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A STUDY OF TEMPORALIS FASCIA GRAFT VERSUS COMPOSITE GRAFT IN TYMPANOPLASTY

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Abstract:

Background: Chronic suppurative otitis media (CSOM) is a widespread disease in developing countries, treated by tympanoplasty.Temporalis fascia is an excellent graft material, with characteristics of low basal metabolic rate, and morphology similar to normal tympanic membrane with good graft take up rate and better hearing result.The present study is aimed to compare the results of tympanoplasty with Temporalis fascia alone and with cartilage as a support to temporalis fascia (Composite graft).

Methods: This is a Prospective and Comparative study conducted at NRI INSTITUTE OF MEDICAL SCIENCES, VISAKHAPATNAM between December 2020 to October 2022.Sample size- 60 patients. All the patients between 15–60 year age group satisfied the inclusion and exclusion criteria were included in the study.

Results: Out of 60 patients, 24 (40%) cases were in 16-30 years age group, 14(23.3%)cases were in 31-45 years age group and 22 (36.6%) were in 46- 60 years age group. 16-30 years age group patients are more in present study .Out of 60 patients, females are of 58.33% (35 cases) and males 41.67%(25 cases).The mean pre operative hearing was at 35.78 db while postoperative PTA after 6 weeks showed 18.44 db average . Out of 60 patients, in 56 cases (93.33%) graft uptake was good while the rest 4 cases had poor graft uptake (6.67%).Graft take up was equal in both the groups with 93.33%preoperative and postoperative air bone gap in the pure tone

audiometry in temporalis fascia graft group and composite graft group. Composite graft group has more hearing improvement compared to fascia graft group. Hearing improved in fascia group 16.45 db, in composite graft 18.23 db.

Conclusion: Composite graft (fascia from temporalis muscle and conchal cartilage) is an excellent graft material when compared to temporalis fascia as the cartilage is rigid & thick with faster healing and easy manipulation during the procedure.

Key words : Chronic suppurative otitis media (CSOM) , Tympanic membrane, Graft

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a widespread disease in developing countries, treated by tympanoplasty. This procedure is most common in otorhinolaryngology.[1] Tympanoplasty is defined as a surgical procedure that is used for repair of eardrum and middle ear pathology. Repair of tympanic membrane perforation when middle ear spaces, ossicles and mucosa, are free of disease is called Myringoplasty.Tympanoplasty is the reconstruction of the tympanic membrane, with/ without reconstruction of ossicles, to prevent reinfection and restore hearing ability[2]. Initially split and full thickness graft were used followed by perichondrium, cartilage, canal wall skin, vein, temporalis fascia graft, fat. Temporalis fascia is the preferred graft material now a days[3]. Temporalis fascia is an excellent graft material, with characteristics of low basal metabolic rate, and morphology similar to normal tympanic membrane with good graft take up rate and better hearing result. The present study is aimed to compare the results of tympanoplasty with Temporalis fascia alone and with cartilage as a support to temporalis fascia (Composite graft).

AIM OF THE STUDY

1) To assess the hearing improvement between Temporalis fascia graft andComposite graft in tympanoplasty.

2) To compare the percentage of graft uptake in Temporalis fascia graft and Composite graft in tympanoplasty.

MATERIALS AND METHODS

Study place: NRI Institute of Medical Sciences

Study design: Prospective and Comparative study

Duration of the study: From December 2020 to October 2022

Sample size: 60 patients

Selection subjects: between 15–60 year age group

Target population: patients who are attending OPD suffering with CSOM

Study variables- clinical examination, tuning fork tests, PTA.

This study has got Institutional Ethics Committee clearance wide file no/IEC/NRIIMS/A//2022/46 dated 14-12-2022.

INCLUSION CRITERIA:

1. Subjects with dry central perforation due to CSOM or trauma

2. Subjects with conductive hearing loss due to CSOM or trauma

3. Those given consent for study.

4. Age between 15-60 year of both sexes

5. Treated nose / para nasal sinus disease.

EXCLUSION CRITERIA:

1. Subjects with Wet perforation, mastoiditis, SNHL

2. Subjects not giving consent for study.

3. Chronic suppurative otitis media atticoantral disease, cholesteatoma.

4. Actively discharging ears

5. Pure tone audiogram evidence of mixed or sensorineural hearing loss

6. Other external or middle ear disease

METHODOLOGY:

All the eligible patients who satisfied the above-mentioned inclusion criteria are included in the present study. Patients were selected for particular procedure randomly. Post operative outcomes such as % of graft uptake, hearing improvement, air bone gap, post operative hospital stay in both groups are measured and correlated.

Preoperative evaluation:

1. Otoscopic examination, tuning fork tests, and pre operative PTA were done to

know the site and size of perforation, air bone gap and to determine the type and

severity of hearing loss.

2.A microscopic examination to determine the condition of middle ear mucosa and

otological examination

3. Cholesteatoma was ruled out.

4. The level of sigmoid plate and dural plate and the mastoid air cell system was evaluated with assist of X-Ray of the mastoids[4].

Investigations carried out in the study: Routine haematological investigations and viral screening .Audiometric analysis- Air conduction and bone conduction were performed. Average AB gap of each patient was calculated preoperatively and postoperatively at a frequency 500Hz, 1000Hz, 2000 Hz.X-ray both mastoids lateral oblique view.Otomicroscopy and otoendoscopy.Patient were admitted day before surgery, brief history taken, local examination of ear, nose, throat done as per proforma. Informed written consent obtained.

SURGICAL TECHNIQUE

Step 1- Position of the patient:

Supine position with the face turned to opposite side so that the operating ear is facing upwards. General anesthesia is preferred for children and apprehensive patients while local anesthesia with sedation for adults.

Postauricular area is injected with 1% lignocaine with 1:1,00,000 adrenaline along with all the four quadrants of external auditory canal.

Step 2- Harvesting temporal fascia:

Post auricular William Wilde's incision was given few mm posterior to the sulcus.

The incision can be extended superiorly to harvest temporal fascia.

Step 3 –Transcanal exposure:

Periosteum is incised after making ―Tshaped incision and elevated. External auditory canal is entered posteriorly. A self-retaining canal retractor was used to expose the bony canal and tympanic membrane.

Step 4 -Freshening the margins of perforation:

The margins of perforation are surrounded by squamous epithelium which prevents graft uptake. So it is freshened using sickle knife and removal of rim using micro scissors.

Step 5- canal incision and elevation of tympanomeatal flap:

The canal incision is based on location of perforation like anterior or posterior. For posterior perforation, U shaped incision made in bony canal wall. Superior incision was made at 11'o

clock position in left ear (1'o position for right ear) anterior and above to lateral process of malleus, extending up to the bony cartilaginous junction. Inferior incision was made at 7'o clock position in right ear (5'o clock position in left ear) just lateral to annulus and joined with the superior incision.Tympanomeatal flap was elevated and middle ear entered.

Step 6: Assessment of ossicular chain:

Each ossicle assessed individually for mobility.

Step 7: Graft placement:

a) 30 patients - temporalis fascia graft was placed.
b) 30 patients - composite graft (temporalis fascia+ conchal cartilage) was used.

Removal of pathology followed by preparation of graft bed by filling the middle ear

with ointment-soaked geofoam. Temporalis fascia graft kept under anterior remnant of tympanic membrane either lateral or medial to malleus handle and over theposterior canal wall.

Step 8- Repositioning of tympanomeatal flap:Tympanomeatal flap repositioned, graft stabilized by keeping the gel foam pieces. External auditory canal is filled with medicated aural pack. Postaural wound closedwith 3-0 plain catgut suture.

POSTOPERATIVE CARE:

Antibiotics, analgesic and antihistamines were given for 2 weeks. Patients were

advised not to blow nose and strain. Mastoid bandage was changed after 48 hours

and sutures were removed on the 7th postoperative day. Gel foam was placed in the

external auditory canal and left in situ for 2 weeks. On the 8th week, status of the

tympanic membrane was examined and PTA done to assess the auditory status.

Statistical analysis:

The mean and standard deviation are calculated for all continuous variables. Distribution of the variables under comparative study was assessed by student t-test for paired data. The association variables case chi- square test was applied. If p-value is less than 0.05 is taken as significant and p-value is less than 0.001 is taken as highly significant. Statistical software namely SPSS version 22.0 is used for statistical analysis and graphs are drawing by using Microsoft Excel.

RESULTS

Out of 60 patients, 24 (40%) cases were in 16-30 years age group, 14(23.3%)cases were in 31-45 years age group and 22 (36.6%) were in 46- 60 years age group. 16-30 years age group patients are more in present study.Out of 60 patients, females are of 58.33% (35 cases) and males 41.67%(25 cases).The mean pre operative hearing was at 35.78 db while postoperative PTA after 6 weeks showed 18.44 db average . Out of 60 patients, in 56 cases (93.33%) graft uptake was good while the rest 4 cases had poor graft uptake (6.67%).Out of 60 patients, in 30(50%) cases temporalis fascia graft was used. In rest 30(50%) cases composite graft was used .Out of 60 patients, graft uptake was good in 16-30 years age group 24 cases(42.8%), 12 cases(21.4%) in 31-45 years age group, 20 cases in (35.7%) in 46-60 age group. 2 cases in each group of 31-45 (3.5%) and 46-60 (3.5%) years had poor graft uptake. Out of 25 male and 35 female cases, graft uptake was good in 22 (88%) and 34(97.14%) cases respectively. Poor graft uptake in 3 males (12%) and 1 female (2.8%).Out of 60 patients, both the grafts were used in equal proportions in all age groups.

Out of 25 male cases, TF graft was used in 8 cases (32%) and composite graft in 17 cases (63%). 35 female cases, temoralis fascia graft used in 22 cases (63%) and composite graft in 13 cases (37%)Graft take up was equal in both the groups with 93.33%preoperative and postoperative air bone gap in the pure tone audiometry in temporalis fascia graft group and composite graft group.

Composite graft group has more hearing improvement compared to fascia graft group. Hearing improved in fascia group 16.45 db, in composite graft 18.23 db.

Table-1 Cases are distributed according to age group

AGE GROUP (YEARS)	FREQUENCY	PERCENTAGE
16-30	24	40
31-45	14	23.33
46-60	22	36.67
TOTAL	60	100

Age (Mean ± S.D) =38.28±12.

Fig 1: Age Distribution

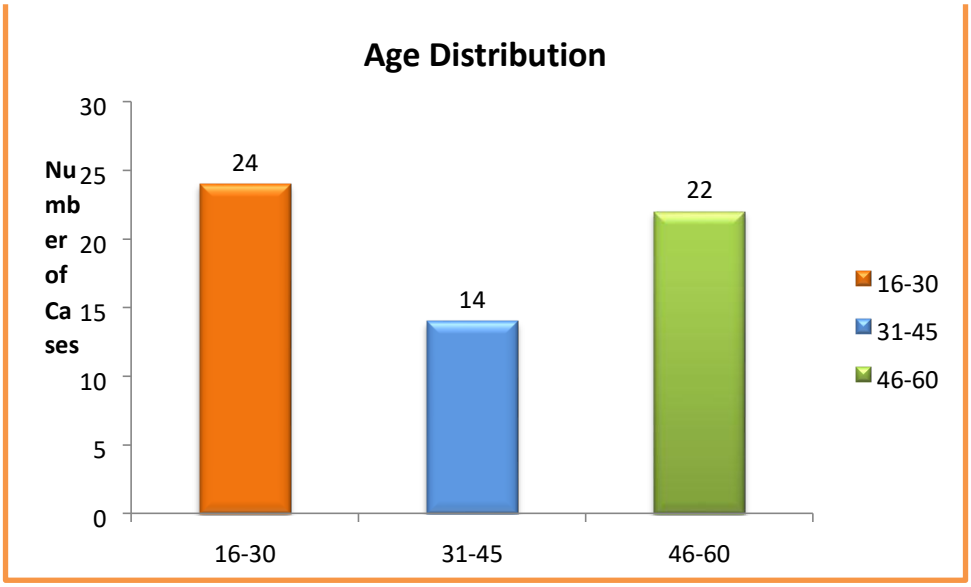


Table 2: Gender distribution

Sex	Frequency	Percentage
Male	25	41.67
Female	35	58.33
Total	60	100

Fig-2: Gender Distribution

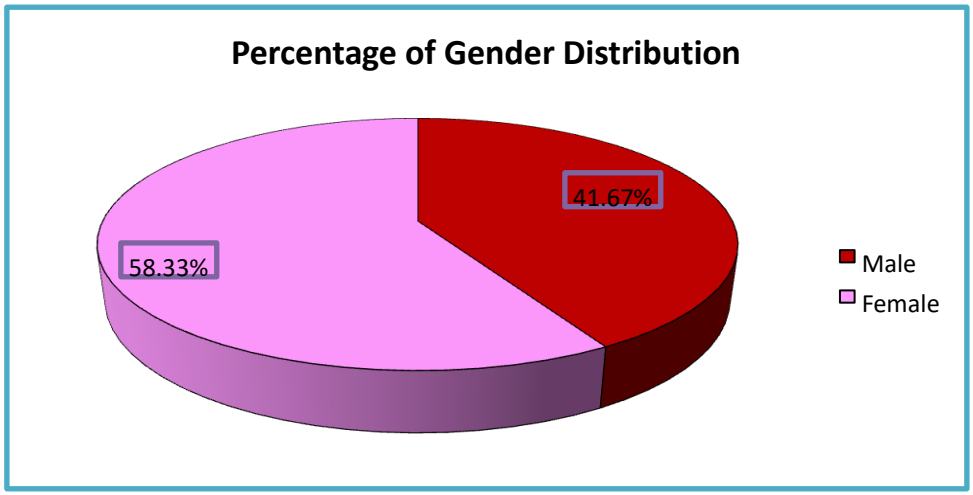


Table-3: PTA before and after Tympanoplasty

PTA	Mean	S.D.	S.E.	T-value	P-value
Before	35.78	2.33	0.30	33.05	0.000
After	18.44	3.2	0.41		

*p<0.05; Statistically Significant.

Fig -3: Means of PTA before and after Tympanoplasty

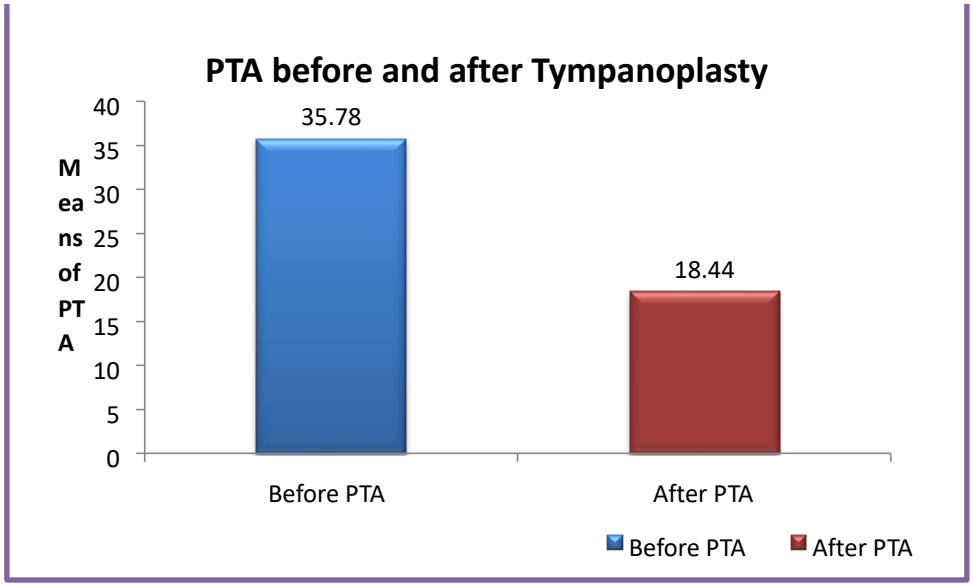


Table-4: Graft Uptake

Graft Uptake	Number of Cases	Percentage
Yes	56	93.33
No	4	6.67

FIG 4: Cases distribution and Uptake of graft

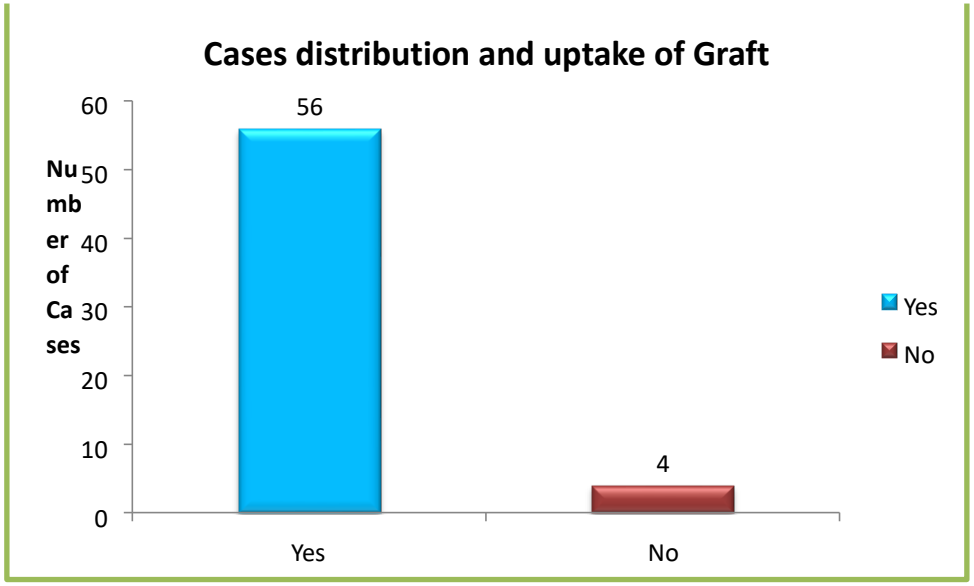


Table:5 Distribution of Type of graft

Type of graft	Number of cases	Percentage
TEMPORALIS FASCIA	30	50
COMPOSITE GRAFT	30	50
TOTAL	60	100

Fig-5: Distribution of Type of Graft

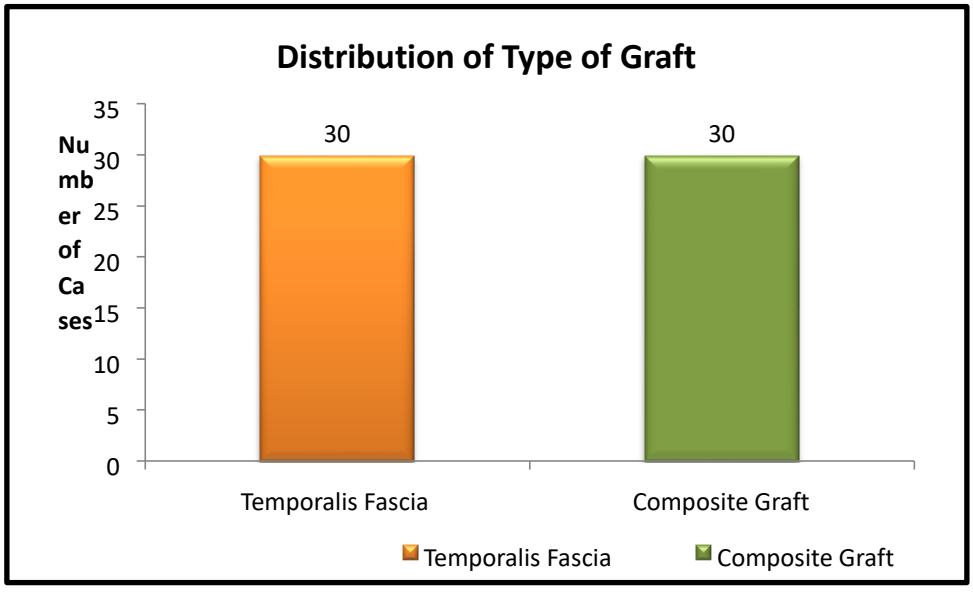


Table-6: Age vs Graft Uptake

Age	Graft Uptake	
	YES	NO
16-30	24 (42.8%)	0

31-45	12 (21.4%)	2 (3.5%)
46-60	20 (35.7%)	2 (3.5%)

Table-7: Gender vs Graft Uptake

Gender	Graft Uptake	
	Yes	No
Male	22 (88%)	3 (12%)
Female	34 (97.14%)	1 (2.8%)

Table-8: Age versus Type of graft

AGE	TYPE OF GRAFT	
	TEMPORALIS FASCIA	COMPOSITE GRAFT
16-30	12 (20%)	12 (20%)
31-45	7 (12%)	7 (12%)
46-60	11 (18%)	11 (18%)
TOTAL	30	30

Table-9: Gender vs Type of Graft

Gender	Type of Graft	
	TEMPORALIS FASCIA	COMPOSITE GRAFT

Male	8 (32%)	17 (68%)
Female	22 (63%)	13 (37%)

Table-10: Graft Uptake vs Type of Graft

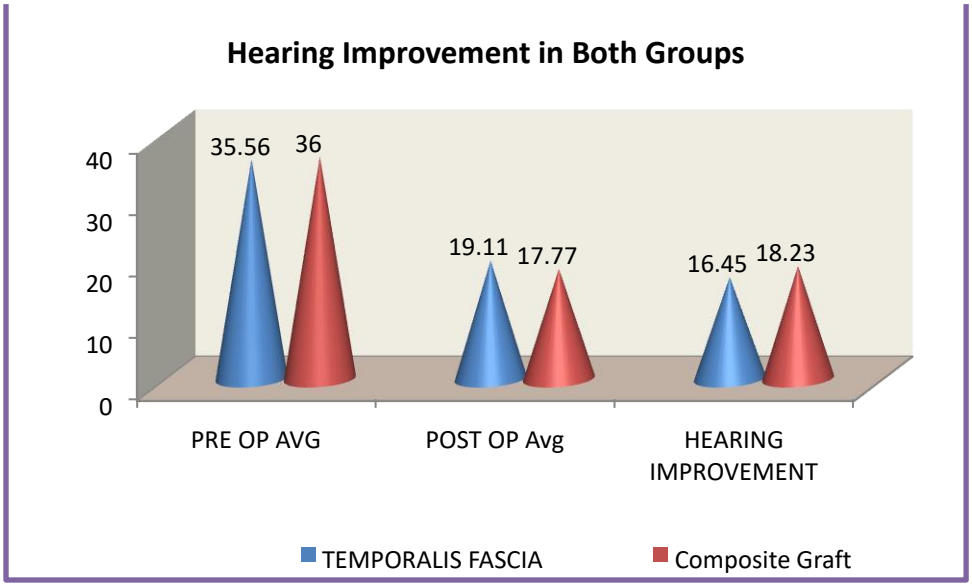
Graft Uptake	Type of Graft	
	TEMPORALIS FASCIA	COMPOSITE GRAFT
Yes	28 (93.33%)	28 (93.33%)
No	2 (6.6%)	2 (6.6%)

Graft take up was equal in both the groups with 93.33%

Table-11: Hearing improvement in both Temporalis Fascia and Composite Graft

Hearing status	Temporalis Fascia	Composite Graft
Pre op avg	35.56	36.00±2.36
Post op avg	19.11	17.77±2.84
Hearing improvement in db	16.45	18.23

Fig-6: Hearing improvement in both Temporalis Fascia and Composite Graft



DISCUSSION

In this present study, temporalis fascia graft and composite graft used in tympanoplasty were compared. In this study conducted on 60 patients, 30 patients selected for temporalis fascia graft and 30 patients selected for composite graft in a random manner. In the present study out of 60 cases, 24 cases in the age group of 16-30 years, 14 patients were between 31-45 years, 22 cases in the age group of 46-60 years. Out of 60 cases in these study 25 cases(41.67%) are males and 35 cases(58.33%) are females. Subjects were selected for this study, ensured with one month period of dry ear prior to surgery. Wet ear has poor graft take up rate. All patients underwent tympanoplasty by underlay technique. Present study was done to evaluate the hearing improvement and take up of graft between temporalis fascia and composite graft used in tympanoplasty. To compare the preoperative and postoperative air bone gap, assessment of graft uptake was done at the end of 6 month .In this study of 60 patients, 30 patients underwent temporalis fascia graft tympanoplasty, out of which 28 (93.3%) patients had a successfully repaired tympanic membrane. Other 30 patients underwent composite graft tympanoplasty,28 (93.3%) patients had successfully repaired tympanic membrane. Total of 60 patients 56 (93.3%) had successful graft uptake. Composite graft used in tympanoplasty has more hearing improvement ((18.23 db) compared to temporalis fascia graft (16.45db). In present study, out of 60 patients, 24 (40%) cases were in 16-30 years age group, 14(23.3%) cases were in 31-45 years age group and 22 (36.6%) were in 46-60 years age group. 16-30 years age group patients are more in present study themean age was (Mean±S.D)=38.28±12.42 yrs. The similar findings were noted in the Patil et al[(5),] Singh et al, Dornhoffer et al, Manasranjan rout et al.Inpatil study 41 (34.16%) cases in 12-20 years age group and less cases 10(8.33%) in age group between 51-60 years. In this study mean age was 29.8 year (range: 12-59 years). Similar results were observed in the study of Singh et al.[(6)]in this study 38% cases in 16-30 years age group mean age was 28.9 years (range: 13-48 years) and similar findings noted in Dornhoffer et al[(7)] In this study 36%

cases in 15-25 years age group. The mean age was 28 years (range: 9-57years).Similar observations seen in Manasranjan rout et al[8], in this study 44.34% in age group between 15-30 years.Out of 60 patients, 25 patients (41.67%) were males and 35 (58.33%) were Females seen in (Table-2) and Graph-2 . Both male and female patients gave consent for the use of fascia from temporalis muscle and composite graft material for tympanoplasty .Out of 25 males 8 cases (32%) used by temporalis fascia, 17 cases (68%) used by composite graft. In 35 female cases 22 cases (63%) used by fascia from temporalis fascia, 13 cases(37%) used by composite graft. These findings arecompared with tht study done by Manasranjan rout et.al[8], Total 300 cases wereselected , in which 182 cases (60.67%) were males, 118 cases (39.34%) were females .In present study temporalis fascia used in females (63%) more than temporalis fascia used in males (32%). In ROUT study temporalis fascia used in males (61.33) more than females (38%).Similar findings found in Caixia et al females are more in this study (48.88%). In Patil and Rout et al males are more in study.

TYPE OF GRAFT AND GRAFT UPTAKE:

The autogenous components used in this investigation included the temporalis fascia, tragalperichondrium. In present study total 60 members were selected, half 30 cases (50%) used by temporalis fascia, half 30 cases (50%) used by composite graft. Out of 60 members 56 cases graft uptake (93.33%) was good. In total 25 males cases 22 cases graft uptake was good. In total 35 female cases 34 cases graft uptake was good. Similar study seen in D.B. Singh[9].Residual perforation rates were equal among cartilage graft and TF graft. During 6th post operative week. But at the end of the 12 th week the residual perforation rates among the cartilage graft was drastically reduced than compared to the temporalis fascia graft. When compared to the temporalis fascia, the cartilage successfully integrated itself in the neotympanic membrane, overcoming the influences of different factors that affected the outcome of the myringoplasty. As a result it withshood the test time. The results in Manasranjan rout et al[8] study was 82.67% with temporalis fascia alone while 95.34% with composite graft.In Pradhan et al[10], study used by temporalis fascia alone success rate was 80% composite graft success rate was 96.7%.In Kulkarni et al[11] study the graft temporalis fascia along with cartilage success rate was 98.3%.

In Mundra et al([12],studied slices of cartilage with temporalis fascia graft take up rate was 98.94%Cartilage palisades and fascia in type 1 tympanoplasty comparison in children by Ozbek et al[13] in 2008 shows ―significantly more graft acceptance rate (100%) than with the fascia technique (70.2%).According to Mauri M, et al ― an evaluation of inlay butterfly cartilage tympanoplasty Show take up rate was 85.3% in the inlay cartilage tympanoplasty and 83.3% in overlay cartilage. According to Kulak Burun et al[14] island technique for correction of tympanic membrane perforation , perforation repair rates with cartilage and fascia group were 91.3% and 88.2%, respectively[14].According to Ben Gamra et al study, better results were seen in 97% of composite group as compared to 94% of the fascia group .There was more reliability on cartilage to repair tympanic membrane perforations and , cartilage using as a first choice in chronic otitis

media.[15]Yung M et al, study ―shows the graft take up rates of cartilage and fascia grafts at 2 years were 80% and 84.2%, respectively. There was no significant difference in the graft take rates or postoperative hearing between the two groups‖.Yung M, Vivekanandan S, Smith P temporalis fascia graft take up rate is more compare to cartilage graft. In our study fascia from temporalis fascia and composite graft take up rate is equal. In Ozbek et al[13]in 2008 and Murali M, et al, Kulak Burun et al, temporalis fascia graft take up was less than cartilage graft. In present study fascia from temporalis muscle and composite success rate is same. Onal K et al, Cartilage island flap and fascia in type I tympanoplasty shows-the graft take rate was 89.6% for the fascia group and 93.2% for the cartilage group.

HEARING ASSESMENT

Hearing improvement versus type of graft in previous studies and presentStudy.In our study, we have evaluated the hearing improvement in each group after 6 months of surgery. Onal K et al comparison of Cartilage island flap and Temporalis fascia in type I tympanoplasty shows Significant recovery was found in the postoperative pure-tone averages and air-bone gaps compared to preoperative thresholds. According to Kulak Burun et al[14]― with island technique for reconstruction of tympanic membrane perforation , perforation closure rates for cartilage and fascia group were 91.3% and 88.2%, respectively. The audiological outcomes revealed that the overall gains of 12.3 dB for the cartilage-perichondrium group and 12.7 dB for the fascia group ($p>0.05$). ― According to Ben Gamra et al[15]―successful closure of the tympanic membrane perforation in 97% of the cartilage group as compared to 94% of the fascia group. The average ACG was 21 ± 11 dB in cartilage group and 20 ± 22 dB in fascia group. There was great reliability on cartilage to close tympanic membrane perforations and , using cartilage as a first choice chronic otitis media was recommended.Yung M et al[16]shows the graft take rates of fascia and cartilage grafts at 2 years were 84.2% and 80%, respectively. The postoperative air-bone gaps and hearing gains at 2 years were 16.97 dB and 13.63 dB, respectively, in the fascia group and 20.63 dB and 12.60 dB, respectively, in the cartilage group. No significant difference in the graft take rates or postoperative hearing between the two groups‖.Intympanoplasty a comparative study of temporalis fascia and island cartilage by Bozdemir K, et al shows ―postoperatively the PTAs and eardrum repair was gavegood result with temporalis fascia compared to cartilage grafting .On specific- frequency comparisons, the pure tone thresholds at the frequencies of 0.5, 1 and 2 kHz gave good results with temporalis fascia. Although the pure tone recovery was very good at 4 kHz with temporalis fascia, the difference between the groups were not significant ($p > 0.05$). Temporalis fascia grafting gave good result in this study than conchal cartilage. (38)In present study the audiological outcomes showed significant hearing improvement in Fascia along with cartilage graft(18.23 db) was more compared to Temporalis Fascia (16.45 db) (Pvalue 0.0001<0.05-SIGNIFICANT) Doubts still exists in the minds of many surgeons with regards to the acoustic benefits of the cartilage . Most of the studies and many literatures suggested the audiological benefits of cartilage graft was gave better results than temporalis fascia. This is the outcome of current study. Dornhoffer studied cartilage graft with perichondrium in type I

tympanoplasty on 1997 Aug. His study ―Tympanic Membrane closure was achieved in all 22 patients who were undergoing cartilage reconstruction. These hearing gains were statistically significant ($P < 0.001$ in each case), but there was no statistically significant difference in hearing results between the cartilage and fascia .Matthew J. et al states air bone gap closures and speech reception threshold― in cartilage and fascia the differences were not statistically significant.The present study very similar with Michael et al in study of 1556 tympanic membrane grafting that there was no difference in graft up take, graft uptake depend on age of the patients. Postoperative impedence audiometry shows B curve in cartilage tympanoplasty. Which noticeably reduces ear canal volume, some patients complaining ear blocking symptoms for sometimes in cartilage. Pre operative PTA mean 35.78 db. Hearing loss increased with increase size of perforation. Similar findings were seen in Roychaudhuri[17]SohilVadiya et al[18], conducted study in Gujarat to differentiate the results of cartilage shield in tympanoplasty with TM fascia in type 1 tympanoplasty. Audiological improvement in both groups almost similar except at 8 kHz frequency where improvement seen more in TM fascia group than cartilage group.Kirazli T et al[19],study on results of hearing after cartilage tympanoplasty with island technique shows there were no statistically significant differences in the postoperative frequency-specific gains in air-bone gap between the cartilage andfascia .[20]The follow up period in majority of the studies including mine has been only 1 or 2 years .Thus a long term follow up is needed to exactly comment upon the acoustic benefits of cartilage graft over temporalis fascia.

CONCLUSION

Despite the various reviews in literature with regard to the advantages of cartilage as a graft material still it has not gained that much popularity as that of temporalis fascia and is being used only as a second option. It has become good choice only for high risk cases and not a routine alternative to temporalis fascia but , the cartilage used as the best grafting material as it is accessible, adaptable , negative middle ear pressures resistant, stable, elastic, well tolerated by the middle ear, resorption resistant. Therefore its use is recommended in less severe middle ear disorders, in which the functional outcome is more essential.To conclude, Composite graft (fascia from temporalis muscle and conchal cartilage) is an excellent graft material when compared to temporalis fascia as the cartilage is rigid & thick with faster healing and easy manipulation during the procedure.

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