

Surgical Outcomes of Tympanoplasty with Various Graft Materials in Chronic Otitis Media: A Retrospective Cohort Study

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ABSTRACT

Introduction: Chronic Otitis Media (COM) is a common ear disorder that predominantly affects underdeveloped countries. It is characterised by persistent middle ear discharge and a perforated Tympanic Membrane (TM). Management typically involves antibiotics and surgical techniques like tympanoplasty to eradicate infections and improve the auditory conduction system. Various graft materials are used, with temporalis fascia being preferred due to its proximity and ease of harvesting.

Aim: To evaluate the surgical outcomes of tympanoplasty procedures utilising different graft materials in patients diagnosed with inactive mucosal COM.

Materials and Methods: This retrospective cohort study was conducted in the Department of Otorhinolaryngology at Acharya Vinoba Bhave Rural Hospital (AVBRH), Wardha, Maharashtra, India, between June 1, 2013, and May 31, 2023. A total of 165 participants with inactive mucosal COM, who had small to subtotal central perforations of the TM, were included. Tympanoplasty, performed by the same surgeon using the Zeiss

surgical microscope model OPMI under general anaesthesia, was the chosen surgical procedure. All cases were executed using the postauricular approach with the underlay technique. A successful anatomical outcome was defined as an intact neo-TM without residual perforation at the end of a three-month follow-up.

Results: The age of participants ranged from 10 to 75 years, with a mean age of 32.45 ± 14.06 years. The age group most frequently affected by mucosal COM was between 31-40 years, comprising 41 (24.85%) cases. Large perforations were observed in 79 (47.88%) patients, followed by moderate perforations in 65 (39.39%) patients. Normal ossicular chains were found in 163 (98.78%) patients, while ossicular erosion was noted in 2 (1.22%) patients during surgery. A total of 118 (100%) patients who came for follow-up, 84 (71.19%) who underwent temporalis fascia graft reconstruction showed successful graft uptake.

Conclusion: This study found that both fascia and cartilage tympanoplasty are suitable for TM repair due to their availability.

Keywords: Cartilage graft, Fat graft, Mastoid antrum, Myringoplasty, Ossicles, Ossicular chain, Temporalis fascia graft, Tympanic membrane perforation

INTRODUCTION

Otitis Media (OM) refers to a complex group of infectious and inflammatory diseases that affect the middle ear. OM is quite common, with research indicating that over 80% of children have experienced at least one episode by the age of three [1,2]. OM is broadly divided into two categories: acute and chronic. Despite adequate antibiotic therapy, Acute Otitis Media (AOM) can progress to Chronic Otitis Media (COM), which is characterised by persistent middle ear discharge and a perforated TM [1]. It is one of the most prevalent ear conditions in developing countries. In India, the incidence of COM is around 30%, with a prevalence rate of 16 per 1,000 in urban areas and 46 per 1,000 in rural areas [3]. Globally, COM affects over 330 million individuals, with 60% of them sustaining significant hearing loss, leading to a disease burden of over 2 million Disability Adjusted Life Years (DALYs) [3]. Symptoms of COM include discharge from the ear canal (otorrhea), ringing in the ears, ear fullness, headache, dizziness, and hearing impairment. The resulting hearing loss can negatively impact a child's speech development, education, and behaviour [4]. The diagnosis of COM can be confirmed through otoscopic or Microscopic Ear Examination (EUM), bacterial culture analysis, audiological assessment, facial nerve topography examination, and an antibiotic resistance testing of the ear discharge. The extent of the disease is assessed by temporal bone imaging through High-Resolution Computed Tomography (HRCT) and Magnetic Resonance Imaging (MRI) [5].

The management of COM involves the use of local and/or systemic antibiotics as the primary treatment, based on

the patient's clinical presentation. Surgical interventions are employed to eliminate infections that exhibit poor responsiveness to medical management and also to enhance the functionality of the auditory conduction system of the ear [6]. Tympanoplasty is a surgical procedure that involves transferring tissue to repair a perforated TM. This procedure aims to restore auditory function and safeguard the middle ear from external factors such as infections. The surgical procedure of tympanoplasty was initially documented by Wullstein H and Sergi B et al., [7,8], with subsequent modifications made by Zöllner F [9]. Tympanoplasty commonly employs endomeatal, endaural, or postauricular routes as procedural techniques. Different surgical outcomes may be observed based on the dimensions, location of the defect, and the specific graft material employed [7].

Heerman J Jr et al., pioneered the use of temporalis fascia as a grafting material [10]. Goodhill V established the concept of grafting tragal cartilage and perichondrium [11]. Several other types of graft materials, such as periosteum, fat, vein, dura, or skin, have subsequently been employed to repair TM perforations [12]. Among these, temporalis fascia remains the preferred choice for surgeons due to its proximity to the surgical site and the ease of harvesting. However, despite its ability to provide effective auditory function, there are notable concerns regarding its dimensional stability properties due to its lack of elasticity. This characteristic renders it more vulnerable to pressure variations, potentially leading to persistent perforation. This is particularly relevant in cases involving adhesive OM, eustachian tube dysfunction, or large TM perforations [13].

Cartilage grafts of suitable dimensions can be obtained from either the concha or the tragus, with minimal risk of morbidity at the donor area. In revision cases, cartilage grafts are commonly preferred by most surgeons due to their advantageous combination of strength and durability. However, these grafts may potentially yield a lower optimal functional outcome in terms of audiological restoration [14]. This study aims to evaluate the surgical outcomes of tympanoplasty procedures utilising different graft materials in patients diagnosed with mucosal COM.

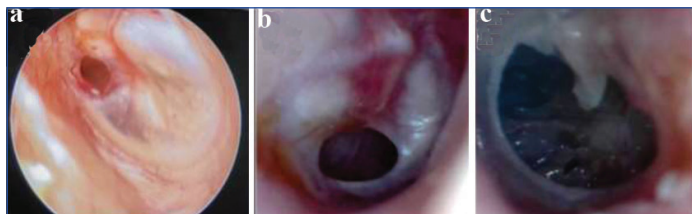
MATERIALS AND METHODS

This retrospective cohort study done in the patients with an inactive mucosal type of COM visiting the Outpatient Department (OPD) and Inpatient Department (IPD) of Otorhinolaryngology at Acharya Vinoba Bhave Rural Hospital (AVBRH), Wardha, Maharashtra, India, over a 10-year period, from June 1, 2013, to May 31, 2023. The study included data analysis and interpretation six months after data collection of 165 participants from September 1, 2023, to December 31, 2023. Before commencement, the study, it was approved by the Institutional Ethics Committee (DMIMS(DU)/IEC/2020-21/9123).

Inclusion criteria: A total of 165 participants with TM perforations in inactive mucosal COM between the age group of 10 and 80 years were included. Patients were included in the study and were posted for tympanoplasty once the ear had been dry for at least six weeks.

Exclusion criteria: Patients with uncontrolled diabetes mellitus, hypertension, active or inactive squamousal COM, and ears with active discharge were excluded from the study.

Participants underwent a thorough and meticulous evaluation along with a demographic profile assessment. All patients were subjected to EUM to examine the status of the TM and middle ear mucosa and determine the size of the perforation [Table/Fig-1a-c].

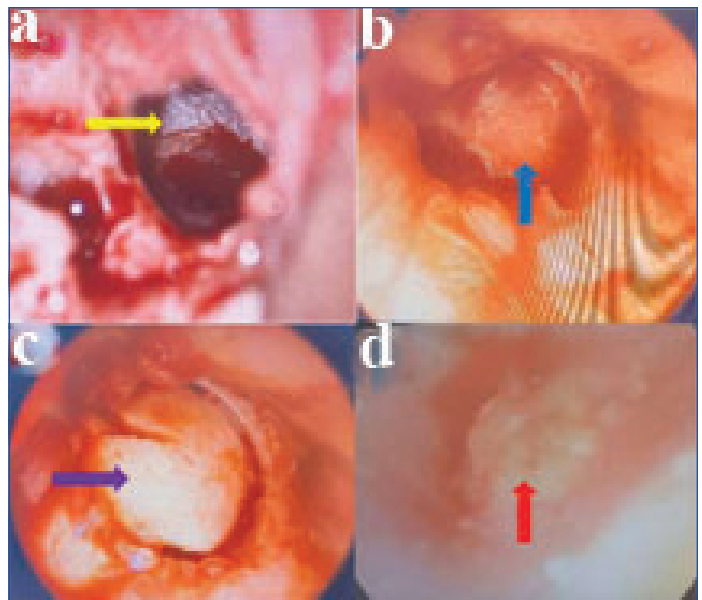


[Table/Fig-1]: (a) Tympanic Membrane (TM) with small central perforation; (b) Tympanic Membrane (TM) with moderate central perforation; (c) Tympanic Membrane (TM) with subtotal perforation

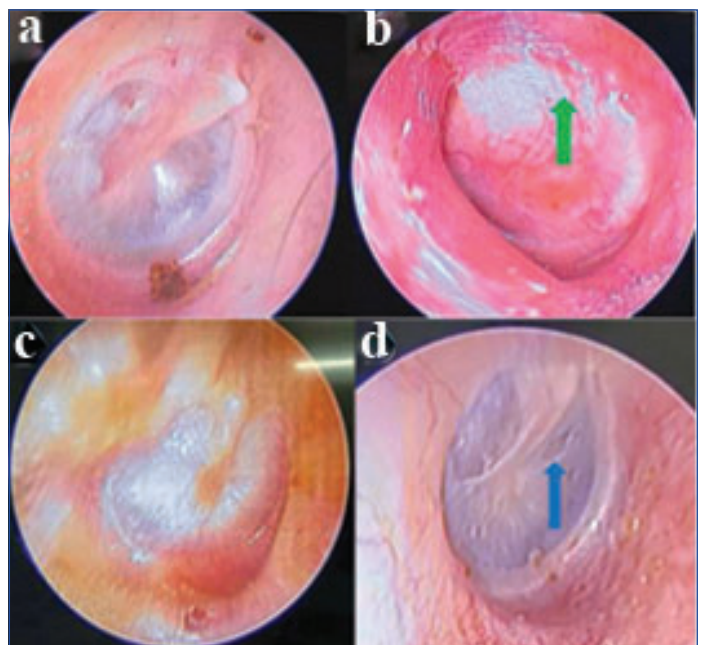
Ossicular chain status and its integrity, along with testing of audiological capacity as regards the disease, were done, along with all necessary investigations. The surgical procedure, tympanoplasty, was performed by the same surgeon utilising the Zeiss surgical microscope model OPMI under general anaesthesia. All cases were performed employing the postauricular approach with the underlay technique of graft placement [Table/Fig-2a-d]. The postoperative graft status and acceptance were studied and analysed [Table/Fig-3a-d].

Surgical technique: To harvest the tragal cartilage, a single incision 15 mm in length was made, positioned 2-3 mm below the apex of the tragus. Traversing through the layers of skin, posterior perichondrium, cartilage, and anterior perichondrium. An extraperichondrial plane was established, and the cartilage was procured with the perichondrium preserved on both sides. Then, the perichondrium was excised from the medial aspect of the cartilage graft, resulting in the formation of a flap. This flap was subsequently positioned beneath the tympanomeatal flap to provide improved reinforcement and vascularisation. The temporalis fascia was obtained via a postauricular incision in all cases.

The margin of remnants of the TM was freshened, and the undersurface of the TM cleared. The tympanomeatal flap with



[Table/Fig-2]: (a) Placement of temporalis fascia graft; (b) Temporalis fascia graft placed over tragal cartilage to repair the perforation; (c) Tragal cartilage along with its perichondrium being used to repair the Tympanic Membrane (TM) perforation; (d) Fat as a graft placed after freshening the margins of the perforation.



[Table/Fig-3]: Neotympanum seen under EUM at the end of three months follow-up (a); Tympanoplasty done with temporalis fascia as graft; (b) Cartilage with temporalis fascia used for reconstruction of the perforation showing neovascularisation (green arrow); (c) Cartilage along with its perichondrium utilised as the graft material; (d) Healed Tympanic Membrane (TM) (blue arrow) seen on follow-up postsurgical reconstruction with fat graft.

the annulus was elevated from the 12 o'clock to the 6 o'clock position, and the handle of the malleus was bared. Ossicular chain integrity and mobility were assessed. The graft was placed over the handle of the malleus by the underlay technique. Following the repositioning of the tympanomeatal flap, the external canal was packed with gel foam.

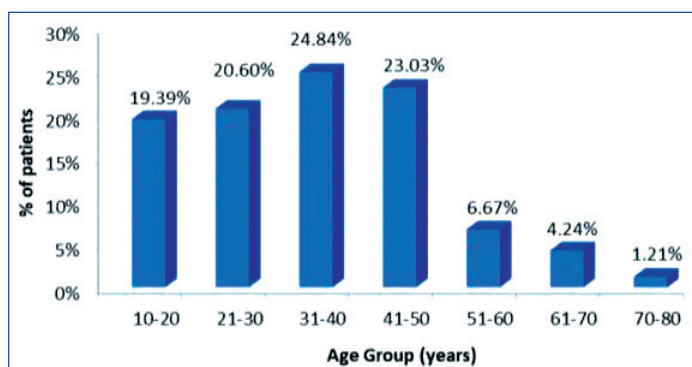
After the surgical procedure, the patients were placed in a postoperative unit where they received antibacterial treatment and analgesics. The mastoid dressing was replaced on the third and fifth days after the surgery to evaluate the condition of the surgical site. On the seventh day after the operation, after suture removal, the patient was discharged on oral antibiotics along with topical antibiotic ear drops. Subsequent postoperative visits took place at weekly intervals for one month, and monthly thereafter for six months. An intact neo-TM without a residual perforation at the end of three month follow-up was considered a successful anatomical outcome.

STATISTICAL ANALYSIS

Statistical analysis was done by using descriptive statistics, and the software used in the analysis was Statistical Package for Social Sciences (SPSS) version 27.0.

RESULTS

The present study involved 165 participants, including 102 (61.82%) females and 63 (38.18%) males with COM mucosal type. The study included participants ranging in age from 10 to 80 years, with the youngest being 10 years old and the oldest being 75 years old, with a mean age of 32.45 years. The age group most frequently afflicted by mucosal COM was between 31-40 years, with 41 (24.85%) cases, as shown in [Table/Fig-4].



[Table/Fig-4]: Distribution of patients according to age group.

A total of 79 (47.88%) patients had large perforations, followed by 65 (39.39%) with moderate perforations [Table/Fig-5].

Type of perforation	n (%)
Small central perforation	13 (7.88)
Moderate central perforation	65 (39.39)
Large central perforation	79 (47.88)
Sub-total perforation	8 (4.85)

[Table/Fig-5]: Distribution of patients based on the type of perforation.

A total of 52 (31.52%) had left-sided disease, 55 (33.33%) had bilateral disease, while 58 (35.15%) had diseased lateralisation in the right ear. In 163 (98.78%) patients among 165 (100%) cases in present study had a normal ossicular chain. In 2 (1.22%) patients, the incus was found to be eroded, and only in 1 (0.61%) were all ossicles missing [Table/Fig-6].

Type of disease	Status of ossicles				Total
	Normal		Diseased		
	M+I+S+	M-I+S+	M-I-S+	M-I-S-	
Tubo tympanic/mucosal type	163 (98.78%)	0	1 (0.61%)	1 (0.61%)	165 (100%)

[Table/Fig-6]: Status of the ossicles in the diseased ear (M=malleus, I=incus, S=stapes).

Among 13 (7.88%) cases with small central perforations, 9 (5.45%) were repaired using temporalis fascia graft, and only 1 (0.61%) with a composite graft of temporalis fascia and tragal cartilage. Fat as a graft was used for repairing only small perforations in 3 (1.82%) cases [Table/Fig-7].

A total of 118 (100%) patients who came for follow-up were considered. 84 (71.19%) patients in which temporalis fascia graft reconstruction was done, 79 (66.95%) had successful graft uptake [Table/Fig-8].

The following table depicts all six cases of graft failure, comparing the size of perforation, graft material utilised, and the status of the other ear leading to a failed surgical outcome [Table/Fig-9].

Graft material	Size of perforation				Total
	Small	Moderate	Large	Subtotal	
Temporalis fascia	9 (5.45%)	55 (33.33%)	47 (28.49%)	2 (1.21%)	113 (68.49%)
Temporalis fascia+tragal cartilage	1 (0.61%)	4 (2.42%)	4v(2.42%)	1 (0.61%)	10 (6.06%)
Tragal cartilage+ Perichondrium	0	6 (3.64%)	28 (16.97%)	5 (3.03%)	39 (23.63%)
Fat	3 (1.82%)	0	0	0	3 (1.82%)
Total	13 (7.88%)	65 (39.39%)	79 (47.88%)	8 (4.85%)	165 (100%)

[Table/Fig-7]: Type of graft material used in various sizes of Tympanic Membrane (TM) perforation.

Type of graft	Follow-up after three months	Outcome	
		Accepted	Rejected
Temporalis fascia	84 (71.19%)	79 (66.95%)	5 (4.24%)
Temporalis fascia+tragal cartilage	9 (7.63%)	8 (6.78%)	1 (0.85%)
Tragal cartilage+perichondrium	23 (19.49%)	23 (19.49%)	0
Fat	2 (1.69%)	2 (1.69%)	0
Total	118 (100%)	112 (94.92%)	6 (5.08%)

[Table/Fig-8]: Outcome of surgery based on the type of graft material used.

Size of perforation	Graft material used	Status of the other (non operated) ear
Moderate	Temporalis fascia	Normal
Large	Temporalis fascia	Large perforation+
Large	Temporalis fascia	Large perforation+
Large	Temporalis fascia	Large perforation+
Large	Temporalis fascia	Grade 3 retraction in pars tensa
Large	Temporalis fascia+tragal cartilage	Normal

[Table/Fig-9]: Comparison of size of perforation and status of other non operated ear with the graft material utilised leading to its failure.

DISCUSSION

The main objective of tympanoplasty is to surgically restore the integrity of the TM, thereby preventing contamination resulting from exposure to pathogens and enhancing the vibratory surface area of the membrane, ultimately leading to improved hearing function [7, 15]. Various factors impact both the anatomical and functional outcomes, such as the size and location of the perforation, the presence of persistent respiratory diseases, adhesion or bilateral ear infections, and the requirement for revision surgery. Hence, it is imperative to consider the characteristics of each graft material, the overall health status of the patient, and the likelihood of graft integration when selecting the appropriate type of graft. In the existing literature, it has been observed that tragal cartilage and temporalis muscle fascia are commonly employed materials for myringoplasty type I, mostly attributed to the convenience of graft procurement and the high surgical success rate [13]. Nevertheless, the comparative advantage of one graft over the other has long been debated.

Age has been widely acknowledged as a critical determinant in achieving favourable outcomes in tympanoplasty. Present study involved 165 participants, including 102 (61.82%) females and 63 (38.18%) males posted for tympanoplasty, with a mean age of 32.45±14.06 years, with the most afflicted age group being 31-40 years, involving 41 (24.85%) cases. Since the institute is a tertiary care facility, it is possible that the age gap is a result of most patients reporting late. Present study exhibited a slight increase in the prevalence among females, indicated by a Male-to-Female (M:F)

ratio of 1:1.62. This finding was consistent with the results reported by Fadl FA, who found a M:F ratio of 1:1.42, Singh BJ et al., who reported a M:F ratio of 1:1.34, and Nagle SK et al., who observed a M:F ratio of 1:1.22 [16-18].

Extensive research has been conducted on the prognostic significance of the contralateral ear in relation to the success of tympanoplasty. Eustachian tube function is often symmetrical; therefore, when localised mucosal illness is absent, success may be predicted by the condition of the opposite ear [19-21]. Nevertheless, no substantial disparities were observed across the groups in terms of the ear affected. However, a slight increase (35.15%) in the disease occurring in the right ear was observed. In keeping with present study finding, an increased incidence of right-sided unilateral TM perforation was observed in 48.9% of patients in a study done by Priyadarshini G et al., [22].

A large majority (79, 47.88%) of the total number of patients in present study had large perforations, followed by 65 (39.39%) with moderate perforations, 13 (7.88%) had small central perforations, and only 8 (4.85%) presented with subtotal perforations. Tripathi P and Nautiyal S studied 67 cases with 44.77% having subtotal perforation, out of which in 15 (22.38%) cases the incus was necrosed [23]. Similarly, in present study, 2 (25%) patients with subtotal perforation had incus erosion found intraoperatively. There is a lack of unanimity among otorhinolaryngologists on the selection of graft material during tympanoplasty. The choice of graft is contingent upon the surgeon's expertise and personal inclination. Temporalis fascia graft is a preferred choice among many surgeons due to its easy technique, versatility, and comparable thickness to the TM. Numerous studies have demonstrated the efficacy of utilising temporalis fascia for the closure of small to moderate perforations. However, it has been observed that large and subtotal perforations, as well as cases involving eustachian tube dysfunction, are associated with a higher risk of graft failure [13,24,25].

The application of composite grafts has witnessed a notable surge, accompanied by the introduction of the usage of new composite grafts. In addition, there have been recent developments in the field of cartilage graft techniques, resulting in the emergence of novel versions of pre-existing methods. The cartilaginous graft can be fabricated to have a reduced thickness and a diameter that is sufficiently modest to reinforce only the weakened area of the affected TM. Alternatively, it can be contoured to address both the repair of a complete perforation of the TM and the reconstruction of ear ossicles, as documented by multiple authors [26-29]. In general, they favour the cartilage's resistance to the varying negative pressure in the middle ear and the relatively longer time required for resorption. One notable advantage of cartilage tympanoplasty is the potential for continued epithelisation on the cartilage surface, even in cases where the graft becomes detached anteriorly [27,29].

At the end of the 3rd month of follow-up, the neotympanum was assessed by otoscopic examination, and in 84 (100%) patients in which temporalis fascia graft reconstruction was done, 79 (94.05%) had successful graft uptake, while uptake with tragal cartilage with or without temporalis fascia in 32 (100%) patients was 31 (96.87%). In the study conducted by Bhattacharya SN et al., on 56 patients initially enrolled and subjected to type I tympanoplasty procedures, the overall graft take rate at three months, specifically focusing on the closure of perforations (referred to as anatomic success). The results indicated that the cartilage group exhibited a graft take rate of 93.3%, while the fascia group demonstrated a rate of 91.7%. However, this difference was not found to be statistically significant [28]. In a similar study conducted by Yegin Y et al., the graft uptake achieved using the temporalis fascia technique was found to

be 65%, while the cartilage approach yielded a graft uptake of 92.1%. The researchers concluded that the anatomical success rate of cartilage tympanoplasty surpassed that of temporalis fascia, and these findings exhibited statistical significance [30]. There have been previous studies that demonstrated that the rate of graft uptake in cartilage tympanoplasty was higher compared to temporalis fascia tympanoplasty [Table/Fig-10] [29,31-36].

Author	Cartilage tympanoplasty (%)	Temporalis fascia tympanoplasty (%)
Pradhan P et al., [31]	96.7	80
Jalali MM et al., [32]	92	82
Kazikdas KC et al., [33]	95.7	75
Demirci S et al., [29]	92	82.9
Kalcioglu MT et al., [34]	94	93
Ozbek C et al., [35]	100	70.2
Chhapola S and Matt I [36]	98.36	84.5
Present study	96.87	94.05

[Table/Fig-10]: Comparison of outcome of cartilage and temporalis fascia tympanoplasty surgery done by various authors [29,31-36].

Tek A et al., proposed the utilisation of the cartilage reinforcement tympanoplasty technique under the anterior portion of the temporalis muscle fascia, an approach deemed simple and practical, since it effectively enhances the graft uptake ratio. It is particularly beneficial for patients with preoperative anterior and subtotal TM perforations [37]. Vashishth A et al., conducted a study examining the benefits of using cartilage palisade tympanoplasty with temporalis fascia. Their findings demonstrate a high success rate, particularly in challenging cases such as atelectasis and subtotal perforation [38]. Fat graft myringoplasty has several advantages compared to other graft materials such as temporalis fascia graft, cartilage, or perichondrium, including simplicity in harvesting, ease of placement, and cost-effectiveness, as it may be conveniently conducted as an office procedure. Historically, the usage of fat graft as the preferred material has been centered on small perforations. Some authors limit the consideration of this graft to cases when the perforation size is less than 25% and confined within the pars tensa [39,40]. According to Dedden AE et al., the size of the perforation is a crucial determinant of success in fat graft material; perforations of more than one quadrant are considered unfavourable for fat grafting [39]. As per the findings of Kaddour HS, it is recommended that the size of the perforation should not surpass 30% of the eardrum [41]. In present study, fat graft myringoplasty was performed in two patients with small perforations, and the graft uptake was 100%. Terry RM et al., who performed fat graft myringoplasty to correct perforations of various sizes, cited a closure rate of 79.4% if the perforation accounted for less than 50% of the TM and 57.1% if the perforation was larger than that [42].

Ambani KP et al., found that the graft uptake rate in fat tympanoplasty was as low as only 53.3% in patients with moderate to large perforations compared to 80% with temporalis fascia graft [43]. Out of the 6 (100%) cases in present study, where graft uptake failed, one had a moderate central perforation, and five had large central perforations. The majority, i.e., 4 out of 6 (66.67%) cases, had diseased contralateral ears, and in 5 out of 6 (83.34%) cases, temporalis fascia graft was used, which could have been one of the associated factors leading to residual perforation resulting in surgery failure. In their study of eight cases, Adkins WY and White B observed a higher rate of failure in tympanoplasty procedures among patients with bilateral perforations. Notably, three out of the four instances of tympanoplasty failure were associated with bilateral perforations [44]. Kessler A et al., observed a greater incidence of post-tympanoplasty re-perforations among individuals with an abnormal contralateral ear [45].

Nevertheless, Koch WM et al., conducted a study comprising 64 tympanoplasties and found no significant link between an abnormal contralateral ear and the outcome of the surgical procedure [46]. Gianoli GJ et al., observed that there was no statistically significant distinction when comparing a subset of nine defective contralateral ears [47].

Therefore, the usage of cartilage grafts has been suggested in ears with a larger size of perforation or with a diseased contralateral ear as a means to enhance the overall outcomes of the surgical procedures.

Limitation(s)

The obvious limitation of the present study was the limited sample size, which restricts the extent to which the findings can be generalised. It is highly ideal to conduct a prospective study that includes a higher sample size and a longer duration of follow-up.

CONCLUSION(S)

This study demonstrates that cartilage grafts exhibit superior graft uptake compared to temporalis muscle fascia grafts used alone in cases with large or subtotal perforations. Fascia and perichondrium require a new vascular supply, but the cartilage is nourished by simple diffusion from the surrounding tissue. It can survive in a relatively avascularised state, making cartilage a viable alternative to the conventional temporalis fascia graft for reconstructing large or subtotal perforations. Cartilage seems to offer high resistance both to the lack of vascularisation and to infections, providing strength and durability in cases of eustachian tube dysfunction.

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