

# Outcome of Myringoplasty Using Cartilage Perichondrium Composite Graft and Temporalis Fascia Graft: A Prospective Study

Sheikh Abdul Zeeshan<sup>1</sup>, Aftab Ahmed<sup>2</sup>, Syed Abrar Hasan<sup>3</sup>

<sup>1</sup>Junior Resident III, <sup>2</sup>Senior Resident, <sup>3</sup>Professor,  
Department of Otorhinolaryngology, J. N. Medical College, AMU, Aligarh, UP, India.

## ABSTRACT

**Aims:** To compare the efficacy of temporalis fascia and cartilage perichondrium composite grafts used in the patients with chronic otitis media undergoing myringoplasty in terms of graft uptake, audiological gain and retraction of graft after successful uptake.

**Subjects and Methods:** A prospective study comprised of 100 patients suffering from chronic otitis media inactive mucosal disease was conducted at a Tertiary care referral hospital. Patients attending the Otorhinolaryngology out patients department were considered for this study. Myringoplasty was performed by underlay technique using temporalis fascia or cartilage perichondrium composite graft in patients suffering from chronic otitis media. Permeatal or postaural approach was used for performing myringoplasty. Evaluation was done in terms of uptake of the graft, post-operative hearing status and the post-operative retraction of the neotympanum for different graft materials used. The patients were followed up for a period of 12 weeks.

**Results:** The successful closure of tympanic membrane perforation was higher with cartilage perichondrium composite graft material; however the difference was not statistically significant. The successful closure of tympanic membrane perforation with both cartilage perichondrium composite graft and temporalis fascia graft was only just higher in permeatal technique with statistically insignificant difference. The rate of retraction of the neotympanum following successful closure of the tympanic membrane perforation was higher with temporalis fascia graft with statistically insignificant difference. The audiological improvement following myringoplasty with both the graft materials used was noted at 6th and 12th week. The preoperative and post-operative AB gap difference was

statistically significant at 6th and 12th weeks for both the graft materials. The audiological gain was found to be marginally better with temporalis fascia graft material at 6th and 12th week as compared to cartilage perichondrium composite graft, however this audiometric improvement was not statistically significant.

**Conclusions:** There was no statistically significant difference in either graft uptake or post-operative hearing in the patients undergoing myringoplasty by temporalis fascia and cartilage perichondrium grafts. The rate of retraction of the neotympanum was more in the patients undergoing myringoplasty by use of temporalis fascia graft. The results of the myringoplasty by permeatal and postaural approach were not affected by the approach used for performing the surgery.

**Key Words:** Cartilage perichondrium composite graft, Chronic otitis media, Myringoplasty, Temporalis fascia graft.

## \*Correspondence to:

**Dr. Aftab Ahmed,**  
Senior Resident,  
Department Of Otorhinolaryngology,  
J. N. Medical College,  
Aligarh Muslim University, Aligarh, India.

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## INTRODUCTION

Chronic otitis media has been an important middle ear disease since prehistoric times. Its incidence appears to depend to some extent on race and socioeconomic factors.<sup>1</sup> Poor living conditions, overcrowding, poor hygiene and malnutrition have been suggested as a basis for the wide spread prevalence of chronic otitis media in developing countries. Patients suffering from chronic otitis media of mucosal type with permanent perforation are handicapped not only because of hearing loss but also from recurrent otorrhea.<sup>1,2</sup>

Tympanoplasty is the surgical technique for the management of chronic otitis media tubotympanic type (chronic otitis media, mucosal type).<sup>3-5</sup> Perforation of tympanic membrane with intermittent discharge and hearing loss of conductive type are the indication of tympanoplasty.<sup>4,5</sup> The aim of operation includes perforation closure with a dry stable grafted membrane and improvement in hearing levels.

Temporalis fascia has long been considered as the ideal graft material for tympanic membrane perforation due to its healing and

acoustic properties.<sup>6</sup> Heerman HJ<sup>7</sup> was first to consider temporalis fascia as a graft material. Storrs<sup>5</sup> successfully employed it thereafter. Its advantages being available from the same incision, sufficiently large availability, its thinness, relative strength and its physiological identity to tympanic membrane.<sup>5,6</sup> Temporalis fascia has long been considered as the ideal graft material for tympanic membrane perforation due to its healing and acoustic properties. However, in situations such as recurrent perforation, total perforation, and chronic mucosal dysfunction or severe atelactatic tympanic membrane, fascia may undergo atrophy and result in graft reoperation.<sup>3,4</sup>

The concept of grafting tragal cartilage and perichondrium was introduced by Goodhill V.<sup>8</sup> The cartilage perichondrium composite grafts are relatively new graft material. The advantages of cartilage perichondrium are, readily availability in operative field, large graft can be harvested from tragus and concha, its own blood supply, easily shapeability, low metabolic rate and low extrusion rate.<sup>6,8</sup> Cartilage perichondrium composite graft would theoretically work well in above mentioned conditions, being tougher and easily neovascularised. The incorporated cartilage would give it the necessary stiffness and mechanical stability to avoid retraction. Also, it has a low metabolic rate and good acceptance in the middle ear.<sup>9,10</sup> Concerns have been raised about stiff nature of cartilage, as it could reduce the vibratory properties of neotympanum. However, adequate thinning of the cartilage seems to overcome this problem.

There are three recognized surgical approaches accessing the tympanic membrane for myringoplasty; endaural, postauricular, permeal/transcanal.<sup>5</sup> In general, the site of perforation and surgeon's experience determine the favoured approach. The endaural approach is preferred for posteriorly based or central perforations, whereas the post-aural approach allows more superior access to anteriorly based perforation. The permeal approach is an option for small central perforation in which the ear canal is wide enough to allow good visualization of the tympanic membrane through an ear speculum.

In our study, we have compared the grafting and acoustic properties of temporalis fascia with cartilage-perichondrium (composite graft) especially in ears with large perforation and an unfavourable eustachian tube function.

## MATERIALS AND METHODS

The study was prospective in nature and was carried out from January 2014 to July 2015. Patients attending outpatient Department of Otorhinolaryngology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India were considered for this study.

The patients were subjected to detailed history, general examination, systemic examination and local examination which included clinical examination of ear, nose, paranasal sinuses, larynx and pharynx. Patients with obvious ossicular dysfunction, external ear pathology were excluded from the study. Patients with ear discharge were initially treated conservatively and were included when their ear became dry for 6 weeks. The complete otological evaluation was done. Any patient requiring ossiculoplasty were excluded. Hearing impairment was assessed by pure tone audiometry with or without masking. The available four frequency (i.e 0.5,1,2 and 4 khz), preoperative, air bone gap

were recorded for each case. 100 patients (of either sex) who fulfilled the inclusion criteria were considered for the study.

## INCLUSION CRITERIA

1. Age group 15 – 50 years.
2. Chronic otitis media mucosal variety, inactive for atleast 6 weeks.
3. Intact middle ear conducting mechanism.
4. Adequate cochlear reserve.

## EXCLUSION CRITERIA

1. Age <15 years and >50 years.
2. Patients having tympanosclerosis, ossicular chain disorder, presence of cholesteatoma and retraction pocket.
3. Patients with sensorineural deafness.
4. Patients with complications of chronic otitis media.
5. Patients having sinonasal pathology like chronic sinusitis, allergic rhinitis etc.
6. Patients having any systemic illness like diabetes mellitus, hypertension etc.

## DATA COLLECTION TECHNIQUE AND TOOLS

The patients were classified as per the following criteria:

1. The patients were classified on the basis of age, gender and rural/urban population.
2. The patients were classified on the basis of duration of dry ear prior to surgery.
3. Patients were also grouped according to surgical technique.
4. Graft material: Patients were also grouped according to graft material used (temporalis fascia or cartilage perichondrium composite).

In all patients, temporalis fascia or cartilage perichondrium composite was used as graft material. Underlay technique was adopted in every case. In patients with bilateral ear disease operation was performed in one ear at a time. All the patients included in the present study were operated by the same surgeon and the surgical technique remained same throughout the period of study.

## DATA ANALYSIS

Data was analyzed by using SPSS 20 and SAS. In order to perform adjusted comparisons logistic regression models (for calculating odds ratio) and repeated measure regression models (for calculating adjusted mean difference) were used. Odds ratio with 95% confidence interval (CI), adjusted mean differences and P values as presented in results. P value of < 0.05 was considered significant while p value <0.01 was considered highly significant.

## RESULTS

The present study was carried out for a period of one and half year from January 2014 to July 2015. The study included 100 patients who underwent type-1 Tympanoplasty for chronic otitis media (mucosal type). Out of total 100 patients 39(39%) were male and 61 (61%) were female and highest prevalence was in age group of 15-25 yr. This group had 54 (54%) of total 100 patients. Table-1 is showing summarization of cases on the basis of demographic and other variables.

## TYMPLASTY SUCCESS RATES FOR DIFFERENT TYMPANIC MEMBRANE GRAFTING MATERIALS

At 6 weeks and 12 weeks, observation on otoscopic examination graft take up was graded as follows:

**Group 1:** Graft taken up- if no remnant perforation in any quadrant.

**Group 2:** Graft partially taken- if perforation remains in any quadrant.

**Group 3:** Graft not taken- if perforation remains as such.

GROUP 1 was considered as successful closure of perforation while GROUP 2 & 3 while considered as failure.

At 6 weeks 86 patients had successful graft uptake (44 Using cartilage perichondrium composite graft and 42 using temporalis

fascia graft) and by the end of 12 weeks all 86 of these patients had successful perforation closure. The success rates for different graft materials and approaches used at both 6 and 12 weeks were the same and they are summarized in table-2.

The average success rate using cartilage perichondrium composite graft by both techniques was 88.0% and average success rate using temporalis fascia graft by both techniques was 84.0%. The overall success rate by both techniques was calculated as 86.0%.

**Table 1: Classification of cases on the basis of demographic and other variables**

	NO. OF CASES	PERCENTAGE
<b>1. AGE GROUP (YEARS)</b>		
15-25	54	54.0%
26-35	31	31.0%
36-50	15	15.0%
<b>2. SEX</b>		
MALE	39	39.0%
FEMALE	61	61.0%
<b>3. POPULATION</b>		
RURAL	66	66.0%
URBAN	34	34.0%
<b>4. DURATION OF DRY EAR</b>		
6 WEEKS-8WEEKS	69	69.0%
MORE THAN 8 WEEKS	31	31.0%
<b>5. GRAFT MATERIAL USED</b>		
CARTILAGE PERICHONDRUM	50	50.0%
TEMPORALIS FASCIA	50	50.0%
<b>6. SURGICAL TECHNIQUE</b>		
POST AURAL	66	66.0%
PER MEATAL	34	34.0%

**Table 2: Success rates for different graft materials and approaches used (at both 6 and 12 weeks)**

VARIABLE	CASES	PERFORATION CLOSURE	SUCCESS RATE
<b>GRAFT MATERIAL</b>			
1.TEMPORALIS FASCIA	50	44	88.00%
2.CARTILAGE PERICHONDRUM	50	42	84.00%
TOTAL	100	86	86.00%
<b>TECHNIQUE</b>			
1.POST AURAL	66	56	84.84%
2.PER MEATAL	34	30	88.23%
TOTAL	100	86	86.00%
<b>CARTILAGE PERICHONDRUM COMPOSITEGRAFT</b>			
1.POST AURAL	33	29	87.87%
2.PERMEATAL	17	15	88.23%
<b>TEMPORALIS FASCIA GRAFT</b>			
1.POST AURAL	33	27	81.81%
2.PERMEATAL	17	15	88.23%
TOTAL	100	86	86.00%

**STATISTICAL ANALYSIS TO EVALUATE SUCCESS RATE FOR DIFFERENT GRAFT MATERIALS AND APPROACHES USED**

The impact of cartilage perichondrium composite graft and temporalis fascia graft on the successful operative closure of the tympanic membrane perforations was measured on the basis of the mentioned observations. For each variable the total numbers of patients were divided into two groups:

**Group 1** included patients with successful closure of tympanic membrane perforation.

**Group 2** included patients with failure of closure of tympanic membrane perforation.

In order to perform adjusted comparisons logistic regression models (for calculating odds ratio) was used. Chi square test was applied for deriving p value for each variable to see its impact on successful operative closure of tympanic membrane perforation. The comparison of success rate for different graft materials and approaches used at both 6 and 12 weeks were the same and they are summarized in table-3.

**Table 3: Comparison of success rate for different graft material and approaches used (at both 6 and 12 weeks)**

	SUCCESSFUL CLOSURE	FAILURE OF CLOSURE	SUCCESS %	P VALUE	ODDS RATIO
<b>GRAFT MATERIAL</b>					
CARTILAGE PERICHONDRIMUM COMPOSITE	44(51.16%)	6(42.85%)	88.0%	0.86	1.12 (CL=0.33-3.83)
TEMPORALIS FASCIA	42(48.83%)	8(57.14%)	84.0%		
TOTAL	86	14	86.0%		
<b>APPROACHES USED</b>					
<b>CARTILAGE PERICHONDRIMUM COMPOSITE</b>					
1.POST AURAL	29(65.90%)	4(66.67%)	87.87%	P = 0.97	1.00 (CL=0.11-8.98)
2.PERMEATAL	15(34.09%)	2(33.33%)	88.23%		
TOTAL	44	6	88.00%		
<b>TEMPORALIS FASCIA</b>					
1.POST AURAL	27(64.28%)	6(75.0%)	81.81%	P = 0.56	1.61 (CL=0.41-6.34)
2.PERMEATAL	15(35.71%)	2(25.0%)	88.23%		
TOTAL	42	8	84.0%		

**Table 4: Comparison of audiological improvement at 6 & 12 weeks**

	GRAFT MATERIAL	CASES	PRE OP AB GAP	POST OP AB GAP	AUDIOLOGICAL IMPROVEMENT	P VALUE
<b>AT 6 WEEKS</b>	CARTILAGE PERICHONDRIMUM COMPOSITE	50	33.3	22.6	10.7	0.0001
	TEMPORALIS FASCIA	50	33.4	21.7	11.7	
<b>AT 12 WEEKS</b>	CARTILAGE PERICHONDRIMUM COMPOSITE	50	33.3	21.0	12.3	<0.001
	TEMPORALIS FASCIA	50	33.4	20.5	12.9	

**Table 5: Retraction of successful neotympanum at 12 weeks**

GRAFT MATERIAL	HEALTHY	RETRACTION	RETRACTION%	P VALUE	ODDS RATIO
CARTILAGE PERICHONDRIMUM COMPOSITE	43(53.09%)	1(20.0%)	2.27%	P=0.15	4.68 (CL=0.50-44.30)
TEMPORALIS FASCIA	38(46.91%)	4(80.00%)	9.52%		
TOTAL	81	5	5.81		

**MEAN, FOUR-FREQUENCY, AIR CONDUCTION AUDIOMETRY RESULTS FOR PATIENTS WITH SUCCESSFUL TYMPANOPLASTY**

Pure tone audiometry following successful closure of tympanic membrane perforation was done at 6 & 12 weeks and audiological improvement (taken as closure of air bone conduction gap) was measured in successfully completed type 1 tympanoplasties. AB gap (air – bone conduction gap) per case was calculated as mean of AB gap at four frequencies (500Hz, 1000Hz, 2000Hz & 4000 Hz) pre operatively and post operatively. For each variable mean preoperative and postoperative AB gap was calculated. The mean was calculated as sum of all preoperative AB gap values for each case divided by the total number of cases. Similarly mean was calculated for postoperative AB gap. Audiological improvement was calculated as difference of mean postoperative AB gap and mean preoperative AB gap.

Out of 100 patients 86 patients (44 + 42) had successful tympanic membrane perforation closure. Audiological improvement was assessed in these 86 patients at 6 weeks and 12 weeks.

The mean pre-operative AB gap of 50 patients using cartilage perichondrium composite as graft material was calculated as 33.3 db (range 28 -38 db). The mean post-operative AB gap at 6 weeks was 22.6 db and at 12 weeks was 21.0 db.

The mean pre-operative AB gap of 50 patients using temporalis fascia as graft material was calculated as 33.4 db (range 28 -38 db). The mean post-operative AB gap at 6 weeks was 21.7 db and at 12 weeks was 20.5 db.

**STATISTICAL ANALYSIS TO EVALUATE AUDIOLOGICAL IMPROVEMENT IN SUCCESSFUL CLOSURE OF TYMPANIC MEMBRANE PERFORATION USING VARIOUS GRAFT MATERIALS**

Paired t test was used to calculate p value to assess the audiological improvement outcome in successful closure of tympanic membrane perforation using various graft material. Paired t test was applied since data in each group corresponded to normal Gaussian data. The audiological improvement outcome was assessed both at 6 and 12 weeks. The comparison of audiological improvement at 6 & 12 weeks are summarized in table-4.

**RETRACTION OF SUCCESSFUL NEOTYMPANUM AT 12 WEEKS**

Thus at 6 week only 1 neotympanum using temporalis fascia graft has retraction while at 12 weeks 4 neotympanum using temporalis fascia and 1 neotympanum using cartilage perichondrium composite graft developed retraction. The results of retraction of successful neotympanum are summarized in table-5.

From the above observed values of different parameters and calculated p-values applying different tests of significance following results are derived:

The success rate of type 1 tympanoplasty in our study was 86%.

The successful closure of tympanic membrane perforation was higher with cartilage perichondrium composite graft material (88.0% v/s 84.0%). However the success percent was not statistically significant with odds ratio 1.12 (CI 0.33-3.83) and p=0.86.

The successful closure of tympanic membrane perforation with cartilage perichondrium composite graft was only just higher in permeal technique (88.23% vs 87.87%). However this difference in tympanic membrane closure success was also statistically insignificant with odds ratio 1.00 (CI 0.11-8.98) and p=0.97.

The successful closure of tympanic membrane perforation with temporalis fascia graft was also higher in permeal technique (88.23% vs 81.81%). However this difference in tympanic membrane closure success was also statistically insignificant with odds ratio 1.61 (CI 0.41-6.34) and p=0.56.

The audiological improvement following successful closure of tympanic membrane perforation with both the graft materials was noted at 6th and 12th week. The preoperative and post-operative AB gap difference was statistically significant at 6th and 12th weeks for both the graft materials used (for Cartilage Perichondrium Composite: 10.7 dB, p=0.0001 and 12.3 dB, p=0.0001 was the difference at 6 and 12 weeks respectively and for Temporalis Fascia Graft: 11.7 dB, p=0.0001 and 12.9 dB, p=0.0001 was the difference at 6 and 12 weeks respectively).

The audiological gain was found to be marginally better with temporalis fascia graft material at 6<sup>th</sup> and 12th week as compared to cartilage perichondrium composite graft. However this audiometric improvement was not statistically significant (at 6 weeks gain = 0.9 dB , p=0.06 and at 12 weeks gain= 0.5 dB , p= 0.12).

The rate of retraction of the neotympanum following successful closure of the tympanic membrane perforation was higher with temporalis fascia graft (9.52% vs 2.27%). However this difference in retraction of successful neotympanum was statistically not significant with odds ratio 4.68 (CI 0.50-44.30) and p=0.15.

**DISCUSSION**

Chronic otitis media is one of the most common diseases in our country. It is more prevalent in low socio-economic population, which may be due to overcrowding, poor hygiene and ignorance. The ear discharge is most common symptom in chronic otitis media followed by hearing loss of conductive type. The task to restore conductive deafness has always fascinated the otologists but it was Berthold in 1978<sup>11</sup> who first time successfully closed perforation with a full thickness skin graft. Since then numerous developments have taken place using different techniques and materials. In addition, the operating microscope has also revolutionized the whole concept of management of perforated tympanic membrane.

The present study has been undertaken to compare the audiological and graft uptake results of myringoplasty using cartilage perichondrium composite and temporalis fascia graft. The study was done by analyzing the results of 100 patients of chronic otitis media (mucosal type) with varying degree of disease and conductive deafness. Out of 100 cases of tympanic membrane perforations, 50 were operated upon for type 1 tympanoplasty with cartilage perichondrium composite graft by underlay technique and 50 were operated upon for type 1 tympanoplasty with temporalis fascia graft by underlay technique. The tympanic membrane perforation was classified according age, gender and rural/urban population, duration of dry ear prior to surgery, according to surgical technique and according to graft material (temporalis fascia or cartilage perichondrium composite graft) as discussed in material & methods & its impact on tympanic membrane perforation closure was assessed.

The cases were studied post operatively for:

1. Graft uptake at 6 weeks and 12 weeks
2. Audiological improvement at 6 and 12 weeks
3. Retraction of successful neotympanum at 12 weeks

In our study, most of the cases were of younger age group (54%). These cases presented in the second and third decades of the life. This is in accordance with Srikrishna BH et al (2013)<sup>12</sup> and Bijan Basak et al (2014)<sup>13</sup> who also reported highest prevalence in second and third decades of life in their groups of 600 and 1717 patients respectively. This might be due to an increase in the general level of awareness among this age group of people. Most patients were concerned about the hearing loss and ear discharge. The remaining few in middle age group were worried about their social life.

In our study which included 100 patients, 39 (39%) are males and 61 patients (61%) are females. Females are thus relatively more affected by the disease. Our result is in concurrence with J D Wasson et al (2009)<sup>14</sup> who reported 54% females and 46% males and Yadav et al (2011)<sup>15</sup> who also found 54.8% females and 45.2 % males suffering from the disease. However our study was not in concurrence with the study conducted by Ahmad M et al (2010)<sup>16</sup> who reported 54.2% males and 45.8% females in their group of 120 patients.

Majority of cases (66%) were from rural area and of low socio-economic status. This is in accordance with Mohammad Shafiqul Islam et al (2010)<sup>17</sup> who found 65.33% rural and 34.67% urban prevalence in their study. This might be due to ignorance on the part of patients, poverty and inadequate specialized medical facilities in our rural areas. This was further proved by the fact that as many as 59% of patients had long duration of the disease (5-10 or more years) and had ignored their ear problem for that long duration.

Type 1 tympanoplasty was performed and all the patients were evaluated for graft uptake at 6 weeks. 86 of 100 patients (44 with cartilage perichondrium composite and 42 with temporalis fascia graft) showed complete graft uptake and were considered as success while rest 14 had either graft failure or had graft uptake with some deficiency. These 14 patients were considered as failures. The operative closure success rate of type 1 tympanoplasty was calculated as 86.0%. Success rate with use of cartilage perichondrium composite graft was 88.0% and with temporalis fascia graft was 84.0%.

The success rate was in accordance with various studies conducted on outcome of tympanoplasty in children and adults.

Palva et al (1987)<sup>18</sup> reported 97% success of tympanic membrane repair while J D Wasson (2009)<sup>14</sup> showed success of 80.5% in their study.

Rizer et al (1997)<sup>19</sup> in a retrospective study of tympanoplasty with underlay technique using temporalis fascia reported 88.8% tympanic membrane perforation closure rate.

Mukherjee et al (1997)<sup>20</sup> showed grafting success with tragal cartilage perichondrium composite graft to be 84.0% and with temporalis fascia graft to be 68.0%.

Dornhoffer J et al (2003)<sup>21</sup> in their study of 1000 patients concluded that Cartilage tympanoplasty achieves good anatomical and audiologic results when pathology and status of the ossicular chain dictate the technique utilized. Umopathy et al (2003)<sup>22</sup> reported a success rate of 90.0%. Karkanevatos et al (2003)<sup>23</sup> reported a success rate of 83.3% which also compares favorably with this study.

Hung et al (2004)<sup>24</sup> showed graft integration rate of 85.7% in children and 82.4% in adults.

#### **IMPACT OF TECHNIQUE ON SUCCESSFUL OPERATIVE CLOSURE**

Post aural approach was used in majority of the patients (66) while permeal approach was used in rest of the patients (34).

Our results were also in accordance with the findings of Dinesh Kumar Sharma et al (2009)<sup>25</sup> where they compared all three approaches, permeal, endaural and postaural, in 90 cases of myringoplasty and found that there was no significant difference in graft uptake and improvement in hearing in all the three approaches. The overall success rate was 81.1%, and significant improvement in post-operative patients. This suggests that neither of two surgical approaches is optimal over the other in tympanoplasty.

#### **IMPACT OF GRAFT MATERIAL ON SUCCESSFUL OPERATIVE CLOSURE**

In our study of 100 patients, 50 perforations were classified as undergoing type 1 tympanoplasty with cartilage perichondrium composite graft and 50 perforations were classified as undergoing type 1 tympanoplasty with temporalis fascia graft. The success rate of tympanic membrane perforation closure following type 1 tympanoplasty was 88.0% (44 out of 50) for cartilage perichondrium composite graft and 84.0% (42 out of 50) for temporalis fascia graft. Although lower success rates were observed for patients with temporalis fascia graft, statistical analysis demonstrated no significant difference in surgical success rates between both the graft materials [odds ratio 1.12 (CI 0.33-3.83), p=0.86]. Thus, on the basis of this study, the difference in the use of the two types graft materials in successful type 1 tympanoplasty was not significant and comparable.

Our study is in accordance with the study conducted by Sapci T et al (2006)<sup>26</sup> who concluded success rates of 92.0% with cartilage perichondrium composite grafts and 85.0% in temporalis fascia group. The difference was also not statistically significant.

#### **AUDIOLOGICAL GAIN FOLLOWING SUCCESSFUL CLOSURE**

86 patients who had successful operative closure were evaluated for audiometric improvement at 6 and 12 weeks. The mean pre-operative AB gap of 50 patients with cartilage perichondrium composite graft was 33.3 db (range 28db to 38 db) and the mean pre-operative AB gap of 50 patients with temporalis fascia graft was 33.4 db (range 28db to 38 db). After tympanoplasty the mean post-operative AB gap of these patients was 22.6 db at 6 weeks and 21.0 db at 12 weeks for cartilage perichondrium composite graft and 21.7 db at 6 weeks and 20.5 db at 12 weeks for temporalis fascia graft. The overall improvement of 10.7 db at 6 weeks (p=0.0001) and 12.3 db at 12 weeks (p=0.0001) for cartilage perichondrium composite graft was statistically significant and the overall improvement of 11.7 db at 6 weeks (p=0.0001) and 12.9 db at 12 weeks (p=0.0001) for temporalis fascia graft was also statistically significant. Such achievement of an audiometric gain in hearing thresholds following successful myringoplasty has been widely demonstrated, both in paediatric and adult populations in various studies.

Jose Carlos Bolini di Lima et al (2011)<sup>27</sup> in their study of 39 patients found the mean preoperative air-bone gap decreased from 27.1 dB to 10.3 dB postoperatively which was statistically significant and similar to the result of our study. Nemer Al-Khtoum et al (2009)<sup>28</sup> in their study in 35 children found the mean pre-operative AB gap to be 27.4 db while post-operative AB gap was

11.4 db. This audiological improvement was statistically significant. The study conducted by Ashfaq Ahmed Shaikh et al (2009)<sup>29</sup> showed mean preoperative AB gap of 25 db which improved to 12 db post operatively. J D Wasson et al (2009)<sup>14</sup> in their study of 130 patients found mean pre-operative AB gap of 41.6 db which reduced to 34.8 db post operatively. The audiological improvement of 6.8 db was statistically significant. Achievement of an audiometric gain in hearing thresholds following successful myringoplasty has also been documented by Umopathy N et al (2003)<sup>22</sup>, Gierak et al (2004)<sup>30</sup>, Yetiser S et al (2009)<sup>31</sup> and M.T.Kalcioglu et al (2013)<sup>32</sup>.

Based on these results, we concluded that there was a statistically significant improvement in the quality of post-operative hearing of patients undergoing tympanoplasty ( $p < 0.001$ ) with both types of graft material. We believe this improvement was due to graft integration and better conditions in the middle ear and ossicular chain as a result of surgery. The clinical examination revealed significant subjective improvement in hearing. The Rinne's was positive in most of the cases and absolute bone conduction test & Schwabach's test normal in all the post-operative cases. The restoration of normality of the drum might be the cause of this improvement. The improvement in hearing may also be due to fact that the transformer mechanism, phase difference and effective surface area (Helmholtz, 1920) of tympanic membrane were restored to normal.

#### **IMPACT ON AUDIOLOGICAL OUTCOME BETWEEN BOTH THE GRAFT MATERIALS**

In our study the audiological gain was found to be marginally higher with temporalis fascia graft material at 6th and 12th week as compared to cartilage perichondrium composite graft (Temporalis fascia graft 6th week-21.7 db and 12th week-20.5 db and cartilage perichondrium composite graft 6th week-22.6 db and 12th week-21.0 db) However this audiometric improvement was not statistically significant (at 6 weeks gain = 0.9 dB,  $p=0.06$  and at 12 weeks gain= 0.5 dB,  $p=0.12$ ).

In 2004, Gierak et al<sup>30</sup> performed 112 cases with cartilage and 30 cases of temporalis fascia. They showed that there was no significant hearing difference between both groups which is in accordance to our study.

Yetiser S et al (2009)<sup>31</sup> who in their study of 113 patients undergoing type 1 tympanoplasty with tragal cartilage perichondrium composite graft and temporalis fascia graft concluded the average air and bone thresholds and air-bone gap were found to be statistically different in cartilage group as compared to those in the temporalis fascia group. Our study is contradictory to this.

Our study is in accordance with the study performed by M.T.Kalcioglu et al<sup>32</sup> who in long term follow up of 3 years in 77 patients undergoing cartilage perichondrium composite graft and temporalis fascia graft found no statistical difference in the audiological outcome between both the graft material.

#### **IMPACT OF RETRACTION RATE BETWEEN BOTH GRAFT MATERIALS**

In our study post-operative retraction was found to be marginally higher in successful neotympanum with temporalis fascia graft material at 12th week as compared to cartilage perichondrium composite graft (Temporalis fascia graft retraction- 9.52%; cartilage perichondrium composite graft retraction- 2.27%)

However this retraction rate was not statistically significant [odds ratio=4.68 (CI 0.50-44.30),  $p=0.15$ ]

Our study is in accordance to S Mukherjee et al (1997)<sup>20</sup> who in their study of 50 cases found lesser long term retraction rates with tragal cartilage perichondrium composite graft as compared to temporalis fascia graft.

Our study also is in accordance with study conducted by Sunita Chhapola et al (2012)<sup>6</sup> in 132 patients who found more retraction in temporalis fascia graft neotympanum compared to cartilage perichondrium graft neotympanum.

#### **CONCLUSION**

Type 1 Tympanoplasty / Myringoplasty was done in 100 cases of chronic suppurative otitis media (safe type) by underlay technique using cartilage perichondrium composite graft in 50 cases and temporalis fascia graft in 50 cases via post aural or permeal approach.

All the patients fulfilled the accepted criteria for tympanoplasty. Follow-up of the cases was done at 6 weeks and 12 weeks after operation. The following conclusions were drawn from this study:

1. Chronic suppurative otitis media (safe type) is more common in younger age (54%) and rural population (66%) with low socio-economic status in this part of country.
  2. In our study of 100 cases, females (61%) were affected more than males.
  3. The overall success rate for graft take up was 86% at the end of 3 months of follow-up.
  4. The successful closure of tympanic membrane perforation was higher with cartilage perichondrium composite graft material (88.0% v/s 84.0%). However it was not statistically significant [odds ratio 1.12 (CI 0.33-3.83),  $p=0.86$ ].
  5. The permeal technique offered better successful closure of tympanic membrane perforation with both cartilage perichondrium composite graft (88.23% v/s 87.87%) and temporalis fascia graft (88.23% v/s 81.81%). But this difference was statistically insignificant in both [odds ratio 1.00 (CI 0.11- 8.98),  $p=0.97$  and odds ratio 1.61 (CI 0.41-6.34),  $p=0.56$  respectively]
  6. The pre and post-operative audiological difference following successful myringoplasty with both the graft materials was significant (for Cartilage Perichondrium Composite: 10.7 dB,  $p=0.0001$  and 12.3 dB,  $p=0.0001$  was the gain at 6 and 12 weeks respectively and for Temporalis Fascia Graft: 11.7 dB,  $p=0.0001$  and 12.9 dB,  $p=0.0001$  was the gain at 6 and 12 weeks respectively).
  7. The audiological gain was found to be marginally better with temporalis fascia graft at 6th and 12th week as compared to cartilage perichondrium composite graft with no statistically significant difference (at 6 weeks gain = 0.9 dB,  $p=0.06$  and at 12 weeks gain= 0.5 dB,  $p=0.12$ ).
  8. The rate of retraction of the successful neotympanum was higher with temporalis fascia graft (9.52% v/s 2.27%). However this difference was insignificant with odds ratio 4.68 (CI 0.50-44.30,  $p=0.15$ ).
- Myringoplasty is an operative procedure done for repairing perforated tympanic membrane and thereby improving hearing. Various studies have been done in the past to assess the impact of various factors on successful outcome of the procedure. On the basis of our study neither of the two graft material had an

advantage over the other on the success rate of the procedure along with the type of approach/technique used. Significant audiological improvement was found following successful closure of tympanic membrane perforation. However neither of the two grafts material offered better audiological gain than the other. Therefore cartilage perichondrium composite graft can be considered a viable alternative to temporalis fascia graft.

The retraction of neotympanum was higher with temporalis fascia graft than with cartilage perichondrium composite graft but it was not statistically significant. However cartilage perichondrium composite can be considered of some value to prevent long term retraction and reperforation. This is of importance in poor eustachian tube function where incorporation of the cartilage perichondrium composite would counteract the negative middle ear pressures.

### COMPLIANCE WITH ETHICAL STANDARDS

- All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
- Informed consent was obtained from all individual participants included in the study.
- Approval was taken from the Institutional Ethics Committee before starting this prospective study.

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