TORP Ossiculoplasty Outcomes with and without a Stapes Footplate Prosthesis

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. The titanium stapes footplate prosthesis (FPP) was designed to ensure a stable connection of a total ossicular replacement prosthesis (TORP) to the stapes footplate and maximize acoustic coupling by centering the footplate on the oval window. Our goal was to assess the impact of the FPP on TORP ossiculoplasty outcomes.

Study Design. Case series with chart review.

Setting. Tertiary care center.

Subjects. Adult patients undergoing TORP ossiculoplasty with (n = 53) or without (n = 108) a stapes FPP.

Methods. Rate of prosthesis displacement and audiologic outcomes were tabulated for statistical analysis.

Results. A lower rate of prosthesis displacement and statistically better audiologic outcomes were seen in FPP patients. The pure-tone average air-bone gap (PTA-ABG) was closed to ≤20 dB in 69.8% (37/53) of patients in the study arm and 44.4% (48/108) of patients in the control arm (P = .003). The PTA-ABG was decreased by a mean ± SD of 19.3 ± 11.7 dB and 12.6 ± 11.0 dB in the study and control groups, respectively (P = .0012).

Conclusions. Use of the titanium stapes FPP during TORP ossiculoplasty provides a statistically significant advantage in short-term PTA-ABG closure and a higher rate of successful rehabilitation of conductive hearing loss. Further studies are necessary to assess any long-term advantages a FPP may offer.

Keywords

total ossicular replacement prosthesis, TORP, ossiculoplasty, stapes footplate

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The ideal ossicular prosthesis re-creates the acoustic characteristics of the human ossicular chain while matching its long-term structural integrity. More than 70 different ossicular reconstruction prostheses are currently available in the United States. These implants vary in shape and are constructed from a variety of materials, including titanium, hydroxyapatite, bone cement, and HAPEX (hydroxyapatite-reinforced polyethylene composite). Despite advances in materials and design, none of the currently available prostheses have consistently shown closure of the airbone gap (ABG) to that of the healthy, native ossicular chain, and none are impervious to failure.1-5

Reasons for late ossiculoplasty failure have been described as being disease related, prosthesis related, or surgeon related, with persistence of middle ear disease being the most important, followed by displacement of an implanted prosthesis.6 Implant displacement leads to functional failure of the prosthesis as a coupling mechanism between the tympanic membrane and oval window, resulting in a maximal conductive hearing loss and poor patient satisfaction.

Two-point fixation of a prosthesis during ossicular chain reconstruction is a strategy aimed at minimizing the rate of device displacement. In the case of a total ossicular replacement prosthesis (TORP), the 2 points of fixation are the prosthesis head to the tympanic membrane and malleus (or tympanoplasty graft) and the prosthesis shaft to the stapes footplate. Several methods of ossicular prosthesis stabilization have been described, including cartilage grafting techniques7,8 and at least one similarly designed implant.9 The titanium stapes footplate prosthesis (FPP; Grace Medical, Memphis, Tennessee) was designed to create a stable connection between a TORP and the stapes footplate. In addition, the design of this prosthesis specifically centers the footplate on the oval window, which is thought to optimize ossicular coupling.10,11 This study was undertaken to determine if these attributes of the FPP led to improved

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and control groups comprised patients with similar or used for the calculations. The preoperative and postoperative pure-tone average air-conduction thresholds, as deemed valid by the Hearing Committee of the American Academy of Otolaryngology Head and Neck Surgery.12 Pure-tone averages were calculated by averaging the patient’s thresholds for 500, 1000, 2000, and 3000 Hz. In cases where 3000-Hz thresholds were not measured, this value is calculated based on middle ear findings at the time of surgery taken from the operative report and information obtained from records of the preoperative history and clinical examination (see Table 1). Duration of time between surgery and postoperative audiometry was similar between both groups, at 1.48 and 1.43 years for the FPP and non-FPP groups, respectively.

**Surgical Technique**

The titanium stapes FPP is a device that is implanted at the same time as a TORP. The FPP is designed to rest between the bony remnants of the stapedial crura and offer a stable point of fixation between the stapes footplate and an implanted TORP. In cases where the stapes superstructure is absent or present but malpositioned with respect to the footplate, the use of a TORP is also indicated. The FPP may be used in conjunction with a TORP in either of these situations and was employed in all situations where a TORP was used during the time period after during and after March 2007 within this study. The prosthesis resembles a “shoe” into which the TORP shaft is placed and acts to center the prosthesis on the footplate (see Figure 1).

The FPP is positioned between the remnant crura first, followed by insertion of the TORP. The shaft is placed into the shoe opening, and the head of the prosthesis is gently rotated under the malleus or under the cartilage tympanic

**Methods**

**Patient Population**

All research was performed under the guidance and approval of the institutional review board affiliated with the University of Arkansas for Medical Sciences (IRB No. 201910). A retrospective chart review was performed on all patients undergoing TORP ossiculoplasty between January 1998 and August 2012 at the university hospital. This hospital serves only adult patients, so children were not included in this study. A cohort of patients who underwent the same surgery prior to the availability of the FPP (March 2007) served as a control group. All cases of TORP ossiculoplasty during and after March 2007 used the FPP, and all cases of TORP ossiculoplasty prior to March 2007 did not use the FPP. All patients who met inclusion criteria and underwent TORP ossiculoplasty within the designated time frame were included in this study. The criteria for use of a TORP remained the same after introduction of the FPP. Both groups were identified using the otologic database that was initiated in 1998. To be considered for inclusion, patients must have had a record of preoperative and postoperative audiometry and at least 2 months of postoperative follow-up, in line with currently accepted recommendations.12 Exclusionary criteria included previous stapedectomy or stapedotomy, a history of aural atresia of the operative ear, or inadequate records or duration of follow-up.

**Data Acquisition**

The following was extracted from each patient’s chart: preoperative and postoperative audiometry records, patient age at the time of surgery, sex, laterality of procedure, indication for surgery, procedure(s) performed, model number of prosthesis or protheses placed, information regarding history of surgery on the operative ear, presence of preoperative otorrhea, and intraoperative status of the mucosa (thickened, fibrotic, etc) and ossicles (malleus absent vs present and usable for reconstruction).

Preoperative and postoperative audiometry records were used to compile air conduction and bone conduction thresholds for 500, 1000, 2000, 3000, and 4000 Hz. In cases where 3000-Hz thresholds were not measured, this value was calculated as an average of the 2000-Hz and 4000-Hz thresholds, as deemed valid by the Hearing Committee of the American Academy of Otolaryngology Head and Neck Surgery.12 Pure-tone averages were calculated by averaging the patient’s thresholds for 500, 1000, 2000, and 3000 Hz. The preoperative and postoperative pure-tone average air-bone gap (PTA-ABG) was calculated for each patient. The postoperative audiogram at the most recent follow-up was used for the calculations.

In addition, to determine the degree to which the study and control groups comprised patients with similar or dissimilar preoperative middle ear disease severity, the ossiculoplasty outcome parameter staging (OOPS) index13 was employed. This index was designed to prognosticate ossicular reconstruction in the context of the middle ear environment and is calculated based on middle ear findings at the time of surgery taken from the operative report and information obtained from records of the preoperative history and clinical examination (see Table 1). Duration of time between surgery and postoperative audiometry was similar between both groups, at 1.48 and 1.43 years for the FPP and non-FPP groups, respectively.

**Table 1. Factors Used to Calculate the 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></td>
</tr>
<tr>
<td>None</td>
<td>0</td>
</tr>
<tr>
<td>Present &gt;50% of 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>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>

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![](Figure 1)

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membrane reconstruction if the malleus is not present. Gelfoam is generally not necessary for support in the malleus-present situation (see Figure 2). For the purpose of this study, all surgeries were performed by the senior author (J.L.D.) or by senior residents under his direct supervision.

**Statistical Analysis**

A paired t test was performed to assess the difference between the preoperative and postoperative PTA-ABG ($\Delta$PTA-ABG) for the FPP group and the control group. The difference between preoperative and postoperative PTA-ABG was noted to be significant for both groups. The calculated $\Delta$PTA-ABG was used as a measure of hearing outcome as a result of ossicular chain reconstruction. The $\Delta$PTA-ABG was calculated for each patient, and these data for the study group and the control group were compared using the Mann-Whitney $U$-test.

Surgery was deemed successful based on closure of the PTA-ABG to a 20-dB hearing level (HL) or less. This rate of success was compared between the FPP and non-FPP groups using a $\chi^2$ test. A $P$ value of less than .05 was used as the measure for statistical significance in all calculations.

**Results**

Results were analyzed and conclusions were drawn in accordance with accepted recommendations for the evaluation of results of treatment of conductive hearing loss.14,15

**Patient Demographics**

Of the 245 adult patients initially identified, a total of 161 (53 FPP patients, 108 control patients) met the study criteria. Their demographic data are summarized in Table 2. Both the study group and the control group had an average OOPS index of 6.7. In the non-FPP group, 87% (94/108) of patients underwent revision surgery, and 68% (64/94) of revision cases were performed on patients who previously underwent a canal wall-down (CWD) procedure, which may have taken the form of radical mastoidectomy, modified radical mastoidectomy, or retrograde mastoidectomy with canal wall reconstruction. In the FPP group, 79% (42/53) of patients underwent revision surgery, and 71% (30/42) of these patients had a prior CWD procedure.

**Audiometric Results**

In Figure 3, the postoperative PTA-ABG results of the FPP and non-FPP groups are arranged in 10-dB bins for comparison, showing a majority of FPP patients in the 11- to 20-dB bin. These same data were used to determine the rate of successful closure of PTA-ABG to $\leq$20 dB HL for each group and the $\chi^2$ test was used for statistical comparison. The PTA-ABG was closed to 20 dB HL or less in 69.8% (37/53) of patients in the FPP group and 44.4% (48/108) of patients in the non-FPP group. This result was statistically significant ($P = .003$).

The average preoperative and postoperative PTA-ABG values and $\Delta$PTA-ABG for the FPP and non-FPP groups are illustrated in Figure 4. Preoperatively, there was no significant difference in average PTA-ABG between the groups (35.4 dB HL for the FPP group vs 34.6 dB HL for the non-FPP group; Mann-Whitney $U$-test; $P = .543$), but the average postoperative PTA-ABG was significantly lower in the FPP group (16.5 dB HL vs 22.0 dB HL in the non-FPP group; Mann-Whitney $U$-test; $P = .0013$). The change in PTA-ABG from pre- to postoperative audiometry was compared similarly, and there was noted to be a significantly larger change in the FPP group (19.3 dB HL vs 12.6 dB HL in the non-FPP group; Mann-Whitney $U$-test; $P = .0012$).

**Discussion**

The human ossicular chain acts as a cantilever mechanism, transforming the acoustic stimulus acting on the tympanic membrane into the mechanical energy that stimulates the oval window. Ossicular coupling is the descriptor for the
phenomenon of sound pressure gain occurring through the tympanic membrane and ossicular chain\textsuperscript{16} and is thought to be an important factor influencing the audiologic results of ossicular reconstruction. Thus, optimization of coupling may hold the key to improving outcomes in the surgical management of conductive hearing loss. The stapes superstructure in and of itself offers negligible acoustic gain in the reconstruction, but if it is present and oriented appropriately, it does provide a stable attachment point for a partial ossicular reconstruction prosthesis (PORP). In cases where the superstructure is not perpendicular to the footplate, a PORP would be angulated and result in suboptimal ossicular coupling and a higher risk for displacement. Ossicular reconstruction in the absence of a stapes superstructure or in the presence of an inappropriately oriented superstructure presents a significant challenge for creating a stable long-term solution. Utilization of the FPP in conjunction with a TORP in either of these situations represents one technique to help achieve this end.

Results of our study show that implementation of the titanium stapes FPP offered a significant advantage in PTA-ABG closure and a higher rate of successful rehabilitation of conductive hearing loss, at least in the short term. We believe these results to be due to the more effective ossicular coupling of the tympanic membrane to the oval window provided by the FPP. Other studies have shown similar encouraging results using other means for imparting stability at the level of the footplate with a TORP prosthesis, including construction of a cartilage footplate shoe\textsuperscript{7} and a floating cartilage sandwich shoe.\textsuperscript{8} A recent study examined outcomes of TORP ossiculoplasty using a similar footplate prosthesis and found similar short-term outcomes to ours for both patient groups.\textsuperscript{9} Other outcomes studies of total ossicular replacement prostheses (for TORP performed without FPP) have shown similar postoperative air-bone gaps as well.\textsuperscript{1,2}

The limitations of this study are those usually associated with a retrospective chart review. There was a selection bias in the sense that the control group was operated on earlier, before the introduction of the footplate shoe. This suggests the possibility of a learning curve effect, although this is not considered likely. The senior author had nearly 10 years of experience with ossicular reconstruction prior to the institution of the database used for this study. Despite this temporal limitation, the demographics were fairly well matched between the 2 groups, and the average timing for postoperative audiometry was very similar at 1.48 years (range, 60 days to 3.9 years) and 1.43 years (range, 60 days to 3.1 years) for the FPP and non-FPP groups, respectively. The severity of the middle ear environment was nearly identical based on the OOPS score. There were slightly more revisions in the control group but more CWD revisions in the FPP group.
A final limitation is that this study includes only adult patients. This is mainly because our database is not complete at our associated children’s hospital. Our previous study showed that the OOPS score was more predictive of outcome than age, but certainly a direct comparison of adults and children is in order and is currently ongoing.

Finally, the audiometric results of this study represent relatively short-term follow-up, another common problem associated with retrospective chart reviews at tertiary medical centers. Keeping in mind the fact that several factors (middle ear atelectasis, prosthesis-tympanic membrane interface, ongoing middle ear disease, etc) contribute to the overall durability of an ossicular reconstruction, evaluation of larger patient populations over a longer duration of postoperative follow-up will offer a better opportunity to identify any long-term structural advantages the use of a FPP may offer.

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Author Contributions
Matthew D. Cox, conception and study design, acquisition, analysis and interpretation of the data, drafting and revision of the manuscript; James S. Russell, acquisition and interpretation of the data, revision of the manuscript; John L. Dornhoffer, conception and study design, interpretation of the data, revision of the manuscript.

Disclosures
Competing interests: Matthew D. Cox, James S. Russell, and John L. Dornhoffer: J.L.D. designed the prosthesis being studied, which is manufactured by Grace Medical (Memphis, Tennessee). None of the other authors were involved in the design of this prosthesis. All profits are donated to charity and none of the authors hold any financial interest in the company.

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