

Comparative Study Of The Efficacy Of Cortical Bone V/S Torp (Total Ossicular Replacement Prosthesis) As Ossiculoplasty Material.

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Abstract

With large number of grafts available for ossiculoplasty, choice becomes difficult. An ideal ossiculoplasty material should be safe, easily available, cost efficient, with good hearing results, uptake and low extrusion rates. The otologists are still facing the indecision over type of material to be selected. A prospective study was conducted in Department of Otorhinolaryngology, K. D. Medical College and Hospital, Mathura (September 2022 to March 2024) on 60 patients, 12-60 years of age, of either sex. This study aims to compare the efficacy of cortical bone and Teflon TORP as ossiculoplasty materials. Auto-graft included Mastoid Cortical bone and Synthetic graft was Teflon TORP. Graft uptake/failure was noted at 3 weeks and 3 months. PTA was done at 3 months postoperatively. Net hearing gain (change in ABG) was calculated for both materials used and analysed. Net hearing gain (change in ABG) was calculated for both materials used and analysed. Graft uptake for cortical bone group was 30 (100%), whereas, graft uptake in Teflon TORP was 19 (63.66%), with extrusion in 11 cases (36.66%) with p-value less than 0.001% (highly significant). Mean hearing gain when N of both groups was taken as 30, in cortical bone group $19.327 \pm 3.01SD$ and TORP group was $11.31 \pm 9.00 SD$. Mean hearing gain when N of cortical bone group was taken as 30 and TORP group was taken as 19 (after excluding 11 cases of extrusion), was $19.327 \pm 3.01SD$ and TORP group was $17.868 \pm 2.67 SD$. Cortical bone having less extrusion rate, is preferred choice for ossiculoplasty.

Keywords: Ossiculoplasty, Auto-grafts, Synthetic grafts, Hearing gain, TORP.

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I. Introduction

One of the most frequent reasons for hearing loss and disability is chronic otitis media (COM). Disruption of the ossicular chain is a common finding of COM. When there is ossicular discontinuity, the cochlear partial pressure which drives the cochlear travelling wave between the round and oval windows is weakened and the ossicular coupling-led preferential distribution of sound to the oval windows is lost.¹

Ossiculoplasty is the reconstruction of the middle ear ossicular chain, which has been disrupted or destroyed, by the use of different ossiculoplasty materials, which help in regaining the original mechanics of the ossicular chain to transfer the sound energy to the inner ear.²

The ideal prosthesis should be cheap, robust, bio-compatible, readily available for ossicular restoration, and produce the best possible sound transmission. The compatibility and simplicity of prosthesis during surgery are two important considerations when choosing one.

Ossiculoplasty uses a variety of materials, including:-

Auto-grafts-taken from patient itself, include ossicles, cortical bone, cartilage (conchal, tragal)

Homograft- taken from human donor includes ossicles, cortical bone and cartilage.

Alloplastic materials- include polytetrafluoroethylene, polyethylene,

Plastipore, proplast, titanium.

Two types of prosthesis are used:-

a) TORP (Total Ossicular Replacement prosthesis)- used in case of absence of stapes suprastructure.

b) PORP (Partial Ossicular Replacement Prosthesis)-used in cases where stapes suprastructure is present.

Zöllner (1960) and Andersen et al. (1962) were the first to report the use of cortical bone as a shaped graft between the stapes and the malleus handle or tympanic membrane. Zöllner referred to this prosthesis as a columella and explained how to obtain the ideal bone form.³

Cortical bone offers advantages of being autologous bone, having low risk of extrusion or infection, and customization. However, it has possibility of long-term resorption. TORP is commercially available, and can be easily obtained in various sizes and shapes^{4,5}, but it has risk of extrusion.

Total ossicular replacement prosthesis (TORP) is a viable solution when the stapes suprastructure is absent.⁶

Although several materials have been employed for ossicular repair, there is on-going debate over the best material for ossiculoplasty.

This study aims to compare the results of ossiculoplasty done using cortical bone and Teflon TORP (total ossicular replacement prosthesis).

II. Materials And Methods

This is a prospective study designed to evaluate and compare the results of ossiculoplasty using cortical bone v/s Teflon TORP.

The study design was approved and informed consent was obtained from the Ethical Committee K.D. Medical College & Research Center, Mathura (Uttar Pradesh)

The study was done from September 2022 to March 2024.

SAMPLE SIZE:-60

GROUPS FOR STUDY

GROUP 1- Patients of chronic otitis media with absent stapes suprastructure in whom cortical was used for ossiculoplasty.

GROUP 2- Patients of chronic otitis media with absent stapes suprastructure in whom TORP (Total Ossicular Replacement Prosthesis) was used for ossiculoplasty.

Randomization- Study was started by using cortical bone for ossiculoplasty in 1st patient and TORP in 2nd patient and this alternate sequence was followed.

SELECTION OF SUBJECTS

Patients presenting in Otorhinolaryngology department of K.D.MEDICAL COLLEGE, with Chronic Otitis Media with intra-operative finding of absent stapes suprastructure.

Inclusion Criteria

1. Good cochlear reserve (No SNHL)
2. Age(>12 years and <60 years)
3. Presence of Air-Bone Gap (>40 dB)
4. Eroded incus and stapes suprastructure +/- malleus erosion.

Exclusion criteria

- 1 Age (<12 years and >60 years)
2. Otosclerosis
3. Stapes footplate abnormalities
4. Eustachian Tube dysfunction
5. Mixed hearing Loss
6. Chronic debilitating disease or haematological abnormalities.

After assessing patients for inclusion and exclusion criteria and getting the informed consent signed they were subjected to detailed history and clinical examination according to predesigned proforma.

Pre-operative audiometry was done in all cases.

Before surgery patient's ear must be dry for minimum 6 weeks.

Written informed consent was obtained from each patient before surgery

In all cases surgery was performed by post aural approach.

Locally harvested Temporalis fascia was used as graft material.

Cortical bone was harvested from squamous part of temporal bone using drill and shaped. The size was kept 4 mm.

Mastoidectomy, either canal wall up or canal wall down was done whenever required. Ossiculoplasty was done by cortical bone shaped as ossicles in patients of Group 1 and Teflon TORP (Total Ossicular Replacement Prosthesis) in patients of Group 2. In all cases a piece of conchal cartilage was placed over the cortical bone and the total ossicular replacement prosthesis (TORP), over which underlay grafting was done using temporalis fascia.

Gel foam was placed to keep the assembly stabilized and keep the graft intact. Antibiotics, decongestants, analgesics (if required) and topical antiseptic was given for 3 weeks post-operatively.

Follow Up Of The Patients

FOLLOW UP- was done at 1 week, 3 weeks, and 3 months.

For assessment of:

- a. Postoperative complications.
- b. Graft uptake
- c. Postoperative Air bone gap.

Otoscopic examination was done to see the condition of canal and graft on all follow-up visits. Complaints, if any, were noted. Pure Tone Audiometry was done on 3rd month follow-up of post-operative period. Hearing level was determined using three frequency pure tone averages of 500 Hz, 1000Hz, 2000 Hz, as recorded before and after surgery. The Air-Bone Gap was calculated as the difference between post-operative Air conduction and post-operative Bone conduction. Successful outcome was defined as closure of Post-operative Air-Bone Gap by ≤ 20 dB in accordance with American Association of Otolaryngology.⁵

Post Operative Follow Up Visits

Immediate post-operative complications:

1. After 1 week; Inspection of surgical site, Ear discharge
2. After 3 weeks; Surgical Site, T.M. Graft Integrity
3. After 3 months; Air-Bone Gap, Surgical Site, T.M. Graft Integrity, T.M. Status (Position, Mobility)

III. Result

This table shows T-test between ossiculoplasty materials and other variables where N in terms of both cortical bone and TORP was taken as 30(including even the 11 extruded TORPs). Significant results were found with respect to Post-Op ABG and Hearing Gain with p- values <0.05.

Table 1: T-test comparing both Ossiculoplasty Material in terms of hearing gain (taking N in both groups as 30)

	Ossiculoplasty Material	N	Mean	Std. Deviation	Significance
Pre-Op ABG in Db	Cortical Bone	30	36.737	5.30	t=-1.624 df=57 p = >0.05
	TORP	30	39.307	8.26	
Post-Op ABG	Cortical Bone	30	16.8267	5.51	t = -2.577 df = 58 p = <0.05
	TORP	30	11.58	9.69	
Hearing Gain	Cortical Bone	30	19.327	3.01	t = 4.618 df = 58 p = <0.05
	TORP	30	11.31	9.00	

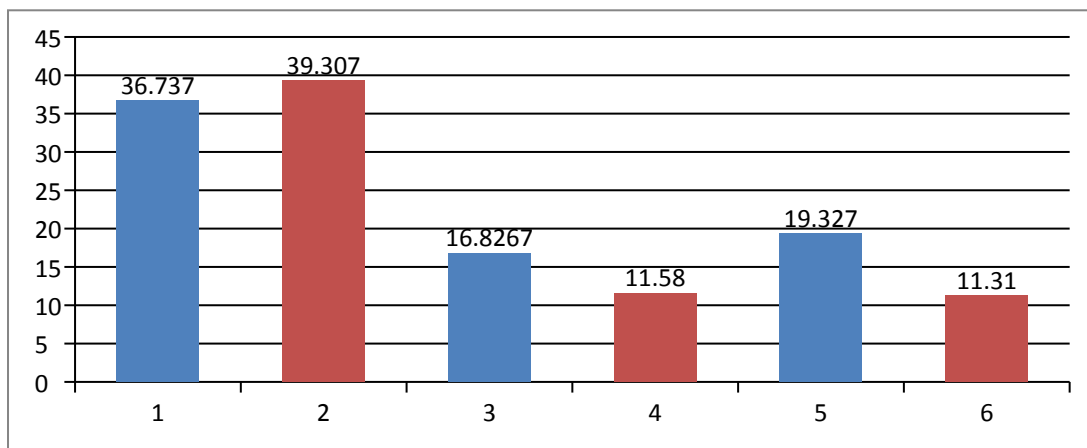


Figure 1: Bar Graph showing T-test between Ossiculoplasty Material and other variables (taking N in both groups as 30)

Table 2: T-test comparing both Ossiculoplasty Material in terms of hearing gain (N for TORP 19)

This table shows T-test between ossiculoplasty materials and other variables where N in terms of TORP was taken as 19(after extrusion of 11 TORP). Significant results were found with respect to Post-Op ABG and Hearing Gain with p- values <0.05.

	Ossiculoplasty Material	N	Mean	Std. Deviation	Significance
Post-Op ABG	Cortical Bone	30	16.8267	5.50	t = -0.954 df = 47 p = <0.05
	TORP with Intact TM	19	18.2842	4.68	
Hearing Gain	Cortical Bone	30	19.327	3.01	t = 1.721 df = 47 p = <0.05
	TORP with Intact TM	19	17.868	2.67	

Table 3: Relation between Ossiculoplasty Material and other variables

The table shows the chi-square test to examine the association between ossiculoplasty material (Cortical Bone or TORP) and various categorical variables i.e. TM graft integrity, TM position and TM mobility.

In 2nd and 3rd follow-up in terms of TM graft integrity, Group 1 had all intact TMs whereas Group 2 has 22 and 19 intact TMs respectively. p value for this is <0.005, which is significant.

In terms of position, Group 1 had 26 patients with normal position and 4 with grade 1 retraction but Group 2 has 17 with normal position and 2 with grade 1 retraction.

	Label	Cortical Bone N=30 (%)	TORP N=30 (%)	Total	Significance
TM Graft Integrity – 2nd Follow-up					<0.005 Significant
	Intact	30(100)	22(73.33)	52	
	Perforation with TORP Extrusion	0 (0)	8 (26.66)	8	
TM Graft Integrity – 3rd Follow-up	NA	0 (0)	8 (26.66)	8	<0.001 Significant
	Intact	30 (100)	19 (63.66)	49	
	Perforation with TORP Extrusion	0 (0)	3 (10)	3	

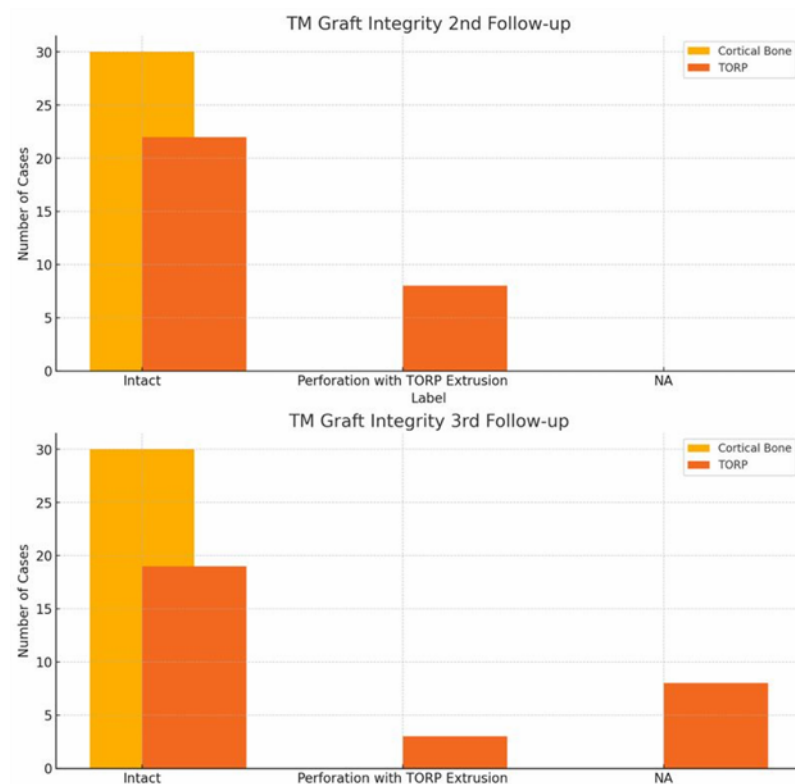


Figure 2: Bar Graph showing relationship between ossiculoplasty materials with other variables.

IV. Discussion

Ossiculoplasty, after it started decades back, has developed largely and it is still a developing procedure. The primary aim of this procedure is to get a stable and functional ossicular chain reconstruction for getting best results in terms of hearing gain.

This study compared the efficacy of cortical bone and TORP as ossiculoplasty materials, based on postoperative hearing gain, TM graft integrity, and complications such as extrusion of prosthesis.

TM Graft Integrity

Graft uptake is a pre-requisite for success of ossiculoplasty procedure, as perforated neotympanum or failure of graft uptake will result in sub-optimal or no hearing gain at all.

In Group 1(cortical bone), neotympanum was intact in all 30(100%) patients and in Group 2(TORP), neotympanum was intact in 22 among 30 patients (73.3%) at 3 weeks.

At 3 months, in Group 1(cortical bone) all 30(100%) patients had intact neotympanum and in Group 2(TORP), 19(63.33%) patients had intact neotympanum and 11(36.66%) had perforation with TORP extrusion. The number of patients with TORP extrusion was 8 at 3 weeks which increased to 11 at 3 months.

In a study done by Sharma et al., the extrusion rate of TORP was 9(45%) out of 20 patients while in our study shows extrusion rate of 36.66% i.e.11 out of 30 patients.⁷ Similar results were seen in a study done by Jha et al.⁸et al.

According to Moretz et al. where he reviewed series of cases of A and C of Austin Kartush classification that underwent ossiculoplasty. The known failure rate or prosthesis extrusion was 24%.⁹

In a study done by Khanam et al. where Teflon TORP was used in 15 patients, there was no evidence of extrusion stated by the author. This difference may be because of smaller sample size.¹⁰

According to study done by Lamba et al. 27 patients underwent ossiculoplasty using synthetic material out of which 13 received Teflon TORP. 6 out of these 13 patients showed extrusion which is 46.15%.¹¹

According to a study done by Vincent R. et al. 96 patients underwent ossiculoplasty using Titanium TORP with silastic banding out of which 1(1%) patient showed TORP extrusion. The lower extrusion rate might be because the material used in prosthesis was titanium which has been found to have lower extrusion rate compared to Teflon, additionally the author used silastic banding to further stabilize the prosthesis.¹²

In most of the above studies extrusion rate of Teflon TORP is quite high as observed in our study and seems to be a major demerit of Teflon TORP as ossiculoplasty material while no extrusion was seen in any of the patient where mastoid cortical bone was used as ossiculoplasty material.

Hearing Gain

In our study, when we calculated hearing gain taking all the 30 patients of both the groups, Group 1(cortical bone) has hearing gain of 19.32 ± 3.01 SD and in Group 2(TORP), it is 11.31 ± 9.00 SD.

On other hand when taking 19 patients of Group 2, after excluding the 11 patients with TORP extrusion, it is 17.86 ± 2.67 SD at 3 months.

Whereas, a study done by Sharma T et al. showed post-op ABG closure of 2.51 ± 4.90 SD at 6 months in Teflon TORP group.⁷

An earlier study done in the same institute by Singh PK et al. where, 50 out of 200 patients received Teflon TORP as ossiculoplasty material. The mean post-op ABG closure was 19.53 dB, very similar to our study showing post-op mean ABG closure of 17.86 ± 2.67 SD.¹³

Similar study with smaller sample size done by Khanam et al. showed post-op hearing gain of 11.3 dB (at 3 months) in Teflon TORP group ,whereas our study shows post-op mean hearing gain of 17.86 ± 2.67 SD (at 3 months).¹⁰

In contrast, a study done by Lamba et al. overall hearing gain in those patients who received synthetic material for ossiculoplasty showed mean hearing gain of 14.57 ± 13.12 SD, out of which those who received Teflon TORP showed hearing gain of 24.14 ± 9.90 SD.¹¹

In our study we also observed the post-operative status of neotympanum in terms of position and mobility. Various factors affect the position and mobility of TM graft such as fibrosis and fixation around the prosthesis and displacement of prosthesis apart from Eustachian tube dysfunction.

In Group 1(cortical bone), 26(86.66%) has normal TM position while there are 4(13.33%) patients with grade I retraction. On other hand in Group 2 number of patients with normal TM position is 16(53.33%) and with Grade I retraction is 3(10%).

In Group 1(cortical bone), 26(86.66%) has normal TM mobility while there are 4(13.33%) patients with decreased mobility. On other hand in Group 2 number of patients with normal TM mobility is 16(53.33%) and with decreased mobility is 3(10%).

This observed difference in the position and mobility of the graft between two groups was not found to be significant.

The ideal prosthesis should be cheap, robust, biocompatible, easily available for ossicular restoration, and produce the best possible sound transmission. The compatibility and simplicity of the configuration of prosthesis during surgery are two important considerations when choosing one.

Teflon TORP comes pre-manufactured and can be easily used after adjusting the size. But being a synthetic material it has more risk of foreign body reaction, displacement and extrusion which is also observed in our study.

Cortical bone being an autologous material is easy to harvest does not cause any foreign body reaction and financial burden. We did not observe extrusion of the cortical bone in any of the patients of Group 1. Cortical bone appears to be a better alternative with regard to this parameter.

Trial and error has led to the evolution of ossiculoplasty procedures. Studying the impact of a single factor at a time is practically challenging because there are numerous factors that affect hearing improvement following ossiculoplasty, in addition to the decision of selecting the most effective technique and implant material. These factors include the surgeon's experience, case selection, post-operative care, and precautions.

V. Conclusion

Based on study we can state that cortical bone is a better choice for ossiculoplasty material over TORP because of high extrusion rate and poorer overall hearing gain of Teflon TORP. In order to better understand problems related to different prosthesis materials and improve surgical outcomes, longer-term follow-up and larger-scale research are required. More studies are required to validate these results and improve the treatment plans for patients undergoing ossiculoplasty, especially those with longer follow-up times and larger sample size.

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