

Comparison of Effectiveness of Homograft Septal Cartilage and Grommet as Partial Ossicular Replacement Prosthesis

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ABSTRACT

Introduction

Ossiculoplasty is the reconstruction of the middle ear ossicular chain. Hearing improvement largely depends on mechanical stability and bio-compatibility of prosthesis used.

Materials and Methods

This was a prospective study conducted on 62 Chronic Otitis Media (COM) patients who underwent type III tympanoplasty with ossiculoplasty. Patients in the age group of 18 years to 50 years and with conductive hearing loss of 45 dB to 60 dB with an air-bone (AB) gap of more than 45 dB, were included. Patients were randomly divided into two groups. Group A had ossiculoplasty with septal cartilage while Group B had it with grommet as the prosthesis. The outcome was measured using Pure Tone Audiometry (PTA), in terms of postoperative hearing gain and AB gap reduction at 3 months and 6 months.

Results

Mean age of the study population was 34.84 ± 11.396 years, with male-to-female ratio 1: 1.07. Left ear was the most operated one. Major complaints were hearing loss and ear discharge. Squamosal disease was present in 62.9% of patients. Incus was the most involved ear ossicle. Mean PTA in both groups showed significant improvement when compared pre- and postoperatively. A comparison between the two study groups in terms of AB gap reduction and hearing gain pre- and postoperatively didn't reveal any statistically significant differences. Most common postoperative complication was secondary perforation. Extrusion was present in 3 patients of Group B.

Conclusion

Grommet can be an effective ossicular prosthesis with hearing outcomes and complications comparable to conventional grafts such as septal cartilage.

Keywords

Chronic Otitis Media; Ossiculoplasty; Septal Cartilage; Grommet; Partial Ossicular Replacement Prosthesis

Chronic Otitis Media (COM) is an inflammation of a part or whole of the middle ear cleft that is characterized by continuous or intermittent discharge through a persistent tympanic membrane perforation.¹ It remains a common cause of conductive hearing loss despite improvements in public health and medical care. The most frequent cause of mild to moderate hearing loss among children and young people in poor countries, as per WHO, is COM. The fact that chronic otitis media is a frequent cause of avoidable deafness makes it even more relevant.

According to WHO, a COM prevalence rate of more than 4% in a given community is a sign of a serious public health issue that has to be addressed right away.² COM

is a persistent infection that can be seen in two forms. A central pars tensa rupture surrounded by residual tympanic membrane characterizes the tubotympanic variety of chronic otitis media, whereas the atticointral variant affects the posterosuperior part of the middle ear cleft.

The conductive hearing loss in COM can be due to tympanic membrane perforation or ossicular disruption/

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disease. The most frequent ossicular defect found in both tubotympanic and atticofacial types of chronic otitis media is incudo-stapedial joint erosion with intact malleus. According to research by Austin, the malleus and stapes suprastructure are intact in roughly 60% of instances. Patients with ossicular erosion have a hearing loss of greater than 40 dB, according to a pure tone audiogram.³

Ossiculoplasty aims at reconstructing the ossicular chain after eliminating the middle ear disease to prevent recurrence. This is because, in more than 80% of the patients, the etiology for ossicular damage is COM with or without cholesteatoma.⁴ Improvement in hearing after surgery can be assessed by pure tone audiometry (PTA).

The goal is now to achieve a post-operative middle ear status that is functionally very similar to the normal state and a near-normal neomembrane with a continuous ossicular chain. Surgery for chronic ear illness aims to cure the condition and rebuild the mechanism that transmits sound. The ossicular chain has been rebuilt using a variety of ossiculoplasty methods.

Even though PORP (Partial Ossicular Replacement Prosthesis) materials are widely accessible and produce better sound transmission, their cost has been a barrier to their use in ossiculoplasty.⁵ When compared to other materials, a grommet can be an acceptable substitute for fulfilling this goal without compromising sound quality.⁶ The optimal material for ossiculoplasty should be biocompatible, stable, safe, inexpensive, and readily available. For ossicular reconstruction, autografts, homografts, and synthetic prostheses can be adopted.

The purpose of our study was to evaluate the outcome of ossicular reconstruction for ossicular discontinuity using septal cartilage autografts and grommets and to compare their hearing results postoperatively using PTA.

Materials and Methods

After obtaining approval and clearance from the institutional ethics committee (ethics committee number) and informed written consent a prospective randomized control study was carried out, in the Department of ENT of a tertiary care teaching institute in Bangalore, from

August 2022 to January 2024. A total of 62 participants between the ages of 18-50 years were recruited. The inclusion criteria included patients of chronic otitis media with conductive hearing loss of 45 dB to 60 dB with an air-bone (AB) gap of more than 45 dB, and patients who underwent type III tympanoplasty with ossiculoplasty. Participants with other rare causes of conductive hearing loss were excluded from the study.

Patients were divided into two groups (Group A and Group B) randomly using a computer random sequence generator. Group A included the patients who underwent ossiculoplasty with homograft septal cartilage and Group B had patients of ossiculoplasty using a teflon grommet as the ossicular prosthesis. Postoperatively, sterile mastoid dressing was put after packing the external auditory canal with medicated gauze, which was removed after 1 week of surgery along with postaural sutures and EAC packs. Patients were kept under antibiotic coverage for at least 2 weeks, with weekly follow-up till 1 month. Postoperative PTA was done at 3 months and 6 months. The AB gap reduction on PTA postoperatively was graded as: none (< 5 dB), minimal (5-10 dB), satisfactory (10-15 dB) and good (>15 dB). Statistical Package for Social Sciences [SPSS] for Windows Version 22.0 Released 2013. Armonk, NY: IBM Corp., has been used to perform statistical analyses of the study results.

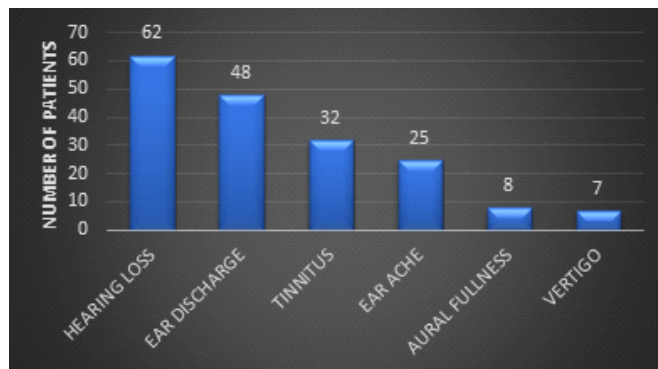
Results

The average age of the study population was 34.84±11.396 years. The maximum number of patients were in the age group of 46-50 years (18 patients), whereas the 26-35 years group had 17 patients (27.4%). There were 12 patients in the age group of 36-45 years, and 15 patients (24.2%) were between 18 and 25 years. The male-to-female ratio was 1: 1.07, with 30 men (48.4%) and 32 women (51.6%). Group A consisted of 18 men and 13 women, while Group B included 12 men and 19 women.

All our patients had hearing loss (100%). Ear discharge was present in 48 patients (77.4%), 32 patients (51.6%) had tinnitus, 25 patients (40.3%) had ear pain, 8 patients (12.9%) complained of aural fullness, and 7 patients (11.3%) experienced vertigo (Graph 1). Left ear was the

Table I: Statistical Analysis of PTA Improvement at 3 Months and 6 Months Postoperatively with Respect to Preoperative Values

GROUP		PTA	MEAN DIFF	SD DIFF	p-VALUE
GROUP A	Preoperative PTA	Postoperative PTA at 3 months	10.983	0.989	<0.001
		Postoperative PTA at 6 months	11.603	1.099	<0.001
	Postoperative PTA at 3 months	Postoperative PTA at 6 months	0.621	0.331	0.197
GROUP B	Preoperative PTA	Postoperative PTA at 3 months	9.733	1.442	<0.001
		Postoperative PTA at 6 months	10.600	1.600	<0.001
	Postoperative PTA at 3 months	Postoperative PTA at 6 months	0.867	0.459	0.208

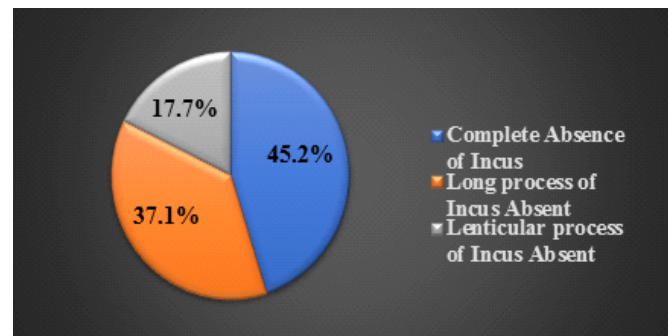


Graph 1: Presenting Complaints

most operated one (54.8%). Squamosal disease with retraction pocket was present in 13 patients (21%), whereas 26 patients (41.9%) were without retraction pocket. Remaining 23 patients (37.1%) had mucosal type of COM.

Incus was the most involved ear ossicle (100%), followed by malleus (37%) and stapes (32.2%). Complete erosion of incus was observed in 28 patients (45.2%), 23 patients (37.1%) had an absent long process of incus, and rest of them (11 patients; 17.7%) had involvement of lenticular process of incus (Graph 2).

The mean PTA of the patients in Group A preoperatively was 58.60 ± 9.467 dB. Postoperatively, it was 48.87 ± 9.630 dB at 3 months, and 58.25 ± 9.442 dB at 6 months. The mean PTA of the patients in Group B was 58.25 ± 9.442 dB preoperatively. At 3 months follow-



Graph 2: Involvement of Incus

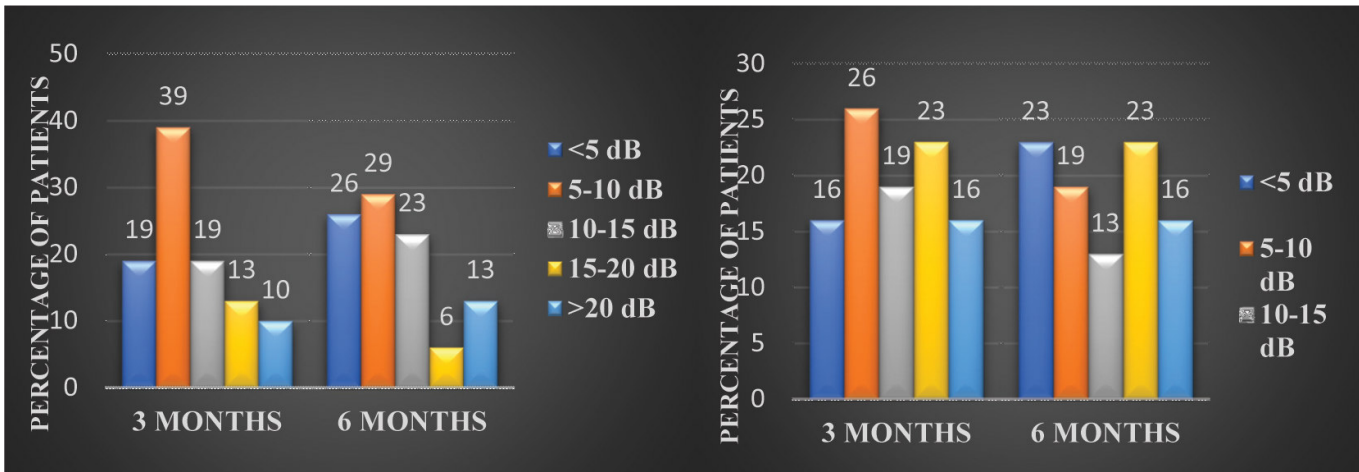
up, it was 45.93 ± 12.976 dB, and at 6 months, it was 45.57 ± 13.788 dB.

The comparison of the mean PTA at different time points (pre- and postoperatively at 3 and 6 months) in Group A and Group B was found to be statistically significant ($p < 0.001$) (Table I). On postoperative evaluation, Group A had minimal AB gap reduction in most of the patients (39% of patients) and good AB gap reduction in 23% of the patients, at the end of 3 months. There were 6 patients each in <5 dB and 10-15 dB AB gap reduction categories. Group B had a good AB gap reduction in 39% of patients while 26% of patients had minimal reduction at 3 months postoperatively. Satisfactory outcome was observed in 19% of patients and 16% patients had <5 dB AB gap reduction (Table II).

At 6 months postoperatively, Group A had minimal

Table II : Postoperative AB Gap Reduction at 3 Months

AB GAP REDUCTION		GROUP A		GROUP B	
		NO OF PATIENTS	PERCENT (OUT OF 31)	NO OF PATIENTS	PERCENT (OUT OF 31)
AT 3 MONTHS	<5 dB (none)	6	19	5	16
	5-10 dB (minimal)	12	39	8	26
	10-15 dB (satisfactory)	6	19	6	19
	>15 dB (good)	7	23	12	39



Graph 3: Postoperative Hearing Gain in Group A and Group BB

Table III : Postoperative AB Gap Reduction at 6 Months

AB GAP REDUCTION		GROUP A		GROUP B	
		NO OF PATIENTS	PERCENT (OUT OF 31)	NO OF PATIENTS	PERCENT (OUT OF 31)
AT 6 MONTHS	<5 dB (none)	8	26	7	23
	5-10 dB (minimal)	9	29	6	19
	10-15 dB (satisfactory)	7	23	4	13
	>15 dB (good)	6	19	12	39
	Lost to follow-up	1	3	2	6

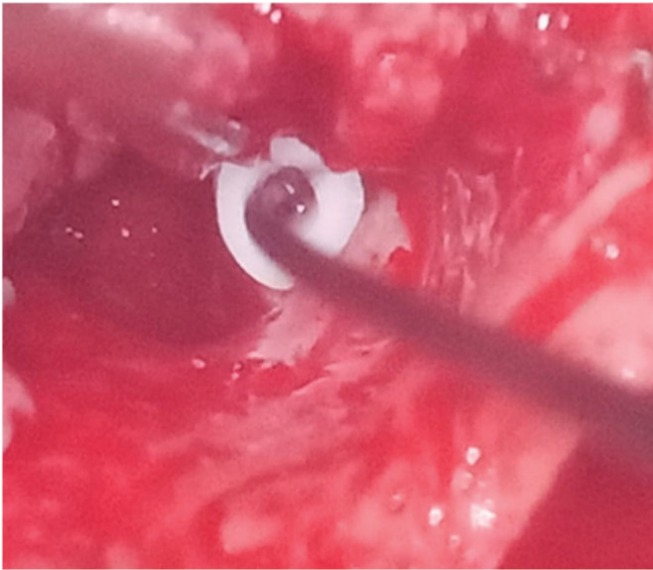


Fig. 1. Grommet Insertion over stapes head

AB gap reduction in most of the patients (29% of patients) and <5 dB AB gap reduction in 26% of the patients. There were 6 patients in >15 dB and 7 patients in 10-15 dB AB gap reduction categories. In the follow-up, one patient of Group A was lost. In Group B, good AB gap reduction was seen in 39% of patients while 19% of patients had minimal reduction, at 6 months follow-up. Satisfactory outcome was present in 13% of patients whereas 23% of patients had <5 dB AB gap reduction, and 2 patients had missed their follow-up (Table III).

The AB gap reduction at 3 months and 6 months postoperatively in both the study groups were compared and was statistically insignificant with p-values of 0.721 and 0.392 respectively. This points out a similar outcome of ossiculoplasty in both study groups in terms of AB gap reduction.

In 3-month follow-up, >20 dB hearing gain was present in 3 patients of Group A and 5 patients of Group B. There were 4 patients of Group A and 7 patients of Group B with 15-20 dB hearing gain. Hearing gain of 10-15 dB was observed in 6 patients of each group.

Most of the patients had 5-10 dB hearing gain, in either of the groups. Group A had 6 and Group B had 5 patients with <5 dB hearing gain. Postoperative PTA at 6 months

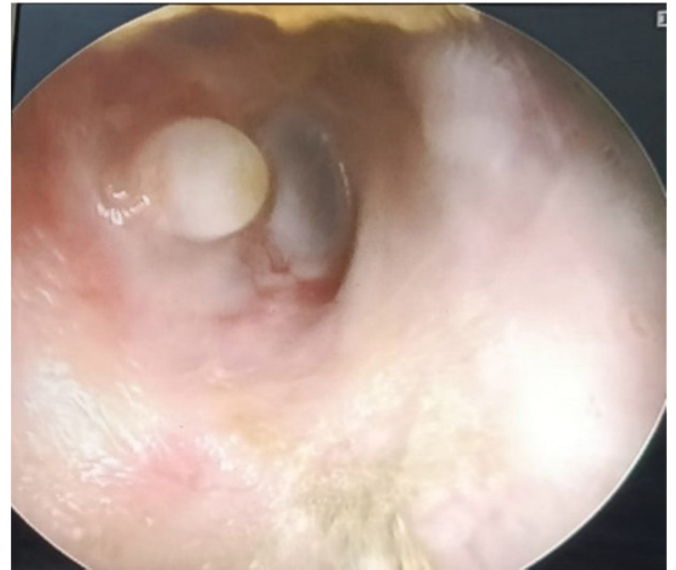


Fig. 2. Grommet Extrusion into the External Auditory Canal

in Group A shows >20 dB hearing gain in 4 patients and 15-20 dB gain in 2 patients. Most of the patients (29%) had 5-10 dB hearing gain. There were 7 patients with 10-15 dB gain, and 8 patients with <5 dB gain.

In Group B, 23% of the patients fell into both <5 dB and 15-20 dB categories. A gain of 5-10 dB was observed in 6 patients, 10-15 dB in 4 patients and >20 dB in 5 patients. Postoperative hearing gain at three and six months, indicated no statistically significant difference between Group A and Group B (p-values of 0.675 and 0.392, respectively) (Graph 3).

The most common postoperative complication was secondary perforation (19.3% in group A and 22.5% in group B). Granulations were present in 5 patients of group B. There was persistent ear discharge in 3 patients of group A and 6 patients of group B. Postoperative earache was present in 3 patients of each group. Out of 62 patients who underwent surgery, only 3 patients of group B had extrusion while none of the group A patients had. This was observed in 6-month follow-up (Figure 2).

Discussion

Conductive hearing loss often arises from ossicular discontinuity. Ear surgery aims to restore hearing post-

disease eradication. Various materials can be used to achieve this ossicular continuity. An ideal graft should be readily available, affordable, durable, and produce good hearing outcomes with minimal extrusion, migration, or foreign body reactions. With numerous grafts and prostheses available, selecting the right one is challenging.

In our study, 62 patients meeting the inclusion criteria were enrolled, with a demographic picture similar to prior studies by Sharma et al.⁷ and Khanam et al.⁸ Patients were randomly assigned into two groups: Group A, which used refashioned septal cartilage, and Group B, which used a 0.9 mm grommet for ossicular reconstruction.

Participants were in the age group of 18 to 50 years, with an average age of 34.84 ± 11.396 years. The age group of 46-50 years had the highest number of patients (29%), followed by the 26-35 years group (27.4%). This distribution was consistent with studies by Lamba et al.,⁹ Laha et al.,¹⁰ and Lakshmipathiraju et al.,¹¹ where most patients were in their third or fourth decades of life. The study included 30 men (48.4%) and 32 women (51.6%), with a male-to-female ratio of 1:1.07, mirroring the gender distribution found in Sharma et al.⁷ and Khanum et al.,⁸ showing a slight female predominance. Most patients were from rural or lower-middle-class backgrounds, likely due to factors like overcrowding, poor hygiene, poverty, and limited access to healthcare, which are known risk factors for chronic otitis media (COM).⁹

Surgery was performed on the left ear in 54.8% of patients and on the right ear in 45.2%. This aligns with findings from Olowookere et al.¹² and Chavan et al.,¹³ where the left ear was more affected, although Lamba et al.¹⁶ found a higher prevalence of right ear involvement.

Hearing loss was the most common presentation (100%), followed by ear discharge (77.4%). Tinnitus, earache, auditory fullness, and vertigo were also reported. Consistent with Khanum et al.⁸ and Sharma et al.,⁷ all patients had hearing impairment. Most patients had squamosal type of COM, with or without a retraction pocket, similar to Khanum et al.⁸'s findings.

The incus was the most commonly affected ossicle (100%), followed by the malleus (37%) and stapes (32.2%). Erosion of the incus long process was the most

prevalent, corroborating findings from Prakash et al.⁶, Lakshmipathiraju et al.,¹¹ and other studies. The results were found to be better when only incus was eroded, middle ear mucosa was healthy, and in mucosal cases. Contrary to these observations, Laha et al.'s¹⁰ results document incudo-stapedial joint and the lenticular process of incus as the common sites of ossicular discontinuity.

Granulations accounted for 72% of the primary disease in Lamba et al.⁹ study, followed by cholesteatoma in 46% patients. Yorgancılar et al.¹⁴ and Zhu et al.¹⁵ on the other hand, discovered cholesteatoma as the main disease contributing to ossicular erosions. Additionally, the work by Mahanty et al.¹⁶ provides evidence supporting cholesteatoma as the predominant pathology. In our study, cholesteatoma was present in 29 individuals, while 47 patients had hypertrophied middle ear mucosa. No cases of COM complications were encountered.

The mean pure-tone audiometry (PTA) in Group A improved from 58.60 dB preoperatively to 48.87 dB at 3 months, while Group B improved from 58.25 dB to 45.93 dB. The mean PTA reduction at 6 months showed Group A at 58.25 dB and Group B at 45.57 dB. The differences were statistically significant ($p < 0.001$), indicating both groups showed significant hearing improvement.

At 3 months, 39% of Group A and 23% of Group B had minimal AB gap reduction, with better results in Group B. At 6 months, Group B showed a good AB gap reduction in 39% of patients. There was no significant difference in hearing gain between the two groups.

Extrusion occurred in 3 patients from Group B and was observed in 6 months followup. The most common postoperative complication was secondary perforation (19.3% in Group A and 22.5% in Group B). Other issues included granulations, earache, and ear discharge. No graft extrusion was noted in Group A.

Middle ear adhesion formation after surgery can limit the success of ossicular reconstruction. This was limited by the removal of unhealthy mucosa and granulations in the middle ear cleft, and stabilizing the ossicular continuity with antibiotic- and steroid-soaked gel-foam.

Reconstruction of the ossicular chain is still a growing surgical specialty in otolaryngology. The purpose of

ossiculoplasty is to create a firm and consistent connection between the tympanic membrane and the mobile stapes footplate to provide optimum hearing results, while keeping the ear dry as well. A notable improvement in hearing was obtained with the use of a grommet as a PORP, in our study. Around the world, grommets have been standard equipment in otosurgeries for years. The substances utilized in the manufacturing of grommets has undergone the usual testing procedures for prostheses used in ossiculoplasty and has been certified for use in middle ear surgery.⁵ Also, its biocompatible, mechanically stable, and cost-effective.

The surface of the grommet is extremely resistant to the development of biofilms and thereby reduces the chances of subsequent rejection. The extrusion rates attributed to the use of prostheses can be minimized by interpositioning a cartilage cap between the tympanic membrane graft and the prosthesis, as per Kumar.S et al.⁴ The use of synthetic prostheses eliminates the chances of transmitting prions or harboring microscopic diseases as in preserved homografts. On the other hand, it can be vulnerable to immune-mediated rejection or foreign body reactions.

Reduction of operating time and surgical ease were another two advantages. Sculpturing the cartilage graft requires the skill and expertise of the surgeon. The time consumed in this refashioning of cartilage was saved with usage of grommet. The sound conduction via the restored ossicular chain depends greatly on the mass and stiffness of the prostheses. Zenner et al.¹⁷ suggested a mass of less than 5mg to ensure maximum sound transmission. By virtue of its shape and size, grommets can be stably fixed over stapes head. Promising results were obtained with grommet ossiculoplasty, in terms of graft uptake, improvement of hearing, and patient satisfaction, when compared to cartilage ossiculoplasty.

Cartilage grafts have the disadvantage of complete reabsorption like the original ossicles if the infection persists/recurs. Negative middle ear pressure and tubal insufficiency can also lead to graft rejection.⁶ Graft failure in natural or autologous grafts may be brought on by atrophy, revascularization of marrow spaces, refixation, or disease recurrence as a result of residual disease. For

prolonged durations, autografts can keep their size, form, contour, and physical integrity; nevertheless, when middle ear suppuration occurs frequently, osteitis can cause resorption, which is comparable to what happens to ossicles in COM. Chavan R. P et al.¹⁸ suggested that the chances of reabsorption can be minimized by providing adequate freedom of movement to the ossicular chain, rather than snugly fitting it under the tympano-meatal graft.

Considering the hearing outcome, AB gap reduction, and extrusion rate, both the groups in our study had no statistically significant difference. This concludes that grommet can be an effective alternative for the conventional prostheses of ossiculoplasty. Better understanding of middle ear mechanics and microscopic dimensions of middle ear pathologies in recent years has greatly influenced the success rates of ossicular reconstruction surgeries.

Conclusion

Chronic Otitis Media (COM) remains a major cause of conductive hearing loss, particularly in rural and low socioeconomic areas where medical care access and treatment costs are significant factors. This study included a balanced number of males and females, mostly in their third or fourth decade of life, many of whom had delayed medical treatment despite long-term hearing loss and ear discharge.

Ossicular chain restoration is crucial for functional recovery as per various studies comparing different ossiculoplasty materials. This research compared septal cartilage and grommet ossiculoplasty, finding both methods significantly improved hearing without a statistically significant difference between them. Grommets, while avoiding issues like reabsorption and graft sculpturing, may still face risks of extrusion and foreign body reactions. Despite these risks, grommets offer ease of use and time efficiency, making them a viable alternative to traditional materials without compromising the hearing gain. The study's sample size is limited, suggesting a need for larger, long-term trials to better evaluate the outcomes. However, our findings indicate that well-executed single-stage

ossiculoplasty can notably improve hearing and quality of life.

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