ORIGINAL RESEARCH

To evaluate the effectiveness of cartilage as grafting material in terms of graft uptake following type-I tympanoplasty

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ABSTRACT

Background and objectives: Chronic Suppurative Otitis Media (CSOM) is one of the most common ear diseases in South East Asia having a prevalence of approximately 5.2% in the general population.Cartilage material is criticized in terms of hearing results due to its thickness. The objective of this study was to evaluate the effectiveness of cartilage as grafting material in terms of graft uptake and post-operative hearing following Type-I tympanoplasty.

Materials and methods: All patients undergoing Tympanoplasty in Govt. ENT Hospital, Osmania Medical College, Hyderabad, who comply with inclusion and exclusion criteria, and who were diagnosed as Tubotympanic type of chronic suppurative otitis media and were taken up for Type-I Tympanoplasty were included in the present study for a period of one and half years from November 2015 to June 2017. 50 subjects were enrolled and Subjects were reviewed on 8thpost-operative day, 6thand 12thpost-operative weeks. The graft uptake and post-operative hearing were evaluated.

Results: The graft uptake on 6th and 12th post-operative weeks was 87.7% & 86.6% respectively. The difference of means of air bone gaps for pre-operative, 6th post-operative week and 12th post-operative week were 30.11 ± 1.66 dB, 18 ± 1.50 dB, 15.86 ± 1.50 dB respectively. The results were statistically significant, showing improvement in hearing after surgery. On 12th post-operative week 5 subjects had no hearing gain. Closure of air-bone gap within 30 dB was achieved in 81.10% subjects.

Conclusion: The cartilage was found to be excellent grafting material in terms of both the graft uptake rates and hearing results after type 1 tympanoplasty.

Keywords: tympanoplasty; Tragal cartilage; Temporalis fascia.

INTRODUCTION

"Tympanoplasty is a procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting", commonly done after chronic otitis media.. The goal of tympanoplasty today is to control the disease, retain normal anatomy and whenever possible to restore hearing.¹

Temporalis fascia and perichondrium retains the most commonly used materials today for tympanic membrane reconstruction and successful closure is anticipated in approximately 90% of primary tympanoplasties. But, in certain situation such as atelectatic ear, cholesteatoma and revision tympanoplasty, fascia and perichondrium used for tympanic

membrane reconstruction have been shown to undergo atrophy and subsequent failure in postoperative period. These observations have led to use of more rigid and less complaint materials for tympanic membrane repair. Cartilage, because of its more rigid quality, tends to resist resorption and retraction even in the milieu of continued Eustachian tube dysfunction. It has been shown in both clinical and experimental studies that cartilage is well tolerated by middle ear, and long term survival is the norm, and despite the thickness of graft, the hearing results appears to be good.^{2,3}

Various criteria must be satisfied before accepting graft or prosthesis for use in tympanoplasty. The prosthesis should be inert, nontoxic, easily mould into any shape, size and it should be inexpensive. 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.⁴ 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. It is a prospective, non-comparative study.

MATERIALS AND METHODS

A prospective Interventional study with follow up of patients for 3 months(November 2015 to June 2017). All patients attending GOV'T ENT Hospital/Osmania Medical College, Hyderabadwho had satisfied the Inclusion criteria and exclusion criteria mentioned below were included in the study. Otoscopic examination and tuning fork tests, X ray mastoids Schuller's view and pre-operative pure tone audiometry (PTA) was done to know the perforation, degree of hearing loss, cellularity of mastoid, air bone gap. Audiometric analysis was done at the frequencies of 500Hz, 1000Hz, and 2000 Hz. Pre-operative routine investigations were done. Post-operative PTA was done to assess outcomes such as improvement in hearing that is air bone gap closure are measured. These post-operative assessments are done after the 6thpostoperative week and 12thpostoperative week. The variables studied included — age, sex, side, size of perforation, cellularity of mastoids, preoperative and postoperative hearing. All the patients in my study had unilateral perforations. All the selected patients were operated using 0 degree wide angled endoscope assisted underlay technique. The tympanomeatal flap raised was superiorly based tragal cartilage was harvested in all the cases

INCLUSION CRITERIA

Age>15 years and <60years, Muscosal type of CSOM with central, subtotal perforation, Conductive hearing loss < 50 dB and Quiescent and inactive Stage of CSOM.

EXCLUSION CRITERIA

Squamosal type of CSOM, marginal and attic perforation, Previous ear surgery, Patient with sensorineural hearing loss, Bilateral tympanic membrane perforations, Active stage of infection of the ear, CSOM with intracranial complications, HbsAg and HIV positive patients and other chronic inflammatory diseases that would interfere with wound healing, Hypertension, Diabetes mellitus, chronic cardiac illness, chronic renal failure patients, malignancies, and patients medically certified as unfit for the anesthesia

Informed consent was taken from all the patients pre-operatively after explaining the procedure. Ethical approval was taken from the Ethical Review Board of Osmania medical college, Hyderabad.

All subjects fulfilling the inclusion criteria were taken into consideration. In history, importance was given to conditions such as hearing loss, otorrhoea, previous otology procedures, tinnitus, otalgia, vertigo and facial paralysis. General physical examinations, routine surgical profile, ear examinations with otoscope and tuning fork tests with 256, 512, and 1024 Hz were done. Pure tone Audiometry test was performed by a certified trained Audiologist within 1 week before surgery, 6th week (42ndpost-operative day) after surgery and 3rdmonth (90thpost-operative day) after surgery. It was tested in a sound treated room. Hugson and Westlake technique was used for audiometric evaluation. Test was performed through air conduction and bone conduction. Air-conduction included frequencies at 250Hz, 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz and 8000Hz. Three frequencies pure tone average was calculated from 500Hz, 1000Hz and 2000 Hz. It was documented both pre- and post — operatively.

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). Qualitative data was measured in terms of Proportions and Percentages. Pre-op and Post-op data was analysed. The findings were noted in the audio logical evaluation sheet (Appendix 9.1).Patients were admitted or called on OPD basis according to the availability of bed in the ward. Oral antibiotic (amoxicillin, clavulinic acid 500/125 mg PO q12hr) were prescribed the day before surgery and continued for 10 days postoperatively. Part preparation was done in the morning on the day of surgery. Surgery was done either under local or general anaesthesia. Patient who underwent surgery in local anaesthesia were given injection promethazine 0.5mg/kg(maximum of 25 mg) intramuscularly in deltoid region an hour before surgery for sedation. Four quadrant block was given with 2% xylocaine with adrenaline (1:100000) to anaesthetize the operating ear. A thorough endoscopic examination was done just a day before the surgery.

SURGICAL TECHNIQUE

Patient was prepared for operation. The ear to be operated was pointing towards the ceiling. Painting and draping was done, operating endoscopic camera was cleaned with spirit swab. Instruments for the procedure were prepared.Transcanal approach was used to access the tympanic membrane and middle ear according to necessity or convenience of the surgeon.

After the endoscope tip was sprayed with defogging solution, the scope is inserted through the external auditory meatus. Any bleeding is a source of additional difficulty; therefore, great care was taken to avoid canal skin abrasions and canal hematomas. The endoscope was advanced through the external auditory canal under direct vision via the video monitor and examination of tympanic membrane perforation and middle ear was done. Local anaesthesia (xylocaine 1% with 1:100000 adrenaline) were administered as in any other transcanal procedure and also into the suprauricular area. Adequate local anesthesia can be achieved by application of a lignocaine solution to the tympanic membrane. This solution was placed on a small piece of Gelfoamthat was Placed on the-tympanic membrane for 10 minutes, until bleaching occurs in the area of the eardrum perforation. Its anesthetic action lasts approximately 35 to 40 minutes. Local anesthetic was used to infiltrate the ear canal, we used 2% lignocaine with adrenaline 1:100,000, in the absence of any contraindications. If anticipated patient compliance is poor, or if the patient explicitly requests it, one may switch to general anaesthesia.

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 medial surfaces and then harvested with perichondrium intact on one side. The donor site was closed with vicryl 3/0 cutting body. The endoscope was introduced into the ear canal. The edges of the perforation were freshened and undersurface of the tympanic membrane was roughened 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 10' o clock to 2' o clock positions in right ear or 2'o clock to 10' o clock in left ear, at 1cm lateral to the tympanic membrane and tympanomeatal flap was raised anteriorly. Middle ear was entered under the annulus near posterior-inferior quadrant first as the attachment of the annulus tympanicus to sulcus tympanicus was less adherent and then all over with help of side knife.Ossicular integrity & movement was confirmed by touching handle of malleus and observing movement of incudostapedial joint and by 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 flap repositioned over graft. Once the graft was adequately secured across the bone the meatus was packed with gelfoam 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

Alternate day dressing was done and patients were discharged on post-operative day 4 and asked to review after 7 days to check for wound integrity. Thereafter the patients were called at the end of 3rdweek, 6thweek, and 3rd month. The 3rdmonth follow up findings were taken up for the analysis. Postoperative audiometry was done at 6thweek and at the end of 3rdmonth.The patients were studied for the following parameters.Graft acceptance at third month or longer - Categorized as either intact tympanic membrane or failure. Post-operative hearing levels at 3rd month 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 20dB, 21-30dB and above 30 dB

RESULTS

The total numbers of subjects enrolled for the study were 50 in which six subjects were lost to follow up. Amongst the total number of subjects there were 12 male subjects (27.2%) and 32 female (72.7%) subjects. The age of the subjects ranged from 15 years to less than 60 years. Majority of the subjects were from 21-30 years (68.88%). subjects had perforated tympanic membrane in left ear(54.5%), 20 subjects had in right ear(45.4%).

Among the 44 subjects 21 subjects had small perforation (47.7/0), 10 subjects had large perforations (22.7413 subjects had subtotal perforations (29.5%).24 subjects had sclerotic mastoids(54.54%),14patients had cellular mastoids (31.8%) and 6 subjects had diploic mastoids(13.63%).

Air conduction	500hz		1 khz		2 khz		Average (0.5 khz, 1khz, 2khz)	
	Mean	Standard Error	Mean	Standard Error	Mean	Standard Error	Mean	Standard Error
	54.32	2.34	48.75	2.61	40.43	2.42	47.79	2.21
Average air bone	29.94	1.48	30.23	2.02	29.93	1.85	30.114	1.66
gap								

Table 1: Pre-operative Hearing status

After the 6th post-operative week, failure of graft uptake was observed in 4 patients (9%). The most common type of failure was observed to be residual perforation. There was no blunting, lateralization, medialization or retraction of graft. Subjects had graft failure after the 12th post-operative week.

All the failure cases (12) were reported to be due to residual perforatic on the l2th postoperative week. The mean pre-operative 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 pre-operative air-bone gap was found to be 29.94 dB, 30.23 dB & 29.93 dB at 500 Hz, 1 KHz & 2 KHz respectively.

 Table 2: Post-operative Hearing status after 6thweek of Successful cartilage tympanoplasties

Post OP AC on the	500hz		1 khz		2 khz		Average (0.5 khz, 1khz, 2khz)	
6 th week	Mean	Standard	Mean	Standard	Mean	Standard	Mean	Standard
		Error of		Error of		Error of		Error of
		Mean		Mean		Mean		Mean
	27.95	2.49	23.41	2.52	25.11	2.13	25.57	2.22
Average	18.35	1.68	15.63	1.59	19.89	1.52	18	1.5
ABG on								
6 th week								

The mean air conduction after the 6th post-operative week 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 after the 6th post-operative week was found to be 18.35 dB, 15.63 dB & 19.89 dB at 500 Hz, 1 KHz & 2 KHz respectively.

Table-3: Post operative hearing status after 12th week

Post OP	500hz		1 khz		2 khz		Average	
AC							(0.5 khz, 1khz, 2khz)	
	Mean	Standard	Mean	Standard	Mean	Standard	Mean	Standard
		Error of		Error of		Error of		Error of
		Mean		Mean		Mean		Mean
	25.23	2.63	23.29	2.34	22.84	2.54	23.77	2.36
Average	15.85	1.61	14.66	1.427	17.1	1.69	15.86	1.5
ABG at 12								
th week								

The mean air conduction after the 12th post-operative week 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 after the 12thpost-operative week was found to be 15.85 dB, 14.66 dB &17.1 dB at 500 Hz, 1 KHz & 2 KHz respectively.

 Table 4: Comparison of pre-operative and post-operative hearing status of successful cartilage tympanoplasties after 6thweek

Group (B) Tragal	Pre OP	Post OP	Paired	P Value
Cartilage		12 th week	t test	
Average AC	47.79	25.71	11.098	0.000
Average ABG	30.11	18.00	8.402	0.000

The pre-operative average air conduction threshold is 47.79 dB and the post-operative 6^{th} week average air conduction is 25.71dB. The difference between the two means is found to be statistically significant (p<0.001). The pre-operative average air-bone gap is 32.28 dB and the post-operative 6^{th} week average air-bone gap is 18.00 dB. The difference between the two means is found to be statistically significant (p<0.001).

	week			
Group (B)	Pre OP	Post OP	Paired	Р
Tragal Cartilage		12 th week	t test	Value
Average AC	47.79	23.77	12.94	0.000
Average ABG	30.11	15.86	6.836	0.000

 Table 5: Comparison of pre-operative and post-operative hearing status of successful cartilage tympanoplasties on 12th week

The pre-operative Average Air conduction threshold is 47.79 dB and the post-operative 12^{th} week average air conduction is 23.77dB. The difference between the two means is found to be statistically significant (p<0.001). The pre-operative average air-bone gap is 32.28 dB and the post-operative 12^{th} week average air-bone gap is 15.86 dB. The difference between the two means is found to be statistically significant (p<0.001).

DISCUSSION

The objectives of this study were to assess the graft uptake and post-operative hearing results of type 1 tympanoplasty using Tragal cartilage as graft material. Calculated sample size was 50 and analysis was done in 44 subjects, 6 among them were excluded as they were lost to follow up.

The age of the subjects ranged from 15 years to 60 years. Majority of the subjects in both the age groups were from 21-30 years. This group of patients are probably very much concerned about the disturbance created by ear discharge and decrease in hearing and are willing to undergo surgery with ease. There was almost homogenous distribution of the patients in both the groups. The most common age groups undergoing myringoplasty are similar in other studies.^{5,6}In the study group 12 subjects were malesand 32 subjects were females, 24 subjects had left ear perforated tympanic membrane, 20 subjects had right ear TM perforation.

Out of 44 subjects 21 subjects had small perforation,10 subjects had large perforations,13 subjects had subtotal perforations. X-ray of mastoids schuller's view showed 24 subjects had sclerotic mastoids,14 patients had cellular mastoids and 6 subjects had diploic mastoids.

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

Graft uptake and hearing results were assessed after 6 weeks and 12 weeks of surgery. Prasad et al⁷ 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 at ⁸ 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.

After the 6thpost-operative week, successful graft uptake was observed in 40 patients out of 44 (90.9%), with 4 subjects having graft failure, after the 12thpost-operative week, successful graft uptake was 84.1% with 7 subjects having graft failure.Our results are similar to those of Ulku et al⁹ who had found graft uptake rate of 91.3% with perichondrium cartilage in subtotal perforations in his retrospective study.

Also, Ozbek et al ¹⁰ reported graft uptake rate of 70.2% in temporalis fascia group and 100% in cartilage group in >50% TM perforation but this study was done in children. Khullar et al²² found 91% graft uptake in tragal composite cartilage graft.Gamraet al¹¹ had successful closure rate of 97% in cartilage tymanoplasty. El-Hennawi DEM et al¹² In their study of myringoplasty showed that the take rate for tragalperichondrium was 85%, temporalis fascia 75% and fat from ear lobule was 100%. Overall success rate was 84%. Graft failed in 35(16%) ears. They concluded that tragal perichondrium is superior to temporalis fascia.

Pure tone audiometry was done in sound treated two room set up with calibrated equipment. Three frequencies pure tone average was calculated from 500, 1000 and2000 Hz. Use of only 3 frequencies 500, 1000 and 2000 Hz for measurement is also common.

In our study, the pre-operative average air conduction was 47.80 dB (SEM=2.21). The 6^{th} post-operative week 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 pre-operative average air-bone gap was 30.11 dB (SEM=1.66). The 6^{th} post-operative week 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 6thpost-operative week, there was significant Improvement on air conduction and air-bone gap between the pre-operative and post-operative audiometry results.

After the 12^{th} postoperative week, 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 pre operative 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 12thpost-operative week, there was significant improvement on air conduction and air-bone gap between the pre-operative and post-operative audiometry results.

This observation is similar to the studies conducted by, Ozbek et al¹⁰compared palisade cartilage and temporalis fascia and there was no significant audiological difference them, Albirmawy et al²⁷ compared ring graft technique with a temporalis fascia graft in which there was no significant difference in audiometric results between the two groups, Cabra et al¹³found no significant difference in hearing results between cartilage and temporalis fascia group, Gierek et al.¹⁴also found no significant difference in hearing between the two groups cartilage perichondrium composite and temporalis fascia group.

Successful graft uptake was seen in 40 cases after the 6thpostoperative week. 5 subjects had no hearing gain in spite of successful graft uptake. Closure of air-bone gap within 10 dB was achieved in 20% of subjects. Closure of air-bone gap within 20 dB was achieved in 35% of subjects. Similarly, closure of air-bone gap within 30 dB was achieved 75 % of the subjects.

Successful graft uptake was seen in 37 subjects after the 12thpostoperative week. 2 subjects had no hearing gain inspite of successful graft uptake. Closure of air-bone gap within 10 dB was achieved in 27.02% of subjects. Closure of air-bore gap within 20 dB was achieved in 37.85% of subjects. Similarly, closure of air-bone gap within 30 dB was achieved in 81.1 of subjects.

These results are similar to Gamraet al.¹¹where they observed good functional hearing results (ABG <20 dB) in 89% cases with cartilage graft. El-Hennawi DEM et al¹² found hearing improvement in 75% cases with tragalerichondrium cartilage.Milewskiet a1¹⁵ had ABG of < 10 dB in 43.6% of cases and <30 dB % of cases.

Thecurrent study suggests that tragal cartilage is an excellent graft material both in terms of graft uptake and hearing improvement. An issue cartilage tympanoplasty concerns cartilage thickness. An elegant study using the laser Doppler interferometer and cadaver cartilage conducted by Zahnert at al¹⁶ demonstrated that the ideal acoustical thickness of cartilage should be about 0.5 mm, compared to the full thickness at harvest- 0.7-1mm. While these findings are not disputed, the techniques described herein utilize full-thickness grafts. The reason is technical. Typically, perichondrium is left attached to one side of the cartilage for stability. When the perichondrium/cartilage island flap is thinned, the graft curls unacceptably toward the side with the perichondrium, making placement difficult and less exact. Full-thickness grafts are believed, in our experience, to give moreprecise reconstruction. Therefore, because our hearing results have been goad, we recommend full-

thickness grafts for cartilage reconstruction of the eardrum the post-operative ABG closure indicates that full thickness cartilage does not interfere with sound conduction.

The use of cartilage tympanoplasty, while encouraging, also provides some specific challenges, the first of which is learning a new surgical technique. The only real difference in this technique and traditional procedures is harvesting and shaping the cartilage graft. This has not been a significant challenge, especially with the perichondriumi/cartilage island flap. The second major challenge, and one that continues to present some difficulty, represents the inability to predict, preoperatively, eustachian tube function. This has been the subject of numerous articles, and the general consensus continues to be that no specific exam finding or test reliably predicts tubal function.¹⁷

CONCLUSION

The rate of morphological success i.e., graft uptake with the use of cartilage was found to be excellent. On analyzing the pre and post-operative audiometric results, it was found that there was a statistically significant improvement in functional outcomes i.e. hearing results following cartilage type 1 tympanoplasty.

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