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ORIGINAL ARTICLE

To Evaluate and Compare the Result of Ossiculoplasty Using Different Types of Graft Materials and Prosthesis in Cases of Ossicular Discontinuity in Chronic Suppurative Otitis Media Cases

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Abstract Chronic suppurative otitis media, with and without cholesteatoma, frequently results in disruption of the ossicular chain. The present study was designed to compare the outcome using autologous ossicle and titanium prosthesis in two groups of suitable patients presenting with chronic suppurative otitis media for middle ear reconstructive surgeries. A prospective study done from July 2012 to December 2013, at Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur (Rajasthan). The target group included patients with chronic suppurative otitis media admitted and planned for reconstructive middle ear surgery. The study group patients among the target group requiring certain ossicular reconstruction. The patients included were patients with CSOM with or without cholesteatoma in which there was ossicular discontinuity. The patients were divided in two groups A and B. In group A patients autologous incus was used and in group B titanium prosthesis either TORP or PORP was used for ossicular replacement. Out of 340 patients as target group, 88 patients were included in study group. Further 88 patients of study group, 51 patients were included in group A; rest 37 patients were included in group B. In group B patients partial ossicular replacement platinum prosthesis was used in 31 patients while in rest 6 patients a total ossicular replacement prosthesis was used. Out of 88 patients, 79 were primary cases and 9 were revision cases. Pre and post operative air bone gap were noted. Pre operatively both of the groups were identical in relation to air–bone gap. The postoperative air–bone gap was calculated as the difference between postoperative air conduction and preoperative bone conduction. On comparison of preoperative and post-operative hearing results there was improvement in air conduction threshold and air bone gap in both the groups. Post operatively difference in air bone gap closure between group A and group B was found statistically significant (P value $= 0.032$) suggesting better hearing outcomes after using titanium ossicular replacement prosthesis. On comparing partial or total ossicular replacement prosthesis no significant difference was found for the audiological outcome ($P = 0.434$). Various prognostic factors were also noted for air bone gap closure. Titanium ossicular replacement prosthesis have better outcome, and no significant difference found in audiological outcome for TORP and PORP.

Keywords CSOM · Prosthesis · Autologous incus

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Introduction

Chronic suppurative otitis media, with and without cholesteatoma, frequently results in disruption of the ossicular chain. Bone resorption from the cholesteatomas may occur owing to enzyme production by the expanding epithelial lining and lead to bony erosion of the ossicles, otic capsule,

and mastoid [1]. Conductive hearing loss from ossicular chain abnormalities may result from either discontinuity or fixation of the ossicular chain. In order of frequency, discontinuity most commonly occurs because of an eroded incudostapedial joint, an absent incus, or an absent incus and stapes superstructure. In more than 80% of patients, the cause of ossicular damage i.e. discontinuity is chronic suppurative otitis media with or without cholesteatoma. Trauma or congenital malformations account for most of the remaining causes of ossicular damage [1, 2].

Ossiculoplasty is defined as the reconstruction of the ossicular chain [2]. The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe, easily insertable, and capable of yielding optimal sound transmission [1]. Selection of a particular prosthesis, must be based on several factors, including compatibility and ease of configuring the prosthesis during surgery [3, 4].

Materials used in ossiculoplasty include autografts such as autologous ossicles, cartilage, and bone; homologous grafts such as homologous bone; and synthetic materials such as plastipore, hydroxyapatite, and titanium [3]. The goal of ossiculoplasty in individuals with conductive hearing loss is to improve hearing. The success of ossiculoplasty is influenced by various factors, including the status of the middle ear mucosa and ossicles, surgical technique, and Eustachian tube function [1, 4]. Other factors affecting postoperative hearing results include patient age, length of the prosthesis, revision surgery, otorrhea, tympanic membrane perforation and cholesteatoma [5].

The present study was designed to compare the outcome using autologous ossicle and titanium prosthesis in two groups of suitable patients presenting with chronic suppurative otitis media for middle ear reconstructive surgeries.

Materials and Methods

This is a Prospective study designed to evaluate and compare the result of ossiculoplasty using different types of graft materials and prosthesis in cases of ossicular discontinuity in chronic suppurative otitis media cases.

The study design and the collection of patient data were approved by the Institutional Research Review Board and Ethical Committee. Informed consent was obtained and approved by ethical committee for the study. No animal was used for the study and no human was harmed during the period of study.

The study was conducted upon the patients of chronic suppurative otitis media with ossicular discontinuity admitted for reconstructive surgery at hospital. Study is done from July 2012 to December 2013. The Target group included patients with Chronic Suppurative Otitis Media admitted and planned for reconstructive middle ear surgery. The Study group patients among the target group requiring certain ossicular reconstruction.

Inclusion criteria is patients with CSOM with or without cholesteatoma in which there was ossicular discontinuity.

The exclusion criteria is patients with Active ear infection, with Sensorineural/Mixed hearing loss, Patients with ossicular fixation or ossicular anomalies without CSOM, Non reconstructable posterior canal wall/extensive cholesteatoma warranting canal wall down procedures/cholesteatoma with complications, or Any systemic and hematological disorder.

The patients were divided in two groups

Group A Patients of Chronic Suppurative Otitis Media with ossicular discontinuity/erosion in whom autologous incus was used for ossiculoplasty.

Group B Patients of chronic suppurative otitis media with ossicular discontinuity/erosion in whom total/partial titanium ossicular replacement prosthesis was used for ossiculoplasty.

The Sample size: Minimum 30 cases in each group.

Randomization: Patients were assigned into group A and group B alternately.

To begin with, a detailed history was taken. General and local examinations including otoscopic examination were done, noting the defect in the tympanic membrane and other co existent pathology. Preoperative pure tone audiometry was done to assess the status of hearing. Hearing thresholds performed at frequencies recommended by AAO-HNS at 500, 1000, 2000 and 3000 Hz.

X ray nose and paranasal sinus (Water's view) was done to rule out any septic foci in the nose and paranasal sinus. In patients with discharging ear, an antibiotic course was given for 3 weeks preoperatively and the patient was operated only after the ear was dry for a minimum of 6 weeks.

In all cases ossiculoplasty was performed in one stage with tympanomastoidectomy with post aural approach. Temporalis fascia was used as the graft material.

Status of the middle ear structures was then assessed to decide the type of tympanoplasty and size and shape of tragal cartilage graft required. Mastoidectomy either cortical or canal wall down mastoidectomy was done as per the requirement. Then ossicular chain was checked. If the ossicular chain was intact than type I tympanoplasty via underlay technique was done.

If there was necrosis of the ossicles, ossiculoplasty according to assigned group using either autologous incus/malleus/cortical bone/cartilage or titanium prosthesis was done. Depending upon the intra-operative finding, either the Tita-prosthesis type Partial Vario Campana [for partial ossicular reconstruction (POR)] or the Tita-prosthesis type Total Vario Cask [for total ossicular reconstruction (TOR)] was used [Eon Meditech Pvt. Ltd., India].

In all cases a piece of conchal cartilage was placed over the autologous bone and titanium prosthesis over which underlay grafting was done using temporalis fascia. Gel foam kept in middle ear to stabilize the assembly and keep the graft in position. Patients were given antibiotic cover for 3 weeks.

Follow up was done at 1 month, 6 weeks and 3 months. At each follow up the complaints of the patients were noted. Microscopic examination was done to see the condition of the canal and the graft. Pure tone audiometry was done at 6th month of follow up.

Hearing level was determined using four-frequency pure tone averages, of 500, 1000, 2000, and 3000 Hz, as recommended before surgery and 6 months after surgery. The postoperative air–bone gap (ABG) was calculated as the difference between postoperative air conduction (AC) and preoperative bone conduction (BC). As per AAO-HNS guidelines, successful outcome is defined as closure of post-operative AB gap by $\leq$20 dB so we considered postoperative ABG $<$ 20 dB as successful. We also calculated the closure in ABG as the difference between pre- and post-operative ABG.

The data was compiled and analyzed with regards to the pure tone average (PTA) of air conduction and the air–bone gap. Comparison of pre-operative and post-operative pure tone averages of air conduction (AC) and air–bone gaps (ABGs) was performed at frequencies recommended by AAO-HNS (0.5, 1, 2, 3 kHz). The most recent post-operative audiogram of the patient was considered for comparison to the pre-operative audiogram. The following parameters were calculated:

Pre-operative PTA (AC): average of pre-operative AC threshold of 0.5, 1, 2, 3 kHz.
Pre-operative ABG: PTA (pre-operative AC)—PTA (pre-operative bone conduction (BC).
Post-operative PTA (AC): average of post-operative AC threshold of 0.5, 1, 2, 3 kHz.
Post-operative ABG: PTA (post-operative AC)—PTA (pre-operative BC).

Average hearing level was described as mean ± standard deviation (SD). Pearson's Chi-square test and Fisher's exact test were used for comparisons of categorical variables, and the Mann–Whitney test for comparisons of continuous variables. A P value of less than 0.05 was considered statistically significant.

Results

Out of total 340 patients (Table 1) 88 patients fulfilled the criteria for the study and included in the study group. The age of the patients included in the study ranged from 12 to 56 years with mean age of presentation of 31.8 ± 11.87 years. There were 46 males (54%) and 42 females (46%). The commonest complaint of patients was ear discharge, seen in 100% of the patients. Second common presenting complaint was hearing impairment which was seen in 84% of patients.

These 88 patients were randomized into group A and group B. In group 'A' patients ossicular reconstruction was done using autologous Incus. In group 'B' patients titanium ossicular replacement prosthesis was used. Out of total 88 patients, 51 patients were included in group A rest 37 patients were included in group B. Out of those 37 patients Partial Ossicular Replacement Platinum Prosthesis was used in 31 patients while in rest 6 patients a Total Ossicular Replacement Prosthesis was used. Out of 88 patients, 79 were primary cases and 9 were revision cases.

Pre-operatively mean air conduction in group A was 41.60 ± 8.86 dB. Mean bone conduction was 8.72 ± 3.7 dB and mean air bone gap was 32.88 ± 7.08 dB. Similarly, Pre-operatively mean air conduction in group B was 42.80 ± 9.19 dB. Mean bone conduction was 9.86 ± 3.82 dB and mean air bone gap was 32.97 ± 7.25 dB. Both the groups were identical in relation to Air–Bone gap (Tables 2, 3, 4, 5, 6).

In group 'A' post-operative mean air conduction was 33.82 ± 8.0 dB, mean bone conduction was 9.41 ± 4.03 dB and mean air–bone gap was 24.41 ± 5.90 dB. Similarly, in group 'B' the post-operative mean air conduction was 32.97 ± 9.02 dB, mean bone conduction was 10.48 ± 3.98 dB and mean air–bone gap was 22.37 ± 7.59 dB.

On comparison of pre-operative and post-operative hearing results there was improvement in air conduction threshold and air bone gap in both the groups. On applying 't' test it showed that this difference was highly significant (P value $<$0.001) thus verifying the efficacy of ossiculoplasty and reconstruction of tympanic membrane in restoring the distorted sound conduction mechanism of the ear.

On analyzing the audiometric parameter of air–bone gap by the same paired 't' test there was again significant improvement in air–bone gap after surgery in both the groups (P value $<$0.001).

When we analyze the air-bone closure in group A and group B, we found that the air-bone closure in group A was 8.47 ± 4.17 and group B was 10.59 ± 4.9. The difference between group A and group B was statistically significant (P value = 0.032) suggesting better hearing outcomes after using titanium ossicular replacement prosthesis.

On comparison of pre-operative and post-operative hearing results there was improvement in air conduction threshold and air bone gap in both the groups. On applying 't' test it showed that this difference was highly significant

Table 1 Epidemiology of the patient operated for chronic suppurative otitis media during study period

Total number of patients underwent middle ear surgery during the study period (target group)	340 cases
Male	198
Female	142

Study group	
Total number of patients	88
M:F	46:42
Age	
Mean ± SD	31.1 ± 11.87 (range 12–56)

	Group A	Group B
Total number of patient enrolled (n)	51	37
Male	24	22
Female	27	15
Age distribution		
Mean ± SD	30.78 ± 13.08	31.6 ± 10.11
Range	12–56 years	13–48 years
Clinical presentation		
Ear discharge	51	37
Hearing impairment	44	30
Ear ache	12	6
Tinnitus	2	3
Previous history of ear surgery	5	4

Table 2 Pre-operative hearing status

	Group A			Group B		
	Range (dB)	Mean (dB)	SD (dB)	Range (dB)	Mean (dB)	SD (dB)
Air conduction	25–60	41.60	8.86	15–60	42.8	9.19
Bone conduction	5–25	8.72	3.7	5–25	9.86	3.82
Air bone gap	15–44	32.88	7.08	5–44	32.97	7.25

Table 3 Post-operative hearing status

	Group A			Group B		
	Range (dB)	Mean (dB)	SD (dB)	Range (dB)	Mean (dB)	SD (dB)
Air conduction	15–48	33.82	8	18–48	32.97	9.02
Bone conduction	5–25	9.41	4.03	5–25	10.48	3.98
Air bone gap	10–38	24.41	5.90	10–38	22.37	7.59

in PORP cases (P value < 0.001) and significant in TORP cases (P value < 0.05) thus verifying the efficacy of ossiculoplasty and reconstruction of tympanic membrane in restoring the distorted sound conduction mechanism of the ear by titanium PORP and TORP.

When we analyze the air-bone closure in PORP and TORP group, we found that the air-bone closure in patients with PORP was 10.48 ± 4.87 and in patients with TORP was 11.16 ± 5.98. The difference between TORP and PORP group was statistically insignificant (P value = 0.434).

Table 4 Comparison of pre-operative and post-operative hearing results

Hearing results	Pre-operative (mean ± SD)	Post-operative (mean ± 2 SD)	*P* value
Air conduction			
Group A	41.60 ± 8.86	33.82 ± 8	<0.001
Group B	42.8 ± 9.19	32.97 ± 9.02	<0.001
Bone conduction			
Group A	8.72 ± 3.7	9.41 ± 4.03	0.37
Group B	9.86 ± 3.82	10.48 ± 3.98	0.496
A–B gap			
Group A	32.88 ± 7.08	24.41 ± 5.90	<0.001
Group B	32.97 ± 7.25	22.37 ± 7.59	<0.001
A–B gap closure			
Group A	8.47 ± 4.17		0.033
Group B	10.59 ± 4.98		

Table 5 Comparison of pre- and post-operative hearing results in patients implanted with titanium total and partial ossicular replacement prosthesis

Hearing results	Pre-operative (mean ± SD)	Post-operative (mean ± 2 SD)	*P* value
Air conduction			
PORP (31)	41.0 ± 8.64	31.32 ± 8.29	<0.001
TORP (6)	52.33 ± 5.57	41.5 ± 8.3	0.024
Bone conduction			
PORP	8.90 ± 2.85	9.58 ± 2.75	0.343
TORP	14.83 ± 6.21	15.16 ± 6.08	0.928
A–B gap			
PORP	32.09 ± 7.58	21.61 ± 7.51	<0.001
TORP	37.5 ± 2.16	26.34 ± 7.39	0.005
A–B gap closure			
PORP	10.48 ± 4.87		0.434
TORP	11.16 ± 5.98		

Table 6 Prognostic factors for air–bone gap closure

Factor for ABG closure	*P* value
Titanium total and partial ossicular prosthesis [PORP (n = 31) vs. TORP (n = 6)]	0.434
Malleus intact/eroded (n = 79/n = 9)	0.045
Stapes supra structure intact/eroded (61/27)	0.878
Cholesteatoma/non-cholesteatoma (32/56)	0.085
Previous surgery (9/79)	0.01

The prognostic factors for ABG closure were persistence of intact malleus for better results ($P = 0.045$). Similarly, postoperative ABG closure was better in patients with primary surgery in comparison to the patients who had previously been operated ($P = 0.01$). No significant difference was found for the audiological outcome with partial or total ossicular replacement prosthesis ($P = 0.434$). Similarly, we found no significant difference regarding the presence or absence of the stapes ($P = 0.878$) and cholesteatoma ($P = 0.085$).

Discussion

Current techniques of ossiculoplasty have evolved empirically as a result of trial and error. With the evolution of newer surgical techniques and advances in the instrument armamentarium available to the otologist, the hearing outcome of ossiculoplasty has shown a noticeable improvement over recent years. Success in ossiculoplasty is determined by technical ability and, to a large extent, case selection.

A wide range of prosthesis designs and materials has been used for ossicular reconstruction in middle-ear surgery. To optimize postoperative functional results, ossicular grafts and prostheses must couple well at their ends to

bone or soft tissue, but must remain suspended in air elsewhere in order to transmit sound effectively.

In the present study, the study group comprises of 88 patients being operated for chronic suppurative otitis media with or without cholesteatoma. The mean age at presentation was 31.1 ± 11.87 (range 12–56), with the patients ranging from 12 to 56 years of age. There was almost equal male: female ratio (1.09:1).

Ear discharge was the most common complaint among patients (100%), followed by decrease hearing (84%) in this study. A minority of patients also complained of tinnitus (5.68%), earache (20%), and vertigo (3.4%). The right ear was involved in 41 patients, the left ear in 34 cases and both in 13 cases.

Out of total 88 patients, 51 patients were included in group A (ossiculoplasty with autologous incus group) rest 37 patients were included in group B (ossiculoplasty with titanium prosthesis group).

All patients were operated with a post aural incision. 40 patients were operated under general anesthesia and in 48 patients, local anesthesia was used. Attico antral disease was seen in 50 out of 88 cases (56.81%). Cholesteatoma was present in 36.36% of cases.

The pathologic condition of the middle ear as a predictor of outcome is a variably described in the literature. Dornhoffer et al. [6] reported that the pathologic condition associated with the surgical indication was not significant. He found that the mucosal status and presence of drainage were more significant than the pathologic conditions initiating the surgical procedure. According to this report, it was not the presence of cholesteatoma, but the associated middle ear disease that was found to be significant. On contrary Black [7] found the middle ear mucosa to be a predictor of postoperative hearing outcome. Albu et al. [8] also found similar results.

In the present study, the long process of incus was the most susceptible part of the ossicular chain, affected due to the disease process in all 88 patients, followed by the stapes in 27 patients (30.68%) with the malleus being the most resistant amongst the three, being affected in only 9 cases (10.22%). This correlates with the precarious blood supply to the long process of incus that results in the incus being the most susceptible ossicle for erosion [1, 2, 5].

In the literature, when cartilage is placed between the prosthesis head and the tympanic membrane, extrusion rates decrease to less than 2% [9, 10]. Cartilage interposition between the prosthesis and the tympanic membrane is able to reduce but not eliminate extrusion in alloplastic materials [9, 11]. In the present study, all patients had cartilage interposition. We noted implant extrusion in three cases (3.4%) two in group A and one in group B but all three patients had post-operative Pseudomonas infection. Prosthesis or underlying cartilage displacement due to too short a prosthesis was implicated as a prime cause of functional failure in various studies, in agreement with the present findings [12, 13]. In the study by Schmerber et al. [13], insufficient length of the prosthesis, especially TORP, explained poorer functional results and secondary displacement.

The size of cartilage cover is one of the few variables that the surgeon has control over during the ossiculoplasty. Increasing cartilage size does not improve the acoustic results, and can even make them worse at low frequencies. Smaller cartilage pieces seem to have a better acoustic result [14]. Experimental studies suggested that a thickness between 0.3 and 0.5 mm is optimal, as vibration values are then similar to those of a natural tympanic membrane [15]. We have used a conchal cartilage of 0.5 mm thickness in every case.

Successful graft uptake was achieved in 81 (92%) of the 88 operated ears. In 7 ears, residual perforation was seen at the end of 6 months' study period.

Pre-operatively both of the groups were identical in relation to Air–Bone gap.

Post-operative air–bone gap up to 25 dB was achieved in 59% patients. Success was defined as an ABG < 20 dB as recommended by AAO-HNS guidelines. Post-op ABG < 20 dB was achieved in 26 (29.54%) out of 88 patients. In group A air bone gap of <20 dB was seen in 12 (23.53%) patients only while in group B 14 (37.83%) out of 37 showed post-operative air bone gap of <20 dB. This difference was statistically insignificant ($P > 0.05$) showing better outcome with titanium ossicular replacement prosthesis in comparison to autologous incus.

Jha et al. [16] concluded that cartilage, bone, and gold are better and more cost-effective alternatives to plastipore and titanium. In pure tone audiometry, successful functional results (ABG ≤ 20 dB) with the Kurz titanium prosthesis range from 57 to 76% [17, 18]. In the present study, the success rate in group B was (37.83%) where 14 out of 37 showed post-operative air bone gap of <20 dB.

No significant difference was found for the audiological outcome with partial or total ossicular replacement prosthesis ($P = 0.434$). Yung [10] found no difference between the different types of prostheses used. While Jackson et al. [19] achieved better results with Teflon TORP than PORP in his study of 141 cases of ossiculoplasty. Begall and Zimmermann [20] reported better results for TORP prostheses, whereas Krueger et al. [21] obtained better results with PORP. Stupp et al. [22] reported no significant difference in postoperative ABG closure between the PORP and TORP prostheses.

There was no immediate post-operative or long term complications of surgery in present study.

The prognostic factors for ABG closure were found to be persistence of intact malleus for better results ($P = 0.045$), but we found no significant difference regarding the presence or absence of the stapes ($P = 0.878$). Mishiro et al. [23] reported that both the stapes suprastructure and the malleus handle were significant in predicting the outcome of ossiculoplasty. However, he found the mobility of the stapes footplate to be an insignificant factor. Our study is consistent with that of Yung [10] who found that the malleus handle was the significant factor to determine the outcome of ossiculoplasty in the long run. Dornhoffer et al. [6], similarly found only the malleus manubrium to be significant.

To conclude titanium ossicular replacement prosthesis have better outcome, and no significant difference found in audiological outcome for TORP and PORP. Presence of the handle of malleus (P value $= 0.045$) and absence of previous surgery (P value $= 0.01$) indicated a favorable outcome for ossiculoplasty.

We encounter certain limitations in the study, the most important is inability to follow strict randomization as the cost of implant is a limiting factor and patients do not agree for the placement of implants. Second important issue is regarding the sample size as each middle ear is different and there are so many different situations that sufficient representation in each group cannot be ensured. Also the middle ear findings unfolds while progressing the surgery so the situation and conditions changes. Third is duration of follow-up, long term results and analysis of different implants and situation are necessary to improve our knowledge and understanding of stability and durability of ossiculoplasty.

Compliance with Ethical Standards

Conflict of interest None.

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