



OSSICULOPLASTY – A Comparative Analysis Of Different Graft Materials

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Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Background: Tympanic membrane perforations are a common presentation at ENT outpatient department. Ossicular discontinuity is co-existent in majority of cases of chronic otitis media. Ossiculoplasty is very useful in post operative hearing outcome of these cases. The objective of this study is to analyze the post operative hearing outcome with different graft materials used for Ossiculoplasty.

Material&Methods: This is a prospective comparative study on 50 patients aged between 11-67 years with ossicular chain defect in addition to tympanic membrane perforation presenting to the Outpatient Department in a tertiary care centre for a period of 2 years. The clinical presentation, type of ossicular defect and management with different grafts were analyzed. The post-operative hearing was categorized as Satisfactory (A-B gap on PTA <20db), Unsatisfactory (A-B gap >20db) and Failure (No improvement or deterioration in hearing).

Results: Age group of under30-40 years was most affected (50%). Females outnumbered males with Male to female ratio being 1:0.42. M+S+ was the most common ossicular chain defect found in 35 cases followed by M-S+ observed in 10 cases. According to the defect, majority of cases were managed with Conchal cartilage (30 cases) followed by sculptured incus (10 cases) and reshaped malleus (5 cases). Post operative hearing was Satisfactory in 80% and unsatisfactory in 16%. Failure occurred in only 2 cases.

Conclusions: Ossiculoplasty procedure should be done where ossicular chain discontinuity is encountered to significantly reduce the air bone gap and improve the quality of hearing.

Keywords: Chronic otitis media, Ossiculoplasty, Sculptured incus graft, PORP, TORP

Introduction

Tympanoplasty refers to any operation involving reconstruction of the tympanic membrane and or the ossicular chain.¹ Reconstruction of ossicular assembly is required when there is a discontinuity. The discontinuity of the ossicular chain is caused by chronic otitis media, trauma and by purposeful removal of ossicles during surgery. Retraction pockets and cholesteatoma are often associated with ossicular erosion.

The Austin classification is widely accepted classification system for ossicular chain defects and is based upon the presence or absence of the malleus handle(M+, M-) and stapes superstructure (S+, S-). According to this classification there are four types of ossicular defects: type A (M+,S+), type B (M+,S-), type C (M-, S+), and type D (M-,S-).² The commonest defect is erosion of the long process of the incus³ with intact malleus handle and stapes

superstructure(type A), followed by types B, C, and D.

Tympanoplasty can be achieved using various types of graft, including temporalis fascia, perichondrium or fascia lata.⁴ For the reconstruction of middle ear ossicular assembly, different materials include Autologous Conchal and tragal cartilage, autologous incus and malleus, preserved allografts, septal spur cartilage, biomaterials like PORP (partial ossicular reconstruction prosthesis) and TORP (total ossicular reconstruction prosthesis).

In the present study, different graft materials used in ossicular reconstruction and the post operative hearing outcomes were analyzed.

Materials & Methods:

This comparative prospective study was conducted on 50 cases of chronic otitis media with ossicular discontinuity during a period of two years, from July 2021 to July 2023. All patients presenting to ENT Outpatient Department meeting the inclusion criteria were included in the study.

Inclusion Criteria:

Patients of age group 10 - 70 years with a clinical presentation of tympanic membrane perforation, documented pure tone audiogram indicative of ossicular discontinuity and suspicious ossicular discontinuity on examination under microscope were included in the study.

Exclusion Criteria:

Patients of age below 10 years and above 70 years, pregnant and lactating women were excluded from the study.

Cases with fixation pathology of ossicles were also excluded from the study.

All cases in the study were examined under microscope and pure tone audiogram was done which was indicative of more than 40db conductive hearing loss in the respective ear. Cases with adequate canal size and large perforation were also examined with rigid 0 degree and angled endoscopes when required.

Most of the cases were operated under local anesthesia while few apprehensive patients were operated under general anesthesia. Depending on the extent of the disease, tympanoplasty and canal wall up or canal wall down mastoidectomy procedures were performed. The extent of ossicular damage was assessed intra operatively and different graft materials were used accordingly.

All the ossiculoplasty procedures were single stage only. Different materials used for ossiculoplasty were

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Autograft – (i) Ossicles – Incus as shown in **figure 1**.
(ii) Conchal cartilage, shown in **figure 2** and **figure 3**.

Fig 1. Showing incus graft



Fig 2. Showing harvested Conchal cartilage



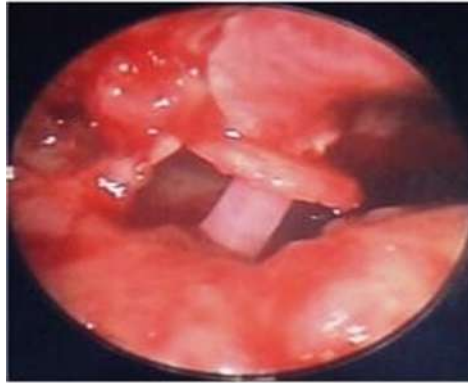
Fig 3. Intra operative placement of Conchal cartilage



Preserved Allograft – (i) Ossicles – incus, malleus (ii) Septal spur cartilage

Biomaterials – (i) Partial ossicular replacement prosthesis (PORP) as shown in figure 4. (ii) Total ossicular replacement prosthesis (TORP)

Fig 4. PORP



The post operative outcomes were evaluated according to hearing status as observed in pure tone audiogram and categorized as:

Satisfactory: Post-operative air-bone gap (a-b gap) of 20 decibels (dB) or less.

Unsatisfactory: Post-operative air-bone gap of 20 to 30 dB.

Failure : No Post-operative improvement in hearing or deterioration in hearing

All the patients were followed up at regular intervals during the course of the study and the data was analyzed and results tabulated.

Results:

In this present study a total of 50 cases with some sort of ossicular mechanism defect except fixation pathology were studied and the post operative hearing outcomes analysed.

Age and sex distribution:

Age group of 30-40 years was mostly affected (50%) in our study followed by 40-50 year age group which comprised 24 percent. The youngest patient was 11 years old and the oldest 69 years.

Number of males was 15 while females were 35 out of the total 50 cases. Male to female ratio was 1:0.42. The data is presented in Table 1.

Table 1: Showing Age and sex distribution of cases.

Age group (in years)	Male	Female	Total number of cases	%
10-20	01	02	03	6
21-30	02	04	06	12
31-40	07	18	25	50
41-50	04	08	12	24
51-60	01	02	03	6
61-70	00	01	01	2
Total	15	35	50	100

Type of ossicular chain defect

In this study, the most common ossicular defect was absence of long process of incus or incus as a whole (70%) followed by absent incus and malleus with intact stapes superstructure (20%). The list is presented in Table 2. (M= Malleus, S= Stapes super structure)

Table 2: Showing type of Ossicular chain defect

Defect	Total number of cases	Percentage (%)
M+S+	35	70
M+S-	03	6
M-S+	10	20
M-S-	02	4
Total	50	100

Different graft materials for ossiculoplasty

The whole list of graft materials used for ossiculoplasty in different scenarios is presented in Table 3.

Table 3: Type of Graft material used in ossiculoplasty.

Defect (total cases)	Sculptured Incus (Preserved allograft and fresh autograft)	Reshaped Malleus (Preserved allograft)	Conchal cartilage	Septal Spur Cartilage (Preserved allograft)	PORP	TORP
M+S+ (35)	7	5	23	0	0	0
M+S- (3)	0	0	2	1	0	0
M-S+ (10)	3	0	5	0	2	0
M-S- (2)	0	0	0	1	0	1
Total (50)	10	5	30	2	2	1

Hearing outcomes of the procedure performed

In this study, the post operative outcomes were measured in hearing status observed in pure tone audiogram and categorized:

1. Satisfactory: Post-operative air-bone gap (a-b gap) of 20 decibels (dB) or less.
2. Unsatisfactory: Post-operative air-bone gap of 20 to 30 dB.
3. Failure : No Post-operative improvement in hearing or deterioration in hearing

The post operative result was Satisfactory in majority of the cases (40) with unsatisfactory result in few cases (8) only. 2 cases were labeled as failure. All the patients were followed up at regular intervals and the results documented. The satisfaction levels remained largely similar at all the intervals. The details are in Table 4.

Table 4: Hearing outcome of the procedure

Result	Total number of cases	Percentage (%)
Satisfactory	40	80
Unsatisfactory	08	16
Failure	02	4

Detailed Analysis of the outcome with the graft used

* **M+S+ (35 cases):** In the 35 cases having the defect of absent incus with M+S+, majority (23) were dealt with fresh autologous Conchal cartilage interposed between malleus and stapes superstructure while in only 7 cases sculptured incus was used to complete the ossicular assembly. In 5 cases, preserved reshaped malleus was used to bridge the existing malleus and stapes. Out of all the 35, satisfactory result with closure of air bone gap to <20db was obtained in 31 cases and unsatisfactory result was obtained in the remaining 4 cases (One case in which Conchal cartilage was used and other 3 (1case in which incus graft and 2 cases of malleus graft). There was no failure.

* **M+S- (3 cases):** Among the 3 cases of this category, in 2 cases autologous Conchal cartilage was used and in 1 case, preserved septal spur cartilage was used in Ossiculoplasty. Satisfactory result was obtained in 2 while only 1 case was labeled unsatisfactory in which septal spur cartilage was used.

* **M-S+ (10 cases):** Out of the 10 cases, 5 were dealt with autologous Conchal cartilage. In 3 cases, autologous sculptured incus was used in 2 and preserved incus was used in 1 case. In the remaining 2 cases, Partial ossicular reconstruction prosthesis (PORP) was used atop the stapes superstructure. Satisfactory result was obtained in 7 cases and unsatisfactory result in 2 cases (of incus graft). A singular case of Failure was encountered in this category in which the PORP used got extruded out at 6 months post operative period.

***M-S- (2 cases):** Among the 2 cases in this group, in 1 case stored septal spur cartilage was used as a

long collumella stapes graft. In the remaining one case, Total ossicular reconstruction prosthesis (TORP) was used. The post operative outcome was unsatisfactory in the 1 case of long collumella stapes graft. The sole case of TORP usage resulted in a failure due to displacement of the prosthesis.

Satisfaction levels with Graft used

- 1. Autologous Conchal cartilage: Total 30 cases:** 29 Satisfactory (96.67%); 1 Unsatisfactory (3.22%)
- 2. Sculptured Incus: Total 10 cases:** 7 Satisfactory result (70%) ; 3 Unsatisfactory (30%)
- 3. Reshaped Malleus: Total 5 cases:** 3 Satisfactory (60%); 2 Unsatisfactory (40%)
- 4. Preserved Septal spur cartilage: Total 2 cases:** 2 Unsatisfactory (100%)
- 5. PORP: Total 2 cases:** 1 Satisfactory (50%); 1 Failure (50%)
- 6. TORP: Total 1 case:** Failure (100%)

Discussion:

Attempts to rebuild the middle ear transformer mechanism began after the introduction of tympanoplasty and great advances have been made in the physiological functioning and biocompatibility of autografts and implants.⁵Ossicular repositioning was described in 1957⁶ and continues to be used today. Several classifications of ossicular chain discontinuity and their management have been proposed. The most common ossicular defect is absent long process and precisely the lenticular process of incus. If the lenticular process of the incus is eroded, and if the malleus is in close proximity to the stapes superstructure, sculptured incus prosthesis is a good option with satisfactory post operative

hearing outcome. This management method has been described by Pennington⁷ and Austin. Over the years, several graft materials comprising autografts (Conchal cartilage, tragal cartilage, ossicles-malleus&incus), allografts (preserved cartilage and ossicles), preserved septal spur cartilage, biomaterials (PORP, TORP) have been employed for ossiculoplasty with variable success rates.

In this study different graft materials were used in all the 50 cases of ossicular chain defects and the hearing outcomes assessed according to the post operative pure tone audiogram air bone gap correction. Satisfactory results (A-B gap <20db) were obtained in majority of cases (80%). The study comprised of age group 10-70 years with majority (50%- 25 cases) in the age group of 31-40 years. The youngest was 11 years and the oldest 69 years. In a study by Thotambailuet al⁸, age of the patients ranged from 18 to 65 years, with a mean of 34.17 years. The median age group in their study was 31.5 years. This is similar to the result obtained in the present study.

In the present study, females outnumbered males with male to female ratio being 1:0.42. Particularly females in the mid 30s age were observed to be more in number. In the study by Khanamet al⁹ on 60 patients, there were 32 (53.3%) female and 28 (46.7%) male patients with a male to female ratio of 1:1.4. This observation shows almost equal number of male and female patients which is in contradiction to the present study.

In this study, the most common ossicular defect was absent incus with intact malleus and stapes (M+S+), found in 35 out of the 50 cases (70%). Absent Malleus and incus with intact stapes (M-S+) was the next common presentation found in 10 cases, followed by M+S- (3 cases) and M-S- (2 cases). This finding is similar to the study by Thamizh arasan¹⁰ who observed that incus was absent in 104 (62.27%) cases with the presentation being M+S+. This is also similar to the study by Singh et al¹¹ who observed that out of 8 patients with ossicular involvement, commonest ossicle involved was the lenticular process of incus followed by long process of incus with lenticular involvement. However in the study by Somesh Mozumder et al¹², in 10(16.67%) cases ossicular status was M+ I+ S+, in 9(15%) cases it was M+ I- S+, in 14(23.33%) cases it was M+ I- S-, in 12(20%) cases ossicular status was M- I- S+ and

in 15(25%) cases ossicular status was M- I- S-. Therefore, the commonest ossicular chain status was M- I- S followed by M+ I- S- & M- I- S+. This finding is in contradiction to the present study.

In the present study, Autologous conchal cartilage was used in majority of cases (30), followed by autologous and preserved sculptured incus (10 cases), preserved malleus (5 cases) and preserved septal spur cartilage (2 cases).Biomaterials like PORP was used in 2 cases and TORP in 1 case. The post operative hearing outcome was declared Satisfactory when <20db of AB gap closure was achieved.

With Conchal cartilage graft, the satisfaction level was 96.67%.In the study by Acharya SK et al.¹³, 60% satisfactory result was obtained with cartilage graft ossiculoplasty which was similar to ossicular graft (70% satisfactory result). With Sculptured incus graft, we have obtained a satisfaction level of 70% combining all the different scenarios which is similar to the study of Acharya SK et al. This finding is also similar to the study by Ikramullah Khan et al¹⁴ on 150 cases of tympanoplasty and ossicular chain reconstruction, who achieved an overall success rate of 80% with autologous sculptured incus graft.

In the present study, reshaped preserved malleus was used in 5 cases with a satisfaction level of 60%. This is in agreement with the study by Mahadevaiah et al¹⁵ who in their retrospective study of 119 patients who underwent Ossiculoplasty obtained Serviceable hearing (<20 dB air bone gap closure) in 24 out of 37 (65%) over long-term follow up of more than 1 year.

Preserved septal spur cartilage was used in only 2 cases of the study with 100% unsatisfactory hearing outcome in post-operative period. This is in contradiction to the study by Rukmini M Prabhu, et al¹⁶, who used preserved septal cartilage in the presence of the stapes superstructure and achieved 90% hearing improvement after surgery.

PORP was used in 2 cases with a Satisfaction level of 50% which is similar to the study by Schember S et al.¹⁷ who achieved post operative A-B gap closure <20db in 77% of PORP usage cases. TORP was used in only one case in the present study and it was a failure due to extrusion of prosthesis. A proper comparative analysis could not be made as one case was a very small number.

Conclusion:

Ossiculoplasty if done in a tailor-made fashion according to the case presentation will significantly reduce the post operative air-bone gap. In this study, different graft materials were used in Ossiculoplasty with the post operative A-B gap closure < 20db being achieved in 80% cases. The type of graft material used was according to the demand of the situation coupled with operational challenges. Ossiculoplasty should be done wherever possible in addition to closure of tympanic membrane perforation as a single stage procedure during the disease removal itself to improve the patient's hearing and quality of life.

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