

A study of various graft materials used for ossicular chain reconstruction at tertiary health care centre

Vikas Sudhakar Kulkarni¹, Vasanti Vilasrao Patil^{2*}, Veena V Kulkarni³

¹Associate Professor, Department of ENT, Krishna institute of Medical Sciences and Deemed University, Karad, Maharashtra, INDIA.

²Assistant Professor, Department of ENT, Rcsm, Government Medical College, Kolhapur, Maharashtra, INDIA.

³Director of V V ENT and endoscopy Hospital PVT Ltd Islampur, Maharashtra, INDIA.

Email: drvasantient@gmail.com

Abstract

Background: The middle ear ossicles are uniquely shaped structures that collect sound waves from the tympanic membrane (TM) and conduct them to the inner ear. Infective agents, inflammatory processes, and trauma can prevent the normal functions of these structures. Ossiculoplasty involving ossicular chain reconstruction using graft materials is frequently used in the treatment of conductive hearing loss. **Aim and Objectives:** To study operative ease and post-operative hearing results in patients undergoing ossicular chain reconstruction with different types of prostheses. **Material and Methods:** A prospective randomized study of 30 patients with Chronic Otitis Media, undergoing ossiculoplasty was conducted at a tertiary health care centre. The ossicular chain was reconstructed with a tragal cartilage, conchal cartilage, refashioned incus, hydroxyapatite and titanium prostheses in 06 patients each. Subjects with mixed hearing loss, multiple co-morbidities and revision surgeries were excluded. Hearing assessment was done by pure tone audiometry pre-operatively and 04 and 12 weeks postoperatively. **Results:** Among the patients studied, male to female ratio was 2:3 and a maximum of individuals belonged to third and fourth decades of life. Using synthetic material for grafting during the procedures saved time. Compared to others, titanium prosthesis gives maximum surgical ease. Post-operative air-bone gap reduction within 20 dB was seen in all, irrespective of type of prostheses. **Conclusion:** Patients those were managed surgically showed considerably better outcome with titanium prostheses; however the improvement seen in Air-Bone gap reduction was equally noticed with all types of graft materials used. **Key words:** Chronic otitis media, Ossicular Chain reconstruction.

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*Address for Correspondence:

Dr. Vasanti Vilasrao Patil, Assistant Professor, Department of ENT, Rcsm, Government Medical College, Kolhapur, Maharashtra, INDIA.

Email: drvasantient@gmail.com

Received Date: 21/11/2017 Revised Date: 15/12/2017 Accepted Date: 06/01/2018

DOI: <https://doi.org/10.26611/1016516>

Access this article online

Quick Response Code:



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www.medpulse.in

Accessed Date:
20 January 2018

INTRODUCTION

Despite the advances in the field of ear surgery, otologists are still having a challenging problem in treating chronic otitis media (COM). In the presence of infection, ossicles

are destroyed by the osteoclast cell. Some authors have revealed that 'pseudomonas aeruginosa' is the most common organism found in COM.¹ Unfortunately about 60%-82% of patients, who refer to otology clinics, have ossicular defect.^{2,3} There are three common types of ossicular reconstruction in COM surgery. Partial ossicular replacement prostheses (PORP) refer to the operation in which the prosthesis extends from a stapes supra-structure to the malleus or tympanic membrane. Total ossicular replacement prostheses (TORP) refers to the operation in which prostheses are placed between the stapes footplate to the malleus or tympanic membrane. Incus interpositional prosthesis, refers to the operation in which the curved incus bone is connected to the stapes capitulum into the malleus.⁴ Many different materials have been used for ossicular reconstruction over the past

50 years, including both biologic and alloplastic materials, with varying degrees of success. Ideally, the ossicular reconstruction prosthesis should be biocompatible, safe, easy to fit and handle, and capable of efficient sound transmission. Biologic materials include autograft or homograft ossicles, cortical bone, teeth, and cartilage. Body of Incus, often reshaped, has been most commonly used as autograft ossicular prosthesis. Hydroxyapatite prostheses, introduced by Grote in 1981, are some of the most common currently used ossicular reconstruction implants.⁵ Hydroxyapatite is a bioactive ceramic of calcium phosphate that in composition resembles the matrix of bone. In the 1970s, Titanium was established as an excellent biocompatible material and was introduced as an alloplastic material for ossiculoplasty in 1993.⁶

MATERIAL AND METHODS

A prospective randomized study of 30 patients with Chronic Otitis Media, undergoing ossiculoplasty was conducted at a tertiary health care centre from June 2014 to December 2016. The research protocol was approved by institutional ethics committee. Written preformed consent was obtained from all patients. Preoperative assessment of severity of hearing loss was done by pure tone audiometry. Audiometric testing was done in double-walled sound protective rooms with standard procedures. Preoperative audiometric testing was performed at 500, 1000, 2000 and 3000 Hz. All Patients were re-evaluated postoperatively during the follow up period, and examination was done by micro-otoscopy. Postoperative air and bone-conduction scores were recorded at 500, 1000, 2000 and 3000 Hz. Preoperative and perioperative findings noted were: status of tympanic membrane, ossicles and attic; presence of cholesteatoma; presence of granulation. Most patients underwent surgery under local anesthesia. Local anesthetic is administered in the form of 2% lignocaine with 1 in 80,000 epinephrine. Tragal cartilage was used in 06 patients, conchal cartilage in 06 patients, refashioned incus in 06 patients, hydroxyapatite in 06 patients and titanium prostheses in 06 patients. Subjects with mixed hearing loss, multiple co-morbidities and revision surgeries were excluded from the study. Post-operative hearing assessment was done by pure tone audiometry at 04 weeks and 12 weeks after surgery. Results were analyzed statistically.

RESULTS

The total population in this study included 30 ears of 30 patients with a mean age of 37 years (range from 15-71 years). 18 ears (60%) belong to female patients and 12 ears (40%) to male patients. Ossiculoplasty was performed in the right ear side in 20 patients (66.67%) and in the left ear side in 10 (33.33%). All of these

patients during the oculoplasty procedure were operated in the two stages.

Table 1: Age and Gender wise distribution of patients

Age intervals	Gender		Total
	Male	Female	
0-20	01	03	04
21-40	05	08	13
41-60	04	06	10
61-80	02	01	03
Total	12	18	30

Table 2: Patient distribution depending on Type of grafts material used

Sr. No	Type of Graft materials	Number of patients
01	Tragal cartilage	06
02	Conchal cartilage	06
03	Refashioned incus	06
04	Hydroxyapatite prostheses	06
05	Titanium prostheses	06

There are many different materials currently being used for ossiculoplasty. They can be categorized into autografts, homografts and allografts. In the present study, the ossicular chain was reconstructed with a tragal cartilage, conchal cartilage, refashioned incus, hydroxyapatite and titanium prostheses in 06 patients each.

Table 3: Pre-operative Air-Bone Gap distribution

Air-Bone Gap	Number of patients	Percentage
26-35 dB	18	60%
36-45 dB	12	40%

Table 4: Post-operative Reduction in Air-Bone Gap

Air-Bone Gap	04 weeks post-op	12 weeks post-op
11-20 dB	21	30
21-30 dB	09	00

Above Table 03 shows the pre-operative Air- Bone Gap, while Table 04 shows the postoperative Air-Bone Gap Reduction. A postoperative air-bone gap of 20 dB or less was used as the criterion for “success following ossiculoplasty” since this has been described by the majority of authors. Particular attention was given to the size of the population, the length of the follow-up period and the average frequency for reporting of hearing results. In the present study, we found that the Incus was the most commonly involved ossicle. No cases of graft extrusion or failure were encountered. Patients with prosthesis showed faster Air-Bone gap closure than those having undergone autologous ossiculoplasty. Using tragal or conchal cartilage took almost equal time as autologous incus. Using synthetic material saved time. Compared to other graft materials available, ‘Titanium prosthesis’ gives maximum surgical ease. Equally good results may be achieved with various autograft materials used when compared with prosthetic ossiculoplasty.



Figure 1



Figure 2



Figure 3

DISCUSSION

The main objectives of tympanoplasty operations are to ensure a disease-free middle ear with a favourable sound transmission between the tympanic membrane flap and inner ear. Various prostheses and different stabilization techniques have been described for different conditions. The incudostapedial joint and the lenticular process of the incus are the most common sites of ossicular discontinuity. This defect can lead to an air-bone gap of up to 60 dB. Interposition of incus body as a bridge between the stapes and the malleus was the original ossicular reconstruction surgery. Disadvantages of autograft ossiculoplasty are: prolonged operative time, possible displacement or resorption, possibility of the autograft harboring microscopic cholesteatoma, poor fit if the stapes superstructure is absent. Advantages of autograft ossiculoplasty are: low extrusion rate, low cost and excellent biocompatibility.⁷ Bance *et al.*⁸ first reported that the malleus to stapes assembly showed a better vibration transmission than the TM to stapes on cadaver temporal bone models and significantly related with tension. Since then, different studies have clinically shown that the preservation of the malleus maintains better hearing outcomes. Cartilage size and thickness may also affect hearing outcomes. Shimizu and Goode⁹ mentioned that a decrease in the cartilage size could cause a loss in higher frequencies, and Zahnert *et al.*¹⁰ recommended the cartilage thickness should be 0.5 mm. Sushil Jha *et al.*¹¹ studied 76 patients prospectively who underwent ossiculoplasty. Majority of the patients were between the age group of 14 to 35 years and the study revealed very good results with the titanium prosthesis with about 75% of success rate. 52.6% of patients with gold prosthesis had a hearing improvement between 10-30 dB at 5 months of follow-up. Titanium has also been found to have excellent biostability in the middle ear. A theoretical advantage of Titanium implants is that the prosthesis weight is more similar to the native ossicles compared with Hydroxyapatite. Truyet *al.*¹² compared 2 groups of patients who underwent

Titanium versus Hydroxyapatite ossiculoplasty and found no significant difference in hearing results or extrusion rates, although on long term follow-up, the results did favour Hydroxyapatite slightly. Gelf and YM *et al.* in their study found no significant difference in hearing result between the Hydroxyapatite and Titanium implant groups.¹³ Ossiculoplasty with biocompatible alloplastic materials like Teflon, Poroplast have sometimes resulted in migration, extrusion or penetration into the inner ear. On long-term follow-up, Goldenberg RA *et al.* found a satisfactory hearing result (defined as a postoperative ABG of ≤ 20 dB) in more than 50% of their patients.¹⁴

SUMMARY AND CONCLUSION

It is clear from our present study that, there is no significant difference between different implants in terms of hearing results. We evaluated only short-term audiological results, and it is possible that differences between different prostheses may appear on long-term follow-up. The selection of prosthesis will largely depend upon surgeon's personal preference and comfort. We found surgical ease is considerably better with titanium prostheses. A large, randomized, long term prospective study is necessary for a more definitive comparison between different prostheses.

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Source of Support: None Declared
Conflict of Interest: None Declared

