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### Evaluation of hearing outcomes with sculpted incus ossiculoplasty

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## Abstract

**Background:** The most common ossicular pathology encountered in middle ear disease is absence of long process/lenticular process of the incus with an intact malleus and stapes suprastructure (Austin Kartush Group A). Therefore, surgical correction of the same is very important in restoring hearing. This study evaluates the ease of use, efficacy, risk factors and hearing outcomes of sculpted incus interposition/transposition ossiculoplasty in cases with Group A ossicular defects.

**Materials and methods:** It was a prospective study conducted over an 18-month period with 55 study participants who underwent tympanoplasty with/without cortical mastoidectomy and with ossiculoplasty using sculpted incus. Pre and post operative ABG (Air Bone Gap) on Pure Tone Audiometry was compared.

**Results:** The mean pre-operative ABG was  $33.74 (\pm 2.9)$  dB and the mean post-operative ABG was  $12.37 (\pm 3.25)$  with a statistically significant difference between the

two. Success rate of this technique of ossiculoplasty (defined as post-operative ABG of less than 20dB) was 91%.

**Conclusion:** Sculpted incus provides an excellent option for ossicular reconstruction in Type A Austin Kartush ossicular defects with reasonably good hearing outcomes and lower rates of complications with the added advantage of being easy to access, biocompatible, widely available, technically simple and cost effective.

**Keywords:** Ossiculoplasty, Ossicular Reconstruction, Otology, Sculpted Incus, MERI

## Introduction

The diagnosis and surgical correction of an ossicular pathology leading to deafness is perhaps one of the most challenging and equally gratifying experiences for the new-age ENT surgeon. As we move ahead from disease eradication to hearing preservation, innovative methods have been devised to reconstruct the hearing apparatus. When we categorise cases of ossicular defect based on

Austin-Kartush classification, it is seen that 60% of the cases belong to Group A wherein there is a missing/incomplete incus with intact malleus and stapes superstructure. Bridging this gap between the malleus and stapes superstructure becomes the mandatory task for the otologist. (1) The ideal prosthesis should be stable, easy to access, technically easy to fit, biocompatible with low extrusion rates and capable of optimal sound transmission. (2) Various methods available for ossicular reconstruction include biological autograft or homograft's made of bone or cartilage, partial ossicular replacement prosthesis (PORP) made from plastic, ceramic, or metal and bone cements. (3) The purpose of this study is to evaluate the ease of use, efficacy and hearing outcomes of sculpted incus interposition/transposition ossiculoplasty in cases with Group A ossicular defects. We also evaluated preoperative middle ear status with the post operative hearing outcomes in such cases.

#### **Materials and Methods**

**Patients:** A prospective study over a duration of 18 months was conducted between February 2021 to March 2022 in a tertiary care hospital. Patients with middle ear pathologies like chronic otitis media, adhesive otitis media, retraction pockets, ossicular discontinuity who were planned for surgery were included in the study. Those with extensive cholesteatoma with erosion of stapes/malleus, stapes fixation, patients lost to follow up were excluded from the study.

All the patients included in the study were assessed by Kartush's Middle Ear Risk Index (MERI) to evaluate the pre-operative middle ear status. They also underwent a Pure Tone Audiometry test not more than 1 week before the surgery. Surgical technique: Patients in the study population underwent single staged tympanoplasty with/without cortical mastoidectomy and ossiculoplasty under general an aesthesia. The surgical technique followed has been originally described by Glasscock and refined accordingly (4) After temporalis fascia graft harvest, tympan meatal flap elevation and clearing the disease from the middle ear, the ossicular chain was inspected for integrity. Once mobility of stapes footplate was confirmed, the eroded incus was dislocated from the incudomalleolar joint and retrieved. Using a fine 1 mm cutting burr, the long and short processes of the incus were gently drilled out. The surface of the ossicle that articulates with the malleus was sculpted and a small fenestra was created at the opposite end for articulation with the head of the stapes. In cases where the distance and angle between the handle of malleus and stapes superstructure were favorable, the sculpted incus was placed between them (interposition) where as in cases where the distance and angle were not favorable, the sculpted incus was placed between the stapes head and the tympanic membrane or temporalis fascia graft. Stability of the reconstructed ossicular chain was confirmed and middle ear was packed with gel foam.

**Post-operative assessment:** The patients were initially assessed 15 days after surgery to look for graft uptake and early extrusion. Subsequently, a detailed otoscopic examination was done at 3 months post-op to assess complete healing and a post-op Pure Tone Audiometry was performed.

**Analysis:** The pre-operative air-bone gap was compared with the post-operative air-bone gap. Air-bone gap closure of less than 20 dB was considered successful hearing outcome. Pre-operative MERI score was compared with the post-operative air-bone gap to

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correlate the middle ear status with hearing outcomes. A p value of <0.05 was considered statistically significant.

## Results

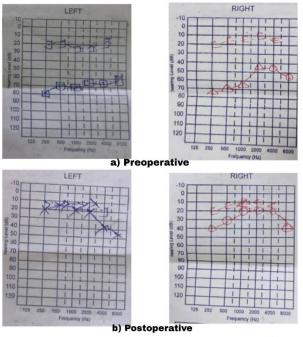
There was a total of 55 patients included in the study who met the inclusion and exclusion criteria. Out of this, there were 32 females and 23 males with an average age of 38 years with the youngest at 22 years and oldest at 54 years of age. 50 of the 55 patients had a diagnosis of chronic otitis media with central perforation of the tympanic membrane and the remaining 5 had adhesive otitis media.

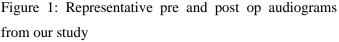
The mean pre-operative ABG was  $33.74 (\pm 2.9)$  dB. Out of the 55 patients, 16 underwent incus interposition while the remaining 39 underwent incus transposition ossiculoplasty. A posterior canaloplasty of the deep meatus was done in 12 patients for better visualization of the incudostapedial joint.

The mean ABG at the first postoperative audiogram which was done 3 months after surgery was 12.37 ( $\pm$ 3.25). The difference between the mean pre and postoperative ABG was found to be statistically significant (p value 0.003). 50 patients in our study achieved AB gap closure to within 20 dB, with the majority having achieved post-op values of less than 15dB. (Table I) Figure 1 depicts representative pre and post op audiograms where a satisfactory air bone gap closure can be appreciated. Table I represents air bone gap closure rates.

Air	Bone	0-15 dB	15-20 dB	>20 dB
Gap				
N		44	6	5
Percentage %		81%	10%	9%

Table 1 : Post-operative Air Bone Gap closure rates





There was no statistically significant difference between the initial diagnosis and the post operative ABG that could be ascertained. Similarly, there was no significant difference between the technique of ossiculoplasty (interposition vs transposition) and the post operative hearing. However, it was noticed that patients with higher MERI scores indicating more risk factors had lesser values of ABG closure after ossiculoplasty. This comparison was found to be statistically significant.

No graft failure or extrusion of ossicle was noted in our study until the last patient follow-up.

### Discussion

Erosion of the long process/ lenticular process of the incus is the most common ossicular pathology encountered in chronic middle ear infections due to the nature of the bone and its precarious blood supply. (5) These cases pose a significant challenge to otologists during routine tympanoplasty surgeries and must be addressed in order to achieve good hearing outcomes. Over the years, several techniques have come forth to

reconstruct this defect. Initial attempts at reconstruction with wires and plastic proved to be of no value and have been universally rejected. (4) Commonly practiced techniques include reconstruction with autologous or homograft ossicle (incus or head of malleus), cartilage, placement of a partial ossicular replacement prosthesis (PORP) made up of hydroxyapatitie, ceramic or titanium and rebridging the gap between incus remnant and stapes superstructure using bone cement (6) Our study was a prospective evaluation of the outcomes of sculpted incus ossiculoplasty in patients with Type A Austin Kartush ossicular defects. We found that both incus interposition well as transposition provided excellent and as comparable hearing outcomes in terms of closure of Air Bone Gap on pure tone audiometry. 81% of our patients had post operative air bone gap less than 15 dB. We had a success rate of 91% as per guidelines set by the American Academy of Otolaryngology-Head and Neck Surgery (Air Bone gap closure to within 20dB). A study conducted by Mokhtarinejad F. et al. on 25 patients undergoing sculpted incus ossiculoplasty saw a success rate of 76% with 88% of patients having post-op ABG less than 25%. A larger study by Iurato and Marioni observed postoperative ABG within 10 dB in 55% and postoperative ABG within 20 dB in 85% of cases. (7) Similar success with sculpted incus interposition grafts have been reported throughout recent academic literature (1), (6), (8). Being an autologous graft, sculpted incus seems to have very low extrusion rates. It also has the advantage of ease of access, simplicity of technique and low cost. All these factors have made sculpted incus ossiculoplasty a popular and efficient method of ossicular reconstruction.

In a study to elicit the hearing outcomes using titanium prosthesis ossiculoplasty, Lahlou et al (9) observed

surgical success, defined as a postoperative ABG  $\leq 20$ dB, in 59% (n = 166) of cases at 2 months postoperatively, and in 65% (n = 117) of cases at 12 months after surgery. Another study that compared long term hearing outcomes with cartilage ossiculoplasty and PORP found success rates of 80.8% and 76.2% respectively. (10) Hearing gain observed in our study cohort is significantly higher than what other authors have achieved with titanium prosthesis, cartilage and PORP. A systematic review of 1055 patients across 14 studies comparing hearing outcomes between sculpted incus and PORP ossiculoplasty demonstrated a net dB gain of 12.76 dB with a SD of 14.97 dB for the incus group and 11.75 dB with a SD of 15.02 dB for the PORP group with a no statistically significant difference between the two. They observed ABG closure rates of 64.48% in the sculpted incus group and 71.32 PORP group (2) The authors attribute the slightly higher gains with PORP ossiculoplasty to better surgical reproducibility when compared to sculpted incus which depends on instruments used for sculpting, the surgeon's prowess and the quality of the bone.

However, no technique is without flaws. Sculpted incus can be subject to graft resorption and instability or dislodgement from the stapes head. Furthermore, the ossicle may harbor residual cholesteatoma in cases of squamosal disease which could result in a recurrence. There are studies in literature which do not support our results when compared to other ossiculoplasty techniques. In a study comparing incudostapedial rebridging with bone cement with incus interposition, F Celenk et al found that the mean hearing gain was  $15.2 \pm$ 9.01 dB with a 63.2% success rate in the incus interposition group and  $19.36 \pm 9.08$  dB with 78%

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success rate in the bone cement group, favoring bone cement rebridging. (10) Similar results favoring hydroxyapatite bone cement for ossiculoplasty was observed by Somers et al. (11)

Our study also found a statistically significant correlation between MERI scores and the postoperative hearing outcomes. Just as with tympan mastoid surgeries (12), there are studies in literature which are in tandem with our findings of lower MERI scores being associated with better hearing outcomes. (13) (14)

Lastly, we found no graft failures or extrusion of the sculpted incus in our study cohort. While other studies have shown varying rates of displacement or extrusion in cases of titanium prosthesis (9) (15)(16), Plasti-pore or hydroxyapatite PORP (17), the same has found to be almost negligible with sculpted incus ossiculoplasty. (1) (5) However, our study requires a longer patient follow up to corroborate these findings.

#### Conclusion

Sculpted incus provides an excellent option for ossicular reconstruction in Type A Austin Kartush ossicular defects with reasonably good hearing outcomes and lower rates of complications with the added advantage of being easy to access, biocompatible, widely available, technically simple and cost effective.

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