

## Comparison of Outcomes of Hearing Reconstruction Techniques for Isolated Incus Long Process Defects

### ABSTRACT

**Background:** Different techniques are available for ossicular reconstruction in isolated incus defects. Our objective was to compare hearing reconstruction techniques in Austin–Kartush Group A (incus defect, intact manubrium mallei and mobile stapes are present) ossicular defects.

**Methods:** Patients with isolated incus long process defect whose hearing impairment was reconstructed and followed-up for 12 months were reviewed. The hearing outcomes of bone-cement manubrio-stapedioplasty, bone-cement incudostapedopexy, and partial ossicular replacement prosthesis techniques were compared.

**Results:** In the study, 49 ears of patients aged between 10 and 53 years (median 30) who underwent ossiculoplasty between June 2017 and July 2018 were included. All groups had statistically significant improvement in both air-conduction thresholds (ACT) and closure of the air-bone gap (ABG). There was no deterioration in bone-conduction thresholds (BCT) in any frequency. When the success rates of the groups were compared, there was no statistical difference.

**Conclusion:** In patients with a defective incus, intact manubrium mallei, and mobile stapes, high success rates could be achieved with appropriate and careful surgery using all 3 hearing reconstruction methods.

**Keywords:** Bone cement, ossiculoplasty, incus, prosthesis, PORP

### INTRODUCTION

Conductive hearing loss due to incus discontinuity is one of the most commonly encountered ossicular defects in otologic surgery.<sup>1</sup> The degree of discontinuity correlates with the hearing impairment in chronic otitis media. Repairing or relocating, and thereby fixing the discontinuity is an important aim of tympanoplasty.

Many ossiculoplasty techniques are described in the literature, such as using autografts, plastipore, or titanium grafts.<sup>2</sup> Autografts have the advantages of biocompatibility, low cost, and a decreased extrusion rate. However, necrosis, fixation to the surrounding tissue, and the time required for shaping the ossicles are disadvantages.<sup>3</sup> On the other hand, replacement prostheses are better from these angles, but they have disadvantages regarding availability, stability, and cost.<sup>4</sup> Bone cement is another option for ossiculoplasty, which has the advantages of lower cost and easy applicability, but it has the disadvantages of leading to foreign-body reactions and traumatic fractures.<sup>5,6</sup>

In this study, we aimed to compare the advantages, disadvantages, and hearing outcomes of these hearing reconstruction techniques for patients with Austin–Kartush Group A.<sup>7,8</sup> Except the autografts, prostheses, and bone cement, the applications were all performed by the same surgeon.

### METHODS

We retrospectively analyzed patients who had undergone ossiculoplasty in a tertiary center between June 2017 and July 2018, performed by the same surgeon. The status of the tympanic membrane and hearing results were noted at the postoperative 12th



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month in all patients. The study was approved by the Kocaeli University Ethical Committee of Non-invasive Clinical Research (KOU-GOKAEK 2019/350).

### Patients and Reconstruction Groups

All patients had the ossicular status of the malleus and stapes being present, but the incus being absent or deficient (Austin–Kartush Group A), and all had the etiology of traumatic ossicle damage or chronic otitis media without cholesteatoma, and had an intact tympanic membrane after the surgery. The exclusion criteria were the existence of a cholesteatoma, the existence of a tympanic membrane graft defect after the surgery, ear drainage until 1 month before the surgery, lack of ossicular pathology, and requirement of a canal wall down procedure.

The patients were evaluated using ossiculoplasty techniques to measure hearing outcomes, and were divided into 3 groups based on reconstruction techniques. The first group had malleus to stapes glass-ionomer bone cement (Ketac Cem Radiopaque, ESPE, Dental Products D-82229, Seefeld, Germany) re-bridging; the second group had incus to stapes glass-ionomer bone cement (Ketac Cem Radiopaque, ESPE, Dental Products D-82229) re-bridging; and the third group had partial ossicular replacement prostheses (Causse Polycel® Partial with Fluoroplastic Shaft, Medtronic Xomed Inc., Jacksonville, FL, USA).

### Operative Procedure

#### Group I (MS-Manubrio-stapedioplasty)

The procedure was similar to the manubrio-stapedioplasty technique defined by Sennaroglu et al.<sup>9</sup> The incudomalleolar joint was separated, the malleus head was cut and removed, and 1 drop of bone cement was applied from the manubrium mallei to the head of the stapes. Manubrio-stapedioplasty was performed in cases where a defective long process was not sufficient to augment and the malleus was long and healthy enough to reach the stapes suprastructure. This method of reconstruction is not appropriate for the physiological transmission of sound, but was found to be effective enough to achieve success.

## MAIN POINTS

- In patients with defective incus, intact manubrium mallei, and mobile stapes, with appropriate and careful surgery, bone-cement manubrio-stapedioplasty, bone-cement incudostapedopexy, and partial ossicular replacement prosthesis techniques resulted in high success rates.
- All 3 groups had statistically significant improvement in both air-conduction thresholds and closure of the air-bone gap, compared to the preoperative values.
- No statistically different results were obtained among groups in terms of hearing outcomes.
- No complications (infection, prosthesis extrusion, or revision requirement, etc.) were detected during the 12th month follow-up in all groups.
- The surgeon can choose from all 3 techniques as appropriate for patients, for hearing reconstruction.

#### Group II (IS-Incudostapedopexy)

The procedure was performed in the existence of a mobile incudomalleolar articulation and a defect in the long process of the incus. One drop of bone cement was applied from the incus remnant to the head of the stapes (not only to the head but also to the stapes footplate's arch-superior border). Incudostapedopexy was performed in cases where the long process of the incus was long and healthy enough for augmentation or to reach the stapes suprastructure.

#### Group III (PORP-Partial ossicular replacement prosthesis)

Where an effective incus long process was absent, fluoroplastic PORP was applied between the head of the stapes and the tympanic membrane by a cartilage graft under it. PORP was chosen in cases where the long process of the incus was not sufficiently healthy to apply bone cement, etc., or if the remnant of the incus could not be seen directly for any reason (i.e., a prominent tympanic annulus, a narrowed external ear canal, etc.).

### Audiological Analysis

Patients' preoperative and postoperative ACT, bone-conduction thresholds (BCT), and ABG values were compared in terms of hearing improvement. Intergroup comparisons were also done. The data given in this article were appropriate to the guideline recommended by the American Academy of Otolaryngology-Head and Neck Surgery.<sup>10</sup> Additionally, web-based scattergrams have been generated and presented in the article.<sup>11</sup> An ABG level of 20 dB or less was considered as the criterion for success.

### Statistical Analysis

All statistical analyses were performed using IBM SPSS for Windows Version 20.0 (IBM Corp., Armonk, NY, USA). Kolmogorov–Smirnov tests were used to test the normality of data distribution. Continuous variables were expressed as mean  $\pm$  standard deviation and median (25th–75th percentiles), and categorical variables were expressed as counts (%). Comparisons of normally distributed continuous paired variables between the times were performed using the paired samples *t*-test, two-way ANOVA, and Tukey post-hoc test. Comparisons of non-normally distributed continuous variables between the times were performed using the Wilcoxon *t*-test, the Friedman analysis of variance by ranks, and the Tukey post-hoc test. Comparisons of non-normally distributed continuous variables between the groups were performed using the Kruskal–Wallis test. A value of  $P < .05$  was considered statistically significant.

## RESULTS

### General Information

Between June 2017 and July 2018, 136 ossiculoplasty surgeries were performed. Excluded from the study were 45 patients with canal wall down surgery, 21 patients with intact ossicular chain, 4 patients with postoperative tympanic membrane defect, 25 patients with cholesteatoma, and 12 patients with low-quality follow-up. Thus, the remaining 49 patients were included in the study. There were 29 (59.2%) females and 20 (40.8%) males, and the age distribution was between 10 and 53 years, with a median of 30 (21.0, 38.0) years. There were 13 (26.5%) patients in the MS group, 22 (44.9%) in the IS group, and 14 (28.6%) in the PORP group.

### Audiologic Assessment

The MS group, with 13 patients, experienced an improvement in both the ACT and the ABG ( $P = .002$ ). The median preoperative ACT was 52.5 dB (33.8, 60.0) and the median postoperative ACT was 27.5 dB (18.1, 36.3). The median preoperative ABG was 28.8 dB (21.9, 35.5) and the median postoperative ABG was 8.8 dB (4.6, 13.1). The median preoperative BCT was 18.8 dB (13.8, 23.8) and the median postoperative BCT was 15.0 dB (10.5, 23.5). The BCT had no significant deterioration ( $P > .05$ ). The success rate of having ABG < 20 dB was 92.3% (12 patients out of 13).

The IS group, with 22 patients, experienced improvement in both the ACT ( $P = .003$ ) and the ABG ( $P = .001$ ). The median preoperative ACT was 40.6 dB (29.7, 51.9) and the median postoperative ACT was 24.3 dB (20.0, 29.1). The median preoperative ABG was 24.5 dB (18.8, 31.8) and the median postoperative ABG was 8.8 dB (3.8, 11.6). The median preoperative BCT was 16.3 dB (10.8, 18.2) and the median postoperative BCT was 18.1 dB (11.6, 20.3). The BCT had no significant deterioration ( $P > .05$ ). The success rate for achieving ABG < 20 dB was 94.5% (21 patients out of 22).

The PORP group, with 14 patients, experienced improvement in both the ACT ( $P = .003$ ) and the ABG ( $P = .001$ ). The median preoperative ACT was 33.1 dB (27.2, 54.3) and the median postoperative ACT was 23.1 dB (18.8, 30.0). The median preoperative ABG was 20.6 dB (14.4, 25.5) and the median postoperative ABG was 5.6 dB (1.3, 16.3). The median preoperative BCT was 13.8 dB (9.7, 18.8) and the median postoperative BCT was 14.4 dB (12.5, 20.0). The BCT had no significant deterioration ( $P > .05$ ). The

success rate for achieving ABG < 20 dB was 100% (14 patients out of 14).

The medians of the average ACT, BCT, ABG, and the  $P$  values of each group are shown in Table 1. The preoperative and postoperative number of patients whose ABG levels were less than 20 dB for each group are shown in Figure 1.

Figure 2 shows the preoperative ACT and the word recognition scores (WRS) of all patients in this study. There is mild to moderate hearing loss, consistent with chronic otitis media or trauma.

The postoperative hearing gains according to ACT and WRS are shown in Figure 3. There was 1 ACT that worsened by 21-30 dB. In the study, 25 out of 49 patients experienced both WRS and ACT improvement.

In the 12th month, the postoperative ABG < 20 dB in the MS group was 92.3%; in the IS group it was 94.5%, and in the PORP group it was 100%. When the groups were compared in terms of hearing improvement, the ACT and the ABG values did not show statistical differences ( $P > .05$ ).

### Complications

All patients were assessed in the 12th month postoperatively. No complications in terms of infection, prosthesis extrusion, or revision requirement were pointed out.

**Table 1. The Averages of the Hearing Thresholds According to the Groups**

	Percentiles			<i>P</i>
	25th	Median	75th	
<b>Manubrio-stapedoplasty (MS) (<i>n</i> = 13)</b>				
Preoperative ACT	33.8	52.5	60	.002
Postoperative ACT	18.1	27.5	36.3	
Preoperative BCT	13.8	18.8	23.8	.36
Postoperative BCT	10.5	15	23.5	
Preoperative ABG	21.9	28.8	35.5	.002
Postoperative ABG	4.6	8.8	13.1	
<b>Incudo-stapedopexy (IS) (<i>n</i> = 22)</b>				
Preoperative ACT	29.7	40.6	51.9	.003
Postoperative ACT	20.0	24.4	29.1	
Preoperative BCT	10.8	16.3	18.2	.35
Postoperative BCT	11.6	18.1	20.3	
Preoperative ABG	18.8	24.5	31.8	.001
Postoperative ABG	3.8	8.8	11.6	
<b>PORP (<i>n</i> = 14)</b>				
Preoperative ACT	27.2	33.1	54.3	.003
Postoperative ACT	18.8	23.1	30	
Preoperative BCT	9.7	13.8	18.8	.31
Postoperative BCT	12.5	14.4	20	
Preoperative ABG	14.4	20.6	25.5	.001
Postoperative ABG	1.3	5.6	16.3	

Data are given as median, 25th percentile, and 75th percentile in decibels (dB).

ACT, air-conduction threshold; BCT, bone-conduction threshold; ABG, air-bone gap, *n*, number of patients; PORP, partial ossicular replacement prosthesis.

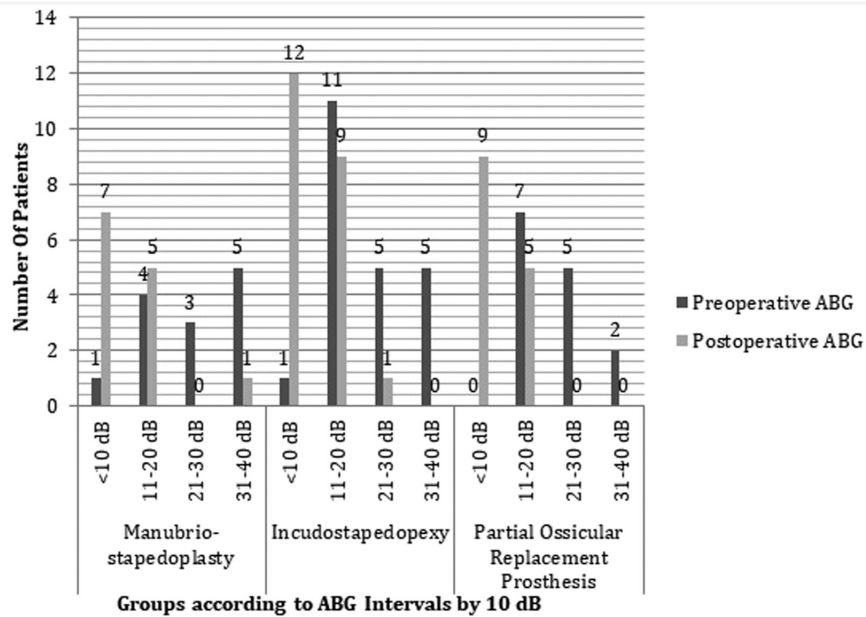


Figure 1. The preoperative and postoperative number of patients whose ABG levels were less than 20 dB, according to the reconstruction methods. MS, manubrio-stapedioplasty; IS, incudostapedexy; PORP, partial ossicular replacement prosthesis.

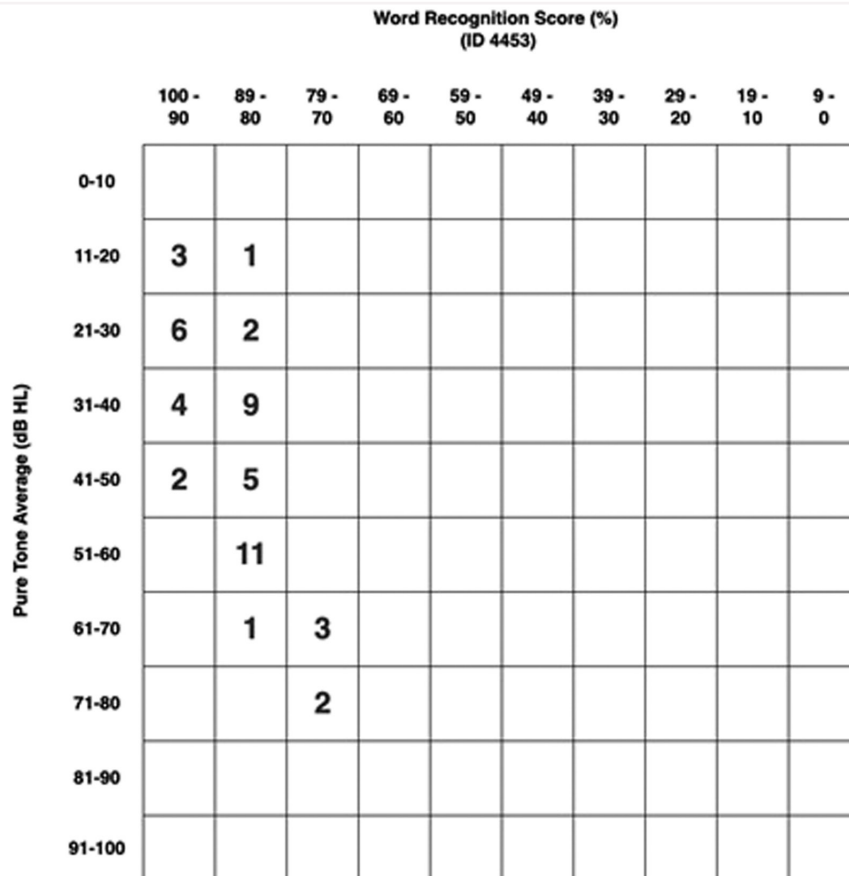


Figure 2. Preoperative pure-tone averages (PTA) and word recognition scores (WRS) in all patients are shown in the scattergram.

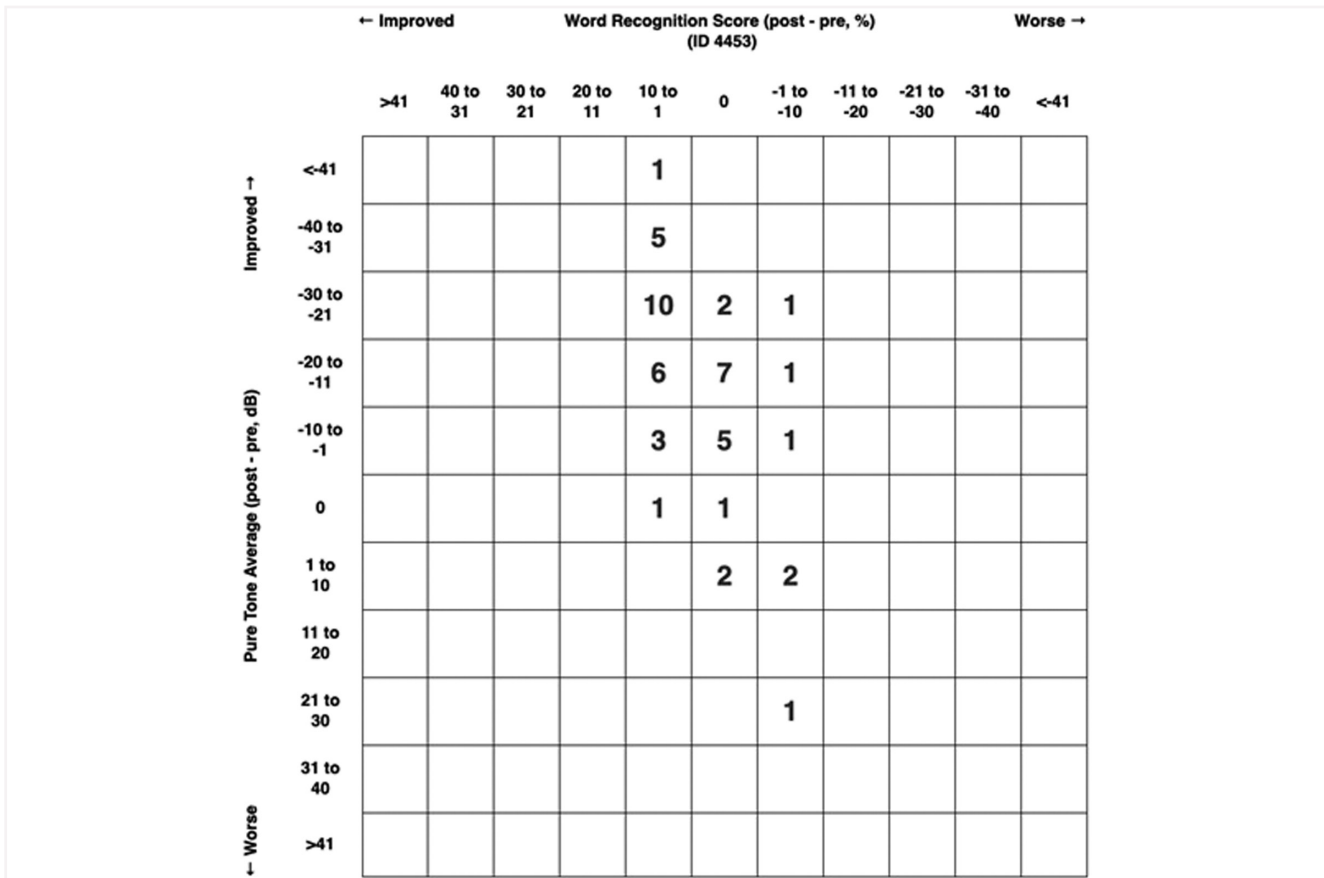


Figure 3. The postoperative changes in PTA and WRS of all patients are shown in the scattergram.

## DISCUSSION

As a goal of tympanoplasty, hearing improvement is very valuable for the patient. Both improving AC and avoiding deterioration of BC is very important. For these situations, minimal interventions that achieve these aims should be performed.

The most common ossicle absence is the defect of the long process of the incus. To overcome this discontinuity, many techniques and materials are being used in daily practice. Prostheses and bone cement have a wide range of uses in these operations. Both have advantages and disadvantages.<sup>1</sup>

For fluoroplastic prostheses, dislocation, extrusion, and cost can be mentioned as disadvantages.<sup>12</sup> They are cheaper than titanium prostheses. Polycel®, which we used as PORP, is a widely used material, which mostly consists of micropores and thus has good stability. We used cartilage between the prosthesis and the tympanic membrane graft in all patients to reduce the extrusion rate—otherwise the extrusion rate would be higher, as reported previously.<sup>15</sup> After 1-year follow-up, we did not encounter any extrusion or dislocation of the prosthesis, which favors the use of cartilage between the prosthesis and the membrane.

Glass-ionomer bone cement has the advantages of easy applicability.<sup>1</sup> In this technique, the distance between the eroded incus and the stapes suprastructure is not a limitation for the

surgeon. It is also cheaper than prostheses. The surgeon has to be experienced in applying bone cement consistently. If the field is wet and the bone cement is not firm enough, it can spread to neighboring structures. Therefore, there must be a dry and clean area to apply the cement. Several techniques have been reported previously to ensure a dry surface.<sup>14,15</sup> We used cotton embedded with adrenaline to ensure a dry and live tissue. The exothermic reaction can harm the neighboring soft tissues, like facial nerves, chorda tympani, or the oval window. If it spreads to the facial nerve, it can cause foreign-body reaction but not facial nerve paralysis.<sup>16</sup> If any spreading occurs, it must be suctioned from the area immediately. In our study, we did not have any cases of facial paralysis or uncontrolled spread.

There were reports of fragmentation in the long-term follow-up.<sup>6</sup> In the manubrio-stapedioplasty group, we cut the tensor tympani muscle to reduce the force on the bone cement. We observed no such lesion at the 12th month.

There was positive hearing gain from all techniques performed in this study. Statistically significant improvements were observed in both PTA and ABG. All of our patient groups had the advantage of the presence of the malleus handle, the presence of the stapes suprastructure, and an absence of a cholesteatoma, which were pointed out in previous studies.<sup>13</sup> For postoperative hearing success, the presence of the stapes and an intact tympanic membrane are perceived to be the most important parameters.

In this study, we pointed out that appropriate hearing reconstruction in these patients would ensure successful results. Every group experienced significant improvement and had high success rates. No difference was found between the groups. The surgeon can choose from all 3 techniques as appropriate for the patients for hearing reconstruction. Because of the similar success rates of these 3 methods, the appropriate method can be decided by assessing the ease of applicability, cost, degree of risks, surgery time, and patient-specific potential complications. It is advantageous to be familiar with all 3 techniques because of differences that are specific to the patients, choices, and anatomic variations.

All procedures were performed by an experienced surgeon, paying attention to the points indicated above. The preparation of the bone cement was undertaken by a surgical nurse in line with the manufacturer's recommendations. The consistency of the prepared bone cement and the dryness of the surface to which the bone cement was applied were the key points of the performance. We replaced a full prosthesis-covering cartilage between the graft and the prosthesis. Although repairing the defect seems to be a simple procedure, all surgical teams must pay maximal attention to ensure maximum success. Possibly with these careful interventions, we had high rates of success in this study, evaluated against the criteria of ABG < 20; in the PORP group 100%, versus 51.1% in Moon's study,<sup>12</sup> and in all patients, without restriction to groups, 95.9% versus 85% in Iurato's study.<sup>17</sup>

IS was the easiest and the fastest procedure, but this group had the most limitations. The minimum deficiency should be in this group. The MS group needed the most experience, especially to focus on the stability of the malleus. Though PORP was the simplest to perform, the cost, adjusting the effective length, the stability of prostheses and preventing extrusion were hard tasks. Although there was no significant difference, the PORP group had the most success. We did not observe any complication, and therefore we could not compare groups on this during follow-up. All 3 procedures are safe, effective, and promising.

Although complications can affect the functional success of the reconstruction method, and usually occur in the first year after surgery, late complications can occur in the following years and hearing can worsen. A limitation of this study is that the given results are for the postoperative first year. Long-term follow-up will give better information. However, there was no difference between the groups in the first year, and the alteration possibility rates are relatively low. There were 13-22 patients in our 3 groups. A higher number of patients would yield better results, but the patient numbers were sufficient to have a strong result when comparing the groups statistically.

The advantages of this study were that the same surgeon performed the surgeries; that other pathologies that could affect the functional outcome were excluded; and there was maximal similarity of the groups.

In conclusion; bone-cement manubrio-stapedioplasty, bone-cement incudostapedopexy, and partial ossicular replacement

prosthesis are cost-effective and reliable methods for hearing reconstruction in Austin–Kartush Group A patients. Great success can be achieved if attention is paid to the process. Because of the similar success of these 3 methods, the appropriate method can be decided on by an assessment of the ease of applicability, the cost, the degree of risk, surgery time, and patient-specific potential complications.

**Ethics Committee Approval:** Ethical committee approval was received from the Kocaeli University Ethical Committee of Non-invasive Clinical Research (KOU-GOKAEK 2019/350; December 11, 2019).

**Informed Consent:** Written informed consent was obtained from all participants who participated in this study.

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