

# Clinico-Audiological Comparison between Classical Type-III Tympanoplasty and Ossiculoplasty using Autograft Ossicles in Patients with Austin Type A Defect

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## ABSTRACT

**Introduction:** Ossicular chain necrosis, a frequent complication of COM can be of various types. Austin type-A defect where only the incus is damaged can be treated by either type-3 tympanoplasty or with ossiculoplasty using sculpted autologous incus as interposition graft. This study was done to compare the hearing outcomes in patients underwent these two procedures in a teaching hospital in India and to analyse and compare the hearing outcomes and graft uptake rates between the above mentioned procedures in Austin type-A ossicular defect.

**Material and Methods:** The Non-randomized prospective clinical study was conducted in the Department of ENT in a teaching hospital, from February 2013 to August 2014. 40 patients were selected based on inclusion and exclusion criteria. They underwent either tympanoplasty using sculpted autologous incus interposition between malleus and stapes or classical type-3 tympanoplasty. Post-operative evaluation and documentation done upto at least 6 months and results were analysed in terms of graft take-up rates and hearing improvement. Hearing results were measured by PTA-air bone gap (PTA-ABG) and graft take-up rate calculated at the end of 6 month.

**Results:** Amongst the 40 patients, 20 underwent tympanoplasty with autologous sculpted incus strut placement were termed as Group-A; other 20 underwent type-3 tympanoplasty were termed Group-B. Mean post-operative AB Gap reduction in Group-A was 31% in comparison to Group B where reduction was 14.4%. Graft uptake rate was almost same in both Groups.

**Conclusion:** This study couldn't establish statistically significant difference in the outcome between the two procedures.

**Keywords:** Chronic otitis media; Austin type-A defect; Tympanoplasty; Ossiculoplasty; Incus auto-graft;

## INTRODUCTION

Chronic Otitis Media (COM) is a chronic inflammatory disease of the middle ear and mastoid that often results in partial or total loss of the tympanic membrane (TM) and ossicles, leading to conductive hearing loss that can range in severity up to 60dB. COM is a common condition seen in patients attending the otolaryngology clinic and is an important public health problem with substantial economic and social costs, affecting 0.5 – 30% of the community. A conservative estimate of the no. of people in the world suffering from COM is over 20 million<sup>1</sup> As per WHO, the prevalence of COM in Indian population is approximately 7.8% which is comparatively higher than that found in developed countries like that of USA and UK where the prevalence is <1%.<sup>2,3</sup> According to another study, the prevalence of squamous type of COM is approximately 3.4% in India.<sup>4</sup> Among the various causes of ear diseases, COM is a major global cause of hearing impairment and may have serious long term effects on language, auditory, cognitive development

and educational progress.<sup>4</sup>

With the advancement in understanding of the middle ear mechanics, it is now known that the hearing deterioration in COM is attributed to the destruction of ear drum and/or damage to the ossicular chain. So the therapeutic practices and regimes have also evolved over time. Ossicular involvement in COM patients can present in many ways and the commonest finding is erosion of incus but intact malleus and stapes (Austin type-A ossicular defect).<sup>5-7</sup> Over time the otologists have used a wide array of materials and surgical techniques to give the patient maximum benefit, however, till date there is no universal protocol or guidelines to manage these cases.<sup>8</sup>

In this study we selected 40 patients of COM with Austin type-A ossicular defect and subjected them to two surgical procedures-- classical type-3 tympanoplasty or tympanoplasty with placement of incus strut and assessed post-operatively for drum closure and hearing improvement. With both procedures, improved hearing results have been demonstrated earlier in various studies. In this study we intend to document, analyse and compare the result of both the procedures in this particular presentation of COM.

## MATERIAL AND METHODS

A total of 40 patients in the age group between 12 and 65 years, attending ENT OPD of our hospital between February 2013 and August 2014, were included in this study. Study sample was based on the inclusion exclusion criteria followed in the study. The inclusion criteria for the patients were those with chronic otitis media with conductive hearing loss having Austin type-A ossicular discontinuity, ie, patients with intact malleus and stapes superstructure and eroded long process of incus. Patients with sensorineural or mixed hearing loss, gross cholesteatoma, intra-cranial complications were excluded from our study. The patients underwent detailed ENT examination followed by audiological and radiological assessment of temporal bone and after per-operative confirmation of Austin type-A defect (intact malleus and stapes with eroded long process of incus) they were included in the study. These patients randomly underwent two surgical procedures—(a) tympanoplasty with placement of

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**How to cite this article:** Bivas Adhikari, Amit Kumar Ghosh, Sudipta Pal, Faizanul Haque. Clinico-Audiological comparison between classical type-III tympanoplasty and ossiculoplasty using autograft ossicles in patients with austin type a defect. International Journal of Contemporary Medical Research 2016;3(8):2422-2425.

sculpted autologous incus in between malleus and stapes and ( b) classical type-3 tympanoplasty after removal of the eroded incus. Those who underwent tympanoplasty with placement of sculpted autologous incus in between malleus and stapes were included in Group-A and those who underwent classical type-3 tympanoplasty were included in Group-B. Both the groups were followed post-operatively and assessed clinically and audiotically up to the end of 6 months.

Ethical clearance was obtained from the institution’s ethical committee for research on human subjects. Written informed consent was obtained from all the cases.

**Surgical Procedures**

All procedures were done under general anaesthesia by the same team of surgeons. Post-aural approach through Wilde’s incision was done in all the patients. Limited atticotomy was done to expose the ossicular chain which was later reconstructed with tragal cartilage. In cases included in Group-A, the eroded incus was taken out, reshaped and sculpted with the help of 0.5mm diamond burr. The remaining long process was drilled into cylindrical shape with a flat base where a socket for the head of stapes was made. A groove was also made in short process to accommodate the malleus handle. The sculpted incus was then interposed in between malleus and stapes head and the contact sites were covered with small strip of temporalis fascia. To reconstruct the tympanic membrane, sliced tragal cartilage and temporalis fascia graft was used. In patients of Group-B, the eroded incus was disarticulated from the malleus and removed. The head of stapes was covered by sliced tragal cartilage along with temporalis fascia graft placed lateral to the cartilage.

**Outcome Measures**

Post-operative PTA was done at end of 6 months follow up using 4 frequencies— 500 Hz, 1 KHz, 2 KHz and 4KHz. Post-operative air conduction threshold (AC), bone conduction threshold (BC) and air-bone gap (ABG) were calculated. Anatomical closure of the perforation and integrity of the neo tympanum was assessed microscopically.

**STATISTICAL ANALYSIS**

All data were subjected to standard statistical analysis using

Age distribution (years)	Group A (n=20)		Group B (n=20)	
	Male	Female	Male	Female
15-25	4	1	11	4
26-35	4	3	0	2
36-45	4	4	0	1
46-55	0	0	1	0
56-65	0	0	0	1
Total	12	8	12	8

**Table-1:** Age and Sex distribution

Microsoft excel, 2010 software. Unpaired t-test was used to determine the statistical significance between the two groups and paired t-test was used to analyse the pre-operative and post-operative hearing result in the same group.

**RESULTS**

A total of 40 patients were included in the study among which 20 patients underwent tympanoplasty with placement of sculpted autologous incus (Group-A) and other 20 patients underwent classical type-3 tympanoplasty.

**Age and Sex Distribution**

The age of patients in this study varied between 15-65 years. The mean age in Group A was 31.15 years and in Group B was 29.35 years. In both groups majority of patients were males (Group A- 60%, Group B- 60%). The ratio between total male and total female was 3:2. Maximum age in group-A and group-B were 45 years and 63 years respectively, whereas the minimum age in both the groups was 15 years. (Table-1)

**Graft Take-Up Rate**

The graft take-up rate in Group-A at 6th post-operative month was 90% (18 out of 20) where as it was 85% (17 out of 20) in Group-B. Number of graft failure in Group-A was 2(10%) and it was 3 (12.5%) in Group-B. However the anatomical closure rate in the two procedures did not have any statistically significant difference as per the present study.

**Assessment of Hearing Improvement**

On comparing the improvement in mean AC threshold during the post-operative period in Group A, it was found that there was a 24.27% change, from 50.25 dB in the pre-operative period to 38.05 dB at the end of 6 months.(t test=8.666, p=0.0001). Similarly in Group B there was an improvement of around was 13.71 %, from pre-operative 51.05 dB to 44.05 dB in 6 months post-operative (t test=3.908, p=0.0009), hence a significantly better improvement in air conduction threshold could be achieved in both the groups. (Table-2)

The mean post-operative AB Gap in Group-A was 29.6 dB (SD 13.4 ) showing 31% improvement over pre-operative mean AB Gap of 42.6 dB and this was statistically significant (paired t-test: t=9.185,p<0.0001). Whereas in Group-B this improvement was 14.4%; mean pre-op AB Gap 42.4 dB, mean post-op AB Gap 36.3 dB (SD 12.1), (paired t-test: t=3.954, p=0.0009); (Table-3) and this was also statistically significant. However the difference in hearing improvement between the two groups was statistically insignificant. ( unpaired t-test: test t value=1.644; critical t value=2.024 at p=0.05,ie, test t value< critical t value at p=0.05) So, from this study, it was established that there is no significant difference between the two procedures as far as hearing improvement and perforation closure is concerned.

Group	Pre-op AC (mean) (dB)	Post-op AC (mean) at 6 <sup>th</sup> month (dB)	Statistical test
A(n=20)	47.7	38.05	t test=8.666,p=0.0001
B(n=20)	51.05	44.05	t test=3.908,p=0.0009

**Table-2:** Pre and post-operative average AC threshold in either

Group	Pre-op AB Gap(dB) (Mean)	Post-op AB Gap(dB) at 6 <sup>th</sup> month(Mean)	Statistical test
A(n=20)	42.6dB	29.6 dB	t test=9.185,p<0.0001
B(n=20)	42.4dB	36.3 dB	t test=3.954,p=0.0009

**Table-3:** Pre and post-operative mean AB Gaps in either group

**DISCUSSION**

The term tympanoplasty was coined in 1953 by Wullstein to describe surgical techniques for reconstruction of middle ear hearing mechanism that had been impaired or destroyed by chronic middle ear disease.<sup>5</sup> Tympanoplasty implies clearance of the disease from the middle ear and attic with reconstruction of the hearing mechanism. It may include ossiculoplasty as a part of reconstruction of hearing mechanism. The long process of incus is most commonly eroded because of its peculiar anatomical position and the course of its blood supply.<sup>5,6</sup> And maybe that's why Austin type-A is the commonest ossicular defect found in COM.<sup>7</sup> Various surgical techniques and materials have been used for ossicular chain reconstruction since the second half of nineteenth century, but still there is no standardized technique and ideal material accepted worldwide. Three general classes of materials are used today are autograft, homograft and allograft.<sup>6</sup> Allograft prostheses are readily available, which are pre-cultured, and made of synthetic materials like hydroxyapatite, plastipore, titanium, glass ceramics, etc., and designed to be biocompatible. But in the long term, ossicular necrosis, extrusion, displacement, and unsatisfactory hearing restoration have been encountered with virtually every type and design. Extrusion of the prosthesis has been reported to be as high as 39%.<sup>9</sup>

Autograft include ossicles (incus, malleus), cartilages (septal, tragal), cortical bone etc. Advantages of autografts include a very low extrusion rate, no risk of transmitting disease, biocompatibility, and no necessity for reconstitution.<sup>10</sup> Cost effectiveness compared to PORP or TORP or other alloprosthetic materials, particularly to the financially challenged patients in our study area and the ease of harvesting were the main reasons to go for autograft in our study.

In this study the mean age in Group A was 31.35yr and 26.95yr in Group B. In Group A the age range was 15-45 years and in Group B it was 15-63 years. However no particular relationship could be established between the age of the patients and success rate of both the procedures as was seen from the studies of Iliana Fukuchi et al.<sup>11</sup>

Quantitatively the drum closure was better in tympanoplasty with incus strut placement at 6th post-operative month than in

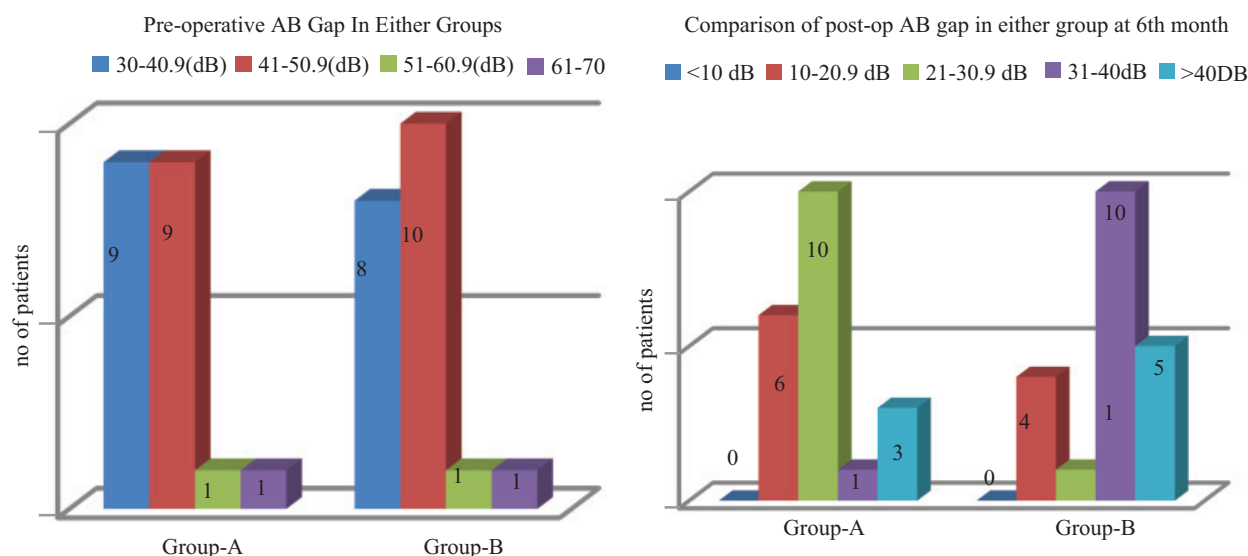
classical type-3 tympanoplasty (stapes columella). There was graft failure in 2 cases with incus transposition group and in 3 cases with classical Type 3 tympanoplasty group. None of the patients develop retraction pocket in the newly formed ear drum.

Post-operatively, the patients in Group-A who underwent incus transposition achieved mean post-operative AB Gap of 29.6 dB, that is, 31% improvement over pre-operative mean AB Gap of 42.6dB which was statistically significant. Whereas in Group-B this improvement was 14.4% (mean pre-op AB Gap is 42.4 dB, mean post-op AB Gap is 36.3 dB) and this was also statistically significant. However, 1 patient in Group-A and 3 patients in Group-B had deterioration of hearing post-operatively with increase in the air-bone gap. This may be due to rejection of graft and reinfection in the same patients. Thirty percent of the patients who underwent incus transposition achieved an air-bone gap within 20dB, 40% within 25dB and 85% within 30dB. Whereas among the patients who underwent classical type-3 tympanoplasty only 20% achieved air-bone gap within 20dB but 75% within 30dB (Figure-1). It was seen that hearing improvement was better in those patients who had lesser air-bone gap pre-operatively. However, regarding hearing improvement, there was no statistically significant difference between the two procedures using standard analysis.

Robert C O'reilly et al. study<sup>12</sup> showed that with the use of autograft incus he had achieved a mean postoperative AB gap of 18.6dB. The study by K. Ojala<sup>13</sup> and Naragund et al.<sup>8</sup> attained a mean AB gap of 25.8dB and 24.5dB respectively. Our study achieved a mean post-operative AB gap of 29.6 dB using autograft ossicles in Group A patients.

Shrestha BL et al in their study of classical type-3 tympanoplasty<sup>14</sup> achieved a mean post-operative AB gap of 29.8 dB with a variation from 15 to 61.2dB. Je-Yeob Yeon, Woo-Jin Jung et al<sup>15</sup> showed 37.4% hearing improvement with classical type-3 tympanoplasty at 3 month follow-up with a mean post-operative AB Gap of 25.1 dB which became 29.1 dB at 1 year follow-up. In our study the mean post-operative AB Gap with classical type-3 tympanoplasty was 36.3dB.

Iurato<sup>16</sup> reviewed the literature at length to investigate hearing results from ossicular reconstruction in Austin-Kartush type A



**Figure-1:** Comparison of AB Gaps pre and post operatively

patients. At 12 months minimum follow-up, 84% patient had air-bone gap within 20dB. Emir<sup>17</sup> reviewed 304 patients who underwent Ossiculoplasty with intact canal wall. Autologous incus interposition resulted in 58% success rate (mean postoperative air-bone gap of less than 20 dB).

Thus it was observed that both the procedure achieved significant improvement over the pre-operative air conduction threshold (AC) and air-bone gap (ABG). However clinical trials, like this study, are less available in the literature which compared both the anatomical and functional outcome of classical type-3 tympanoplasty and tympanoplasty with incus interposition. Although it must be admitted that the follow up is short-term and patient compliance for follow up is a concern in this part of the world.

## CONCLUSION

This study reveals significant hearing improvement with both the procedures in (Austin type-A ossicular defect) chronic otitis media. It was also noted that hearing restoration was better in cases with lesser air-bone gap pre-operatively irrespective of the procedures performed. The lack of statistical difference in the hearing outcome of the two procedures may be due to the limitation of clinical trial with the small sample size and limited statistical power in the comparison of surgical techniques. Besides, the follow up period was also short. So it would be worthwhile to conclude that further clinical trials with a larger sample size and longer follow-up period are needed to standardize a particular procedure or technique to be considered as ideal in the management of particular presentation of COM.

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**Source of Support:** Nil; **Conflict of Interest:** None

**Submitted:** 19-06-2016; **Published online:** 31-07-2016