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ORIGINAL ARTICLE

A Prospective Randomised Comparative Study Between Cartilage and Fascia Tympanoplasty in a Tertiary Care Hospital to Look for Better Alternative in High Risk Cases

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Abstract

Introduction CSOM patients are most commonly managed surgically by type I tympanoplasty using either cartilage shield technique or underlay grafting technique. In our study, we have compared the graft uptake and hearing results of type I tympanoplasty using temporalis fascia and cartilage shield, and also reviewed the literature regarding the results of these two methods.

Materials and Methods 160 patients aged between 15 and 60 years were randomized into two groups of 80 patients each, with odd numbers subjected to conchal or tragal cartilage shield grafting in group I, while in group II with even numbers, the patients underwent temporalis fascia grafting by underlay technique.

Results Three months post-surgery, the graft uptake was seen in 76 patients (95%) in the cartilage shield group as compared to 58 patients (72.5%) in the temporalis fascia group, which was statistically significant between the two groups **[*Fisher's exact value* = 0.000]**. The uptake rate was much higher in cartilage shield graft as compared to fascia graft even in complicated cases like revision tympanoplasty (TP), discharging ear, subtotal perforation and retracted/adhered TP. Also, the hearing improvement in fascia and cartilage shield group was not statistically significant comparing pre- and post-operative patients, indicating that there was not much difference in audiological outcomes between the two groups.

Conclusion We advocate the use of cartilage shield graft as a substitute for fascia graft in all feasible cases as well as in complicated situations to improve the success rate of type I tympanoplasty, without compromising on the hearing improvement, as seen in our study.

Keywords Fascia graft · Cartilage shield graft · Type I tympanoplasty · CSOM

Introduction

In chronic suppurative otitis media (CSOM), there is chronic inflammation of the epithelium of the middle ear and mastoid cavity.[1] Patient usually presents with persistent or intermittent otorrhoea, tympanic membrane perforation, and hearing loss.[1] Long term eustachian tube dysfunction with poorly aerated middle ear space, multiple bouts of acute otitis media, persistent middle-ear infection, allergy or other chronic inflammatory stimulus leads to CSOM.[2] CSOM are of two main types- tubotympanic type is characterized by a perforation in the parse tensa, with low risk of complications,[3, 4] whereas atticoantral type is characterized by the formation of a retraction pocket in which keratin and desquamated epithelial debris accumulates to produces cholesteatoma, and it mostly involves pars flaccida and posterior superior quadrant of pars tensa. Atticoantral type is considered a dangerous type, as there are high chances of development of many intracranial and extracranial complications. [3, 4, 5]

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The etiopathogenesis of CSOM is because of the complex interaction between the environment, microbes and the host, leading to the development of this multi-factorial disease. Various risk factors for development of CSOM are overcrowding, poor hygiene, poor nutrition, poor living conditions, high rates of nasopharyngeal colonization with potentially pathogenic bacteria, inadequate and unavailable health care, recurrent upper respiratory tract infections and nasal diseases.[6, 7]

Traditional management of CSOM is underlay tympanoplasty, which is done to prevent recurrent middle ear infection from external pathogens and restoration of the vibratory area of TM to improve hearing. Various autologous graft materials used for closure of perforation are temporalis fascia, perichondrium, cartilage, fascia lata, vein and fat. Surgeons usually prefer temporalis fascia or perichondrium, as they are available at the surgical site, provide good healing, and have tensile strength and acoustic property similar to normal TM. But, these grafts can become infected and can retract under negative pressure gradient during the postoperative period, leading to hampered long term results. [8–10] Hence, more rigid and more resistant graft materials, as an alternative to fascial grafts, are nowadays used for TM reconstruction. [11–13].

Conchal cartilage is frequently being used as an alternative grafting material, as it produces minimal inflammatory tissue reaction and is well incorporated with tympanic membrane layers. It is especially used for repairing large perforations, for scutum defects, for preventing or revising the failure of previous procedures associated with chronic tubal dysfunction, for atelectatic tympanic membrane and for enhancing the biocompatibility of ossicular prosthesis with the tympanic membrane. The greatest advantage of cartilage graft is considered to be its very low metabolic rate, as it receives its nutrition by diffusion, easy to work with because of its pliability and can resist deformation from pressure variations.[14] Also, perichondrium with cartilage have the quality of mesenchymal tissue with fascia, but they are thicker and stiffer.[14] Cartilage prevents retraction and is resistance to infection, during healing phase. So, the chance of recurrent perforation of tympanic membrane is greatly reduced. [15, 16]

The only drawback of cartilage graft is that, it may mechanically reduce the vibratory pattern of the tympanic membrane, leading to decreased hearing, especially in the higher tones. Literature describe success rates with cartilage tympanoplasty in terms of achieving a closed dry ear and hearing results, equivalent to those of traditional graft materials.[6, 15, 16] Various studies show that audiological data in hearing outcome of cartilage tympanoplasty is comparable to fascia or perichondrium tympanoplasty.[15, 16]

In this study, we analysed the success rate of graft uptake and hearing outcome in cartilage tympanoplasty (with or without perichondrium), and compared it with success rate of fascia tympanoplasty. We also compared our results using fascia and cartilage tympanoplasty, with those mentioned in the literature.

Aims and Objectives of Our Study

1. To study the graft success rate in primary type I tympanoplasty using cartilage shield and fascia.
2. To study the audiological outcome in type I tympanoplasty using cartilage shield and fascia.
3. To study the graft success rate in type I tympanoplasty using cartilage shield and fascia in complex situations like discharging ear, small versus large perforation, revision surgery and in retracted TM.
4. To assess and compare the rate of graft retraction and failure post-surgery in type I tympanoplasty using cartilage shield and fascia.

Materials and Methods

A prospective study was carried out, in which 160 patients with complaints of ear discharge and hearing loss, who visited out-patient department (OPD) of Ear Nose and Throat (ENT), Institute of Medical Sciences, Banaras Hindu University, Varanasi, between January, 2018 to June, 2019, and were being diagnosed as tubo-tympanic type of CSOM, were included in our study. All included patients were diagnosed by taking complete history and by performing thorough general and local clinical examination of ear nose and throat (ENT), and informed consent was taken from all of them. Otoscopic examination and examination under microscope (EUM) was done to determine the size of perforation, and classify them into small, medium, large and subtotal, depending on the involvement of quadrants. The relevant details were recorded and patients were then subjected to routine investigations alongwith a battery of otological investigations namely

1. Audiological tests-.

a. Pure tone audiometry (PTA).
b. Impedence Audiometry (IA).

2. Otomicroscopy.
3. Eustachian tube function assessment by tympanometry.

Hearing status was assessed with pure-tone audiometry (PTA). Both air and bone conduction hearing thresholds at 500 Hz, 1000 Hz, 2000 Hz and 3000 Hz were assessed and air-bone gap (ABG) was calculated. Hearing loss was graded into mild (26–40 dB), moderate (41–55 dB), moderate-severe (56–70 dB) and severe (71-90dB), according to audiometry. Diagnostic nasal endoscopy and indirect laryngoscopy were done to rule out any pathology and foci of infection in nose and throat. Pre-operative assessment of status of ear before surgery (inactive/active), Eustachian tube function and type of hearing loss (conductive/mixed/SNHL) were done and recorded.

Inclusion Criteria

All patients aged between 15–60 years, who visited ENT OPD between January,2018 to June,2019 with central perforation of tympanic membrane, including revision ear surgery, were included in our study:-

- Patients with history of chronic ear discharge, whether unilateral or bilateral with perforation or retracted/adhered tympanic membrane, and diagnosed as tubotympanic type of CSOM.
- Patients with complaints of hearing loss (documented by PTA) with previous history of ear discharge, and diagnosed as tubo-tympanic type of CSOM.
- Patients for revision ear surgery, having residual perforation and diagnosed as tubo-tympanic type of CSOM.

Exclusion Criteria

- Patients aged less than 15 years or more than 60 years.
- Those diagnosed as attico-antral or squamous type of CSOM.
- Those with traumatic tympanic membrane perforation.
- Those presenting with otorrhoea, earache or decreased hearing and diagnosed with otomycosis, otitis externa or mass in the external auditory canal (EAC).
- Any co-morbid illness in the patient, which was a contradiction for surgery.

Study Groups

The sample was taken between January, 2018 to June, 2019 and during this period, 160 patients diagnosed with tubotympanic or mucosal type of CSOM with pure conductive hearing loss, were randomized into two groups, with group I having 60 females and 20 males, while group II had 50 females and 30 males. We determined the sample size of 160 patients by taking into account our exclusion criteria and the specified time period of 11/2 years (January, 2018-June, 2019). Also, these 160 patients were collected from the OPD of single faculty only (OPD was once in a week), and only those patients were included, who were willing for surgery.

On the basis of occupation, patients in both the groups mostly belonged to either student or housewife group. The patients in both the groups were also divided into two categories of low income group and middle and high income group, based on their socio-economic status. The P-value comparing various demographic factors in both the groups was not statistically significant, ruling out any bias due to any confounding factors.

Those with discharging ears were given systemic antibiotics (according to culture and sensitivity), anti-histamines, local antibiotic ear drops, and patients were advised to take water precautions to make ear dry before surgery.

Method of Randomization

The patients were randomized into two groups of 80 patients each, with odd numbers allocated to group I, and these patients were subjected to conchal or tragal cartilage shield grafting, while even number patients were allocated to group II, and these patients were subjected to temporalis fascia grafting by underlay technique. So, the patients did not know which type of surgery they were undergoing, but the surgeon was aware of the allocation. Also, the statistician did not know about the data allocation. So, it was double-blinded study and there was no bias in the randomisation of the patients. Hence, complete concealment was followed in the group allocation.

Follow-up

All the patients were followed up at 1, 3 and 6 months, during which assessment of graft uptake by otoscopy and hearing assessment by PTA was done. Subjective evaluation of hearing, tinnitus or any other complaints by patients was also noted. A healed graft was considered as a good uptake. Any residual perforation, severe retraction, or reperforation

of graft after uptake within 6 months was considered as a failure. PTA and Eustachian tube function tests were done at 3 months in each patient to assess the audiological improvement. These findings were then compared with preoperative findings.

Surgical Technique

Surgery in all patients was performed by the same surgeon to avoid inter-surgeon variability. Surgical procedure was performed under local anaesthesia [2% xylocaine with adrenaline]. Preparation of surgical site was done by removing about 2 cm hairs in the pre- and post-auricular region. A Wilde's incision was made in post-auricular region to open the canal. In group I, cartilage was harvested from conchal or tragal site and moulded with knife to shape like shield. A V-shaped notch was made in cartilage shield graft to accommodate the handle of malleus. Tympano-meatal flap was elevated completely all around from the bony canal, i.e. around 360 degrees. Cartilage was put at the level of annulus, and fixed around handle of malleus in an underlay fashion. Temporalis fascia was put over the cartilage for epithelisation and tympano-meatal flap was reposited back over the temporalis fascia. In group II, temporalis fascia graft was harvested and was put in an underlay fashion after elevating the tympano-meatal flap completely all around from the bony canal, i.e. around 360 degrees. In both groups, Gelfoam was put in the middle ear and EAC to support the graft medially and laterally and to pack the external auditory canal. Canaloplasty was performed in all those cases having narrow EAC. Finally, post-auricular incision was closed by double layered sutures and mastoid dressing was done.

Post-operative Care

Post-operatively, patients were discharged next day following surgery. All patients were advised to avoid air travel and swimming for a month. Patients were also called up between 7 and 10 days for suture removal. After 7–10 days, all patients were advised for regular follow-up at 1 month, 3 months and 6 months post-operatively. Assessment of graft uptake was done at 1 and 3 months by cleaning the debris and otoscopic examination, while audiological assessment was done in each patient at 3 months by repeating the PTA.

Hearing Assessment

PTA was done before surgery and after 3 months of surgical procedure to assess the change in hearing loss in both the groups. Pre- and post-operative air conduction threshold average was calculated at frequencies of 0.5, 1, 2 and 3 kHz and change was calculated. Also, pre- and post-operative air-bone gap (ABG) was calculated by subtracting pure tone average for air conduction minus the same average for bone conduction. Air-bone gap (ABG) closure was calculated by subtracting pre-operative air-bone gap from post-operative air-bone gap.

Statistical Analysis

Statistical analysis was performed with the SPSS software, version 17.0 (Statistical Package for the Social Sciences, SPSS Inc, Chicago, Illinois, USA). The statistical comparison of demographic and audiometric data was performed using Chi-square test. In the present era, Chi-square test has been regarded as the most accurate test. The purpose of this test is to determine, if the difference between observed data and expected data is by chance or it is due to a relationship between the variables. The null hypothesis of the Chi-square test states that no relationship exists on the categorical variables in the population, and they are independent. In tables, where the expected values were less than 5, Fisher's exact test was applied to get the proper statistical results. The statistical parameters were thoroughly checked and all tests were performed thrice to ensure the reproducibility of the results.

Observations and Results

The present study was carried out in patients with tubo-tympanic type of CSOM, having unilateral or bilateral perforation of tympanic membrane. In our study, 50 patients were male and 110 were female. A comparison table of basic characteristics of both the groups was also made and the data was statistically correlated to rule out any bias or confounding factors. (Table 1) The mean age of patients in our study was 38 ± 15 years (range was 15–60 years) (Table 2). Most of our patients were students (50.0%), followed by house-wives (37.5%). Maximum patients belonged to rural area (75.0%). Most of our patients had unilateral ear involvement (71.3%), while 28.7% cases had bilateral ear involvement. The mean follow-up for all the patients in both the groups was 6 months. Most of our patients had either small, large or subtotal perforation (93.7%). Only, 6.3% (10 patients) had either severely retracted or adhered TM.

Table 1 Table comparing basic characteristics of two groups with statistical correlation

Basic Characteristics			Group I (Cartilage TP)	Group II (Temporalis Fascia TP)	P-value
Gender	Male		20	30	0.157
	Female		60	50	
Age	11–20 yrs		24	36	0.678
	21–30 yrs		37	30	
Occupation	Student		46	34	0.110
	Housewife		27	33	
Residence		Urban	24	16	0.007
		Rural	55	65	
Economic status		Low socio-economic status	50	45	0.288
		Middle socio-economic status	30	35	
Laterality		Unilateral	54	60	0.308
		Bilateral	26	20	
Revision cases			10	8	0.366

Table 2 Distribution of cases according to age-group

Age (in years)	No. of cases	Percentage
11–20	60	37.5
21–30	67	41.9
31–40	17	10.6
41–50	12	7.5
> 50	4	2.5
Total	160	100.0

3 months (Table 3), which was more statistically significant in favour of cartilage tympanoplasty **(P-value = 0.000269)**, (Fisher's exact value = 0.000). In our series, the success rate in revision cases in fascia and cartilage tympanoplasty were found to be 70% and 96.6% respectively, which was again statistically significant towards cartilage TP (Table 4). The probability of graft acceptance or graft rejection was not dependent on the size of perforation in cartilage tympanoplasty (Table 5) but, the probability of graft uptake in temporalis fascia cases were more in small perforation as compared to large perforation in our study (Table 6). 6.3% (10 patients) had either severely retracted or adhered TM.

Table 5 Table showing the graft uptake rate in large perforation and small perforation using cartilage graft

Type of perforation	Graft accepted after cartilage TP	Graft rejected after cartilage TP	Total
Subtotal and Large perforation	49(96.07%)	2(3.92%)	51(68.9%)
Medium and Small perforation	22(95.6%)	1(4.34%)	23(31.08)
Total	71	3	74

Fisher's Exact value- 1.000

1-sided Fisher's Exact value- 0.679

The graft uptake was assessed at 1 and 3 months with otoscopic examination. 58 out of 80 cases(including perforation and retraction cases) in fascia tympanoplasty and 76 out of 80 cases(including perforation and retraction cases) in cartilage shield tympanoplasty showed successful graft uptake at

Table 3 Table showing graft success rate in primary cartilage and fascia tympanoplasty

Type of graft	Accepted	Rejected	Success percentage (%age)
In temporalis fascia (80 cases)	55	25	68.75%
In conchal/tragal cartilage (80 cases)	76	04	95%

Fisher's exact value = 0.000

1-sided Fisher's exact Value- 0.000

Table 4 Comparison of success rate in revision cases using temporalis fascia and cartilage graft

Type of graft	Graft accepted after surgery in revision cases	Graft rejected after surgery in revision cases	Total
In temporalis fascia graft	2 (25%)	6(75%)	8
In conchal cartilage graft	9(90%)	1(10%)	10
Total	11	7	18

Fisher's Exact value- 0.001

1-sided Fisher's Exact value- 0.002

Table 6 Table showing graft uptake rate in large perforation and small perforation using temporalis fascia

Type of perforation	Graft accepted after fascia TP	Graft rejected after fascia TP	Total
Subtotal and Large perforation	32 (65.30%)	17(34.69%)	49(64.4%)
Medium and small perforation	25 (92.59%)	2 (7.40%)	27(35.5%)
Total	57	19	76

Pearson Chi^2 value- 6.9126

P-value = 0.009 (Significant at P < 0.05)

Table 7 Comparison of graft uptake rate in discharging ear at the time of surgery using fascia and cartilage graft

Result in discharging ear	In temporalis fascia	In conchal cartilage	Total
Graft accepted	12	22	34
Graft rejected	10	02	12
Total	22	24	46

Pearson Chi^2 value- 4.59

P value = 0.032 (significant at p < 0.05)

Table 8 Comparison of mean air-conduction thresholds in pre- and post-operative patients of fascia and cartilage graft

P-value = 0.88 (not Significant at P < 0.05)

	Mean pre-op hearing loss in fascia group (in dB)	Mean post-op hearing loss in fascia group (in dB)	Mean pre-op hearing loss in cartilage group (in dB)	Mean post-op hearing loss in cartilage group (in dB)
Mean air-conduction threshold in dB (mean of 500, 1000, 2000 & 3000 Hz)	37 ± 4.4	28.3 ± 4.2	40.2 ± 4.2	30.4 ± 4.1

Table 9 Comparison of mean air-bone gap in pre- and post-operative patients (mean ABG) in fascia and cartilage graft

Frequency (in Hz)	Mean pre-operative A-B gap in fascia group (in dB)	Mean post-operative A-B gap in fascia group (in dB)	Mean pre-operative A-B gap in cartilage group(in dB)	Mean post-operative A-B gap in cartilage group(in dB)	P-value
500 Hz	25.8 ± 4.1	15.1 ± 5.2	24.6 ± 5.4	14.3 ± 4.3	0.946
1000 Hz	21.5 ± 5.2	13.9 ± 4.8	20.2 ± 3.4	11.4 ± 5.1	0.704
2000 Hz	19.1 ± 4.8	11.9 ± 3.8	18.8 ± 4.1	10.6 ± 4.8	0.869
3000 Hz	18.2 ± 3.5	9.6 ± 4.9	17.9 ± 3.8	8.7 ± 4.2	0.852

The success rate for these patients (6 underwent cartilage TP but 4 had graft uptake and 4 underwent fascia TP but only 1 had graft uptake) were much higher in cartilage group compared to fascia group, though the results in both the groups was not statistically significant due to small number of patients present. All patients with retracted TM also underwent cortical mastoidectomy to aerate the mastoid air cells and open the attic. At the time of surgical repair, the discharging ear was present in 24 out of 80 patients in cartilage TP, whereas the discharging ears in fascia TP were 22 out of 80, though randomisation. The graft uptake rate in discharging ear between cartilage TP and fascia TP was statistically significant in favour of cartilage TP in our study (p = 0.032) (Table 7).

Before surgery, most patients (62.5%) had mild hearing loss while 14.4% patients had moderate hearing loss in both the groups combined. Post-operatively after 3 months, most patients (67.5%) had hearing in normal range while almost 1/3rd patients improved to mild hearing loss in both the groups combined. Hearing assessment was done by comparing average of normal speech frequencies in pre-op PTA with post-op PTA at 3 months. The air-bone gap (ABG) was calculated in pre-op as well as post-op PTA and the difference was calculated in both the groups to assess the hearing improvement. In our study, the improvement in mean air-conduction threshold in fascia and cartilage group was not statistically significant in pre- and post-operative patients, indicating that there was no significant difference in hearing outcome in the two groups (Table 8). In our study, the difference in mean ABG seen in fascia and cartilage tympanoplasty in normal speech frequencies was almost similar, indicating that there was no significant difference in hearing outcome seen between the two groups post-operatively (Table 9). The P-value was also not significant statistically, when calculated for different speech frequencies separately. Deterioration of bone-conductive thresholds indicative of sensori-neural hearing loss was not seen in any of the cases in both the groups. The mean ABG (air-bone gap) at each of the four speech frequencies improved in both the fascia and cartilage shield groups. Both groups showed an improvement in the ABG at all speech frequencies after surgery, but there was no statistically significant difference seen between the two groups (p = 0.99) (Table 10). At 500 Hz, the improvement in mean ABG for the cartilage group

Table 10 Comparison of mean air-bone gap (ABG) closure in fascia and cartilage TP

Frequency (in Hz)	Mean ABG closure between pre- and post- surgery fascia group	Mean ABG closure between pre- and post-surgery cartilage group
500 Hz	10.7	10.3
1000 Hz	7.6	8.8
2000 Hz	7.2	8.2
3000 Hz	8.6	9.2

P-value = 0.99 (not Significant at P < 0.05)

was 10.3 dB versus 10.7 dB for the fascia group (P = 0.9). At 1000 Hz, the improvement in mean ABG for the cartilage group was 8.8 dB versus 7.6 dB for the fascia group (P = 0.7). At 2000 Hz, the improvement in mean ABG for the cartilage group was 8.2 dB versus 7.2 dB for the fascia group (P = 0.8), and at 3000 Hz, the improvement in mean ABG for the cartilage group was 9.2 dB versus 8.6 dB for the fascia group (P = 0.8).

Postoperatively, recurrent retraction or residual perforation was not seen in any of the patients in cartilage shield group, but 8 healed cases in fascia group had grade I or grade II retraction of the graft post-operatively after 3 months, which got improved after valsalva manuevre. With an average follow-up of 6 months (range was 3–12 months), no patient had persistent ear discharge at 6 months in cartilage TP group, while 6 cases in fascia TP group had wet ear at 6 months post-surgery, for which revision surgery was advised. There were no other major complications in any of our patients.

In this table, we compared the basic characteristics of both the groups alonwith their statistical correlation. As most of the paramaters in both the groups were not satistically significant, this shows that there was no bias or confounding factors favouring any of the groups.

Most of the patients belonged to 21–30 years of age-group (41.9%), followed by 11–20 years of age-group (37.5%). The youngest patient in our study was 15 years old girl and oldest was 60 years old male patient.

In our study, the graft uptake rate in fascia tympanoplasty was 72.5%, while in cartilage tympanoplasty, the graft uptake rate was 95%. The result in both the groups was statistically significant, though it was much higher in cartilage tympanoplasty.

In our study, the success rate is in revision cases between fascia tympanoplasty (25%) versus cartilage tympanoplasty (90%) was statistically significant towards cartilage TP, though the number of cases was very less in both the groups.

In our study, the probability of graft acceptance or graft rejection was not dependent on the size of perforation in cartilage tympanoplasty cases.

In our study, the probability of success of graft uptake was more in small perforation as compared to large perforation in temporalis fascia cases.

In our study, the success rate in discharging ear between cartilage TP and fascia TP was highly statistically significant in favour of cartilage TP (**P-value = < 0.032)**

In our study, the improvement in mean air-conduction threshold in fascia and cartilage group was not statistically significant in pre- and post-operative patients, indicating that there was not much difference in audiological improvement in two groups.

In our study, the difference in mean A-B gap seen in fascia and cartilage tympanoplasty in normal speech frequencies was almost similar, indicating that there was not much difference in audiological improvement seen between the two groups post-operatively.

In our study, the comparison of pre-operative and post-operative air-bone gap closure in fascia and cartilage tympanoplasty was not statistically significant in any of the speech frequencies checked, indicating that there was not much difference in audiological improvement seen between the two groups post-operatively.

Discussion

Chronic suppurative otitis media (CSOM) is a major public-health problem in India, having high prevalence of 46 per 1000 in rural population and 16 per 1000 in urban population.[6] CSOM can have long-term effects on early communication, language development, auditory processing, educational process and physiological and cognitive development, as it is an important cause of preventable hearing loss in children in the developing world, and can lead to substantial economic burden on the health care system of our country, if not treated in time. Untreated CSOM can cause destructive changes in the middle ear, leading to further hearing loss.[17]

The study done by Basumatari S et al[18] showed female preponderance (57.2%), similar to our study, where 68.8% were females. But, contrary to our study, Browning et al. [19] and Vertiainen E and Kajra J [20] found the incidence of CSOM to be higher in males (55%) as compared to females (45%). In the study done by Indorewala et al. [21], the 21–40 years age-group was the most affected group (36%), like our study, where maximum patients belonged to 21–30 years of age-group (41.9%). The average age of the patients in our study was 38 ± 15 years (range was 15–60 years), similar to study by Indorewala et al.,[21] with a mean age of 35 ± 15.8 years. There was no significant difference in the age and sex distributions of patients in fascia and cartilage tympanoplasty groups. Most of our patients belonged

to rural area (75.0%), similar to studies done by Basumatari S et al. [18] and Ramanuj B et al. [22].The reason for higher incidence in the rural areas could be lower standard of living, poor hygiene, malnutrition, illiteracy, negligence on the part of patient and family members and lack of proper medical facilities. Most of our patients had unilateral ear involvement (71.3%), while 28.7% cases had bilateral ear involvement, similar to studies done by Basumatari S et al[18] and Saha et al. [23]. The chief complaints in most of our patients were decreased hearing, discharge from ears and ringing sensation, which were similar to studies done by Basumatari S et al. [18] and Shetty et al. [24]. Otoscopic examination & examination under microscope revealed that subtotal and large perforation of tympanic membrane was seen in 60% cases approximately, whereas medium and small perforation was seen in around 40% cases in our study. Kumar et al. [25] in their study observed that 46.87% had large and subtotal while 43.75% had medium tympanic membrane perforation respectively.

Since its introduction approximately 50 years ago, cartilage tympanoplasty has been well described for patients with bilateral and/or subtotal perforation, discharging ears, revision cases, coexisting craniofacial abnormalities, atelectatic ears, cholesteatoma cases and in tympanosclerosis cases with damaged submucosal capillary circulation, with excellent uptake results.[11, 26, 27] Butterfly cartilage graft harvested from concha or tragus is easy to obtain, thick, resistant to negative middle ear pressure and resorption, stable, sufficiently elastic for good sound conduction, well tolerated, and convenient for shaping according to the size of the perforation.[26, 28] Cartilage provide a stiffer, harder alternative to traditional graft materials. Temporalis fascia may demonstrate radical and unpredictable changes in shape because of uneven shrinking and thickening, whereas cartilage demonstrates higher mechanical stability, considerable stiffness and slower metabolism and can therefore be considered as a reliable graft material for tympanoplasty. [29, 30] Furthermore cartilage is resistant to infection, perhaps due to its high concentration of the highly resistant protein elastin.[31] The abnormal environment and function of the middle ear in chronic non-cholesteatomatous type of CSOM is usually mucosal in origin. In cases with negative middle ear pressure, reliable, robust reconstruction with cartilage graft resists continued eustachian tube dysfunction and provides good structural stability to allow the mucosa to revert to a more normal state naturally. In our institution, we frequently use cartilage shield grafts in high risk cases of tubo-tympanic type of CSOM to get good uptake, but in cases of retracted/adhered TM, we also perform cortical mastoidectomy alongwith cartilage TP.

The main cause of failure in fascia TP in our study has been either retraction of the graft due to Eustachian tube dysfunction or residual perforation, whereas the cause of failure in cartilage TP was mainly uncontrolled allergic rhinitis leading to post-operative infection. In a study conducted by Onal et al. [32] in 2011 among 80 patients, success rate was 65.9% in fascia group and 92.3% in cartilage group, which was almost similar to our findings. Similarly, a study with palisade cartilage graft by Kazikdas et al. [33] found a 95.7% graft take-up when compared with a 75% take-up with temporalis fascia graft. In our study, retracted or adhered TM were treated either by fascia or cartilage shield technique, with higher success rate achieved in cartilage group, though not statistically significant (due to small number of patients probably).

Some surgeons think that using a thick material like cartilage in tympanoplasty can damage the elasticity of the tympanic membrane and worsen the hearing outcome. But various studies mentioned in the literature,[12, 31, 34, 35] found no significant statistical difference in hearing gains between cartilage graft and temporalis fascia graft, similar to our results. Similar studies conducted by Mohamad et al. [36]and Lyons et al. [37]found no statistical difference in hearing outcomes between the fascia and cartilage TP. Khan and Parab [35] have reported a closing rate of 98.20% and an average improvement of 7.06 dB air-bone gap (ABG) in their study using thinned tragal cartilage grafts, whereas there was 8–10 dB improvement seen in ABG, both in fascia and cartilage TP at normal speech frequencies in our study. In agreement with our results, Atef et al. [38] showed that there was no statistically significant difference in graft integration rate and hearing improvement between those treated with full-thickness and those treated with half thickness island cartilage graft, though we used butterfly cartilage grafts in our study. There is no consensus on various aspects of cartilage tympanoplasty like the appropriate thickness of the cartilage graft and the best technique of cartilage tympanoplasty, despite the availability of different methods. Literature suggests that the increased thickness, stiffness and the mass of the cartilage may negatively influence the graft uptake and hearing results [39]. Possibility of low hearing gain at high frequency with cartilage graft should be explained to the patients before surgery and an informed consent should be taken for the same before surgery.

The mean ABG (air-bone gap) at each of the four speech frequencies improved in both the groups, though there was no significant statistical difference seen in our study. These results corrobates with the results achieved by Gerber et al, [12] where he demonstrated overall hearing improvement in cartilage tympanoplasty comparable to that after fascia grafting. Additionally, our study also evaluated and compared the various speech frequency-specific data between the two groups, which was not mentioned in many other studies in the literature. It is reasonable to expect that

replacing a large portion of the tympanic membrane with cartilage would add stiffness and/or mass that would affect individual frequencies, but would not significantly impact averaged audiometric data such as ABG. With that in mind, pre- and post-operative air and bone-conduction thresholds at 500, 1000, 2000, and 3000 Hz were examined and compared in our study in both the groups.

Thus, the objective of our study was to analyze, compare and discuss the results of graft uptake and hearing outcome between cartilage shield graft and temporalis fascia graft in patients undergoing surgery for tubo-tympanic type of CSOM. We tried to analyse and compare the results in various complicated situations between fascia and cartilage TP. We also did an extensive literature review to assess the results mentioned in the literature and compared it with our data.

Conclusion

Our hospital based prospective study analyzed the clinical profile associated with patients of chronic suppurative otitis media (CSOM) and compared the graft uptake rate and audiological improvement seen in fascia and cartilage TP. CSOM is still a major health problem in our country, and it is of utmost importance to diagnose and treat CSOM at an early stage. By improving the living standards, health care facilities & awareness among the population particularly in lower socioeconomic class and rural areas, the incidence & prevalence of CSOM can be reduced. This in turn will help in substantial reduction in morbidity associated with CSOM i.e. hearing loss, which subsequently will ease the social and economic burden on the health care delivery system of our country.

Although temporalis fascia has high success rates in the early postoperative period, but traditional techniques show much poorer prognosis in high-risk cases. Cartilage shield graft is the most effective alternative graft material for reconstruction of tympanic membrane perforation in complicated situations, as its stiffness can easily counter negative pressure in the middle ear, with negligible impact on middle ear mechanics, making a good balance between the graft stability and acoustic sensitivity.Thus to conclude, we advocate the use of cartilage graft as a substitute for fascia graft in all feasible cases as well as in complicated situations to improve the success rate of type I tympanoplasty, without compromising on the hearing improvement, as seen in our study.

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Authors' Contributions All authors have contributed equally in the research work of our study.

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Data Availability Patients coming to our hospital were included and the results were compiled.

Declarations

Statement of Ethics Our work involved the routine surgery being done in our department for a long time. So, ethical approval was exempted for our study by our institute. The authors assert that the research was conducted ethically in accordance with the World Medical AssociationDeclaration of Helsinki. Also, proper consent has been taken from all the participants before including in the study.

Consent for Publication All authors have given the consent for publication of our work.

Competing Interests Nil.

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