptually, one might expect worse hearing results in a canal-wall-down situation because a shallow middle ear cleft is less acoustically efficient, and preservation or reconstruction of the canal wall favors a more physiologic ossiculoplasty, with less chance for contact and fibrosis of the prosthesis to the promontory or facial nerve (8). Currently, we are performing partial mastoid obliteration and reconstruction of the tympanic ring with cartilage when performing canal-down surgery in an attempt to deepen the middle ear cleft, and have had encouraging hearing results (14). A statistical comparison of this technique with standard canal-wall-down surgery is being performed and is the subject of another report.

In agreement with others (8,12), revision surgery was associated with significantly worse hearing outcomes, with a relatively high predictive weight. However, the indications for revision surgery, which included planned second-stage surgery for ossicular reconstruction, were not predictive of outcome. Likewise, the tympanic membrane pathologic process associated with these cases did not show a significant association. Intuitively, one would anticipate more fibrosis in revision surgery, a factor that was found to be significant and could be an explanation for the worse results in these cases. However, the correlation matrix portion of the multivariate analysis did not show a significant correlation with revision surgery and fibrosis over the group as a whole, indicating other factors are at play.

Using the regression coefficients determined statistically, the OOPS Index we have devised, and which is currently used at UAMS, is shown in Table 2. Although this staging system has proven to be quite helpful in our practice for predicting results, it does not entirely take into account the human issue. For example, not shown in Figure 1 but included in the statistical analysis, are five or six “outliers” that fell well outside the expected range for hearing results because of issues that are uncertain but must include human error and aberrant healing, substantiating the acronym “OOPS” for this index. The staging system should therefore be considered a guide, but certainly not a guarantee. Likewise, the analysis reflects the experience with one prosthesis design and a single surgeon’s philosophical approach toward otologic reconstruction. Whether this system can be extrapolated to other prostheses or surgical techniques has yet to be determined.

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