ORIGINAL ARTICLE
OTOLOGY
DOI: 10.5152/B-ENT.2022.21788

Comparative Study Between Cartilage Interposition and Partial Ossicular Replacement Prosthesis in Ossiculoplasty

Ali K. Mahrous, Ahmed Nabil Elsamnody

Department of Otorhinolaryngology, Al-Azhar University Hospitals, Cairo, Egypt

Cite this article as: Mahrous AK, Elsamnody AN. Comparative study between cartilage interposition and partial ossicular replacement prosthesis in ossiculoplasty. B-ENT 2022;18(1):52-58.

ABSTRACT

Background: The aim of this study was to compare the hearing outcome in patients who underwent ossiculoplasty with cartilage interposition versus those with partial ossicular replacement prosthesis.

Methods: A total of 47 ears from 45 consecutive patients with ossicular discontinuity were enrolled in the study. Cartilage interposition was used in 27 consecutive cases (group A), and partial ossicular replacement prosthesis (group B) was performed in 20 consecutive cases. Preoperative and postoperative air conduction, bone conduction, and air-bone gap were evaluated and compared in both groups. Visual analog scale was used to give a rough indication of patients' satisfaction with their hearing after surgery.

Results: In group A, the average preoperative air-bone gap was 32.8 dB, while the average 12-month postoperative air-bone gap was 8.2 dB. The average preoperative and 12-month postoperative air-bone gap in group B was 29.6 and 9.5 dB, respectively. The difference between the preoperative and postoperative ABG was highly significant in both groups. However, no significant difference was noted between both groups in preoperative or postoperative air conduction, bone conduction, or air-bone gap. A postoperative air-bone gap at 12 months within 20 dB was achieved in 80.8% in group A and 76.2% in group B. This difference was not statistically significant. The difference between preoperative and postoperative hearing satisfaction measured by visual analog scale was significant in both groups ($P < .001$). However, the postoperative satisfaction level on visual analog scale showed no statistically significant difference between both groups.

Conclusions: Both techniques yielded similar results where there was no significant difference between these 2 groups according to hearing results.

Keywords: Audiogram, conductive hearing impairment, ossicular chain reconstruction, tympanic membrane, tympanoplasty

Introduction

Eradication of the chronic ear disease is the main target for ear surgery and then restoration of sound conduction mechanism could be gained.[1] A successful ossicular chain reconstruction restores the connection between the tympanic membrane and the inner ear. Numerous ossiculoplasty techniques and variable materials were studied to find an ideal technique for ossiculoplasty with a more safe, available, and easily operated material.[2]

Even though erosion can occur at any part of the ossicular chain, the long process of incus is more liable to erosion because it had poor blood supply.[2] Austin[3] studied by dividing the patients divided into 4 groups according to their pathology; 60% of cases had the presence of handle of the malleus and stapes superstructure (group A), 23% of cases had the absence of stapes superstructure only (group B), 8% of cases had partially eroded long process of incus (group C), and another 8% of cases had the absence of both handle of the malleus and stapes superstructure (group D). Kartush[4] had another classification that was obtained from series of cases classified as Austin–Kartus.

Since the introduction of ossiculoplasty by Hall and Rytzner in the late 1950s,[5] many researchers studied several techniques for incudostapedial reconstruction listed as follows:

(1) Interposition of natural materials in the form of either autograft or allograft (e.g., sculpted incus, malleus, cortical bone,

Corresponding author: Ahmed Nabil Elsamnody, ansamnody@hotmail.com
Received: December 9, 2021 Accepted: December 21, 2021
Available online at www.b-ent.be

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and cartilage), bypassing the malleoincudal joint.[6] Although such materials can be tolerated well by the body, partial necrosis and growth of ossifying bridges or displacement can occur.

(2) Partial ossicular replacement prosthesis (PORP) was then developed as an alternative to autologous material. Although a variety of biomaterials is available (plastics, gold, steel, titanium, hydroxyapatite, teflon, ceramics, etc.), hydroxyapatite and titanium prostheses are the most commonly used for ossiculoplasty. Though readily available, stability problems, extrusion, and erosion of the ossicle at the contact place with the prosthesis can develop.[6,7]

(3) The most recent technique is incudostapedial re-bridging with bone cement. Bone cement was primarily used in the maxillofacial surgery. However, its use in otology field is becoming more popular, allowing a "physiological" reconstruction of the ossicular chain.[8,9] Nevertheless, inflammatory reactions have been detected when in contact with middle ear mucosa or dura.[7] All techniques have their advantages and disadvantages, and no single technique has received universal acceptance. Cartilage has been used by otologists for tympanic membrane reconstruction, ossiculoplasty, and repair of bony meatal wall defects.[10,11]

Methods

A retrospective chart review of 47 ears was studied from 45 consecutive patients. Two patients had bilateral ossicular discontinuity. Cases were assigned to 2 groups according to the surgical technique used for the restoration of ossicular chain continuity. Group A (cartilage interposition) included 27 ears from 26 patients and 1 bilateral case, and group B (PORP) included 20 ears from 19 patients and 1 bilateral case. The surgical procedures were performed between December 2015 and November 2018. All patients, classified as Austin–Kartush group A (eroded long process of the incus only), were included. Two senior surgeons operated on all patients but according to surgeon's preference, group A patients were operated upon by McGee and Hough [2] and group B (PORP) by Bayazit et al.[1] Patient visits postoperatively were done at 3 and 12 months. Exclusion of cases with concurrent cholesteatoma was done. The study was approved by medical ethical committee of Al-Azhar University hospital in the number (11/2015ENT/214), and a written consent was obtained from each patient.

Surgical Techniques

Trans-canal approach was performed in the following situations if the anatomy of the external auditory canal (EAC) was favorable: cases of small posterior perforation, intact tympanic membrane with conductive hearing loss, or as a part of a second look procedure following cholesteatoma surgery. The postauricular approach was used in cases in which the anatomy of the EAC was not favorable such as narrow EAC, humpy anterior meatal wall, or very thin anterior rim of the perforation, and so on.

Surgical Technique for Group A

A small rectangular piece of conchal or tragal cartilage was harvested with preservation of perichondrium. The choice of whether it was conchal or tragal cartilage was dependent on the surgical approach. The conchal cartilage was harvested in the postauricular approach as it was closer to the vicinity while the tragal cartilage was used.

Surgical Technique for Group B (Partial Ossicular Replacement Prosthesis)

The malleus handle was carefully dissected from the tympanic membrane. The eroded incus was disarticulated at the incudo-malleolar joint. The tensor tympani tendon was then divided close to its insertion to the malleus neck. According to the malleus relocation technique described by Vincent et al.[12] the surgeon placed a 90° hook anterior to the position of the malleus neck to facilitate its relocation posteriorly until it came to lie directly over the stapes head. Such a technique improves the vertical position of the prosthesis and helps alignment. The hydroxyapatite PORP was put related to the stapes with positioning the malleus over the head of the prothesis.

Outcomes

(1) Audiological outcomes: Depending on the guidelines prepared by the Committee on Hearing and Equilibrium that related to the American Academy of Otolaryngology-Head and Neck Surgery,[13] air conduction (AC), bone conduction (BC), and air-bone gap (ABG) were measured at 500, 1000, 2000, and 3000 Hz frequencies. The main average for measuring the threshold results for AC and BC were 2000 and 4000 Hz, respectively. Pure-tone audiograms were done before and after the operation at 3 and 12 months.

(2) Patient satisfaction: Both preoperative and postoperative subjective evaluation as regard hearing satisfaction was analyzed using visual analog scale (VAS). A scale from 0 to 10 was used with the 2 ends representing the extremes of satisfaction and dissatisfaction. The patients were asked one specific question: if you were to rate your satisfaction/dissatisfaction in terms of hearing from 0 to 10 where 0=totally not satisfied and 10=totally satisfied, where would you rate yours?

Data Analysis

All statistical analyses were performed at a 5% confidence interval, and a P value $< .05$ was considered significant. The statistical software packages Statistical Analysis System 9.2 (SAS Institute, Cary, NC, USA) and Statistical Package for the Social Sciences 15.0 (SPSS Inc., Chicago, Ill, USA) were used for the analysis of the data. In addition to the standard descriptive statistical calculations as mean, standard deviation (SD) (min-max), the results on categorical measurements were presented in numbers (%). The mean and SD of hearing loss in dB pre- and postoperatively were compared using the paired t-test. Raw data of hearing outcomes at 3 and 12 months were

Main Points

- Upon comparing hearing outcomes with either cartilage interposition or partial ossicular replacement prosthesis (PORP) in Austin–Kartush group A patients in the context of ossiculoplasty, there are higher rates of air-bone gap closure among PORP group.
- There is also better patient satisfaction with PORP group.
- There is less chance of persistent perforation in PORP group compared with cartilage interposition group.

displayed in the Amsterdam Hearing Evaluation plots[14] (AHEP) in Figures 1 and 2.

Results

A total of 47 ears from 45 consecutive patients with Austin–Kartush group A (2 bilateral cases) were included, 29 cases were female, and 16 cases were male. The mean age of studied cases was 32.4 ± 10.5 ranging from 21 to 44 years. Of the total 47 ears from 45 patients, 27 were left ears and 20 were right ears. Group A (cartilage interposition) included 26 ears from 25 patients, 1 bilateral case (17 females and 8 males) (17 left-sided and 9 right-sided ears). The age of the studied cases ranged from 23 to 44 years with mean age about 34.4 ± 9.5 years. Group B (PORP) included 21 ears from 20 patients, 1 bilateral case (12 females and 8 males), 10 left, and 11 right ears. The mean age was 29.5 ± 11.3 years (range 21-40 years).

Preoperative and postoperative audiometric outcomes for both groups were presented and compared in Table 2. Between the cartilage interposition (group A) and PORP group (group B), there was no significant difference in preoperative AC, BC, or ABG. The same applies for 3- and 12-month postoperative AC, BC, and ABG. The AC was 46.6 dB preoperatively, 26.3 dB 3 months, and 25.7 dB 12 months postoperatively in group A. The preoperative and postoperative (3 and 12 months) AC in group B were 49.5, 27.2, and 26.9 dB, respectively. The ABG was 32.8 dB preoperatively, 9.9 dB at 3 months postoperatively, and 8.2 dB at 12 months postoperatively in group A. The preoperative ABG in group B was 29.6 dB, whereas postoperative ABG (3 and 12 months) were 11.4 dB and 9.5 dB, respectively.

A postoperative (3 and 12 months) ABG within 20 dB was achieved in 88.5% and 80.8%, respectively, in the cartilage interposition group (group A). Postoperative ABG (3 and

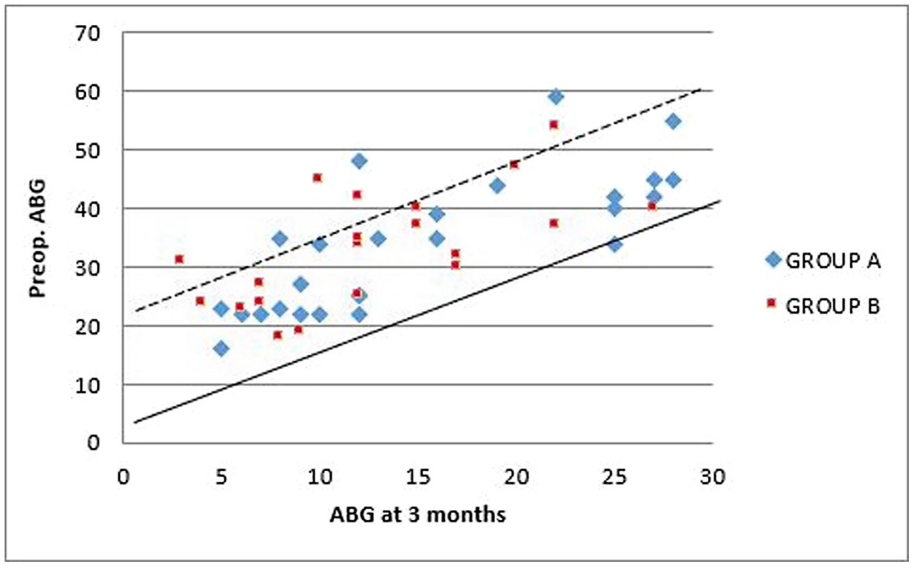

Figure 1. Amsterdam Hearing Evaluation plot results after 3 months for group A (blue dots) and group B (red dots).

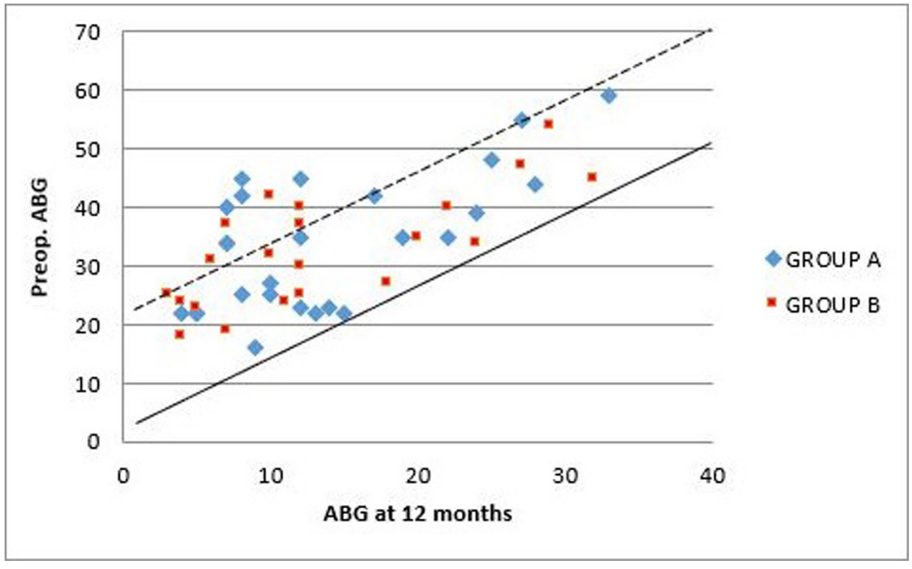

Figure 2. Amsterdam Hearing Evaluation plot results after 12 months for group A (blue dots) and group B (red dots).

Table 1. Distribution of Patient's Characteristics and VAS Results

		Results	
		Group A	Group B
Age		Range, 23-44 years (mean ± SD, 34.4 ± 9.5)	Range, 21-40 years (mean ± SD, 29.5 ± 11.3)
Gender	Male	8 (35.6%)	8 (35.6%)
	Female	17 (64.4%)	12 (64.4%)
Side of perforation	Right	9	11
	Left	17	10
Incision	Post-auricular	22 (46.8%)	19 (40.4%)
	Trans-canal	25 (53.2%)	28 (59.6%)
Pathology	Anterior perforation	22 (46.8%)	19 (40.4%)
	Posterior perforation	11 (23.4%)	14 (29.8%)
	Intact tympanic membrane	8 (17%)	9 (19.2%)
	Second look	6 (12.8%)	5 (10.6%)
VAS test	Preoperative	(mean ± SD, 4 ± 1.6)	(mean ± SD, 3.3 ± 0.8)
	Postoperative	(mean ± SD, 8.7 ±1.5)	(mean ± SD, 7.8 ±1.4)

VAS, visual analog scale; SD, standard deviation.

12 months) within 20 dB in the PORP group (group B) was attained in 80.1% and 76.2%, respectively. This difference was not statistically significant (Table 2).

Preoperative and postoperative ABG after 3 and 12 months for each group were compared in Table 2. The difference in preoperative and postoperative 3 and 12 months ABG was highly significant in both groups (P=.0001). None of the 47 operated ears had vertigo, facial palsy, sensorineural hearing loss, or wound complications at postoperative evaluation. However, in group A, 3 (11.5%) of 5 cases who displayed no closure of ABG presented with persistent perforation after 12 months. On the other hand, out of 5 cases in group B who showed no closure of ABG, 2 cases (9.5%) presented with persistent perforation after 12 months.

Preoperative and postoperative ABG after 3 months and 12 months for each group were compared in Table 3. The difference in preoperative and postoperative 3 and 12 months ABG was highly significant in both groups (P=.0001).

Table 2. Audiological Outcomes in Both Groups

Variables Among 47 Patients				*P*
Groups		**Group A**	**Group B**	
Bone conduction	Preoperative	16.7 ± 4.1	17 ± 3.7	0.824N**S***
	Postoperative 3 months	14 ± 4.1	14.7 ± 3.8	0.544N**S***
	Postoperative 12 months	17 ± 4.6	17 ± 5.7	0.874N**S***
Air conduction	Preoperative	46.6 ± 8	49.5 ± 8.7	0.233N**S***
	Postoperative 3 months	26.3 ± 7.8	27.2 ± 6.5	0.434N**S***
	Postoperative 12 months	25.7 ± 6.4	26.9 ± 5.7	0.374N**S***
ABG	Preoperative	32.8 ± 7.5	29.6 ± 7.3	0.146N**S***
	Postoperative after 3 month	9.9 ± 6.4	11.4 ± 7.6	0.479 N**S***
	Postoperative 12 months	8.2 ± 4.3	9.5 ± 5.1	0.453N**S***
Postoperative ABG at 3 months within 10 dB		11 (42.3%)	7 (33.34%)	0.77 NS**
Postoperative ABG at 3 months within 20 dB		23 (88.5%)	17 (80.1%)	0.266 NS**
Postoperative ABG at 12 months within 10 dB		10 (38.5%)	7 (33.34%)	0.716 NS**
Postoperative ABG at 12 months within 20 dB		21(80.8%)	16 (76.2%)	0.266 NS**

NS, non-significant (P > .05); S, significant (P ≤ .05); HS, highly significant (P ≤ .001); ABG, air-bone gap
*Student's *t*-test; **Chi-square test.

Table 3. Preoperative and Postoperative ABG After 3 Months and 12 Months

Variable Among 47 patients				
Groups	**Preoperative ABG**	**Postoperative ABG (3 months)**	**Postoperative ABG (12 months)**	***P***
Group A	32.8 ± 7.5	9.9 ± 6.4	13.2 ±6.3	.00001 HS
Group B	29.6 ± 7.3	11.4 ± 7.6	14.5 ±5.1	.00001 HS

NS, non-significant ($P > .05$); S, significant ($P \leq .05$); HS, highly significant ($P \leq .001$); ABG, air-bone gap.

None of the 47 operated ears had vertigo, facial palsy, sensorineural hearing loss, or wound complications at postoperative evaluation. However, in group A 3 (11.5%) out of 5 cases who displayed no closure of ABG presented with persistent perforation after 12 months. On the other hand, out of 5 cases in group B who showed no closure of ABG, 2 cases (9.5%) presented with persistent perforation after 12 months.

Mean VAS for group A was 4 ± 1.6 and 8.7 ± 1.5 for preoperative and postoperative results consequently with highly significant difference ($P < .001$), while the mean VAS for group B was 3.3 ± 0.8 and 7.8 ±1.4 for preoperative and postoperative results consequently with highly significant difference ($P < .001$). The differences in VAS values were non-significant comparing the preoperative results of both groups (P value .479), as well as for the postoperative results of both groups ($P = .132$) (Table 1).

There was a significant correlation between postoperative audiometric hearing results (patients whose ABG was within 10 dB, within 20 dB, and >20 dB) and the subjective satisfaction measured by VAS in both groups.

As shown in Fig. 3, the correlation between the postoperative ABG and VAS score for group A was significant (Spearman's correlation (r) = −0.5155), $P = .007033$. In group B, the correlation between postoperative ABG and VAS was also significant as (Spearman's correlation (r) = −0.55348), $P = .009246$.

Discussion

Chronic otitis media is one of the major causes of bone erosion that could be due to the inflammatory process and cytokines such as interleukins and tumor necrosis factor.[15] The long process of incus is the most common part of ossicles that is liable to necrosis is due to its structure, weak oteoblastic nature, and tenuous blood supply. The duration of the inflammatory process and eustachian tube dysfunction are other factors responsible for ossicular necrosis.[16]

The ideal material used in ossiculoplasty should be biocompatible, readily available, technically easy to manipulate, and should provide the best possible hearing results. Throughout the years, a variety of materials have been tried to meet these criteria.[2]

The sculpted incus interposition is the most used allograft for restoration of the incudostapedial discontinuity. Different surgical techniques, types of prostheses, the experience of the surgeon, the duration of the inflammatory process, the status of the residual ossicular chain, as well as eustachian tube function are important factors in determining the success of the ossiculoplasty.[17] The advantages of autografts (sculpted incus, cortical bone, and cartilage) are low cost on the patient, no need for another surgical field, and less rates of displacement. On the other hand, partial necrosis, complete absorption, ankylosis to the bony wall, and displacement have been blamed as potential disadvantages.[18] Chaudhary et al[19] reported on 82 patients

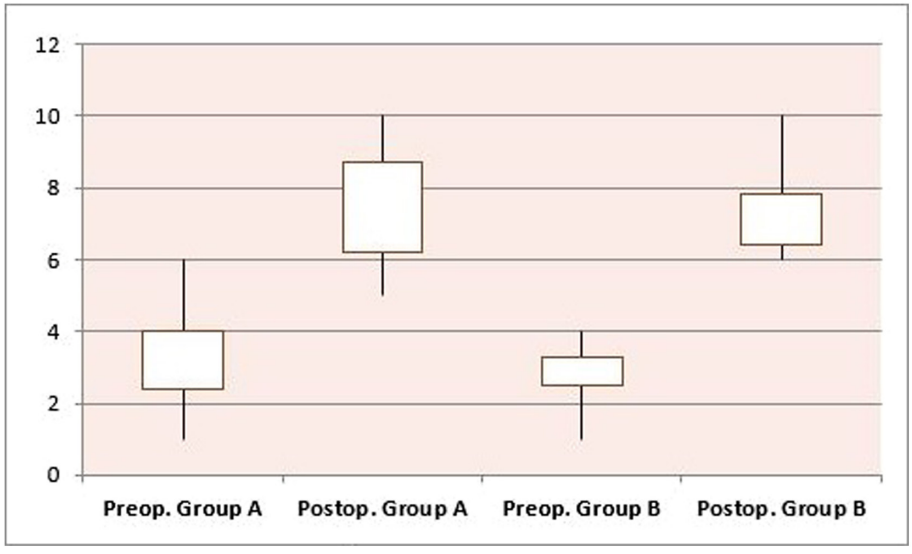

Figure 3. Mean visual analog scale.

with mucosal chronic otitis media who underwent ossiculoplasty with either autograft cartilage or bone for reconstruction of the ossicular defect. They concluded that better hearing results were obtained with either bone or cartilage autografts. More than 80% of cases had ABG gain ranging from 5 to 20 dB. A detailed literature review of a total of 931 patients classified as Austin–Kartush group A who underwent ossiculoplasty using auto- or homograft showed an ABG within 10 dB in 48% of the cases, and on a total of 779 patients, a postoperative ABG within 20 dB was obtained in 84% of the cases.[20] These outcomes are in accordance with our findings for the cartilage interposition group as postoperative ABG within 10 dB in 42.3% at 3 months and 38.5% at 12 months was achieved. A postoperative ABG within 20 dB was obtained in 88.5% and 80.8% at 3 and 12 months, respectively.

Several synthetic materials such as plastics, gold, steel, titanium, hydroxyapatite, teflon, and ceramics have been used in the production of partial ossicular replacement prosthesis. Although allograft prostheses are readily available, ossicular necrosis and eustachian tube dysfunction may lead to displacement of the protheses.[6,7] Extrusion rates however can be lowered by placing cartilage between the prosthesis head and the tympanic membrane.[21] Extrusion is a frequently mentioned complication in ossiculoplasty reports. However, reports of long-term effects of PORP concluded relatively good hearing outcomes. Hess-Erga et al[22] reported long-term results (mean of 5.2 years of follow-up) on 44 patients who were subjected to ossiculoplasty with PORP; 82% of patients had postoperative ABG ranging from 5 to 20 dB. In a similar study, Berenholz et al [23] reported ABG less than 20 dB in 71.4% and 57.1% of cases after 3 and 12 months, respectively, in the PORP group. In our study, the postoperative ABG within 10 dB in the PORP group both after 3 and 12 months was 33.3% and the postoperative ABG within 20 dB was obtained in 80.1% and 76.2% at 3 and 12 months, respectively. These results compare well with a literature review by Iurato et al[20] who studied 256 patients who underwent incus reconstruction using different materials. They showed different levels of postoperative ABG, 50% of these studied cases were within 10 dB.

Preoperative and postoperative ABG after 3 and 12 months showed a statistically significant difference after undergoing incudostapedial reconstruction using either cartilage or PORP. Galy-Bernadoy et al[10] approved with our results depending on different techniques of incus reconstruction.

To obtain more better results in ossiculoplasty, cases should have intact incus and malleus should be placed articulated with the stapes.[12,24] In the present study, complete dissection of the malleus from the tympanic membrane, divisions of the tensor tympani tendon, and malleus posterior relocation were entertained.

There were many limitations in this study such as small number of patients and short follow-up period. Another limitation is the lack of classification of the patients according to the length of the eroded segment of the incus and accordingly the distance between incus remnant and the stapes head. Such classification would help analyze which technique should be chosen for each patient regarding the variable length of the defects.

Conclusion

Our study showed comparable hearing outcomes with either cartilage interposition or PORP in Austin–Kartush group A patients in the context of ossiculoplasty. There was no statistically significant difference between these 2 techniques based on both audiological outcomes and VAS.

Ethics Committee Approval: This study was approved by Ethics committee of Al-Azhar University, (Approval No: 11/2015ENT/214).

Informed Consent: Written consent was obtained from the patients who agreed to take part in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.N.E.; Design – A.K.M.; Supervision – A.K.M.; Resources – A.N.E.; Materials – A.N.E.; Data collection and/or Processing – A.K.M.; Analysis and/or Interpretation – A.K.M.; Literature Search – A.N.E.; Writing Manuscript – A.K.M.; Critical Review – A.K.M.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: The authors declared that this study has received no financial support.

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