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Original Article

Hearing Outcome after Ossiculoplasty with Teflon Ossicular Replacement Prosthesis in Modified Canal Wall Up Mastoidectomy

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Abstract:

Background: Cholesteatoma commonly leads to damage of ossicular chain. Modified canal all up mastoidectomy is one of the commonly performed procedure for cholesteatoma worldwide. Ossiculoplasty means the operation performed to reconstruct the ossicular chain.

Aim: To evaluate the hearing outcome after ossiculoplasty with teflon ossicular replacement prosthesis in modified canal wall up mastoidectomy.

Methods: A prospective observational study was conducted at the Dept. of Otolaryngology-Head & Neck Surgery, Bangabandhu Sheikh Mujib Medical University, Shahbagh, Dhaka from March 2018 to June 2020. Total 34 patients with cholesteatoma underwent modified canal wall up mastoidectomy and ossiculoplasty with teflon TORP or PORP were included in this study. All patients were followed up post-operatively upto 6 months with PTA.

Results: Hearing improvement was better in ossiculoplasty with PORP. Successful results (ABG closure to within 20dB) were obtained in 35.29% & 70.58% cases in TORP & PORP group respectively after six month post-operatively.

Conclusion: Ossiculoplasty with teflon ossicular replacement prosthesis gives satisfactory hearing gain.

Keywords: Ossiculoplasty, Cholesteatoma, Teflon, TORP, PORP.

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Introduction:

Cholesteatoma is a mass in the middle ear and/or mastoid, formed by keratinizing stratified squamous epithelium, sub-epithelial connective tissue and by the progressive accumulation of keratin debris with or without surrounding inflammatory reaction¹. Bone resorption properties of cholesteatoma leading to destruction of ossicular chain & can cause conductive hearing loss >50 dB².

Treatment of cholesteatoma is surgical. There are two main aims of surgical treatment. 1. Dr. Shah Soheli – Assistant Registrar, Dept. of ENT & Head-Neck Surgery, Shaheed M Monsur Ali Medical College Hospital, Sirajganj.

First, the eradication of disease to produce a dry, stable, safe & waterproof ear. Second, the preservation and/or improvement of hearing³. First goal can be achieved by either canal wall up (CWU) or canal wall down (CWD) mastoidectomy and second goal can be achieved by ossiculoplasty in presence of ossicular chain abnormality⁴.

The term ossiculoplasty refers to the operation performed in the middle ear to restore hearing mechanism by reconstruction of hearing mechanism. The goal of ossiculoplasty is to establish a stable and reliable connection between the tympanic membrane and the mobile footplate of stapes and to achieve the best long term hearing result⁵. Ossiculoplasty is indicated in presence of ossicular chain erosion or discontinuity. Ossicular chain damage is found in all types of chronic otitis media (COM), but tends to be more extensive in presence of cholesteatoma. Most frequently affected ossicle is the long process of incus followed by stapes superstructure. Today, it is believed that ossicular erosion in cholesteatoma is due to enzymatic destruction rather than pressure effect. Austin has classified the ossicular chain defect depending on the presence or absence of malleus and stapes superstructure in absence of incus. Depending on the ossicular defects various types of ossiculoplasty are planned⁶.

First recorded ossiculoplasty was attempted by Matte in 1901⁷. Since the 1950s, when the concept of ossicular chain reconstruction was introduced, it has made more sense to approximate the original anatomy and physiology of the impedance matching system of the middle ear to rehabilitate conductive hearing loss⁸. Ossiculoplasty can be done using autograft or homograft ossicles, bones & cartilages and various alloplastic materials. Over last two to three decades prosthesis becomes more popular than autologous ossicles in reconstruction of ossicular chain⁹. Alloplastic materials that are used for ossiculoplasty include solid plastics (polytetrafluorethylene, polyethylene), solid metals (stainless steel, gold, titanium), porous sponge like plastics (proplast, plastipore) and ceramics (aluminium oxide, hydroxyapatite)¹⁰. An ideal prosthesis for ossicular reconstruction should, from a surgical standpoint of view, require easy manipulation, reduce surgeries to partial or total variants and be made of stable & biocompatible material. And from an acoustic standpoint of view, a prosthesis should weigh 10 to 40 mg, provides proper tension between the tympanic membrane (TM) and the stapes, form less than a 30-degree angle with the TM and accommodate the malleus¹¹.

Hearing improvement following ossiculoplasty depends upon several factors like the materials used, the stage of the disease, degree of destruction of ossicular chain, state of middle ear mucosa, Eustachian tube function and the degree of pre-operative hearing loss¹². Kartush (1994) described MERI scoring system to stratify the patients according to disease severity. Dornhoffer & Gardner developed another scoring system named OOPS (Ossiculoplasty Outcome Parameter Index) to predict hearing outcome after ossiculoplasty. In both scoring system higher the score lower outcome of ossiculoplasty¹³.

Common cause of Ossiculoplasty failure is inadequate contact between the prosthesis and graft that may be caused by sliding or resorption of the cartilage. Additional factors that lead to functional failure include improperly sized prosthesis, fracture of stapes crura, contraction and movement of healing tympanic membrane¹⁴.

The selection of a particular prosthesis is based on several factors that include cost, compatibility, technical ease of use and hearing results of the prosthesis². It is considered that Titanium is an excellent material for ossicular reconstruction and gives better long term hearing results than Teflon. But Chavan et al. (2014)⁷ found no statistical difference in the use of different types of ossicular implants for ossiculoplasty, i.e. refashioned incus or teflon. As ossicular replacement prosthesis Teflon is good because of its high biocompatibility, biostability, low weight, high rigidity and adjustable shaft length which are the characteristics suitable for good sound transmission. Moreover Teflon is MRI compatible. We used Teflon as it is cost effective, easily available & commonly used for ossiculoplasty in our country. First reported ossiculoplasty with Teflon was performed by Austin in 1962.

This study was conducted to see the hearing outcomes after ossiculoplasty with Teflon TORP (EON Meditech Pvt. Ltd., India) & PORP (EON Meditech Pvt. Ltd., India) in modified canal wall up mastoidectomy, which was described by Tos in 1982, for cholesteatoma¹⁵.

Materials and methods:

This prospective observational study was conducted at the Department of Otolaryngology-Head & Neck Surgery of Bangabandhu Sheikh Mujib Medical University, Shahbagh, Dhaka from March

2018 to June 2020. Patients were selected purposively according to selection criteria. After selection of the subjects, the nature, purpose and benefit of the study were explained to each patient in details. They were encouraged for voluntary participation. They were allowed to withdraw their name from the study whenever they feel like. Informed written consent was taken from all the participants. Ethical clearance was obtained from the Institutional Review Board (IRB) of BSMMU. Patients aged from 10 to 55 years. Patients with cholesteatoma limited to middle ear cleft with eroded ossicular chain diagnosed with HRCT scan & per-operative findings with conductive hearing loss not more than 60 dB and underwent modified canal wall up mastoidectomy (CWU) with ossiculoplasty using teflon PORP or TORP were included in the study.

Patient with extensive cholesteatoma (petrous apex cholesteatoma or cerebello-pontine angle cholesteatoma), recurrent or residual disease, cholesteatoma with intracranial and/or extracranial complication (s), gross erosion of meatal wall, gross anatomical/congenital abnormalities, only hearing ear, mixed or sensorineural hearing loss, having sino-nasal pathology were excluded from the study.

All patients attended first in outpatient department, where detailed history was taken and thorough general & ENT examination was performed. Otomicroscopic & otoendoscopic examination was performed in indoor setup. PTA for subjective assessment of hearing loss was performed in all cases. Hearing loss was calculated by averaging the threshold of hearing at 500, 1000 & 2000 Hz from PTA. In every case HRCT scan (with 0.5 to 0.6 mm thickness cut) of temporal bone was performed for diagnosis & extension of cholesteatoma and to see the status of ossicular chain⁷. Other investigations

for general anaesthetic fitness were performed prior to surgery.

Every case was operated through post aural incision and under general anesthesia. Modified CWU was done in all cases. Ossiculoplasty was performed with TORP in absence of stapes superstructure in one group and with PORP in presence of stapes superstructure in another group.

Post-operatively patients were followed up at 7th & 15th post-operative day and after 1st, 3rd & 6th post-operative months to assess wound healing^{7,17}. During follow up patients were assessed with proper history, clinical examination including otoendoscopic & otomicroscopic examination. Hearing was evaluated with PTA in all patients at 3rd & 6th months after surgery⁴. Pure tone average was calculated by averaging the threshold of hearing at 500, 1000 and 2000Hz following the guidelines recommended by the committee on hearing and equilibrium of the American Academy of Otolaryngology for the evaluation of result of treatment of conductive hearing loss (1995)¹⁸. During follow up HRCT scan was performed in selected cases when there was suspicion of disease recurrence or failure of ossiculoplasty both clinically and/or with PTA. Successful results were considered when postoperative air bone gap closure to within 20 dB both for PORP & TORP group¹³.

Data were presented as mean \pm standard deviation (SD) or percentages. To compare the data of each parameter before and after

operation paired student's t-test were used. Chi square test was performed to test categorical variables. A *p*-value of less than 0.05 was considered statistically significant.

Results:

Total 34 patients (17 patients in each group) were operated among them 2 patients from TORP group and one patient from PORP group had missed the last follow up (at 6th months postoperatively), thus excluded from the study. Finally, the results of total 31 patients were calculated. Postoperatively maximum duration of follow up was 6 months.

Age of the patients ranged from 14-50 years. Mean age was 25.6 ± 7.47 years in TORP group and 29 ± 7.44 years was in PORP group. Maximum patients of both TORP & PORP group were within 21-30 years age group. Majority of the patients were male & constituting about 54.83%. Right ear was operated more in both cases & was 61% of patients.

Preoperatively average speech frequency (500, 1000, 2000 Hz) PTA-ABG for the TORP group was 30.33 ± 5.33 dB, with a range of 15 to 38.33 dB. The average postoperative PTA-ABG after 3rd month was 26.67 ± 5.77 dB, with a range of 13.34 to 38.33 dB and after 6th month was 22.11 ± 5.94 dB, with a range of 6.67 to 35 dB. These were statistically significant improvement ($P < 0.05$). In this group, successful results (ABG closure to within 20 dB) were obtained in 40.00% (6) cases (Table I & II).

Table I : Post-operative hearing gain with TORP (n=15):

ABG (dB)	Pre-operative	Post-operative	
		3 rd month	6 th month
0-10 (Excellent)	0	0	1 (6.67%)
11-20 (Good)	1 (6.67%)	1 (6.67%)	5 (33.33%)
21-30 (Fair)	8 (53.33%)	10 (66.67%)	9 (60.00%)
>30 (Poor)	6 (40.00%)	4 (26.66%)	0

Table II: Air-Bone Gap (ABG) average (dB) in TORP group (n=15):

Preoperative (Mean ± SD)	Post-operative		Improvement	P-value
	Follow up	(Mean ± SD)		
30.33 ± 5.33	After 3 rd month	26.67 ± 5.77	3.66	0.02-0.01
	After 6 th month	22.11 ± 5.94	8.22	0.01-0.005

Paired student's t-test was used to calculate P value.

Preoperatively average speech frequency (500, 1000 & 2000 Hz) PTA-ABG for the PORP group was 28.64 ± 2.96 dB, with a range of 23.33 to 35.00 dB. The average postoperative PTA-ABG after 3rd months was 24.27 ± 2.63 dB, with a range of 20 to 30 dB and after 6th

months was 15.67 ± 4.72 dB, with a range of 8.33 to 23.34 dB. These were statistically significant improvement ($P < 0.05$). In this group, successful results (ABG closure to within 20 dB) were obtained in 75.00% (12) cases.

Table III: Post-operative hearing gain with PORP (n=16)

ABG (dB)	Pre-operative	Post-operative	
		3 rd month	6 th month
0-10 (Excellent)	0	0	4 (25.00%)
11-20 (Good)	0	2 (12.50%)	8 (50.00%)
21-30 (Fair)	11 (68.75%)	14 (87.50%)	4 (25.00%)
>30 (Poor)	5 (31.25%)	0	0

Table IV: Air-Bone Gap (ABG) average (dB) PORP group (n=16):

Preoperative (Mean ± SD)	Post-operative		Improvement	P-value
	Follow up	(Mean ± SD)		
28.64 ± 2.96	After 3 rd month	24.27 ± 2.63	4.37	0.005
	After 6 th month	15.67 ± 4.72	12.97	0.005-0.0002

Paired student's t-test was used to calculate P value.

Table V: Factors affecting ossiculoplasty (N = 31)

Factors		No. of cases	Success Rate	P value
Title	Description			
Severity of ear discharge	No discharge	00	00	<0.01
	Minimal discharge*	22	72.72%	
	Intermediate discharge**	09	22.22%	
	Profuse Discharge***	00	00	
Middle ear mucosa	Normal	05	80.00%	>0.1
	Abnormal	26	53.85%	
Mastoid cellularity	Pneumatic	21	71.43%	<0.05
	Sclerotic	10	30.00%	
Handle of malleus	Present	25	68.00%	<0.025
	Absent	06	16.67%	
Stapes superstructure	Present	16	75.00%	<0.05
	Absent	15	40.00%	

*Discharge accumulating in EAC but not soiling linen at night; **Discharge soiling linen at night;

***Discharge reappearing immediately after cleaning the ear⁷. P value was calculated using a²- test.

Failure of ossiculoplasty was considered in our study, when one or more of the followings happened:

- Severe sensory neural hearing loss, which is defined as a worsening of BC in PTA by 15 dB or more;
- Postoperative ABG on PTA greater than 20 dB.
- Dizziness in combination with a positive fistula sign.

No patient developed post-operative severe SNHL or dizziness with positive fistula test. But some complications were observed in this series & are listed in table 4.5. Only 3 patients of which 2 (13.33%) in TORP & 1 (06.25%) in PORP group were developed mild sensory neural hearing loss. There were only 2 (06.45%) extrusions among 31 cases. One extrusion occurred earlier at 3 months in PORP group. That extrusion was related to persistent postoperative cellulitis. Second case of prosthesis extrusion was in TORP group at 6th month. It occurred may be due to a slipped prosthesis that was confirmed by HRCT scan. Extrusion rate of this series was low probably due to meticulous surgical technique and use of a piece of cartilage in between prosthesis head & tympanic membrane. Also 3 (09.67%) patients developed postoperative perforation.

Discussion:

The goal of every otologist during ossiculoplasty is to restore hearing mechanism to achieve the best possible hearing results and to satisfy their patient's expectations. Different types of prosthesis made of various materials are commercially available & are used to reconstruct the damaged ossicular chain. A good prosthesis should be easy to handle, made of biocompatible materials, should weigh 10 to 40 mg, provide proper tension between the

tympanic membrane & stapes and should maintain long term hearing.

This study was conducted to see the hearing outcome of ossiculoplasty with teflon TORP or PORP in modified canal wall up mastoidectomy. As searching for ideal prosthesis continues one should use the best possible prosthesis for their patients & search the other possible factors like surgical techniques depending on the types of ossicular chain defects and so on that can improve the results.

Use of teflon as an implant material reported in the literature as early as in 1962, when Austin was first time reported its use. Tetrafluoroethylene (Teflon) is prosthesis is light, easy to handle, length of prosthesis can be adjusted by cutting through with surgical blade (with no-11 surgical blade), biocompatible with middle ear environment, can provide adequate tensile strength between tympanic membrane & stapes. Teflon prosthesis is MRI compatible, provides good long-term hearing. Moreover, it is cost effective, easily available and commonly used in our country. Thus, we decided to use this Teflon prosthesis for ossiculoplasty.

In this current study, cholesteatoma was removed with modified canal wall up mastoidectomy & ossiculoplasty was done with Teflon TORP in 15 patients and with PORP in another 16 cases. In this study, about 54.84% populations were female. Maximum patients of these groups were within 21-30 years of age with a range from 14-50 years and mean age of TORP group was 25.60 ± 7.47 years & in PORP group it was 29 ± 7.44 years. Most of the patients presented to us with COM with cholesteatoma in third decade of their life because earlier they took medical treatment but their problem did not resolve with that.

In this study, unilateral COM was 77.42%, out of which right was involved in 66.67% and left ear in 33.33% of cases.

These findings are consistent with the findings of Sharma & Kuchhal (2017) and Chavan et al. (2014). Mean age at presentation was at third decade and unilateral involvement was in 78.33% cases in Sharma & Kuchhal's series¹⁹. Chavan et al.⁷ found slight male predominance (52.50% male) and more right ear involvement (52.50%) in their series.

Hearing impairment (100%) and ear discharge (100%) were the commonest presenting symptoms among the patients, followed by tinnitus in 6 (19.35%), earache in 5 (16.13%), aural fullness in 5 (16.13%) & vertigo in 2 (6.45%) patients. Most of the patients had history of aural discharge for 3-15 years.

This study was consistent with the study conducted by Chavan et al.⁷ Otorrhoea and hearing impairment were also the commonest presenting symptoms in their study.

In this study, gradual worsening outcome was observed as the severity of disease was increased, but the status of middle ear mucosa did not significantly affect the outcome of ossiculoplasty. These findings correlate well with those of Kotzias et al. where they showed that there was a definite relationship with the severity of middle ear disease & the worsening of surgical outcome. But, Dornhoffer differs with the findings of this study and he found significant relationship between the condition of middle ear mucosa and post-operative hearing outcome. He commented that, a trend towards worsening of hearing results with mucosal thickening but statistically significant results observed only when fibrosis of middle ear mucosa was present. Our study fails to detect this probably may be due to our small sample size.

Mastoid cellularity, presence or absence of stapes superstructure and handle of malleus significantly affects the post-operative outcome. This study finding also supported by the finding of Chavan et al. that they found

statistically significant effect of mastoid cellularity, presence or absence of stapes superstructure and handle of malleus on post-operative hearing outcome.

In this study, preoperatively average PTA-ABG for the TORP group was 30.33 ± 5.33 dB, with a range of 15 to 38.33 dB. The average postoperative PTA-ABG after 3rd month was 26.67 ± 5.77 dB, with a range of 13.34 to 38.33 dB and after 6th month was 22.11 ± 5.94 dB, with a range of 6.67 to 35 dB. These were statistically significant improvement ($P < 0.05$).

In this TORP group, successful results (ABG closure to within 20 dB) were obtained in 40.00% (6) cases. Wilson et al. (2013) observed successful results in 42% cases with TORP reconstructions²⁰. Bayazit et al. observed their ossiculoplasty successful outcome by using plastipore prosthesis 43.1% in TORP²¹. Vincent et al. (2011) found audiological success in 86.9% cases²². Probable causes of his success was his different surgical techniques as he used TORP with silastic banding & malleus relocation technique in presence of intact & mobile stapes.

In this study using Teflon TORP average hearing gain was 8.22 dB 6 months after surgery. This result is consistent with study conducted by Mills (1993), where he found 6.0 dB hearing gain after ossiculoplasty with TORP²³. Bayazit et al. (1999) showed around 16.0 dB hearing gain with TORP reconstructions²¹. Vincent et al. (2011) observed 23.3 dB hearing improvement with TORP²².

In this study, preoperatively average speech frequency (500, 1000, 2000 Hz) PTA-ABG for the PORP group was 28.64 ± 2.96 dB, with a range of 23.33 to 35.00 dB. The average postoperative PTA-ABG after 3rd months was 24.27 ± 2.63 dB, with a range of 20 to 30 dB

and after 6th months was 15.67 ± 4.72 dB, with a range of 8.33 to 23.34 dB. These were statistically significant improvement ($P < 0.05$). In this group, successful results (ABG closure to within 20 dB) were obtained in 75.00% (12) cases.

Findings of this study are consistent with the following studies. Jha et al. (2011) reported their audiological successful results with titanium PORP in 75% cases. Wilson et al. (2013) observed successful results in 71% cases with PORP reconstructions. Dornhoffer (1998) found successful hearing gain in 69% cases with PORP. Slater et al. (1997) published their successful results using porous polyethylene TORP in 81% of cases after first 6 months²⁴. Vincent et al. (2011) found audiological success in 70.4% cases of TORP reconstructions.

In this study, using Teflon PORP average hearing gain of our patients is 12.97 dB 6 months after surgery. This finding is consistent with the followings. Martins et al. (2011) reported 13.20 dB hearing gain using titanium PORP²⁵. Mills (1993) reported around 14.0 dB hearing gain after ossiculoplasty with TORP. Vincent et al. (2011) observed 12.5 dB hearing improvement with PORP. These studies are consistent with our study.

Previously prosthesis extrusion was one of the most important causes of failure of ossiculoplasty with alloplastic materials. We overcome this by using a piece of cartilage having one sided perichondrium in between prosthesis head & tympanic membrane.

Prosthesis extrusion rate in this current study was 6.45%. This result is consistent with the followings. Mobashir et al. reported 5.26% extrusion rate in their series. Vincent et al. observed their extrusion rate 3.4% in PORP & 4.2% in TORP group. Bayazit et al. (1999) found 4.2% prosthesis extrusion in their series. Though Slater et al. differs this result,

they reported 0.89% extrusion rates in their series, possibly due to use of more biocompatible materials hydroxyapatite prosthesis.

In this study postoperatively 3 patients (8.82%) developed mild degree sensory neural hearing loss. Vincent et al. observed less postoperative SNHL than this current study and it was 0.3%.

In this study, postoperatively dry, small, central perforation found in 3 (8.82%) patients. This finding is consistent with the results of following studies. Mobashir et al. reported 10.52% graft failure in their series. According to Chouhan et al. (2014) 3 of their patients (6.0%) had a residual perforation after surgery.

Conclusion:

Among various types of ossicular replacement prosthesis made of different materials, Teflon is one of the commonly used prosthesis in Bangladesh. In our study ossiculoplasty with Teflon prosthesis in active squamous variety of COM with ossicular chain erosion gives satisfactory hearing gain & with PORP it was 12.97 dB & with TORP it was 8.22 dB.

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