

**A STUDY ON COMPARATIVE STUDY OF AUTOLOGOUS
OSSICULAR GRAFT VERSUS TITANIUM PROSTHESIS (TORP &
PORP) IN OSSICULOPLASTY FOR OSSICULAR PATHOLOGY**

Dissertation submitted to
THE TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY

**In partial fulfillment of the regulations
For the award of the degree of
M.S., (Oto-Rhino-Laryngology)
Branch – IV**

**Department of ENT
Kilpauk medical college,
Chennai -10.**



**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY
CHENNAI**

April 2014

CERTIFICATE

This is to certify that the dissertation on “A STUDY ON COMPARATIVE STUDY OF AUTOLOGOUS OSSICULAR GRAFT VERSUS TITANIUM PROSTHESIS (TORP & PORP) IN OSSICULOPLASTY FOR OSSICULAR PATHOLOGY” presented herein by Dr.P.THAMIZHARASAN, is an original work done in the Department of Oto-Rhino-Laryngology, Govt kilpauk Medical College, Chennai-10, and submitted in partial fulfillment of the regulations laid down by The Tamil Nadu Dr. M.G.R.Medical University, Chennai for M.S.,Degree Examination Branch IV– Oto-Rhino-Laryngology, under my guidance and supervision during the academic period 2012-2014.

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I Dr.P.THAMIZHARASAN solemnly declare that the dissertation on
“A STUDY ON COMPARATIVE STUDY OF AUTOLOGOUS OSSICULAR
GRAFT VERSUS TITANIUM PROSTHESIS (TORP & PORP) IN
OSSICULOPLASTY FOR OSSICULAR PATHOLOGY” was done by me
at Government Kilpauk Medical College, Chennai-10 under the guidance and
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The dissertation is submitted to the Tamil Nadu DR.MGR medical
university towards the partial fulfillment of the requirements of
MS Branch IV – Otorhinolaryngology degree examination.

Chennai

Date

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ACKNOWLEDGEMENT

I thank our respected Dean Prof. Dr.P.RAMAKRIHNNAN, M.D.,D.L.O., Kilpauk Medical College, Chennai for permitting me to utilize the facilities of the college for this work.

I have great pleasure in expressing my deep gratitude to my guide, Prof.Dr.K.RAVI, M.S., D.L.O.,D.N.B., Professor of ENT, Department of ENT, Kilpauk Medical College, Chennai, for his kind encouragements and valuable guidance during the period of the study without which this dissertation would not have materialized.

I express my sincere thanks to Prof.Dr.G.SANKARANARAYANAN, M.S., D.L.O., M.N.A.M.S., Head of the department, Department of ENT, Kilpauk Medical College, Chennai for his valuable suggestions and encouragement during my study.

It is my privilege to thank my assistant professors Dr.V.PRITHIVIRAJ, Dr.R.RANJANAKUMARI, Dr.J.NIRMALKUMAR, Dr.K.M.ELANGO and Dr.K.SANJAYKUMAR, for their timely help and support.

I am very grateful to all my fellow Post Graduates for their invaluable help rendered during this study.

I am also very grateful to professors, assistant professors and postgraduates of other departments and all the staff members of Kilpauk medical college hospital and Govt. Royapettah hospital who have helped me in the course of my study.

Last but not the least I thank our patients for willingly submitting themselves for the study.



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CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "A Study on Comparative Study of Autologous Ossicular Graft Versus Titanium Prosthesis(TORP&PORP) in Ossiculoplasty for Ossicular Pathology" for dissertation purpose.submitted by Dr.P.Thamizharasan, 1st year MS(ENT), PG Student, Govt. Kilpauk Medical College, Chennai.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.




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TITLE: A STUDY ON COMPARATIVE STUDY OF AUTOLOGOUS OSSICULAR GRAFT VERSUS TITANIUM PROSTHESIS (TORP & PORP) IN OSSICULOPLASTY FOR OSSICULAR PATHOLOGY

KEY WORDS: Autologous incus, Ossiculoplasty, Titanium TORP & PORP

ABSTRACT

To analyze and compare the outcomes of ossiculoplasty in terms of hearing results and intra and post operative course, using autograft incus and titanium middle ear prosthesis in patients with ossicular chain erosion. Patients between 12 and 60 years of age with a history of chronic ear discharge with moderate conductive deafness (>40 dB HL) were included in the study. The patients after assessment of ossicular erosion were subjected to ossiculoplasty with autologous incus or titanium prosthesis randomly. The patients were followed up after 3 months to analyze the functional and anatomical results. Out of 21 patients with ossicular chain defect were included in the study, of whom 10 patients underwent ossiculoplasty with autograft incus and 11 with titanium prosthesis. Postoperative hearing evaluation by pure tone audiogram was done after 3 months, which showed successful hearing. Complications and extrusion rate were nil. In patients with incus average Post operative pure tone average was 43.5 dB and Net gain in hearing was 10.6 decibels. In patients with titanium prosthesis, average Post operative pure tone average was 41.4 dB and Net gain in hearing was 15.9 decibels. Incus and titanium has equal postoperative hearing. In terms of hearing gain Titanium prosthesis gave a better hearing gain than Ossicular transposition. Complications in the short period studied are nil in both groups.

CONTENTS	PAGE NO
1. INTRODUCTION	1
2. ANATOMY OF MIDDLE EAR OSSICLES & HEARING	5
3. OSSICULAR PATHOLOGY & RECONSTRUCTION	21
4. REVIEW OF LITERATURE	37
5. AIM OF OUR STUDY	47
6. MATERIALS & METHODS	48
7. RESULTS	61
8. DISCUSSION	77
9. CONCLUSION	87
10. BIBILIOGRAPHY/ REFERENCES	88
11. ANNEXURE	92
MASTER CASE SERIES	
PROFORMA	
CONSENT	

**A STUDY ON COMPARATIVE STUDY OF AUTOLOGOUS
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INTRODUCTION

Hearing is one of the most important special senses of human being.

A good hearing is important for acquiring good knowledge and improved productivity of human beings. A person who is having hearing impairment has decreased privilege of enjoying the aesthetics of life and mostly have difficulty in carrying out his day to day activities.

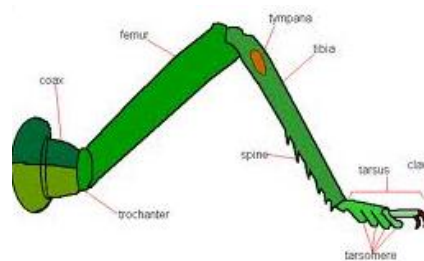
In India, according to world health organization estimation we have 63 million people who have significant hearing impairment ¹. Reports of NSSO survey in the year 2001 suggest that there are 291 persons per one lakh population suffering from severe to profound hearing loss ¹.

Causes of hearing loss may be a conductive component or sensorineural component. Almost all conductive causes of hearing loss have a surgical option for complete cure. In our study we are trying to find a better option for one such cause - ossicular pathology causing hearing loss.

EVOLUTION OF HEARING MECHANISM FROM INVERTEBRATES TO MAMMALS

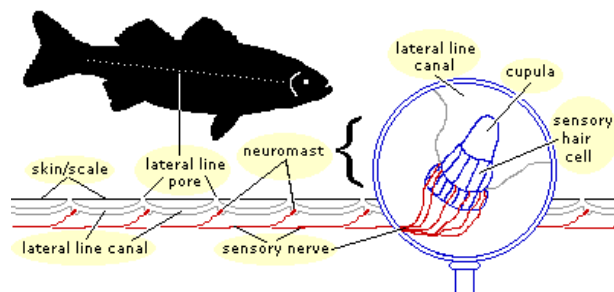
Invertebrates do not have ears. But they can detect sound using other kinds of sense organs.

Insects have tympanal organs situated on the side of head or along the body or legs to perceive distant sounds².



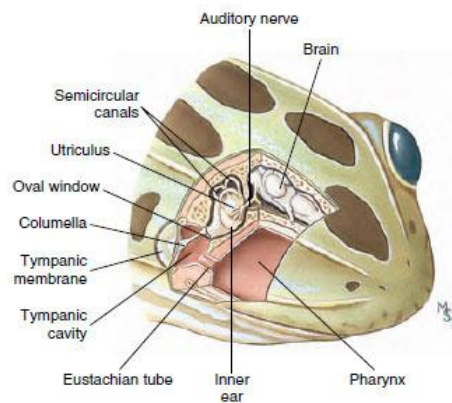
The sound perception for insects is mainly for mating and location

Fish perceive sounds with the help of lateral lines that are present in the side of their bodies³.



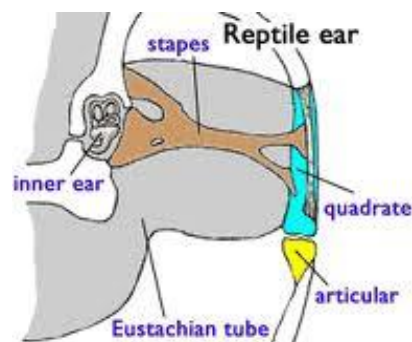
These lines detect mild changes in water currents and vibrations which are perceived as sound and helps in locating movement of nearby fish and prey.

Amphibians have no external ears. But the middle ear is developed. It has an ear drum on the side of head like a disc of cartilage. To the inside of this ear drum a thin rod of cartilage and bone (ossicle) known as columella passes in a air filled cavity (middle ear) upto the inner ear. The columella terminates as an expansion like the stapes which is in relation to oval window.



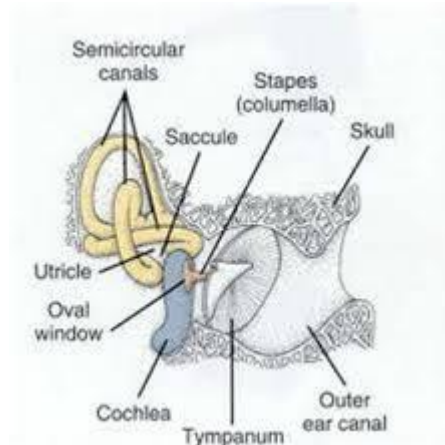
Cut section of frog head

In reptiles the tympanic membrane is bulging out alongside the jaw bones quadrate and articular. The membrane is again connected to inner ear by a single bone, stapes.



In birds there is an outer ear, meatus with muscles around the meatus.

The middle ear consists of two bones an osseous inner part, columella and a cartilaginous extra columella that is in contact with tympanic membrane.



Bird's ear cross section

Over the course of transition from reptiles to mammals⁴, one lower and one upper jaw bone (the articular and quadrate) become of no use in the jaw and migrated to the middle ear, connecting to the stapes and forming a chain of three bones (collectively called the ossicles) which amplify sounds and allow more accurate hearing. In mammals, these three bones are known as malleus, incus, and stapes (hammer, anvil, and stirrup respectively). While the stapes is present in many types of tetrapods, the addition of the incus and malleus in the middle ear is a unique feature of mammals, distinguishing them from other vertebrates.

ANATOMY OF MIDDLE EAR OSSICLES & HEARING

EMBRYOLOGY OF OSSICLES⁵

The First branchial pouch begins to expand forming the Eustachian tube, middle ear and mastoid around fourth to sixth week of gestational life. It is filled with mesenchyme until there is resorption, ossicular development and expansion of the pharyngeal pouches to replace the mesenchyme.

The malleus, incus and the suprastructure of stapes develops from the mesoderm of the first and second branchial arch. The stapes foot plate develops from the otic capsule which is a derivative of the neuroectoderm.

The first arch derivatives are head of malleus and body and short process of incus. The second arch gives rise to the caudal structures the manubrium of the malleus, long process of incus and the suprastructure of the stapes. They start to develop around fifth week of intrauterine life. The incudostapedial joint starts to form around seventh week. The endoderm of the middle ear cleft develops into the mucosal lining as supporting mesenchymal tissue reabsorbs freeing the ossicular chain. Failure of this process leads to a fused incudomalleolar mass which remains attached to the atretic plate.

The stapes as mentioned already has two origins. The second arch cartilage gives rise to the suprastructure and tympanic part of the foot plate. The vestibular portion of the foot plate and the annular ligament are derived from otic capsule. The process of stapes formation starts around five weeks and completed at 26 weeks.

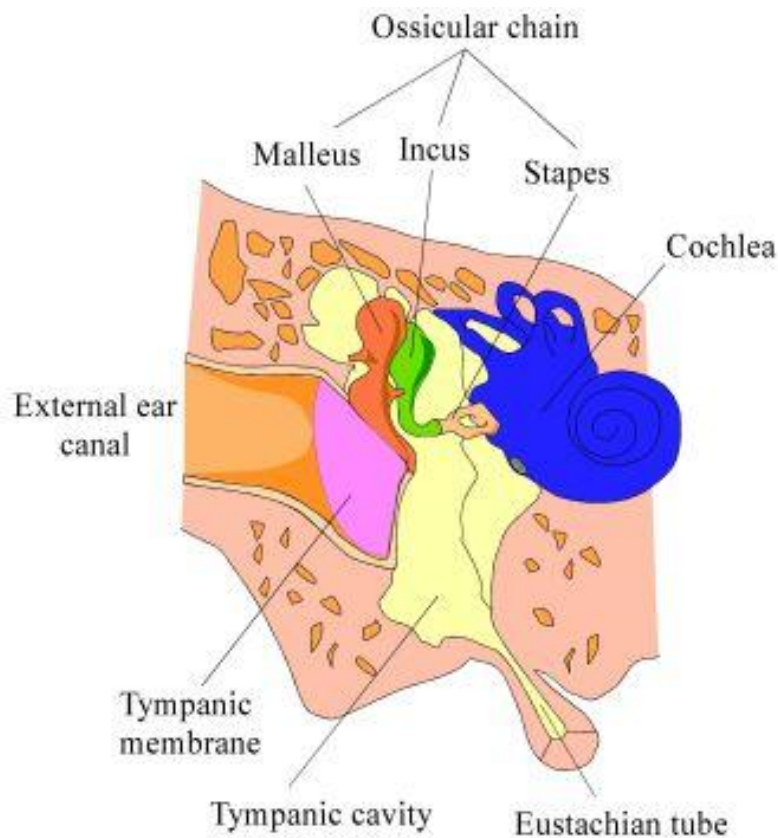
Ossicular abnormalities are frequently encountered. They may be near normal development to ossicular fusion or a rudimentary monoblock ossicular mass. If an atretic plate is present malleus is always fused to it.

Congenital Ossicular abnormalities⁵ include:

1. Absence of manubrium of malleus
2. Shortened long process of incus
3. Failure of incus to connect with stapes
4. Fusion of incudostapedial joint
5. Incudomalleolar fixation
6. Stapedial foot plate fixation

In our study we have not encountered any congenital abnormalities.

ANATOMY OF MIDDLE EAR AND OSSICLES IN HUMAN BEINGS⁶



The middle ear cleft is made up of Eustachian tube, middle ear and mastoid air cell system. The middle ear is a six sided structure with anterior, posterior, superior, inferior, medial and lateral walls. It consists of ossicles, facial nerve, muscles (tensor tympani and stapedius) along with air which is the main constituent.

TYMPANIC MEMBRANE

The tympanic membrane forms the medial end of External auditory canal and the lateral wall of the middle ear.

Tympanic membrane is a three-layered, concave-shaped thin membrane. It is connected centrally to the manubrium of handle of malleus and peripherally to the tympanic sulcus. The tip of the malleus attachment produces a depression known as the umbo. Fibrous layer of the tympanic membrane is divided into two dense layers, an outer layer and a deeper layer, which provide the structural support for thin EAC skin laterally and middle ear mucosa medially.

The outer radial fibrous layer inserts on the manubrium of the malleus, and deeper circular fibrous layer is arranged circumferentially close to the circumference of the tympanic membrane. Both layers become integrated in the periphery to form a fibro cartilaginous ring, the tympanic annulus which anchors the tympanic membrane to a bony sulcus in the tympanic ring.

This tympanic sulcus terminates superiorly at anterior and posterior spines, to which the most superior edge of the fibrous layer is attached to form posterior and anterior malleolar folds that insert on the lateral process of the malleus. The small area of tympanic membrane located superior to the anterior and posterior malleolar folds lacks a fibrous layer and is attached superiorly to the bony rim of the notch of Rivinus. The superior segment of tympanic membrane

is thin known as pars flaccida or Shrapnel's membrane, and the thicker inferior part is known as pars tensa.

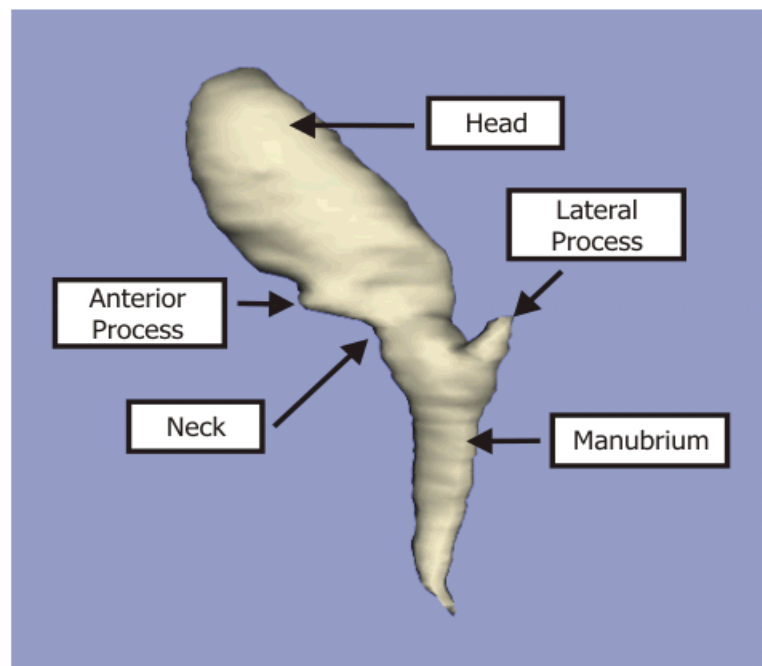
OSSICLES:

There are 3 ossicles in the middle ear which conducts sound from external ear to inner ear. They are Malleus, Incus and Stapes.

Malleus

Malleus is the lateral and largest of the ossicles. It is about 8 to 9 mm long.

1. Head – It is rounded and lies in the attic. It articulates posteriorly with the body of incus. It gives attachment to superior and lateral malleolar ligaments.
2. Neck – Lies against the pars flaccida and related medially to Chorda tympani.

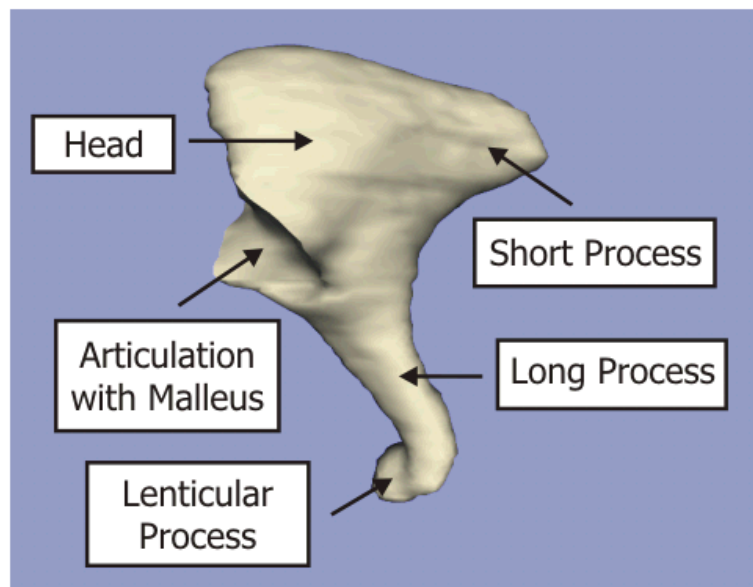


3. Anterior process – It is connected to the petro tympanic fissure by the anterior malleolar ligament.
4. Lateral process – It projects from upper end of the handle and provides attachment to the malleolar folds.
5. Handle – Extends downwards, backwards and medially and it is attached to upper half of the tympanic membrane.

Incus

The parts of incus are

1. Body – Large with its articular surface directing forwards.

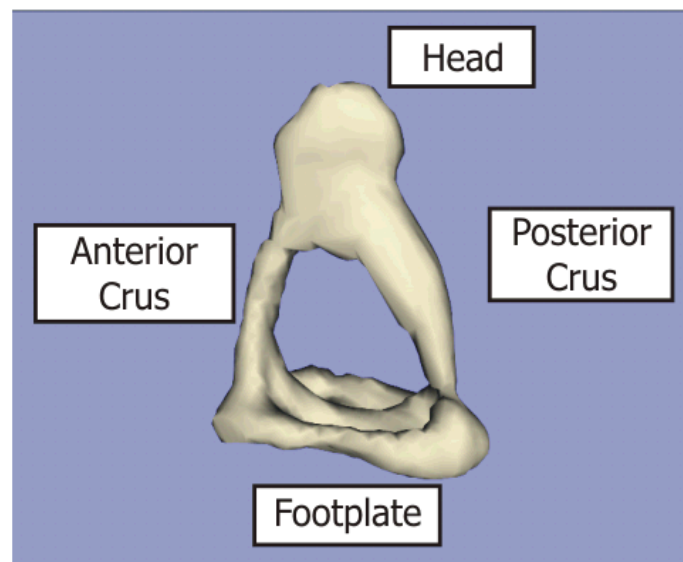


2. Short process – It is directed backwards and is fixed to fossa incudis just below the aditus.

3. Long process – it is directed downwards into the cavity just behind and parallel with the handle of malleus. Its tip bears a lentiform process which is directed medially to get articulated with stapes head.

Stapes

This is the medial most and smallest of the 3 ossicles. It has following parts



1. Head – It has a small concave facet which articulates with lentiform nodule.
2. Neck – It is the narrowest part giving insertion to tendon of stapedius.
3. Crura – They are 2 in number, the anterior and posterior one. The anterior crura is shorter and less curved. The limb diverges from neck and gets attached to the foot plate.
4. Foot plate – It is oval in shape and fits into the oval window

The middle ear is divided into epitympanum, mesotympanum and hypotympanum. The epitympanum is that portion of the middle ear which is above the level of neck of malleus. The Mesotympanum that part that lies between the two horizontal lines drawn at the level of upper and lower edges of pars tensa of the tympanic membrane. The Hypotympanum is that part that lies below the level of bony ear canal.

Anteriorly there are three parts, superiorly the opening for canal of Tensor tympani muscle, then an opening for eustachian tube, and anteroinferiorly there is a thin plate of bone which separates the middle ear from the internal carotid artery. The bony canal between the two tensor tympani and Eustachian tube continues posteriorly on the medial wall like a curved lamina which is called Processus cochleariformis. The posterior end of this process forms a pulley around which this tensor tympani muscle turns 90 degrees to get attached to the upper part of handle of malleus.

Medially, the most prominent structure is Promontry which is the basal turn of cochlea. Fenestra Vestibuli or Oval window is an oval shaped opening in the posterosuperior aspect of medial wall. Oval window communicates with the

vestibule of the inner ear and it is closed by foot plate of stapes. Fenestra Cochleae or Round window is an opening lying posteroinferior to the promontory. It opens into Scala tympani of the cochlea and it is covered by a thin membrane called secondary tympanic membrane.

Posteriorly on the superior part there is aditus, through which epitympanum communicates with mastoid antrum. Fossa incudis is a depression which lodges the short process of incus. There is a conical projection in the posterior wall called as pyramid with an opening in its apex. This opening transmits tendon of stapedius muscle which gets attached to the posterior surface of neck of stapes.

The mucous membrane lining the tympanic cavity forms various mucosal folds. Both the ossicular chain and associated mucosal folds partition the middle ear. Separation of mesotympanic and epitympanic regions is by the

1. Tensor fold
2. Interosseous fold and
3. Medial incudal fold leaving the isthmus tympani anticus and isthmus tympani posticus as the only remaining openings.

Other mucosal folds are

4. Obturatoria stapedis
5. Plica stapedis
6. Superior incudal fold
7. Anterior malleal fold
8. Superior malleal fold
9. Incisura tensoris
10. Anterior malleal ligament
11. Superior malleal ligament
12. Posterior incudal ligament.

PRUSSAK'S SPACE:

It is bounded laterally by pars flaccida, medially by neck of Malleus, inferiorly by lateral process of malleus and superiorly by lateral malleolar fold

POSTERIOR POUCH OF VON TROELTSCH:

It lies in between the tympanic membrane and the posterior malleolar fold.

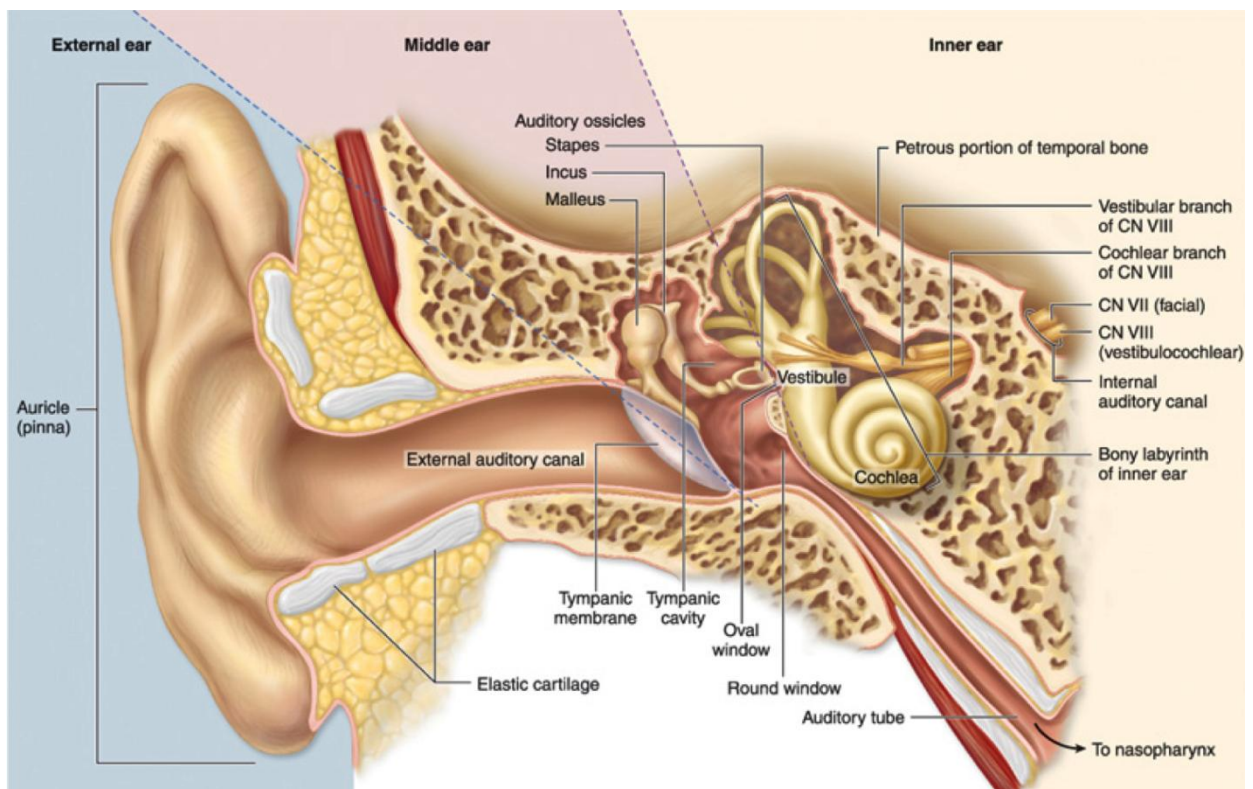
ANTERIOR POUCH OF VON TROELTSCH:

It lies in between the tympanic membrane and the anterior malleolar fold.

MECHANISM OF HEARING IN HUMAN BEINGS

The sound waves travel from environment to ear through

Pinna - External canal - Tympanic membrane – Ossicles - Oval window into Cochlea and then to Auditory nerve.



Pinna:

It protects the entrance to the ear canal. It contributes to our ability to locate sounds, esp. at higher frequencies

External auditory meatus:

It is the pathway for the auditory signal and it protects inner ear from

direct impact of sound. It also acts as a tube resonator favoring transmission of high- frequency sounds (2000-4000 Hz) and generally between 500- 4000Hz.

Tympanic membrane :

It is deflected by air pressure variations caused by sound. The air pressure variations are transmitted to the auditory ossicles and are converted into mechanical movement.

Auditory ossicles: Malleus, incus, stapes

They pick up the mechanical movement of the eardrum and convey it to the inner ear through oval window. They transform air pressure variation into equivalent mechanical movements. The contraction between incus and stapes can reduce amplitude of sound thereby protecting inner ear.

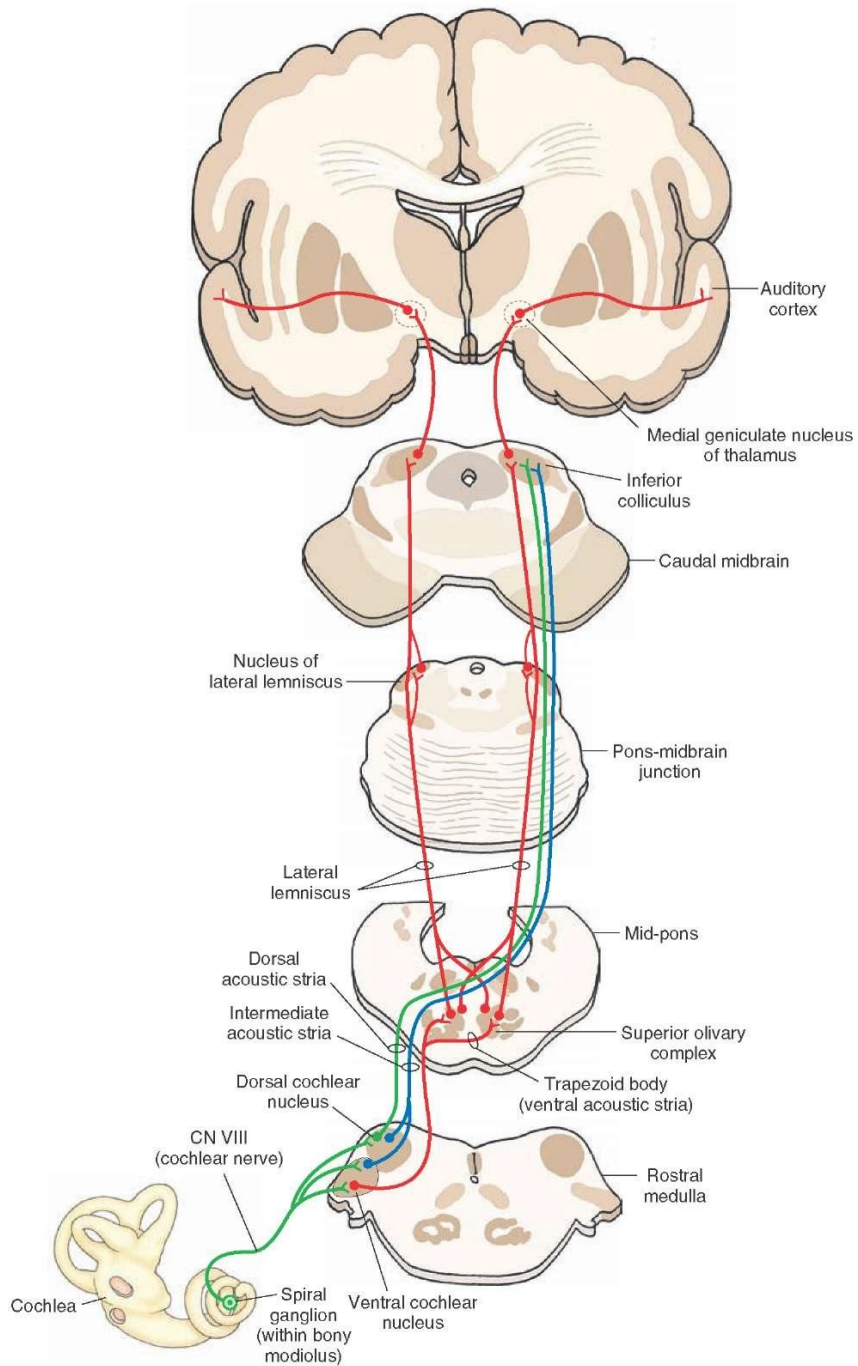
Oval window:

It acts as an interface between middle and inner ear transmitting mechanical movement into the cochlea.

Eustachian tube :

It equalizes air pressure differences between outer environment and middle ear.

Any pathology affecting structures from pinna to oval window will cause
 conductive hearing loss. From cochlea the sound pathway is as follows.



Any pathology affecting pathway from cochlea to auditory cortex will cause
 Sensorineural hearing loss.

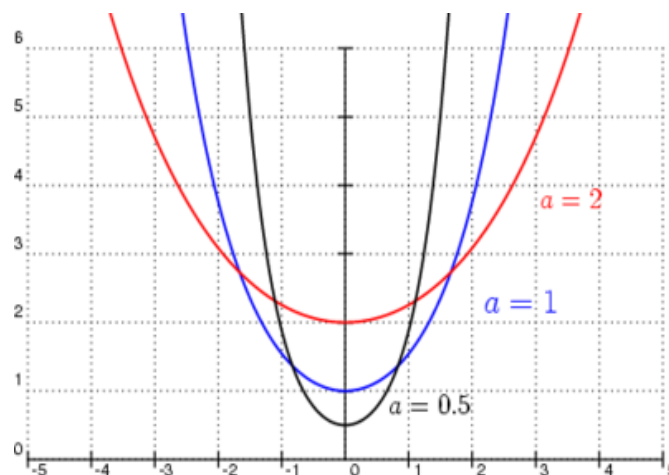
ESSENTIAL OF MIDDLE EAR OSSICLES FOR HEARING

The human middle ear transforms the low impedance sound energy in the external auditory canal through the tympanic membrane and ossicles to a high impedance of perilymph inside oval window.

The sound transmitting mechanism of middle ear is classified as three systems.

1. Catenary lever – by tympanic membrane
2. Ossicular lever – by auditory ossicles
3. Hydraulic lever – by the difference between tympanic membrane and the stapes foot plate

CATENARY LEVER



The tympanic membrane is rigidly attached to annulus. This cause increase in energy at handle of Malleus because of the middle fibrous layer of

tympanic membrane. Since the annulus is fixed the sound energy runs from periphery to centre and thereby handle of Malleus perceives the sound.

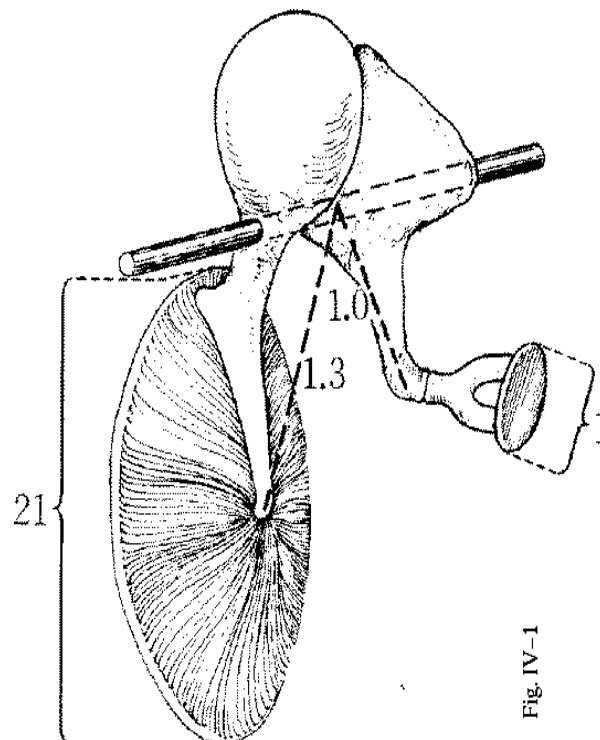
OSSICULAR LEVER

The Malleus incus assembly moves together thereby causing a gain of 1.3:1 because of difference in length of manubrium of Malleus and long process of incus. Both levers, Ossicular and catenary gives a ratio of 1:2.3

HYDRAULIC LEVER

The sound conducted from a large tympanic membrane to small foot plate gives a increase force at the level of foot plate. The total ratio is 20.8:1.

Ossicular, catenary and hydraulic lever gives a sound gain of 34 decibels.



OSSICULAR COUPLING

It is the real gain in pressure of sound while sound travels from tympanic membrane through the ossicles. It depends on frequency and not 34decibels always. It is 20 decibels in 250 to 500hz and 25 decibels in 1000hz then decreases to 6decibels for every octave thereafter. This is because in higher frequencies the tympanic membrane vibrates at different portions.

Also the Ossicular chain slips at higher frequencies.

Acoustic coupling

The sound conducted hits oval and round window and normally there is nothing much appreciated. In case of operated ears the difference may be significant enough to cause hearing loss.

Stapes cochlear input impedance

This indicates the factors causing impairment of movement of foot plate of stapes into oval window thereby increasing the impedance and hearing loss.

Middle Ear Aeration

Middle ear should contain air normally. If there is inadequate air or air is replaced by liquid or soft tissue then it impairs conduction of sound definitely.

OSSICULAR PATHOLOGY AND RECONSTRUCTION

CAUSES FOR OSSICULAR PATHOLOGY

Ossicles may be either fixed or in discontinuity.

The causes of Ossicular fixation is

1. Malleus head ankylosis. The reason for ankylosis is idiopathic.
2. Ossicular tympanosclerosis secondary to healing following perforations
3. Scar bands following chronic otitis media.

The causes for Ossicular discontinuity is

1. Trauma
2. Erosion by chronic otitis media and cholesteatoma

The most common ossicles eroded in order of frequency are

1. eroded incudostapedial joint. Lenticular process of incus is commonly eroded.
2. absent incus
3. absent incus and stapes superstructure
4. erosion of head of Malleus
5. handle of Malleus is the least common part to erode following cholesteatoma.

Mechanism of Ossicular erosion

The proposed mechanism for erosion is chronic middle ear inflammation following increased production of cytokines—TNF alpha, interleukin-2, fibroblast growth factor, and platelet derived growth factor. They all produce hypervascularisation, osteoclast activation and bone resorption which leads to ossicular damage. TNF-alpha also produces neovascularisation and hence granulation tissue formation.

METHODS FOR ASSESSING OSSICULAR PATHOLOGY

Clinical examination includes otoscopic examination or under microscope

- Looking for any congenital abnormality and examining external auditory canal
- Status of the tympanic membrane and middle ear if seen

CT scan of temporal bone will give the following information

- Extent of middle ear pathology (cholesteatoma)
- Tympanic cavity, Ossicular chain status, Malleus fixity, Otosclerosis
- Inner ear anatomy

Ossicular discontinuity is suspected when the patient has conductive hearing loss more than 50dB in Pure Tone Audiogram .

Ugo Fisch classification of Ossicular defects with hearing outcomes.

ABG	Pre op status of ossicles and mastoid
<10 db	Malleus: Handle intact Incus: Absent Stapes: Intact
<20 dB	Malleus: Handle intact Incus: Absent Stapes: Fixed /no superstructure
<30 dB	Open/closed cavity mastoidectomy Malleus: Absent Incus: Absent Stapes: Mobile/fixed/mobile footplate

Austin classification of types of condition regarding Ossicular status.

1. Perforation of tympanic membrane with intact ossicles
2. Perforation of tympanic membrane with Ossicular discontinuity
3. Complete erosion of the tympanic membrane and ossicles
4. Normal tympanic membrane with Ossicular discontinuity .
5. Congenital Ossicular defects

MATERIALS USED OF OSSICULOPLASTY

The idea of connecting tympanic membrane with oval window by reconstruction started in 1901. The materials used for ossiculoplasty are biological or alloplastic in nature.

BIOLOGICAL MATERIALS

The biological materials used in reconstruction of ossicles are autograft or homograft ossicles, bone and cartilage. Autologous cartilage was the first material used for Ossiculoplasty. Cartilage shows erosion approximately after three years. Chondromalacia may be seen in cartilage reconstructed ears due to ingrowth of blood vessels with subsequent chondritis. Hence cartilage was concluded as not ideal for long term. Autologous Ossicular graft is the gold standard of ossicular reconstruction. Its availability depends on the presence of ossicular remnants. Irradiated homograft ossicles introduced in 1960 not in use due to risk of transmission of AIDS, Cruetzfeldt-Jakob disease with prions.

ALLOPLASTIC MATERIALS

Nowadays alloplastic materials are commonly used and are classified as

- Biocompatible - Bioinert - Bioactive

Biocompatible Materials

During 1950-1960 bio compatible material such as polyethylene tubing, Teflon, and protoplast were used. The problems encountered were Migration, Extrusion, Movement into the inner ear and reactivity of tympanum.

Other biocompatible materials are silastic, stainless steel, titanium and gold.

Bioinert Materials

They are derivatives of aluminum oxide and do not produce any byproducts. Bio inert implants can be placed directly to tympanic membrane without cartilage.

Bioactive Materials

They react with the body tissue to produce soft tissue attachments with direct chemical bond to the surface of the material and not just mechanical.

The first of this type is Bioglass and Ceravita introduced in 1970. Bioglasses has been used little because of its inability when infection sets in.

Autologous ossicles

Autologous ossicles are easy to shape to the required size and shape with diamond burrs. The commonly used autograft is incus body. Advantages are low extrusion, low cost, biocompatibility, no risk of transmitting disease.

Autologous Ossicular strut maintains their contour, shape, size and physical integrity for atleast 11 years. Failure of ossicular reconstruction relate to lateralisation, bony fixation, atrophy and displacement. But subsequently they undergo new bone formation and remodeling by slow creeping and substitution of revascularised bone. But neoosteogenesis reduces sound conduction. The disadvantages with autologous ossicles are

1. Autologous ossicles are not always available in chronically infected ears
2. In cholesteatoma ossicles with microsquamous may lead to residual disease
3. Prolonged operative time to sculpt and shape
4. Resorption or loss of rigidity
5. Possible fixation to the walls of middle ear
6. Persistent osteitis in the ossicles

Titanium¹⁰

Titanium is an excellent biocompatible material, is light but strong, and allows for many different prosthetic designs. It has good long term success rates. Titanium forms a biostable titanium oxide layer when combined with oxygen. Titanium has shown significant biostability in the middle ear for the past 10 years. It has low ferromagnetism. Moreover titanium is lightweight and rigid, making it a good sound conductor.

The advantages are

1. Available pre-sculptured with every type and design
2. Surgery time is reduced
3. No disease residual or transmitted

The disadvantages of titanium is

1. Cost
2. Ossicular necrosis
3. Extrusion
4. Displacement
5. Unsatisfactory hearing restoration

PROGNOSTIC FACTORS IN OSSICULOPLASTY

Austin in 1972 defined four groups of Ossicular status

A. malleus handle present, stapes superstructure present (60%) M+ S+

B. malleus handle present, stapes superstructure absent (23%) M+ S-

C. malleus handle absent, stapes superstructure present (8%) M- S+

D. malleus handle absent, stapes superstructure absent (8%) M- S-

Kartush in 1994 described a scoring system to find the success probability

Table I. Middle ear risk index (MERI) scores [10].

Risk factor	Risk value
Otorrhoea	
I: Dry	0
II: Occasionally wet	1
III: Persistently wet	2
IV: Wet, cleft palate	3
Perforation	
Absent	0
Present	1
Cholesteatoma	
O: M+I+S+	0
A: M+S+	1
B: M+S-	2
C: M-S+	3
D: M-S-	4
E: Ossicle head fixation	2
F: Stapes fixation	3
Middle ear: granulations or effusion	
No	0
Yes	1
Previous surgery	
None	0
Staged	1
Revision	2

Dornhoffer designed the Ossicular Outcomes Parameters Staging (OOPS)

TABLE 2. *Ossiculoplasty outcome parameter staging index*

Risk factor	Risk value
Middle ear factors	
Drainage	
None	0
Present >50% of time	1
Mucosa	
Normal	0
Fibrotic	2
Ossicles	
Normal	0
Malleus +	1
Malleus –	2
Surgical factors	
Type of surgery	
No mastoidectomy	0
Canal-wall-up mastoidectomy	1
Canal-wall-down mastoidectomy	2
Revision surgery	
No	0
Yes	2

To summarise the principal determinants⁸ of the method of reconstruction and the expected hearing results are

1. Mobility of the stapes footplate
2. Integrity of the stapes superstructure
3. Presence/absence of a malleus handle

METHODS FOR OSSICULAR RECONSTRUCTION³¹

Zoellner and Horst Ludwig Wullstein, H. in the year 1956 in his publication of Theory and practice of tympanoplasty (The Laryngoscope, 66: 1076–1093) mentioned five types of tympanoplasty depending upon the ossicular status.

Type I: Tympanoplasty (or myringoplasty) when all three ossicles are normal, and should result in normal hearing.

Type II: graft (or tympanic membrane) is in contact with the incus and the stapes is present, both of which are connected and mobile, which produces a minimal hearing loss only.

Type III: graft (or tympanic membrane) is in direct contact with the suprastructure of the stapes (columella effect), causing mild hearing loss.

It is also known as myringostapediopexy.

Type IV: Ossicular chain is absent and the tympanic membrane is in contact with a mobile stapes footplate (Cavum minor) causing moderate hearing loss..

Type V: A window is surgically made in the horizontal semicircular canal causing hearing similar to a Type IV. It also known as a fenestration.

DEFINITION

Ossiculoplasty is the reconstruction of Ossicular chain which aims to surgically optimize the ear transfer mechanism so that sound energy is transmitted from the environment to the inner ear with minimal loss.

Tympanoplasty preserved the available hearing which is left over by the disease. Ossiculoplasty tries to enhance hearing by reconstructing middle ear.

Ossiculoplasty using a Partial Ossicular Reconstruction Prosthesis (PORP) is done when the stapes superstructure is intact.

Ossiculoplasty with Total Ossicular Reconstruction Prosthesis (TORP) is required when the stapes superstructure is absent and the footplate is mobile.

OPERATIVE STEPS OF OSSICULOPLASTY

OSSICULOPLASTY FOR PARTIAL OR COMPLETE ABSENCE OF INCUS

When the long process of the incus is eroded, continuity of the ossicular chain may be re-established by interposing autologous incus, head of malleus, a cortical bone chip, cartilage, or a PORP between the stapes head and malleus handle. In our study we compared only between autologous incus and PORP.

Autologous incus interposition

Autologous incus was used whenever possible as

- it does not cost anything,
- is situated in the surgical field
- has a low extrusion rate through the tympanic membrane.

But sometimes it is unusable when the incus may be absent, eroded, or covered by cholesteatoma. Other reconstructions are also indicated when the incus does not fit well e.g. when the stapes superstructure and/or the malleus handle are absent. Incus interposition is performed at the time of primary surgery. The techniques for open and closed cavities are similar.

The incus is removed by rotating it laterally with a 45° hook

A small curved clamp is used to hold and stabilise the body of the incus while shaping it with a diamond drill.

Looking through the microscope, the long process of incus drilled with a diamond drill. A notch is drilled in the body of the incus to accommodate the stapes head using 0.6mm and 0.8mm diamond burrs.

Use the largest microsuction tube to pick up the prosthesis and place it in the

middle ear, lateral to the preserved chorda tympani.

Using the 1.5mm 45° hook the incus is kept in position with the notch drilled in the body of incus over the head of stapes

PORP interposition

Titanium Prosthesis is used. The PORP is placed on the stapes head.

To prevent extrusion, a piece of cartilage is interposed between the prosthesis and tympanic membrane.

OSSICULOPLASTY WHEN ONLY STAPES IS INTACT

1. Stapes superstructure intact, mobile footplate

A PORP may be placed over the mobile stapes.

A TORP can be placed between the crura of the intact stapes; this allows for a more stable reconstruction.

They must be covered by cartilage to prevent extrusion

2. Stapes superstructure eroded, mobile footplate

A TORP may be placed onto the stapes footplate.

Techniques used to stabilise the foot of the prosthesis on the footplate include:

Perforation of the center of the footplate with a wire spike placed in the foot of

the prosthesis. Placing gelfoam at the footplate around the prosthesis

Cutting small wedges of cartilage and placing them on the footplate on either side of the prosthesis. Fisch devised a cartilage shoe with a central perforation to accommodate the shaft of the Fisch titanium total prosthesis to stabilise the prosthesis on the footplate.

Tragal or conchal cartilage is harvested and the perichondrium is removed.

A hole is made in the cartilage with a 0.6mm diamond burr.

A disc is cut around the perforation in the cartilage to the dimensions of 1.5x3mm. These dimensions are slightly larger than the oval window.

Using a microscope the final sizing is done to fit the oval window niche.

The prosthesis shaft is placed through the central perforation of the cartilage disc before placing it in the oval window niche.

Contraindications for ossiculoplasty

Acute infection of middle ear and Persistent disease because it leads to poor healing, extrusion of Prosthesis. The condition of middle ear at the time of ossiculoplasty determines the outcome. Eustachian tube function is important.

Staging of ossiculoplasty

In some cases as above it may be preferable to do ossiculoplasty as a staged procedure, not at the same time as doing a tympanoplasty or mastoidectomy.

Staging improves the outcomes of Ossicular reconstruction because of,

- Better assessment of the position of the tympanic membrane and eustachian

tube function 6-12months after primary surgery

- If mucosa around the oval window have been traumatised, there is a risk of

scarring of the oval window. If ossiculoplasty is performed in as single stage

procedure then staging allows damaged mucosa of the middle ear to first to heal

- With cholesteatoma surgery, to verify that no residual cholesteatoma is

present, the 2nd stage (ossiculoplasty) surgery is delayed for about a year after

the primary surgery .

- It may be preferable to stage ossiculoplasty if only the stapes is present in the

setting of a tympanic membrane perforation

If ossiculoplasty is staged and the middle ear mucosa has been traumatised and or if eustachian tube function is poor, then thin silastic sheeting is placed in the protympanum of the middle ear to allow the middle ear mucosa

to heal and to reduce adhesions that may form between the middle ear mucosa and the tympanic membrane.

Postoperative followup

Patients are advised to avoid increasing pressure in middle ear for first two weeks after surgery. They also advised to avoid water entering ear till external auditory canal and tympanic membrane heals.

Complications

- Prosthesis extrusion more common in 1-3 years after surgery. Extrusion rate is 5-39% in literature
- injury to semicircular canal, chorda tympani, labrynth
- persistent or new perforation
- Infection
- Tinnitus
- Rarely facial nerve paralysis

No hearing improvement after surgery is a functional complication.

Revision ossiculoplasty is considered after 1 year if there is no improvement.

REVIEW OF LITERATURE

Ossiculoplasty with autologous incus versus titanium prosthesis:

A comparison of anatomical and functional results¹¹

Amith I Naragund, R S Mudhol, A S Harugop, P H Patil

Departments of ENT and HNS, KLE University's Jawaharlal Nehru Medical

College,

Nehru Nagar, Belgaum, Karnataka, India

They evaluated a total of 24 patients with ossicular chain defect in the study, of whom 12 patients underwent ossiculoplasty with autograft incus and 12 with titanium prosthesis. Cholesteatoma was found in 18 cases during of ossiculoplasty, 4 cases were non-cholesteatomatous mucosal type of chronic otitis media and 2 cases had adhesive otitis media. The ossiculoplasty was performed during the primary operation in 21 cases and as the second-stage procedure in only 3 cases wherein titanium prosthesis was used. Canal wall down mastoidectomy with ossiculoplasty was performed in 5 cases in each group. Follow-up with postoperative audiological evaluation ranged from 3 to 12 months, with an average of 4.5 months. Average postoperative ABG closure

of less than 20 dB was considered as successful hearing gain, which was seen in 7 cases (58%) with autologous incus and 4 cases (33.3%) with titanium prosthesis.

The mean preoperative ABG values in autoincus, titanium TORP and PORP groups were 43.3 dB (SD 8.34), 44.2 dB (SD 10.17) and 42 dB (SD 5.7), respectively, whereas the postoperative ABG closure values were 24.5 (SD 9.15), 30.7 (SD 15.66) and 25 dB (SD 6.12), respectively. There was a statistically significant improvement in preoperative PTA ABG of 43.3 dB \pm 8.34 SD to mean postoperative ABG of 24.5 dB \pm 9.16 SD ($P = 0.046$) in autologous incus group.

Postoperative complications with autologous incus group were 25% as compared with titanium prosthesis in which the complication rate was 41.6%.

Hearing results after ossiculoplasty with autologous incus were significantly better as compared with those obtained after titanium prosthesis. Also, complications and extrusion rate were higher in patients with titanium prosthesis. This indicates that ossiculoplasty with autoincus offers better hearing results with minimal complications and extrusion rates as compared to titanium.

However, the results were better in both groups if canal wall was preserved or reconstructed. Complication rates were more with titanium TORP than with PORP. Further patient follow-up is required to assess the long-term outcomes of ossiculoplasty, but patient compliance for longer follow-up is a matter of concern.

They concluded that there is a need for many more clinical trials with a larger sample size and longer follow-up period to standardize the ossiculoplasty techniques and accept an ideal ossicular prosthesis.

Comparative results of type 2 ossiculoplasty: incus transposition versus titanium

PORP²⁹ ceccato SB Maunsell R MorattaGC PortmannD

They did a retrospective study of 98 patient having type 2 with the incus and 50 patients received PORP titanium. Rate of extrusion was 1% incus and 4% PORP. Postoperative air bone gap was 16.9 dB titanium group 25.5 dB in incus group. Gain was 18.7 dB in incus and 4.3 dB in titanium. They concluded that titanium is well tolerated and material of choice when incus is not usable.

Ossicular reconstruction: incus versus universal titanium prosthesis

Woods O, Fata FE, Saliba I.³⁰ Montreal, Quebec, Canada.

They compared audiological outcomes of incus reconstruction, titanium partial ossicular replacement prosthesis (PORP) and total ossicular replacement prosthesis (TORP) and results based on surgical technique, history of previous surgery, form of the prosthesis head, pathology and frequency. Postoperative mean air-bone gap and mean pure tone average are significantly lower using incus reconstruction compared with the titanium prosthesis groups. PORP and TORP groups yielded similar outcomes. Closure of ABG is similar in all three groups. Postoperative results were better using an intact canal wall mastoidectomy compared with a canal wall down technique, but ABG closure similar in both groups. Primary surgeries gave better results than revisions of reconstructions performed by the senior author or elsewhere. They concluded that though titanium prostheses are effective in ossicular reconstruction, incus reconstruction is at least as effective when feasible. Canal wall down mastoidectomy should be reserved for cases where preservation of the canal wall is contraindicated.

OTHER IMPORTANT STUDIES

Pasha¹³ in the year 2000 studied 33 consecutive cases of ossiculoplasty with Hydroxyl apatite PORP, TORP, or Kartush incus strut. Hearing results, based on postoperative mean ABG were studied. The best results were obtained when incus struts were used. Patients receiving incus struts had lower MERI scores in general, and, of course, had malleus handle present. 3 PORPs extruded; no incus struts or TORPs extruded. Cartilage caps were not placed over the prostheses. A weakness of the study is that hearing results are not reported as percentage of patients closing ABG to within 20 dB. This study supports the use of the Kartush incus strut when both the handle of the malleus and the stapes superstructure are preserved

House¹⁴ in the year 2001 reported on a retrospective chart review of 1210 consecutive ossicular reconstructions with HydroxylApatite and Plastipore TORPs (n = 560) or PORPs (n = 650). Closure of the ABG to within 20 dB was 63% (68% of PORPs, 58% of TORPs). Hearing results were better for cases who had not had previous surgery, in those with a diagnosis other than chronic otitis media, when a cartilage graft was used, and for Plasti-Pore rather than

hydroxylapatite. Overall extrusion was 4%, with no difference between HA and Plastipore, but statistically lower when cartilage cap was used. House's study refutes claims that the stapes superstructure is unimportant to hearing results. It also reinforces the importance of placing a cartilage cap between the prosthesis head and the tympanic membrane.

Iurato¹⁵ in the year 2001 reviewed the literature at length to investigate hearing results from ossicular reconstruction in Austin-Kartush type A patients. At 12 months minimum follow-up, success was shown to be 84% vs 82% for incus interposition vs allograft (ceramics or HA) PORP. He also demonstrated that, on his own series of patients, success rate of homograft ossiculoplasty was 85% and hearing was stable over 3 years post-op. Of note, Iurato reported no extrusions or displacements of his autografts.

Ho¹⁶ in the year 2003 reported on retrospective chart reviews on patients who had undergone ossiculoplasty using titanium middle ear implants. 64% and 45% of patients achieved air-bone gap less than 20 dB with PORP and TORP respectively. With the placement of cartilage graft interposed between the prosthesis and the tympanic membrane, no extrusions were observed.

Neff¹⁷ in the year 2003 studied 18 patients who underwent tympano-ossiculoplasty with a titanium TORP. Hearing results showed 89% surgical success. The average follow-up time was 8 months (range, 2-21 months). The results compare favorably with his own results using a porous polyethylene TORP in which 67% had success. No extrusions were seen in their short follow up time.

Rondini-Gilli¹⁸ in the year 2003 reported on 100 patients who received a HydroxylApatite PORP (n=65) or TORP (n=35). Extrusion or displacement of the implants occurred in 10% of cases. These displacements were more common when no cartilage cap was placed. The results were not reported as successful closure less than 20 dB ABG. In addition to an absent stapedial arch with type 3 tympanoplasty, a radical mastoidectomy and a previous tympanoplasty were related to poorer auditory results.

Hillman¹⁹ in the year 2003 published a retrospective study. Review of 84 patients undergoing tympanoplasty with the Plastipore prosthesis and 53 with titanium. There was 1 extrusion in the titanium group. There was an additional single incidence of prosthesis failure in the titanium group. 60% of patients had

postoperative air-bone gap of 20 dB or less in the Plastipore group. In the titanium group, 45.3% achieved a 20 dB or less air-bone gap.

Gardner²⁰ in the year 2004 published a retrospective chart review comparing titanium reconstructions to non-titanium reconstructions. Successful rehabilitation of conductive hearing loss was obtained in 70% of PORPs and 44% of TORPs when titanium prostheses were used. Comparison data revealed successful rehabilitation in 48% and 21% of non-titanium-based partial and total reconstructions, respectively.

Martin²¹ in the year 2004 reported on a retrospective chart review of 68 ossicular procedures using a titanium TORP (n = 30) or PORP (n = 38). He obtained closure of the ABG to within 20 dB in 57% of cases. Hearing results were better for primary versus revision cases for PORPs versus TORPs and for intact canal wall (ICW) procedures versus canal wall-down (CWD) procedures. Extrusion rate was 1.5%.

O'Reilly²² in the year 2005 published a retrospective review of 137 patients (Austin-Kartush group A) demonstrating the effectiveness of incus interposition. 66.4% of patients had successful closure of the air-bone gap to

within 20 dB. (mean 15.8 months post-op). There was no statistical correlation between MERI score and surgical success.

Schmerber²³ in the year 2006 reported on a retrospective chart review of 111 patients implanted with either a titanium PORP or TORP. Success was obtained in the PORP group in 77% of the cases, versus 52% of the cases in the TORP group. 2 extrusions (1.8%) of the prostheses were observed at 17 and 20 months after surgery. Revision procedures for functional failure were carried out in 20 patients (18%). The major factors influencing good audiometric results were surgical procedures preserving the external auditory canal and the presence of the stapes.

Vassbotn²⁴ in the year 2007 published a retrospective study of procedures involving 73 titanium prostheses (38 PORPs and 35 TORPs). Mean follow-up was 14 months. Success was obtained in 77% of the patients, 89% for the Bell (PORP) prosthesis, and 63% for the Arial (TORP) prosthesis. The overall extrusion rate was 5%. The combination of CWD and TORP gave significant inferior hearing thresholds as compared to TORP/CWU and PORP/CWD combinations.

Siddiq²⁵ in the year 2007 prospectively assessed the early results of titanium partial and total ossicular replacement prostheses in chronic ear disease. 33 consecutive patients (20 PORPs and 13 TORPs) were analyzed. PORP (85%) had a higher success rate than TORP (46%).

De Vos²⁶ in the year 2007 reported on 149 ears all implanted with titanium PORPs and TORPs. Success rate was 60% with no difference between PORP and TORP. Prosthesis extrusions occurred in 3.5% of patients and displacement of the prosthesis occurred in 4.3%.

Emir²⁷ in the year 2008) reviewed 304 patients who underwent ossiculoplasty with intact canal wall. Autologous incus interposition resulted in 58% success rate, whereas plastipore PORPs resulted in 56% success rate. 9.3% of implants extruded.

Coffey²⁸ in the year 2008 reviewed 105 cases, including 80 performed with titanium and 25 with nontitanium implants. Success was achieved in 50.0% of nontitanium cases and 77.1% of titanium cases. Extrusion was observed with two nontitanium prostheses (8.0%) and three titanium prostheses (3.8%).

AIMS OF OUR STUDY

To compare the efficacy of autologous Ossicular graft versus titanium prosthesis (TORP total Ossicular replacement prosthesis and PORP partial Ossicular replacement prosthesis) in terms of

1. Operative course
2. Post operative sequelae
3. Complications
4. Anatomical results
5. Functional results

MATERIALS & METHODS

The study population consisted of patients who attended the ENT outpatient department at Govt. Kilpauk medical college hospital and Govt. Royapettah hospital, Chennai.

Study place

Kilpauk medical college, Chennai

Study design

Prospective cohort study of patients undergoing ossiculoplasty in our hospital.

Study period

December 2012 to December 2013

Financial support

Self

Inclusion criteria

1. 12-60 years of age group
2. Patients suffering from chronic otitis media with Ossicular erosion
3. Patients with Ossicular discontinuity following trauma

Exclusion criteria

1. Age below 12 years
2. Patients with Eustachian tube dysfunction like cleft palate
3. Patients with Sensorineural and mixed hearing loss
4. Patient medically unfit
5. Coexisting preoperative facial nerve palsy and labrynthitis.
6. Adhesive otitis media
7. Patients with active discharge inspite of culture specific antibiotics
8. Disease over foot plate of stapes not able to remove completely.

PATIENT HISTORY

Patients suffering from chronic otitis media with Ossicular erosion and Patients with Ossicular discontinuity following trauma were selected from outpatient of ENT department at Govt. Kilpauk medical college hospital and Govt. Royapettah hospital, Chennai.

Patients were subjected to routine medical investigations such as Complete blood count, Blood sugar, serum creatinine, electrocardiogram, X ray chest Posteroanterior view

Visual analogue scale is used to analyse the symptom severity

1. Ear discharge
2. Hard of hearing
3. Ear pain
4. Giddiness
5. Tinnitus

1. Ear discharge gives an idea of middle ear status.

If continuous, scanty, purulent, foul smelling, it indicates cholesteatoma.

If intermittent, profuse, mucoid discharge it indicates tubotympanic.

Duration of discharge and period of dryness indicates whether disease is

- Active,
- Quiescent (dry for less than 3 months), or
- Inactive (dry for more than three months).

2. Hard of hearing for whisper, conversation, loud sounds indicate the degree of hearing impairment.

3. Ear pain indicates active inflammation, intracranial complication or otitis externa.

4. Giddiness indicates vestibular involvement of disease

5. Tinnitus indicates Cochlear pathology.

Preoperatively patients underwent pure tone audiogram.

Pure tone audiogram gives quantitative and qualitative analysis of hearing.

The degree of hearing loss is assessed by taking pure tone average of

hearing intensities in decibels at frequencies of 500, 1000, and 2000 hertz since

they are the speech frequencies essential for day to day activities. .

The degree is quantified as

Very mild = 15 – 25 dB

Mild = 25-40 dB

Moderate = 41-55 dB

Moderately severe = 56-70 dB

Severe = 71-90 dB

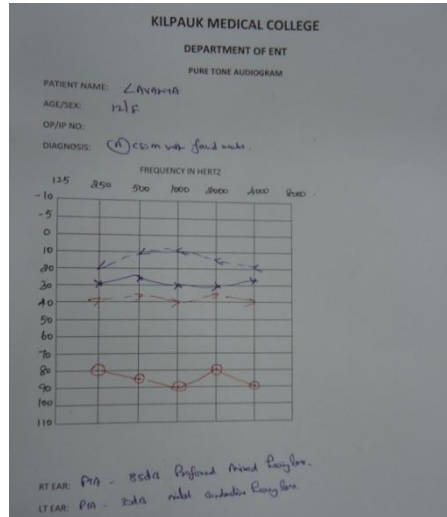
Profound = > 91 dB

The type of hearing loss is classified as

1. Conductive hearing loss when bone conduction is normal and

threshold for air conduction is increased.

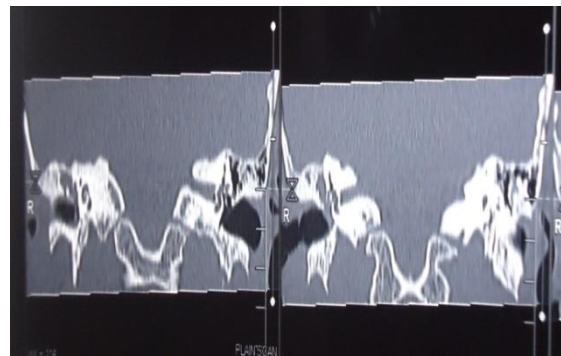
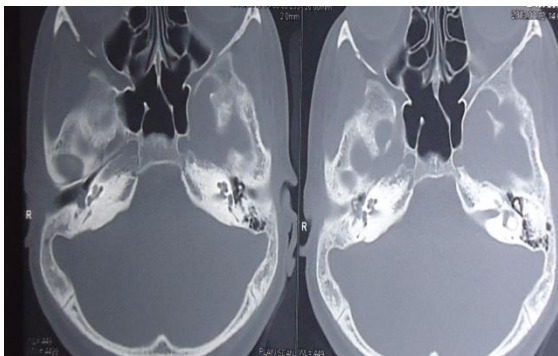
2. Sensorineural hearing loss when threshold for both bone conduction and air conduction is increased.



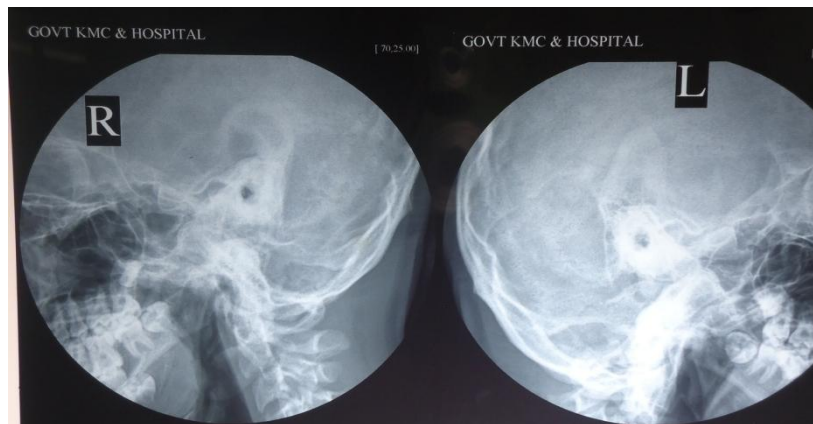
3. Mixed hearing loss when threshold for both bone conduction and air conduction is increased but with significant difference air-bone gap

Computed tomography was done in most of the case to assess the

- extent of middle ear pathology (cholesteatoma)
- Ossicular chain abnormalities
- inner ear anatomy.



Xray mastoid lateral oblique view done routinely before surgery.

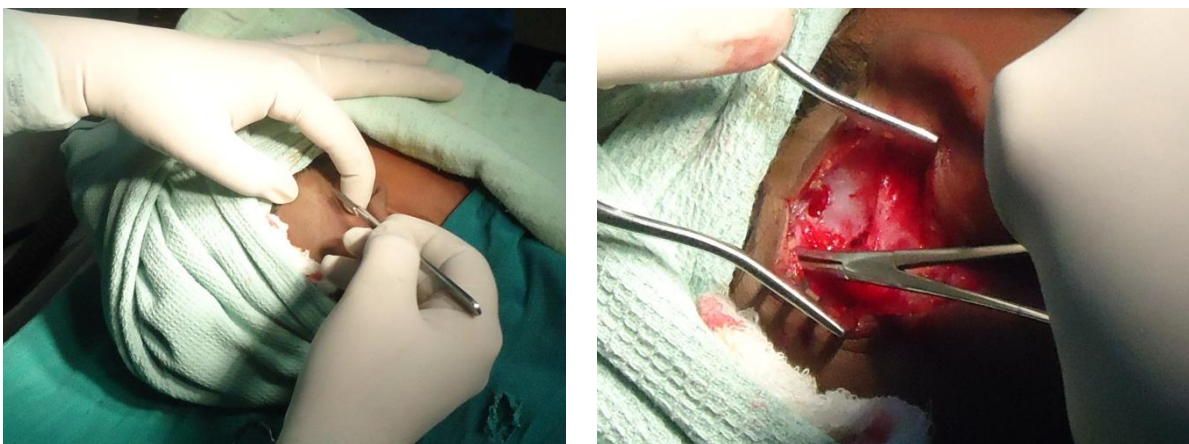


Impedance audiometry was done in selected cases with intact tympanic membrane. Type Ad curve indicates Ossicular discontinuity.

PROCEDURE ADOPTED

After these investigations all patients were operated under general anesthesia after getting informed consent for participating in our study.

MASTOIDECTOMY

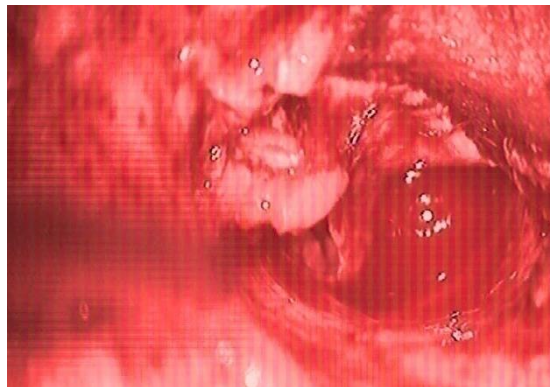


Using post aural incision Temporalis fascia graft harvested.

A T-shaped incision is made through the soft tissues and periosteum elevated.



The meatal skin is now incised about 5 to 6 mm from the edge of the tympanic membrane. Tympanomeatal flap elevated.



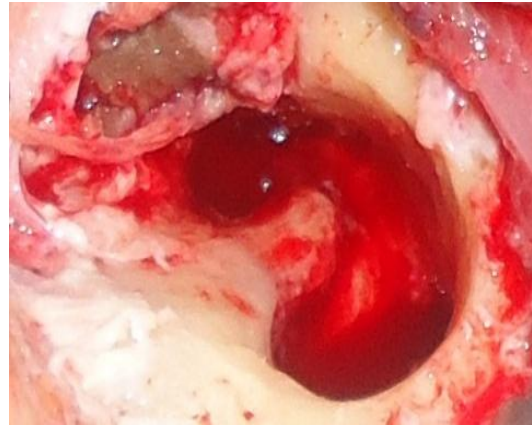
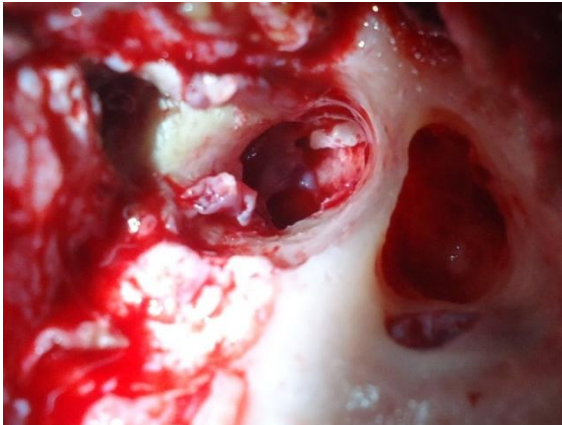
Ossicular chain status is noted. The mastoid is opened through McEwans triangle with a drill. Mastoid antrum is usually located at a distance of

1 to 1.5 cm from the surface of the mastoid cortex. The following analysed.

1. Extent of disease determining canal wall up or canal wall down technique
2. Availability of disease free ossicles according to Austin classification

M = Malleus, I = Incus, S = stapes, + = present, - = absent, p = partially eroded

Canal wall up preserves posterior canal wall



Canal wall down procedure involves removal of posterior canal wall by removal of bridge, reducing anterior and posterior buttress, reducing down the facial ridge, removal of contents of epitympanum thereby making middle ear and mastoid into a single cavity.

The ossiculoplasty is deferred or staged after the primary surgery if,

1. The disease clearance is inadequate especially remnant disease over foot plate
2. The patient has sensorineural or mixed hearing loss
3. The middle ear has extensive granulations or active discharge

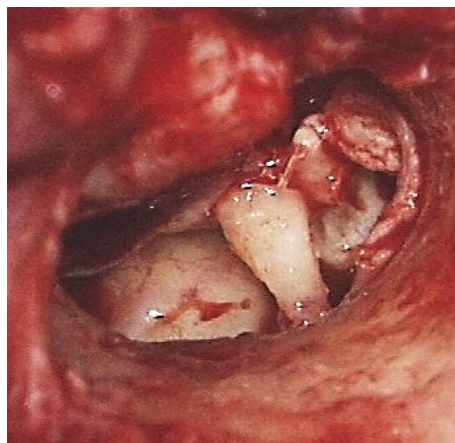
After disease clearance is confirmed then the ossiculoplasty is decided to be done in the primary setting itself.

Autologous Ossicular graft

Autologous incus if available is the first choice always.

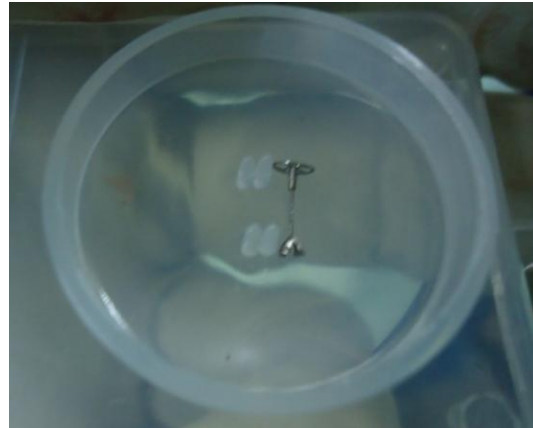
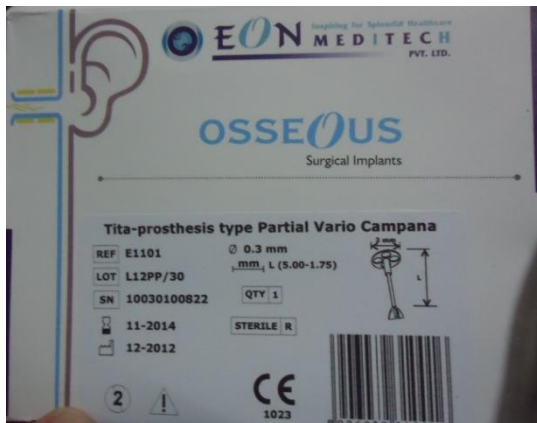


The height of incus is assessed if it is adequate from the foot plate or suprastructure to the tympanic membrane. The incus is reshaped with ossicles holding forceps with diamond burr with a facet for suprastructure of stapes or flattened edge for footplate of stapes and tympanic membrane or graft placed.



The time taken for ossiculoplasty is noted and recorded.

Titanium Prosthesis



If incus is not available or height of incus is inadequate then a titanium prosthesis (TORP or PORP) total or partial ossicular reconstructing prosthesis depending the presence or absence of suprastructure of stapes.

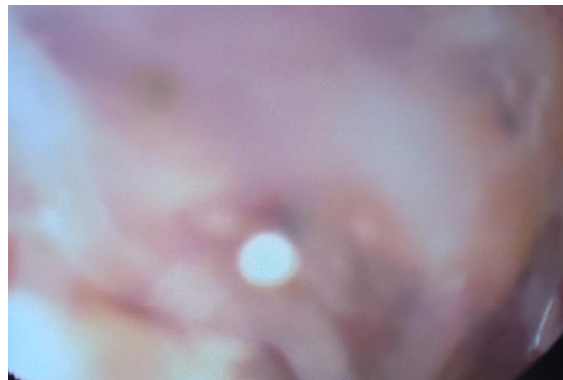


The prosthesis is measured for distance between tympanic membrane and footplate or suprastructure of stapes. The ossiculoplasty is done with a cartilage cap over the prosthesis as interface between prosthesis and tympanic membrane.

In intact canal wall mastoidectomies tragal cartilage was harvested and in canalwall down mastoidectomies conchal cartilage removed during meatoplasty was used. The duration taken for Ossicular reconstruction was noted.

POSTOPERATIVE PERIOD & FOLLOWUP

All the patients were started on Intravenous Cefatoxime antibiotic along with tablet diclofenac and tablet ranitidine and vitamin supplements in the postoperative period. All patients stayed inpatient till suture removal on 8th postoperative day. External auditory canal medicated pack was removed on 8th postoperative day. All patients were started on Neomycin hydrocortisone ear drops three drops two times a day after discharge on the 8th postoperative day. Patient was followed up with otoscopic examination every week for first one month and monthly for next 3 months. Pure tone audiogram done at 3 months.



TITANIUM PORP 3 MONTHS POST OP PICTURE

PATIENTS UNDERGONE OSSICULOPLASTY (n=21)

Among 21 patients who underwent ossiculoplasty the following observations were made.

10 patients with incus transposition and 11 patients with titanium.

Among titanium

7 patients with TORP total Ossicular replacement prosthesis.

4 patients with PORP partial Ossicular replacement prosthesis.

During the intra operative period the time taken for ossiculoplasty for both incus and titanium prosthesis were almost the same and had variations according to individual cases.

Incus had to be reshaped, made sure it is disease free, and of adequate length to fit in. Similarly titanium prosthesis which we used in all cases has also to be altered in length and cartilage has to be harvested separately if not while meatoplasty and the time taken is considerable.

In the postoperative period minor complaints such as cavity problems, otomycosis, within the three month period was equal in both cases and was independent of type of Ossicular reconstruction done.

Other complications such as Facial palsy, Graft extrusion with residual perforation, Severe sensory neural hearing loss, Perilymph fistula and atelectasis noted in other studies were nil in our series.

All patients were on ear drops continuously during the three month period. Initially with neomycin hydrocortisone ear drops, if refractory 1% acetic acid (diluted vinegar) was used which almost gave a dry ear in the postoperative period at three months in all cases.

In the three month period there were no signs of extrusion in all cases. May be a longer follow up period or a challenge of ear discharge without the prescribed ear drops coverage must be needed to declare that there is no extrusion in all the cases.

There was no giddiness or tinnitus in all cases. This may be due to the case selection with appropriate indications in the cases selected for the study group as excluded in the previous section.

Our case series is not big enough and the period of study is one year and data after three month period follow up is not included in the study which may be suggested as pitfalls in our study.

RESULTS

The results were analysed by following up the patients post operatively every week for first one month and then every month for next two months.

1. Written consent obtained and privacy maintained
2. Interview with Questionnaire done
3. Thorough examination and necessary investigation done.
4. Intra operative findings recorded
5. Postoperative findings recorded
6. Whole data compiled. Statistical analysis was done using statistical software.

The results obtained are,

(If P-Value <0.05 then statistically significant)

The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results reveal that all the variable follows Normal distribution. Therefore to analyse the data Parametric methods are applied. To compare the mean values between two groups independent samples t-test is applied. To compare proportions between groups Chi-Square test is applied, if the expected cell frequency is less than 5

then Fisher's exact test is used. To compare the mean values between groups one way ANOVA is applied followed by Tukey's HSD post hoc tests for multiple pairwise comparisons. SPSS version 20.0 is used to analyse the data.

Independent samples T-Test to compare the mean values between groups.

Variables	Group	N	Mean	Std. Dev	P-Value
Age	Incus	10	33.60	12.349	0.038
	TORP/PORP	11	22.73	9.951	
Pre op PTA	Incus	10	54.20	13.139	0.337
	TORP/PORP	11	59.00	8.989	
Post op PTA	Incus	10	43.50	7.934	0.483
	TORP/PORP	10	41.40	4.789	
Hearing gain	Incus	10	10.70	15.478	0.403
	TORP/PORP	10	16.00	11.981	
Percentage change	Incus	10	15.11	26.79	0.303
	TORP/PORP	10	26.02	18.41	

Oneway ANOVA to compare the mean values between procedures

Descriptive statistics

Variable	Procedure	N	Mean	Std. Dev	Min	Max	P-Value
Pre op PTA	CWD	13	56.54	10.936	36	72	0.949
	Intact canal wall	5	58.00	14.832	40	75	
	Tympanoplasty	3	55.33	8.737	48	65	
	Total	21	56.71	11.141	36	75	
Post op PTA	CWD	12	45.67	5.228	36	56	0.002
	Intact canal wall	5	35.00	3.000	32	38	
	Tympanoplasty	3	42.00	5.292	38	48	
	Total	20	42.45	6.468	32	56	
Hearing gain	CWD	12	9.33	12.309	-12	26	0.178
	Intact canal wall	5	23.00	15.379	2	40	
	Tympanoplasty	3	13.33	12.583	0	25	
	Total	20	13.35	13.743	-12	40	
Percentage change	CWD	12	13.754	23.3684	-33.33	40.00	0.200
	Intact canal wall	5	35.9060	19.75331	5.00	53.33	
	Tympanoplasty	3	22.2545	19.93115	.00	38.46	
	Total	20	20.5673	23.06069	-33.33	53.33	

ANOVA Tables

Variables	Sum of Squares		df	Mean Square	F-Value	P-Value
Pre op PTA	Between Groups	14.388	2	7.194	0.052	0.949
	Within Groups	2467.897	18	137.105		
	Total	2482.286	20			
Post op PTA	Between Groups	402.283	2	201.142	8.708	0.002
	Within Groups	392.667	17	23.098		
	Total	794.950	19			
Hearing gain	Between Groups	659.217	2	329.608	1.913	0.178
	Within Groups	2929.333	17	172.314		
	Total	3588.550	19			
Percentage change	Between Groups	1741.910	2	870.955	1.771	0.200
	Within Groups	8362.202	17	491.894		
	Total	10104.113	19			

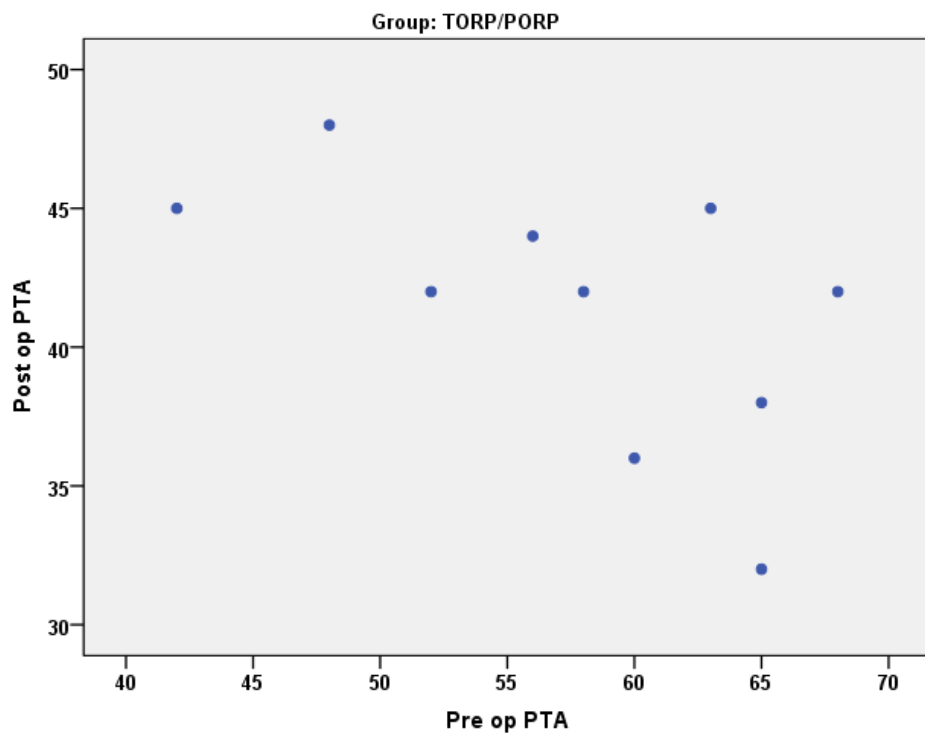
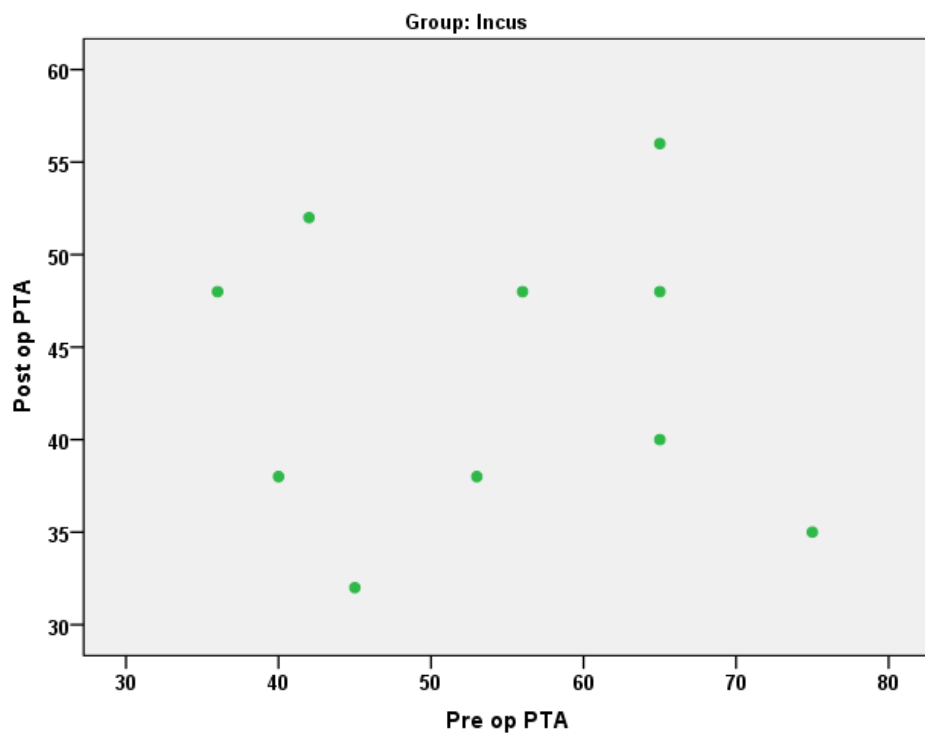
Tukey HSD Post Hoc Test for Multiple Comparisons

Dependent Variable	Procedure done		Mean Difference	P-Value
Post op PTA	CWD	Intact canal wall	10.667	0.002
		Tympanoplasty	3.667	0.479
	Intact canal wall	Tympanoplasty	-7.000	0.144

Paired T-Test to compare the pre and post treatment mean values

Group	Pair	Variable	N	Mean	Std. Dev	P-Value
Incus	Pair 1	Pre op PTA	10	54.20	13.139	0.057
		Post op PTA	10	43.50	7.934	
TORP/PO RP	Pair 1	Pre op PTA	10	57.70	8.314	0.002
		Post op PTA	10	41.40	4.789	

Scatter plot for pre and post values



Chi-Square test to compare the proportions between groups

Age group (yrs)	Group				Total	
	Incus		TORP/PORP		N	%
	N	%	N	%		
<= 20 yrs	2	20.0	6	54.5	8	38.1
21 - 30 yrs	2	20.0	3	27.3	5	23.8
31 - 40 yrs	3	30.0	1	9.1	4	19.0
> 40 yrs	3	30.0	1	9.1	4	19.0
Total	10	100.0	11	100.0	21	100.0

Chi-Square Test	Value
Fisher's Exact Test	0.301

Gender	Group				Total	
	Incus		TORP/PORP		N	%
	N	%	N	%		
Male	5	50.0	7	63.6	12	57.1
Female	5	50.0	4	36.4	9	42.9
Total	10	100.0	11	100.0	21	100.0

Chi-Square Test	Value
Fisher's Exact Test	0.670

MALLEUS	Group				Total	
	Incus		TORP/PORP		N	%
	N	%	N	%		
Present	8	80.0	2	18.2	10	47.6
Partial erosion	1	10.0	4	36.4	5	23.8
Absent	1	10.0	5	45.5	6	28.6
Total	10	100.0	11	100.0	21	100.0

Chi-Square Test	Value
Fisher's Exact Test	0.026

INCUS	Group				Total	
	Incus		TORP/PORP		N	%
	N	%	N	%		
Partial erosion	10	100.0	1	9.1	11	52.4
Absent	0	.0	10	90.9	10	47.6
Total	10	100.0	11	100.0	21	100.0

Chi-Square Test	Value
Fisher's Exact Test	<0001.

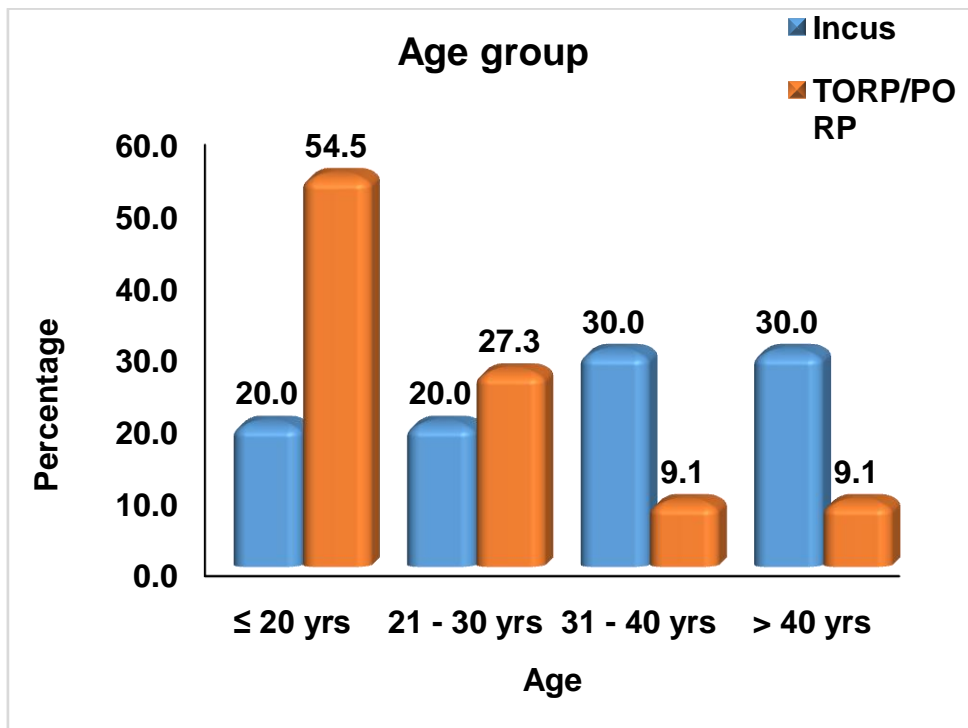
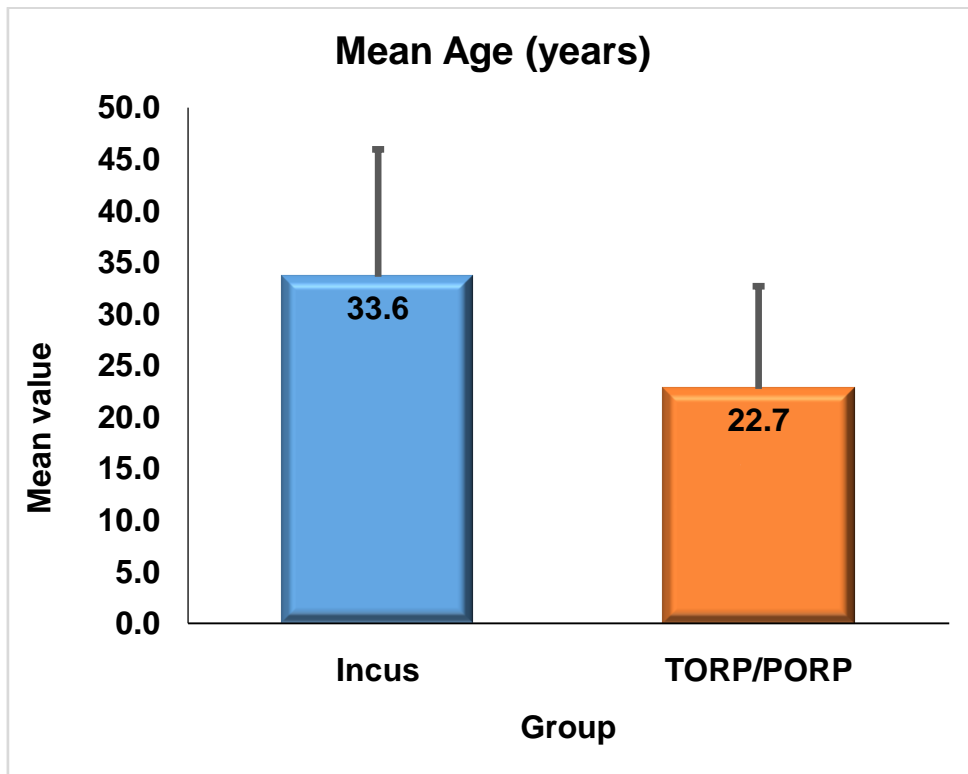
STAPES	Group				Total	
	Incus		TORP/PORP		N	%
	N	%	N	%		
Present	4	40.0	2	18.2	6	28.6
Absent	6	60.0	9	81.8	15	71.4
Total	10	100.0	11	100.0	21	100.0

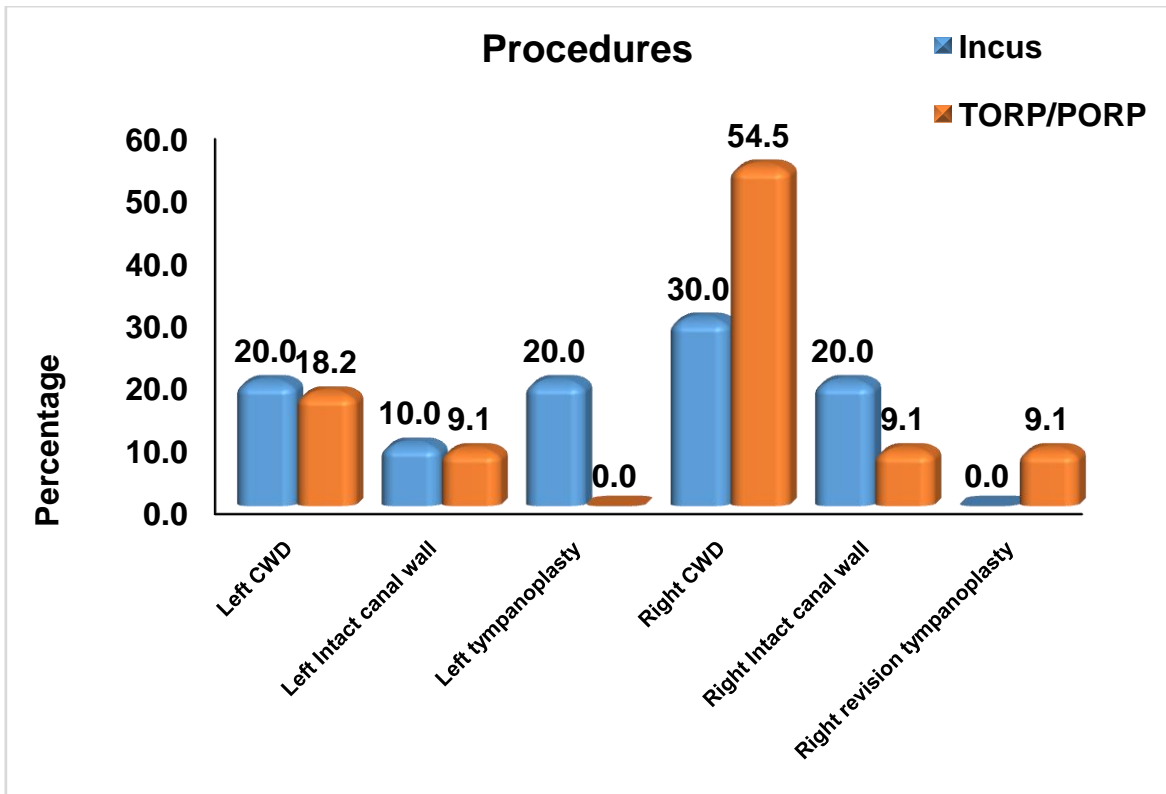
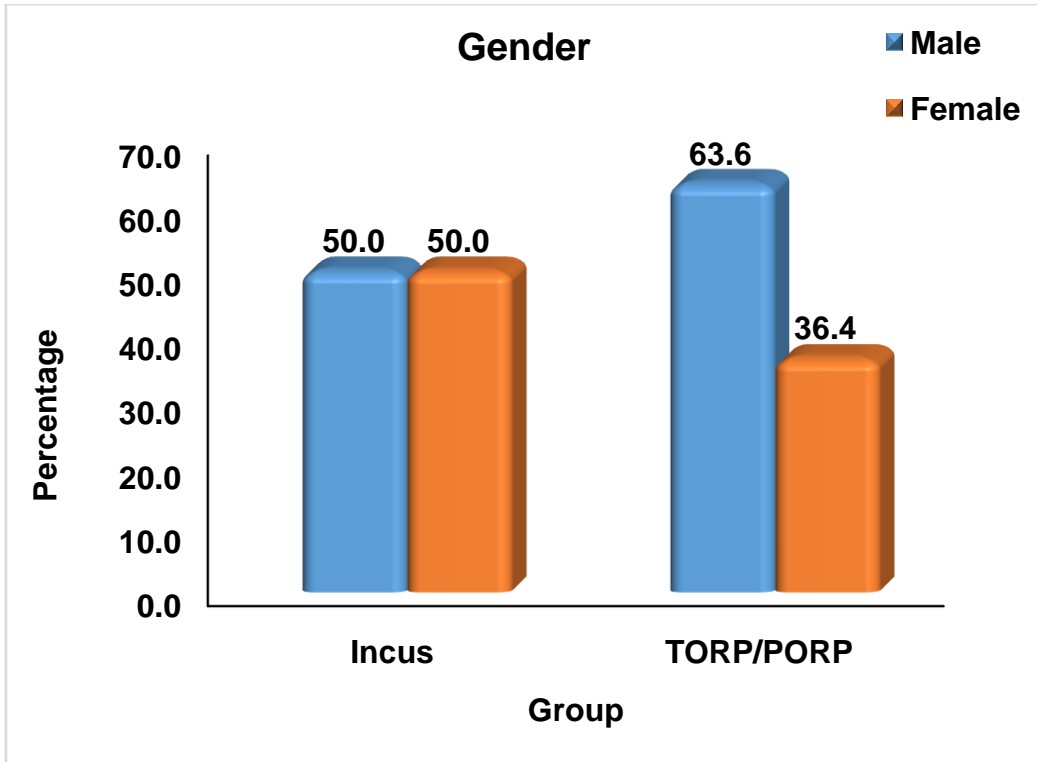
Chi-Square Test	Value
Fisher's Exact Test	0.361

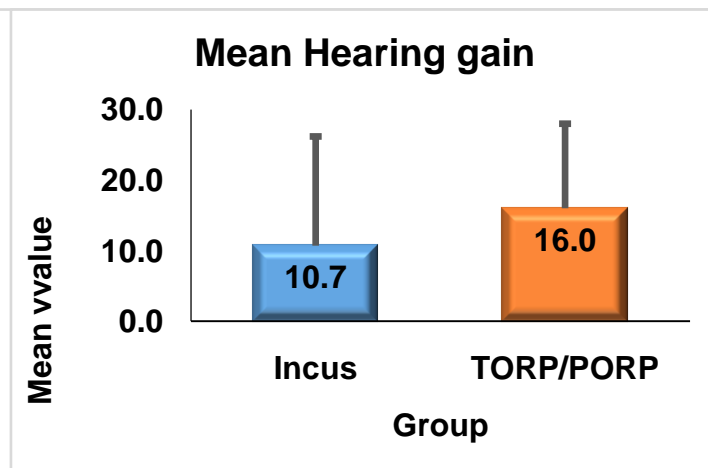
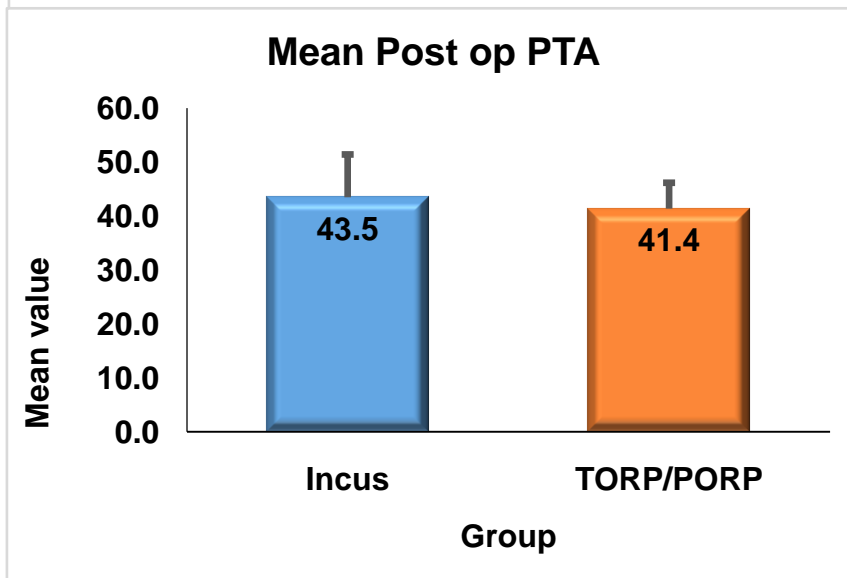
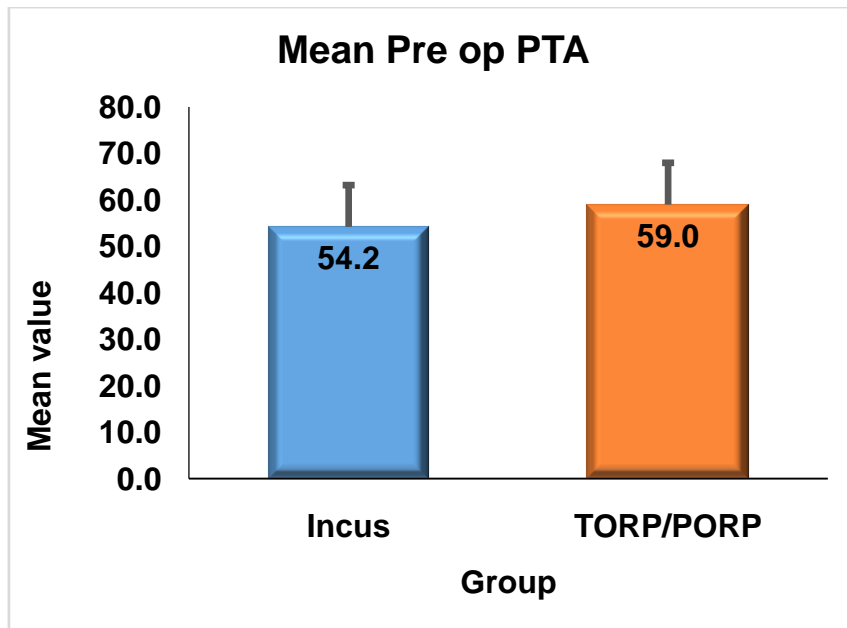
Procedure done	Group				Total	
	Incus		TORP/PORP		N	%
	N	%	N	%		
Left CWD	2	20.0	2	18.2	4	19.0
Left Intact canal wall	1	10.0	1	9.1	2	9.5
Left tympanoplasty	2	20.0	0	0.0	2	9.5
Right CWD	3	30.0	6	54.5	9	42.9
Right Intact canal wall	2	20.0	1	9.1	3	14.3
Right revision tympanoplasty	0	0.0	1	9.1	1	4.8
Total	10	100.0	11	100.0	21	100.0

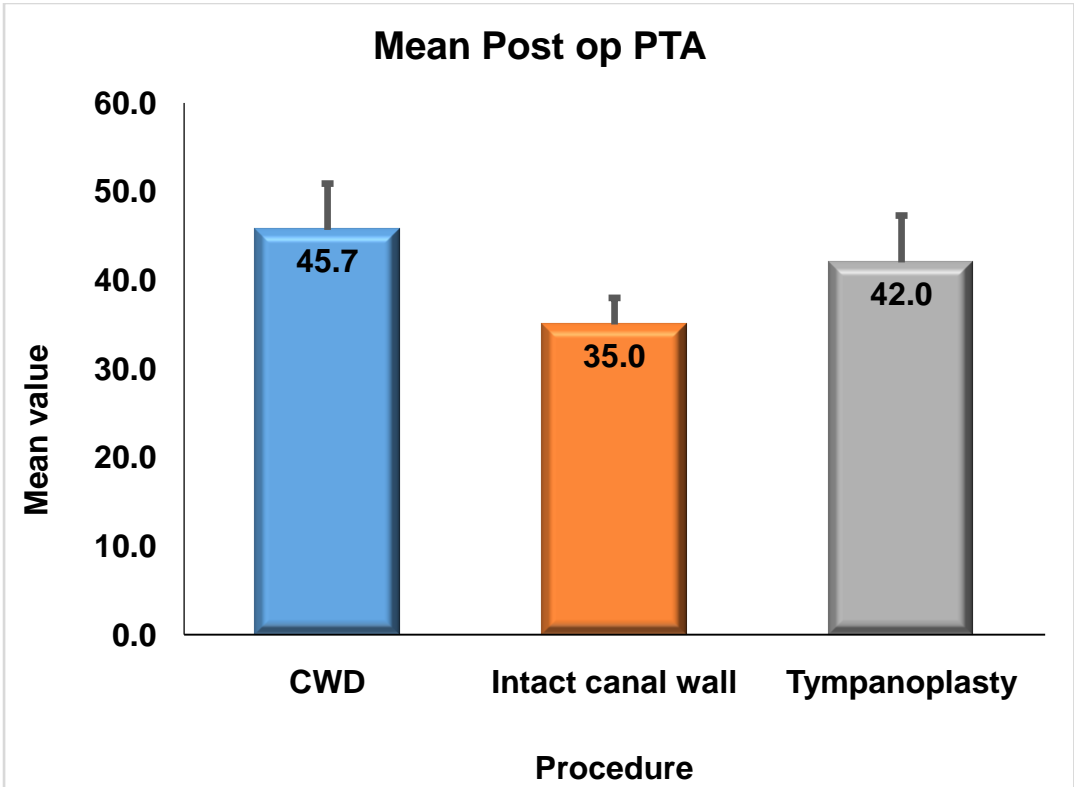
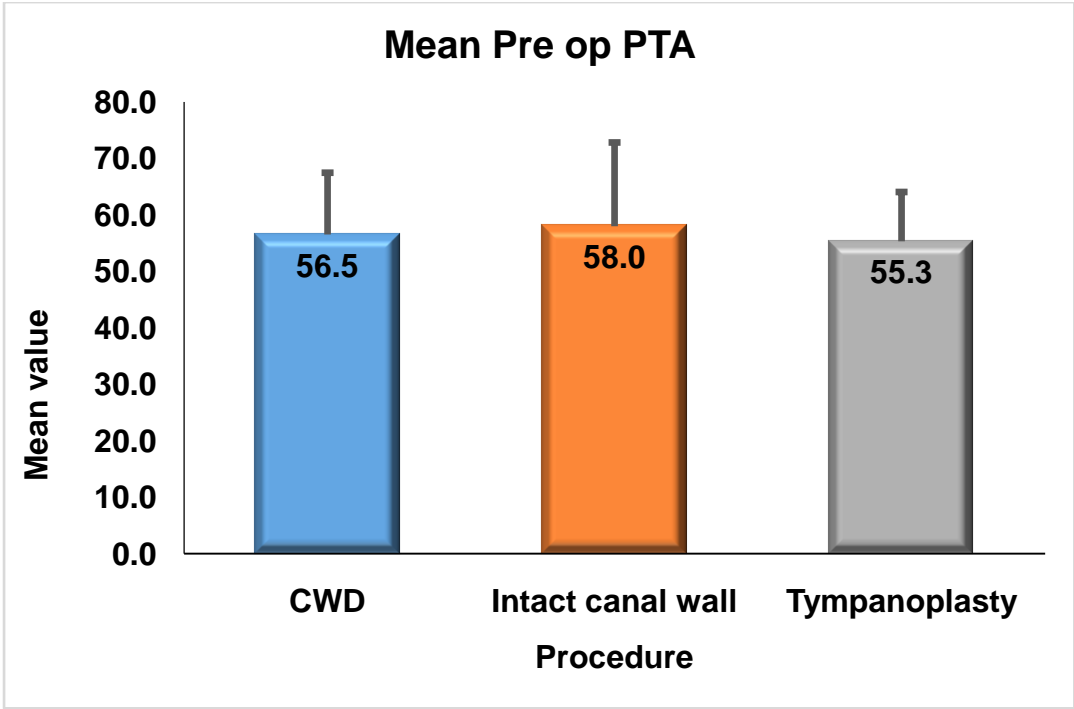
Chi-Square Test	Value
Fisher's Exact Test	0.700

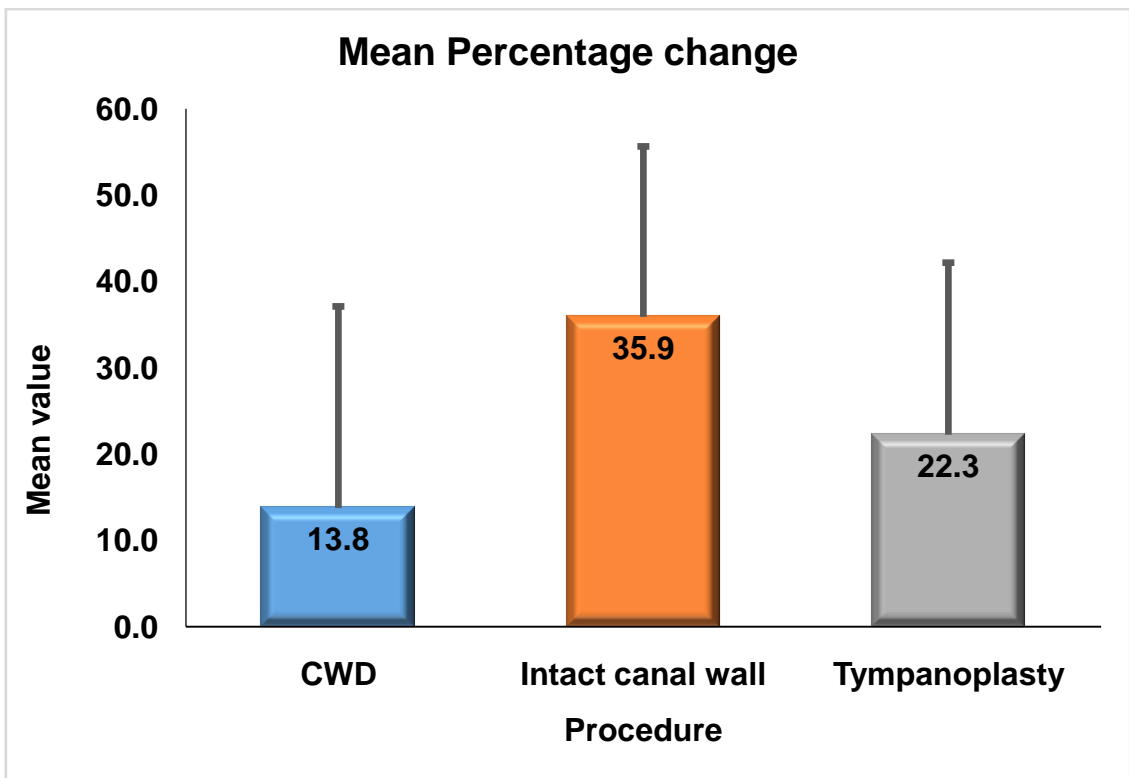
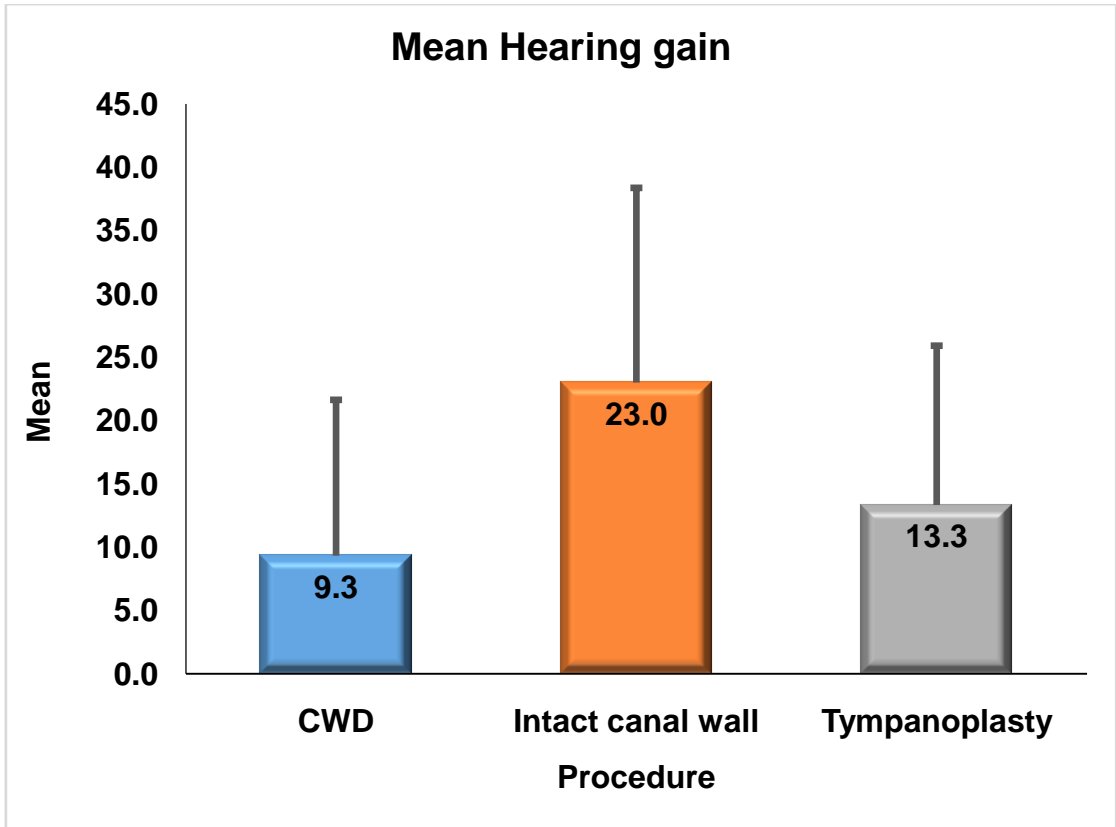
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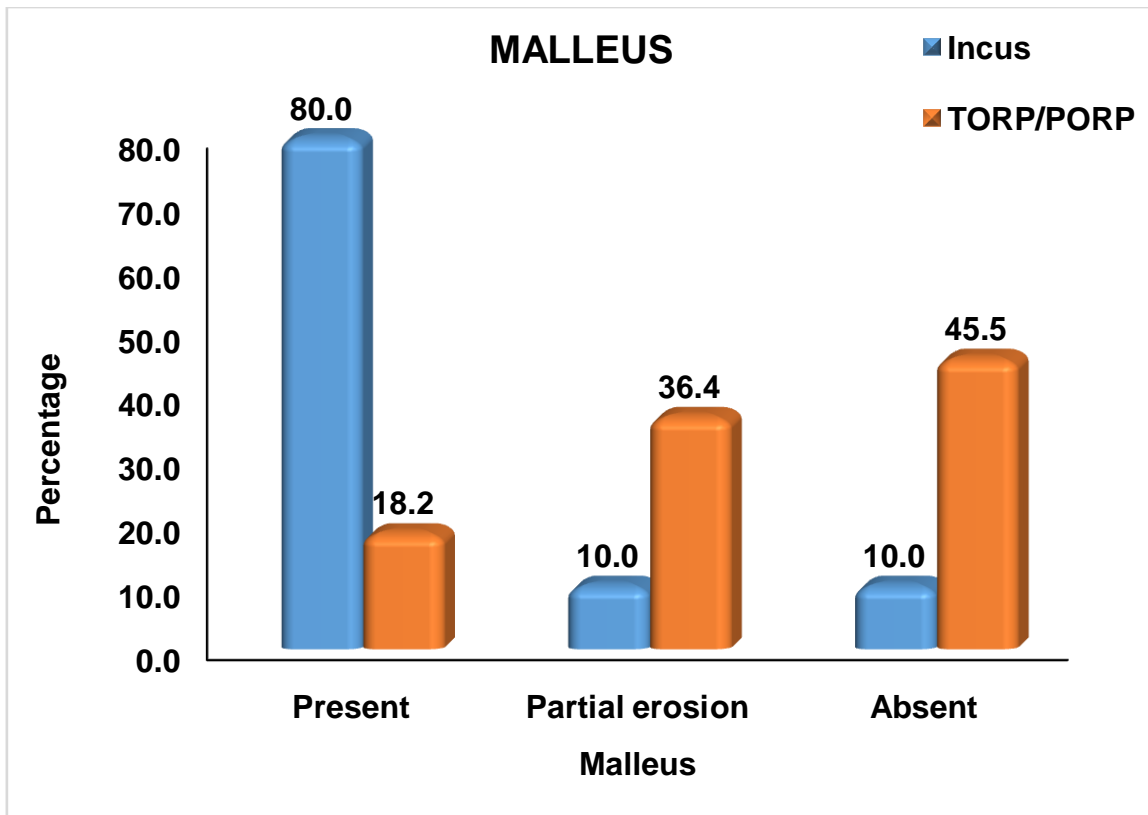
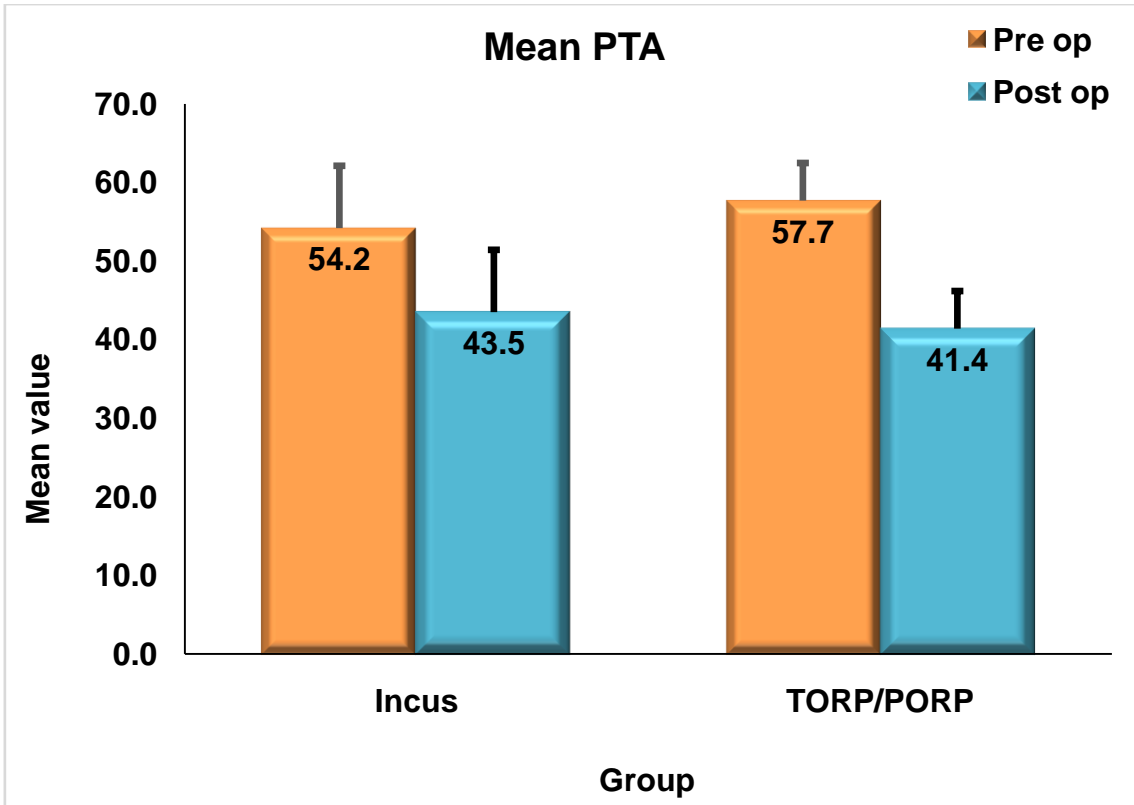


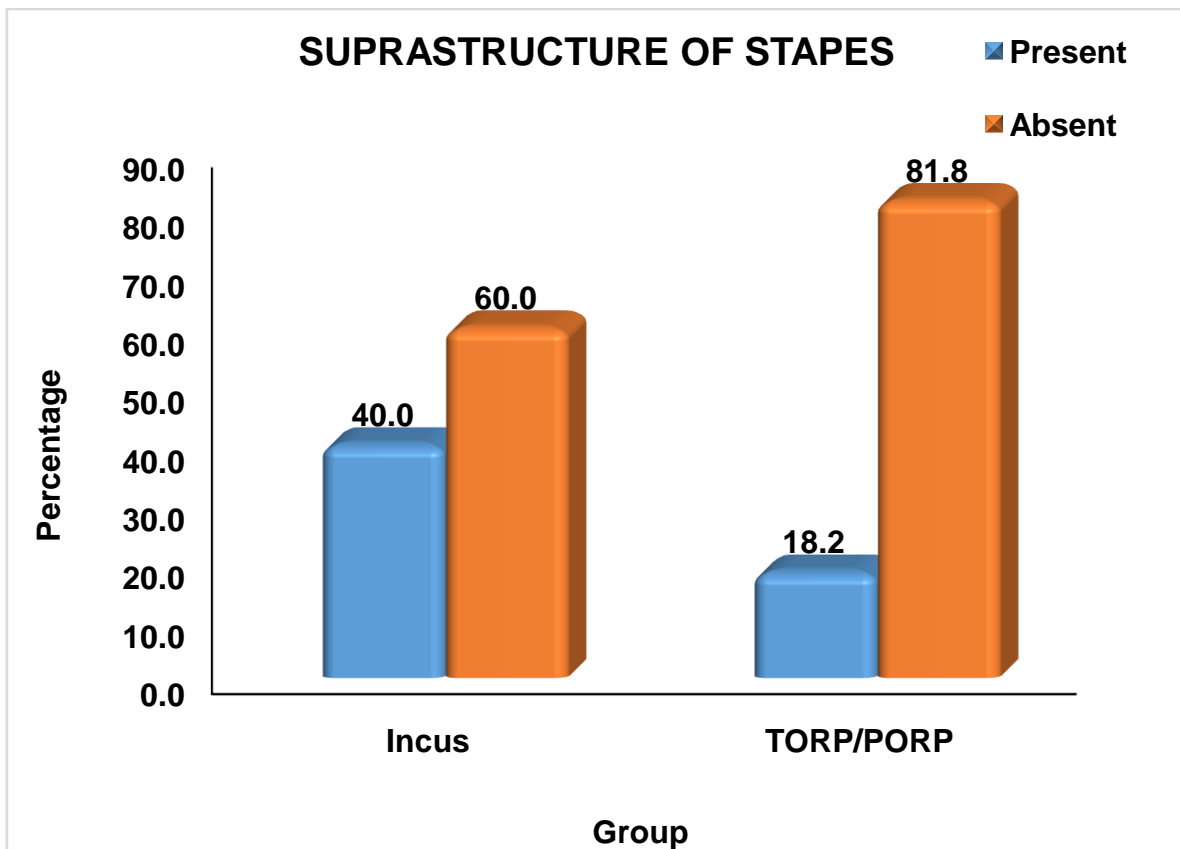
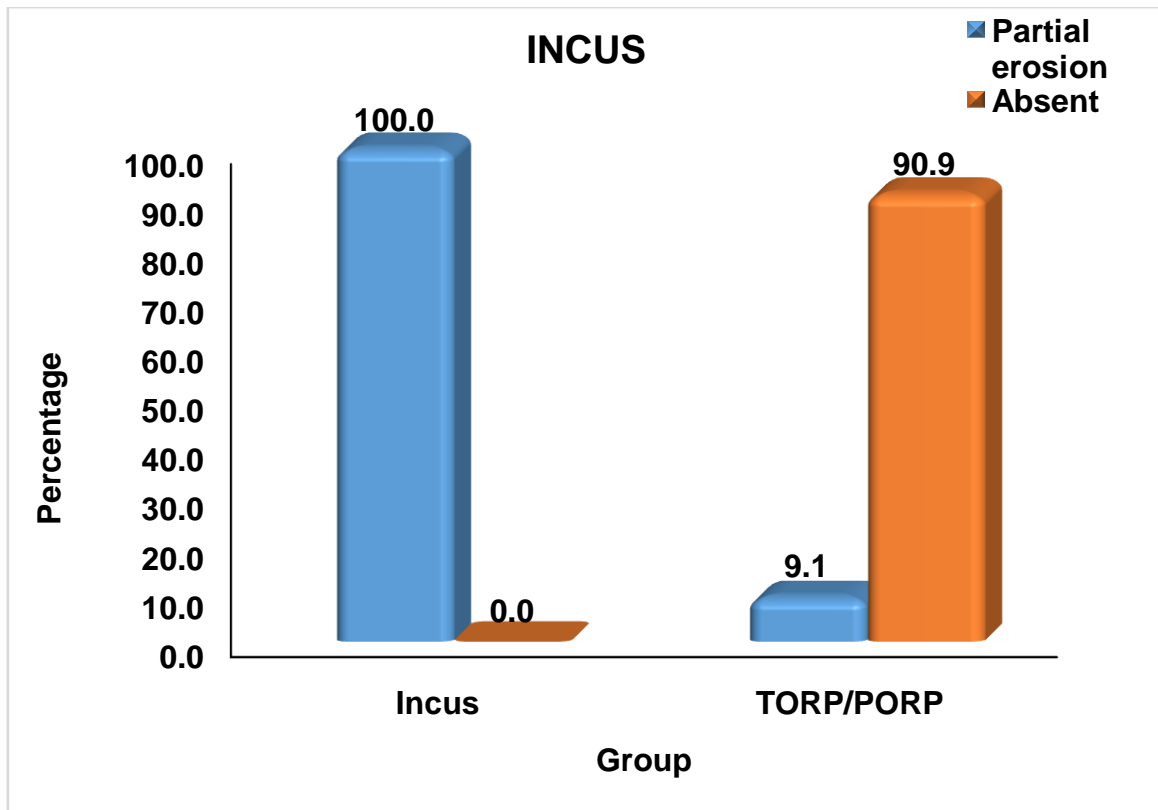












DISCUSSION

The age group of the study group is between 14-56 years of age. There were 12 male patients and 9 female patients. 8 patients were less than 18 years of age in whom consent was obtained from parents. 5 patients between 19-30 years, 4 patients between 31-40 years of age and 4 patients above 40 years of age.

10 patients with incus transposition and 11 patients with titanium.

Among titanium

7 patients with TORP total Ossicular replacement prosthesis.

4 patients with PORP partial Ossicular replacement prosthesis.

According to Ossicular status

Incus was always involved either partial or complete erosion in all cases.

Supra structure of stapes was present in 6 patients.

Out of them 4 patients had partial incus and intact Malleus.

2 patients underwent tympanoplasty with incus transposition

2 patients underwent intact canal wall mastoidectomy with incus transposition

Other 2 patients underwent canal wall down mastoidectomy with titanium

Suprastructure of stapes was eroded in 15 patients.

Incus was partially present in seven patients.

Out of them 6 patients underwent incus transposition.

One incus was not of adequate length; hence titanium was used in that case.

In the rest of titanium prosthesis was used. Total 9 patients with titanium.

According to type of surgery

Only tympanoplasty was done in 3 cases.

1. One case was traumatic Ossicular discontinuity which had incudostapedial dislocation with eroded tip of incus. Malleus and stapes was intact. M+ Ip S+

Incus repositioned over suprastructure of stapes.

2. One case was localized scutum erosion. Incus partially eroded. Malleus and stapes was intact. Atticotomy and tympanoplasty was done. M+ Ip S+

Incus repositioned over suprastructure of stapes.

3. One case was revision tympanoplasty after modified radical mastoidectomy three years back. All ossicles, Malleus, incus, stapes were absent. M- I- S-

Titanium prosthesis was placed over foot plate of stapes.

Intact canal wall mastoidectomy was done in 5 cases.

1. Partial incus and intact suprastructure of stapes and Malleus was noted in 2 cases. Incus was used in both cases. M+ Ip S+

2. Partial incus and eroded suprastructure of stapes and intact Malleus and foot plate of stapes was noted in 2 cases. M+ Ip S-.

1 case was reconstructed with incus over foot plate of stapes.

1 case was reconstructed with titanium TORP over foot plate of stapes as the available incus was not of adequate length.

3. Partial Malleus and eroded suprastructure of stapes and incus was noted in 1 case. Mp I- S-. Titanium TORP placed over foot plate of stapes.

Canal wall down mastoidectomy was done in 13 cases.

1. Erosion of head of Malleus and complete incus with intact stapes noted in 2 cases. Mp I- S+. Titanium PORP was placed over the suprastructure of stapes.

2. Intact Malleus and eroded long process of incus and suprastructure of stapes was seen in 3 cases. M+ Ip S-. Incus repositioned over foot plate of stapes.

3. Erosion of handle of Malleus, long process of incus and suprastructure of stapes was noted in 1 case. Mp Ip S-. Incus repositioned over foot plate.

4. Erosion of entire Malleus, long process of incus and suprastructure of stapes was noted in 1 case. M- Ip S-. Incus repositioned over foot plate of stapes.

5. Erosion of all ossicles except handle of Malleus seen in 2 cases. Mp I- S-.

Both cases had titanium prosthesis.

6. Erosion of all ossicles Malleus, incus and stapes was seen in 4 cases.

Titanium TORP placed over foot plate of stapes in all those patients.

According to hearing gain

Hearing gain was compared by assessing the difference between pure tone averages of preoperative hearing and postoperative hearing. Pure tone average was taken from average of intensity thresholds in decibels for 500hz, 1000hz and 2000hz.

In patients with tympanoplasty

Incus was used in 2 cases

1. Hearing gain was 25 dB for Ossicular discontinuity due to trauma

2. Hearing gain was 15 dB for diseased ossicles

Average hearing gain for incus ossiculoplasty in tympanoplasty is 20 dB

Titanium was used in 1 case of revision tympanoplasty which had no net gain.

Average postoperative pure tone average for ossiculoplasty with tympanoplasty is 42 dB.

In patients with intact canal wall mastoidectomy

Incus was used in 3 cases. All were cases of cholesteatoma

1. one case had absent suprastructure of stapes and incus was placed over foot plate. There was a hearing gain of 40 decibels.

2. one case had intact suprastructure incus repositioned over it. There was only 2 decibel hearing gain.

3. one case had intact suprastructure incus repositioned over it. There was only 13 decibels hearing gain.

Average hearing gain for incus ossiculoplasty in intact canal wall is 18.33 dB

Average post operative pure tone average for intact canal wall mastoidectomy with incus ossiculoplasty is 35 dB.

Titanium was used in 2 cases. Both cases where retraction pockets without cholesteatoma.

1. Titanium TORP was used in one case. There was a gain of 33 decibels

2. Titanium PORP was used in one case. There was a gain of 27 decibels

Average hearing gain in titanium ossiculoplasty with intact canal wall is 30 dB

Average post operative pure tone average for intact canal wall mastoidectomy with titanium ossiculoplasty is 30 dB.

In patients with canal wall down mastoidectomy

Incus was used in 5 cases. All cases had cholesteatoma with absent suprastructure of stapes.

1. one case had hearing loss of 12 dB
2. one case had hearing loss of 10 dB.

Both cases probably had bridging cholesteatoma in the place of eroded ossicles and the reconstructed incus could not transmit sound as like them.

3. one case had hearing gain of 17 dB
4. one case had hearing gain of 9 dB
5. one case had hearing gain of 8 dB

Average hearing gain in incus ossiculoplasty with canal wall down is 2.4 dB.

Average post operative pure tone average for canal wall down mastoidectomy with incus ossiculoplasty is 50.4 dB.

Titanium PORP was used in 3 cases.

1. one case had hearing loss of 3 dB
2. one case had hearing gain of 7 dB
3. one case had hearing gain of 24 dB

Average hearing gain for titanium PORP ossiculoplasty with canal wall down is 9 dB.

Average post operative pure tone average for canal wall down mastoidectomy with titanium PORP ossiculoplasty is 41 dB.

Titanium TORP was used in 5 cases. Suprastructure of stapes was absent in all cases.

1. one case had hearing gain of 12 dB
2. one case had hearing gain of 16 dB
3. one case had hearing gain of 18 dB
4. one case had hearing gain of 26 dB
5. One case lost followup.

Average hearing gain for titanium TORP ossiculoplasty with canal wall down is 18 dB.

Average hearing gain for titanium ossiculoplasty as a whole with canal wall down is 14.285 dB.

Average post operative pure tone average for canal wall down mastoidectomy with titanium TORP ossiculoplasty is 41.8 dB.

In patients with incus

Average Pre operative pure tone average was 54.2 dB

Average Post operative pure tone average was 43.5 dB

Net gain in hearing was 10.6 decibels

In patients with titanium prosthesis

Average Pre operative pure tone average was 59 dB

Average Post operative pure tone average was 41.4 dB

Net gain in hearing was 15.9 decibels

The average postoperative hearing after ossiculoplasty is 43.5 dB

Average post op hearing in patients without and with ossiculoplasty

Procedure	Post op PTA without ossiculoplasty
Intact canal wall	52.15 dB
Canal wall down with type 3 tympanoplasty	55.625 dB
Canal wall down with type 4 tympanoplasty	63.66 dB

Average = 57.145 dB

Procedure	Post op PTA with incus ossiculoplasty
Tympanoplasty (2 cases)	39 dB
Intact canal wall	35 dB
Canal wall down	50.4 dB

Average = 43.5 dB

Procedure	Post op PTA with titanium ossiculoplasty
Tympanoplasty (1 case)	48 dB
Intact canal wall	30 dB
Canal wall down	41.8 dB

Average = 41.4 dB

Average hearing gain in patients with incus and titanium ossiculoplasty

Procedure	Hearing gain with incus ossiculoplasty
Tympanoplasty (2 cases)	20 dB
Intact canal wall	18.33 dB
Canal wall down	2.4 dB

Average = 10.6 dB

Procedure	Hearing gain with titanium ossiculoplasty
Tympanoplasty (1 case)	0 dB
Intact canal wall	30 dB
Canal wall down	14.285 dB

Average = 15.9 dB

CONCLUSION

1. Ossiculoplasty definitely gives better hearing in comparison to cases where ossiculoplasty is not done.
2. Ossiculoplasty should be done in all cases with conductive hearing loss secondary to Ossicular pathology either at primary sitting or second sitting.
3. Incus and titanium has equal postoperative hearing. In terms of hearing gain Titanium prosthesis gave a better hearing gain than Ossicular transposition.
4. Autologous ossicles are not available in the desired length in all cases.
5. Cost of titanium is a concern.
6. Complications in the short period studied are nil in both groups.
7. Both incus and titanium are taken up well in the three month followup.
8. Long term results are awaited.

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ANNEXURE

MASTER CASE SERIES – STUDY GROUP

CASE REGISTER OF PATIENTS WITH INCUS OSSICULOPLASTY

S.No	Name	Age / sex	No.	Date of surgery	diagnosis	Procedure done	Ossicular status	Pre op PTA	Post op PTA	Hearing gain
1.	LALITHA	48/F	114291	18-12-2012	Left traumatic ossicular discontinuity	Left tympanoplasty	M+ Ip S+	65 dB	40 dB	+ 25 dB
2.	RAJA	18/M	2436	19-02-2013	Right PSRP with cholesteatoma	Right CWD	M+ Ip S-	36 dB	48 dB	- 12 dB
3.	SYED IMRAN	27/M	17884	01-03-2013	Right CSOM with granulation	Right Intact canal wall	M+ Ip S-	75 dB	35 dB	+ 40 dB
4.	YUVARAJ	41/M	2974	19-03-2013	Right PSRP with cholesteatoma	Right CWD	M+ Ip S-	42 dB	52 dB	-10 dB
5.	RAJAMMAL	33/F	16327	22-03-2013	Left CSOM with dry CP	Left tympanoplasty	M+ Ip S+	53 dB	38 dB	+15 dB
6.	KRISHNAVENI	56/F	10034	31-05-2013	Right CSOM with cholesteatoma	Right CWD	M+ Ip S-	65 dB	48 dB	+17 dB
7.	NADHIYA	25/F	11953	21-06-2013	Left PSRP with cholesteatoma	Left Intact canal wall	M+ Ip S+	40 dB	38 dB	+2 dB
8.	ARUMUGAM	35/M	1317651	26-06-2013	Left attic cholesteatoma	Left CWD	M- Ip S-	65 dB	56 dB	+9 dB
9.	KALAIVANI	18/F	11353	17-07-2013	Right PSRP with cholesteatoma	Right Intact canal wall	M+ Ip S+	45 dB	32 dB	+13 dB
10.	GUNASEKARAN	35/M	1323592	22-08-2013	Left attic cholesteatoma	Left CWD	Mp Ip S-	56 dB	48 dB	+ 8 dB

M – MALLEUS I – INCUS S – STAPES + - PRESENT p – PARTIAL EROSION - - ABSENT

PSRP- posterosuperior retraction pocket CWD – canal wall down

CASE REGISTER OF PATIENTS WITH TITANIUM OSSICULOPLASTY

S.No	Name	Age / sex	No.	Date of surgery	diagnosis	Procedure done	Ossicular status	Titanium	Pre op PTA	Post op PTA	Hearing gain
1.	THANGAVELU	27/M	114950	28-12-2012	Right attic cholesteatoma	Right CWD	Mp I- S+	PORP	42 dB	45 dB	- 3 dB
2.	ASAITHAMBI	23/M	17009	04-01-2013	Right attic cholesteatoma	Right CWD	Mp I- S+	PORP	52 dB	42 dB	+ 7 dB
3.	SARULATHA	15/F	4331	08-03-2013	Right CSOM granulation	Right CWD	Mp I- S-	TORP	56 dB	44 dB	+ 12 dB
4.	SEETHALAKSHMI	36/F	9451	27-05-2013	B/L attic cholesteatoma	Left CWD	M- I- S-	TORP	58 dB	42 dB	+16 dB
5.	SOORYA	14/M	4870	03-06-2013	Right cholesteatoma	Right CWD	M- I- S-	TORP	63 dB	45 dB	+18 dB
6.	VIGNESH	13/M	1316409	14-06-2013	Left CSOM with PSRP	Left Intact canal wall	M+ Ip S-	PORP	65 dB	38 dB	+27 dB
7.	BASHARATH	15/M	11346	17-06-2013	Right attic cholesteatoma	Right CWD	M- I- S-	TORP	72 dB	Lost followup	
8.	AJITH KUMAR	17/M	13092757	01-07-2013	B/L attic cholesteatoma	Right CWD	M- I- S-	TORP	68 dB	42 dB	+26 dB
9.	SHANTHI	43/F	2103	29-07-2013	Right post MRM residual perforation	Right revision tympanoplasty	M- I- S-	TORP	48 dB	48 dB	Nil
10.	VAITEESWARI	18/F	12935	02-08-2013	B/L CSOM with PSRP	Right Intact canal wall	M+ I- S-	TORP	65 dB	32 dB	+ 33 dB
11.	PURUSHOTHSMAN	29/M	14540	07-08-2013	Left attic cholesteatoma	Left CWD	Mp I- S-	PORP	60 dB	36 dB	+ 24 dB

M – MALLEUS I – INCUS S – STAPES + - PRESENT p – PARTIAL EROSION - - ABSENT

PSRP- posterosuperior retraction pocket CWD – canal wall down

PROFORMA

Name :

Age & Sex :

Occupation :

OP / IP No :

History :

Complaints : (Visual Analogue Scale)

	Right	Left
1. Ear Discharge	Yes/No	Yes/No
If yes,		
Type of discharge		
Continuous or Intermittent		
Foul smelling or Not		
Blood stained or Not		
2. Hard of Hearing	Yes/No	Yes/No
3. Ear Pain	Yes/No	Yes/No
4. Tinnitus	Yes/No	Yes/No
5. Giddiness	Yes/No	

H/o Trauma

Past History:

Treatment History:

H/o previous surgery:

H/o Medication:

Clinical Examination:

Ear:

Right

Left

1. Pre auricular region
2. Pinna
3. Post auricular region
4. External auditory canal
5. Tympanic membrane
6. Tuning Fork Tests
7. Vestibular function Tests
8. Higher Function Examination

Nose:

Throat:

DIAGNOSIS:

Investigations

1. Ear swab culture & sensitivity
2. X-ray mastoids/ CT Temporal bone
3. Pure tone Audiogram

சுய ஒப்புதல் படிவம்

ஆய்வின் தலைப்பு: செவி சிற்றெழுப்பு சீரமைப்பில் சுய மாதிரி மற்றும் உலோக உறுப்பு மாதிரி பயன்படுத்தி ஒப்பாய்வு செய்தல்.

ஆராய்ச்சி நிலையம் : காது, மூக்கு, தொண்டை துறை
கீழ்ப்பாக்கம், மருத்துவக் கல்லூரி,
சென்னை - 600 010.

பங்கு பெறுபவரின் பெயர் : வயது :
பங்கு பெறுபவரின் எண். :

பங்கு பெறுபவது இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்று அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதைச் சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்போது இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான முடிவுகளையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கூறப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

இந்த ஆய்வில் எனக்கு தேவையான ரத்த பரிசோதனை, செவி பரிசோதனை மற்றும் CT ஸ்கேன் செவி பகுதியில் செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்இடம்தேதி
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம்இடம்தேதி

ஆய்வாளரின் பெயர்

PATIENT CONSENT FORM

STUDY DETAIL: COMPARISON OF AUTOLOGOUS OSSICULAR GRAFT VERSUS TITANIUM PROSTHESIS (TORP & PORP) IN OSSICULOPLASTY FOR OSSICULAR PATHOLOGY

STUDY CENTRE: Kilpauk Medical College and Hospital, Chennai

Patient Name:

Patient Age:

Identification Number:

Patient to tick (✓) these boxes

I confirm that I have understood the purpose of procedure for the above Study.
I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason, without my legal rights being affected.

I understand that Investigator, Regulatory authorities and the Ethics committee will not need my permission to look at my health records both in respect to the current study and any further research that may be conducted in relation to it, even if withdraw from the study, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully co operative with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms,

I hereby give consent to participate in this study.

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, Diagnostic Nasal, Endoscopy, radiological, tests.

Signature / Thumb impression :

Place

Date

Patient Name and Address :

Signature of the Investigator :

Place

Date

Study Investigator's Name :