

**A Study to Evaluate and Compare the Outcome of Ossiculoplasty Using Autograft (Ossicle/Cartilage) Versus Allograft (Porp) In Intact Canal Wall Surgery**

Aviral Verma<sup>1</sup>, Deepchand<sup>2</sup>, Gaurav Gupta<sup>3</sup>

<sup>1</sup>Senior resident, <sup>2</sup>Senior professor and HOD, <sup>3</sup>Associate professor Department of ENT

Department of Otorhinolaryngology, Head and Neck Surgery, S. P. Medical College & A.G. of Hospitals, Bikaner, Rajasthan, India.

**Corresponding Author:** Aviral Verma, Senior Resident, Department of Otorhinolaryngology, Head and Neck Surgery, S. P. Medical College & A.G. of Hospitals, Bikaner, Rajasthan, India.

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**Abstract**

**Objectives:** There is the difference in hearing improvement when allografts and autografts are used in ossiculoplasty, so this study was done to evaluate and compare the outcome of these two methods in CSOM patients.

**Methods:** This study was conducted on 20 patients of chronic suppurative otitis media visiting ENT OPD at PBM Hospital, Bikaner. Different types of grafts used for Ossiculoplasty and the patients were divided into two equal groups A (Autograft in ICW) and C (PORP in ICW) of 10 each. Postoperatively patients were followed up for hearing improvement at 3 weeks, 6 weeks, 12 weeks and 24 weeks.

**Results:** After 6 weeks post operative follow-up AC improved by **29.89 %** in **Group A** and by **49.53 %** in **Group C**. After 12 weeks and 24 weeks post operative follow-up, AC improved by **34.02 %** in **Group A** and by **57.01 %** in **Group C**. After 6 weeks post operative follow-up ABG improved by **38.89 %** in **Group A** and by **63.89%** in **Group C**. After 12 weeks and 24 weeks

post operative follow-up ABG improved by **43.05 %** in **Group A** and by **69.44 %** in **Group C**.

**Conclusion:** The improvement in hearing following surgery was significant in all groups of patients 24 weeks after surgery. In our study (n=10 in each group) the groups with allograft had a obvious improved hearing outcome as compared to the groups with the autograft but it was not found to be statistically significant.

**Keywords:** Autograft, Allograft, Ossiculoplasty, TORP

**Introduction**

The term Ossiculoplasty<sup>1</sup> refers to the operation performed on the middle ear to restore the hearing mechanism by ossicular chain reconstruction. The operation removes disease and pathology from the tympanum and reconstructs the tympanic membrane and ossicular chain. The goal is a stable and reliable connection between the tympanic membrane and the mobile stapes footplate, and to achieve the best long term hearing result. Chronic Otitis Media (COM) in almost any form can result in the disruption of the integrity of the ossicular chain. Cholesteatoma is by far the most common

cause, and chronic oto-mastoiditis without cholesteatoma can also cause erosion of the ossicles. The pathology can be restricted to the incudostapedial joint with loss of the lenticular process, sometimes with preservation of a soft-tissue connection; usually, however, there is a complete loss of some portion of the distal incus. The entire long process of the incus can be eroded, particularly in cases of cholesteatoma, along with the stapes superstructure<sup>2,3</sup>. Surgical removal of the ossicles during cholesteatoma removal is another obvious and common cause of ossicular discontinuity. In most instances this involves the entire (remaining) incus and the head of the malleus<sup>2</sup>. There are studies which have shown that results obtained in terms of improvement in hearing post Ossiculoplasty is good using bone and cartilage graft<sup>4</sup>. Extrusion rate in these studies were very low, risk of disease transmission was nil. There are also studies demonstrating the difficulties in terms of it being a technically challenging procedure requiring long intra-operative time for harvesting, fashioning and reconstructing the graft. There have been studies using synthetic grafts like hydroxylapatite/ Teflon/ Titanium as graft. This procedure has an advantage of it being a technically straightforward procedure, readily available of graft thus reducing the intra-operative time and there is no risk of leaving behind any residual disease<sup>5</sup>. However, synthetic grafts are expensive. There still exists a considerable difference of opinion in using either type of graft in terms of selection of graft material, graft remodeling intra-operatively, extrusion rates and post operative hearing outcome. Thus, there is a need felt to comprehensively and holistically evaluate the outcome of Ossiculoplasty using Autograft versus Synthetic Graft.

**Aims and Objectives:** To evaluate and compare the outcome of Ossiculoplasty using Autograft (Ossicle/ Cartilage) versus Synthetic Graft (Teflon).

#### **Methodology**

Source of data: All patients diagnosed with Chronic suppurative otitis media who attend ENT OPD at Sardar Patel Medical College and Hospital, Bikaner

Study period: 1 July 2014 to 30 June 2015

Sample size: 20 cases

Method of collection of data: This study was conducted on patients visiting ENT OPD at PBM Hospital, Bikaner prospectively from 1 July 2014 to 30 June 2015 to evaluate and compare the outcome of Ossiculoplasty using Autograft (Ossicle) versus Synthetic Graft (Teflon).

#### **Inclusion Criteria**

1. Patients with symptoms of Chronic Otitis Media.
2. Hearing loss of more than 30 decibels air bone gap.
3. Patients in the age group 10 – 60 years.

#### **Exclusion Criteria**

1. Patient with an acute exacerbation of Chronic Otitis Media.
2. Patients with sensorineural hearing loss.
3. Patients with bilateral Chronic Otitis Media where the ear to be operated is the only hearing ear.
4. Patients < 10 years and > 60 years.

Data analysis:

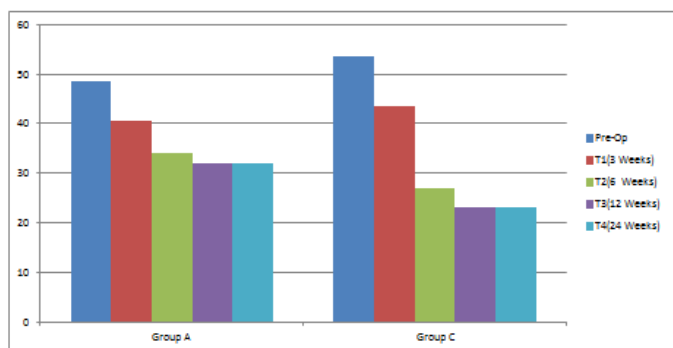
A detailed clinical evaluation (history and examination) and relevant laboratory investigations were done for all patients. The selected patients after complete assessment and pre operative analysis were subjected to the surgical management involving Tympanoplasty with Ossiculoplasty. Intra operative decision was taken on the type of graft used for Ossiculoplasty and the patients were divided into two equal groups A (Autograft in ICW), C (PORP in ICW) of 10 each. Material used in PORP is

Teflon. Postoperatively patients were followed up at 3 weeks, 6 weeks, 12 weeks and 24 weeks for improvement in symptoms. Patients were followed by hearing assessment by using PTA and Tuning fork test. The qualitative hearing loss/ improvement pre-operative and postoperative at 3 week, 6 weeks, 12 weeks and 24 weeks were analyzed in each group. The mean values for Air conduction and Air Bone gap were compared between Pre-operative and at time points (at 3 week, 6 weeks, 12 weeks and 24 weeks) using paired t-test. The mean values between the two groups were compared using Student's t-test. SPSS version 16.0 was used to perform the statistical tests. Statistical test with  $p < 0.05$  was considered statistically significant.

**OBSERVATIONS AND RESULTS-**

Air Conduction – dB (SD)					
	Pre- Op	T1(3 Weeks)	T2(6 Weeks)	T3(12 Weeks)	T4(24 Weeks)
Group A	48.5(4.12)	40.5(8.32)	34(10.49)	32(11.83)	32(11.83)
Group C	53.5(6.26)	43.5(9.14)	27(12.74)	23(13.37)	23(13.37)

**Table 1: Pre and Post operative AC in all groups at different intervals of time**

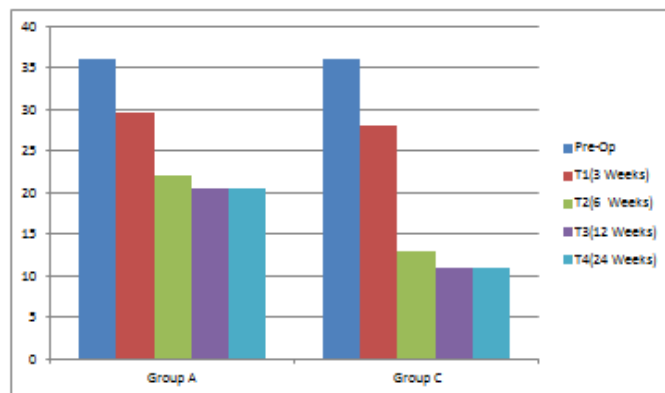


Upon comparing the improvement in AC during the post operative period in Group A, it was found that there was a **29.89 %** change, from 48.5 dB to 34 dB at the end of 6 weeks (T2), in Group C it was **49.53 %** (53.5 dB to 27

dB). After 12 weeks and 24 weeks post operative follow-up, it was found that AC improved by **34.02 %** in Group A and by **57.01 %** in Group C.

ABG – dB (SD)					
	Pre- Op	T1(3 Weeks)	T2(6 Weeks)	T3(12 Weeks)	T4(24 Weeks)
Group A	36(3.16)	29.5(6.43)	22(9.19)	20.5(10.92)	20.5(10.92)
Group C	36(2.11)	28(6.75)	13(9.77)	11(9.37)	11(9.37)

**Table 2: Pre and Post operative ABG in all groups at different intervals of time**



Upon comparing the improvement in ABG during the post operative period in Group A, it was found that there was a **38.89 %** change, from 36 dB to 22 dB at the end of 6 weeks (T2), in Group C it was **63.89 %** (36 dB to 13 dB). After 12 weeks and 24 weeks post operative follow-up, it was found that ABG improved by **43.05 %** in Group A and by **69.44 %** in Group C.

**Statistical Analysis**

(a) The qualitative hearing loss/ improvement pre-operative and postoperative at 3 week, 6 weeks, 12 weeks and 24 weeks were analyzed in both groups.

(b) The mean values for Air conduction and Air Bone gap were compared between Pre-operative and at time points

(at 3 week, 6 weeks,12 weeks and 24 weeks) using paired t-test.

(c) The mean values between the two groups were compared using Student’s t-test.

SPSS version 16.0 was used to perform the statistical tests.

Statistical test with  $p < 0.05$  was considered statistically significant.

Follow up time	Group A (Mean±SD)	Group C (Mean±SD)	t test
Preoperative	48.5(4.12)	53.5(6.26)	t=(-)2.110, df=18, p=0.049*
6 weeks post-op	34(10.49)	27(12.74)	t=1.342, df=18,p=0.196
12 weeks post-op	32(11.83)	23(13.37)	t=1.594,df=18, p=0.128
<b>Repeated measure ANOVA</b>	F=21.516 df=9 p=0.000**	F=46.877 df=9 p=0.000**	

**Table 3: Comparison for Air conduction between Group A and Group C at different times of follow up**

On comparing AC between group A (ICW + Autograft) & group C (ICW + PORP) it was evident that there was an obvious improved hearing outcome. This improvement however was not found to be statistically significant (p value- 0.128).

	Group A (Mean±SD)	Group C (Mean±SD)	t test
Preoperative	36 (3.16)	36 (2.11)	t=0.000, df=18, p=1.000
6 weeks post-op	22(9.19)	13(9.77)	t=2.121, df=18, p=0.048*
12 weeks post-op	20.5(10.92)	11(9.37)	t=2.088, df=18, p=0.051
<b>Repeated measure ANOVA</b>	F=16.010 df=9 p=0.000**	F=43.066 df=9 p=0.000**	

**Table 4: Comparison of ABG between Group A and Group C at different times of follow up**

On comparing AC between group A (ICW + Autograft) & group C (ICW + PORP) it was evident that there was an obvious improved hearing outcome. This improvement however was not found to be statistically significant (p value- 0.128). **CONCLUSION-** Ossiculoplasty is a procedure to restore the hearing mechanism by ossicular chain reconstruction that is achieved by using biologic (autografts/ homografts) or alloplastic materials. COM forms a large proportion of patients presenting to the ENT OPD with hearing impairment. The aim of management in such cases is to provide a safe and dry ear and restore the hearing. This is possible by surgery (tympanoplasty which may be combined with Ossiculoplasty). Minimally destroyed ossicle (autograft) can be utilized for Ossiculoplasty. In case of complete destruction of ossicles, other materials may be used such as Teflon (allograft).

The improvement in hearing following surgery was significant in all groups of patients 24 weeks after surgery. It was further observed in our study (n=10 in each group) that the groups with allograft had a obvious improved hearing outcome as compared to the groups with the autograft but it was not found to be statistically significant.

**Discussion**

Reconstruction of the ossicular chain is still a developing surgical discipline in otolaryngology. The operation removes disease and pathology from the tympanum and reconstructs the tympanic membrane and ossicular chain. The goal is a stable and reliable connection between the tympanic membrane and the mobile stapes footplate, and to achieve the best long term hearing result. In this study with 20 patients (10 per group A,C) who underwent tympanoplasty with Ossiculoplasty for COM. The common symptoms in patients who presented with COM,

as seen in this study in Group A were hearing loss (100%) and ear discharge (90%). Other less common symptoms were earache (40%), tinnitus (30%). In Group C the main symptoms were hearing loss (100%) and ear discharge (70%). Other less common symptoms were earache (30%), tinnitus (20%) and giddiness or vertigo (10%). In this present study, the pre - operative assessment of patients included an otoscopic examination, otomicroscopic examination, assessment of hearing and radiological evaluation.

The patients underwent Tympanoplasty type II / type III with Ossiculoplasty, majority under local anesthesia and few under general anesthesia. In **group A** the right ear was operated in 60% patients and the left ear in 40% patients. In **group C** the right ear was operated in 60% patients and the left ear in 40% patients. In **Group A**, hearing loss was the symptom in all the 10 patients and after Ossiculoplasty in ICW using Autograft (Ossicle), improvement was seen in 20% at the end of 3 weeks of surgery. The improvement was further enhanced with 70% of patients at the end of 6 weeks which further improves after 12 weeks of surgery and was constant on further follow up. In **Group C**, hearing loss was the symptom in all the 10 patients and after Ossiculoplasty in ICW using PORP (Teflon), improvement was seen in 10% at the end of 3 weeks of surgery. The improvement was further enhanced with 80% of patients at the end of 6 weeks of surgery and 90 % of patients at the end of 12 weeks of surgery which was constant on further follow up. Upon comparing the improvement in AC during the post operative period in Group A, it was found that there was a **29.89 %** change, from 48.5 dB to 34 dB at the end of 6 weeks (T2), in Group C it was **49.53 %** (53.5 dB to 27 dB). After 12 weeks and 24 weeks post operative follow-up, it was found that AC improved by **34.02 %** in Group

A and by **57.01 %** in Group C. Upon comparing the improvement in ABG during the post operative period in Group A, it was found that there was a **38.89 %** change, from 36 dB to 22 dB at the end of 6 weeks (T2), in Group C it was **63.89 %** (36 dB to 13 dB). After 12 weeks and 24 weeks post operative follow-up, it was found that ABG improved by **43.05 %** in Group A and by **69.44 %** in Group C. On comparing AC between group A (ICW + Autograft) & group C (ICW + PORP) it was evident that there was an obvious improved hearing outcome. This improvement however was not found to be statistically significant (p value- 0.128). On comparing AC between group A (ICW + Autograft) & group C (ICW + PORP) it was evident that there was an obvious improved hearing outcome. This improvement however was not found to be statistically significant (p value- 0.128). Emir (2008)<sup>6</sup> reviewed 304 patients who underwent Ossiculoplasty with intact canal wall. Autologous incus interposition resulted in 58% success rate, whereas Plastipore PORPs resulted in 56% success rate. Incidentally 9.3% of implants extruded. In our study in intact canal wall groups autograft (Incus) group resulted 50% success rate, PORP (Teflon) group resulted in 90% success rate

### Summery and Conclusion

- 1) Ossiculoplasty is a procedure to restore the hearing mechanism by ossicular chain reconstruction that is achieved by using biologic (autografts/ homografts) or alloplastic materials. COM forms a large proportion of patients presenting to the ENT OPD with hearing impairment. The aim of management in such cases is to provide a safe and dry ear and restore the hearing. This is possible by surgery (tympanoplasty which may be combined with Ossiculoplasty).
- 2) Minimally destroyed ossicle (autograft) can be utilized for Ossiculoplasty. In case of complete

destruction of ossicles, other materials may be used such as Teflon (allograft).

- 3) The improvement in hearing following surgery was significant in all groups of patients 24 weeks after surgery. It was further observed in our study (n=10 in each group) that the groups with allograft had a obvious improved hearing outcome as compared to the groups with the autograft but it was not found to be statistically significant.

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