International Journal of Otorhinolaryngology and Head and Neck Surgery
*Mhashal SK et al. Int J Otorhinolaryngol Head Neck Surg. 2017 Oct;3(4):821-825*
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20173202

**Original Research Article**

# Assessment of short term hearing improvement in patients of cartilage interposition ossiculoplasty for lenticular process of incus necrosis in cases of chronic suppurative otitis media: mucosal disease

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**Received:** 26 June 2017
**Accepted:** 11 July 2017

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## ABSTRACT

**Background:** Chronic suppurative otitis media is a highly prevalent disease in developing countries. Hearing loss associated with this disease is significantly more in cases associated with ossicular necrosis along with tympanic membrane perforation.
**Methods:** We would like to present a study of such cases of mucosal chronic suppurative otitis media associated with lenticular process necrosis treated by cartilage interposition ossiculoplasty. The patients were followed up for a minimum period of 6 months and their pre op and post op hearing was documented and analyzed.
**Results:** An average air bone gap of 39.07 decibels in pre op was reduced to 18.13 decibels in post-operative period and these improvements persisted over 6 months of follow-up.
**Conclusions:** We have hereby concluded that the hearing improvement is comparable to other methods of ossiculoplasty with minimum disruption of natural hearing assembly in lenticular process of incus necrosis.

**Keywords:** Ossiculoplasty, Cartilage interposition, Austin Kartush type A, Chronic suppurative otitis media, Lenticular process necrosis

## INTRODUCTION

Otitis media is a highly prevalent disease of the middle ear and is a serious health problem worldwide,more so in developing countries where large percentage of the population lack specialized medical care, suffer from malnutrition and live in poor hygienic environmental conditions.[1] Chronic suppurative otitis media (CSOM) is defined as a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges or otorrhoea through a tympanic membrane perforation. Otitis media presents an early acute phase, with essentially reversible mucosal and bony pathological changes, which continues to a late chronic phase with well established, intractable mucoperiosteal disease. The recurrent episodes of otorrhoea and mucosal changes are characterized by osteoneogenesis, bony erosions, and osteitis that include the temporal bone and ossicles.[2] This is followed by ossicular destruction and/or ankylosis which, together with the tympanic perforation, contribute to the hearing loss.[3,4] The proposed mechanism for erosion is chronic middle ear inflammation due to overproduction of cytokines—TNF alpha, interleukin-2, fibroblast growth factor, and platelet derived growth factor, which promote hypervascularisation, osteoclast activation and bone resorption causing ossicular damage. TNF-alpha in addition also causes neovascularisation and hence granulation tissue formation. CSOM is thus an inflammatory process with a defective wound healing mechanism.[5] This inflammatory process in the middle ear is more harmful the longer it stays and the nearer it is to the ossicular chain.[6] Pathologies that interrupt the ossicular chain result in large hearing losses. Complete disruption of the ossicular chain can result in a 60 dB hearing loss.[7,8] Incus was observed to be the most common ossicle to get necrosed in cases of CSOM.

Varshney et al reported that, incus was found intact in 61.33% cases, eroded in 21.34% cases and absent in 17.33% cases. The commonest defect was erosion of the lenticular process in 19.33% cases followed by long process in 16.67% cases. In safe CSOM, incus was intact in 92.23% cases, eroded in 5.55% cases and absent in 2.22% cases while in unsafe CSOM it was intact in 15.00% cases, eroded in 45.00% cases and absent in 40.00% cases. The most frequently involved parts were again the lenticular process (40.00%) and the long process (38.33%) of incus.[9] Udaipurwala et al, had a very similar incidence of necrosis of the incus at 41.00%. The long process of incus was found to be the most commonly necrosed part as compared to Varshney et al, where lenticular process was more commonly necrosed. This can be explained, as Udaipurwala et al. have probably considered the lenticular process to be a part of the long process of incus, since they have not mentioned it separately.[10] Austin reported the most common ossicular defect to be the erosion of incus, with intact malleus and stapes, in 29.50% cases.[11] Kartush found erosion of long process of incus with an intact malleus handle and stapes superstructure (type A) as the most common ossicular defect.[12] Shreshtha et al and Mathur et al, also reported similar findings in unsafe CSOM.[13,14]

The most commonly used autograft material has been the incus body, which is often reshaped to fit between the manubrium of the malleus and the stapes capitulum. Autograft materials are not always available, or as in patients with cholesteatoma—an ossicle may have microscopic squamous epithelium infiltration that precludes such use. Autografts have several disadvantages, including lack of availability in chronically diseased ears, prolonged operative time to obtain and shape the material and resorption. Additionally, osteitis may exist within the ossicles, and the risk of residual cholesteatoma may be increased in patients with cholesteatoma.

Irradiated homograft ossicles and cartilage were first introduced in the 1960s in an attempt to overcome some of the disadvantages of autograft implants. Homograft ossicles or cartilage may be presculpted by the manufacturer, or they may be sculpted during surgery. Since 1986, homograft materials rarely are used because of the risk of disease transmission (e.g., AIDS, Creutzfeldt-Jakob disease).

Because of the perceived disadvantages of autograft materials and the potential risk of infection from homograft implants, alloplastic materials are the most commonly used materials for ossicular reconstruction today. Commonly used materials are Teflon hydroxyapatite, stainless steel, titanium and gold. Use of tragal or conchal cartilage as autograft material in cases of ossicular discontinuity in cases of necrosis of long process and lenticular process of incus in case of mucosal disease has largely been left un-investigated.

In this study we would determine the short term hearing improvements in such patients.

## METHODS

We have conducted a prospective comparative study on patients of mucosal type of chronic suppurative otitis media from the year 2013 to 2016 treated in a tertiary care centre. The study population comprised of 30 adults in the age group between 20 and 70 years undergoing cartilage interposition ossiculoplasty with canal wall up mastoidectomy for lenticular and long process of incus erosion.

### *Inclusion criteria*

Inclusion criteria were age group in between 20-70 yrs.s of safe type of; patients of mucosal type of chronic suppurative otitis media with good cochlear reserve and good eustachian tube fuction, all cases selected are those which required intact canal wall mastoidectomy only, intra op findings of osscicular discontinuity in the form of erosion of long process of incus with malleus and stapes intact (Austin's type A).

### *Exclusion criteria*

Exclusion criteria were patients with previous history of ear surgeries; patients with atticoantral disease and cholesteatoma; patients with sensorineural or mixed hearing loss; patients who require canal wall down mastoidectomy as part of their treatment

The procedure was done under local or general anesthesia determined as per convenience and safety of the patient. The surgery was done by postaural or endaural route depending on the external auditory canal of the patient. After raising the tympanomeatal flap, the middle ear was examined for other diseases like cholesteatoma. Cortical mastoidectomy was done if needed and patency of aditus was established. Status of the ossicular chain was assessed. Only those patients who were seen to have an intact malleus and stapes with erosion of only the lenticular and long process of incus intraoperatively, which can be bridged by cartilage transposition between the stapes head and the remanent of the incus were considered for the study. Autologous tragal cartilage was used as the autograft to bridge the ossicular gap. The extracted cartilage was then shaped and sized appropriately and placed in the gap between the remnant of the long process of incus and the head of stapes and mobility checked. Temporalis fascia was used to close the perforation by underlay technique.

Outcome of the study was determined as follows

a) Pre-operative air bone gap calculated from pure tone averages of 500Hz, 1000Hz, 2000Hz

b) Post-operative air bone gap calculated from pure tone averages of 500Hz, 1000Hz, 2000Hz at 3 months and 6 months after surgery.

The above data was analyzed as follows

a) Data was collected using case record forms and will be entered on to the master chart.
b) Paired 't' test was used to compare the air bone gap, before and after surgery and between those after 3 months and 6 months of surgery.

**Figure 1: Lenticular process necrosis and ossicular gap between long process of incus and stapes head.**

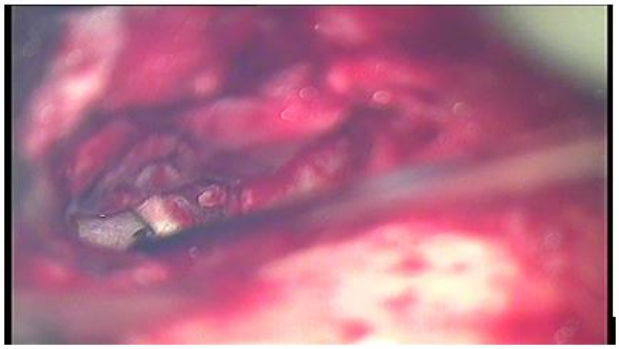

**Figure 2: Tragal cartilage graft being introduced in the ossicular gap.**

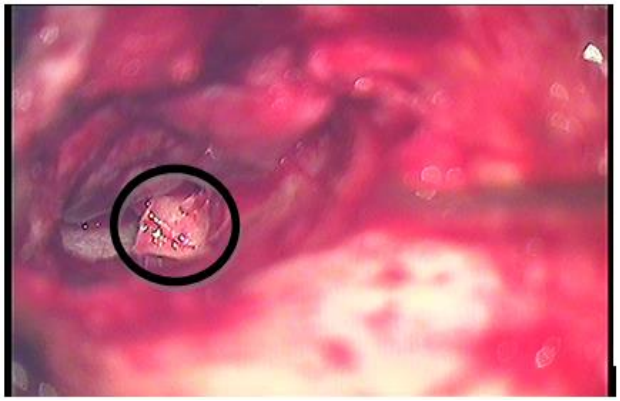

**Figure 3: Tragal cartilage graft bridging the ossicular gap.**

## RESULTS

### *Comparison of air bone gap*

We observed that the group of 30 patients exhibited a mean air bone gap of 39.07 decibels with a standard deviation of 4.22. After 3 months of surgery the mean air bone gap had reduced to 18.13 with a standard deviation of 4.67. On statistical analysis of the above data, we observed that a p value of less than 0.01 was obtained which makes the improvement in the study group statistically significant.

**Table 1: Comparison of air bone gap after 3 months postoperative.**

| Variable | Mean | SD | SE | p- value |
|---|---|---|---|---|
| **PTA (AB gap) Baseline** | 39.07 | 4.22 | 0.77 | <0.01 |
| **PTA (AB gap) 3 month** | 18.13 | 4.67 | 0.85 | |

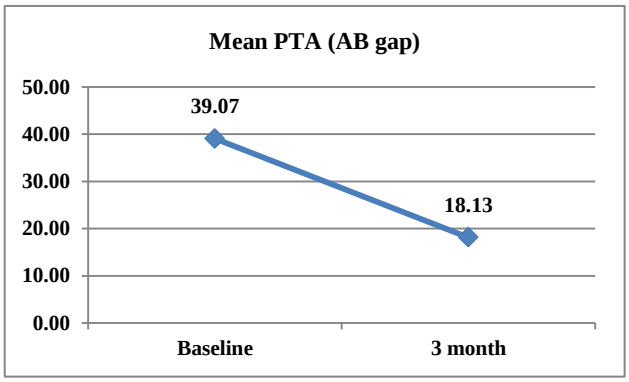


**Figure 4: Comparison of air bone gap after 3 months postoperative.**

After 6 months of surgery the mean air bone gap had remained unchanged at 18.13 with a standard deviation of 4.67.

**Table 2: Comparison of air bone gap pre op and 6 months postoperative.**

| Variable | Mean | SD | SE | P value |
|---|---|---|---|---|
| **PTA (AB gap) baseline** | 39.07 | 4.22 | 0.77 | <0.01 |
| **PTA (AB gap) 6 months** | 18.13 | 4.67 | 0.85 | |

Thus the results can be summarized graphically as follows:

Thus a mean air bone gap of 18.13 decibels with a standard deviation of ±4.67 decibels was achieved post-surgery.

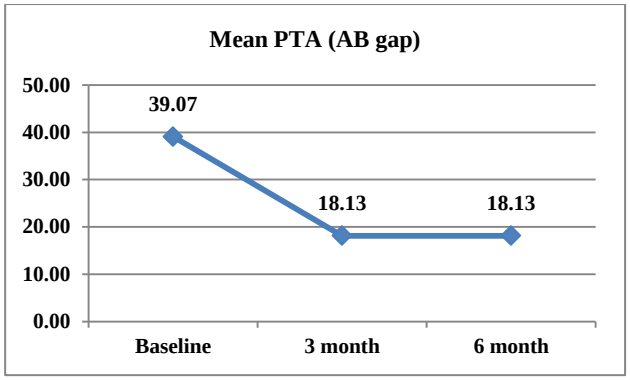


**Figure 5: Comparison of air bone gap at 3 months and 6 months post-surgery.**

The size of perforation, age, sex and preexisting co morbidities had no statistically significant impact on the hearing outcome in the current standard of post-operative care.

## DISCUSSION

The technique of cartilage interposition ossiculoplasty involves the use of tragal or conchal cartilage for bridging the gap in the ossicular chain left by the necrosis of the ossicles caused by the disease. The tragal cartilage was used in all of our cases under study as harvesting is relatively simpler and the extraction of adequate amount of cartilage is possible. Compared to conchal cartilage the tragal has no innate curvature and is hence easier to work with and is also thicker than the conchal in most patients. A separate incision is required to extract the tragal cartilage but it is still covered under the same dressing and heals simultaneously. According to Desarada et al[15] from India when various types of incudo-stapedial assemblies for ossicular reconstruction by tragal cartilage and perichondrium struts such as L-shape, T-shape, Bow-shape and Boomerang strut have been used the success rate was 84% with the audiometric thresholds revealing 15 -20 dB A-B gap closure of 110 cases of cartilage ossiculoplasty. Chaudhary et al concluded that using autogenous bone (incus remnant and cortical bone) and autogenous cartilage (tragal and conchal) for reconstruction of ossicular chain at 18 months follow up has shown fairly good hearing improvement i.e., 84% patients had closure of air bone gap within 20 dB and 37% had closure of air bone gap within 10 dB.[16]

As there are not many studies on cartilage ossiculoplasty exclusively and the criteria's that this study has adhered to has further narrowed down the study population as we are considering patients with only Austin type A discontinuity, we can only compare it to studies carried out with different prosthesis and we can statistically conclude that 66.66 percent of our study population has a hearing improvement in the range of 0 to 20 decibels which is within range of the above studies.

**Table 3: Comparison of air bone gap closure in various studies of ossiculoplasties with auto grafts.**

| | Desarada et al [15] | Chaudhary et al [16] | Our study |
|---|---|---|---|
| **Air bone gap closure** | 15 -20 db (84%) | 20 db (84%) | 20 db (66.66%) |
| **Materials used for ossiculoplasty** | Tragal cartilage and perichondrium | Autogenous bone (incus remnant and cortical bone) | Tragal cartilage |

**Table 4: Comparison of air bone gap closure in ossiculoplasties with various materials and tragal cartilage.**

| | Iiurato et al [17] | Our study |
|---|---|---|
| **Post op air bone gap** | 0 to 20 dB (54% to 93%) | 0 to 20 dB (83.33%) |
| **Materials used for ossiculoplasty** | Various materials | Tragal cartilage |

The mean air bone gap closure was observed to be 20.70±5.1 in our study population of 30 patients.

25 of our patients had a post op air bone gap of 0 to 20 dB hence 83.33 percent of the patients had an air bone gap of 0 to 20 dB post op which can be compared to Iiurato et al who in their retrospective review of large series of Austin-Kartush type A ossiculoplasties of various surgeons showed air-bone gap of 0 to 10 dB for 20% to 68% of patients and of 0 to 20 dB for 54% to 93% of patients post-surgery.[17]

The above observations remained unchanged over the next 3 months and these patients had similar hearing threshold even 6 months post-surgery, this is a testament to the survival of the cartilage in the middle ear and also to the stability of the assembly for this period of time. Extrusion of the cartilage was not noticed in any of the patients and hence is not noted as a complication. Use of cartilage as a material for inter position has advantage of being easy to extract, reducing operative time as use of incus requires removal of incus remnant and reshaping of the bone which adds to the surgical time, use of cortical bone faces similar challenges. Not disturbing the natural assembly of the ossicles has additional advantage of maintaining the ossicular ratios as close to natural as possible and not removing the incus prevents retraction of the tympanic membrane in the future. Preserving the perichondrium on one side of the interposed cartilage ensures a snug fit of the interposed cartilage and adhesion to the remnant of the incus. Least risk of extrusion, foreign body reactions and no additional costs are some added benefits of the procedure.

## CONCLUSION

In conclusion, we would like to say that the results of cartilage ossiculoplasty in this scenario is comparable to other methods of ossiculoplasties along with the above mentioned additional advantages and consideration of this procedure for further long-term study and gain insight into long term hearing results and the effect of further avascular necrosis of the long process of incus and its effect on the prognosis even when the area of contact is adequate between the cartilage and remnant of incus is sufficient intraoperatively is warranted. Follow up period of 6 months can predict the outcome of the procedure but long term outcome of the surgery and sustained hearing improvement can be determined by longer periods of follow-up and a larger sample size.

## ACKNOWLEDGMENTS

Dr. Sameer Bhargava honorary consultant, Dept. of otorhinolaryngology HBT Medical College and Dr. Juthika Sheode Honorary consultant Dept. of otorhinolaryngology HBT Medical College for their invaluable guidance in the entire study.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: Not required*

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