Factors Influencing Hearing Outcomes after Ossiculoplasty Using Polycel® Prosthesis in Patients with Chronic Otitis Media

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Background and Objectives: The goal of ossiculoplasty is to improve hearing, but it's results are influenced by many factors. We evaluated clinical outcomes and factors predictive of hearing improvement after ossiculoplasty using Polycel® in chronic otitis media patients.

Subjects and Methods: We reviewed the results of 136 patients who underwent ossiculoplasty using Polycel® prosthesis between 2000 and 2003 at Asan Medical Center and had been followed up postoperatively for more than 1 year. The mean postoperative air–bone gap (ABG) and changes in mean hearing loss were analyzed using four-frequency (0.5, 1, 2, and 3 kHz) pure tone average. Patients were divided into three groups based on their levels of postoperative ABG: ≤10 dB, ≤20 dB, and ≤30 dB. Several prognostic factors, such as the presence of cholesteatoma, status of middle ear mucosa, presence of malleus handle, primary or revision surgery and surgical procedures, were analyzed. Hearing outcomes were considered to be successful when the postoperative ABG was less than 20 dB.

Results: Of the 136 patients, 20 (15.7%) had postoperative ABG ≤10 dB, 50 (36.8%) had postoperative ABG ≤20 dB, and 85 (61.8%) had postoperative ABG ≤30 dB. The presence or absence of a malleus handle significantly influenced the success rate. Ossiculoplasty with concurrent mastoidectomy showed significantly worse prognosis of ABG closure and a significantly lower success rate than ossiculoplasty only.

Conclusions: The presence of a malleus handle and ossiculoplasty without mastoidectomy were factors influencing the successful outcomes of ossiculoplasty using Polycel®.

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KEY WORDS: Ossicular replacement · Polyethylene · Ossicular prosthesis · Otitis media.

Introduction

Materials used in ossiculoplasty include autografts such as autologous ossicles, cartilage, and bone; homologous grafts such as homologous bone; and synthetic materials such as plastipore, hydroxyapatite, and titanium. Due to its relatively good biocompatibility and excellent cost-effectiveness, plastipore has been widely used since its introduction in 1976.1) Compared with other porous materials, Polycel®, a polyethylene type material with multiple microscopic pores, is easy to use and has a low rate of autoimmune reactions.2) The reported extrusion rate of Polycel® is 3.8% to 4.0%,2,3) compared with 4% to 21.6% for hydroxyapatite and 0% to 4.4% for titanium prosthesis.4)

The goal of ossiculoplasty in individuals with conductive hearing loss is to improve hearing. The success of ossiculoplasty is influenced by various factors, including the status of the middle ear mucosa and ossicles, surgical technique, and Eustachian tube function.5) Surgeons should recognize these factors before surgery to counsel their patients properly.6) Other factors affecting postoperative hearing results include patient age, length of the prosthesis, revision surgery, otorrhea, tympanic membrane perforation and cholesteatoma.2,6)

The primary aim of this retrospective study was to evaluate the factors affecting postoperative hearing results in a large group of patients with chronic otitis media (COM) who underwent ossiculoplasty using Polycel® (Medtronic Xomed, Jacksonville, USA).

Subjects and Methods

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Medical Center between January 2000 and December 2003. The design of this study and the collection of patient data were approved by the institutional review board of Asan Medical Center. Patients with ossicular fixation or ossicular anomalies without COM were excluded. The study population consisted of 136 patients with COM (59 males, 77 females), 45 (33.1%) with non-cholesteatomatous COM and 91 (66.9%) with cholesteatomatous COM. Patient age ranged from 4 to 66 years, with a mean age of 39 years. The mean follow-up period was 43 months (range, 12–87 months).

Methods

Ossiculoplasty was performed in one stage with tympanomastoidectomy. Temporalis fascia was used as the graft material for the tympanic membrane. Partial ossicular replacement prosthesis (PORPs) were used in patients (n=82, 60.3%) with intact stapes including the superstructure, whereas total ossicular replacement prosthesis (TORPs) were used in patients (n=54, 39.7%) with only the remaining footplate of stapes.

Hearing level was determined using four-frequency pure tone averages, of 500, 1000, 2000, and 3000 Hz, as recommended before surgery and 1 year after surgery. The postoperative air-bone gap (ABG) was calculated as the difference between postoperative air conduction (AC) and preoperative bone conduction (BC). The criteria for successful ossiculoplasty have varied in previous studies. In general, postoperative ABG<30 dB or <20 dB has been considered successful and ≤10 dB as excellent. We regarded postoperative ABG<20 dB as successful. We also calculated the closure in ABG as the difference between pre- and post-operative ABG. Variables that could influence hearing outcomes, including the presence of cholesteatoma, the status of the middle ear mucosa, the presence of a malleus handle, and surgical methods were collected and analyzed.

Statistics

Average hearing level was described as mean±standard deviation (SD). Pearson’s Chi-square test and Fisher’s exact test were used for comparisons of categorical variables, and the Mann-Whitney test, the Kruskal-Wallis test and the Spearman correlation test for comparisons of continuous variables. We also performed multiple logistic and multiple linear regression analyses to assess the contribution of various factors to surgical success. All statistical analyses were performed using SPSS version 12.0J software (SPSS Inc., Chicago, USA). A p value of less than 0.05 was considered statistically significant.

Results

Our 136 patients who underwent ossiculoplasty using Polycet® prosthesis had a mean preoperative ABG of 32.8±12.8 dB and a mean postoperative ABG of 26.5±16.1 dB. Success, defined as a postoperative ABG≤20 dB, was observed in 50 patients (36.5%).

Univariate analysis of the effects of several variables on hearing success is summarized in Table 1. The presence of a malleus handle and the performance of primary (as opposed to post-primary) surgery were significantly associated with success rate, whereas only canal wall up (CWU) mastoidectomy was significantly associated with closure ABG.

Status of ossicles

The 82 patients who received PORP had an average postoperative ABG of 24.9±16.3 dB, with 33 patients (40.2%) showing postoperative hearing success (Table 2). In comparison, the 54 patients who received TORP had an average postoperative ABG of 29.1±15.7 dB, with 17 (31.6%) showing postoperative hearing success (Table 2). Neither the success rates nor the closure of ABG (7.4±17.8 dB vs. 4.7±12.9 dB, p=0.333) differed significantly between the PORP and TORP groups (Table 2).

The mean postoperative ABG in the 106 patients with intact malleus handles was 25.0±15.4 dB, with 45 patients (42.5%) showing postoperative hearing success. In contrast, the average postoperative ABG in the 30 patients without intact malleus handles was 32.1±17.3 dB, with only 5 (16.7%)
Table 2. Overall hearing results, determined using multiple variables

<table>
<thead>
<tr>
<th>Case (n=136)</th>
<th>Postop A&amp;G (dB)</th>
<th>≤10 dB</th>
<th>&gt;20 dB</th>
<th>&gt;30 dB</th>
<th>Closure of A&amp;G (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osciculoplasty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PORP (%)</td>
<td>82</td>
<td>24.9±16.3</td>
<td>12 (14.6)</td>
<td>33 (40.2)</td>
<td>56 (68.3)</td>
</tr>
<tr>
<td>TORP (%)</td>
<td>54</td>
<td>29.1±15.7</td>
<td>7 (13.0)</td>
<td>17 (31.5)</td>
<td>27 (50.0)</td>
</tr>
<tr>
<td>Malleus handle</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present (%)</td>
<td>106</td>
<td>25.0±15.4</td>
<td>17 (16.0)</td>
<td>45 (42.5)</td>
<td>69 (65.1)</td>
</tr>
<tr>
<td>Absent (%)</td>
<td>30</td>
<td>32.1±17.3</td>
<td>2 (6.7)</td>
<td>5 (16.7)</td>
<td>14 (46.7)</td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present (%)</td>
<td>91</td>
<td>25.5±16.1</td>
<td>13 (14.3)</td>
<td>38 (41.8)</td>
<td>55 (60.4)</td>
</tr>
<tr>
<td>Absent (%)</td>
<td>45</td>
<td>28.7±16.1</td>
<td>6 (13.3)</td>
<td>12 (26.7)</td>
<td>28 (62.2)</td>
</tr>
<tr>
<td>MIDDLE EAR MUCOSA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diseased (%)</td>
<td>120</td>
<td>27.2±16.4</td>
<td>14 (11.7)</td>
<td>43 (35.8)</td>
<td>72 (60.0)</td>
</tr>
<tr>
<td>Normal (%)</td>
<td>16</td>
<td>21.7±13.2</td>
<td>5 (31.3)</td>
<td>7 (43.8)</td>
<td>11 (68.8)</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary (%)</td>
<td>99</td>
<td>25.9±17.1</td>
<td>15 (15.2)</td>
<td>42 (42.4)</td>
<td>63 (63.6)</td>
</tr>
<tr>
<td>Revision (%)</td>
<td>37</td>
<td>28.3±12.9</td>
<td>4 (10.8)</td>
<td>8 (21.6)</td>
<td>20 (54.1)</td>
</tr>
<tr>
<td>With mastoidectomy (%)</td>
<td>124</td>
<td>27.6±16.2</td>
<td>15 (12.1)</td>
<td>42 (33.9)</td>
<td>72 (58.1)</td>
</tr>
<tr>
<td>Ossiculoplasty (%)</td>
<td>12</td>
<td>15.7±11.3</td>
<td>4 (33.3)</td>
<td>8 (66.7)</td>
<td>11 (91.7)</td>
</tr>
</tbody>
</table>

*Independent sample t-test, †Pearson’s Chi-square test, ‡Fisher’s exact test. A&G: air-bone gap, PORP: partial ossicular replacement prosthesis, TORP: total ossicular replacement prosthesis

showing postoperative hearing success. Although the success rate differed significantly between these two groups (p=0.010), there was no significant difference in closure of ABG (p=0.319) (Table 2).

Cartilage grafts were interposed between the tympanic graft and Polycel® in 102 patients (75%). The postoperative ABG in patients with and without cartilage grafts was 27.8±16.8 and 22.9±13.2 dB, respectively (p=0.126), and the closure of ABG was 5.1±16.4 and 9.9±14.4 dB, respectively (p=0.131).

Extrusion of the prosthesis was observed in 6 patients (4.4%), 3 (3.7%) in the PORP and 3 (5.6%) in the TORP groups, a difference that was not significant. Median time of extrusion was 15.6 months after operation (range, 11-32 months). Extrusion of the prosthesis was observed in 4 of 34 patients (11.8%) without cartilage grafts and in 2 of 102 patients (2.0%) with cartilage grafts (p=0.014) (Table 3).

Presence of cholesteatoma

The preoperative ABG in the 91 patients with cholesteatoma was 30.4±12.8 dB and the preoperative ABG in the 45 patients without cholesteatoma was 37.7±11.7 dB. The preoperative ABG of the cholesteatoma group was statistically low ABG, statistically. However, the average postoperative ABG in the patients with cholesteatoma was 25.5±16.1 dB and 38 (41.8%) showed postoperative hearing success. In comparison, the average postoperative ABG in the patients without cholesteatoma was 28.7±16.1 dB and 12 (26.7%) showed postoperative hearing success. Neither the success rates (p=0.086) nor the closure in ABG (p=0.171) differed between patients with and without cholesteatoma (Table 2).

Status of middle ear mucosa

We considered middle ear mucosa ‘diseased’ when inflammatory, edematous, or granulomatous tissues were found during surgery. The 16 patients with healthy mucosa had an average postoperative ABG of 21.7±16.4 dB, with 7 (43.8%) showing postoperative hearing success. In comparison, the 120 patients with ‘diseased mucosa’ had an average postoperative ABG of 27.2±16.4 dB, with 43 (35.8%) showing postoperative hearing success. Although the postoperative success rate did not differ between these two groups, patients with normal mucosa were more likely to have a postoperative ABG<10 dB than patients with diseased mucosa (31.3% vs. 11.7%). Closure of ABG was 12.8±10.4 dB in patients with healthy mucosa and 5.5±16.5 dB in patients with di-
Factors associated with successful hearing results after ossiculoplasty include the presence of a stapes superstructure, the presence of a malleus handle, the status of the middle ear mucosa, perforation of the tympanic membrane, the presence of cholesteatoma, the composition of the prosthesis, Eustachian tube function and revision surgery. Among these, the presence of a malleus handle, the status of the middle ear mucosa, and the presence of a stapes superstructure have been found to be most important. Our results were similar. Patients who underwent PORP had better hearing re-

### Discussion

The ideal prosthesis for ossiculoplasty should be biocompatible with surrounding tissues, stable, cost-effective, capable of optimal sound transmission, easy to harvest, and easy to handle during surgery. Polycel, one of the most widely used synthetic prosthesis, is a thermal-fused, composite polymer made of porous polyethylene, with 70–80% of the total volume composed of 250 μm micro pores.

The efficacy of a prosthesis and of the surgical procedure are usually evaluated 2–3 months post-surgery, with overall clinical outcomes assessed after at least 1 year, and up to 3–5 years postoperatively. The Committee on Hearing and Equilibrium recommended that the efficacy of the prosthesis and the procedure be determined after 2 months, and that clinical assessments be performed after 1 year. We therefore analyzed the hearing results 1 year after surgery.

The use of Polycel resulted in postoperative hearing success in 36.8% of our patients, comparable to the 34.2% reported in one series, but less than the success rates of 51.1% and 56% reported in other series. Usually, staged operation is recommended in patients with severe inflammation or cholesteatoma. In this study, however, these factors could not be analyzed because ossiculoplasty was used in patients with wide range of inflammation or cholesteatoma. Hydroxyapatite has recently been reported to be a better material, due to its good hearing results. The success rate of hydroxyapatite (postoperative ABG ≤20 dB) has been reported to vary from 24% to 92%. However, the thick head portion of an hydroxyapatite prosthesis may screen the stapes head or footplate during surgery. More recently, titanium prosthesis have been reported to have success rates similar to those of hydroxyapatite.

Factors associated with successful hearing results after ossiculoplasty include the presence of a stapes superstructure, the presence of a malleus handle, the status of the middle ear mucosa, perforation of the tympanic membrane, the presence of cholesteatoma, the composition of the prosthesis, Eustachian tube function and revision surgery. Among these, the presence of a malleus handle, the status of the middle ear mucosa, and the presence of a stapes superstructure have been found to be most important. Our results were similar. Patients who underwent PORP had better hearing re-

- **Table 3. Odds ratios regarding the effect of cartilage grafts on prosthesis extrusion rate**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Contrast</th>
<th>Odds ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartilage graft</td>
<td>(+)</td>
<td>0.074 (0.01, 0.69)</td>
<td>0.022*</td>
</tr>
<tr>
<td></td>
<td>(−)</td>
<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>

*multiple logistic regression-backward elimination. CI: confidence interval

- **Table 4. Multivariate analysis of the success rate of ossicular chain and mastoidectomy**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Contrast</th>
<th>Odds ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malleus handle</td>
<td>Present</td>
<td>4.33 (1.38, 13.6)</td>
<td>0.012*</td>
</tr>
<tr>
<td></td>
<td>Absent</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Mastoidectomy</td>
<td>(−)</td>
<td>3.91 (1.11, 13.7)</td>
<td>0.011*</td>
</tr>
<tr>
<td></td>
<td>(+)</td>
<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>

*multiple logistic regression analysis-backward elimination. CI: confidence interval

Revision surgery

The 37 patients underwent revision ossiculoplasty who underwent revision surgery had an average postoperative ABG of 28.3 ± 12.9 dB, with 8 (21.6%) showing postoperative hearing success. Ten patients (27.0%) of them had recurrent COM or cholesteatoma, and 27 patients (73.0%) had conductive hearing loss after primary operation. In comparison, 99 patients who underwent primary surgery had an average postoperative ABG of 25.9 ± 17.1 dB, with 42 (42.4%) showing postoperative hearing success. The success rate was significantly higher in patients undergoing primary surgery (p<0.05), although closure of ABG (7.3 ± 17.2 dB in patients undergoing primary surgery vs. 3.8 ± 11.9 dB in patients undergoing revision surgery) did not differ significantly (Table 2).

Surgical procedures

The mean postoperative ABG in the 124 patients who underwent mastoidectomy plus ossiculoplasty was 27.6 ± 16.2 dB, with 42 (33.9%) showing postoperative hearing success. In contrast, the average postoperative ABG in the 12 patients in whom mastoidectomy were not performed was 15.7 ± 11.3 dB, and 8 (66.7%) of these patients showed postoperative hearing success, significantly higher than the success rate in patients who underwent mastoidectomy (Table 2). The mean closure in ABG was 5.4 ± 15.9 dB and 15.8 ± 14.0 dB, respectively (p=0.032) (Table 2).

Multivariate analysis of variables affecting postoperative hearing outcome

Univariate analysis showed that the presence of a malleus handle, the performance of primary (vs. revision) surgery and the inclusion of mastoidectomy were significantly associated with success rate (Table 1). Multivariate analysis showed that the presence of a malleus handle (R=1.225, p<0.05) and mastoidectomy (R=1.839, p<0.05) were independently associated with surgical success rate (Table 4). The inclusion of mastoidectomy was the only factor significantly associated with closure ABG.

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acoustically efficient, and preservation of the canal wall facilitates hearing results because a shallow middle ear cleft is less disadvantageous for patients with CWD mastoidectomy than those who underwent CWU mastoidectomy. Conceptually, well-aerated mastoid cavity. Furthermore, patients who underwent CWD mastoidectomy had more severe disease than those who underwent primary surgery. The percentage of patients who underwent CWD mastoidectomy was significantly higher among patients who underwent revision surgery (40.5%, n = 15) than among those who underwent primary surgery (17.2%, n = 17), perhaps explaining why revision surgery was associated with poorer hearing results.

The most frequent cause of poor hearing results after ossiculoplasty is extrusion. Although the extrusion rate of hydroxyapatite is generally as low as 0–4%, it can range to as high as 14% and 29%. Titanium has a relatively low extrusion rate, 0–4.4%. We observed an extrusion rate of 4.4%, comparable to the 3.8% and 3.2% reported previously for both of PORP and TORP. To reduce the likelihood of prosthesis extrusion, cartilage grafts were used in 75% of our patients. We found that patients who did not receive cartilage grafts had a significantly higher rate of extrusion (11.8%) than those who did receive such grafts (2.0%) (p = 0.22, multiple logistic regression test). We found that postoperative hearing results were not influenced by the insertion of cartilage, in agreement with previous reports. Therefore cartilage graft should be considered in ossiculoplasty with Polycel®. No other factors significantly influenced the extrusion of the prosthesis.

**Conclusion**

We found that the presence of a malleus handle, the performance of primary (vs. revision) surgery and ossiculoplasty-only (vs. ossiculoplasty plus mastoidectomy) were significant predictors of outcome in ossiculoplasty using Polycel® for patients with COM. Cartilage interfaces should be considered during ossiculoplasty with Polycel® because cartilage grafts between the prosthesis and the tympanic membrane can reduce the extrusion of the prosthesis without influencing hearing results.

**REFERENCES**