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A study of outcome of ossiculoplasty using autologous cartilage, refashioned incus, and polytetrafluoroethylene (Teflon) prosthesis in patients of chronic suppurative otitis media

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Abstract

Aim To find out the mean air conduction thresholds (ACT) and air–bone gap (ABG) closure across the treatment groups at the end of 3 and 6 months of follow-up.

Material and methods Sixty patients diagnosed with COM with conductive hearing loss were included in the study. Air conduction threshold (ACT) and air–bone gap were calculated and recorded pre-operatively. Surgery was done with clearance of disease followed by reconstruction of hearing in single-stage operation using autologous conchal cartilage, refashioned incus, and polytetrafluoroethylene (Teflon) prosthesis (PORP, TORP) depending upon the intra-operative findings during surgery. Patients were followed for up to 6 months for assessing the hearing outcome in terms of the mean air conduction threshold and mean air–bone gap closure for each group separately.

Results The outcome of each ossiculoplasty material was calculated in terms of mean air conduction threshold and mean AB gap closure. Preoperative and postoperative air conduction threshold (ACT) at 3 months and 6 months follow-up of each group was as follows: for the autologous conchal cartilage group, 41.3 (\pm SD 6.69), 29.2 (\pm SD 5.39), and 21 (\pm SD 4.66); for autologous refashioned incus group, 40.4 (\pm SD 5.43), 28.4 (\pm SD 6.73), and 20.8 (\pm SD 4.33); for the Teflon PORP group, 42.9 (\pm SD 5.68), 31.4 (\pm SD 6.86), and 34.9 (\pm SD 6.37); and for the Teflon TORP group, 43.1 (\pm SD 5.40), 32.5 (\pm SD 5.91), and 36.2 (\pm SD 5.31). The mean air–bone gap preoperatively and postoperatively at 3 months and 6 months respectively were as follows: for autologous conchal cartilage, 40.6 (\pm SD 4.57), 23.7 (\pm SD 4.48), and 20 (\pm SD 5.28); for autologous refashioned incus, 39.3 (\pm SD 4.92), 21.9 (\pm SD 5.61), and 19.4 (\pm SD 5.82); for Teflon PORP 43.0 (\pm SD 4.48), 32.8 (\pm SD 4.84), and 36.3 (\pm SD 5.56); and for Teflon TORP, 44.5 (\pm SD 5.56), 33.2 (\pm SD 5.53), and 35.2 (\pm SD 5.10).

Conclusion The hearing outcome of ossiculoplasty varies with the type of ossiculoplasty material used. Most favorable results were obtained with refashioned autologous incus followed by autologous conchal cartilage. Teflon prosthesis has a significant improvement in hearing outcomes although the results are less favorable.

Keywords Chronic suppurative otitis media, Ossiculoplasty, Air conduction thresholds, Air–bone gap, PORP, TORP

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Background

Chronic suppurative otitis media (CSOM) or chronic otitis media (COM) is one of the common causes of hearing impairment and disability [1]. CSOM with or without cholesteatoma frequently results in disruption of the

auditory ossicular chain [2, 3]. In ossicular discontinuity, the ossicular coupling-led preferential distribution of sound to the oval window is lost, and the cochlear partition pressure between the round and the oval windows, which drives the cochlear traveling wave, is compromised [4]. The auditory ossicles, malleus incus and stapes, are involved in the amplification of sound waves through the generation of a lever mechanism. This lever mechanism is lost with the disruption of the ossicular chain resulting in conductive hearing loss [5–8]. Conductive hearing loss from ossicular chain abnormalities may result from either discontinuity or fixation of the ossicular chain. In more than 80% of patients, the cause of ossicular damage is chronic suppurative otitis media with or without cholesteatoma [9]. Trauma or congenital malformations account for most of the remaining causes of ossicular damage. In order of frequency, discontinuity most commonly occurs because of an eroded incudostapedial joint, an absent incus, or absent incus and stapes superstructure [2, 3, 10, 11]. Approximately half of the cases have more than one ossicle involved [12, 13]. In up to 55% of conductive hearing loss cases, ossicular discontinuity or fixation was found to be responsible [14]. Austin divided the ossicular damage into four types based on the presence or absence of malleus and stapes suprastructure assuming incus being absent in all cases. Type A (M+, S+), type B (M+, S–), type C (M–, S+), and type D (M–, S–) [15, 16]. The most commonly encountered ossicular defect is type A, followed by types B, C, and D in this order. This was modified by Kartush [16] with the addition of three further categories to include a normal ossicular chain and cases of fixation [17].

The treatment of CSOM has improved from just preventing complications to a focus on the improvement and restoration of hearing with the development of ear microsurgery techniques for chronic suppurative otitis media (CSOM) [1]. Various techniques of tympanoplasty have evolved from time to time, and improvisation is being done based mainly in terms of hearing improvement using ossicular reconstruction (ossiculoplasty) after clearance of disease [18]. Materials used in ossiculoplasty include autografts such as autologous ossicles, cartilage and bone and homologous grafts such as homologous bone and synthetic materials such as polytetrafluoroethylene (Teflon), plastipore, hydroxyapatite, and titanium. The selection of a particular prosthesis must be based on several factors, including compatibility, ease of configuring the prosthesis during surgery, availability, and cost [19, 20]. There still exists a considerable difference in opinions in using either type of graft in terms of the selection of graft material, graft remodeling intra-operatively, extrusion rates, and postoperative hearing outcome [21]. The ideal ossicular prosthesis should be manageable,

versatile, biocompatible, and stable over time [22, 23]. Thus, there is a need felt to comprehensively and holistically evaluate the outcome of ossiculoplasty using autograft (cartilage and refashioned incus) and synthetic graft polytetrafluoroethylene (Teflon).

The aim of the present study was to find out the mean air conduction thresholds (ACT) and air–bone gap (ABG) closure across the treatment groups at the end of 3 and 6 months of follow-up using different types of graft materials such as autologous cartilage, autologous refashioned incus, or synthetic grafts like Teflon partial ossicular reconstruction prosthesis (PORP) and total ossicular reconstruction prosthesis TORP.

Methods

Setting of the study

This prospective study was conducted in the Department of ENT & HNS, Government Medical College (GMC), Srinagar, J&K, India. The study was conducted from September 2018 to August 2020 over a period of 2 years.

Population

The population comprised patients attending the ENT Outpatient Department of Otolaryngology SMHS Hospital of GMC Srinagar.

Sample size

The sample size consisted of 60 patients who were admitted to the ENT Department and fulfilled the criteria for sample selection.

Study design

It was a prospective study.

Criteria for sample selection

The following are the inclusion criteria:

- a) Patients of CSOM (safe and unsafe) with ossicular erosion
- b) Patients aged 10 years to 50 years

The following are the exclusion criteria:

- a) Patients of CSOM with complications or seeking revision surgery
- b) Patients of CSOM with SNHL or mixed loss
- c) Patients of CSOM with associated comorbidities

Tools and techniques

Sixty patients who satisfied the criteria of selection were taken as a sample of the study. History was taken, and an examination was done as a part of the routine workup.

All patients were subjected to complete ENT examination including otoscopy, otoendoscopy, and tuning fork tests (TFT). Investigations like pure tone audiometry (PTA) and high-resolution computed tomography (HRCT) of the temporal bone (if otherwise indicated) were done.

Pure tone audiometry (PTA) (preoperative/post-operative at 3 and 6 months)

Air conduction threshold (ACT) and air–bone gap (ABG) were calculated. Hearing thresholds were calculated at frequencies as per the recommendation of AAO-HNS at 500, 1000, 2000, and 3000 Hz.

Surgery

After explaining the need for the surgery and obtaining written informed consent, the surgical procedure followed: The surgery was performed under general anesthesia except in 17 patients who were operated under local anesthesia. All patients were operated through post-aural approach. Tympanoplasty without mastoidectomy was performed in 23 (38.3%) patients, and tympanoplasty with mastoidectomy was performed in 37 (61.6%) patients as per indication. Out of 37 (61.6%) patients with unsafe CSOM, canal wall up mastoidectomy was performed in 16 (26.6%) patients whereas canal wall down mastoidectomy was performed in 21 (35%) patients. The decision to use any ossiculoplasty material for each patient was taken after examining the extent of disease intraoperatively. Autologous materials preferred were possible. In case autologous materials could not be used due to some factors like non-availability in chronically diseased ears, microscopic squamous infiltration of incus in cholesteatoma ears etc. in these cases prosthetic material TORP or PORP was used. Autologous conchal cartilage was reshaped and was used as short columella (malleus/tympanic membrane-stapes assembly) in 14 (23.3%) patients and long columella (malleus/tympanic membrane-footplate assembly) in 3 (5%) patients. Refashioned incus was used as short columella (malleus/tympanic membrane-stapes assembling) in 12 (20%) patients and long columella (malleus/tympanic membrane-footplate assembling) in 2 (3.3%) patients. Teflon PORP was placed over stapes suprastructure in 14 (23.3%) patients whereas Teflon TORP was placed over the footplate in 15 (25%) patients. Disease was unified by the distribution of safe and unsafe ears equally among the study groups and similar air–bone gap (ABG) preoperatively among the study groups. The surgical procedure was unified by the distribution of the ossiculoplasty without mastoidectomy, canal wall up mastoidectomy, and canal wall down mastoidectomy procedures equally among the study groups.

Patients were followed up postoperatively at 3 and 6 months

At each of these follow-ups, otoscopic/otoendoscopic examination and PTA were done.

- Pre- and postoperative air conduction threshold (ACT) improvement at 3 and 6 months was recorded.
- Pre- and postoperative air–bone gap (ABG) closure at 3 and 6 months was recorded.

Statistical evaluation

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to the data editor of SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean \pm SD, and categorical variables were summarized as frequencies and percentages. Graphically, the data was presented by bar and pie diagrams. Paired *t*-test and repeated measure ANOVA were employed to compare the various parameters before and after surgery. *P*-value < 0.05 was considered statistically significant. All *P*-values were two-tailed.

Results

A total of sixty patients were included in the study. The mean age in years was 24.3 ± 6.74 . There were 32 (53.3%) female and 28 (46.7%) male patients with a male:female ratio of 1:1.4. All 60 (100%) patients complained of impaired hearing followed by 44 (73.3%) patients with ear discharge (persistent/intermittent), 29 (48.3%) patients with tinnitus, 28 (46.7%) patients with earache, 9 (15%) patients with aural fullness, and 5 (8.3%) patients with vertigo. Among twenty-three patients with safe CSOM, active central perforation with granulations was seen in 10 (16.6%) patients, active central perforation with edematous middle ear mucosa and ear discharge was seen in 9 (15%) patients, and dry central perforation with myringosclerosis was observed in 4 (6.6%) patients. In 37 patients of unsafe CSOM, cholesteatoma without retraction pockets was seen in 21 (35%) patients followed by cholesteatoma with retraction pockets in 16 (26.6%) patients. The left ear was operated on in 39 (65%) patients whereas the right ear was operated on in 21 (35%) patients.

Material used for ossiculoplasty (Table 1)

In this study, autologous cartilage (conchal) was used in 17 (28.3%) patients, refashioned incus was used in 14 (23.3%) patients, Teflon (PORP) was used in 14 (23.3%) patients, and TORP was used in 15 (25%) patients for ossiculoplasty. Out of 14 patients who had ossiculoplasty with refashioned incus, 12 (20%) patients had malleus/tympanic membrane-stapes assembly and 2 (3.3%) patients had malleus/tympanic

Table 1 Material used for ossiculoplasty [$n = 60$]

Material used		No. of patients	Percentage
Autologous cartilage (conchal)		17	28.3
Autologous refashioned incus		14	23.3
Teflon ossicular prosthesis	PORP	14	23.3
	TORP	15	25
Total		60	100

membrane-footplate assembly. Teflon PORP was placed over stapes suprastructure in 14 (23.3%) patients whereas TORP was placed over the footplate in 15 (25%) patients.

Postoperative air–bone gap (ABG) at 3 months with different ossiculoplasty materials (Table 2)

In this study, ABG was calculated as per the American Academy of Otolaryngology and Head and Neck Surgery criteria. Postoperative ABG was first assessed at 3 months. In 17 patients who had ossiculoplasty with autologous conchal cartilage, 9 patients had air–bone gap between 11 and 20 dB followed by 4 patients between 21 and 30 dB and 4 patients > 30 dB at 3 months postoperatively. In 14 patients who had ossiculoplasty with autologous refashioned incus, 7 patients had air–bone gap between 11 and 20 dB followed by 5 patients between 21 and 30 dB and 2 patients > 30 dB at 3 months postoperatively. In 14 patients who had ossiculoplasty with Teflon (PORP), 6 patients had air–bone gap > 30 dB followed by 5 patients between 21 and 30 dB and 3 patients between 11 and 20 dB at 3 months postoperatively. In 17 patients who had ossiculoplasty with Teflon (TORP), 7 patients had air–bone gap > 30 dB followed by 5 patients between 21 and

30 dB and 3 patients between 11 and 20 dB at 3 months postoperatively.

Postoperative air–bone gap (ABG) at 6 months with different ossiculoplasty materials (Table 3)

In this study, postoperative air–bone gap (ABG) was also assessed at 6 months. In 17 patients who had ossiculoplasty with autologous conchal cartilage, 8 patients had air–bone gap between 11 and 20 dB followed by 6 patients between 21 and 30 dB, 2 patients between 51 and 60 dB, and 1 patient between 31 and 40 dB at 6 months postoperatively. In 14 patients who had ossiculoplasty with refashioned incus, 7 patients had air–bone gap between 11 and 20 dB followed by 5 patients between 21 and 30 dB, 1 patient between 31 and 40 dB, and another 1 patient between 51 and 60 dB at 6 months postoperatively. In 14 patients who had ossiculoplasty with Teflon (PORP), 6 patients had air–bone gap between 21 and 30 dB followed by 3 patients between 31 and 40 dB, 2 patients between 11 and 20, 2 patients between 51 and 60 dB, and 1 patient between 41 and 50 dB at 6 months postoperatively. In 15 patients who had ossiculoplasty with Teflon (TORP), 5 patients had air–bone gap between 21 and 30 dB followed by 4 patients between 31 and 40 dB, 3 patients between 51 and 60 dB, and another 3 patients between 11 and 20 dB at 6 months postoperatively.

Preoperative and postoperative mean air conduction thresholds (ACT) at 3 months and 6 months (Table 4)

In this study, the mean preoperative and postoperative (3 months and 6 months) air conduction thresholds were compared. In patients where autologous conchal cartilage was used for ossiculoplasty, the preoperative air conduction threshold mean was 41.3 (\pm SD 6.69), and the postoperative air conduction threshold mean at 3 months was 29.2 (\pm SD 5.39); at 6 months, it was 21 (\pm SD 4.66). In patients where autologous refashioned incus was

Table 2 Postoperative air–bone gap (ABG) at 3 months with different ossiculoplasty materials ($n = 60$)

ABG (dB)	Autologous cartilage (conchal)	Refashioned incus	Teflon	
			PORP	TORP
0–10	0	0	0	0
11–20	9	7	3	3
21–30	4	5	5	5
31–40	3	2	4	3
41–50	0	0	1	2
51–60	1	0	1	2
Total	17	14	14	15

Table 3 Postoperative air–bone gap (ABG) at 6 months with different ossiculoplasty materials ($n = 60$)

ABG (dB)	Autologous cartilage (conchal)	Refashioned incus	Teflon	
			PORP	TORP
0–10	0	0	0	0
11–20	8	7	2	3
21–30	6	5	6	5
31–40	1	1	3	4
41–50	0	0	1	0
51–60	2	1	2	3
Total	17	14	14	15

Table 4 Preoperative and postoperative air conduction thresholds (ACT). Mean at 3 months and 6 months ($n=60$)

Material used	Preoperative AC		3 months AC		6 months AC		P-value
	Mean	SD	Mean	SD	Mean	SD	
Cartilage	41.3	6.69	29.2	5.39	21	4.66	0.003*
Refashioned incus	40.4	5.43	28.4	6.73	20.8	4.33	< 0.001*
PORP	42.9	5.68	31.4	6.86	34.9	6.37	0.182
TORP	43.1	5.40	32.5	5.91	36.2	5.31	0.319

* Statistically significant difference (P -value < 0.05)

used for ossiculoplasty, the preoperative air conduction threshold mean was 40.4 (\pm SD 5.43), and the postoperative air conduction threshold mean at 3 months was 28.4 (\pm SD 6.73); at 6 months, it was 20.8 (\pm SD 4.33). In patients where Teflon PORP was used for ossiculoplasty, the preoperative air conduction threshold mean was 42.9 (\pm SD 5.68), and postoperative air conduction threshold mean was 31.4 (\pm SD 6.86) at 3 months, and at 6 months, it was 34.9 (\pm SD 6.37). In patients where Teflon TORP was used for ossiculoplasty, the preoperative air conduction threshold mean was 43.1 (\pm SD 5.40), and the postoperative air conduction mean was 32.5 (\pm SD 5.91) at 3 months, and at 6 months, it was 36.2 (\pm SD 5.31). Pre and postoperative air conduction P -values for autologous conchal cartilage, refashioned incus, PORP, and TORP materials used for ossiculoplasty were recorded as 0.003, < 0.001, 0.182, and 0.319, respectively.

Preoperative and postoperative air–bone gap (ABG) mean at 3 months and 6 months (Table 5)

In this study, the mean preoperative and postoperative air–bone gap at 3 months and 6 months was compared. In patients where autologous conchal cartilage was used for ossiculoplasty, the preoperative air–bone gap mean was 40.6 (\pm SD 4.57), and the postoperative air–bone gap mean was 23.7 (\pm SD 4.48) at 3 months, and at 6 months, it was 20 (\pm SD 5.28). In patients where autologous refashioned incus was used for ossiculoplasty, the preoperative air–bone gap mean was 39.3 (\pm SD 4.92), and the postoperative air–bone gap mean was 21.9 (\pm SD 5.61)

at 3 months, and at 6 months, it was 19.4 (\pm SD 5.82). In patients where Teflon PORP was used for ossiculoplasty, the preoperative air–bone gap mean was 43.0 (\pm SD 4.48), and the postoperative air–bone gap mean was 32.8 (\pm SD 4.84) at 3 months, and at 6 months, it was 36.3 (\pm SD 5.56). In patients where Teflon TORP was used for ossiculoplasty, the preoperative air–bone gap mean was 44.5 (\pm SD 5.56), and the post-operative air–bone gap mean was 33.2 (\pm SD 5.53) at 3 months, and at 6 months, it was 35.2 (\pm SD 5.10). Pre- and postoperative air–bone gap P -values for autologous conchal cartilage, refashioned incus, PORP, and TORP used for ossiculoplasty were recorded as < 0.001, < 0.001, 0.227, and 0.114, respectively. Statistically significant difference (P -value < 0.05) was observed in pre- and postoperative ABG (at 3 and 6 months) where autologous conchal cartilage (< 0.001) and refashioned incus (< 0.001) were used for ossiculoplasty (Fig. 1).

Discussion

Reconstruction of the ossicular chain is still a developing surgical discipline in otolaryngology. The goal in ossiculoplasty is to have a stable and reliable connection between the tympanic membrane and the mobile stapes footplate in order to achieve the best hearing result in addition to achieving a dry ear.

This study was designed to find out the hearing outcome in patients with CSOM using different ossiculoplasty materials. Accordingly, patients were divided into four groups: autologous cartilage group, refashioned

Table 5 Preoperative and postoperative air–bone gap (ABG). Mean at 3 months and 6 months ($n=60$)

Material used	Preoperative ABG		ABG, 3 months		ABG, 6 months		P-value
	Mean	SD	Mean	SD	Mean	SD	
Cartilage	40.6	4.57	23.7	4.48	20	5.28	< 0.001*
Refashioned incus	39.3	4.92	21.9	5.61	19.4	5.82	< 0.001*
PORP	43.0	4.48	32.8	4.84	36.3	5.56	0.227
TORP	44.5	5.56	33.2	5.53	35.2	5.10	0.114

* Statistically significant difference (P -value < 0.05)

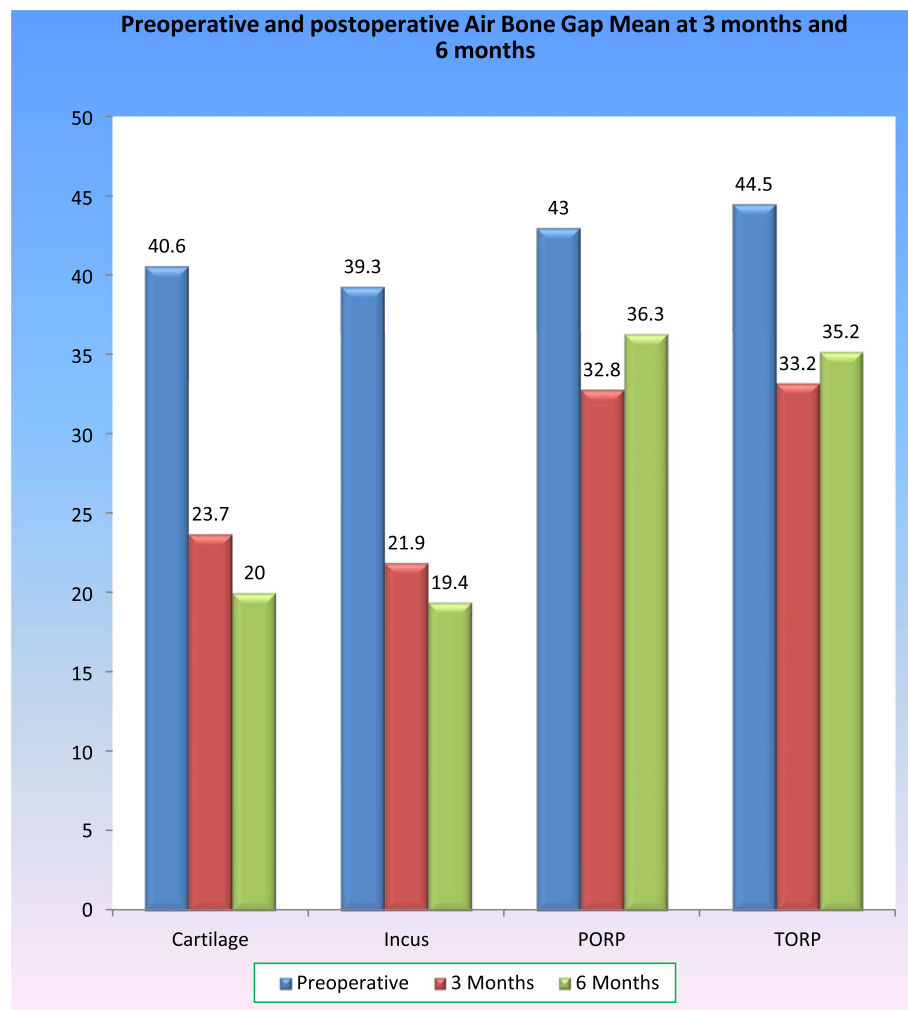


Fig. 1 Preoperative and postoperative air–bone gap mean at 3 months and 6 months

incus group, PORP group, and TORP group. In this study, out of 14 patients who had ossiculoplasty with refashioned incus, 12 (20%) patients had malleus/tympanic membrane-stapes assembly and 2 (3.3%) patients had malleus/tympanic membrane-footplate assembly. Teflon PORP was placed over stapes suprastructure in 14 (23.3%) patients whereas TORP was placed over the footplate in 15 (25%) patients. Choudhary et al. [24] included 50 patients in their study out of which 28 patients (56%) underwent autologous reshaped incus ossiculoplasty and 22 patients (44%) underwent ossiculoplasty using PORP. Chaudhary, Anand, and Taperwal [25] distributed 100 of their patients according to the type of reconstruction in which 27% of patients underwent malleus stapes assembly, 17% of patients malleus footplate assembly, 23% of patients short columella, and 15% of patients long columella. Robert et al. [26] included 137 patients in which autologous or homologous sculpted incus interposition

was used between intact malleus and stapes suprastructure. In a study by Mahanty et al. [27], refashioned incus was interposed between the handle of malleus and the stapes suprastructure. Hajela et al. [28] placed autograft incus between the manubrium of the malleus and the stapes head. Pathan et al. [29] included 100 patients categorized intraoperatively into two groups of 50 patients where one group underwent ossiculoplasty with tragal cartilage and the other with PORP. Group division and surgical technique used in our study were similar to most of the abovementioned previous studies.

Preoperative ACT was similar in all four groups and was between 41 and 43 dB (Table 4). Postoperatively, the mean air conduction threshold of <20 dB was obtained with autologous conchal cartilage and refashioned incus but not with the Teflon prosthesis (PORP, TORP). Statistically, a significant difference (P -value < 0.05) was observed in pre- and postoperative air conduction at 3

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