The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 3, Issue 7, 2025

HEARING OUTCOME IN OSSICULOPLASTY WITH AUTOGRAFT VS ALLOPLASTIC IN CHRONIC SUPPURATIVE OTITIS MEDIA; A COMPARATIVE STUDY

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DOI: https://doi.org/10.5281/zenodo.15869029

Keywords
conductive hearing loss, ossiculoplasty, autograft, otitis media, allograft

Article History
Received: 07 April, 2025
Accepted: 27 June, 2025
Published: 12 July, 2025

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Abstract

Objective: *To compare the hearing outcome of ossiculoplasty in terms of Air-Bone Gap closure using auto graft vs. alloplastic in Chronic Suppurative Otitis Media patients.*

Study Design: *Randomized control Study*

Study Duration: *06 months*

Study Place: *Capital Hospital, CDA Hospital, Islamabad*

Methods: *A consecutive non probability sampling technique was used and sample size of 60 individuals was calculated using open EPI Calculator. The individuals were divided into two equal groups. Patients in group A underwent Ossicular reconstruction using autograft (incus) and group B underwent Ossicular reconstruction using alloplastic material (fluoroplastic). Patient in both groups were assessed using Pure Tone Audiometry (PTA) preoperatively and postoperatively at 1st and 2nd month to compare air bone gap closure. The data was entered and analyzed using SPSS 23.0*

Results: *In our study, total 60 patients were included, among them 28 were males and 32 were females. Patients had been divided into 02 equal groups. At start of study, AB gap in group A was 27.7±7.9 and in group B was 29.4±7.9. When compared at 1st month, AB gap in group A was 22.6±8 and in group B was 26.3±7.5 and when seen at 2nd month, it was 19.1±8.1 in group A and 23.8±7.7 in group B. There was also significant improvement in parameters like vertigo and tinnitus in group A as compared to the group B.*

Conclusion:

From our study, we concluded that autologous incus grafts carried superior prognosis as compared to allografts.

INTRODUCTION

Hearing loss is defined as partial or complete loss of ability to hear. It can be classified as conductive, sensory or mixed type, and it can involve both ears or confined to only one. The normal frequency which

humans can hear range from 20Htz to 20,000 Htz and in decibels, it range from 0-20 decibels.[1] Hearing loss can be present from birth (congenital), can also present in adolescence and young adults but it is most common occurring in people aged more than 70 years.[2] Males are more likely to be affected from hearing loss and at present around 10% of world population suffered with some form of hearing loss. Around 5% of adults in age range 45-54 years have experienced disabling hearing loss and rate increases 10% in age groups 55-64% and greater than 55% in people aged 75 or older.[3] It is estimated that over 700 million people may have disabling hearing loss by 2050.[4] 50% of hearing loss cases can be preventive especially in children under 15 years, where ratio is up to 60%, by adaptive strategies such as vaccination against rubella and vaccinations against H. influenza and S. pneumonias and also by avoiding high volume sound.[5]

Conductive hearing loss is one of the type of hearing loss and it results from disruption of ossicular chain, its irregularity may result from either discontinuity or fixation of ossicular chain. In ossicular discontinuity, the ossicular coupling led preferential conduction of sound to the oval window is lost. In more than 80% of the patients, the cause of ossicular damage is Chronic suppurative otitis media. Other causes include ear wax, foreign body, swimmers ear, Eustachian tube disorders and otosceloris.[6] Disruption occurs most commonly at incudostapedial joint, an absent incus or absent incus with stapes suprastructure.[7] In approximately half cases, the most commonly involved structure is incus.[8] Austin classified ossicular damage into 04 types based on stapes and malleus presence or absence with incus absent in all cases, which are type A, B, C and D, the most common type being A, where defect lies in malleus and stapes superstructure. The classification is shown at the end of the introduction para.[9]

Chronic Suppurative Otitis Media (CSOM) is among the most common infectious disease of ears and is the leading cause of conductive hearing loss. It results from prolonged inflammation of the middle ear mucosa and mastoid space which leads to perforation of tympanic membrane and discharge (otorrhea).[10] Treatment options include oral vs IV antibiotics, topical antibiotics and antiseptics. In case of chronic cases, where individual suffers from profound hearing loss, or where ossicular chain is disrupted, surgical options are considered i.e. ossiculoplasty by using allograft and autografts.[11]

Ossiculoplasty also known as osicular chain reconstruction is a surgical procedure that repairs the connection between tympanic membrane and inner ear.[12] It aims to reestablish ossicular chain continuity and improve the air conduction thresholds in patients with conductive hearing loss. The aim is to achieve air bone gap of <30 decibels. It is done via both auto graft and allograft, the autograft most common being used is incus. Artificial ossicular prostheses which have been in practiced are made from plastic, metals, and biomaterials.[13] Titanium allografts have gained publicity being more durable, light weight, rigid and biocompatible but their limitation is cost effectiveness.[14] However the incus auto grafts are more preferable as being cost effective, and less post-operative complications.[15]

In our study, we compared improvement in hearing loss between two groups, one with autologous (Incus) graft and the other with allograft(fluoroplastic) graft. Improvement in hearing status was seen in Air Bone gap via pure tone audiometry scale.

Austin/Kartush Classification:

Types	Ossicular Chain Status
O	M+1+S+
A	M+S+
B	M+S-
C	M-S+
D	M-S-
E	Ossicular head fixation
F	Stapes fixation

Methodology:

After the ethical approval from the institute review board, this randomized control study was done in ENT department of Capital Hospital, CDA, Islamabad. The study duration was 06 months and it spanned from Novemeber 1st,2024 to April 30th, 2025. The inclusion and exculsion criteria are as follow:

INCLUSION CRITERIA:

1. Patients diagnosed with CSOM based on otorrhea more than 3 months.
2. Patients with conductive hearing loss more than 20db confirmed by pure tone audiometry.
3. Having no active ear disease.
4. Involving both genders
5. Age group: 10 to 60 years
6. Patients with eroision of incus (Austin type A)

EXCLUSION CRITERIA:

1. Patient unfit for surgery
2. Patients with intracranial or extracranial complications
3. Revision cases
4. Cases with mixed or Sensorineural hearing loss
5. Patients with loss of bone malleus, stapes (Austin type D)
6. Intact Ossicular chain

All CSOM patients attending the OPD Clinic of Ear, Nose and Throat (ENT) who fulfil the inclusion criteria were included in the study after informed consent. Total 60 patients were included in the study among them 28 were males and 32 were females. Sample size was calculated by using EPI open calculator, with level of significance 5% and power of study 80%. A detailed history about the complaint was taken. Examination of ear was done in detail; First, through otoscope then under microscope. All patients underwent radiological examination which included Computed Tomography (CT scan) Temporal bone without contrast. Hearing status was assessed by using tuning fork test and PTA (Pure tone audiometry) by using MAICO 42 audiometer. Hearing loss was calculated by average Air-Bone gap on PTA at frequencies 500, 1k, 2k preoperatively and postoperatively at 1st and 2nd month in terms of Mean and Standard Deviation. All surgeries were done by same otologist under general anesthesia by post auricular approach. The aim of surgery was to eradicate the disease followed by reconstruction of ossicular chain in a single-stage operation by using different graft materials. The subjects were randomly allocated into two groups on the basis of lottery number, each of which contained 30 individuals.

Group A: Ossicular reconstruction using Autograft (Incus)

Group B: Ossicular reconstruction using Alloograft (Fluoroplastic PORP)

In group A, Incus with necrosed long process was removed from incudomalleolar joint and the body was reshaped by using 0.6mm cutting burr. Reconstructed incus was placed between the handle of maleus and stapes superstructure. In group B, Fluoroplastic PORP was placed in similar fashion and was secured by a small piece of cartilage to maintain it's position. The wound was closed back in three layers and aseptic pressure dressing was done which remained intact for 24 hours.

Patients in both groups A and B were also divided based on age in 05 sub- groups, group 1 had people in age range from 10-20 years and in group 2 people from 20-30 year age were present, group 3 included 30-40 years, group 4 included 40-50 year and group 5 comprised 50-60 years age persons. All the subgroups were denoted as A and B respectively as regard to their main group. Data was analyzed using SPSS version 23.0 and both qualitative and quantitative data was presented through graphs and charts. Both groups were compared using t-test and p value <.05 was considered as statistically significant. Qualitative variables include gender, vertigo, operation site, tinnitus and ossiculopasty material used, while quantitative variables include age, air bone gap on PTA.

Age Groups	
Subgroup A	Subgroup B
Group 1 (10-20years)	Group 1 (10-20years)
Group 2 (20-30years)	Group 2 (20-30years)
Group 3(30-40years)	Group 3(30-40years)
Group 4 (40-50years)	Group 4 (40-50years)
Group 5 (50-60years)	Group 5 (50-60years)

Results:

In our study, total 60 patients were included, which were divided into 02 groups, 30 (50%) patients in each group (table1.1). Group A underwent auto graft ossciculoplasty via remodeling of incus and group B underwent allograft ossiciloplasty using fluoroplastic material.

Among 60 patients, there were 16 (53.3%) male patients and 14 (46.6%) female patients in Group A, similarly in group B, 12 (40%) were male patients and 18 (60%) were female patients. Hence among 60 patients, total males were 28 (46.6%) and 32 (53.3%) females. (table 1.2)

In our study, 31(51.6%) patients had right sided conductive hearing loss and 29 (48.3%) had left sided conductive hearing loss. (table 1.3)

Air-Bone Gap was measured Preoperatively and Post operatively at 1st and 2nd month. For Group A, Preop ABG was 27.7±7.9 dB and Post operatively it was 22.6±8 and 19.1±8.1 at 1st and 2nd divided into 5 subgroups from each main group i.e. A and B. In main group A, out of 30 patients, the patients who have most improvement in AB gap falls month respectively. Similarly, Preoperatively AB gap for Group B was 29.4±7.9 dB and Postoperatively it was 26.3±7.5 and 23.8±7.7 at 1st and 2nd month, respectively (Table 1.4). There was a significant improvement of 81.25% in group A as compared to 7 8 % in group B.

In our study, other parameters such as tinnitus and vertigo were also evaluated, with both showing notable significance. A total of 22 (36.6%) patients reported tinnitus, of which 7 (23.3%) were in Group A and 15 (50%) in Group B (Chart 1.1) . After two months, complete resolution of tinnitus was observed in 6 patients from Group A and 5 patients from Group B (Chart 1.2)

Similarly, 10 patients reported vertigo, with 4 belonging to Group A and 6 to Group B. At the two-month postoperative follow-up, symptoms had resolved in 3 patients from Group A and 2 patients from Group B (Chart 1.2).

While comparing age groups, patients were in group 1A, 2A and 3A. Similarly in group B, the patients who showed most recovery falls under the group 2B and 3B.

Table1.1

Sr No.	Group A (Incus)	Group B (Fluroplastic)
1.	n=30	N=30

Table1.2

Sr No.	Group A (Gender)	Group B (Gender)
	M= 16	M= 12
	F= 14	F= 18

Table 1.3

	R Conductive: n= 31
	L Conductive: n= 29

Sr No	Hearing Loss

Table 1.4

	Groups			
Postoperatively closure	**Autograft**		**Allograft**	
A-B Gap	**Mean**	**SD**	**Mean**	**SD**
Preoperatively	27.7	7.9	29.4	7.9
At 1st Month	22.6	±8	26.3	±7.5
At 2nd Month	19.1	±8.1	23.8	±7.7

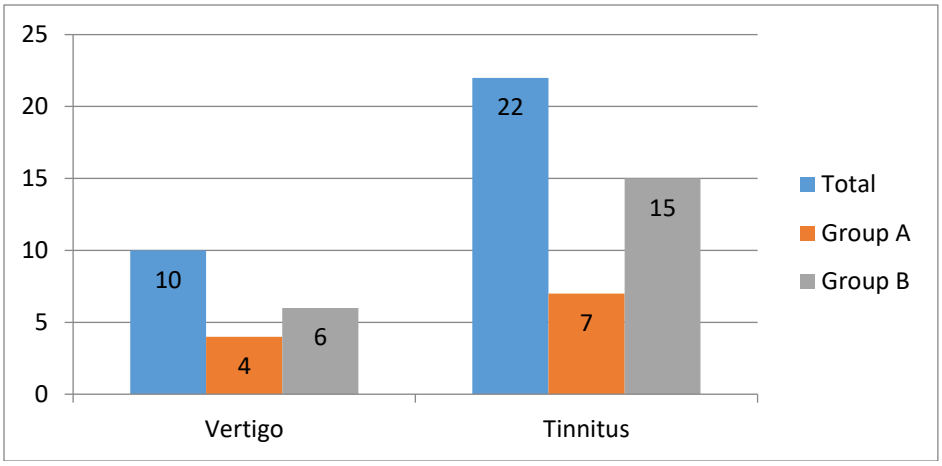

Chart1.1

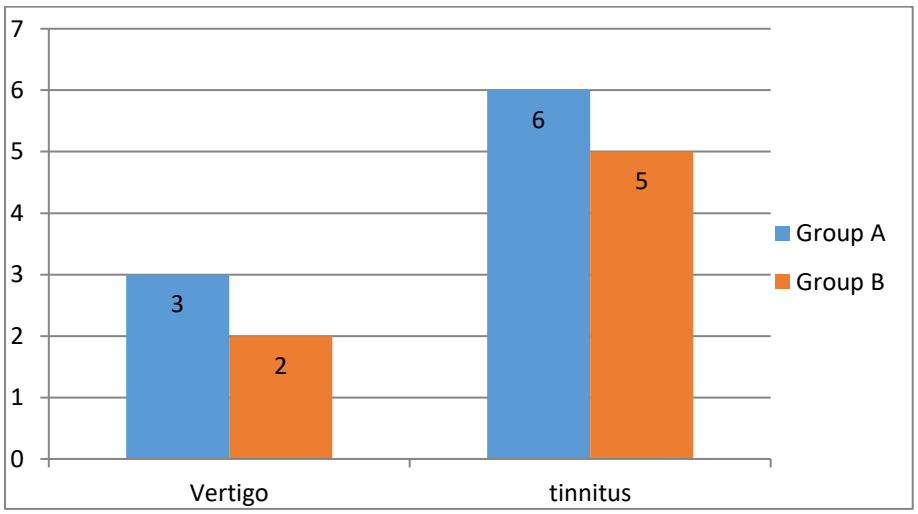

Chart 1.2 (trends of improvement at 2nd month)

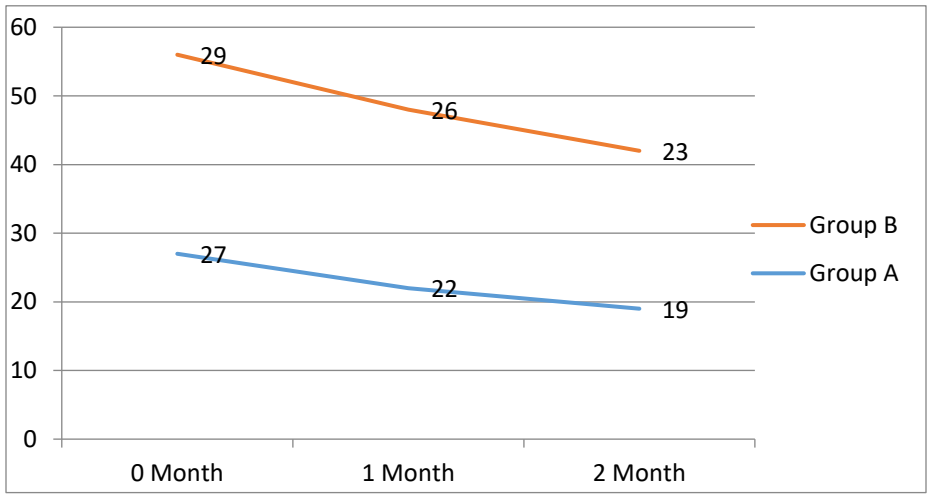

Figure 1.1 (Comparison of AB gap between 2 groups at start of study and when compared at 1st and 2nd months)

Discussion:

Hearing loss is a significant health problem and it leads to both the social and mental health issues, moreover it also effects the caretakers and family members. Hearing loss can be of conductive, sensorineural and mixed. According to WHO, Over 5% of the world's population – or 430 million people – require rehabilitation to address their disabling hearing loss (including 34 million children).[16] Conductive hearing loss results from disruption of sound waves from external ear to middle ear to cochlea. Variety of disorders results in conductive hearing loss which included CSOM, otitis externa, cholestetoma and congenital anamolies. Oscciculoplasty was introduced in as early as 1950s to restore middle ear function.[17]The procedure aims to restore ossicullar chain continuity and improve air conduction threshold, in upto 55% patients repairing ossicullar chain results in improvement of hearing loss.[18]

In our study 60 patients were included, which were divided into 2 equal groups of 30 individual each. Group A patient had modified incus autologous graft while Group B patients had allograft ossiculoplasty. In both the groups, pre Op ABG was 27.7±7.9 dB in group A and 29.4±7.9 in group B.

On comparing both the groups at 01 month interval, patients in group A had AB gap improvement of 68.7% and in group B, it had 62.5% of improvement, depicting a better outcome in patients of group A who were treated with autologous graft. This is in consistent with the study performed by Iuroto et ell, which showed incus based autograft superior as compared to allografts by 84 to 82 %.[19]

It is evident from our study that group A had achieved significantly better improvement in AB gap as compared to the group B. Group A had 36 % total improvement as compared to the group B. In a study performed by Robert et ell on 137 patients which spanned over 15 months, it showed autologous incus grafts were superior to allografts in improving AB gap and furthermore they have low extrusion rate, and enhanced stability over long time.[20] Our study also showed better AB gap improvement in autologous group.

In study by Emir et ell, 304 patients were evaluated who underwent incus autologous ossiculoplasty, the success rate was 58% with incus autologous ossiculoplasty as compared to PORP allograft, which had 56% success rate.[21] Our study has also been consistent with the study mentioned as in our study we also used incus autograft.

In a study by Neudert et ell, three different prosthesis were compared which included titanium angle, incus and titanium clip prosthesis. The study highlighted multiple factors affect choice of prosthesis and use of just 1 specific one was not advocated, rather it was suggested that choice of prosthesis should be based on individual preference, cost effectiveness and regional anatomy.[22] However in our study, we used only one type of prosthesis, which was fluroplastic osciloplasty.

In our study we also found that in both groups, improvement in tinnitus and vertigo also occurred, however the group A showed most improvement in

symptoms of vertigo and tinnitus as compared to the group B.

Limitation of study:
It is a single center study, moreover sample size of only 60 patients was selected. Hence its results cannot be generalized on whole population. However the study set a bench mark for future studies in this field.

Conflict of study: NIL

Conclusion:
From our study, we concluded that autologous incus grafts carried better improvement in AB gap as compared to allografts when compared at 1st and 2nd months post operatively. Moreover the incus based autologous group showed enhanced improvement in symptoms of vertigo and tinnitus. Hence incus based autografts carries superior prognosis as compared to autologous grafts.

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Based on calculations performed by NIDCD Epidemiology, Statistics, and Population Sciences Section staff: (1) using data from the 2015-2020 National Health and Nutrition Examination Survey (NHANES); (2) applying the definition of disabling hearing loss used by the 2010 Global Burden of Disease Expert Hearing Loss Team (hearing loss of 35 decibels or more in the better ear, the level at which adults could generally benefit from hearing aids)

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