

Comparative Study of Clinical and Audiological Outcome between Autologus and Prosthesis in Ossicular Chain Reconstruction

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Abstract

Introduction: Ossiculoplasty is one of the commonly done and challenging surgery in otology and has been done using various graft materials. Materials such as autologous cartilage (tragal or conchal) or allograft (homograft) of the same tissue and synthetic materials like polyethylene TORP, ceramic and hydroxyapatite PORP or Titanium prosthesis have been used. But the latter synthetic materials are expensive and have high extrusion rates. Autologous cartilage grafts are selected for Ossiculoplasty as they are easy to harvest at the same site of operation, non-toxic, has less extrusion rate, minimum shrinkage and lateralization. **Aims and Objective:** The aim of this study is to know the efficacy of autologous graft and prosthesis in ossicular reconstruction and to evaluate hearing outcome along with extrusion rate among them. **Methodology:** It is a prospective study done on patients attending ENT outpatient department in civil hospital Ahmedabad affiliated to BJ medical college Ahmedabad. 60 patients were included in the study who underwent ossicular reconstruction either with canal wall up or down mastoidectomy with tympanoplasty. **Conclusion:** On follow up of 60 patients over six month we followed there is significant air bone gap reduction with prosthesis but there is risk of extrusion which cancel out beneficial effect of prosthesis. Whereas cartilage and incus remodelling give good result in air bone reduction and better take up compare to prosthesis with less extrusion rate. Also, autologous grafting in ossicular chain reconstruction is economical in developing countries like India with disease prevalent among low socioeconomic group.

Keywords: PORP/TORP, Ossicular chain reconstruction, incus remodelling, CSOM, Mastoidectomy

Introduction

Chronic suppurative otitis media (CSOM) is defined as a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges or otorrhea through a tympanic membrane perforation. Chronic infection of middle ear is a widely prevalent condition in India like it is in the other developing countries. CSOM is also called chronic purulent otitis media, chronic otomastoiditis or chronic tympano-mastoiditis.^[1]

Chronic otitis media erodes the bone, destroys the ossicles and has the potential to cause life threatening complications.^[2] As a result of erosion, Discontinuity of incudo-stapedial joint is the most common ossicular problem encountered in chronic otitis media that leads to moderate to severe hearing loss.^[1]

The primary goal of Chronic Otitis Media surgery is to clear the disease and produce a safe and dry ear. Maintenance or improvement of hearing is important but should not be at the cost of the primary goal. There is a longstanding and largely unresolved debate as to whether these goals are best achieved by canal wall down or canal wall up procedure.^[3]

Ossiculoplasty is defined as the restoring the hearing mechanism between the tympanic membrane and oval window by re-establishing a functional ossicular chain. [4]

The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe, easily insertable, and capable of yielding optimal sound transmission. When the surgeon chooses a particular prosthesis, selection must be based on several factors, including compatibility and ease of configuring the prosthesis during surgery. [7]

Conductive hearing loss from ossicular chain abnormalities may result from either discontinuity or fixation of the ossicular chain. In order of frequency, discontinuity most commonly occurs because of an eroded incudo-stapedial joint (occurring in approximately 80% of patients with ossicular discontinuity), an absent incus, or an absent incus and stapes supra structure. Ossicular fixation, exclusive of otosclerosis, most commonly occurs from malleus head ankylosis or from ossicular tympanosclerosis. [8,9,10,11]

Hence this study has been carried out with the aim of improving the hearing by using cost effective and biologically safe material with either autograft conchal/tragal cartilage or by biocompatible implant (Partial Ossicular Reconstruction Prosthesis/Total Ossicular Reconstruction Prosthesis) following canal wall up as well as canal wall down surgeries.

Objectives

1. To evaluate the hearing results following ossicular reconstruction in patient with Chronic Suppurative Otitis Media (Tubotympanic and Atticoantral type).
2. To compare the hearing results following ossicular reconstruction using an autograft cartilage, refashioned ossicle and PORP/TORP.
3. To compare extrusion rate in between groups.

Inclusion criteria:

Patients visiting our OPD in civil hospital Ahmedabad having Chronic otitis media, with conductive hearing loss with AB gap of >20 dB hearing loss on PTA who are more than 12year old, those who will be posted for ear surgery at our institute, willing to undergo PTA in follow up and come for follow up for 6 months. Those who give written consent to be included in study AUG-2020 and NOV -22.

Exclusion criteria:

1. Patients with sensorineural hearing loss.
2. Patients with conductive hearing loss due to other causes, other than COM.
3. Patients not willing to participate in the study.
4. Patients not willing for follow up visits.
5. Patients medically unfit for surgery.
6. Congenital ear anomalies
7. pregnant or lactating mother
8. uncontrolled systemic disease which affect the healing process.
9. only hearing ear

Materials and Methods

This is a prospective observational study involving patients above 12 years, with chronic otitis media and who gave written consent for surgeries and to be included in the study. The study was conducted between aug-2020 and nov-2022 for patients who came to ENT department, B. J. Medical college, Ahmedabad. 60 patients who were to undergo ear surgery by post aural route and transcanal route, were included and all of them were subjected to ossicular reconstruction provided they had ossicular discontinuity. Autograft tragal/conchal cartilage, ossicle remodelling and synthetic prosthesis TORP/PORP were used to regain ossicular integrity.

In follow up, All were subjected to PTA at 3 months and 6 months post operatively. Their air conduction and air bone gap were noted down, preoperative Mean of air and air bone gap were compared with postoperative mean of AC and air bone gap at 3 and 6 months and improvement/deterioration were noted down between 3 groups. The hearing parameters were compared between different reconstruction material and conclusions were drawn.

Outcome of the study was based on Wehr's (1985) classification:[44]

1. Excellent: if A-B gap is 10 or <10 dB
2. Good: if A-B gap is 11-20 dB
3. Fair: if A-B gap is 21-30 dB
4. Failure: if A-B gap is >30 dB

Recommendation were made as per the results.

Each patient were given unique I'd number, coding was only with principal investigator to keep anonymity of patients.

Data analysis:

Entry of data: All data will be entered in Microsoft Office\root\Office16\EXCEL.EXE Excel version 2019.

Sample size: 60 patients

Method used: Randomization: Patients were assigned into Group 1, Group 2 and Group 3 alternately.

Statistics derived: Mean, *p* value, annova test was carried out based on my study protocol as we compared three groups. Open epi software was used to analyze data.

Surgical technique

On microscopy we have seen ossicular chain status and status of disease then we decide approach for disease clearance by various type of mastoidectomy followed by reconstruction of ossicular chain by autologous cartilage/ bone or prosthesis as shown in following intraoperative photos



Figure 1: ME elements exposed absent incus [Patient id: 185844]



Figure 2: Cartilage kept as a bow for augmentation between stapes supra structure and anterior canal wall [Patient id: 325113]

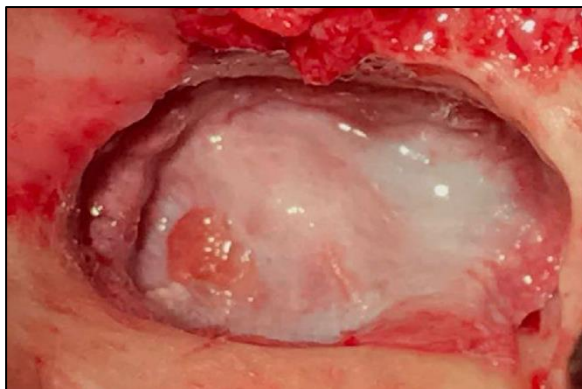


Figure 3: Temporalis fascia graft kept over cartilage [Patient id: 325113]

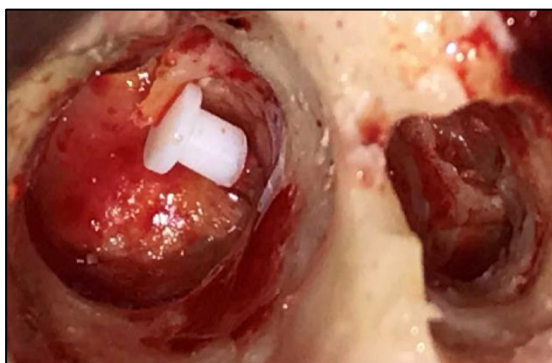


Figure 4: PORP kept over stapes supra structure in relation with malleus [Patient id:404815]



Figure 5: Cartilage and TFG kept over above PORP [Patient id :404815]

Result

In our study 60 patients were included and divided in 3 groups comprising 16 patients in group 1 in which PROSTHESIS GRAFT was used, and 34 patients in group 2 in which CARTILAGE GRAFT was used and 8 patients in group 3 with refashioned ossicle. And in two patient cortical bone used for reconstruction

Age and Gender distribution:

According to the gender of the patients, group 1 has (50%) male and (50%) female. Group 2 has (70%) female and (30%) male. Group 3 has (62.5%) female and (37.5%) Male. All over suggest female preponderance. In my study most common age group: in group 2 & 3 11-20 & 21-30 years in group 1 all age group involvement seen.

Clinical Finding:**Table no.1 comparison of preop otoscopic finding between groups**

SIGNS	GROUP 1	GROUP 2	GROUP 3	TOTAL
Perforation	7(43.75%)	19(55.88%)	8(100%)	34(58.6%)
Retraction pocket	3(18.75%)	15(44.14%)	1(12.5%)	19(32.75%)
Aural polyp	1(6.25%)	3(8.82%)	0	4(6.89%)
Granulation tissue	2(12.5%)	6(17.6%)	0	8(13.79%)
Cholesteatoma	2(12.5%)	7(20.5%)	0	9(15.51%)

- In group 1 7 (43.7%) patients had perforation in tympanic membrane, 3(18.75%) had retraction, 1(6.25%) had aural polyp, 2(12.5%) had granulation and cholesteatoma
- In group 2 19(55.88%) patients had perforation in tympanic membrane, 15(44.14%) had retraction, 3(8.82%) had aural polyp, 6(17.6%) had granulation, 7(20.5%) had cholesteatoma
- In group 3, all patient had perforation in tympanic membrane with 1 (12.5%) patient had PSQ retraction.

Pre operative pure tone audiometry

Both Air Conduction thresholds on Pure Tone Audiometry (PTA) and Air-Bone gap (A-B gap) were recorded preoperatively and postoperatively in all groups by taking an average of 4 speech frequencies (250,500, 1000 and 2000 Hz). This was taken as a baseline for recording improvement in hearing in preoperatively

Table no 2 : pre- operative A-B gap

Pre-Operative A-B Gap (dB)	Group 1	Group 2	Group 3	Total
0-10 dB	0	0	0	0
11-20 dB	0	4	1	5
21-30 dB	2	15	1	18
31-40 dB	4	8	4	16
41-50 dB	8	6	2	16
>50 dB	2	1	0	3
TOTAL	16	34	8	58

As per the Pure Tone Audiometry, the A-B gap was calculated pre operatively. Most patients in group 1 fell in range of 41- 50 dB.

As per the Pure Tone Audiometer, the A-B gap was calculated pre operatively. Most patients in group 2 fell in range of 21- 30 dB and 31- 40 Db. In group 3 most patient in range of 31-40 dB

Post Operative Pure Tone Audiometry A-B Gap

Post-operative audiometry was done 3 month and 6 month after the surgery in each case and was graded as per Wehr's (1985) classification

Table no 3 : Comparison of mean A-B gap within the group 1

A-B GAP	MEAN	S.D.
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Preop	41.25	8.003
Postop at 3 months	22	6.154
Post op at 6 months	14.68	4.5099

The mean (\pm SD) in group 1 pre op A-B gap was 41.25 ± 8.00 and post op A-B gap was 22 ± 6.154 AT 3 month, 14.68 ± 4.5 at 6 month.

Table no.4 : Comparison of mean A-B gap within the group 2

A-B GAP	MEAN	S.D.
Preop	30	9.27
Postop at 3 month	20.7	8.45
Post op at 6 month	16.17	9.97

The mean (\pm SD) in group 2 pre op A-B gap was 30 ± 9.27 and post op A-B gap was 20.7 ± 8.45 at 3 months and 16.17 ± 9.97 at 6 months.

Table no 5 : Comparison of mean A-B gap within the group 3

A-B GAP	MEAN	S.D.
Preop	35	7.43
Postop at 3 month	21.5	3.67
Post op at 6 months	17.625	5.33

The mean (\pm SD) in group 3 pre op A-B gap was 35 ± 7.43 and post op A-B gap was 21.5 ± 3.67 at 3 month and 17.625 ± 5.33 at 6 month

Table 6 : Post-op otoscopic finding in 3 group

Otosopic finding at 6 month	Group 1	Group 2	Group 3	Total
Graft intact	11	25	6	42
Perforation	0	4	0	4
Retraction	1	4	2	7
Granulation	2	2	0	4
Extrusion	2	1	0	3

In this study we have seen extrusion of prosthesis in 2(12.5%) patient in group 1 and 1 (2.94%) patient in group 2 . for this I had applied chi-square test for statistical significance, p-value is 0.2293. not significant at $p < 0.5$.

Most common is retraction seen in 1 patient in group 1, 4 patients in group 2 and 2 patients in group 3. Perforation seen in 4 patients of group 2. Granulation seen in 2 patients of group 1 and group 2

Table no. 7: Hearing gain following ossiculoplasty in terms of airborne gap reduction

	Group 1	Group 2	Group 3	Total
Mean	26.56	14.55	17.375	18.259
Standard deviation	8.49	11.807	8.0167	11.62

Here we had applied one wayanova test for three group, f-value is 7.068 and p value is 0.00168. The result is significant at $p < .05$.

In this study we have done 1 trans-canal incus remodelling in this improvement in AB gap is 10 compare to mean 17.375 in group 3.

We also had used cortical bone chip in ossicular reconstruction in 2 canal wall down mastoidectomy patient didn't given promising result average AB gap reduction was 3 and post operatively on follow up one patient had displaced bone and in other complete retraction around bone chip seen.

Table no. 8 : comparison of hearing gain by reduction of AB gap between groups in type of surgical procedure

Type of mastoidectomy	Group 1		Group 2		Group 3		Total	
	No. of patients	AB gap (mean)	No. of patients	AB gap (mean)	No. of patients	AB Gap (mean)	No. of patients	AB gap (mean)
canal wall up (posterior epitympanotomy , posterior tympanotomy)	7 (43.7%)	25.42	11(32.35%)	14.81	4(50%)	18.5	22	18.9
Canal wall down	1 (6.2%)	24	7(20.58%)	10.8	0	-	8	12.45
Simple mastoidectomy	8(50%)	27.875	16(47%)	16	4(50%)	16.25	28	19.42
Total	16	26.56	34	14.55	8	17.35	58	18.24

From this table we can clearly understands, after canal wall down(CWD) procedure reduction in AB gap is less compare to other approach in all three group. Mean AB gap reduction in cwdis 12.45 dB compared to study mean 18.24 dB

AB gap reduction in all group is better in simple mastoidectomy compare to CWD OR CWU.

In Group 3 where autologous incus used AB gap reduction is more in Canal wall up (CWU) mastoidectomy compared to other methods.

Discussion

In this study, patients with >12yrs of age were included as we had planned for single stage procedure and children being more prone to upper respiratory infection leading to eustachian tube dysfunction. Extremes of age were avoided because of the possibility of existence of the coexistence of sensorineural loss in the elderly, comorbidities and underlying septic foci in children.

In my study the mean age group In Group 1 was 11-20 years & 31-40 years of age, in Group 2 and 3 was 21-30 years of age. 39 of the total patients were female and 21 were male.

Kadambari et al used commercially available **PORP/TORP** ossicular implant and achieved the overall postoperative A-B Gap of 26 dB.**Rahul Kawatra et al** used PORP/TORP ossicular implant and achieved the overall postoperative A-B Gap of 20 dB.^[51] The hearing results in our study using TORP/PORP of Group 1 revealed a mean post operative A-B gap of 14.68 dB which is comparable to the above cited studies.

Kyung et al study in 2022 shows that Ossicle-cartilage composite graft is a biocompatible, easily harvested material that has very few side effects. Reconstruction using OCCG (ossicle cartilage

composite graft) resulted in better hearing outcomes compared to when synthetic materials were used. Ossicle-cartilage composite graft also exhibited no protrusion in this study.^[23] That can be relate in our study too incus remodelling and cartilage ossiculoplasty given promising result.

Prakash et al in 2019 study shows that patients who underwent ossicular reconstruction of ear with cartilage (tragal or conchal) had significant hearing improvement. There were no cases of graft extrusion. There is no risk of transmission of diseases. They are freely available and are easy to carve with no additional economic burden to the patient.^[24]

Our study showed that there was significant statistical difference *P* value [0.00168] with the use of prosthesis for ossiculoplasty compared to autologous cartilage and refashioned incus

Even though extrusions are common with prosthesis ossiculoplasties as per literature, in this study 2 extrusion case was reported among 16 cases done in a time period of 6 month postoperatively and 1 case in cartilage ossiculoplasty the *p* value is 0.229, hence insignificant.

The mean air bone gap observed prior to surgery was 41.25, 30 and 35 for group 1,2 and 3 respectively which reduced to 14.68,16.17, and 17.625 postoperatively at 6 month resulting in air bone reduction of about 26.56 db (mean) in cases underwent prosthesis ossiculoplasty and 14.55db (mean) for those with cartilage and 17. 37db (mean) in incus remodelling giving a *p* value of 0.0168, hence the result found to be significant.

In our study it shows that canal wall down mastoidectomy patient hearing gain is less compared to other patient more in cartilage reconstruction patient. In incus remodelling we have seen hearing gain is more in canal wall up mastoidectomy patients.

In cartilage we have majorly used tragal for reconstruction of ossicular chain and in 2 patient we have used concha cartilage. It produced nearly same result in hearing improvement as tragal cartilage. But for comparison we needed further cases.

We also had used cortical bone chip in ossicular reconstruction in 2 canal wall down mastoidectomy patient didn't given promising result average AB gap reduction was 3 and post operatively on follow up one patient had displaced bone and in other complete retraction around bone chip seen. Prasad et al in their study showed 28% patient showed no improvement in hearing. After reopening, ankylosis, dislocation of ossicle and extrusion were noted.^[52]

Conclusion

From the study, it is evident that prosthesis ossiculoplasty is more beneficial.

compared to autograft (cartilage or remodelled ossicle) regarding hearing restoration depending on ear condition in pre operative stage.

If disease is limited involving ossicle only incus remodelling is also better option for ossicular reconstruction. In extensive disease, when canal wall down mastoidectomy done cartilage reconstruction did not given good result.

A limitation of this study is that the period of follow up is inadequate to assess whether graft particularly prosthesis gets extruded which might reverse the beneficial effects.

All modalities gave statistically significant improvement ($p < 0.05$) in A-B gap closer, leading to improvement in hearing.

1. Ossiculoplasty gives better hearing results in cases of chronic otitis media with ossicular erosion, when compared to cases who do not underwent ossiculoplasty.
2. Ossiculoplasty should be done in all cases with conductive hearing loss due to ossicular erosion
3. It can be done either in primary sitting or second sitting.
4. Comparing autograft and prosthesis, prosthesis ossiculoplasties have a better postoperative hearing, in terms of hearing gain and air bone reduction with risk of extrusion of prosthesis in future which reverse the beneficial effects and give discharging ear to patients.
5. PORP is biocompatible, stable, safe, affordable and easily available.
6. Complications in the short period studied are nil in both groups.
7. Both Cartilage and prosthesis are taken up well in the three-month follow up.
8. Long term results are awaited. However long term follow up with larger sample size is recommended to arrive to better conclusion

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