

# Comparative study of autologous incus, tragal cartilage and partial ossicular reconstruction prosthesis (PORP) in ossiculoplasty

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## Abstract

**Aim:** Ossicular discontinuity is a common complication of chronic otitis media. Ossiculoplasty is done to restore the hearing mechanism. Aim of the study is to compare efficacy of autologous remodelled incus, tragal cartilage and Teflon PORP used for ossicular reconstruction in terms of post-operative hearing improvement. **Material and Methods:** A comparative prospective study of 90 patients of ossiculoplasty using remodelled incus, tragal cartilage and polytetrafluoroethylene (Teflon) partial ossicular replacement prosthesis (PORP) was done to analyse the hearing gain at the end of six months post-operatively. **Results:** All the 3 materials were found to provide significant benefit to the patients in hearing. Out of the 3 materials studied, remodelled incus was found to be significantly better than the other two. **Conclusion:** Autologous remodeled incus to have the best outcome in terms of post-operative closure of air bone gap as compared to tragal cartilage followed by Teflon PORP and it was found to be statistically significant. **Key Words:** Ossiculoplasty, Incus, Cartilage, PORP, TEFLON, Comparative.

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presence or absence of the malleus handle and the stapes suprastructure<sup>3</sup>. A wide variety of materials have been used for ossicular reconstruction, including both biological materials (ossicles, teeth, cartilage) and alloplastic materials (metallic like gold, titanium or non-metallic like polymers or ceramics)<sup>4,5</sup>. We present a comparative prospective study of the outcomes of ossiculoplasty between remodeled autologous incus, tragal cartilage and polytetrafluoroethylene (Teflon) partial ossicular replacement prosthesis (PORP) to analyse the hearing gain at the end of six months postoperatively.

## INTRODUCTION

Ossiculoplasty or ossicular chain reconstruction is the surgical repair of the middle ear ossicles to restore the conductive mechanism in tympanoplasty. Chronic otitis media (COM) is a middle ear pathology which commonly leads to ossicular discontinuity thus affecting the conduction of sound<sup>1</sup>. The earliest recorded attempt of ossiculoplasty was in 1901, when Matte attempted to re-establish connection between the TM and oval window in case of missing ossicles<sup>2</sup>. In 1971, Austin gave the classification of the ossicular defect based on the

## MATERIALS AND METHOD

This is a prospective study of 90 patients who underwent ossiculoplasty at B.J Medical College and Civil hospital, Ahmedabad between 1<sup>st</sup> September 2015 to 31<sup>st</sup> March 2016. Informed consent was obtained from all individual participants included in the study. The patients were examined including history, general examination, ENT examination, Otoscopy and Tuning Fork Test followed by microscopic examination of the ear. Pure Tone

Audiometry was done for all cases planned for surgery. Patients aged 10-65 years having COM with air bone gap (ABG) >30 dB and having ossicular involvement but with intact stapes were included in the study. Those patients having COM with complications (intracranial or extracranial), sensory-neural or mixed hearing loss, revision ear surgeries or having involvement of the stapes were excluded from the study. The patients were randomly divided intraoperatively into three groups of 30 each. Group 1 underwent ossiculoplasty with autologous incus, in Group 2 cartilage was used for ossicular reconstruction and in Group 3, polytetrafluoroethylene (Teflon) partial ossicular reconstruction prosthesis (PORP) was used. Same surgeon performed all the surgeries under local or general anaesthesia. A post aural

(Wilde's) approach was used in all cases. Most of the patients had an eroded incus but with intact malleus and stapes. The necrosed incus was dislodged from the incudomalleolar joint and removed. The decision to perform a mastoidectomy was taken based on the intra-operative findings (discharge/granulation in middle ear, oedematous middle ear mucosa, persistent discharging ear despite iv and local antibiotic therapy). In Group 1, the removed incus was held with an incus holding forceps and a 0.6 mm cutting burr was used to remodel the long process (Figure. 1a) and a groove was made in the inferior end to engage it on the head of stapes. This was interposed between the malleus handle and the stapes superstructure (Figure 1b).

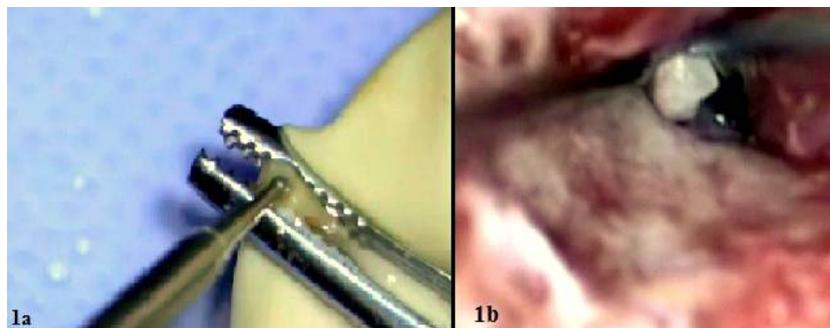


Figure 1: Incus Remodelling

In Group 2, tragal cartilage was harvested (Figure. 2a) and carved such that the longer end was kept at the tympanic annulus and the shorter end over the stapes head (Figure. 2b).



Figure 2: Tragal Cartilage

In Group 3, PORP was kept over the stapes head and the other end at the annulus (Figure 3).



Figure 3: PORP

**Table 1:** Total number of patients in the study

Air Bone Gap (dB)	Autologous Incus (%)	Cartilage (%)	PORP (%)
0-10	01 (3.3)	0 (0)	0 (0)
11-20	13 (43.3)	10 (33.3)	08 (26.6)
21-30	14 (46.6)	12 (40)	10 (33.3)
31-40	02 (6.6)	07 (23.3)	10 (33.3)
41-50	0 (0)	0 (0)	02 (6.6)
>50	0 (0)	01 (3.3)	0 (0)

In all the cases, the perforation was repaired with a temporalis fascia graft kept by the underlay technique followed by stabilization of the graft by gel foam and closure of wound in layers. The patients were followed up on Day 7, 15, 30, 3 months and at 6 months. At the end of 6 months, all patients underwent post-operative pure tone audiometry. Success was defined as closure of post-operative air bone gap to <30 dB.

**RESULTS**

In our study of 90 patients, 37 were males and 53 were females. Intraoperatively, necrosis of the long process of incus was seen in 53 cases and necrosis of long process along with lenticular process was seen in 37 cases.

**Table 2:** Pre-operative Hearing Status

Age Group (years)	Number of patients	Males	Females
10-19	09 (01%)	04	05
20-29	13 (14.4%)	06	07
30-39	28 (31.1%)	11	17
40-49	22 (24.4%)	10	12
50-59	10 (11.1%)	04	06
>60	08 (8.8%)	02	06

**Table 3:** Post-operative Hearing Status

Air Bone Gap (dB)	Number of Patients (%)
30-40	21 (23.3)
40-50	24 (26.6)
50-60	31 (34.4)
>60	14 (15.5)

In Table 2, most of the patients have a pre-operative ABG in 50-60 dB range (34.4%). From Table 3, when post-op hearing status is assessed at the end of 6 months, patients having >30dB ABG are 6.6%, 26.9% and 39.9% when autologous incus, cartilage and PORP are used respectively for ossicular reconstruction. 2 patients were excluded from the final analysis (1 from Group 2 having a perforation in the graft after 6 months and 1 from Group 3 having extrusion of the PORP).

**Table 4:** Statistical Analysis Post-Op Hearing Gain(n=30)

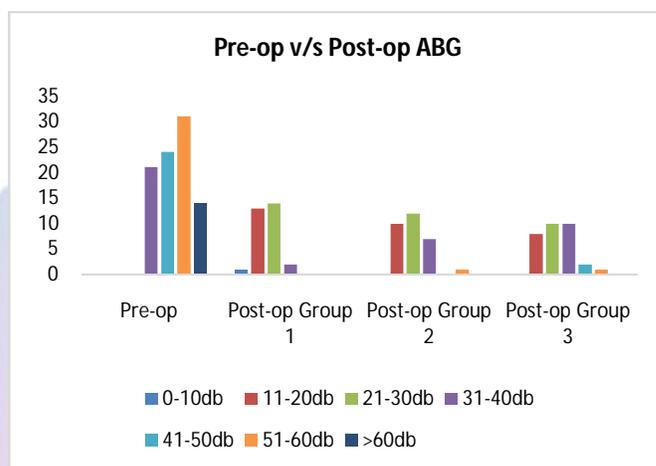
Material Used Parameter	Remodeled Incus (Group 1)	Tragal Cartilage (Group 2)	Teflon PORP (Group 3)
Mean Pre-op ABG	49.16 dB	48.46 dB	49.96 dB
Mean Post-op ABG	19.96 dB	24.3 dB	26.7 dB
P value	<0.0001	<0.0001	<0.0001
Inference	Statistically Significant	Statistically Significant	Statistically Significant

**Table 5:** Success Rate

Material (No. of cases)	Success (%)	Failure (%)
Remodeled Incus (30)	28 (93.4)	02 (6.6)
Cartilage (30)	22 (73.3)	08 (26.9)
PORP (30)	18 (59.9)	12 (39.9)

**Table 6:** Statistical analysis of the material used

Parameters	Mean ABG (dB)	Standard Deviation (S.D)	p Value for ANOVA test	Inference
Remodeled Incus	19.96	6.41	0.01067	Significant at P < 0.05
Tragal Cartilage	24.3	9.2		
Teflon PORP	26.7	9.6		



**Figure 4:** Comparison of preoperative and postoperative conductive loss.

From Table 4, Table 5 and Table 6, the post-operative benefit in terms of hearing improvement is statistically significant in all 3 groups and in terms of Success of the surgery, the best material for ossiculoplasty was found to be remodeled incus (93.3%) followed by tragal cartilage (73.3%) and least by Teflon PORP (59.9%). There is statistical significant difference between the 3 materials used for ossiculoplasty.

**DISCUSSION**

Loss of ossicular continuity is common cause of conductive hearing loss in patients with COM. This can be managed surgically by ossiculoplasty. In our study, we evaluated autologous remodeled incus, tragal cartilage and Teflon prosthesis for the reconstruction of the ossicular chain. All the patients gave a history of ear discharge and decreased hearing. This is consistent with the study by Sheahan which showed that otorrhoea and hearing loss were the most common complains at presentation<sup>6</sup>. Long process of incus was found to be eroded in 70% cases while long process and lenticular process was eroded in

30% cases. Long process of incus is the most common ossicle to undergo necrosis and this can be attributed to its tenacious blood supply. According to the literature, Incus necrosis is very common and was found in about 60-80 % cases<sup>7</sup>. In our study of 90 cases, 3 groups of 30 patients each underwent ossiculoplasty using autologous remodelled incus, tragal cartilage and Teflon PORP respectively. Amongst these, the success rate for remodelled incus was 90%, for cartilage was 70% and for Teflon PORP was 56.6% after 6 months of post-operative hearing assessment by pure tone audiometry. Success was defined as < 30 dB ABG. Jha *et al.* in their comparative study on ossiculoplasty described that the failure and extrusion in case of cartilage were 11.5% and in plastic PORP it was 20%<sup>8</sup>. In study by Naragund A of 24 patients, 12 underwent ossiculoplasty with autograft incus and 12 with titanium prosthesis. Postoperative hearing evaluation by pure tone audiogram was done after 3 months and showed successful hearing improvement in 58% of cases with autologous incus as compared to 33% cases with titanium prosthesis<sup>9</sup>. In a similar study by Mahanty S, when success was defined as <20dB ABG on postoperative pure tone audiometry done after 6 months of surgery, the success rate was 60% for cartilage ossiculoplasty and 56.25% for PORP<sup>10</sup>. Surgical outcome depends on preoperative status of ossicles, intraoperative skill of surgeons, total eradication of disease, proper aeration of middle ear and the connection between the tympanic membrane and stapes which depends upon the prosthesis being used. The mass and stiffness of prostheses can influence the conduction of sound. Studies by Meister *et al.*<sup>11</sup> and Kelly *et al.*<sup>12</sup> have suggested mass the most important variable, and prostheses weight should be as light as possible to optimize transmission of frequencies above 1000 Hz. Zenner *et al.* have determined that a mass of 5 mg or less provides maximum transfer of energy<sup>13</sup>.

## CONCLUSION

The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe and capable of yielding beneficial sound conduction. In our study, we found autologous remodeled incus to have the best outcome in terms of post-operative closure of air bone gap as

compared to tragal cartilage followed by Teflon PORP and it was found to be statistically significant.

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