

## Original Research Article

# Ossiculoplasty: study of hearing results in 50 patients

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### ABSTRACT

**Background:** Ossiculoplasty improves conductive hearing loss. Various reconstruction methods and techniques are developed with use of different graft materials over period of time. Results of ossiculoplasty can be predetermined with consideration of prognostic factors.

**Methods:** The present study is retrospective study of 50 patients who underwent ossiculoplasty in the medical college hospital over the period of 3 years i.e. from January 2013 to December 2016. The pre-operative and post-operative audiometric findings were documented and analyzed to study the hearing improvement with the use of auto graft malleus and incus for ossiculoplasty. The results of ossiculoplasty were also compared with other studies done for ossiculoplasty. Predictors of ossiculoplasty results such as ossicular status and middle ear mucosa were also studied.

**Results:** The average post-operative air bone gap was 12.92 dB. The mean post-operative ABG was within 20 dB in both primary and revision cases. Average air-bone closure in patients with normal mucosa was 32.1 dB and that of adhesive mucosa was 18 dB. Significant improvement in post-operative air-bone closure ( $p < 0.01$ ) was observed in patients with auto graft incus than malleus head as ossiculoplast.

**Conclusions:** 84% ossiculoplasty patients were having post-operative air bone gap within 20 dB. The ossiculoplasty using auto graft ossicle is physiological, biocompatible, stable and has low complication rate.

**Keywords:** Ossiculoplasty, Hearing, Autograft

### INTRODUCTION

Auditory sensation is one of the vital sensations to the man. When such a great vital sensation is lost, life naturally loses its charm. Ossicular discontinuity can occur as sequel of chronic otitis media or due to trauma and result in conductive hearing loss. 60%-82% otology patients suffer from conductive hearing loss due to ossicular defect.<sup>1,2</sup>

The first correction of ossicular defect was done by Zollner in 1955.<sup>3</sup> Since then several studies were done to improve hearing results with different graft material. The results of ossiculoplasties were depends on the several prognostic factors, surgical techniques and experience of surgeon. Nikolaou et al and Zheng et al had shown air bone gap less than 20 dB after ossiculoplasty.<sup>4,5</sup> There is

controversy in literature regarding the prognostic factors of ossiculoplasty.<sup>6</sup> O'reilly et al and Mishiro et al had studied various prognostic factors.<sup>7,8</sup> Knowledge of the prognostic factors are helpful for preoperative assessment of patient.

In present study, we analysed hearing variables with regards to age, sex, middle ear mucosa and intraoperative ossicular status. The goal of this study was to devise a protocol to manage the ossicular discontinuity, provide good hearing to the patients and to demonstrate that use of ossicle for ossicular reconstruction is a safe, physiological, practical, successful and cost effective method.

The study was undertaken with the aim to review the hearing results in patient who have undergone

ossiculoplasty using auto-graft malleus and incus in primary and revision surgeries, to study the air-bone gap in relation to ossicular chain disruption and to study the results of ossiculoplasty in relation to the status of middle ear mucosa intra-operatively.

## METHODS

The present study is retrospective study of 50 patients who underwent ossiculoplasty in the medical college hospital over the period of 3 years i.e. from January 2013 to December 2016.

Most patients presented to us with history of chronic intermittent ear discharge and decreased hearing. Associated history of trauma, tinnitus, and giddiness was noted. A detail of previous ear surgery was noted. Detail clinical examination included general examination and local examination of ear, nose, throat. Examination of ear included otoscopy, tuning fork tests, and examination under microscope. Hemogram and audiogram was done for every patient. ECG and blood sugar was done for patients above 40 yrs. age.

The pre-operative and post-operative audiometric findings were documented and analyzed to study the hearing improvement with the use of auto-graft ossicle for ossiculoplasty. Selection of patients was done intra-operatively. Patients with ossicular discontinuity and revision ossiculoplasty cases were included in the study and patients with any evidence of cholesteatoma were excluded from the study.

The types of ossiculoplasty done were based on the ossicular defects. If the long process of the incus was not in contact with the head of the stapes, re shaped incus was used to connect the head of the stapes with the handle of the malleus. The interposed incus should fit between the stapes head and proximal malleus handle so as to make sure that there is no stress transmitted to stapes. In cases where Incus is completely necrosed malleus head is sculpted and placed over the capitulum.

Results were analysed using Wilcoxon signed ranks test and paired t-test.

**Table 2: Age group vs. average air- bone gap.**

Age	Preoperative average ABG (dB)		Postoperative average ABG (dB)		Average ABG gain(dB)	
	Mean	Std. Dev	Mean	Std. Dev	Mean	Std. Dev
<b>Up to 20 Years</b>	34.53	12.52	12.97	7.59	21.56	9.68
<b>21 to 40 Years</b>	35.57	9.81	12.19	8.02	35.57	62.09
<b>Above 40 Years</b>	34.31	10.07	13.89	8.27	20.43	9.09

### Anesthesia used

Out of 50 patients who underwent ossiculoplasty 44 (88%) were operated under local anaesthesia with sedation and only 6 (12%) required general anaesthesia.

## RESULTS

### Distribution of study group as per sex

Among 50 patients who presented with chronic suppurative otitis media, 29 (58%) patients were male and 21 (42%) were female.

### Distribution of study group as per age

In our study, 48% patients were between 21-40 years age group as given in Table 1.

**Table 1: Age distribution of the study participants.**

Age	Frequency	Percentage (%)
<b>Upto 20 Years</b>	8	16.00
<b>21 to 40 Years</b>	24	48.00
<b>Above 40 Years</b>	18	36.00
<b>Total</b>	50	100.00

### Age group vs. average air- bone gap

We applied Wilcoxon signed ranks test to age groups individually. We also used paired t-test for total sample. In our retrospective study of 50 patients, the average pre-operative air bone gap was 34.95 dB (SD = 10.15) and average post-operative air bone gap was 12.92 dB (SD = 7.92). There was a significant ( $p < 0.001$ ) improvement in most patients who underwent ossiculoplasty with ossicle graft.

### Comparison between primary and revision surgery study group

In our study 39 (78%) of patients underwent ossiculoplasty as primary surgery and 11 (22%) were revision cases. The mean post-operative ABG was within 20 dB in both study groups. The primary group has slightly better result than revision group as shown in Figure 1.

### Hearing improvement

In our study, 22 patients (44%) had the mean post-operative air bone gap within 10 dB and 20 patients (40%) had post-operative air bone gap between 10-20 dB.

Therefore 84% patients were having post-operative air bone gap within 20 dB as in Figure 2.

**Middle ear mucosa vs. average air-bone closure**

In our study 35 (70%) patients had normal middle ear

mucosa, 15 (30%) patients had adhesive tympanic membrane. We found that patients with normal middle ear mucosa had a significant improvement in the hearing after ossicular reconstruction. Average air-bone closure in patients with normal mucosa was 32.1 dB and that of adhesive mucosa was 18 dB as shown in Figure 3.

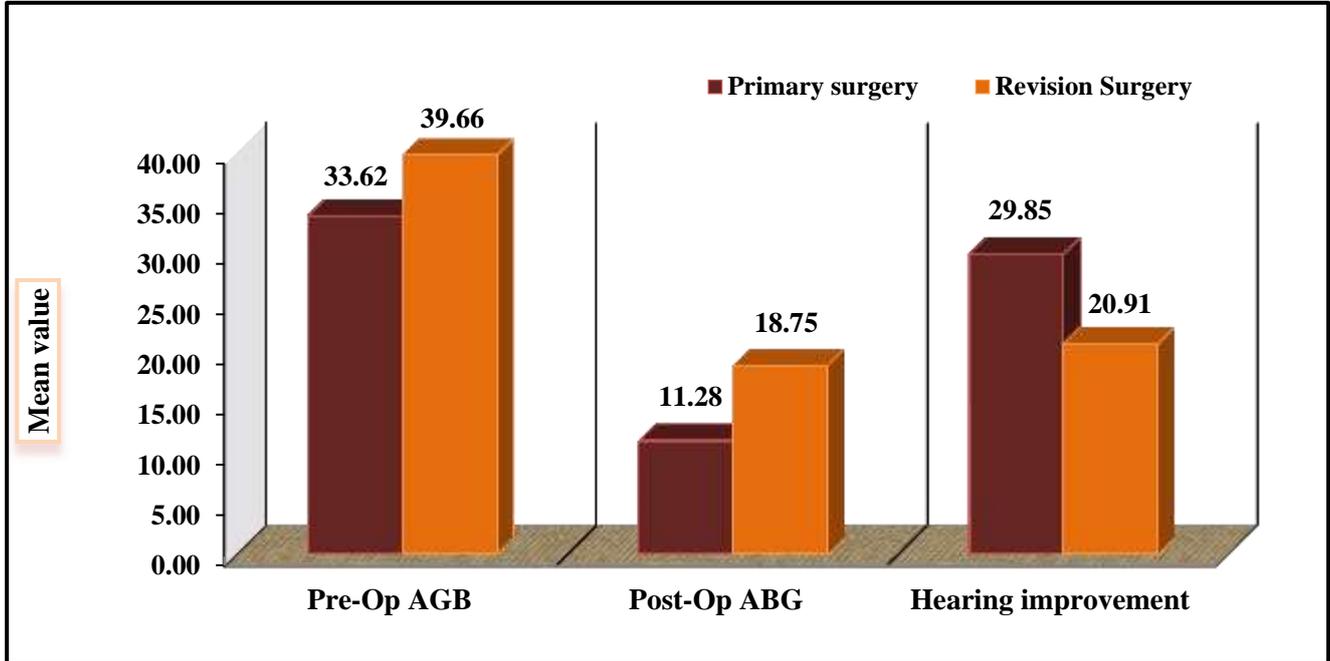


Figure 1: Comparison between primary and revision surgery study group.

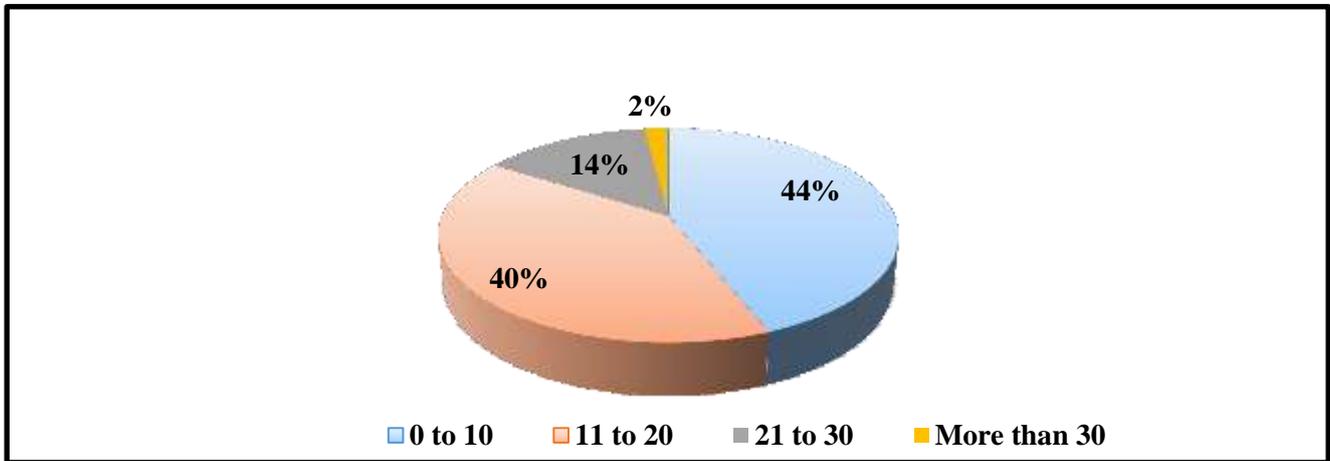
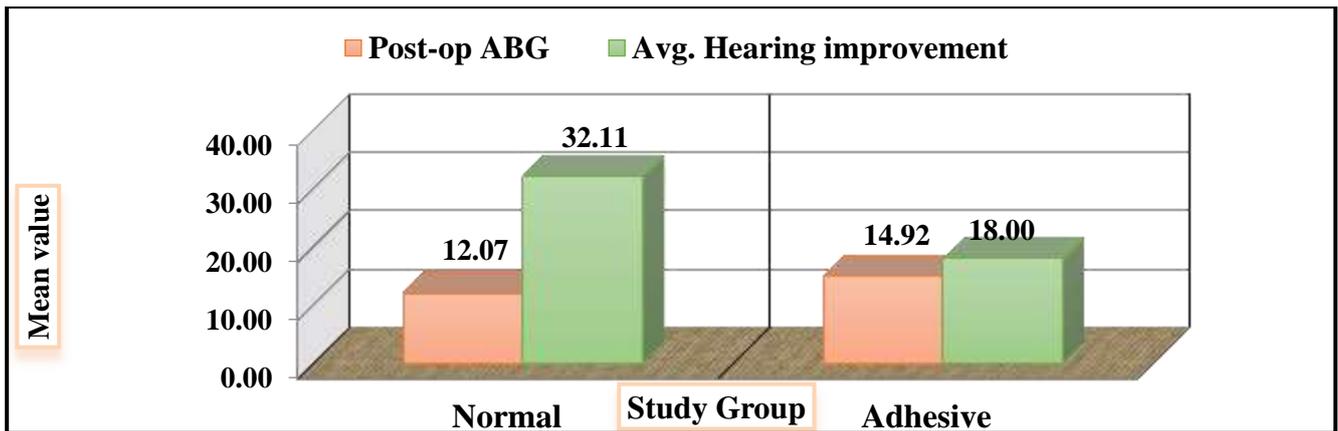


Figure 2: Hearing improvement.

Table 3: Ossicular involvement and air-bone gap.

Ossicles	Frequency	Percentage (%)	Preoperative average ABG	Postoperative average ABG
Incus and Stapes involved	13	26	38.75	17.21
Only Incus	33	66	33.60	11.59
All involved	1	2	41.25	20.00
Incus + Malleus	3	6	29.58	12.08
<b>Total</b>	<b>50</b>	<b>100</b>		



**Figure 3: Intraoperative middle ear mucosa vs. average air-bone closure**

**Ossicular involvement and air-bone gap**

We applied Wilcoxon signed ranks test for paired samples in group with only incus necrosis and incus with stapes necrosis and found that the hearing gain and post-operative air-bone closure in both group was significant and comparable as given in Table 3. Other groups were excluded since sample size was too small.

**Ossiculoplast vs. air-bone gap**

In our study of 50 patients who underwent ossicular reconstruction in 40 patients we used autologous incus as ossiculoplast and in remaining 10 patients in whom incus was absent or necrosed to that extent that cannot be used as ossiculoplast. We used head of the malleus as ossiculoplast. We found that the patients in whom incus was used as ossiculoplast had significant improvement in post-operative air-bone closure ( $p < 0.01$ ) than patients with malleus head as ossiculoplast.

**DISCUSSION**

The challenge during ossiculoplasty has been how to achieve a stable, reliable connection between the

tympenic membrane and mobile stapes footplate that will provide the best long term hearing results, without complications, in a chronically infected ear.

In our study, there was a slightly male predominance, consistent with the sex distribution in the general population.

**Table 4: Comparison of sex distribution with other studies.**

Study	Our study	O'reilly et al. <sup>7</sup> (2005)	Salvatore Iurato et al <sup>9</sup> (2001)
<b>Males</b>	29	72	90
<b>Females</b>	21	65	91
<b>Total</b>	50	137	181

**Age distribution**

The mean age group in our study was 36.44 years; it was consistent with other studies as given in Table 5. The patients within age group above 60 years were 2 but both had very good middle ear mucosa intra-operatively the post-operative air-bone closure was within 20 dB.

**Table 5: Comparison of age distribution with other studies.**

Study	Our study	O'reilly et al. <sup>7</sup> (2005)	Salvatore Iurato et al. <sup>9</sup> (2001)	Masoud Naderpour. <sup>10</sup> (2007)
<b>Mean age (years)</b>	36.44	40	39.5	32.7

**Table 6: Comparison of Overall hearing improvement with other studies.**

Study	Our study	O'reilly et al. <sup>(7)</sup> (2005)	S B Ceccato et al <sup>(11)</sup>	Farrior and Nichols et al <sup>(12)</sup>
<b>n</b>	50	137	98	80
<b>Mean Pre-op ABG (dB)</b>	34.95	26.8	42.8	30.2
<b>Mean Post-op ABG (dB)</b>	12.92	18.6	25.5	19.7
<b>Closure within 10 dB</b>	44%	25.5%	-	-
<b>Closure within 20 dB</b>	84%	66.4%	62%	-

We conclude that the surgery will benefit patients in all age groups. Even in the elderly age group, where there is an imminent sensory neural component to hearing loss, we were able to give a good hearing by reducing the air bone gap.

The mean post-operative ABG in age group of >20 years was 12.19 dB, the group benefitted the most. We conclude that the earlier the patient of mucosal otitis media was treated, the better the results.

#### ***Ossiculoplasty results in primary and revision surgery***

In the study by O'reilly et al. in (2005) the patients with revision surgery had similar results as the primary surgery, but Yasuo Mishiro et al, showed the presence of the stapes and primary surgery was significantly favorable predictive factors.<sup>8</sup>

In our study air bone gap closure is slightly better in primary surgery than revision but both were within 20 dB. We conclude that the revision surgeries will have good results if the middle ear at the time of surgery is healthy.

#### ***Overall hearing improvement***

Recent study done by Naragund et al showed average postoperative ABG closure of less than 20 dB in 7 cases (58%) with autologous incus and 4 cases (33.3%) with titanium prosthesis.<sup>13</sup> Postoperative complications with autologous incus group were 25% as compared with titanium prosthesis in which the complication rate was 41.6%. They found that hearing improvement and graft take-up rate were significantly better in ossiculoplasty with auto-incus.

We conclude that, if there is an option available to use the ossicle, it should be given preference since it is physiological, biocompatible and stable and of course cost effective. Sculpting an ossicle does require expertise and skill of the surgeon.

#### ***Middle ear mucosa vs. hearing improvement***

A study in Japan by Mishiro et al, in 720 patients, done in multiple models showed that mucosal status and the presence of the stapes superstructure and the malleus handle were significant predictors in of results in ossiculoplasty, which is similar to most of the previous reports.<sup>14</sup>

We conclude that if the middle ear mucosa is normal, healthy and middle ear is well ventilated with good Eustachian tube function, then the chances of post-operative graft uptake are excellent. Adhesive mucosa can affect the outcome of ossiculoplasty because of high chances of re-adhesions. In cases with medicalization of handle of malleus the chances of ossicle getting displaced

are high. The adhesive drum itself does not vibrate well with sound waves and therefore the air-bone closure can never be perfect.

We remove the granulation tissue from the middle ear cleft and apply gel-foam with antibiotic and steroid, which improves the results of ossiculoplasty by decreasing adhesion formation.

#### ***Ossicular involvement and air –bone gap***

Dornhoffer and Gardner identified absence of malleus, fibrotic middle ear mucosa, and otorrhea as prognostic factors for outcome of ossiculoplasty.<sup>15</sup> Whereas, in a multivariate analysis by Yung, the results predicted that those with present malleus were 6.36 times more likely to be successful.<sup>16</sup>

We also observed that in more than half (66%) of the patient, incus was either necrosed or lost. The cause of it is now hypothesized to be due to its structure and location than its tenuous blood supply.<sup>17</sup> If the reconstruction is done in a manner where its location is stable, then the chances of it getting resorbed can be minimized. We believe that the ossicle should not be snugly fitted under the tympanomeatal graft but should be loose enough to mobilize when the tympanic membrane vibrates.

We conclude that the post-operative air bone is significantly better if only incus is involved compared to incus and stapes. The reason could be though the lever mechanism for conduction of sound is lost during ossicular reconstruction; the conduction of sound is still adequately good if only incus is involved. When both the incus and stapes superstructure are lost, the ossicular conduction is maintained but not as physiological as with type 1.

#### **CONCLUSION**

Chronic suppurative otitis media causing incus necrosis was the main underlying reason for ossiculoplasty. In our study of 50 patients, 58% were males and 42% were females. There was male predominance. The most common age group who presented to us was in 21-40years. The results in all age group were similar. 84% patients were having post-operative air bone gap within 20 dB. In primary and revision cases the post-operative air bone closure was within the range of 20 dB. 88% ossiculoplasties were performed under local anesthesia and intravenous sedation. The best results were obtained in patients, where the middle ear mucosa was healthy intra-operatively and in patients with isolated incus necrosis. The ossiculoplasty using auto graft ossicle has low complication rate and is preferred.

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