

# Comparison of Ossiculoplasty Using Autograft Ossicle Versus Allograft (Teflon)

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**Abstract** Chronic suppurative otitis media in almost any form can disrupt the integrity of ossicular chain. Various materials have been used for ossicular substitution or reconstruction, including both biologic and alloplastic materials. Teflon piston is now the most widely used prosthesis for reconstruction of the ossicular chain in cases of otosclerosis. The oto-surgeons are still confronted with problems of ossicular reconstruction regarding the surgical procedure to be done, type of graft to be selected especially in low and poor socioeconomic population. Thus, there is a need felt to comprehensively and holistically evaluate the outcome of ossiculoplasty using Autograft ossicle versus Allograft ossicle (Teflon). Total 64 patients of chronic suppurative otitis media with no active ear infection and air–bone–gap of more than 15 dB were admitted for surgery and divided into two groups according to material used for ossiculoplasty as group A (Autograft) and group B (Allograft). Patients were evaluated at 3 and 6 months post-operatively using audiogram. In both Group A and B, the average pre-operative AC was 40.62 dB (SD 9.65) and 39.37 (SD 10.53) respectively. In 3 months there was a change of 8.83% from 40.62 dB to 37.03 dB in Group-A ( $p < 0.109$ , not statistically significant) and 13.10% change from 39.37 dB to 34.21 dB in Group-B ( $p < 0.049$ , statistically significant) whereas at 6 months, air conduction improved by 14.22% in Group-A ( $p < 0.01$ , statistically significant) and by 21.81% in Group-B ( $p < 0.001$ , highly

statistically significant). Post-operatively at 3 months, improved AB gap was 62.5% in Group-A and 68.75% in Group-B patients. Post-operative AB gap at 6 months, improvement was seen in 78.12% in Group-A while it was 81.25% in Group-B patients. Alloplastic Teflon ossicle appears to be a good alternative for ossicular reconstruction where autologous incus is not available or disease precludes its use.

**Keywords** Chronic suppurative otitis media · Ossiculoplasty · Alloplastic Teflon

## Introduction

The term “*Ossiculoplasty*” refers to the operation performed on the middle ear to restore the hearing mechanism by reconstruction of ossicular chain. The operation aims to remove pathology from the middle ear cleft and to surgically optimize the middle ear transformer mechanism so that sound energy is conducted from exterior to inner ear fluid with minimal loss.

Chronic otitis media in almost any form can disrupt the integrity of ossicular chain. The most common site of ossicular erosion is lenticular process of incus. In cases of cholesteatoma, sometimes the entire long process of incus can be eroded along with stapes superstructure. Surgical removal of the ossicle is another common cause of ossicular disruption.

Various materials have been used for ossicular substitution or reconstruction, including both biologic and alloplastic materials. Alloplastic materials such as gold, titanium prosthesis, Teflon, hydroxylapatite, ceramics and synthetic plastipore are used for total or partial ossicular replacement prosthesis.

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The most commonly used autograft material has been the incus body, which is often reshaped to fit between the manubrium of the malleus and the stapes head. Autograft ossicle is inexpensive, safe and helps in primary reconstruction in all patients undergoing chronic ear surgery but are not always available. Autografts have several disadvantages, including lack of availability in chronically diseased ears, prolonged operative time to obtain and shape the material, resorption and/or loss of rigidity (especially with cartilage), and possible fixation to the walls of the middle ear. Additionally, osteitis may exist within the ossicles, and the risk of residual cholesteatoma may be increased in patients with cholesteatoma.

Because of the disadvantages of autograft materials and the potential risk of infection from homograft implants, alloplastic materials were introduced in ossicular reconstruction. Teflon piston is now the most widely used prosthesis for reconstruction of the ossicular chain in cases of otosclerosis. Hearing improvement varies depending upon several factors like the material used, the stage of the disease, degree of destruction, state of middle ear mucosa, eustachian tube function and the degree of pre-operative hearing loss. The oto-surgeons are still confronted with problems of ossicular reconstruction regarding the surgical procedure to be done, type of graft to be selected especially in low and poor socioeconomic population. Thus, there is a need felt to comprehensively and holistically evaluate the outcome of ossiculoplasty using Autograft ossicle versus Allograft ossicle (Teflon).

## Methods

Total 64 patients of Chronic Otitis media, between the age group of 10–50 years with no active ear infection and hearing loss  $\geq 15$  dB air–bone–gap were included in the study. Patients with negative consent, exacerbations of chronic otitis media, associated sensorineural hearing loss and only hearing ear were excluded from the study. All the patients underwent complete otological examination and divided into 2 groups:

Group A-Undergoing Ossicular reconstruction using Autograft ossicle.

Group B-Undergoing Ossicular reconstruction using Allograft Teflon.

Intra-operatively if incus was minimally destroyed then it was refashioned and used for ossiculoplasty and in other cases allograft Teflon (TORP or PORP) was used depending on the situation. The post-operative follow up was performed on 3rd and 6th month. The data was analysed using SPSS (ver.10.0) and  $p \leq 0.05$  was considered statistically significant.

## Results

In our study, the average of pre-operative Air conduction on PTA for commonly used frequencies of 500 Hz, 1000 Hz and 2000 Hz was taken. It was found that the average of pre-operative AC was 40.62 (SD 9.65) and 39.37 (SD 10.53) in Group-A and Group-B respectively (Fig. 1).

The average of post-operative AC at the end of 3 months' time point was 37.03 dB (SD 8.31) and 34.21 dB (SD 10.16) in Group-A and Group-B respectively. It is seen that there has been a slight improvement in the average of post-operative AC in both the groups at the end of 3 months (Fig. 2).

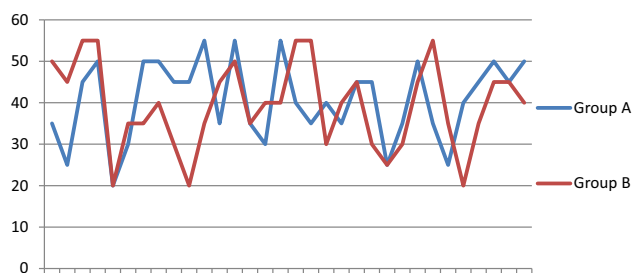
The average of post-operative air conduction on PTA at the end of 6 months was 34.84 dB (SD 8.65) and 30.78 dB (SD 10.24) in Group-A and Group-B respectively. This shows the obvious improvement in mean AC at 6 months in comparison to third month (Fig. 3).

Comparing the improvement in AC at third month post-operative period in Group-A, it was found that there was 8.83% change from 40.62 dB to 37.03 dB at the end of 3 months. Similarly in Group-B, this change was found to be 13.1% (from 39.37 dB to 34.21 dB) demonstrating marginally better improvement in hearing in allograft group than autograft group. At 6 months post-operatively, it was found that AC improved by 14.25% in Group-A and by 21.8% in Group-B, depicting an even better outcome with allograft use (Fig. 4).

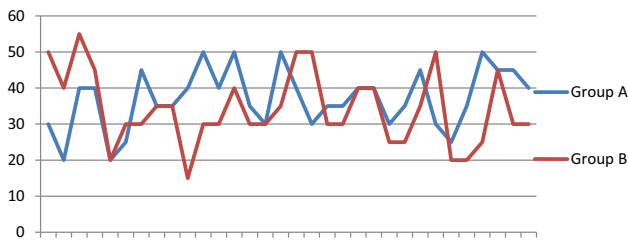
Pre-operatively in Group-A, 37.5% of patients had AB gap between 21–30 dB, 37.5% had  $> 30$  dB and 25% had between 11–20 dB. Similarly in Group-B, 37.5% of patients had an AB gap between 21–30 dB, 31.25% had between 11–20 dB and  $> 30$  dB, in each category (Fig. 5).

We were able to decrease the AB gap in 62.5% of the patients in Group-A and in 68.75% of patients in Group-B on 3 months post-operative evaluation (Fig. 6).

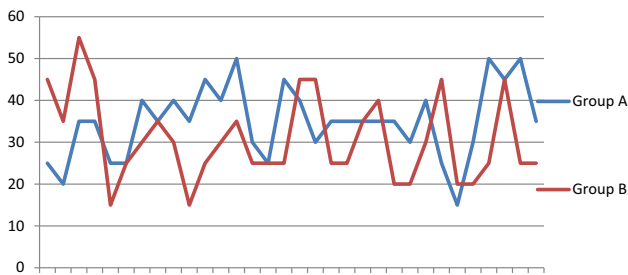
At the end of 6 months, we were able to reduce AB gap in 78.12% of patients in Group-A and in 81.25% of patients in Group-B (Fig. 7).



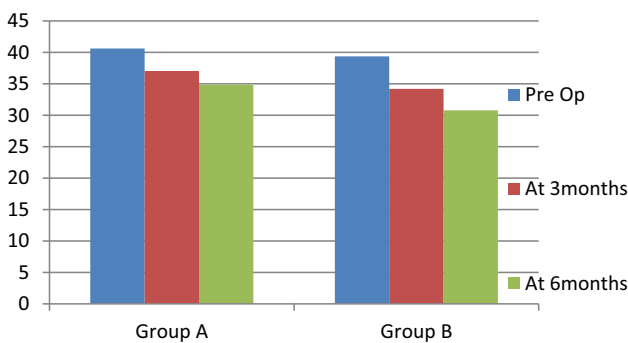
**Fig. 1** Distribution based on average of pre-operative air conduction on PTA



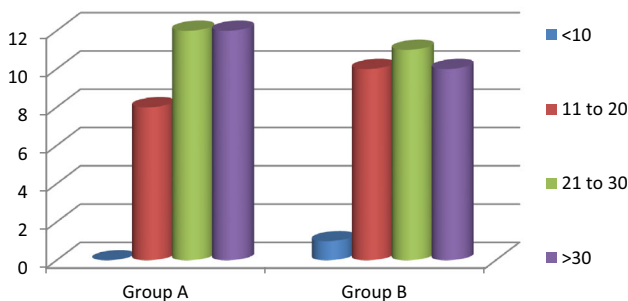
**Fig. 2** Distribution based on average of post-operative air conduction on PTA at 3 months



**Fig. 3** Distribution based on average of post-operative air conduction on PTA at 6 months



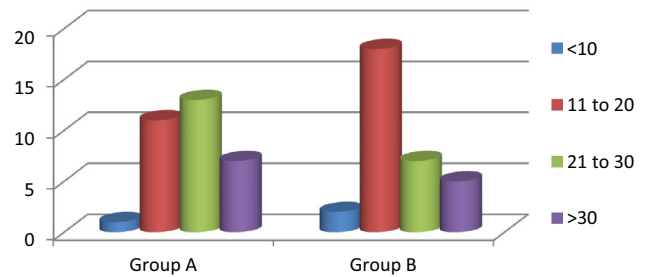
**Fig. 4** Comparison based on pre and post-operative AC in both the groups



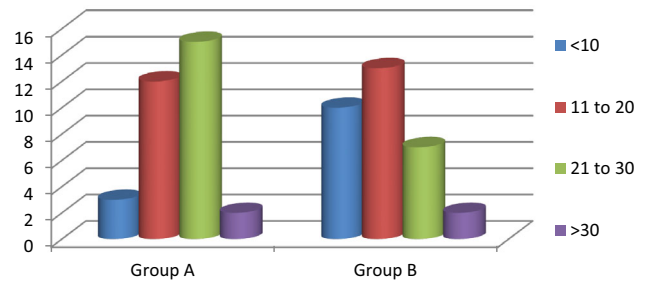
**Fig. 5** Distribution based on pre-operative A–B gap

**Statistical Analysis**

In patients undergoing ossicular reconstruction using autograft ossicle, the mean air conduction pre-operatively and post-operatively at 3 and 6 months were 40.63(SD



**Fig. 6** Distribution based on post-operative A–B gap at 3 months



**Fig. 7** Distribution based on post-operative A–B gap at 6 months

9.65), 37.03(SD 8.314) and 34.84(SD 8.659) respectively. In patients undergoing ossicular reconstruction using Allograft Teflon, the mean air conduction pre-operatively and post-operatively at 3 and 6 months were 39.38(SD 10.53), 34.22 (SD 10.16) and 30.78 (SD 10.24) respectively. Statistically significant results was found between pre-operative AC with post-operative AC at 3 months (*p* value 0.049) and at 6 months (*p* value 0.001).

The mean AB gap in patients undergoing ossicular reconstruction using autograft ossicle pre-operatively, at 3 months and at 6 months post operatively was found to be 28.44(SD 7.976), 25.31(SD 7.507) and 22.81(SD 7.719) respectively. On comparison the pre-operative AB gap with post-operative AB Gap at 6 months, results were statistically significant (*p* value 0.005).

In patients undergoing ossicular reconstruction using allograft Teflon the mean AB gap in preoperative period and post operatively at 3 and 6 months was found to be 26.72 (SD 7.89), 21.56(SD 8.07) and 18.13(SD 8.107) respectively. Statistically significant results were seen between pre-operative with post-operative AB gap at 3 months (*p* value 0.012) and highly significant at 6 months (*p* < 0.001).

**Discussion**

The operation for chronic otitis media not only aims to remove the pathology from tympanic cavity but also ensures a stable ossicular assembly providing good long

term results. Although various studies have been done to evaluate the outcome of ossiculoplasty, the results have been quite variable. Many surgeons are still unclear with the type of surgery to be done, type of graft to be chosen and the type which is most suitable for poor and low socioeconomic population.

In our study, a total of 64 cases of chronic otitis media were enrolled and divided equally in two groups based on type of material used for ossiculoplasty. Group-A patients underwent ossiculoplasty using autograft modified incus while Group-B patients had ossicular reconstruction using allograft Teflon PORP/TORP.

In the two Groups A and B being studied, the average of pre-operative AC was 40.62 dB (SD 9.65) and 39.37 (SD 10.53) respectively.

The average of post-operative AC at the end of 3 months between the two groups was compared. There was a change of 8.83% from 40.62 dB to 37.03 dB in Group-A ( $p < 0.109$ , not statistically significant) and 13.10% change from 39.37 dB to 34.21 dB in Group-B ( $p < 0.049$ , statistically significant); depicting a slightly better outcome with the use of allograft as compared to autograft.

On comparing the pre-operative AC with post-operative AC at the end of 6 months, air conduction improved by 14.22% in Group-A ( $p < 0.01$ , statistically significant) and by 21.81% in Group-B ( $p < 0.001$ , highly statistically significant), further demonstrating a better outcome with the use of allograft. Pre-operatively in Group-A, 25% ( $n = 8$ ) of patients had between 11–20 dB, 37.5% ( $n = 12$ ) had AB gap between 21–30 dB and 37.5% of patients ( $n = 12$ ) had  $> 30$  dB. In Group-B, 31.25% ( $n = 10$ ) of patients had AB gap between 11–20 dB, 37.5% ( $n = 12$ ) between 21–30 dB, 31.25% ( $n = 10$ ) had  $> 30$  dB.

Post operatively at 3 months, Group-A showed an improved AB gap in 62.5% patients. (3.1% ( $n = 1$ ) in  $< 10$  dB, 34.3% ( $n = 11$ ) in 11–20 dB, 40.6% ( $n = 13$ ) in 21–30 dB and 21.8% ( $n = 7$ ) in  $> 30$  dB). In Group-B, an improved AB gap was seen in 68.75% of patients. (6.3% ( $n = 2$ ) in  $< 10$  dB, 56.3% ( $n = 18$ ) in 11–20 dB, 21.9% ( $n = 7$ ) in 21–30 dB and 15.6% ( $n = 5$ ) had  $> 30$  dB.)

On comparing pre-operative AB gap with post-operative AB gap at 6 months, an improvement was seen in 78.12% of patients in Group-A. (9.4% in  $< 10$  dB, 37.5% in 11–20 dB, 46.9% in 21–30 dB and 6.3% in  $> 30$  dB). Similarly, in Group-B, an improvement was seen in 81.25% of patients. (31.3% in  $< 10$  dB, 40.6% in 11–20 dB, 21.9% in 21–30 dB and 6.3% in  $> 30$  dB).

It is evident that the AB gap closure, at the end of 6 month was more in Group-B with allograft (Teflon) ossicle as compared with Group-A, autograft ossicle (modified incus) ( $p < 0.21$ ).

In study by O'Reilly et al. [1], the mean pre-operative AB gap was 26.8 dB and the mean AB gap on the average time line of 15.8 months postoperatively was 18.6 dB. Ojala et al. [2] attained a mean AB gap of 25.8 dB. Our study achieved a mean post-operative AB gap of 22.8 dB using autograft ossicle and 18.13 dB using allograft Teflon.

In study by Zahnert et al. [3], mean postoperative air-bone gap was  $25.5 \pm 1.2$  dB and less than 20 dB in at least 66% of cases without any significant differences between the groups.

Iurato reviewed hearing outcome in Austin Kartosh type A ossicular defects. At 12 months, success was shown to be 84 versus 82% for incus interposition versus allograft (ceramics) PORP. In our study, slightly better results were seen with allograft group and both the results showed similar results [4].

In study by Emir in 2008, 304 patients were evaluated who underwent ossiculoplasty with intact canal wall techniques. Autologous incus interposition resulted in 58% success rate and plastipore PORP's resulted in 56% success rate with 9.3% implant extrusion [5].

In 2003, Hillman and Shelton retrospectively reviewed 84 patients undergoing Tympanoplasty with plastipore prosthesis and 53 with titanium prosthesis. Post-operative AB gap of 20 dB or less was seen in Plastipore group in 60% of patients. In our study 75% of patients were in this range. In titanium group, 45.3% achieved a 20 dB or less AB gap [6].

House reported a retrospective chart review of 1210 consecutive ossicular reconstruction with Hydroxyapatite and Plastipore TORP's ( $n = 560$ ) or PORP's ( $n = 650$ ). Closure of ABG to within 20 dB was 63% (68% of PORP's, 58% of TORP's). Hearing results were better for cases who had not had previous surgery, in those with a diagnosis other than chronic otitis media, when a cartilage graft was used. Overall extrusion rate was 4% and statistically lower when cartilage cap was used [7].

## Conclusion

Alloplastic Teflon ossicle appears to be a good alternative for ossicular reconstruction where autologous incus is not available or disease precludes its use. Moreover it is cheaper and readily available when compared with other ossicular prosthesis available in market. Its use is less cumbersome when compared with modified incus as expertise and skill is required to sculpture autologous incus for ossiculoplasty. Hence, it can be a useful option for amateur otosurgeons.

**Compliance with Ethical Standards**

**Conflict of interest** The authors declare that they have no conflict of interest.

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