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RESEARCH ARTICLE
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EFFECT OF AUDIOLOGICAL OUTCOMES BETWEEN TRAGAL CARTILAGE PERICHONDRIUM AND TEMPORALIS FASCIA GRAFT IN TYMPANOPLASTY TYPE-1 SURGERY

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ABSTRACT

Background: Among the leading causes of hearing loss in the world, Chronic Otitis Media (COM) is one of them. Tympanoplasty is the surgical treatment to repair the defective tympanic membrane in such patients.

Aim: To compare the audiological outcomes using temporalis fascia versus cartilage perichondrium grafts in tympanoplasty type-1.

Methods: A prospective randomized comparative cohort trial was conducted to compare the post-operative audiological outcomes of two graft materials, tragal cartilage perichondrium and temporalis fascia, in tympanoplasty type1 surgery among 60 patients randomized into 2 groups.

Results: Out of the 57 patients out of 60, who complied with the study follow-up, Tympanoplasty type-1 was performed in patients in Group A with Tragal cartilage perichondrium (n=27) and in Group B with Temporalis fascia (n=30). After 3 months, hearing levels were found to have significantly improved in all 57 patients. There was no statistically significant difference in improvement of hearing between the two groups in Pure Tone Audiometry as Group A, patients had a pre-operative mean air-bone gap value of 26.12 dBHL which had improved to 19.19 dBHL while in Group B, the pre-operative mean air-bone gap value was 25.48 dBHL and the post-operative value was 18.8dBHL. Post-operative mean impedance in tragal perichondrium graft Group A was 2.8 daPa was significantly higher than that of Group B with 1.96 daPa.

Conclusion: The results of this study shows that tragal cartilage perichondrium is significantly better than temporalis fascia in terms of audiological outcomes as a graft material in Type-1 tympanoplasty.

KEYWORDS: Tympanoplasty Grafts, Tragal Perichondrium, Temporalis Fascia, Hearing Outcome, Audiometry, Tympanometry

INTRODUCTION

Chronic Otitis Media (COM), is defined as a long standing irreversible inflammation of mucoperiostial lining of the middle ear cleft resulting in changes in the tympanic membrane.[1] It is prevalent in about 65 to 330 million people around the world with 60% of them suffering from

significant hearing loss.[2] Tympanoplasty is the surgical procedure which includes the manipulation of the tympanic membrane and eradication of disease from the middle ear and aim of this procedure are to dry up the ear discharge, eradicate existing disease and to restore hearing. The ideal grafting material used for tympanoplasty should meet certain criteria namely, low rejection rate, sufficient quantity, good tensile strength, conductive properties similar to that of tympanic membrane and easy availability.[3] Numerous materials have been tried as a grafting material namely Homograft, alloplastic, and autologous material but none withstanding the test of time except the autologous materials. It includes skin, fascia lata, temporalis fascia, vein and perichondrium.

In this study, comparison of graft materials done between temporalis fascia and tragal cartilage perichondrium. Advantage of using tragal cartilage perichondrium is that it does not require an additional surgical incision for the harvest of the material in post auricular area and hair shaving and better functional outcome in terms of hearing. However the poor dimensional stability of this material has resulted in residual perforations in large and sub-total tympanic membrane perforations.

A composite graft combining cartilage with perichondrium would theoretically work well, being tougher and easily nourished. 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.

AIM

The aim of this study is to compare the post-operative hearing in tympanoplasty using two different graft materials, temporalis fascia and cartilage perichondrium

MATERIALS AND METHODS

This prospective randomised comparative cohart trial was conducted in the Department of Otorhinolaryngology at a Private Medical College in South India in the year 2020. The study compared the effect of two graft materials, tragal cartilage perichondrium and temporalis fascia, in tympanoplasty and evaluated the post-operative hearing. All patients were explained about the study and a written informed consent was obtained prior to participation. A total number of 60 patients randomised into 2 groups were included in this study (n=60). The patients included in the study are healthy male and female above 18 years of age with mucosal type of ear disease and pure conductive hearing loss. Patients with squamous type ear disease, bilateral ear disease, ossicular dysfunction & external ear pathology, sensorineural hearing loss and mixed hearing loss, previous ear surgery and intracranial / extracranial complications of COM are excluded from the study.

Patients diagnosed with COM – mucosal disease were randomly allotted to one of the 2 groups – Group A (Cartilage perichondrium graft) and Group B (Temporalis Fascia graft). All patients underwent pre-operative Otomicroscopic Examination and Pure Tone Audiometry. A power calculation showed that a sample size of 60 patients would achieve a power of 90%. Patients who met the inclusion criteria were subjected to medical fitness for General Anesthesia (GA).

All surgeries were done under GA. A post auricular incision was placed and Type I tympanoplasty performed. Then harvesting of the graft material was done. For a tragal perichondrial graft, an incision made over the inner surface of the tragus, soft tissues dissected and tragal cartilage perichondrium were identified and harvested. The graft material was dried so that the cartilage and perichondrium were attached at one end. The underlay placement of the graft was done such that cartilage part cover the perforation and perichondrium part stabilised the graft as it came under the tympanomeatal flap. The tragal wound was sutured. Mastoid dressing was done.

The temporalis fascia graft was harvested by placing an incision over post-aural region, soft tissues dissected and temporalis fascia was identified and harvested. The graft material was teased and dried.

Graft material was placed by underlay technique. Medicated gelfoam was placed adequately under the graft to prevent medialisation of the graft material. All patients recovered uneventfully. Patients

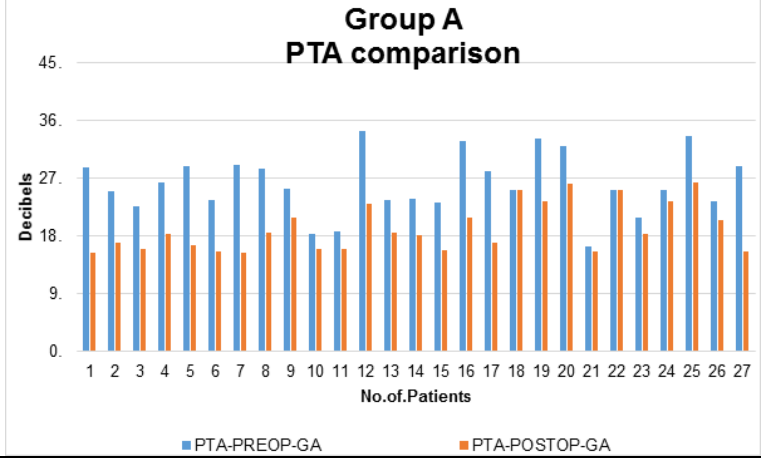
were on parental antibiotics and anti-inflammatory for 3 days, followed by oral antibiotics and anti - inflammatory for 4 days. All the patients were on similar post-operative care and diet. Surgical wound was cleansed and dressing changed everyday. Sutures were removed on 7th post-operative day.

All patients were subjected to otomicroscopic examination at the end of 1 month post-operatively for analysis of neo-tympanum. Pure Tone Audiometry and Impedance were re-assessed at the end of 3 months post-operatively, for analysis of improvement in hearing and middle ear status. Air-bone gap analysis was done using Pure Tone Audiometry – Graphic Audiometry and recorded as "dBHL".

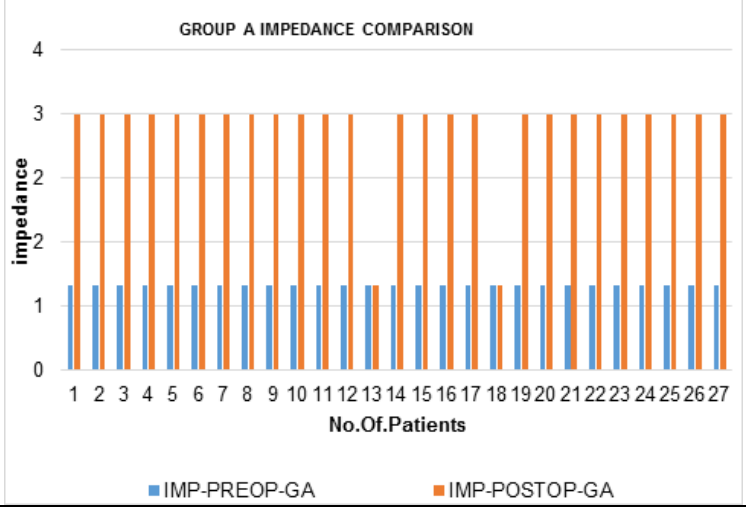
Impedance, using GSI 39 Auto Tymp was recorded as A type, B type or C type curves. They were given scores 3, 2 and 1 respectively **(Table 1).** Statistical analysis was done using the Paired and unpaired t-tests.

Score	Impedance Audiometry curve
3	A type
2	B type
1	C type

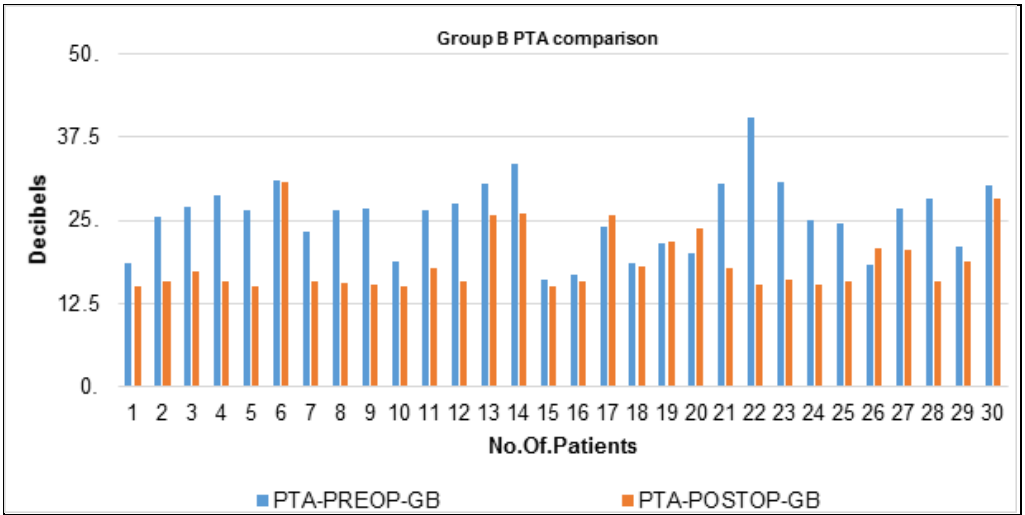
Table 1: Impedance scores



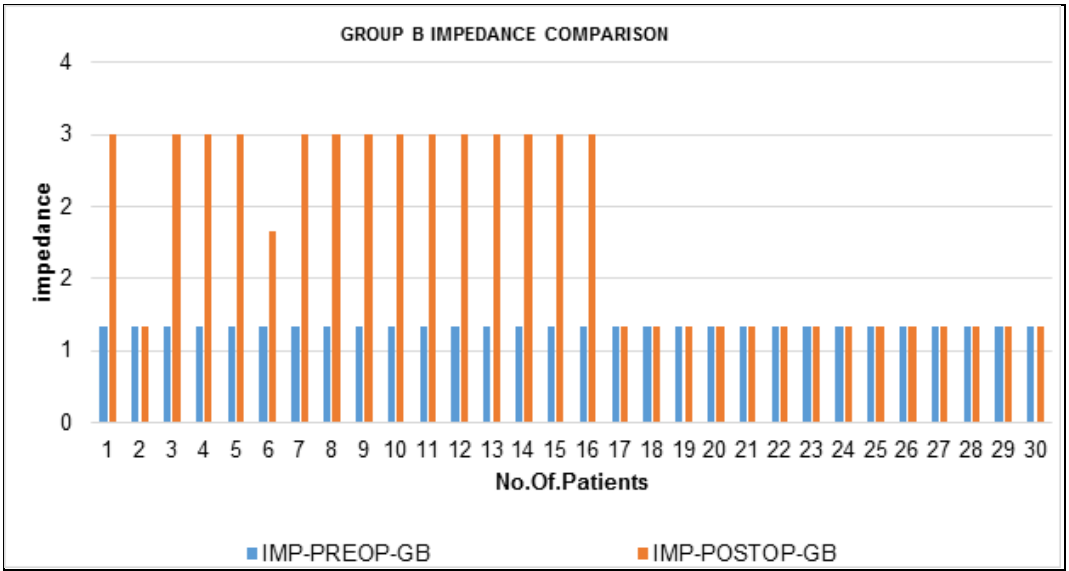
Graph 1: Comparison of Pre-operative and Post-operative pure toneaudiometry among patients in group A



Graph 2: Comparison of Pre-operative and Post –operative impedance in group A



Graph 3: Comparison of Pre-operative and Post-operative pure tone audiometry among group B



Graph 4: Comparative pre-operative and Post-operative impedance among

RESULTS

60 patients with dry central perforation were included in this study. 30 patients were allocated to Group A and 30 to Group B randomly using numbered lots. 57 patients complied with the study protocol, tolerated the surgical procedures and completed the follow-up. 3 candidates of Group A dropped-out of the study after undergoing surgery. Repair of the tympanic membrane in patients in Group A was done with Tragal cartilage perichondrium (n=27) and in Group B with Temporalis fascia (n=30). Of the 27 patients in group A, 10 were males and 17 were females, whereas there were 6 males and 24 females in Group B. All the patients underwent Type I tympanoplasty (n=57).

At the end of 3 months, hearing levels were found to have significantly improved in all 57 patients. In Group A, patients had a pre-operative mean air-bone gap value of 26.12 dBHL which had improved to 19.19 dBHL. In Group B, the pre-operative mean air-bone gap value was 25.48 dBHL and the post-operative value was 18.8dBHL. However, there was no statistically significant difference in improvement of hearing between the two groups in Pure Tone Audiometry (Graph -8, Table - 4).

The pre-operative Impedance for all the patients was recorded as C type curve and were given a score 1. At the end of 3 months, there was statistically significant overall improvement in

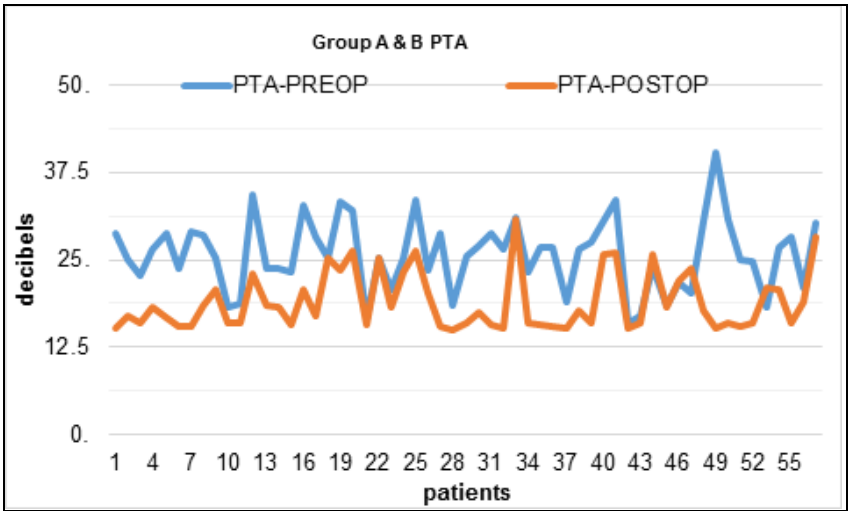
impedance in both the groups (Graphs 5 & 6, Table - 4). The post-operative mean impedance in Group A was 2.8 daPa and that of Group B was 1.96 daPa. The impedance had improved significantly in case of patients who underwent repair with tragal cartilage perichondrium when compared with those with temporalis fascia (Graph – 9).

There was statistical significance in Pure Tone Audiometry and Impedance between the pre-operative and post-operative finidngs in both the groups (Table – 6)

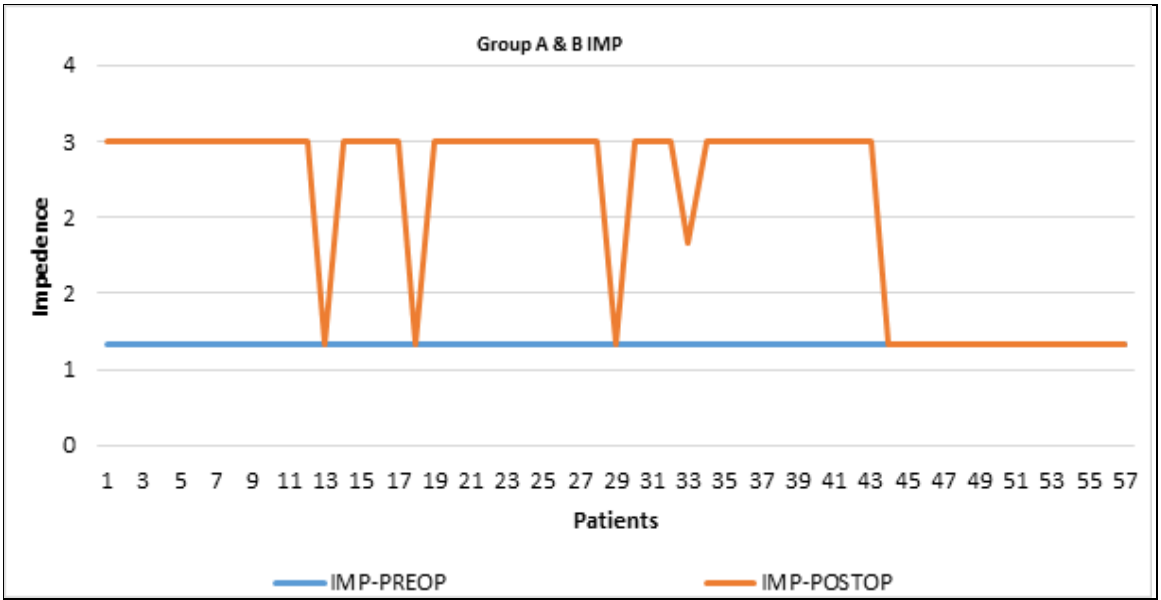
Failure rate

In Group A (Cartilage perichondrium), 1 patient had residual Central perforation (3.7%) whereas in Group B (Fascia), 13 patients had residual Central perforation (43.33%).

Post-operatively, in Group A (Cartilage perichondrium), 1 patient had otomycosis (3.7%) and in Group B (Fascia), 1 patient had otomycosis with pulsatile discharge (3.33%). These patients were managed conservatively and followed up for another 3 months. The neotympanum formation and hearing conduction levels were satisfactory.



Graph 5: Comparison of pre-operative and post-operative Pure Tone Audiometry among group A and group B



Graph 6: Comparison of pre-operative and post-operative impedance among group A and B

Paired Samples Statistics				
	Mean	**N**	**Std. Deviation**	**Std. Error Mean**
PTA_PREOP	25.7865	57	5.09920	.67541
PTA_POSTOP	18.9868	57	4.13828	.54813
PREOP_IMP	1.00	57	0.000	0.000
POSTOP_IMP	2.39	57	.921	.122
Table 2				

Paired Samples Test								
	Paired Differences					**t**	**df**	**Sig. (2-tailed)**
	Mean	**Std. Deviation**	**Std. Error Mean**	**95% Confidence Interval of the Difference**				
				Lower	**Upper**			
PTA_PREOP - PTA_POSTOP	6.79965	5.40866	.71640	5.36454	8.23476	9.491	56	.000
PREOP_IMP - POSTOP_IMP	-1.386	.921	.122	-1.630	-1.142	-11.360	56	.000
Table 3								

Group Statistics					
VAR00002		**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
PTA_POSTOP	1.00	27	26.1219	4.70379	.90524
	2.00	30	25.4847	5.49315	1.00291
IMP_POSTOP	1.00	27	2.8519	.53376	.10272
	2.00	30	1.9667	.99943	.18247
Table 4					

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	**Sig.**	**t**	**df**	**Sig. (2-tailed)**	**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**	
									Lower	**Upper**
PTA_POSTOP	Equal variances assumed	.399	.530	.468	55	.642	.63719	1.36222	-2.09276	3.36713
	Equal variances not assumed			.472	54.876	.639	.63719	1.35103	-2.07048	3.34485
IMP_POSTOP	Equal variances assumed	59.382	.000	4.103	55	.000	.88519	.21573	.45285	1.31752
	Equal variances not			4.227	45.227	.000	.88519	.20940	.46350	1.30687

	assumed									
Table 5										

DISCUSSION

Hearing assessment was done at the end of 3 months. There was no significant difference in hearing in terms of air-bone gap as measured using Pure Tone Audiometry, However there was statistically significant difference in terms of impedance. Thus cartilage perichondrial graft is found to be superior to temporalis fascia graft with respect to hearing.

The thickness and rigidity of the tragal cartilage perichondrium affecting sound conduction is debatable. The tragal cartilage is a full thickness graft and is usually about 1mm thick. This is also harvested along with the perichondrium to add up to the nourishment benefits. This could make the cartilage perichondrium composite graft even more thick. Conceptually, one might anticipate a significant conductive hearing loss with a tympanic membrane that is rigid and thick, a fact that has hampered the routine acceptance of cartilage as a grafting material. Repair of a large or subtotal perforation of the tympanic membrane would require harvesting large amount of perichondrium that adds up to the bulk of the graft material. This resulted in cartilage grafts being tried in tympanoplasty after being sufficiently thinned.[4] Cartilage grafts with thickness of 0.5 mm show stiffness similar to that of healthy tympanic membrane with sufficient mechanical stability and good acoustic properties.[4,5] Zahnert et al[4] used Doppler interferometer and suggested that thinning the cartilage to 0.5mm would give better acoustic results. Therefore cartilage grafts of thickness 0.5mm was considered ideal for tympanoplasty. The cartilage is composed mainly of type II collagen which has high tensile strength and therefore a thin cartilage could also provide sufficient mechanical stability[6]. Overbosch[7] in 1971 first described the microslice technique where he sliced the cartilage by a dermatome into plates with thicknesses of 0.2–1mm and showed improved acoustic properties. thereby not compromising on the acoustic properties. Mundra[8] used perichondrium and fascia grafts in repair of subtotal perforations of the tympanic membrane supported by single sliced cartilage and showed good audiological results and suggested that cartilage did not adversely effect the audiological outcomes. Similar results were shown by Kasbekar et al[9] where they thinned cartilage graft to 0.5 mm and found no adverse effects in hearing and also was effective in preventing retraction. . However thinning the cartilage has resulted in curling of the graft.[4,10] For this reason and to make full use of the stiffness and rigidity of the cartilage graft, many authors advocate the use of cartilage graft without thinning.

In our study we did not employ thinning of cartilage grafts. Yet we were able to see better hearing results compared to temporalis fascia It is shown that full thickness use of cartilage grafts do not impede acoustic properties.[7,10,11] Other studies have also shown that the hearing results are good, regardless of the thickness of the grafts.[10,12,13,14]

Cartilage has been compared with fascia and perichondrium with satisfactory results irrespective of the thickness used. Perichondrium and cartilage were compared in revision type I tympanoplasty, and an ABG of less than 10 dB was observed.[12] Gerber et al compared the cartilage to fascia in a frequency-specific manner and again no significant difference was observed.

CONCLUSION

This study shows that the audiological outcomes with tragal cartilage perichondrium is good. The argument regarding the thickness of the cartilage impairing sound conduction is proved wrong as we did not do thinning of the cartilage perichondrium graft in any of our cases. The results of this study shows that tragal cartilage perichondrium is significantly better than temporalis fascia in terms of audiological outcomes. Therefore we can conclude that tragal cartilage perichondrium is a better grafting material in cases of Type I Tympanoplasty.

REFERENCES

1. Glasscock ME, Shambaugh GE. Surgery of the ear, 6th edition. AJ Gulya, LB Minor, DS Poe; 2010, People's Medical Publishing House – USA, Shelton, Connecticut.
2. Jose A. Chronic otitis media: Burden of Illness and management Child and Adolescent Health and Development Prevention of Blindness and Deafness. Geneva, Switzerland: World Health Organization (WHO); 2004.
3. Chhapola S, Matta I. Cartilage–Perichondrium: An Ideal Graft Material? Indian J Otolaryngol Head Neck Surg 2012;64(3):208–13.
4. Zahnert T, Huttenbrink KB, Murbe D, Bornitz M. Experimental investigations of the use of cartilage in tympanic membrane reconstruction. Am J Otol 2000;21:322-8.
5. Ghanem MA, Monroy A, Alizade FS, Nicolau Y, Eavey RD. Butterfly cartilage graft inlay tympanoplasty for large perforations. Laryngoscope 2006;116:1813-6.
6. Szabo LZ. How can an under laid fascia graft from the middle layer of a reconstructed tympanic membrane? Laryngoscope 2006;116:1674-7.
7. Page C, Charlet L, Strunski V. Cartilage tympanoplasty: postoperative functional results. Eur Arch Otorhinolaryngol 2008;265(10):1195-8.
8. Mundra RK, Sinha R, Agrawal R. Tympanoplasty in Subtotal Perforation with Graft Supported by a Slice of Cartilage: A Study with Near 100 % Results. Indian J Otolaryngol Head Neck Surg 2013;65(Suppl 3):S631-5.
9. Kasbekar AV, Patel V, Rubasinghe M, Srinivasan V. The Surgical Management of Tympanic Membrane Retraction Pockets Using Cartilage Tympanoplasty. Indian J Otolaryngol Head Neck Surg 2014;66(4):449–54.
10. Cavaliere M, Mottola G, Rondinelli M, Iemma M. Tragal cartilage in tympanoplasty: anatomic and functional results in 306 cases. Acta otorhinolaryngologica italica 2009;29:27-32.
11. Neumann A, Schultz-Coulon H, Jahnke K. Type III tympanoplasty applying the palisade cartilage technique: A study of 61 cases. Otol Neurotol 2003;24:33-7.
12. Dornhoffer JL. Hearing results with cartilage tympanoplasty. Laryngoscope 1997;107:1094–9.
13. Dornhoffer J. Cartilage tympanoplasty: indications, techniques, and outcomes in a 1,000-patient series. Laryngoscope 2003;113:1844-56.
14. Puls T. Tympanoplasty using conchal cartilage. Acta Oto Rhino-Laryngol Belg 2003;57:187-91.