A STUDY OF GRAFT UPTAKE AND HEARING IMPROVEMENT IN CARTILAGE TYMPANOPLASTY

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ABSTRACT

BACKGROUND

To evaluate the effectiveness of Cartilage as a grafting material in terms of graft uptake and postoperative hearing following Type I Tympanoplasty.

Tympanoplasty is a procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting commonly due after chronic otitis media and trauma.

MATERIALS AND METHODS

100 subjects were enrolled for the study for a period of 1 1/2 Years from 2015 to 2017 June. All patients between 15 to 60 Years having mucosal type of CSOM with central, subtotal perforation and conductive hearing loss <45dB underwent cartilage Tympanoplasty.

Patients were reviewed on 8th Postoperative day 6th and 12th Postoperative week. The graft uptake and postoperative hearing were evaluated. Statistical analysis was measured in terms of percentage and preposition.

RESULTS

The graft uptake on 42nd and 90th Postoperative day was 87.7% and 86.6% respectively. The results were statistically significant. The difference of mean preoperative 42nd and 90th Postoperative air bone gaps were 30.11 ± 1.66 dB, 18 ± 1.5 db.

CONCLUSION

The cartilage was found to be excellent grafting material in terms of both graft uptakes and hearing results after type I tympanoplasty.

KEYWORDS

Tympanoplasty, Tragal Cartilage, Temporalis Fascia.

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BACKGROUND

Tympanoplasty is a procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting, commonly due to chronic otitis media and trauma.

Surgery of the TM dates back as far as the 17th Century when Binzer (1640), described the first attempt at repair of a TM perforation with a pig's bladder. Over the next century, most of the advances in otologic surgery were focused on the mastoid to treat life threatening infections. In 1853, Toynbee placed a rubber disk attached to a silver wire over a perforation. He reported significant improvement in hearing with this method. Later Yearsley (1863) placed a cotton ball over a perforation and in 1877 Blake proposed

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the paper patch which is still used today for preoperative evaluation of potential hearing improvement. The earliest treatment of TM perforations with chemical cautery was performed by Roosa (1876) and Okneuff (1895). In the literature, reconstructing tympanic membrane perforations was first described by Berthold¹ in 1878, and the term "tympanoplasty" was introduced in 1952 by Wullstein² and Zollner.³

Although tympanoplasty is a highly successful procedure in 70-90% of normally ventilated middle ears, the prognosis is poorer in cases with total dysfunction, adhesive processes, infection, tympanic fibrosis and defect of the entire tympanic membrane.^{4,5} A Tympanoplasty is fundamentally a tissue transference procedure. Various graft materials have been used to close tympanic membrane.

Many autogenous, several allogenous (homogeneous) and a few xenogenous graft materials have been used for ear drum perforation closure and reconstruction of the middle ear. 6

The major advantage of cartilage is its stiffness and bradytrophic metabolism, which make it particularly suitable for difficult conditions, such as subtotal perforations, adhesive otitis and reoperation.⁷

The mucosal type of disease may pass through acute, inactive, quiescent or healed stages. There is discharge in middle ear and external auditory canal with congestion of middle ear mucosa in acute stages. Absence of otorrhoea and normal looking middle ear mucosa are seen in inactive stages.⁸ Tympanoplasty was first described in 1952 by Wullstein and Zollner as the mainstay for tympanic membrane reconstruction. The grafts used to reconstruct the tympanic membrane are varied and range from homograft, heterograft, xenograft, autograft and isograft.⁹ The varied autografts used are skin,¹⁰ perichondrium¹¹

vein,¹² temporalis fascia,¹³ dura¹⁴ and cartilage.^{15,16,17}

Overbosch¹⁸ was the first to describe the microslice technique to improve the acoustic properties for a reconstructed tympanic membrane.

Currently indications of cartilage tympanoplasty include all revision cases as well as certain high risk primary tympanoplasties, which include a subtotal perforation, a perforation in a patient with a previously repaired cleft palate, and an ear draining at the time of surgery.

The present study was undertaken to assess the results of cartilage as graft material for the repair of the tympanic membrane perforation. As these graft materials are easily available in adequate amount, have good contour can be thinned down and possess good survival capacity. Being mesodermal in origin, they are free from the possibility of postoperative cholesteatoma. Type-I Tympanoplasty is a surgical procedure which intends to improve the quality of hearing and life. Assessment of the outcomes will help to determine the merits or demerits of a particular graft. Hence the present study.

Among South - East Asian Countries India has the maximum prevalence of 7.8% populations with CSOM. It is estimated that CSOM contributes to more than half to the global burden of hearing impairment. And among them about two third reside in developing countries. A study of 2000 children aged between 5-13 Yrs. attending health camps organized in 6 different districts of Nepal from January 2005 to December 2008, showed prevalence of CSOM as 7.6%. Unilateral disease is seen in 69.9% and 38.6% had active disease. 83% had CSOM-IT and only 58.8% attended hospital. The prevalence of CSOM in Nepal as quoted by Little et al study is 7.2% ¹⁹ and the prevalence of SCOM as guoted by Adhikari study was found to be 5.7& in the school children of government school children of government schools while it was 4.8% in the school children of private sector.

Bernal-Sprekelesen et al²⁰ conducted a retrospective study in 1992 to evaluate the long term anatomic and functional results after partial and total analogous cartilage palisade Type III Tympanoplasties to assess the efficacy of cartilage palisades in preventing recurrent cholesteatoma. Closure of the tympanic membrane was achieved in 98.3% or patients. The rate of recurrences of cholesteatoma was 2.2% it was concluded that the cartilage palisade technique is effective for the reconstruction of the tympanic membrane and also prevents new retractions and recurrences of cholesteatoma.²¹

Aims and Objectives

To evaluate the effectiveness of Cartilage as a grafting material in terms of graft uptake and post-operative hearing following Type I Tympanoplasty.

MATERIALS AND METHODS

Source of Data

All Patients attending Govt. ENT Hospital/Osmania Medical College, Hyderabad who had satisfied the inclusion criteria and exclusion criteria and exclusion criteria mentioned below were included in the study. Otoscopic examination and tuning fork tests, and preoperative pure tone audiometry (PTA) was done to know the perforation, degree of hearing loss, air bone gap. Audiometric analysis was one at the frequencies of 500 Hz, 1000 Hz, and 2000 Hz, Pre-Operative routine investigation were done. Postoperative PTA was done to assess outcomes such as improvement in hearing that is air bone gap closure are measured. These postoperative assessments are done at time interval of postoperative 42nd day and 90th postoperative day. The variables studies included - age, sex, size of perforations, preoperative and postoperative hearing, unilateral or bilateral perforation. All the selected patients were operated using 0 Degree wide angled endoscope assisted underlay technique. The tympanomeatal flap raise was superiorly based.

Inclusion Criteria

- 1. Age > 15 years and < 60 Years,
- 2. Mucosal type of CSOM with central, subtotal perforation.
- 3. Conductive hearing loss < 45 dB.
- 4. Eustachian Tube should be patent.
- 5. Quiescent and inactive Stage of CSOM.

Exclusion Criteria

- 1. Age < 15 Years and > 60 Years.
- 2. Squamosal type of CSOM, marginal and attic perforation.
- 3. Conductive hearing loss > 45 dB.
- 4. Previous ear surgery.
- 5. Eustachian tube obstruction.
- 6. Patient with sensorineural hearing loss.
- 7. Active stage of infection of the ear.
- 8. CSOM with intracranial complications.
- 9. HbsAg and HIV Positive Patients and other chronic inflammatory diseases that would interfere with wound healing.
- 10. Hypertension, Diabetes Mellitus, chronic cardiac illness, chronic renal failure patients, malignancies, and patients medically certified as unfit for the anaesthesia.

Method of Collection of Data

This study included patients of chronic otitis media, mucosal type, in Inactive or Quiescent stage. All these cases were operated during one and half years' time period from November 2015 to June 2017 in Govt ENT Hospital / Osmania Medical College, Hyderabad.

A detailed history followed by Complete clinical examination was done and 50 patients who compiled the

inclusion criteria of the study were selected for tympanoplasty Type I using Tragal Cartilage Graft. Informed consent was taken from each patient in their own vernacular.

Study Area

Hospital based study Govt. ENT Hospital / Osmania Medical College, Hyderabad.

Study Design

A Prospective Interventional study with follow up of Patients for 3 months.

Study Period

November 2015 to June 2017

Statistical Analysis

All the data was entered in MS excel sheet and subjected to statistical analysis. Quantitative data was measured in terms of Mean and Standard Deviation (S.D.) Quantitative data was measured in terms of Proportions and Percentages Prop and Post Op Data was analysed.

The suggested standard for the operation room setup while performing endoscopic tympanoplasty. The mobile endoscope cart is placed directly in front of the surgeon. The video monitor is positioned in the surgeon's direct line of vision. Patient was prepared for surgery. After the endoscope tip was sprayed with defogging solutions, the scope is inserted through the external auditory meatus.

After the assessment of tympanic membrane pathology, the tragus was injected with local anaesthetic 2% xylocaine with adrenaline (1:200 000). An incision along the free edge of medial side of the tragus was performed leaving 2 millimeter of cartilage in dome of tragus for cosmetics and the subcutaneous tissue was dissected to the lateral border of the cartilage and its perichondrium. The cartilage was then widely exposed on both its lateral and medical surfaces and then harvested devoid of perichondrium. The donor site was closed with vicryl 3/0 cutting body.

The endoscope was introduced into the car canal. The edges of the perforation were freshened and undersurface of the tympanic membrane was roughed using sickle knife and side knife, the endoscope was passed through the perforation into the tympanic cavity. Possible epithelial migration into the middle ear cavity or to the ossicles was visualized with endoscopes and was extirpated using sharp pick or sickle knife.

Using circular / round knife canal wall Rosen's incision given from 100 Clock to 20 clock positions in right ear or 20 Clock to 100 Clock in left ear at 1 cm. lateral to the tympanic membrane and tympanomeatal flap was raised interiorly. Middle ear was entered under the annulus near posteroinferior quadrant first as the attachment of the annulus tympanic us to sulcus tympanic us was less adherent and then all over with help of side knife.

Ossicular integrity and movement was confirmed by touching handles of malleus and observing movement of incudostapedial joint and also be eliciting round window reflex. Once the Ossicular chain integrity confirmed, cartilage graft of adequate size was inserted, touching all the bony walls of the external auditory canal near the tympanic annulus. Then the flat repositioned over graft. Once the graft was adequately secured across the bone the meatus was packed with gel foam soaked in an antibiotic solution and cream. All steps were performed under endoscopic vision.

The Operated ear canal was plugged with cotton ball smeared with antibiotic cream. Wound site at tragal incision was dressed using aseptic precautions.

Postoperative Care

Postoperative Instructions given to Patients

- 1. Nil by Mouth for 4 Hrs. If done under local anaesthesia and for 6 Hours if done under general anaesthesia.
- 2. Inj. Taxim 1g I.V Bid. for 3 Days
- 3. Inj. Voveran 3 cc I.M. Bid. for 3 days
- 4. Inj. Rantac 2 cc I.V. Bid. for 3 days
- 5. Tab. Levocitrizine OD for 3 days
- 6. Keep Operated Ear Up.

Alternate day dressing was done, and patients were discharged on postoperative day 4 and asked to review after 7 days to check for wound integrity. Thereafter the Patients were called at the end of 3rd Week, 6th Week, and 3rd Month. The 3rd Month follow up findings were taken up for the analysis. Postoperative audiometry was done at 6th week and at the end of 3rd month. The patients were studied on the following parameters.

- Graft acceptance at third month or longer Categorized as either intact tympanic membrane or failure.
- Postoperative hearing levels at 3rd month Post Operative air bone gap was considered as the objective method to assess the hearing as well as to compare improvement in hearing. These were grouped as less than or equal to 10dB, 11 to 20 dB, 21-30 dB and above 30 dB.

Sex Distribution	No. of Cases	Percentage					
Male	12	27.2					
Female	32	72.7					
Table 1. Gender Distribution							

Age Group (Years)	No. of Patients				
15 – 20	9				
21 – 30	31				
31 – 40	3				
41 - 60	1				
Total	44				
Table 2. Age Distribution of Subject					

Graft Status	Uptake	Failure					
No. of Patients	40	4					
Table 3. Postoperative Graft Status on 42 nd Day							

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Type of Failure	No. of Patients					
Residual Perforation	4					
Blunting						
Lateralization						
Medialization						
Retraction						
Table 4. Type of Graft Failure on 42 nd Day						

Graft Status	Uptake	Failure				
No. of Patients	37	7				
Table 5. Postoperative Graft Status on 90 th Day						

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Type of Failure	No. of Patients					
Residual Perforation	7					
Blunting						
Lateralization						
Medialization						
Retraction						
Table 6. Type of Graft Failure on 90 th Day						

The mean preoperative air conduction was found to be 54.32 dB, 48.75 dB & 40.43 dB at 500 Hz. 1 Khz & 2 KHz respectively. The average preparative air bone gap was found to be 29.94 dB, 30.23 dB & 29.93 dB at 500 Hz. 1 KHz & 2 KHz respectively.

Pro-On Air	500 Hz		1 KHz		2 KHz		Average (0.5KHz, 1KHz, 2 KHz)	
Conduction	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean
	54.32	2.34	48.75	2.61	40.43	2.42	47.79	2.21
		Та	ble 7. F	Preoperative Heal	ring Sta	atus		
	ABG at 500 Hz.		ABG 1 KHz		ABG 2 KHz			
Dro On	(Pre-Op AC 500 Hz-		(Pre-Op. AC 1 KHz		(Pre-Op AC 2 KHz			
Average Air	Op. Pre-Op. BC 500 Hz) Pre-Op BC 1 KHz) Pre-Op. BC 2 KHz)							
Bone Gap	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean
	29.94	1.48	30.23	2.02	29.93	1.85	30.114	1.66

Table 8. Postoperative Hearing Status on 42nd Day

The mean air conduction in the 42nd Postoperative day was found to be 27.95 dB, 23.41 dB & 25.11 dB at 500 Hz. 1 KHz & 2 KHz respectively. The average air bone gap in the 42nd Postoperative Day was found to be 18.35 dB, 15.63 dB & 19.89 dB at 500 Hz, 1 KHz and 2 KHz respectively.

Pre-Op.		500 Hz 1 KHz 2 KHz		Average (0.5 KHz, 1 KHz, 2 KHz)				
AC on 42 nd Day	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean
	27.95	2.49	23.41	2.52	25.11	2.13	25.57	2.22
Table 9. Postoperative Hearing Status								

Pre-Op.	ABG at 500 Hz. (Post Op AC 500 Hz- Post Op. BC 500 Hz)		ABG 1 KHz (Post-Op. AC 1 KHz Post-Op BC 1 KHz)		ABG 2 KHz (Poste-Op AC 2 KHz Post-Op. BC 2 KHz)		Average (0.5 KHz, 1 KHz, 2 KHz)		
Bone Gap	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	
	18.35	1.68	15.63	1.59	19.89	1.52	18	1.5	
	Table 10. Postoperative Hearing Status on 90th Day								

The mean air conduction in the 90th Postoperative Day was found to be 25.23 dB, 23.29 dB & 22.84 dB at 500 Hz, 1 KHz & 2 KHz respectively. The average air bone gap in the 90th Postoperative Day was found to be 15.85 dB, 14.66 dB and 17.1 dB at 500 Hz, 1 KHz and 2 KHz respectively.

	500 Hz		1 KHz		2 KHz		Average (0.5 KHz, 1 KHz, 2 KHz)	
Post-Op. AC	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean
	25.23	2.63	23.29	2.34	22.84	2.54	23.77	2.36
Table 11. Postoperative Hearing Status on 90th Day of Successful Cartilage Tympanoplasties								

	ABG at 500 Hz. (Post Op AC 500 Hz- Post Op. BC 500 Hz)		ABG 1 KHz (Post-Op. AC 1 KHz Post-Op BC 1 KHz)		ABG 2 KHz (Poste-Op AC 2 KHz Post-Op. BC 2 KHz)		Average (0.5 KHz, 1 KHz, 2 KHz)		
Average ABG	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	Mean	Standard Error of Mean	
	15.85	1.61	14.66	1.427	17.1	1.69	15.86	1.5	
Table 12. (Table 12. Comparison of Preoperative and Postoperative Hearing Status of Successful Cartilage Tympanoplasties								

The Pre-Operative average air conduction threshold is 47.79 dB and the Postoperative 42nd Day average air conduction is 25.71 dB. The difference between the two means is found to be statistically significant (p<0.001). The preoperative average air bone gap is 32.28 dB and the Postoperative 42nd day average air bone gap is 18.00 dB. The difference between the two means is found to be statistically significant (p>0.001).

Group (B) Tragal Cartilage	Pre-Op.	Post Op. 42 nd Day	Paired t Test	P. Value					
Average AC	47.79	25.71	11.098	0.000					
Average ABG	30.11	18.00	8.402	0.000					
Table 13. Comparison of Preoperative and Postoperative Hearing Status of									
Successful Cartilage Tympanoplasties on 42 nd Day									

The preoperative Average Air Conduction threshold is 47.79 dB and the postoperatively 90th Day average air conduction is 23.77 dB. The difference between the two means is found to be statistically significant (p<0.001). The Preoperative average air bone gap is 32.28 dB and the Postoperative 90th Day average air bone gap is 15.86 dB. The difference between the two means is found to be statistically significant (p>0.001).

Group (B) Tragal Cartilage	Pre-Op.	Post OP 90 th Day	Paired t Test	P. Value
Average AC	47.79	23.77	12.94	0.000
Average ABG	30.11	15.86	6.836	0.000
Table 14. Comparison of Preoperative and Postoperative Hearing Status of				
Successful Cartilage Tympanoplasties on 42 nd Day				

DISCUSSION

In the present study, underlay technique was used in all cases. It is acknowledged that underlay technique remains the most common technique nowadays. It has advantages of ease of assessing the middle ear cavity including ossicular chain and its mobility. Underlay technique i.e. easier and is less time consuming. It avoids anterior blunting and lateralization of graft.

The age of the subjects ranged from 15 years to 60 years.

In the study group 12 subjects were males and 32 subjects were females.

Graft uptake and hearing results were assessed after 6 weeks and 3 months of surgery. Prasad et al had also used 6 weeks as the minimum post-operative follow up period after myringoplasty, the time required for complete healing and good hearing results. Brown et al.²² Used minimum of 4 weeks from the date of operation to assess the results. In order to prevent the shortcoming of the study as a short period of follow up, we included 3 months also to assess the status of the graft and hearing results.

On the 42nd postoperative day, successful graft uptake was observed in 40 patients out of 44 (99.9%) with 4 subjects having graft failure. On the 90th Postoperative day, successful graft uptake was 84.1% with 7 subjects having graft failure. Our results are similar to those of Ulku et al,²³ who had found graft uptake rate of 91.3% with

perchondrium cartilage in subtotal perforations in his retrospective study.

In our study, the pre-operative average air conduction was 47.80 dB (SEM=2.21). The Postoperative 42nd Day average air conduction was 25.6 dB (SEM = 2.22). The difference between the two means was found to be statistically significant (p, 0.001). The preoperative average air bone gap was 30.11 dB (SEM=1.66). The postoperative 42nd day average air bone gap was 18 dB (SEM = 1.50). The difference between the two means was found to be statistically significant (p<0.001).

This implies that on a shorter review of the subjects at 42nd Postoperative day, there was significant improvements on air conduction and air bone gap between the preoperative and post-operative audiometry results.

On the 90th postoperative day, the average air conduction was 23.77 dB (SEM = 2.36) and the average air bone gap was 15.86 dB (SEM = 1.50) when compared with the preoperative average air conduction (which is 47.80 dB) and average air bone gap (which is 30.11 dB). The difference between the two means was found to be statistically significant (p<0.001).

This implies that on a longer review of the subjects at 90th Postoperative day, there was significant improvement on air conduction and air bone gap between the preoperative and postoperative audiometry results.

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The current study suggests that tragal cartilage in an excellent graft material both in terms of graft uptake and hearing improvement. The disadvantage of using thicker cartilage thought to interfere with hearing and sound conduction, was overcome by slicing them to achieve a thickness comparable with that of the temporalis fascia. The Postoperative ABG closure with both the tragal cartilage graft and indicates that shielding the cartilage does not interfere with sound conduction.

CONCLUSION

- The rate of graft uptake with the use of cartilage was found to be excellent.
- On analysing the pre and postoperative audiometric results, it was found that there was a statistically significant improvement in hearing results following cartilage tympanoplasty.

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