Total Ossiculoplasty in Children

Predictive Factors and Long-term Follow-up

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Objective: To evaluate the long-term results and predictive factors of a good outcome with the use of a total ossicular replacement prosthesis in children.

Design: Retrospective case review.

Setting: Tertiary referral center.

Patients: The study included 114 children (116 ears).

Interventions: A total of 116 ears underwent total ossicular chain reconstruction with a titanium prosthesis. Cartilage was always used for tympanic membrane reconstruction.

Main Outcome Measures: Audiological results were evaluated according to the guidelines of the American Academy of Otolaryngology–Head and Neck Surgery. Predictive factors of audiological results were determined. Logistic regression and \( \chi^2 \) tests were used for statistical analysis.

Results: The mean age at surgery was 9.8 years. Ossiculoplasty was performed during second-look surgery in 91 ears (78.4%) and during another stage in 25 ears (21.6%). The first-stage procedure was always performed for cholesteatoma. Audiometric results were available for 116 ears at 1 year, for 89 ears (76.7%) at 2 years, and for 42 ears (36.2%) at 5 years. Closure of the average air-bone gap (ABG) to within 20 dB was achieved in 65 ears (56%) at 1 year. The mean (SD) preoperative and postoperative (at 1 year) ABGs were 41.0 (9.5) dB and 22.4 (12.6) dB, respectively. There were no cases of extrusion, but 17 luxations of the prosthesis were confirmed by computed tomography. Luxation occurred on average at 31.4 months. Only three 4000-Hz degradations of bone conduction were reported, with no dead ears. We examined 3 predictive factors of auditory results: preoperative ABG, footplate status, and postoperative otoscopic findings.

Conclusions: Total ossiculoplasty is a reliable technique in children. Long-term hearing outcomes are stable and satisfactory, but luxation can occur at any time. Preoperative ABG and footplate status are negative predictive factors of auditory results.


HOLESTEATOMA IS A COMMON disease and is potentially destructive in the middle ear. It is more aggressive in children than in adults, with a higher frequency of recurrences and residual lesions. Eradication of the disease is the objective of surgery, but auditory rehabilitation is also a concern for the surgeon. This rehabilitation is usually performed during second-look surgery in children and differs with the status of the stapes (partial or total ossiculoplasty). Several materials have been used for ossicular replacement. Autologous material, like cartilage, is especially effective in partial ossiculoplasty in children, as previously reported. Different types of synthetic material, especially titanium, have been used in the past. At present, titanium is the principal material composing partial and total prostheses. Since the first description of ossiculoplasty by Hall and Rytzner in 1957, numerous articles have reported various auditory results of ossiculoplasty. The results are generally superior in partial compared with total ossiculoplasty. Good auditory results occur in approximately 40% to 70% of partial ossiculoplasties and in 20% to 55% of total ossiculoplasties. There is a lack of predictive factors for postoperative results in ossicular reconstruction, especially in children. A few factors have been illustrated in adult studies, eg, persistent or recurrent abnormalities within the middle ear, presence of a malleus handle, and preoperative middle ear mucosa status. Moreover, authors rarely explore the failures of prostheses. However, it stands to reason that such exploration is the most important way to improve our surgical approach for ossicular re-
placement. The goals of the present study were (1) to explore the auditory results of total ossicular replacement prosthesis (TORP) in children for long-term follow-up, (2) to examine predictive factors, and (3) to analyze the failure of TORPs in children.

METHODS

PATIENTS

From January 1995 to December 2009, operations were performed in 116 ears (114 children). The surgeons are considered junior when they are fellows and senior when they have already completed their fellowships and have had more than 5 years of experience in otologic surgery. All fellows who worked in the department during the study received the same training and education from the senior surgeons. This system ensures that all surgeons perform the same procedure with the same surgical protocol. The anatomical results were defined with respect to the tympanic membrane repair and the presence of otitis media with effusion diagnosed by otoscopy or imaging. According to the guidelines of the American Academy of Otolaryngology–Head and Neck Surgery, the auditory results included the pure-tone average air conduction (AC) threshold, the pure-tone average air bone gap (ABG), the inner ear damage represented by a 4000-Hz bone conduction (BC) threshold, and the pure-tone average BC thresholds. A sensorineural hearing loss is characterized by an increase of a 4000-Hz BC threshold greater than 20 dB. A postoperative ABG less than 20 dB is considered a good auditory result. Criteria for prosthesis failure included a postoperative ABG greater than 30 dB or an increase compared with the preoperative ABG. The limit of 30 dB was chosen because it could be considered the social disabling threshold. Unsuccessful postoperative auditory results were mostly explored by computed tomography (CT) to find an explanation. Failures of prostheses were analyzed separately, and the follow-up was excluded from the initial postoperative data of the 116 ears when a revision surgery was performed.

TECHNIQUE

All children were previously operated on for cholesteatoma of the middle ear by a canal-wall-up mastoidectomy on at least 1 occasion. The second-look surgery was performed between 9 and 12 months after the primary surgery. The third or fourth operation was performed at various intervals after the previous one. The tympanic membrane was always repaired with a cartilage shield, as recommended in pediatric tympanoplasty. We always performed ossicular replacement during the revision surgery. Two types of titanium prosthesis were used (Medtronic Xomed [Figure 1] and Spiggle & Theis [Figure 2]). The length of these prostheses is adaptable to the depth of the middle ear.

PREDICTIVE FACTORS

We analyzed ossiculoplasty success at 1 year for several predictive factors. These factors were classified into preoperative, intraoperative, and postoperative factors. The first group included preoperative ABG (range of 10 dB), age at surgery, homolateral and contralateral otoscopy, reason for surgery (scheduled or not), and number of previous operations.

The second group concerned intraoperative factors, including footplate status, tendon of the tensor tympani muscle (sectioned or intact), status of the malleus (intact or eroded), experience of the surgeon (junior or senior), nature of persistent ossicles (intact malleus or handle only), middle ear inflammation (including intraoperative bleeding), percentage of tympanic membrane repaired with cartilage, and type of prosthesis. The postoperative factors were postoperative ABG, otitis media with effusion (present or absent), postoperative otoscopy, and CT findings.

STATISTICAL ANALYSIS

Univariate analysis was performed with the Pearson χ² or the Fisher exact test when the numbers were low (with a bilateral significance threshold of P ≤ .05). Distributions of quantitative data were compared with a 1-way analysis of variance (ANOVA) or a nonparametric Kruskall Wallis test when the results were not normal. All the factors associated with P < .20 were introduced in a logistic regression model and then backward selected to keep the factors associated with the outcome (P ≤ .05). Correspondent odds ratios (ORs) and 95% CIs were computed. SPSS software (SPSS Inc) was used for statistical analysis.

RESULTS

PATIENTS AND ANATOMICAL RESULTS

Over a period of 15 years, 116 ears were operated on, including 25 ears that were surgically treated on more than
2 occasions. Seventeen ears underwent a second operation for an auditory failing and for replacement of the prosthesis. Only 4 children were operated on bilaterally. The mean duration of follow-up was 34 months (range, 12-60 months). The mean age at surgery was 9.8 years (range, 3.4-18.9 years). There were 65 children (<10 years) and 51 adolescents (>10 years). The results of contralateral otoscopy were normal in 70 ears (60.3%), revealed otitis media with effusion in 13 ears (11.2%), and demonstrated chronic otitis media in 33 ears (28.4%). The results of ipsilateral otoscopy were satisfying in 99 ears (85.0%); the other ears demonstrated otitis media with effusion, recurrent disease, or cartilage displacement. Revision surgery was scheduled in 84 ears (72.4%).

Seventy-six ears (65.5%) were operated on by a senior surgeon. Two types of titanium prosthesis were used (Medtronic Xomed [Figure 1] was used in 60 ears [51.7%]; Spiggle & Theis [Figure 2] in 56 ears [48.2%]). During surgery, sectioning of the tendon of the tensor tympani muscle was performed in 50 ears (43.1%). The malleus was absent in 29 ears (25.0%) and intact in only 20 ears (17.2%). The footplate was mobile in 80.2%, blocked in 12.0%, and hypermobile in 7.8%. The middle ear mucosa was inflammatory in 44 ears (37.9%). During the handling of the prosthesis at surgery, there was bleeding in the middle ear in 20 ears (17.2%). No extrusion of the prosthesis was observed during follow-up.

Good anatomical results were achieved in the tympanic membrane in 95 ears (81.9%). Half of the 21 unsuccessful cases of tympanic membrane repair revealed otitis media with effusion on otoscopic examination, a finding that was confirmed by the results of postoperative CT. Tympanic membrane repair was successful in 28 ears (24.1%).

A control CT scan was performed on average 23.9 (16.5) (mean [SD]) months (range, 5.2-85.8 months) after revision surgery in 69 ears. It was performed mostly to detect residual cholesteatoma but also to allow visualization of the TORP position. Seventeen ears were reoperated on; the results are presented in Table 1. The 55 ears that were not reoperated on included 38 ears with the prosthesis in good position without effusion, 9 ears with the prosthesis in good position with effusion, and 8 ears with displacement of the prosthesis without effusion.

### AUDITORY RESULTS

All 116 ears that were operated on underwent auditory evaluation at 1 year; only 89 ears (76.7%) underwent evaluation at 2 years; and 42 ears (36.2%) underwent evaluation at 5 years (Table 2). The mean (SD) preoperative AC threshold was 51.1 (10.8) dB (range, 12.7-70.0 dB). The postoperative AC threshold was 32.3 (13.6) dB (range, 5.0-66.5 dB) at 1 year, 33.2 (14.6) dB (range, 7.7-77.7 dB) at 2 years, and 30.7 (13.9) dB (range, 5.9-56.8 dB) at 5 years. The mean preoperative ABG was 41 dB (range, 11.5-58.5 dB). One year after surgery, the mean ABG was 22.4 dB (range, 0.0-56.0 dB) and has been stable over time. Degradation of a 4000-Hz BC threshold was observed in 3 ears, but no dead ears were encountered. The mean (SD) preoperative BC threshold was 10 (5.2) dB (range, 0.0-25.0 dB). After surgery, the BC threshold was 9.9 (5.0) dB (range, 0.0-30.0 dB). There was no statistical difference between the preoperative BC threshold and the postoperative BC threshold. The auditory results were good (ABG, <20 dB) in 56% of the ears 1 year after ossiculoplasty.

### PROSTHESIS FAILURE

The auditory results were unsatisfactory in 27 ears at 1 year after surgery. Of these ears, 22 were not reoperated on for prosthesis replacement. Most of these cases

<table>
<thead>
<tr>
<th>Patient</th>
<th>Time Between Surgery and Displacement, mo</th>
<th>Time Between 2 Operations, mo</th>
<th>CT Findings</th>
<th>ABG, dB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before Surgery</td>
<td>At 1 y</td>
<td>At 2 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>13.2</td>
<td>17</td>
<td>25</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>2</td>
<td>7.4</td>
<td>18</td>
<td>28</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>3</td>
<td>11.3</td>
<td>30</td>
<td>72</td>
<td>Good position</td>
</tr>
<tr>
<td>4</td>
<td>17.9</td>
<td>103</td>
<td>127</td>
<td>Good position</td>
</tr>
<tr>
<td>5</td>
<td>10.6</td>
<td>15</td>
<td>57</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>6</td>
<td>8.9</td>
<td>24</td>
<td>26</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>7</td>
<td>11.2</td>
<td>8</td>
<td>13</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>8</td>
<td>10.1</td>
<td>15</td>
<td>20</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>9</td>
<td>9.2</td>
<td>?</td>
<td>34</td>
<td>Unknown</td>
</tr>
<tr>
<td>10</td>
<td>16.5</td>
<td>44</td>
<td>76</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>11</td>
<td>12.0</td>
<td>58</td>
<td>64</td>
<td>Posterior displacement</td>
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<tr>
<td>12</td>
<td>16.0</td>
<td>36</td>
<td>102</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>13</td>
<td>13.5</td>
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<td>14.9</td>
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<td>94</td>
<td>Unknown</td>
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<tr>
<td>15</td>
<td>7.1</td>
<td>12</td>
<td>14</td>
<td>Good position</td>
</tr>
<tr>
<td>16a</td>
<td>8.6</td>
<td>Unknown</td>
<td>24</td>
<td>Unknown</td>
</tr>
<tr>
<td>16a</td>
<td>15.3</td>
<td>36</td>
<td>82</td>
<td>Posterior displacement</td>
</tr>
<tr>
<td>Mean</td>
<td>12.0</td>
<td>31.4</td>
<td>52.2</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviations: ABG, air-bone gap; CT, computed tomographic; NA, not applicable.

*Patient 16 was operated on 2 times for prosthesis displacement in the same ear.
were unavailable for follow-up (6 cases) or did not have any explanation for auditory failure (8 cases). Among the remaining 8 cases, 5 children refused another surgery and 3 were operated on later because of a voluminous residual cholesteatoma that would not permit ossiculoplasty at the same time.

During the whole follow-up of the cohort, only 17 prostheses were replaced (Table 1). Patient 6 presented with a new displacement of the prosthesis 2 years after the first one, confirmed by CT findings, but he did not undergo revision surgery. In patients 10 and 13, the auditory results were satisfactory at 6 months, but the prosthesis fell into the posterior recess again toward the end of the first year after revision surgery. Patient 8 presented with ossification of the tympanic cartilage repair, which would explain the absence of improvement after revision. We do not have any explanation for the unsuccessful results in patients 1 and 15; a CT scan showed the prosthesis in a good position. Patient 16 was operated on 2 times for TORP displacement in the same ear.

Displacement of prostheses occurred at 1 year in 2 cases, at 2 years in 6 cases, at 5 years in 5 cases, and after 5 years in 1 case. The date of displacement of 3 TORPs was unknown. Eleven prostheses were displaced toward the retrotympanum at 26.8 months on average after the first ossiculoplasty. The auditory results were improved in 9 of the 11 ears (81.8%). When the prosthesis was not obviously displaced (6 cases), the replacement improved only 66.7% of auditory results. The difference between the groups was not significant ($P = .58$).

### PREDICTIVE FACTORS

The results of ossiculoplasty were not affected by total or partial tympanic membrane repair ($P = .24$); by the tendon of tensor tympani muscle being sectioned or intact ($P = .71$); by the status of the malleus (intact or eroded), which also was not significant ($P = .75$); by the number of previous surgical procedures ($P = .77$); by the experience of the surgeon ($P = .58$); or by the type of prosthesis used ($P = .89$). Furthermore, they were not affected by the percentage of cartilage in the tympanic mem-

### Table 2. Auditory Results of the Cohort

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before Surgery</th>
<th>Years After Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observations</td>
<td>Displacements</td>
</tr>
<tr>
<td></td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td></td>
<td>116</td>
<td>NA</td>
</tr>
<tr>
<td>&lt;10, No. (%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&lt;20, No. (%)</td>
<td>4 (3.4)</td>
<td>15 (12.9)</td>
</tr>
<tr>
<td>&lt;30, No. (%)</td>
<td>15 (12.9)</td>
<td>41</td>
</tr>
<tr>
<td>Sensorineural hearing loss, No.</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Operations for displacement, No.</td>
<td>NA</td>
<td>5</td>
</tr>
</tbody>
</table>

Abbreviations: ABG, air-bone gap; AC, air conduction; BC, bone conduction; BC4, 4000-Hz BC threshold; NA, not applicable.

This study represents one of the most significant reports on TORPs in children. However, the results are consistent with those found in the literature, especially the auditory results (Table 4). In children, good auditory results have been achieved in 19% to 80% cases of total ossiculoplasty, with an average of 51% (Table 4). Sensorineural hearing losses are rare (1 to 3 cases), but conductive hearing loss due to displacement is a more frequent problem (5 to 17 cases). Similarly, in adults, good
auditory results have been achieved in 66% to 89% cases of total ossiculoplasty, with an average of 61% (Table 5). The results in adults are a little better than those in children, but sensorineural hearing losses are also more frequent (2 to 12 cases).

The superior auditory results with the partial ossicular replacement prosthesis (PORP) are well known in both children and adults (Tables 4 and 5).4 One of the major reasons for the superior results involves the persistence of the stapes superstructure, which we can presume indicates less severe middle ear disease and explains the better sound transmission into the middle ear as well.

In this study, mucosal disease and eustachian tube dysfunction did not affect the auditory results, probably because they are less likely to be present in revision surgery than in primary surgery. Staging surgery permits healing of mucosa and stabilization of tympanic membrane reconstruction.11,15 However, some long-term effects, such as footplate ankylosis, still persist, which could explain the unsatisfactory results, even when the CT scan showed an aerated middle ear.

Initially, we hypothesized that the tendon of the tensor tympani muscle plays a role in the positioning of the prosthesis. Positioning of the TORP seemed easier for us when the tendon was cut. The univariate analysis did not...
confirm this opinion. In fact, the sectioning of the tendon changed neither the auditory result nor the secondary displacement of the prosthesis. Similarly, the intraoperative bleeding in the middle ear did not impair the handling of the prosthesis or, accordingly, the auditory results. To our knowledge, these important points have not been mentioned in the literature.

The auditory results were not statistically different between the 2 types of prosthesis. Therefore, the type of the prosthesis did not affect the results. Similarly, we failed to find any difference between the senior and the junior surgeon’s auditory results. Hence, in contrast to Murphy’s and in agreement with Yung, we did not find that the surgeon’s skills or the type of prosthesis played a role in the results of ossiculoplasty. However, in our department, all surgeons are trained to perform ossicular chain replacement using the same standard procedure.

The major problem with TORP in children is displacement, not extrusion. Indeed, extrusion is prevented by systematic cartilage reinforcement of the tympanic membrane. In most cases, authors give the numbers of prosthesis failure but have difficulty in explaining it. Table 1 shows that revision of ossicular reconstruction improves auditory results when a CT scan reveals that the prosthesis is falling toward the retrotymanum. In other words, revision surgery should be discussed with the patients and their family members based on CT findings. Further studies are necessary to generate guidelines for reoperation.

The multivariate analysis reveals 3 predictive factors of auditory results. Preoperative ABG and footplate status are 2 risk factors, and postoperative otoscopy is the only protective factor. The footplate status as a predictive factor could explain some evidence we have found in other ossicular prosthesis studies. Superior auditory results with PORP compared with TORP could be explained by the fact that the footplate should be less functional or more altered when the stapes is eroded. Preoperative ABG (classified in the range of 10 dB) was not statistically more altered when the stapes is eroded. Preoperative ABG and the footplate status are predictive factors of the results of ossiculoplasty. However, in our department, all surgeons are trained to perform ossicular chain replacement using the same standard procedure.

In conclusion, TORP auditory results remain stable over time. The preoperative ABG and the footplate status are predictive factors of the results of ossiculoplasty. In cases of failure, a CT scan may reveal the patients who could possibly benefit from revision ossicular reconstruction.

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Author Contributions: Drs Nevoux and Moya-Plana had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Nevoux, Chauvin, Denoyelle, and Garabédian. Acquisition of data: Nevoux, Moya-Plana, and Garabédian. Analysis and interpretation of data: Nevoux, Moya-Plana, Chauvin, and Denoyelle. Drafting of the manuscript: Nevoux, Moya-Plana, and Chauvin. Critical revision of the manuscript for intellectual content: Nevoux, Chauvin, Denoyelle, and Garabédian. Statistical analysis: Chauvin. Administrative, technical, and material support: Nevoux, Moya-Plana, Denoyelle, and Garabédian. Study supervision: Nevoux, Denoyelle, and Garabédian.

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REFERENCES


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