AN OBSERVATIONAL STUDY TO EVALUATE THE HEARING EFFICACY OF BONE CEMENT OSSICULOPLASTY FOR INCUDOSTAPEDIAL REBRIDGING

A Dissertation submitted to

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CERTIFICATE - I

This is to certify that the dissertation entitled **"AN OBSERVATIONAL STUDY TO EVALUATE THE HEARING EFFICACY OF BONE CEMENT OSSICULOPLASTY FOR INCUDOSTAPEDIAL REBRIDGING"** is a bonafide record of work done by **Dr.R.M.MONISHA** in the Department of ENT, Madurai Medical College and Govt. Rajaji Hospital, Madurai in partial fulfilment of the requirements for the award of the degree of M.S. Branch IV (Otorhinolaryngology), under my guidance and supervision during the academic period 2019-2022.

I have great pleasure in forwarding the dissertation to The Tamil Nadu Dr. M.G.R. medical university

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CERTIFICATE – II

This is to certify that this dissertation work titled **“AN OBSERVATIONAL STUDY TO EVALUATE THE HEARING EFFICACY OF BONE CEMENT OSSICULOPLASTY FOR INCUDOSTAPEDIAL REBRIDGING”** of the candidate **Dr.R.M.MONISHA** with registration Number 221914103 for the award of degree of **M.S.** Branch IV in the branch of **Otorhinolaryngology**.

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I, **Dr.R.M.MONISHA** solemnly declare that the dissertation entitled **"AN OBSERVATIONAL STUDY TO EVALUATE THE HEARING EFFICACY OF BONE CEMENT OSSICULOPLASTY FOR INCUDOSTAPEDIAL REBRIDGING"** is a bonafide record of work done by me during the period of August 2020 – May 2021 at Madurai medical college and Govt. Rajaji hospital, Madurai.

This dissertation is submitted to the Tamil Nadu Dr.M.G.R. Medical University for the examinations to be held in May 2022 in partial fulfilments of the requirements for the award of M.S.Branch IV (Otorhinolaryngology).I have not submitted this dissertation work previously for the award of any degree or diploma from any other University.

Place: Madurai

Date: **Dr.R.M.MONISHA**

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ABBREVIATIONS

COM	- Chronic otitis media
AOM	- Acute otitis media
PORP	- Partial Ossicular Replacement Prosthesis
TORP	- Total Ossicular Replacement Prosthesis
TM	- Tympanic membrane
EAC	- External auditory canal
ET	- Eustachian tube
CP	- Central perforation
PTA	- Pure tone audiogram
AC	- Air conduction
BC	- Bone conduction
ABG	- Air bone gap
HDPS	- High density polyethylene sponge

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ABSTRACT

Background:

The goal of surgery in cases with chronic otitis media both safe and unsafe types is to achieve a maximal disease clearance and restore the near normal hearing. Various techniques of ossiculoplasty have been used to reconstruct the eroded ossicular chain. The ideal material to be employed in ossiculoplasty techniques should be bio active, bio compatible, safe, stable and with easier to apply. Hydroxyapatite, which is a calcium phosphate compound bone cement is similar in composition to living human bone and satisfies all the all above characteristics of an ideal ossiculoplasty material.

Objectives:

The purpose of this study is to evaluate the hearing outcomes of hydroxyapatite bone cement ossiculoplasty done in patients with incudostapedial erosion in both safe and unsafe types of chronic otitis media. The study is also aimed to determine the ideal candidates for bone cement ossiculoplasty.

Methodology:

A total of thirty patients of chronic otitis media with incudostapedial erosion were included in the study. Patients underwent ossicular reconstruction with hydroxyapatite bone cement. Preoperative and post operative hearing results with pure tone audiogram and impedance audiometry were recorded. One year period of follow up was done and reduction in air bone gap was analyzed.

Results:

The post operative air bone gap was found to be significantly reduced after a period of follow up of one year. The mean preoperative and postoperative pure tone averages was found to be 47.46 and 36.86 respectively. The mean preoperative and post operative air bone gaps were 37.89 and 27.28 respectively with $p<0.001$. No complications were recorded during the study in relation to the bone cement.

Conclusions:

Incudostapedial rebridging ossiculoplasty with hydroxyapatite bone cement is a safe and reliable method that is cost effective and provides significant hearing outcomes in selected patients with no complications recorded.

Key words: Hydroxyapatite bone cement. Ossiculoplasty. Incudostapedial rebridging.

INTRODUCTION

Chronic otitis media is the leading cause of conductive hearing impairment particularly in developing countries. Due to the prevalence of this condition inspite of the advancements in medical sciences, WHO considers this as the commonest cause of persistent hearing loss among the pediatric and adult population of the developing countries.[1]

The World Health Organization estimated that 65-330 million people worldwide are affected by chronic suppurative otitis media of whom 50% are affected by hearing loss.

Chronic suppurative otitis media is defined as the chronic inflammation of the middle ear cleft which presents with recurrent ear discharges through a perforation in the tympanic membrane. It may be of two types – mucosal and squamous also called as safe and unsafe types respectively. In addition to the tympanic membrane perforations, erosion or discontinuity of the middle ear ossicles results in conductive type of hearing loss.

Ossicular erosion is more common in unsafe type of CSOM compared to the safe type. It is being reported in 14% of the safe ears. The long duration of the inflammatory process and the release of inflammatory mediators induce the activation of osteoclasts and bone resorption and results in ossicular erosion.

Incudal necrosis is the most prevalent ossicular pathology in CSOM involving most frequently the lenticular process followed by the long process resulting in incudostapedial discontinuity. Conductive hearing impairment of more than 40dB in pure tone audiogram and Ad type curve in tympanometry is suggestive of ossicular erosion. Radiological investigations like high resolution CT scan of the temporal bone and per operative microscopic examination confirms the diagnosis.

It is therefore necessary to restore hearing as close as possible to the physiological hearing in patients with ossicular discontinuity. Ossiculoplasty is a reconstructive procedure performed to rebridge the interruption in the middle ear ossicles.

A successful ossiculoplasty requires a stable connection between the remnant parts of the ossicular chain so as to reduce the air bone gap and increase the efficacy of hearing.[4] Various ossiculoplasty techniques have been employed to reconstruct the osiicular chain and to achieve near normal hearing.

Ideal materials for ossiculoplasty should be biocompatible, stable, safe, affordable and easily available. In our study we used hydroxyapatite bone cement to bridge the erosion between incus and stapes.The objective of our study is to evaluate the hearing outcome after using hydroxyapatite bone cement to rebridge the the incudostapedial erosiom and to know the ideal cases of ossicular erosion to use bone cement. We analysed the preoperative and postoperative air bone gap and tympanometry results in the included study group.

AIMS AND OBJECTIVES

1. The aim of the study is to evaluate the hearing outcome after ossiculoplasty using hydroxy apatite bone cement in patients of chronic otitis media with incudostapedial erosion.
2. To determine the ideal cases of ossicular erosion for application of hydroxyapatite bone cement.

REVIEW OF LITERATURE

Ossicular reconstruction and repositioning began in the 1950s and continues to be practiced till date. Plastic prostheses invented earlier had higher rates of extrusion and created fistulas over the foot plate of the stapes. Homograft materials were then found to be superior to these prostheses but later abandoned largely due to the risk of transmission of viral or prion diseases. Stainless steel, tantalum and platinum wire prostheses were found to be tolerated but had problems of extrusion and displacement over years.

Alloplastic ossicular prostheses were developed thereafter with advancements in biomaterials science. An alloplast made from high density polyethylene sponge (HDPS) – plastipore, was found to be non-reactive and had good porosity that supports excellent tissue growth. It was used either as a partial ossicular replacement prosthesis (PORP) or a total ossicular replacement prosthesis (TORP) based on the type of ossicular erosion. The rate of extrusions of plastipore prosthesis was reported to be around 3 – 5% in a large case series. 70% of the extrusions were due to middle ear pathologies such as atelectasis, middle ear fibrosis and otitis media as attributed by Brackmann.[2]

In 1979, ceramic implants were introduced that were made from both bioinert and bioactive materials. Ceramics are good thermal insulators, fragile materials with good biocompatibility and without any toxic or inflammatory reactions. Frialit – a bioinert ceramic material made of aluminium dioxide (Al_2O_3) was initiated by Jahnke and Plester. Bioceram was another bioinert material introduced by Yamamoto in Japan.

Bioactive ceramics create an ionic balance with the tissues around, thus stimulating the bone growth. Glass ceramics and calcium phosphate ceramics fall under this category. Glass ceramics contain silicon dioxide (SiO_2) that is very similar in property to glass. Calcium phosphate which is nothing but the plaster of paris was used for cavity obliteration in the 1980s by Hogset and Bredberg. Tricalcium phosphates (Ca_3PO_4) also served this purpose.

Hydroxyapatite used in our study has is, in fact, the mineral matrix of bone which makes it an ideal material for reconstruction of the middle ear ossicles. It mimics the bone in its properties and resists degradation and resorption and warrants excellent osseointegration and reconstruction of the ossicles[38]. The Shea prosthesis made with its shaft and head made of hydroxyapatite was used similar to the plastipore prosthesis. The Black prosthesis had an egg shaped head with no sharp edges and was made of hydroxyapatite and the shaft was made up of fluoroplastic. The Kartush prosthesis was made up of hydroxyapatite tube which was used to bridge the head of stapes and handle of malleus. Grote's prosthesis was based on an assembly method which was place between the remnants of the ossicles.

The Yanagihara hydroxyapatite prosthesis was designed with a smooth curved platform and a hollow shaft. A groove was made across the platform helps in fitting the prosthesis between the handle of malleus and stapes. The Wehr incus prosthesis was made either with a single notch or double notch. It has an excellent stability if malleus handle was present. A hybrid prosthesis was developed by Goldenberg (1990) with a head made of hydroxyapatite and a shaft made of plastipore. He published excellent hearing results with this prosthesis, with minimal extrusion rates being 3 – 4% with a mean follow up of about one year. A similar hybrid prosthesis with a hydroxyapatite head and a fluoroplastic shaft was the Black spanner prosthesis.

Glass ionomer cement was obtained by the reaction of glass powder and polyacrylic acid with calcium aluminosilicate glass being the base component. It is used in reconstruction of the bony canal wall and mastoid cavity obliteration in addition to ossicular reconstruction.

The various metal prostheses in use were titanium prosthesis, Gerlach wire basket prosthesis, Palva's two legged and three legged wire prosthesis, gold prosthesis which gained popularity in the 1990s[35].

Ossiculoplasty or ossicular chain reconstruction is the surgical procedure to correct the ossicular chain abnormalities with an aim improving hearing. In patients with chronic otitis media the ear is first made safe then to make it dry and finally to make it compatible for hearing.

Ossiculoplasty done by Matte[3] in 1901 is the earliest one recorded in the history of ossiculoplasty. It was done to establish a connection between the tympanic membrane and the oval window in the case of ossicular abnormalities due to middle ear pathology. It took 50 long years after which Wullstein in 1951 used a vinyl acrylic material to rebridge the ossicular erosion. Following this, various biological and alloplastic materials have been used as prosthetic materials to bridge the ossicular gap and to improve the hearing outcomes post surgery.

The first ossicular reconstruction with autologous incus was done by Hall and Rytzner (1957). Autologous incus is the most common autograft material that is sculpted and placed between the handle of the malleus and the head of stapes. Interposition of handle of Malleus between the tympanic membrane and the head of stapes was also tried in the years thereafter. Bell (1958), Farrior (1960), Portmann (1963), Chandler (1965), Sheehy (1965), Guilford (1965), Wright (1967) , Szpunar (1967), described these techniques.

Austin in 1971 described the ossicular defects classificatioin and also described various interposition techniques for ossicular reconstruction. Techniques similar to Austin were described by Hildyard (1967) and Hough (1970). Later, Pennington in 1973 and Wehrs in 1974 improved the malleus/stapes assembly described by Austin. Interposition techniques were also recommended by Lee and Schuknecht (1971), MacGee (1979), Smyth (1980), and Goodman (1980).

Autologous ossicular grafts obtained from cortical bone of outer mastoid cortex, bony external auditory canal, and Henle's spine were sculptured to the desired size and used by Hough (1958), Zollner (1960, 1969), Farrior (1960, 1966), Kley and Draf (1965), Guilford (1966), Bauer (1966), Wright (1967), and Tos (1974). Similarly, Utech (1960) introduced sculptured auricular cartilage for interposition.

Jansen (1963) suggested the use of autologous septal cartilage and tragal cartilage for interposition between the tympanic membrane and the foot plate assembly and tympanic membrane to head of stapes assembly.

Autograft materials cannot be harvested for use from patients with cholesteatoma as there is risk of squamous epithelium infiltration or intrusion into the ossicles being grafted. To overcome this homograft ossicles were used after preservation alcohol or after being irradiated.

In 1966 Linthicum, House and Patterson introduced reconstruction of ossicular chain with the incus allograft.

Wehrs (1974) introduced the notched Ossiculoplasty: A historical perspective incus autograft or allograft technique.

Smyth [1972], Goodhill, Westerbergh, and Davis [1974], Marquet [1976], Ironside [1979], Smith [1980], Hough [1982], Smith and McElveen [1982] described various techniques for sculpturing the graft materials for malleus/stapes and malleus/footplate assemblies with minor modifications.

Sheehy, House and Glasscock (1969) then introduced the idea of composite allografts that were alcohol preserved, consisting of en bloc tympanic membrane with attached ossicles (tympano-ossicular monoblock grafts) that were used in ears without a tympanic membrane, malleus, and incus, with or without a stapes suprastructure. Homograft ossicular banks were then established in the United states. But due to risk of disease transmission, e.g., HIV, Creutzfeldt-Jakob disease, the use of homografts was restricted since 1968. Increasing chances of resorption of bone and cartilage were also reported.

It then became an era of alloplastic materials because of the disadvantages of autografts and homograft ossicles. It was then the three porous plastic materials, namely Polycel, Proplast, Plastipore and a wide range of ceramic materials were developed for ossicular reconstruction. These materials were further classified as bioinert, bioactive and biocompatible. Risks of penetration into the inner ear, migration and extrusion or significant middle ear reactivity were reported with these materials. This abandoned the use of solid reconstructive materials.

A high-density polyethylene sponge (HDPS) was developed in the 1970s that had nonreactive properties. This was coupled with other materials, such as stainless steel, and lead to a high variety of prosthetic designs. But the use of HDPS resulted in high rates of extrusion which was overcome with the use of cartilage interposition.

Bioglass and Ceravital were the first bioactive implants introduced in the 1970s. The use of these materials is restricted nowadays due to its instability in infected surroundings and posed a difficulty in trimming to the desired size and shapes.

Bone cements came into use thereafter to join the defects between ossicles. Hydroxylapatite is currently one of the most commonly used alloplastic materials for ossicular rebridging. It forms a direct bond with bone at the tissue interface. Other examples of biocompatible materials used for ossicular reconstruction are silastic, stainless steel, titanium, and gold. Titanium, which is lighter material than others and compatible with magnetic resonance imaging.

An ideal prosthetic material for ossiculoplasty should be tissue engineered which is biocompatible, stable, safe, easily insertable, and capable of yielding an optimal sound transmission following surgery

Yildirim A. Bayazit[4] conducted a retrospective study in 2006 from which he concluded that the 57 patients who underwent bone cement ossiculoplasty for incus to stapes bridging and malleus to stapes bridging showed significant improvement in conductive hearing loss and the procedure proved to be cost effective. Mastoidectomy followed by ossiculoplasty was done with Ketac Cem radiopaque which consisted of a formulated powder (33 g) and dissolving liquid (12 ml).

Tekim Baglam[5] et al studied a series of patients who underwent incudostapedial rebridging ossiculoplasty with bone cement in 2009. 136 patients were included and ossiculoplasty was done using glass ionomer bone cement (GIC). Patients were followed up for a period of 1 year. He concluded that patients who underwent bone cement rebridging ossiculoplasty with glass ionomer cement showed no complications in the middle ear related to the bone cements. It also proved to be a reliable and cost effective method and offers satisfactory hearing results particularly in selected patients.

Demir B et al[6] in 2019 analysed 51 patients who underwent bone cement ossiculoplasty for incudostapedial rebridging between 2006 and 2010. Long term hearing outcomes following surgery was analysed. They concluded that bone cement ossiculoplasty is a safe and reliable method with good long term hearing outcomes. They also found that incus long process defects were the most common cause of ossicular discontinuity.

C.Galy – Bernadoy[7] et al studied seventy patients operated between 2007 and 2011. Mean air bone gap was measured preoperatively and 6 months postoperatively. They compared early hearing outcomes of type 2 ossiculoplasty using hydroxyapatite bone cement versus other materials. The study concluded that bone cement had rapidity and ease of application , good biocompatibility and low complication rates. Thus bone cement can be useful in selective patients especially non cholesteatomatous chronic otitis media.

Thomas Somers et al[8] in 2011 conducted a study in two group of patients- one with the standard incus remodelling ossiculoplasty and other with bone cement ossiculoplasty. Significant intermediate term hearing gain was evident with bone cement ossiculoplasty when compared to classical ossiculoplasty techniques. The reconstruction was more physiologic and the surgical procedure was easier and faster when compared with standard ossiculoplasty techniques.

In 2006 Mohamed Nasser Elsheik et al[9] used hydroxyapatite (HA) bone cement to rebridge the incus and studied the physiologic reestablishment of ossicular continuity during excision of retraction pockets. A total of sixty two patients with retraction pockets were chosen for the study. HA procedure was easy to perform and presented a less risk of damage to the cochlea and stapes when compared with ossiculoplasty using standard partial ossicular replacement prosthesis.

O. Yigit et al[10] in 2019 conducted a study to analyze the wideband tympanometry results of bone cement ossiculoplasty. The study took place from 2015 to 2016. Wide band tympanometry was done with these patients. Tympanometric peak pressure, equivalent middle ear volume, static admittance, tympanogram width, resonance frequency, average wideband tympanometry and absorbance measures were analyzed. Patients who underwent bone cement bridging showed a remarkable difference in tympanometric results when compared with the classical type 1 tympanoplasty and the control groups.

Serdar Baylancicek et al[11] in 2014 did a study comparing the ossicular reconstruction procedure with bone cement and partial ossicular replacement prosthesis. A total of forty four patients with incudostapedial discontinuity were included in the study. They observed no significant difference between the two procedures in terms of hearing outcomes.

Magdy Ibrahem Gouda[12] undertook a study to assess the significance of cartilage strip with bone cement. It was a prospective cross sectional study in thirty six patients with chronic otitis media. Results of the study concluded that bone cement along with cartilage strip is a simplest and effective method of reconstruction associated with significant improvement in hearing.

Mahmut Tayyar Kalcıoğlu[13] in a study conducted in Istanbul concluded that, bone cement application may be preferred over incus interposition or PORP for traumatic ossicular chain defects, as the use of bone cement preserves the natural mechanism transmission of voice from the tympanic membrane to the stapes foot plate and recorded better hearing results.

In a study conducted by Mobasher et al[14] in 2014, on 20 patients with ossicular chain defects, it was concluded that rebridging ossiculoplasty for incudostapedial rebridging with ionomeric bone cement is a reliable method for ossicular reconstruction. It proved to be cost effective and offers satisfactory hearing results in selected patients when compared to the standard techniques of ossiculoplasty.

In a study by Essam Fatehy et al[15], successful hearing restoration was achieved after ossiculoplasty by glass monomer bone cement, 96% of the subjects were represented, out of which 52% of the patients showed a improvement in hearing of more than or equal to 10 dB and 26% of subjects had hearing improvement of more than 20 dB, and 18% of had hearing improvement of more than 40 dB, after a follow up period of 1 year.

In the study titled Hearing results according to ossiculoplasty techniques in chronic otitis media by Adil Eryılmaz et al16, it was concluded that the status of the handle of malleus was the most important predicting factor which influences the success of the surgical technique of ossiculoplasty. It stated that the usage of bone cement technique may rule out absorption and extraction of ossiculoplasty material-related problems in selected cases.

Beharey et al17, in their study conducted in Egypt, analyzed the hearing results after ossiculoplasty with, cortical bone autograft, bone cement and incus transposition. All of the three techniques were found to be reliable for ossiculoplasty, with a desirable post operative hearing outcome.

ANATOMY OF THE EXTERNAL EAR

PINNA:

The pinna (auricle) is made of fibrocartilage covered by skin, the cartilage continuous with that of the external auditory auditory canal. It is formed from the sixth gestational week from the six hillocks of His that arise from the first and second branchial arches that completes intrauterine development by 16 weeks[18]. The important function of the external is localization of sounds. The depressions over the lateral surface and the corresponding eminences over medial surface facilitates this function of localization of sounds.

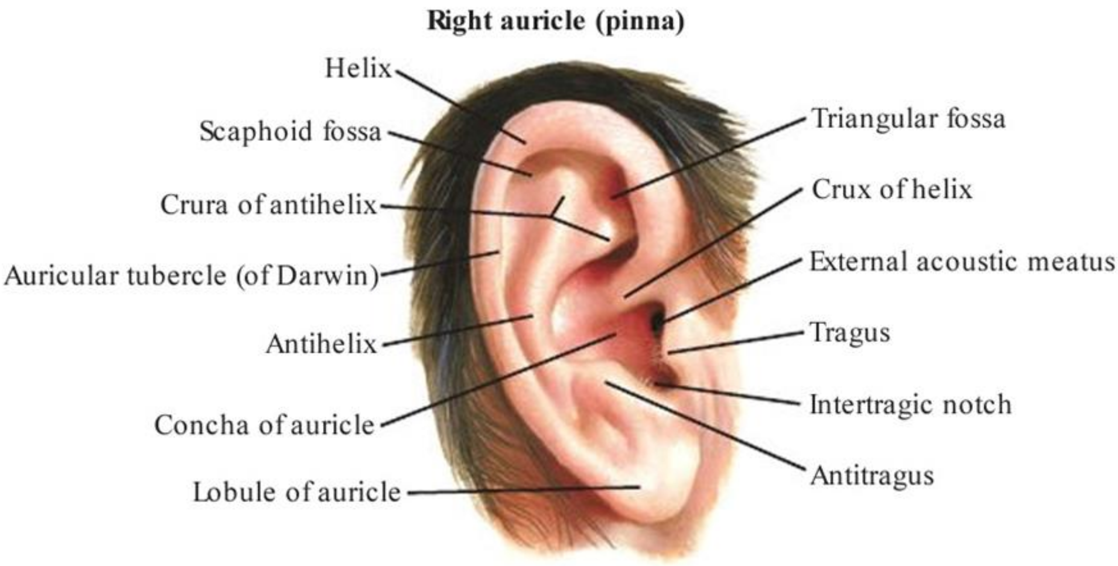


Figure 1: The pinna[21]

Branches of the external carotid artery supply the auricle[19]. The posterior auricular artery is the dominant one and supplies most part of the medial surface. The anterior auricular branch of the superficial temporal artery supplies rest of the auricle.

The superior auricular artery connects the network of posterior auricular artery and the superficial temporal artery. This branch proves to be reliable vascular pedicle for retroauricular flaps.

Somatic cervical nerves and the branchial nerves both supply the pinna[19]. The greater auricular nerve supplies the medial surface and posterior portion of the lateral surface. The lesser occipital nerve supplies the superior portion of the medial surface. The auricular branch of the vagus nerve supplies the concha and the antihelix. The auriculotemporal nerve supplies the tragus, crus of helix and adjacent helix. The facial nerve branches supplies a small region in the root of concha.

EXTERNAL AUDITORY CANAL:

The external auditory canal continues from the cartilage of pinna medially upto the tympanic membrane. It has a total length of 24mm, the lateral 8mm being the cartilaginous part and the medial 16mm being the bony part. It contains two sutures – the tympanosquamous anteriorly and the tympanomastoid posteriorly[20].

The area of skin between these suture lines forms the vascular strip. The external auditory canal transmits the sound collected by the pinna to the middle ear.

The blood supply of the external auditory canal is derived from the external carotid system[19]. Superficial temporal artery branches supply the roof and anterior walls of the canal. The deep auricular artery – branch of the first part of maxillary artery supplies the skin of the anterior meatal wall and the lateral surface of the tympanic membrane. The auricular branches of the posterior auricular artery supply the posterior wall of the external auditory canal.

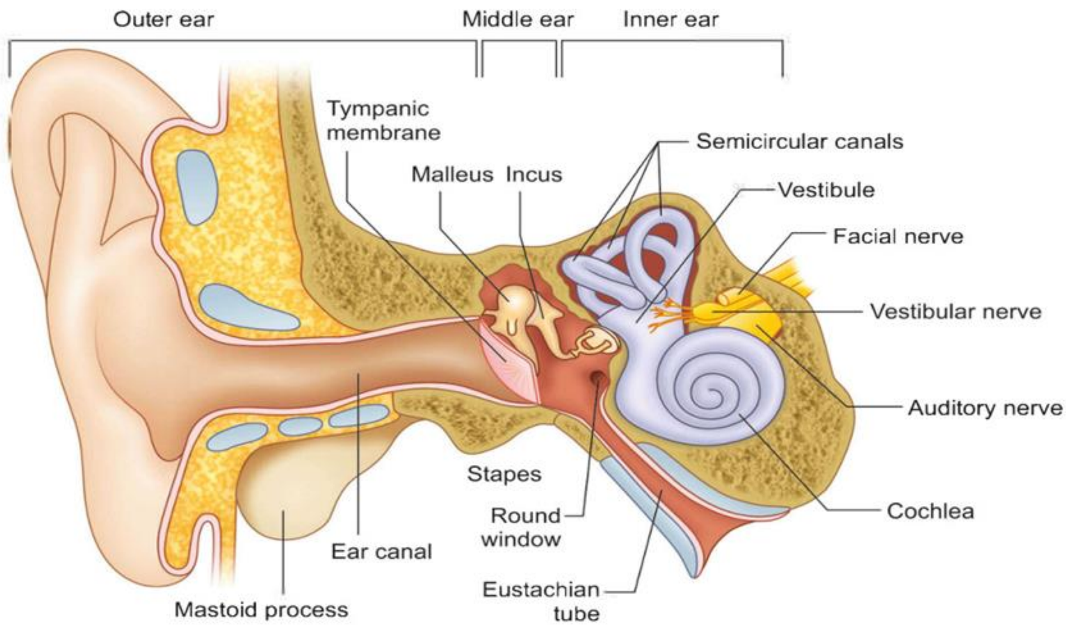


Figure 2: The external auditory canal[20]

Sensory innervation to the external auditory canal is from the trigeminal nerve, facial nerve, glossopharyngeal nerve and the vagus nerve.

TYMPANIC MEMBRANE:

The tympanic membrane (TM) is a trilaminar structure comprising three layers – the outer epithelial, middle fibrous and inner mucosal layer, all the three layers developing respectively from the ectoderm, endoderm, and mesoderm. The middle fibrous layer contains collagen fibres arranged in radial, circular and oblique patterns[22].

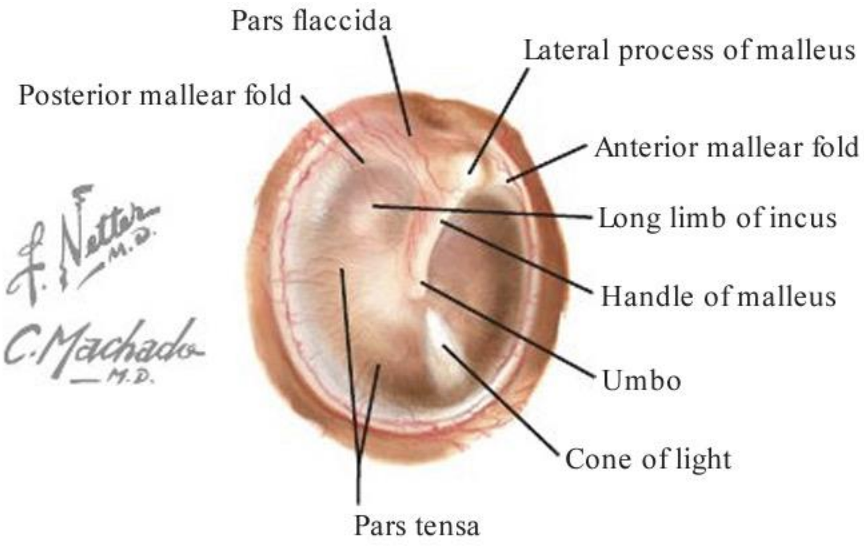


Figure 3: The right tympanic membrane [23]

It has a height of 9-10 mm, width of 8-9mm and thickness of about 0.1mm. The total surface area of TM being $90mm^2$, the functional area is $55mm^2$. It makes an angle of 55^0 with the inferior wall of EAC.

The upper part of the tympanic membrane above the malleal folds is called pars flaccida/ shrapnels membrane in which the middle fibrous layer is less marked. The pars flaccida is attached superiorly to the notch of rivinus. The trimeric inferior part is called the pars tensa.

Blood supply[19]: the inner surface of the tympanic membrane is supplied by the vascular anastomosis between the anterior tympanic artery and a branch from the stylomastoid artery. The outer surface is supplied by the arteria manubrio originating from the deep auricular branch of the internal maxillary artery.

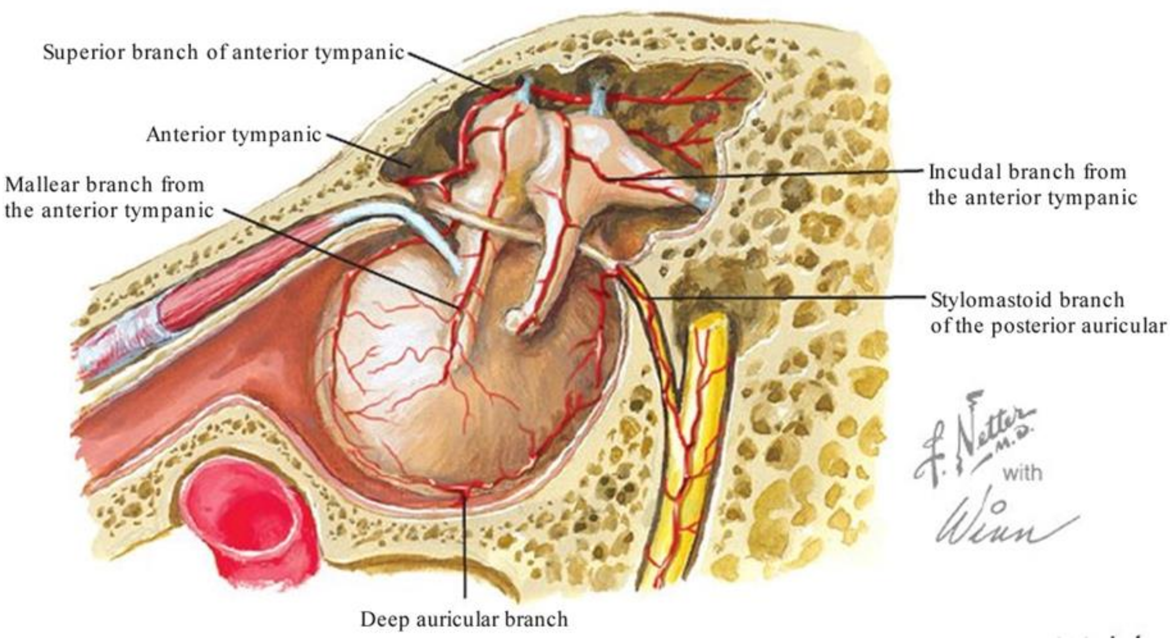


Figure 4: Blood supply of the tympanic membrane[23]

Nerve supply: the auriculo temporal branch of the V_3 supplies the anterior aspect of the external tympanic membrane. The auricular branch of the facial nerve supplies the posterosuperior part of the tympanic membrane. The auricular branch of the vagus nerve supplies the posteroinferior portion of the external tympanic membrane. The tympanic plexus innervates the inner surface of the tympanic membrane and the middle ear mucosa.

MIDDLE EAR:

The middle ear or tympanic cavity is a air filled cavity between the external and inner ear divided into three parts with four walls, a roof and a floor.

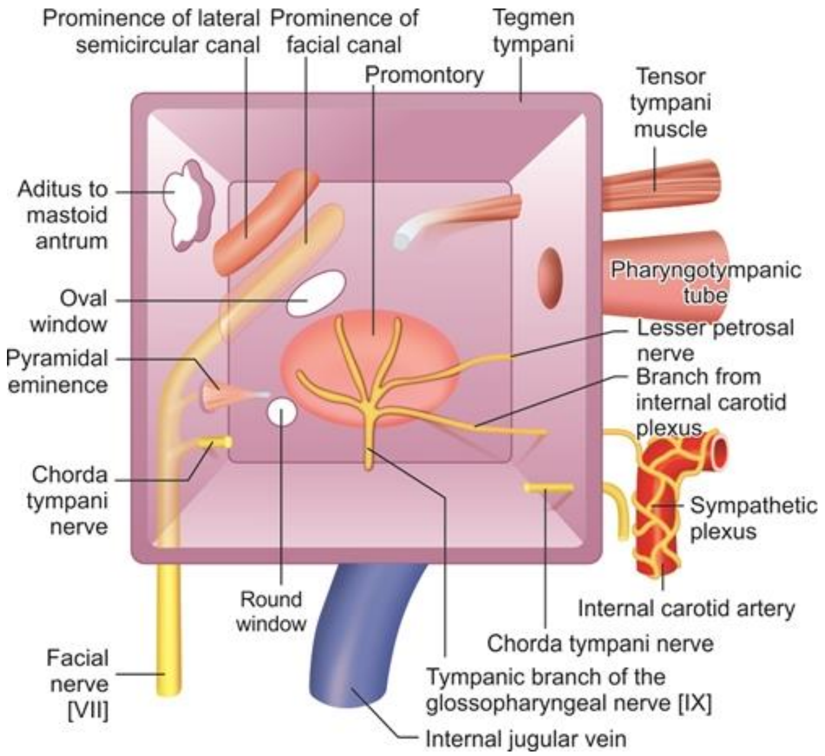


Figure 5: Middle ear

i. Epitympanum – the part of middle ear above the level of superior TM annulus .

ii. Mesotympanum – between the two horizontal lines drawn at the superior and inferior borders of the pars tensa.

iii. Hypotympanum – the part of the middle ear below the level of the bony ear canal or below the level of inferior TM annulus. Protympanum is the area of the middle ear surrounding the orifice of the eustachian tube. The middle ear has four walls, a roof and a floor[36].

Lateral wall:

The lateral wall of the middle ear is formed by the tympanic membrane, bony tympanic ring and the outer attic wall[24]. This the usually accessible wall in clinical e examination and the most common site of middle ear pathologies and provides the classical route of entry to the middle ear.

Inferior wall/floor:

The floor of the middle is narrow and consists of thin bony plate that separates the middle ear from the internal carotid artery anteriorly and the jugular bulb posteriorly[25]. The inferior tympanic canaliculus opens between the jugular fossa and carotid canal near the medial wall. It transmits the tympanic branch of the glossopharyngeal nerve – the jacobsons nerve. The surface of the inferior wall is irregular due to the underlying air cells.

Posterior wall:

This is the highest among the all wall of the middle ear[26], measuring about 14mm. it separates the middle ear from the mastoid air cell system except for the aditus, the passage that connects the mastoid antrum and the epitympanum. The upper part of the posterior wall that houses the aditus and the rest of the lower parts are separated by the incudal buttress that has the incudal fossa to lodge the short process of incus.

The eminences of the posterior wall are three in number namely the pyramidal eminence, the chordal eminence, and the styloid eminence. There are seven ridges that connect the eminences with one another and also with the medial wall (promontory and round window niche) – the chordal ridge of Proctor, the pyramidal ridge, the styloid ridge, the ponticulus, the subiculum, the fustis, the finiculus.

Superior wall/ roof:

It is called the tegmen and separates the tympanic cavity from the overlying middle cranial fossa dura and the temporal lobe. When intact the tegmen prevents infection of middle ear from entering the cranial cavity and also the herniation of the cranial contents. The part of the tegmen overlying the eustachian tube is called the tegmen tubari, the part above the tympanic cavity proper is called the tegment antri and that overlying the mastoid antrum is called the tegmen antri[27] .

Anterior wall:

The medial and lateral walls of the middle ear cavity converge anteriorly in an acute angle. Thus the anterior wall is very narrower.it is formed entirely from the petrous part of the temporal bone. It is divided into three portions – the lower, middle and upper portions. The lower portion is the largest and represents the anterior wall of the hypotympanum[28].

This plate has two openings transmitting the superior and inferior caroticotympanic nerves. The middle portions denotes the protympanuam and has two tunnels, the upper one transmitting the tensor tympani and the lower one corresponding to the bony portion of the eustachian tube. The upper portion of the anterior wall relates to the root of zygoma. The vertical portion of the carotid canal is separated from the middle ear by a thin bony plate that measures 0.25 mm in thickness.

Medial wall/ cochlear wall:

The cochlear promontory forms the major portion of the medial wall. The tympanic segment of the facial nerve, the oval and round windows, the canal for tensor tympani, the cochleariform process, the lateral semicircular canal are the several other important structures forming the medial wall of the tympanic cavity[29].

CONTENTS OF MIDDLE EAR

Ear ossicles – Malleus, Incus, Stapes

Intratympanic muscles – Tensor tympani, Stapedius

Nerves – chorda tympani, tympanic plexus

Mucosal folds and ligaments

OSSICLES:

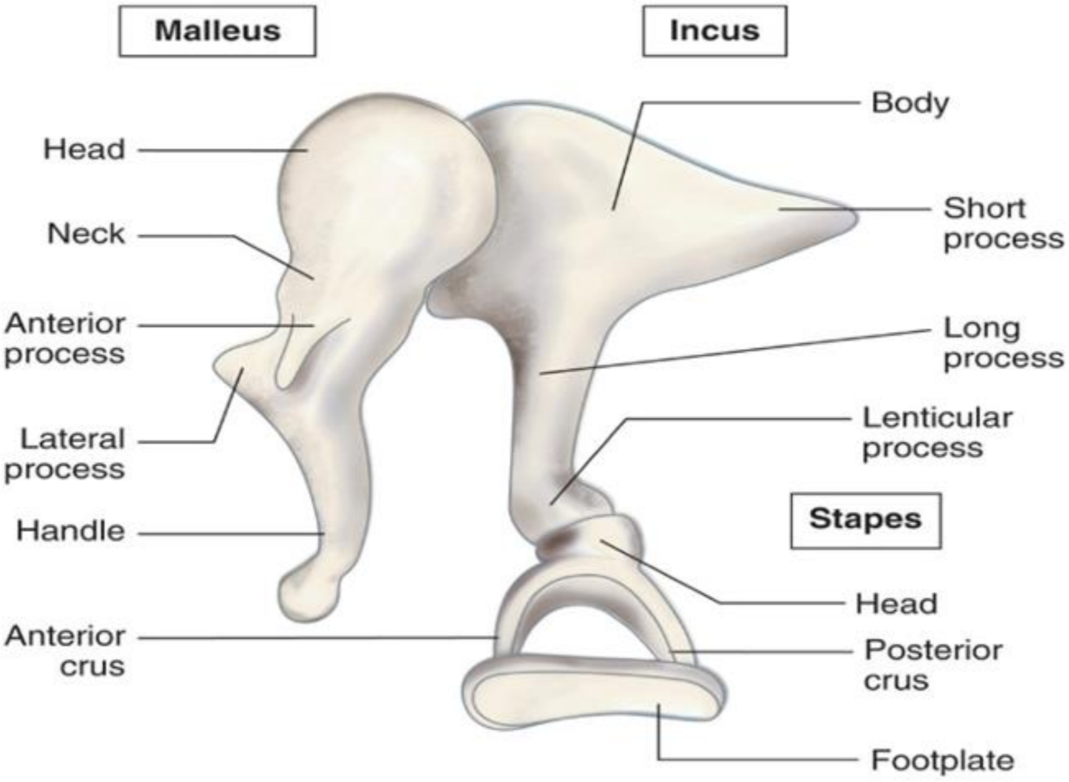


Figure 6: Middle ear ossicles

Auditory ossicles, three in number are suspended in the middle ear cavity by a number of suspensory ligaments and covered by the middle ear mucous membranes. These transmit the sound induced vibrations from the tympanic membrane to the inner ear fluids[37].

Malleus:

The malleus is the largest of all three ossicles and is shaped like a hammer. It measures 8-9 mm in length and weighs 20-25 mg. Parts of the malleus include head, neck, anterior process, lateral process and handle.

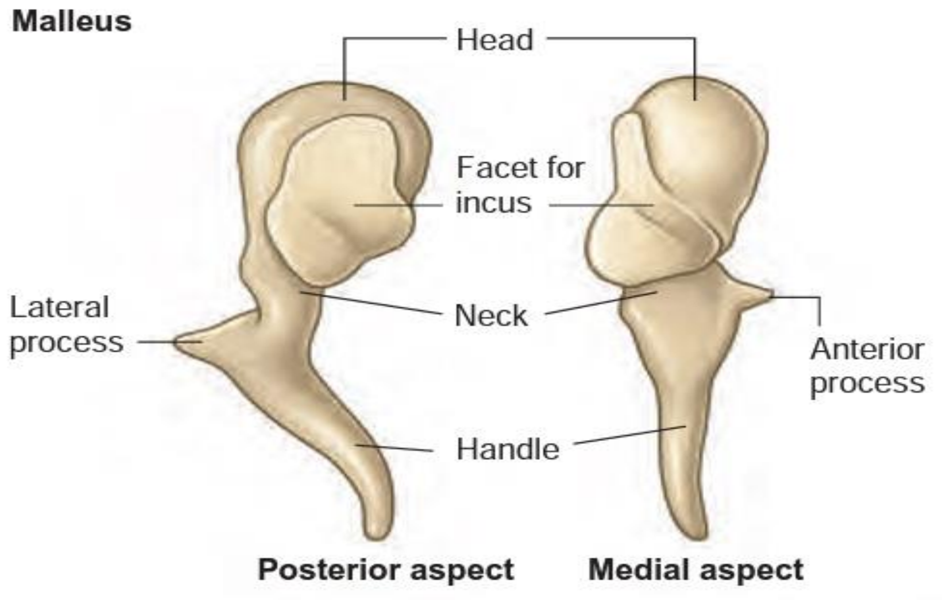


Figure 7: Malleus[30]

1.Head – it lies in the attic region and measures 2.5 * 2 mm in size. It bears an elongated facet on its posteromedial surface for articulation with the incus and forms incudomalleolar joint

2.Neck – this part of the malleus is narrow and falttened. The tensor tympani muscle inserts to the medial surface of the neck and the chorda tympani nerve passes above this insertion on its medial surface. The lateral surface of the neck forms the medial surface of the prussacks space.

3.Handle/ manubrium – it forms an angle of 135-140^0 with the head superoposteriorly. It runs in a downward, slightly backward and medial direction between the middle and inner layers of the tympanic membrane

4.Lateral process – it is a small conical eminence measuring 1mm. the anterior and posterior tympanomalleal ligaments get attached to the lateral process

5.Anterior process – also known as the processus gracilis. It is 3-5 mm long bony spine that extends from the neck of malleus anteriorly into the glasserian fissure. The anterior mallel ligament takes its origin from here

6.Malleus ligaments – stabilization to the malleus is provided by five ligaments namely the anterior suspensory ligament, the lateral suspensory ligament, the superior suspensory ligament, anterior malleal ligament, posterior malleal ligament, the superior malleal ligament

Incus:

It has a trapezoid shaped body, a short process, a long process and a rounded lenticular process, with a size of 5*7 mm an weight of 30mg

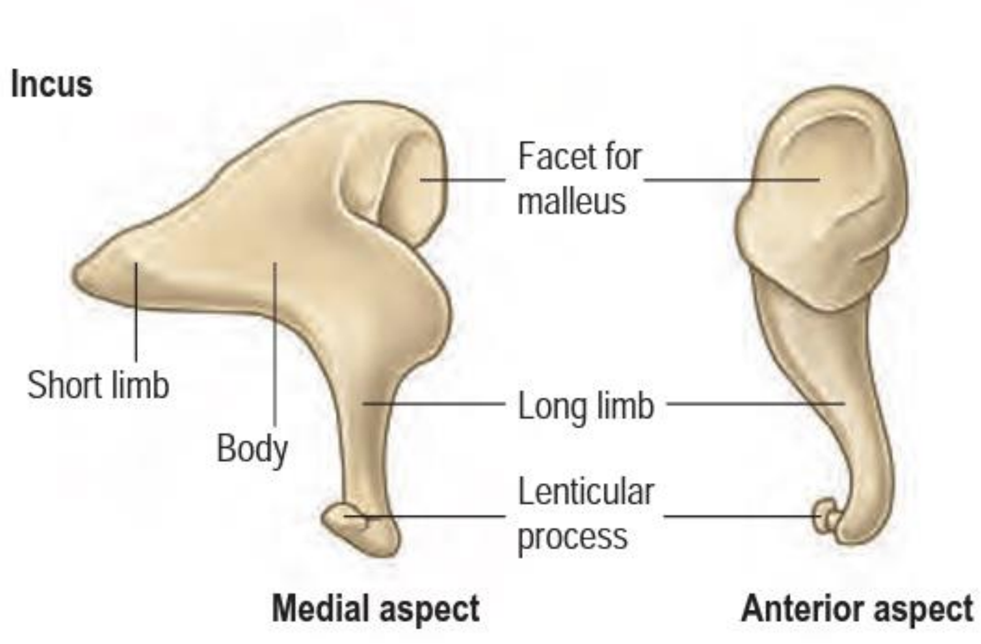


Figure 8: Incus[30]

1.Body – the anterior surface has an elliptical articular surface for the malleus. Two processes arise from the lower posterior part of the body of the incus – the short and long process that are at right angles to each other.

2.Short process – it extends posteriorly as a thick and triangular process. The dorsal end lies in the floor of incudal fossa situated in the posterior wall in the floor of aditus.

3.Long process – its direction is similar to the handle of malleus but a little posterior and medial. Its lower end forms a hook at right angle and continues as the lenticular process. The terminal end has tenuous blood supply and this leads to the high susceptibility of secondary osteitic resorption.

4.Lenticular process – it connects the long process to the head of stapes. It has a narrow bony pedicle and a flattened distal plate. It is often referred to as the fourth ossicle. This helps in the piston like transmission movement of incus with the stapes.

5.Ligaments of incus – these include the posterior incudal ligament and the superior incudal ligament.

Stapes:

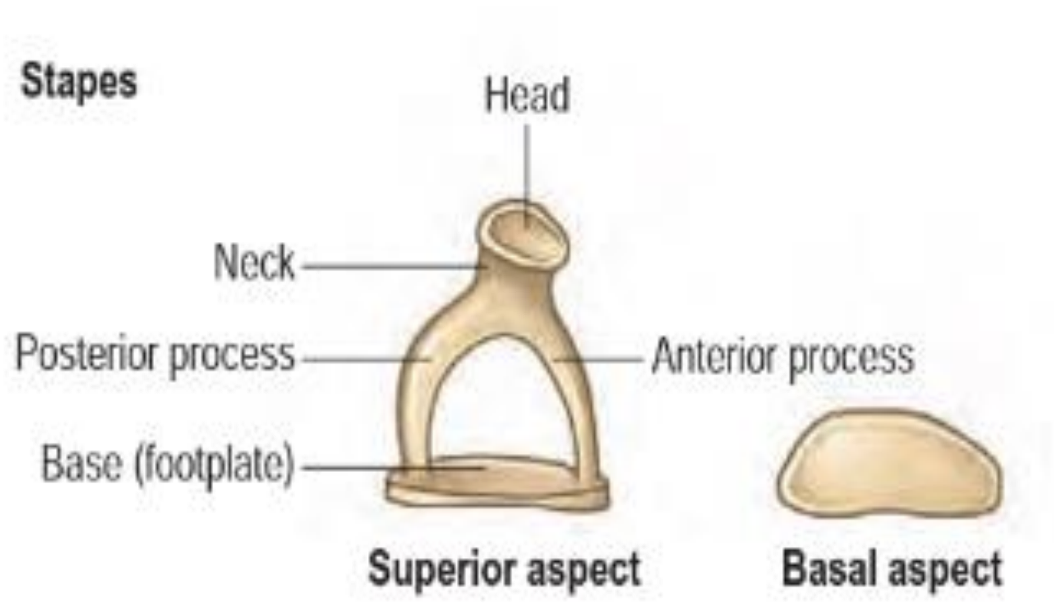


Figure 9: Stapes[30]

The stapes is the smallest bone of the human body weighing approximately 2.4mg and 3.25 * 1.4 mm in size, situated in an almost horizontal plane. It consists of a rounded head, a shorter neck, anterior and posterior crura, and an oval foot plate.

1. **The head** – it is the most lateral part and is cylindrical and discoid in shape. It bears a glenoid cavity – the fovea, that in correspondence to the lenticular process of the incus.
2. **The crura** – the stapes presents with two unequal crura, the posterior one being longer, thicker and more curved than the anterior.
3. **The foot plate** – it is a thin, oval lamellar bone. Length is about 3mm and width about 1.5 mm, thickness of about 0.25mm. the lateral surface of the foot plate is covered by the middle ear mucosa. The medial or the vestibular surface is flat and lined by the endosteum of the otic capsule.

4. **The annular ligament** – it is a fibroelatic ring that attaches the margin of foot plate to the margin of the oval window. It fuses with the periosteum and endosteum all around the borders of the oval window. This allows for the rocking oscillation of the foot plate in the oval window.

OSSICULAR ARTICULATIONS

Incudomalleal articulation:

It is situated in the epitympanum and classified as a synovial joint. The head of the malleus articulates with the body of incus. The synovial cavity of the joint is lined by a synovial membrane and a articular cartilage and has a saddle shaped surface. The capsule of the joint is trilaminar and contains the mucous membrane of the middle ear, the synovial membrane and the fibrous layer that intervenes.

Incudostapedial articulation:

It is a synovial diarthrodial articulation, forming a ball and socket joint joining the lenticular process of the incus and the concave surface of the head of stapes. A fibrous capsule covers the outer surface of the joint. The delicacy of this joint makes it the most often involved joint in fractures.

Stapediovestibular joint:

It is the joint between the stapes foot plate and the oval window. The annular ligament holds the foot plate and the oval window borders together. It is actually a half joint (syndesmosis).

INTRATYMPANIC MUSCLES

The tensor tympani:

The tensor tympani develops from the first branchial arch.it is innervated by a branch from the trigeminal nerve[19]. It is a slender and long muscle originating from the bony walls of eustachian tube. The greater wing of sphenoid and the cartilaginous portion of the eustachian tube may also give origin to some parts of the muscle. From its origin it passess backwards into the middle ear space and lies in the medial wall of the middle ear below the tympanic segment of the facial nerve. It then enters the processus cochleariformis and takes a right angled course to insert to the medial aspect of the upper part of the handle of malleus.

Contraction of the tensor tympani pulls on the malleus to dampen the tympanic membrane.

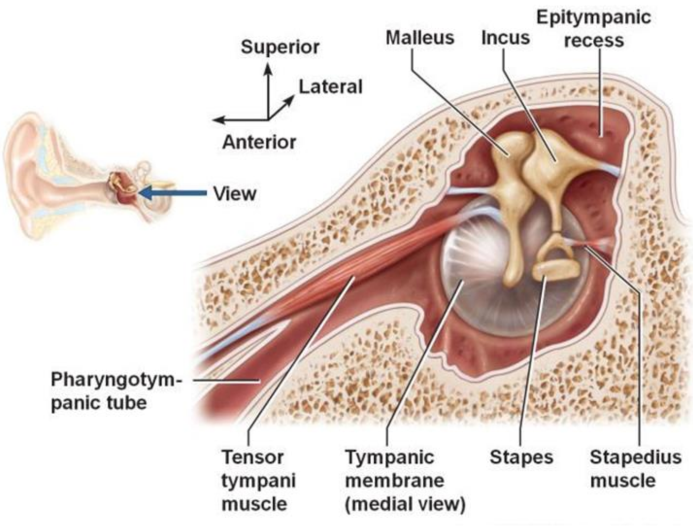


Figure 10: Middle ear muscles

The stapedius muscle:

The stapedius muscle develops from the second branchial arch and is supplied by the facial nerve.

It arises from the walls of the conical cavity within the pyramid and passes in front of the descending part of the facial nerve[19]. A thin tendon arises from the apex of the pyramidal process and inserts into the neck of the stapes. Contraction of the stapedius tilts the stapes and protects the inner ear from loud noises.

MIDDLE EAR NERVES

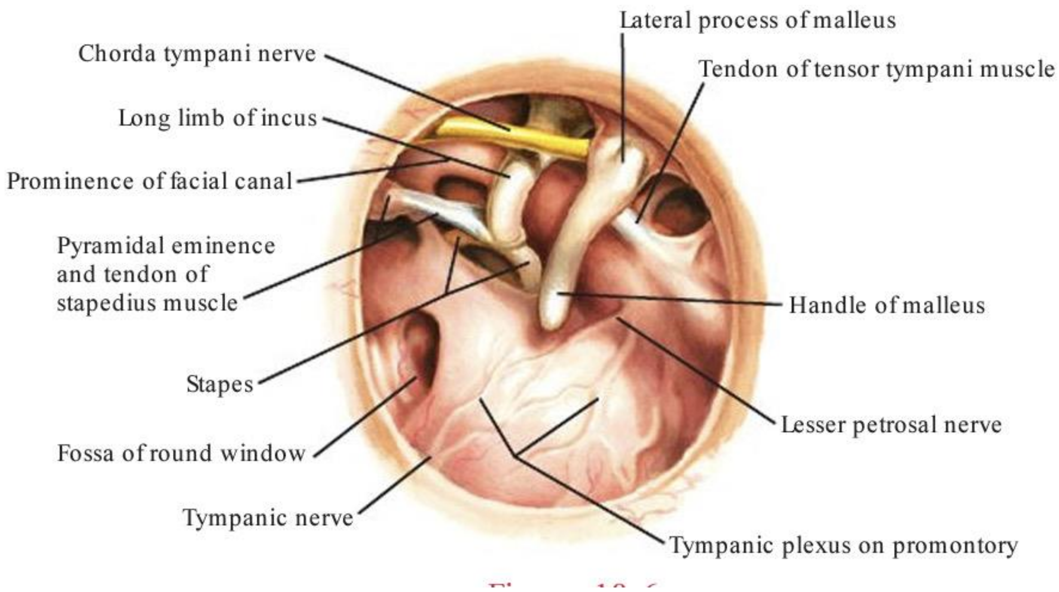


Figure 11: Nerves of the middle ear

The chorda tympani nerve:

It is a branch of the facial nerve that enters the tympanic cavity from the posterior canaliculus which is at the junction of the posterior and lateral wall of the middle ear. It runs along the inner surface of the tympanic membrane between the inner mucosal layer and the middle fibrous layer[19]. it passes medila to the upper portion of the handle of malleus above the tendon of tensor tympani. It continues anteriorly further forwards and leaves the middle ear from the anterior canaliculus.

The tympanic plexus:

The tympanic plexus is formed by the tympanic branch of the glossopharyngeal nerve (IX CN) – the jacobsons nerve, and by the caroticotympanic nerves[19] that enter the middle ear after arising from the sympathetic plexus around the internal carotid artery. A plexus is formed over the promontory and supplies the eustachian tube, mucosal lining of the middle ear, the mastoid antrum and air cells. It also gives branches that joins with the greater and lesser superficial petrosal nerves.

EUSTACHIAN TUBE

The eustachian tube also called the pharyngotympanic tube, connects the nasopharynx with the middle ear cavity. It measures approximately 36 mm in the adult populations. The opening in the nasopharynx lies behind the posterior end of the inferior turbinate. The opening in the tympanic cavity is at a higher level. The posterolateral or upper one third of the tube is bony and measures 12 mm. The lower two thirds is cartilaginous and measures 24 mm.

The pharyngeal ends of the tube bears the tubal tonsils and there is fibrofatty tissue in relation to the membranous portion called the Ostmann’s pad of fat ehich prevents the nasopharyngeal reflux.

Arterial supply[19]: ascending pharyngeal, middle meningeal and sometimes from the artery of the pterygoid canal.

Functions :

i. Equalizes the middle ear pressure and the atmospheric pressure and helps in ventilation of the middle ear.
ii. Prevents the nasopharyngeal reflux of secretions
iii. Clears the secretions from the middle ear

INNER EAR

The inner ear lies inside the petrous temporal bone between the internal acoustic meatus and the medial wall of the middle ear[18]. It comprises

1. The bony labyrinth that has a central part known as vestibule which is connected anteriorly to the bony cochlea and posteriorly to the three bony semicircular canals.
2. The membranous labyrinth has structures named similar to that of the bony labyrinth. It floats within the perilymph of the bony labyrinth and contains endolymph within.

BONY LABYRINTH

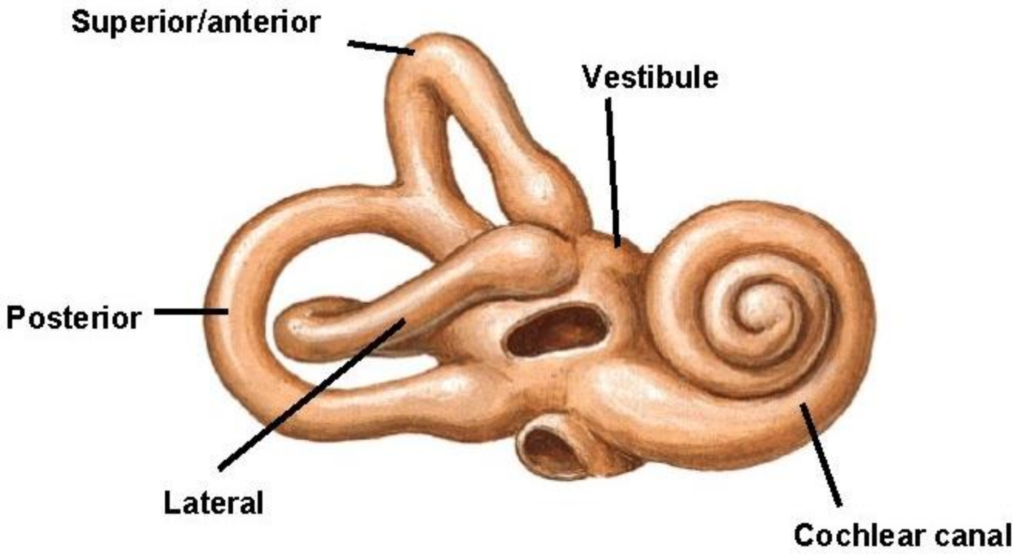


Figure 12: Bony labyrinth

Bony vestibule:

The bony vestibule is the central part. The fenestra vestibuli opens into the lateral part. There is a depression called spherical recess in the front half of the medial wall which is the space for saccule. It is perforated by tiny minute holes called the macula cribrosa media for the passage of the inferior vestibular nerve filaments. There is another elliptical depression behind this for the utricle. There is a diverticulum below the elliptical recess called the aqueduct of vestibule.

Semicircular canals:

The semicircular canals are three in number – superior, posterior or vertical, horizontal or lateral. All of the three canals has a dilation at one end called the ampulla which contains the sensory epithelium.

The angle formed by the three semicircular canals is the solid angle. Trautmann's triangle is the area bounded by the bony labyrinth anteriorly, sigmoid sinus posteriorly and the middle cranial fossa dura superiorly

Cochlea:

It forms the anterior part of the bony labyrinth and resembles a common snail. It is hollow tubular structure with 2.5 to 2.75 turns which turns around a central axis called the modiolus. The osseous spiral lamina winds around the central stalk along the basilar membrane and divides the cochlea into scala media and scala tympani. The three longitudinal channels along the full length of the cochlea are scala vestibuli above, scala tympani below and scala media in between.

MEMBRANOUS LABYRINTH

Membranous vestibule:

It comprises of

i. Saccule
ii. Utricle
iii. The endolymphatic duct and sac

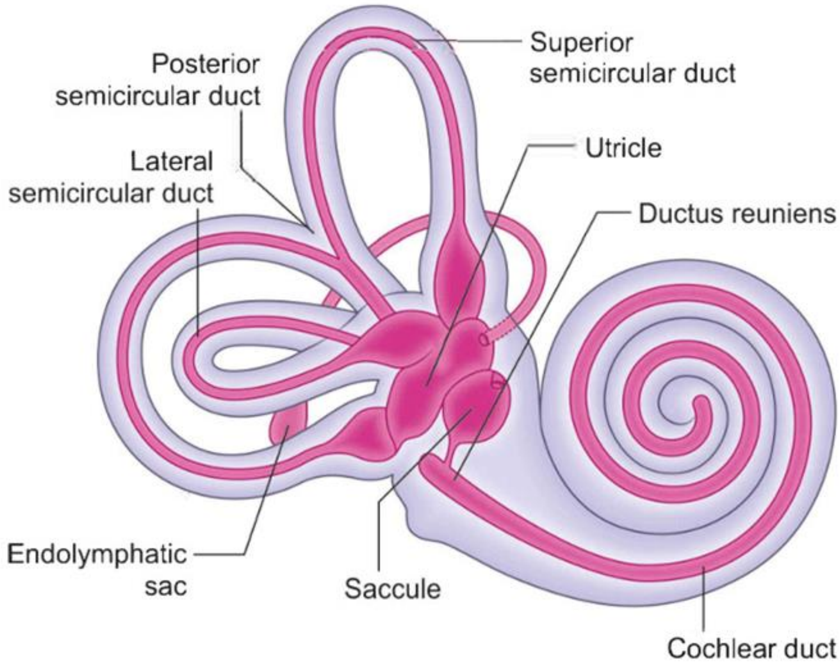


Figure 13: Membranous labyrinth[20]

The vestibular receptor organs of the saccule and utricle are called macula. It is responsible for the linear accelerations.

Membranous semicircular canals:

It is suspended within the bony semicircular canals and opens into the posterior wall of the utricle through 5 openings. The sensory epithelium of the ampullae of the semicircular canals is called the crista. The gelatinous extracellular matrix in the criste is dome shaped and called the cupula.

Membranous cochlea:

It occupies the middle part of the cochlear canal. Floor of this triangular cross section is the basilar membrane and roof formed by the reissners membrane. Lateral wall is formed by the stria vascularis and the cochlear bony wall.

The organ of corti is the sensory organ of hearing and rests over the basilar membrane.

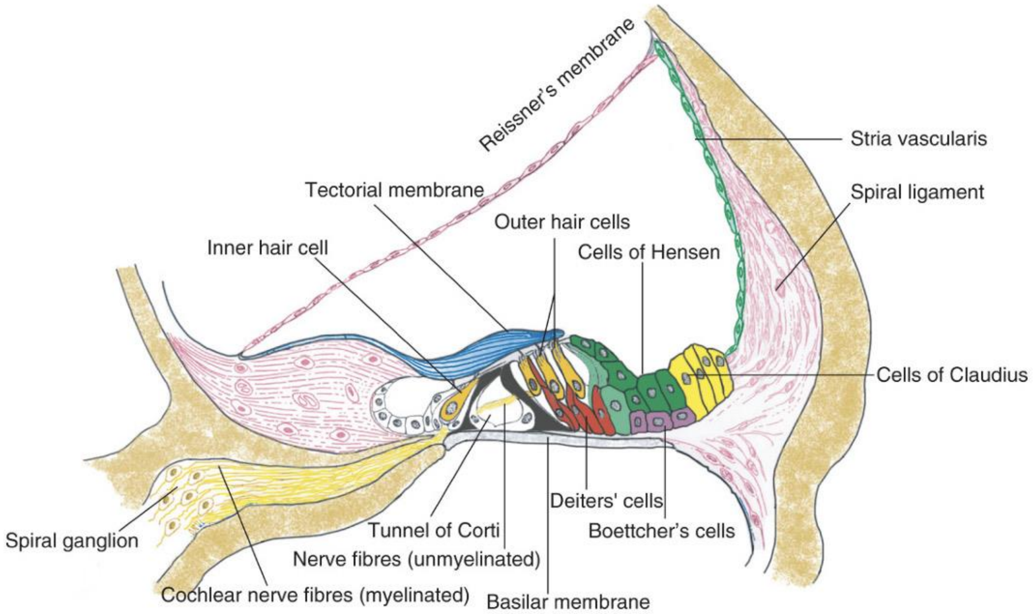


Figure 14: The organ of corti

It has two types of sensory receptors, the outer and inner hair cells. Hair cells are supported by pillar cells, hensens cells and deiters cells. The upper ends of the outer hair cells are attached to the lower surface of the tectorial membrane. The hair cells are stimulated by the shearing forces between the tectorial membrane and the hair cells.

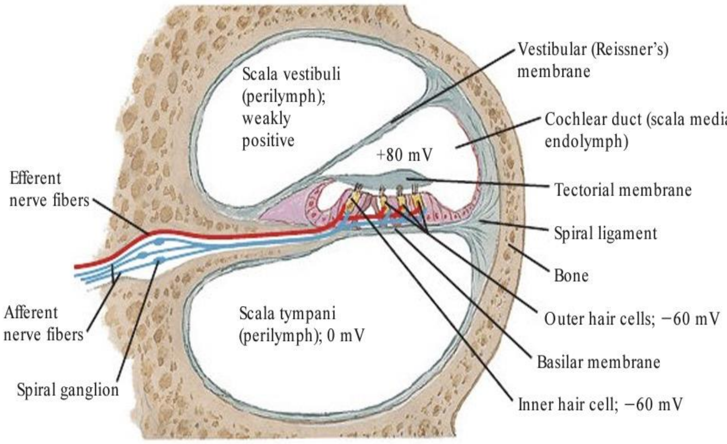


Figure 15: Mechanoelectrical transduction[23]

Blood supply of the inner :

The internal auditory artery arises from the anterior inferior cerebellar artery (AICA). It divides into three branches to supply the inner ear

i. Anterior vestibular artery, that supplies the macula of the utricle and saccule and the cristae of lateral and superior semicircular canals.

ii. Vestibulocochlear branch that supplies the posterior semicircular canal.

iii. Cochlear branch that supplies the cochlea.

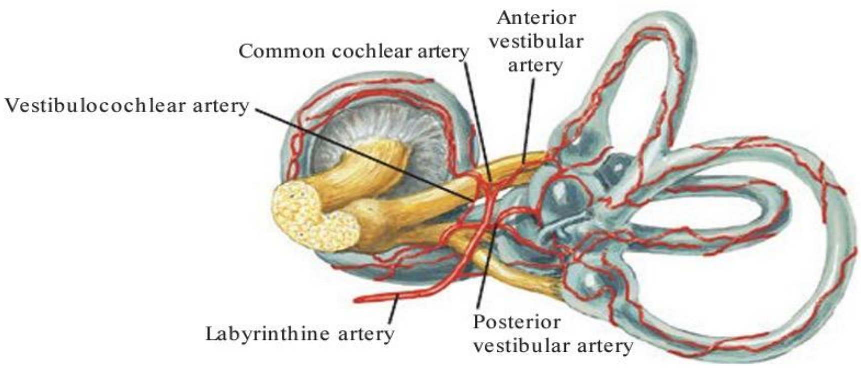


Figure 16: Blood supply of the inner ear[23]

AUDITORY PATHWAY

The spiral ganglion bears the first order neurons that are bipolar. The central process of the neuron terminates in the dorsal and ventral cochlear nuclei and the peripheral processes innervate the hair cells in the organ of corti[18]. Second order neurons are found in the dorsal and ventral cochlear nuclei and most of them terminate in the superior olivary nucleus. Third order neurons lie in the superior olivary nucleus. Fourth order neurons lie in the inferior colliculus. Fifth order neurons lie in the medial geniculate body.

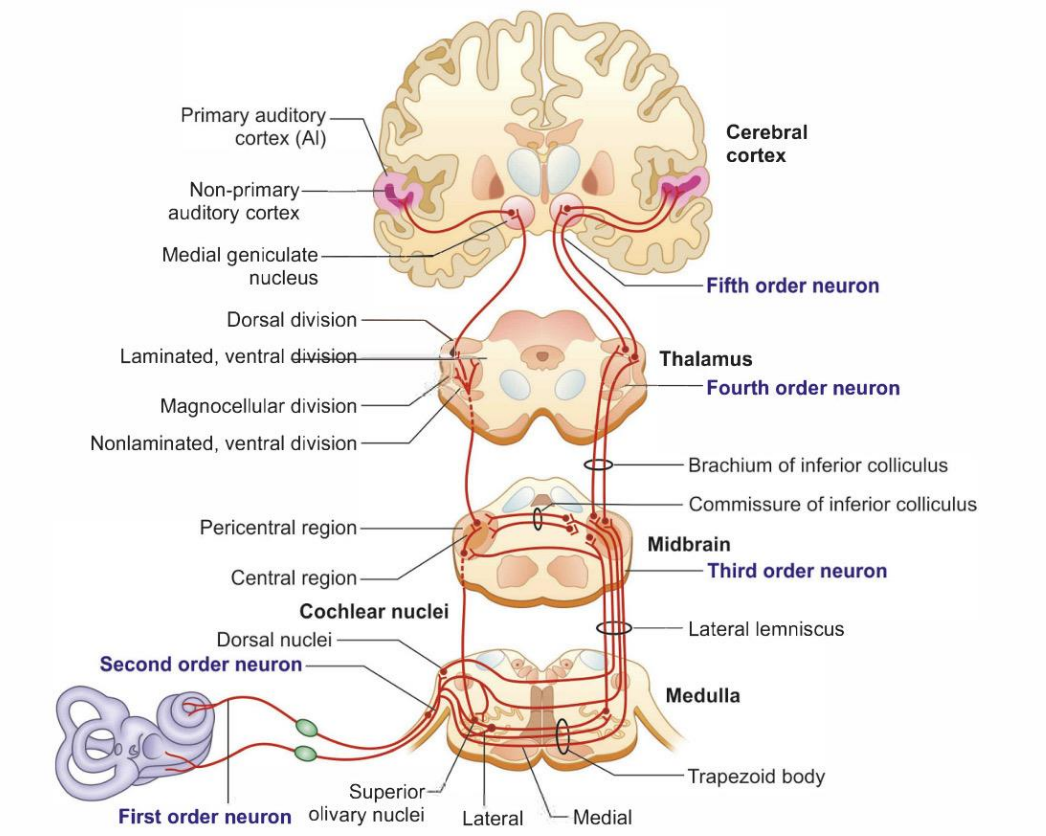


Figure 18: The auditory pathway[18]

PHYSIOLOGY OF HEARING

Hearing occurs only if the basilar membrane is made to vibrate. Therefore there must be established a pressure difference between the oval window and the round window. As the fluid inside the inner ear is incompressible, two windows are essential so that the round window can act as a relief valve. The sound while hitting a medium can either be absorbed or reflected depending on the resistance of the medium. This resistance existing in a medium is called as resistance or impedance. The function of the middle ear to compensate the loss of sound energy by converting sounds with greater amplitude and less force into sounds with lesser amplitude and greater force is called as impedance matching.

External ear:

The pinna helps in localization of sounds in relation to the direction of head. The conchal bowls perform like a megaphone and concentrates the sound energy that enters the external ear from the environment. This property of the pinna increases the sound pressure as much as 6dB. The external auditory canal also can increase the sound pressure at the tympanic membrane by 15 to 22 dB at 4000 Hz.

Middle ear transformer mechanism:

Sound is amplified by the middle ear before reaching the inner ear which is frequency dependent. It is 20dB at 250-500 Hz, 28 dB at 1000 Hz, and decreases at high frequencies about 6 dB for each additional 1 kHz above 1000 Hz. There are three mechanisms that exist for sound amplification. These include hydraulic lever, catenary lever and lever action of the ossicles.

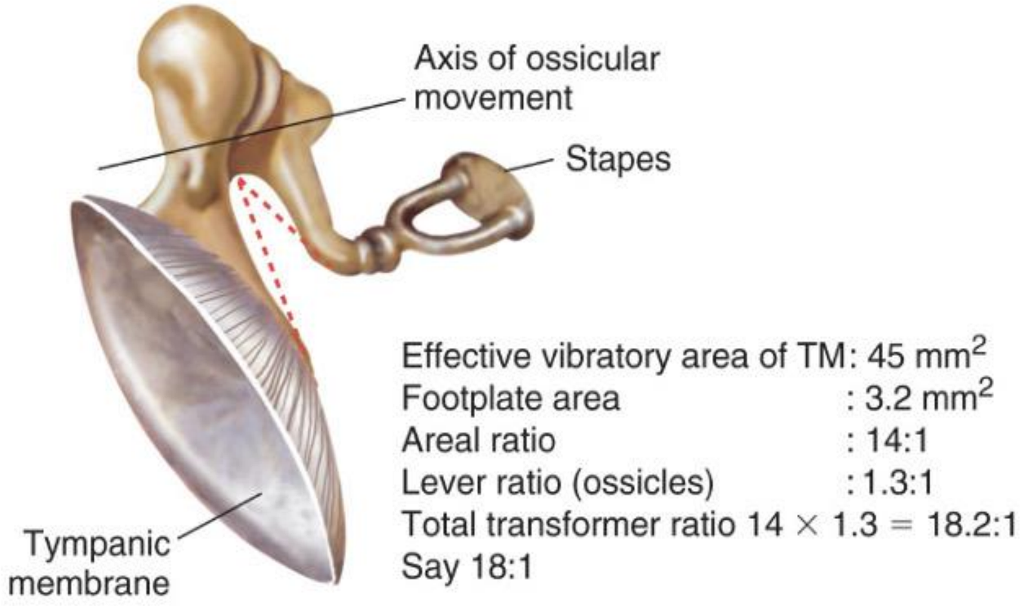


Figure 19: Transformer mechanism[20]

CATENARY LEVER:

The sound power in the external auditory canal is matched with the annulus of the tympanic membrane as the annulus is immobile and sound is directed in wave forms from the periphery to the centre[31].

The attachment of the tympanic membrane at the annulus is responsible for the amplification of sound energy at the malleus because of the elastic properties of the stretched fibres.

This makes the basis of the catenary lever action which is nothing but the ratio of force acting on the tympanic membrane to that acting on the malleus. Large displacements near the tympanic annulus produces small displacements of the malleus. This makes the tympanic membrane itself to increase the force when it moves. Thus this buckling effect increases the pressure by a factor of 2 = 6 dB.

HYDRAULIC LEVER ACTION:

The size difference between the tympanic membrane and the foot plate of the stapes is responsible for the hydraulic lever action. The sound pressure over a large area of tympanic membrane is transmitted to a smaller area of the foot plate results in increase in force that is proportional to the ratio of two areas.

The effective vibratory area of the tympanic membrane is 45 mm^2. The area of the foot plate is 3.25 mm^2. Therefore the effective areal ratio is 14:1. The product of areal ratio and the lever ratio (1.3) gives the hydraulic ratio that is 14 * 1.3 = 18:1.

An intact mobile tympanic membrane and an integrated ossicular function and mobility with normal middle ear volume and ventilation are the essential requirements for the normal catenary lever function of the middle ear.

OSSICULAR COUPLING

It is the sound pressure gain obtained when sound travels from tympanic membrane through the ossicles. It is frequency dependent and hence not 34 decibels always; like 20 decibels with 250 to 500 Hz and 25 decibels at 1000 Hz. Thereafter it decreases 6 decibels for every octave. This is due to the fact that at higher frequencies the tympanic membrane vibrates at different portions and also ossicular chains slips at higher frequencies

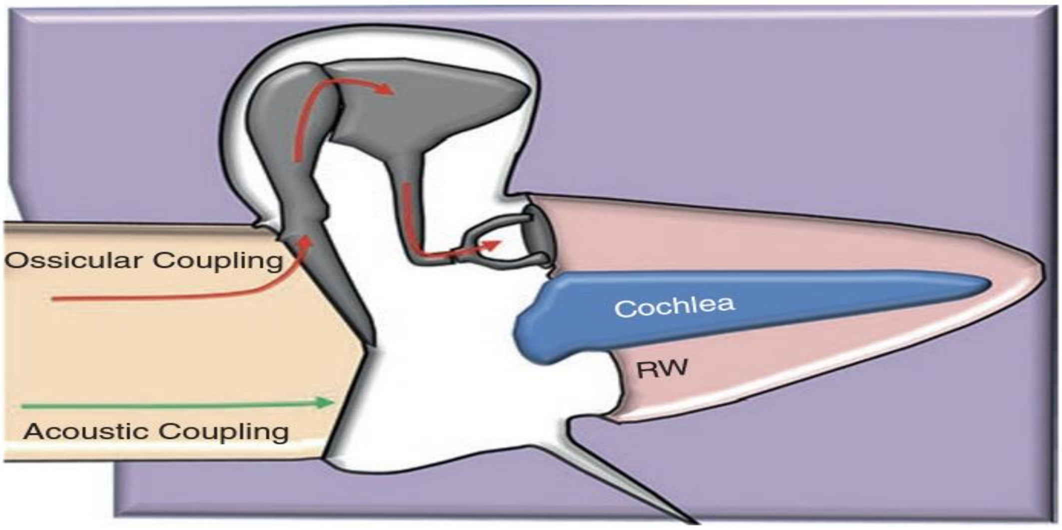


Figure 20: Ossicular and acoustic coupling[31]

ACOUSTIC COUPLING

Acoustic coupling is another mechanism for the stimulation of sounds in the inner ear. Sound pressure acting on oval and round window are not identical. This is because the oval window and round window are separated by few millimetres and are also at different orientation relative to the tympanic membrane. In normal ears, the pressure between both windows are negligible, but is significant in case of some diseased and operated ears that is enough to cause hearing loss. Acoustic coupling is 60 dB lesser than ossicular coupling.

MIDDLE EAR VENTILATION

The middle ear is ventilated via the eustachian tube. The upper unit of the middle ear – the epitympanum/attic is ventilated by two routes.

1. The anterior route: from the protympanum to the supratubal recess (STR) to the anterior epitympanic recess (AER) and the attic through an incomplete

tensor tympani fold (TTF). When the tensor tympani fold is complete, the posterior route is the only source of ventilation

2. The posterior route: through the anterior tymapanic isthmus and the posterior tympanic isthmus.

ETIOPATHOGENESIS OF OSSICULAR CHAIN ABNORMALITIES

Conductive hearing loss due to ossicular chain abnormalities may be due to the fixation or discontinuity of the ossicular chain. Ossicular fixation may be due to

1. Head of malleus fixation
2. Scarring of the mucosal folds/ bands
3. Tympanosclerotic changes of the ossicles

Ossicular discontinuity may be due to:

1. Trauma
2. Chronic otitis media leading to erosion
3. Cholesteatoma leading to erosion

Congenital:

Minor or malformations of the middle ear sometimes involving the tympanic membrane and external ear[32]. Outcomes after reconstruction depends on the severity of the malformation. The ossicular status, presence of round window, middle ear space pneumatization, facial nerve course are the major determinants.

Jahrsdoerfer grading system can be used for the prediction of hearing outcomes. The most common isolated middle ear abnormality is the fixation of stapes foot plate which may occur alone or in association with other ossicular abnormalities. Surgeries for congenital ossicular malformations should be taken with the back up of air conduction or bone conduction hearing aids.

Acquired:

The major and frequent cause is chronic otitis media with or without cholesteatoma. The most common ossicular abnormality being the erosion of long process of incus which may be localized to the incudostapedial joint (ISJ)[32] or can extend superiorly. Stapes superstructure can get eroded partially or completely and malleus handle is least affected ossicle. Discontinuity of the ossicles secondary to trauma may occur following direct injury to the ear drum, following barotrauma, or temporal bone fracture[33]. Idiopathic ossicular chain disruptions in the absence of any middle ear disease is rarely reported in the literature

ASSESSMENT OF OSSICULAR PATHOLOGY

1. Complete otologic and medical history
2. General examination
3. Clinical examination
    i. Otoscopic or microscopic examination
    ii. Pneumatic otoscopy
    iii. Eustachian tube function
4. High resolution computed tomographic scan of the temporal bone helps in identification of the ossicular erosions and also to rule out any inner ear or middle ear lesions.
5. Pure tone audiogram: ossicular discontinuity in the presence of an intact tympanic membrane results in a flat audiogram with 60 dB air bone gap. In the presence of tympanic membrane perforation may result in air bone gap of 40 to 50 dB.
6. Impedance audiometry: may show an Ad type of curve in the presence of ossicular erosion or discontinuity.

MATERIALS AND METHODS

This study was carried out in the Department of ENT, Govt. Rajaji hospital and Madurai Medical College, Madurai.

Study period

August 2020 to July 2021

Study design

Prospective observational study who underwent bone cement ossiculoplasty in our hospital

Study population

Consisted of patients who attended the ENT outpatient department at Government Rajaji hospital with chronic otitis media and ossicular erosion.

Sample size

40

Financial support

Self

INCLUSION CRITERIA :

1. Age between 18 years and 50 years.
2. All cases of Chronic suppurative otitis media –safe type and unsafe type with ossicular erosion.

3. Pure tone audiogram with more than 40dB of conductive hearing loss.

4. All cases with ossicular damage as diagnosed by otomicroscopy and HRCT temporal bone findings.

5. Patients with no active discharge for a period of three weeks

6. Good Eustachian tube function evidenced by diagnostic nasal endoscopy

7. No other external ear, middle ear or inner ear pathology.

EXCLUSION CRITERIA :

1. Patients less than 18 years and more than 50 years
2. Patients with sensorineural hearing loss
3. Chronic otitis media with intracranial and extra cranial complications
4. Uncontrolled metabolic conditions
5. Patients with congenital atresia or ossicular fixation

A total of 30 patients who attended the outpatient department satisfying the above criteria were selected for the study. Complaints and a detailed otologic and medical history was elicited and they were subjected to a detailed clinical examination of the ear, nose and throat.

The size and site of the perforation , middle ear mucosal status , ossicular chain status were examined using otoscope and findings were recorded. Otoendoscopy was done to confirm the clinical findings. Tuning fork tests were done using 256 Hz, 512 Hz and 1024 Hz tuning fork and findings were documented.

All patients were subjected to pure tone audiometry, and graphical recordings of their hearing thresholds were made. Pure tone averages and air bone gap were calculated. Impedance audiometry was done and findings documented.

X ray mastoids plain both sides oblique and lateral views were taken for each patient. Diagnostic nasal endoscopy was done to assess the pharyngeal end of the Eustachian tube and to rule out nasal and nasopharyngeal foci of infection. HRCT scan of the temporal bone was taken for each and every patient before undergoing surgery to know about middle ear and ossicular status and also to rule out cholesteatoma and congenital anomalies of the ear if any.

Systemic examination and investigations were done to assess fitness for surgery. Patients were explained about the surgery and informed written consent was obtained. Patients were posted for cortical mastoidectomy with tympanoplasty and ossiculoplasty using hydroxyapatite bone cement under general anaesthesia.

PROCEDURE ADOPTED

After getting done all the above investigations and obtaining written informed consent for surgery, all patients were operated under general anesthesia.

Figure 21: Surgical site preparation

Figure 22:

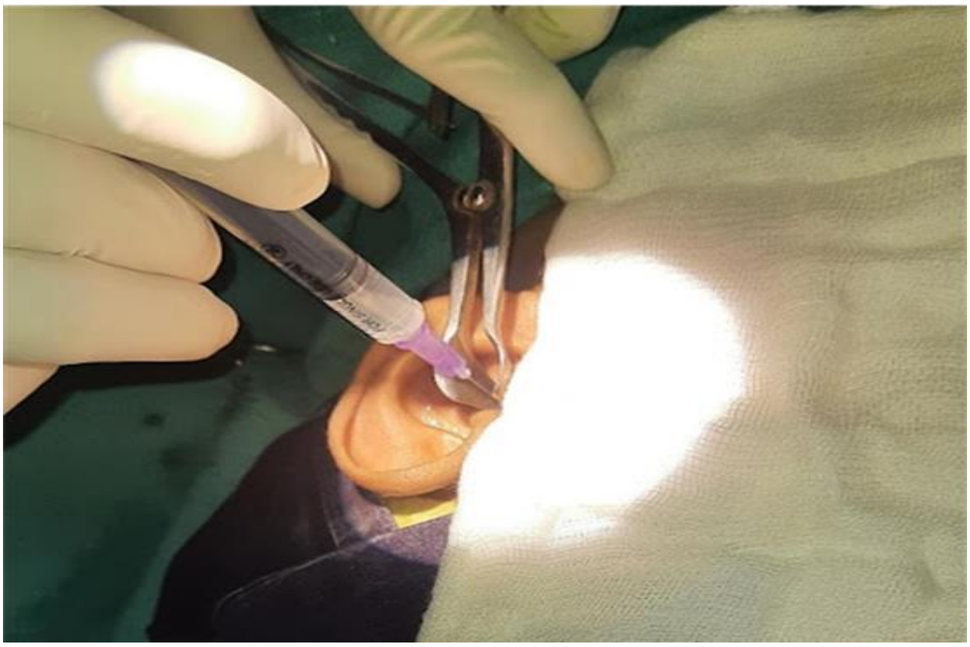


Figure 23:

Figure 22 and 23: Local infiltration with 2% lignocaine and 1 in 200000 adrenaline was given in the post auricular region and 3, 6, 9, 12 o' clock positions of the external auditory canal.

Figure 24: William wilde's post auricular incision

Figure 25:

Figure 26:

Figures 25 and 26: temporalis fascia graft harvested and let dry

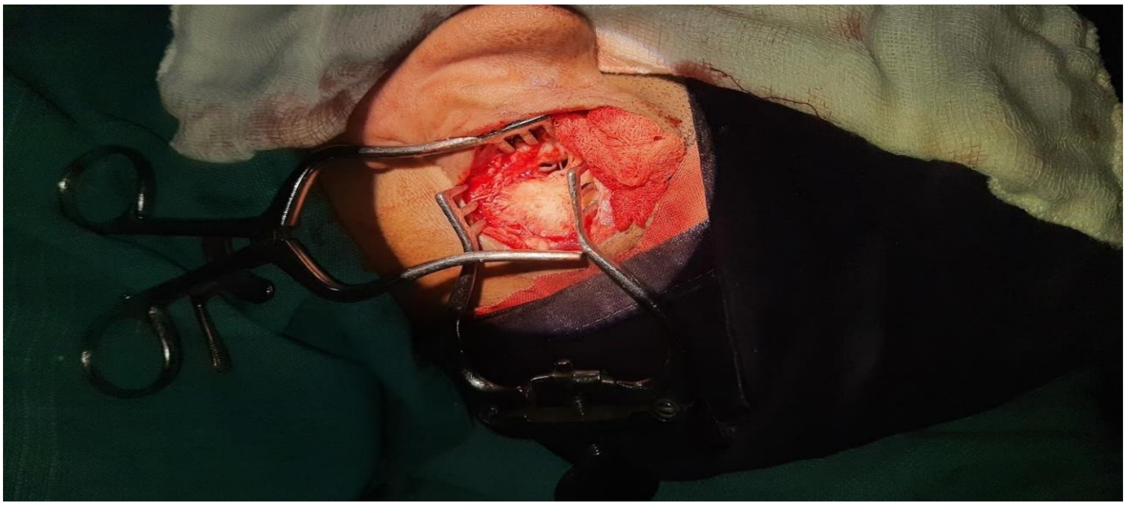


Figure 27:

Figure 27 showing a T shaped incision made in the subcutaneous tissue and a musculoperiosteal flaps being elevated anteriorly and posteriorly exposing the mastoid cortex. Canal wall was exposed by doing a posterior meatotomy thus visualizing the tympanic membrane. Margins of the perforation was freshened.

The canal wall skin was incised about 5 to 6 mm from the lateral surface of the tympanic membrane at 6 o'clock and 12 o'clock positions and tympanomeatal flap was elevated. Ossicular chain and middle ear mucosal status was examined under microscope.

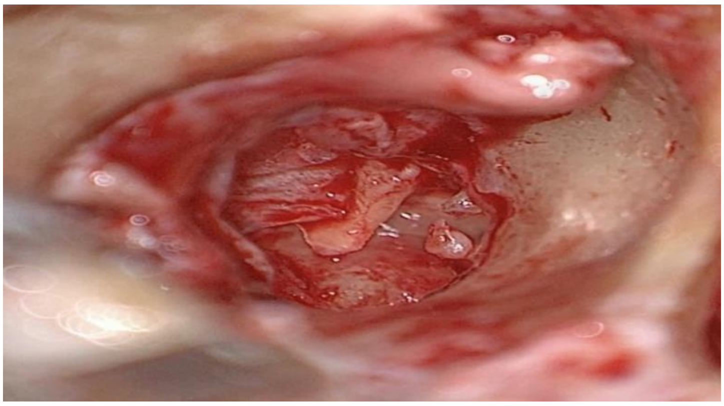


Figure 28: Incudostapedial erosion

The mastoid cortex was opened through McEwans triangle using a micromotor drill. Mastoid antrum was reached and disease clearance was done. Aditus was widened and patency achieved.

BONE CEMENT INTERPOSITION

After thoroughly evaluating the ossicular defect, hydroxyapatite bone cement was applied between the incus remnant and stapes. The cement paste was obtained by mixing the powder component (an hydroxy apatite based mixture of tetracalcium phosphate) with the liquid component (a dilute citric acid) in the ratio of 1:1

Figure 29: Preparation of bone cement paste

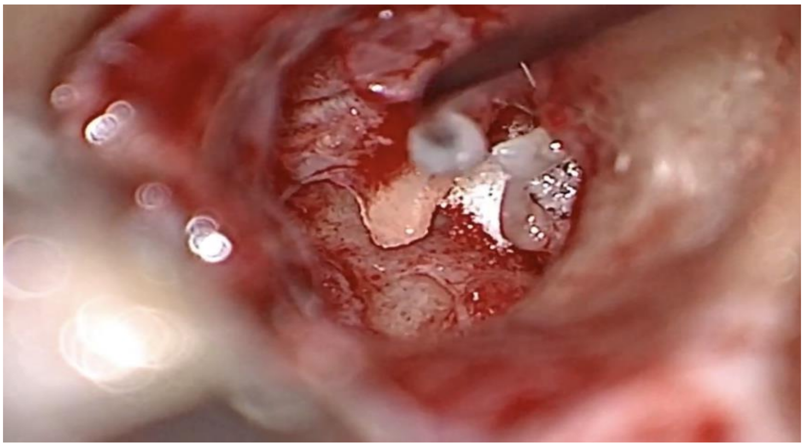


Figure 30: Application of hydroxyapatite bone cement

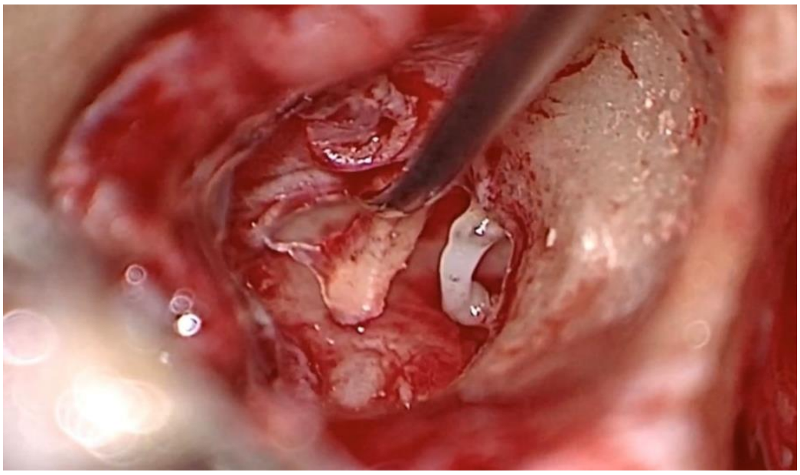


Figure 31:

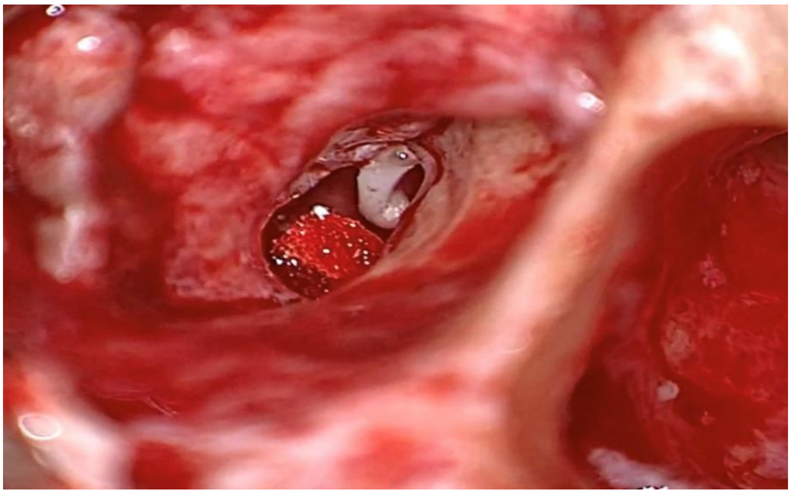


Figure 32:

Figures 31 and 32: Rebridged incudostapedial erosion

The temporalis fascia graft was placed by underlay technique medial to the handle of malleus and tympanomeatal flap was repositioned. Gel foam bed was created. Complete hemostasis achieved. External auditory canal was packed with medicated aural wick. Sterile glasscock – shambaugh mastoid dressing was applied. Patient was reversed from general anaesthesia and extubated safely.

POST OPERATIVE COURSE :

Patients under the study group were monitored and treated post operatively with intravenous antibiotics for one week. Mastoid dressing was changed in a periodical manner. Aural pack removal and suture removal was done on the post operative day eight. After ensuring that the skin wound was healthy and there is no complications, patients were discharged on the ninth post operative day. Discharge advice was given and review was scheduled.

ASSESSMENT OF RESULTS :

Weekly follow up of the patient was done with otoendoscopic examination for the first three weeks thereafter monthly once. Uptake of the graft was checked and recorded. Tuning fork tests were done at the end of 3 months and hearing improvement if present was recorded. Pure tone audiogram and impedence audiometry was done at the end of 3^{rd} month, 6^{th} month and 12^{th} month. Pure tone average, air bone gap, hearing gains were assessed. The results were analyzed in tables and graphs and conclusions were drawn from the data collected.

Age distribution:

A total of 30 patients were taken under this study. All patients were cases of chronic otitis media (COM) both safe and unsafe type with conductive type of hearing loss. The ages of the patients ranged from 18 years to 50 years with the mean age of 32.6 years. The following graph and table shows the age distribution.

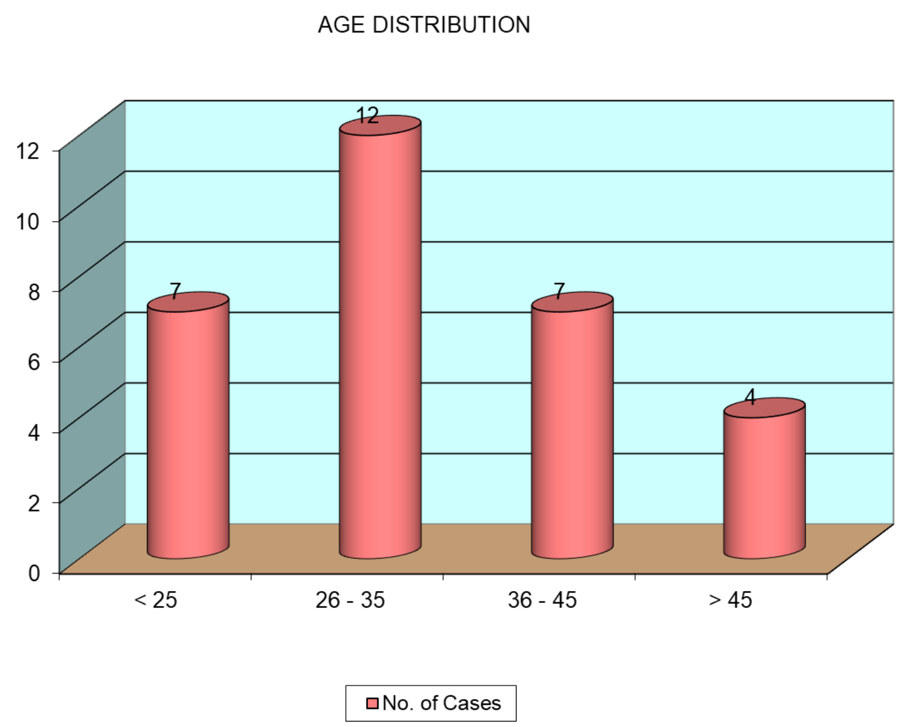


Figure 33: Age distribution

The range of age group with maximal involvement in our study ranged from 26 years to 35 years. 23.33% of patients were less than 25 years of age. 40 % of the people were between 25 and 35 years. Another 23.33 % of the study group ranged between 36 and 45 years. 13.33 % of the study population were above 45 years.

AGE	No. of Cases	Percentage
< 25	7	23.33
26 - 35	12	40.00
36 - 45	7	23.33
> 45	4	13.33
Total	30	100.00
Mean	32.6	
SD	9.605	

Table 1: Age distribution

Gender distribution:

Out of the 30 patients who were a part of our study, 53.33% of the patients were males (16 patients) and 46.67% of them were females (14 patients)

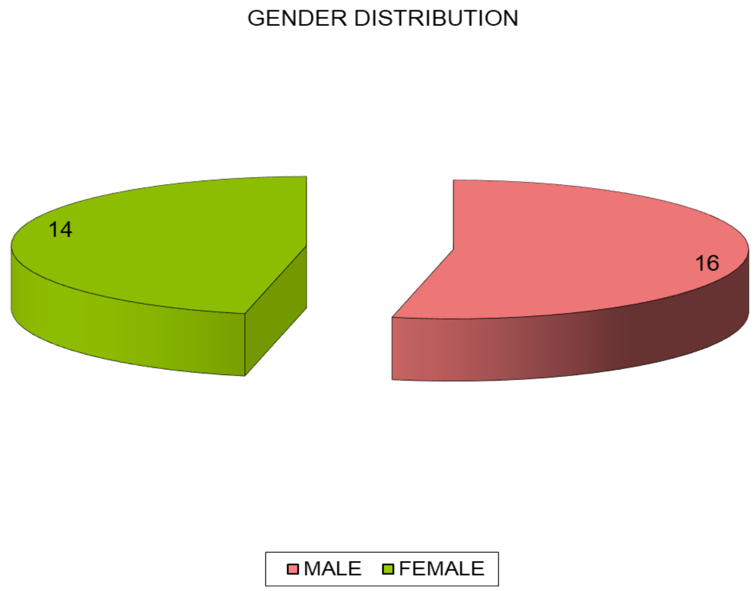


Figure 34: Gender distribution

SEX	No. of Cases	Percentage
MALE	16	53.33
FEMALE	14	46.67
Total	30	100.00

Table 2: Gender distribution

Laterality of the disease:

Among the study group of thirty patients, 60% of the patients showed left sided chronic otitis media and 40% of them showed right laterality.

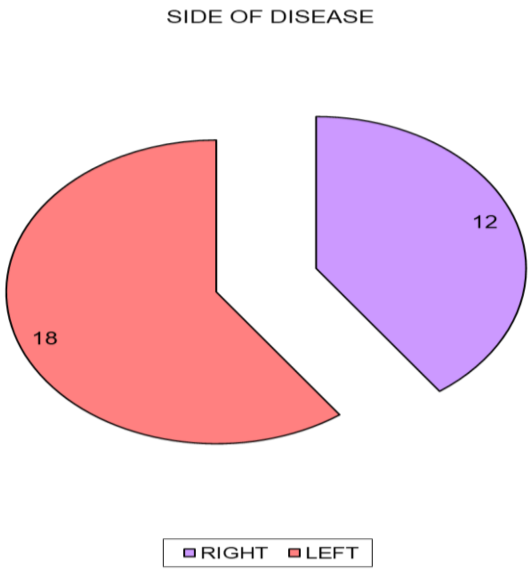


Figure 35: Side of disease

SIDE OF DISEASE	No. of Cases	Percentage
RIGHT	12	40.00
LEFT	18	60.00
Total	30	100.00

Table 3: Side of disease

Duration of the disease:

In our study group that comprised 30 patients maximum number of subjects – 50% (15 patients) had 6 to 10 years of the disease duration.

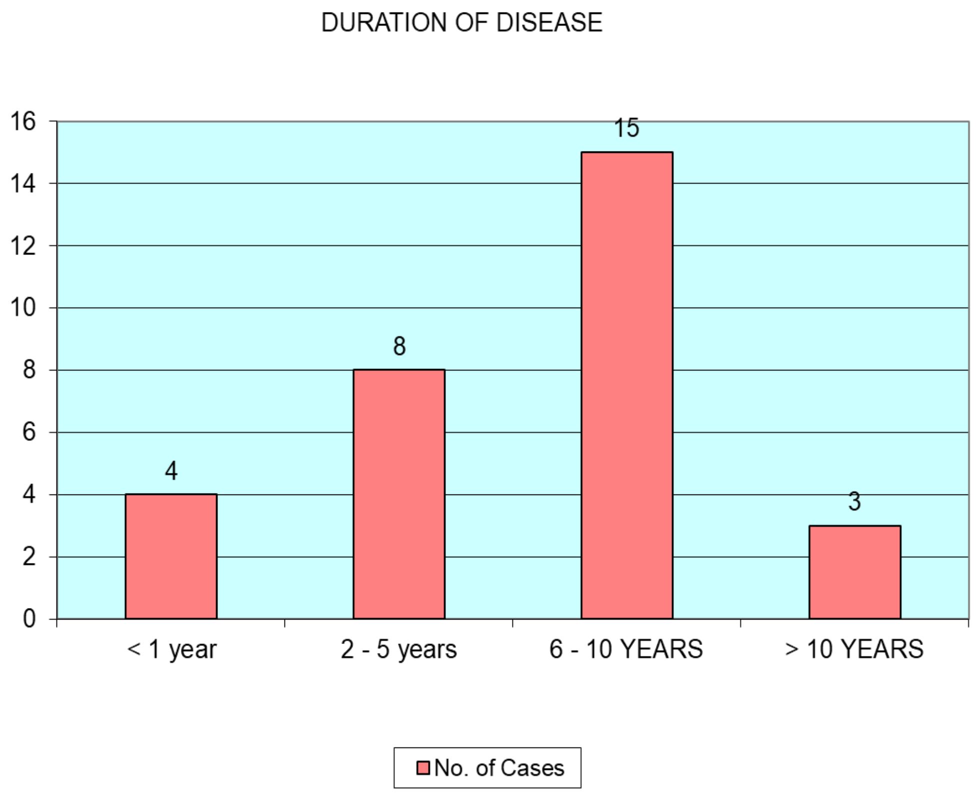


Figure 36: Duration of disease

A total of 8 subjects (26.67%) had duration of the disease between 2 to 5 years. 13.33% of them had disease duration less than one year and 10 % of them had more than ten years duration of the disease.

DURATION OF DISEASE	No. of Cases	Percentage
≤ 1 year	4	13.33
2 - 5 years	8	26.67
6 - 10 YEARS	15	50.00
> 10 YEARS	3	10.00
Total	30	100.00

Table 4: Duration of disease

Provisional diagnosis:

Chart showing the various presentations of chronic otitis media patients who underwent bone cement ossiculoplasty.

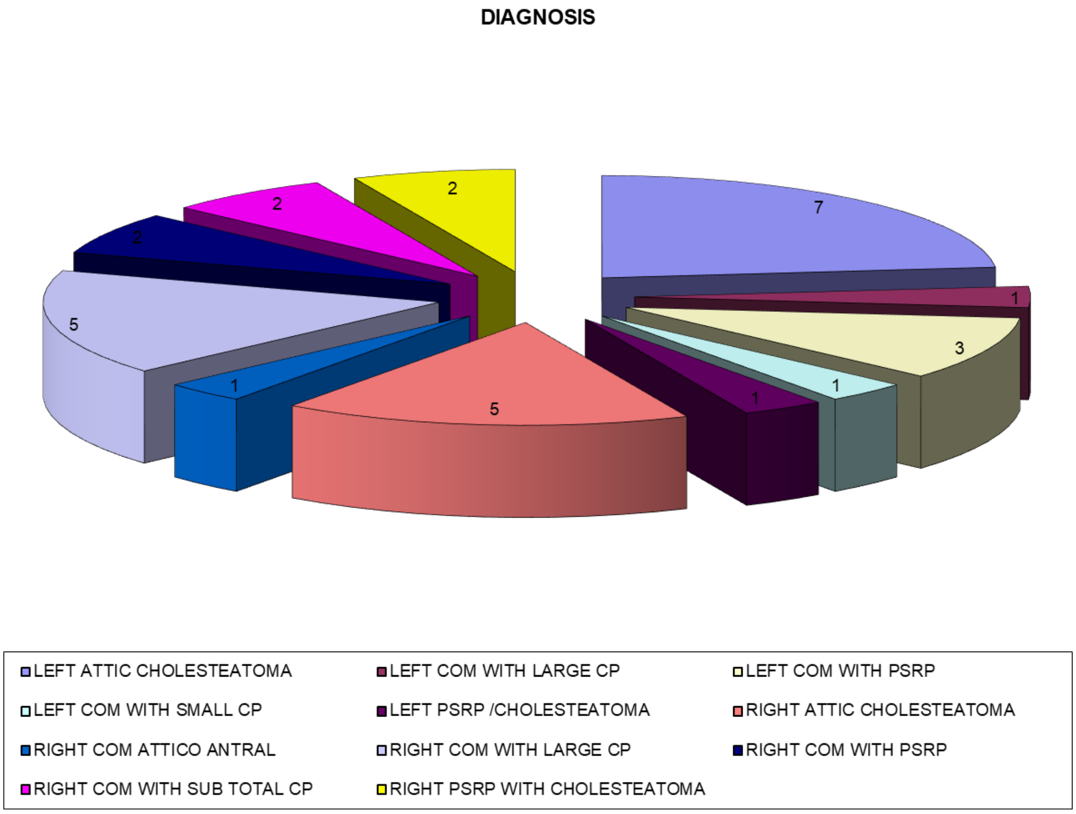


Figure 37: Various presentations of COM

Table 5: Various presentations of the disease

DIAGNOSIS	No. of Cases	Percentage
LEFT ATTIC CHOLESTEATOMA	7	23.33
LEFT COM WITH LARGE CP	1	3.33
LEFT COM WITH PSRP	3	10.00
LEFT COM WITH SMALL CP	1	3.33
LEFT PSRP /CHOLESTEATOMA	1	3.33
RIGHT ATTIC CHOLESTEATOMA	5	16.67
RIGHT COM ATTICO ANTRAL	1	3.33
RIGHT COM WITH LARGE CP	5	16.67
RIGHT COM WITH PSRP	2	6.67
RIGHT COM WITH SUB TOTAL CP	2	6.67
RIGHT PSRP WITH CHOLESTEATOMA	2	6.67
Total	30	100.00

Types of perforation:

In our study group maximum number of the subjects presented with large central perforation (76.67%).

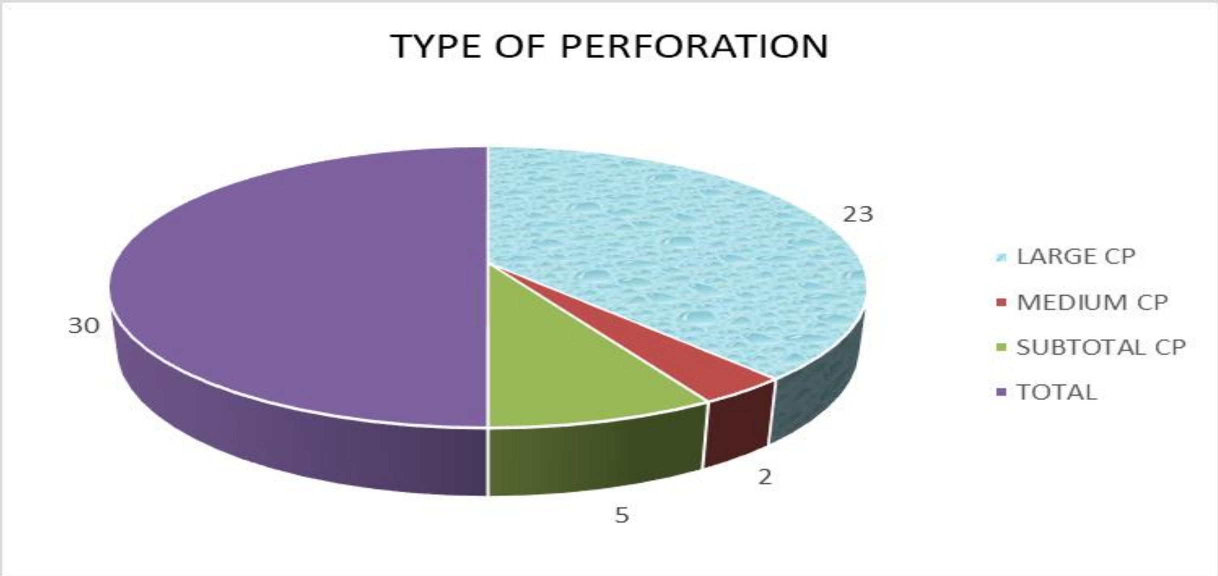


Figure 38: Types of perforation

TYPE OF PERFORATION	No. of Cases	Percentage
LARGE CP	23	76.67
MEDIUM CP	2	6.67
SUB TOTAL CP	5	16.67
Total	30	100.00

Table 6: Types of perforation

Air bone gap (ABG) comparison:

The gain in air bone gap value of 10.61 dB was observed in the population subjected to hydroxyapatite bone cement ossiculoplasty.

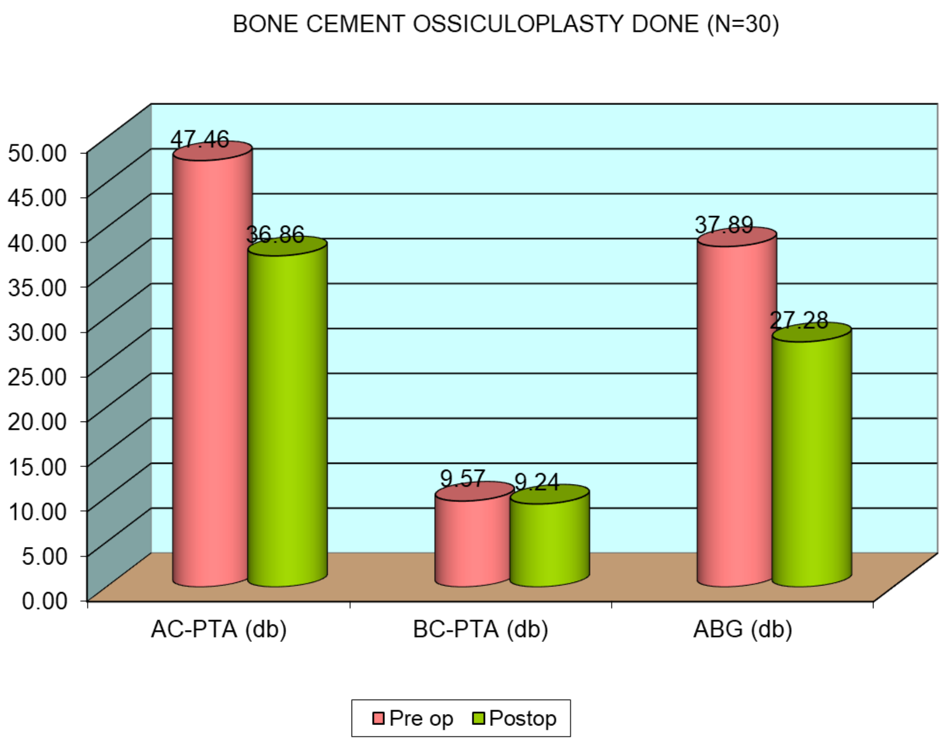


Figure 39

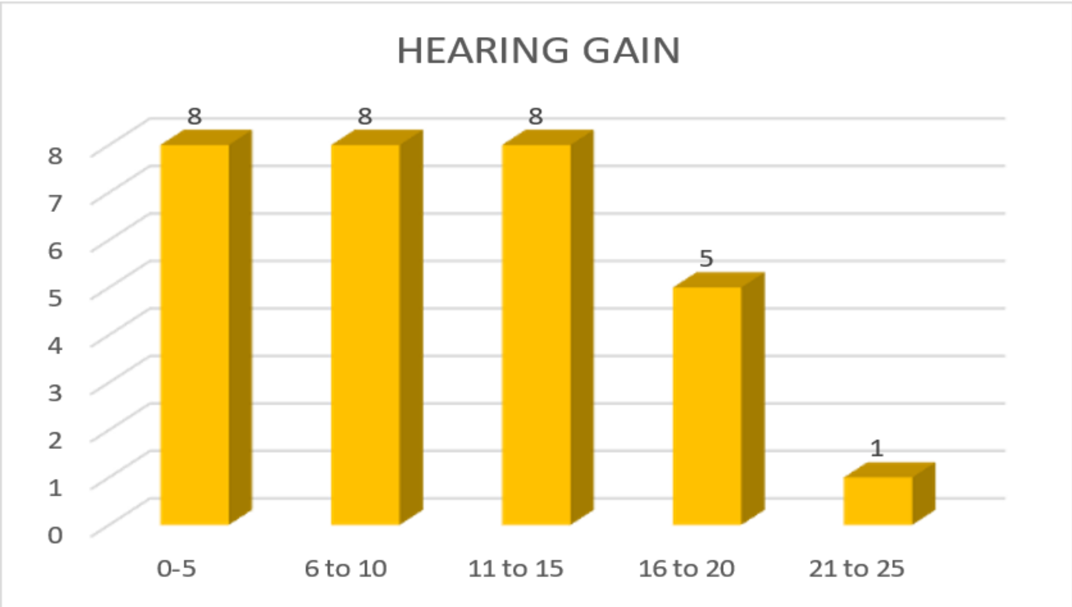
Table 7: ABG comparison

BONE CEMENT OSSICULOPLASTY DONE (N=30)	**Preop**		**Postop**		**p-value**
	Mean	SD	Mean	SD	
AC-PTA (db)	47.463	3.713	36.86	6.305	<0.001
BC-PTA (db)	9.57	2.925	9.243	2.898	0.665
ABG (db)	37.893	4.014	27.283	5.775	<0.001

Post operative hearing gain:

PRE OP AC PTA - POST OP AC PTA	No. of Cases	Percentage
< 5	8	26.67
5.1 - 10	8	26.67
10.1 - 15	8	26.67
15.1 - 20	5	16.67
> 20	1	3.33
TOTAL	30	100.00

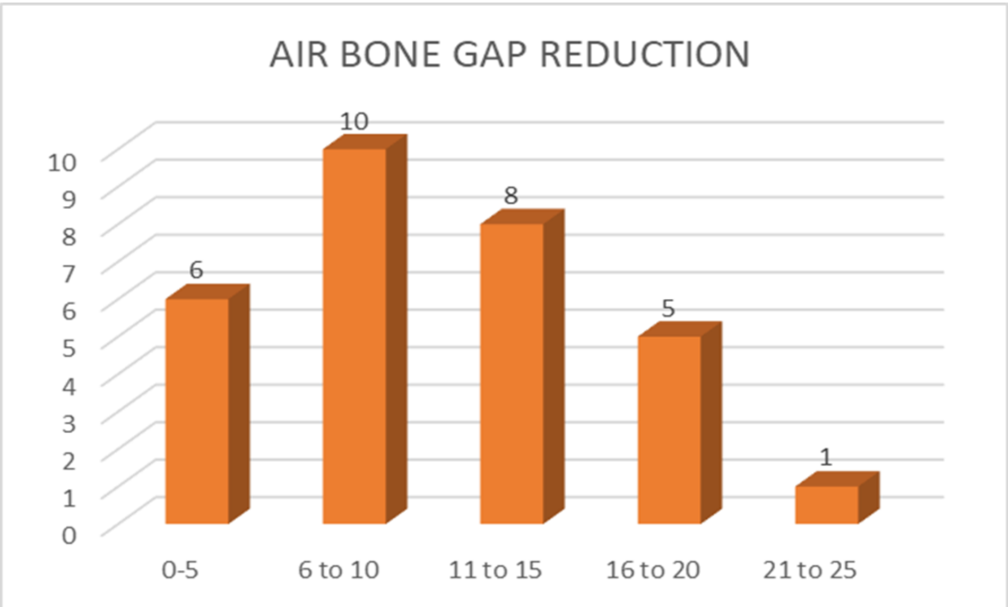
Figure 40 and Table 8: post operative hearing gain



Air bone gap reduction:

PRE OP ABG - POST OP ABG	No. of Cases	Percentage
< 5	6	20.00
5.1 - 10	10	33.33
10.1 - 15	8	26.67
15.1 - 20	5	16.67
> 20	1	3.33
TOTAL	30	100.00

Figure 41 and Table 9: Air bone gap reduction



DISCUSSION

Hearing impairment due to chronic otitis media poses a major disability worldwide. Ossicular discontinuity is the important pathology behind the hearing impairment in patients with chronic otitis media both safe and unsafe type.

In the earlier days surgical correction was done as a staged procedure. The first sitting was aimed at disease clearance. Reconstruction of the ossicles and restoring of the hearing mechanism was planned in the second sitting. Our study was aimed to overcome the drawbacks by combining the disease clearance and ossicular reconstruction as a singled staged procedure.

The material used for ossicular reconstruction in our study was hydroxyapatite bone cement. Calcium phosphates are minerals made out of calcium cations and phosphate anions. They are known as the major inorganic material in around 60% of all local human bones.

The presence of calcium phosphates in bones was first found in 1769, and during the 1800s, calcium phosphates that exist in bones were partitioned into various classes.

Hydroxyapatite (HAP) has been generally utilized in bone recovery. It is a normally happening type of calcium phosphate that establishes the biggest measure of inorganic parts in human bones . The synthetic equation of HAP is $Ca_{10}(PO_4)_6(OH)_2$ with a Ca/P proportion of 1.67 .

HAP is the most steady calcium phosphate with low solvency in physiological conditions characterized by temperature, pH, body liquids, and so forth and the outer layer of HAP can go about as a nucleating site for bone minerals in body liquids . Also, HAP doesn't cause fiery responses when applied clinically

HAP is known to be osteoconductive however not osteoinductive[34]. Therefore particles like fluoride, chloride, and carbonate particles are subbed depending on the situation .For instance, the utilization of fluoride as an anionic replacement expanded the security and the utilization of magnesium as a cationic replacement expanded the natural impact.

In our observational study, outcome of the patients of chronic otitis media be it safe or unsafe type, was evaluated who underwent canal wall up or canal wall down mastoidectomy procedure with ossiculoplasty.

As an end result of this procedure desirable hearing results were able to be made out. On analyzing, this study proved significant difference between pre and postoperative ABG with value 37.89 dB and 27.28 dB respectively when the patients were followed up for a period of 6 months.

CONCLUSION

This study was conducted mainly to analyze the hearing outcome of bone cement ossiculoplasty in cases of chronic otitis media with incudostapedial erosion. Final analysis of this study showed significant p value on comparing preoperative and post operative ABG in which there is a post operative gain. Our study was based on usage of a calcium phosphate bone cement – HYDROXYAPATITE.

To conclude, there is a gain in ABG following surgery. To make this analytical study still definitive, further long term follow up of cases is necessary to analysis the longevity, effectiveness and persistence of gained hearing, disease recurrence and resurgence.

With this available data, this method of ossiculoplasty is worth of trying in patients of chronic otitis media with evident incudostapedial erosion. To conclude,

1. Ossiculoplasty invariably gives a better hearing outcome in cases of chronic otitis media with ossicular erosion when compared to patients who don’t undergo ossiculoplasty.
2. Ossiculoplasty should be performed in all cases with hearing loss of the conductive type due to ossicular erosion
3. Since bone cement has the ease of application and requires minimal expertise, it can be done along with mastoidectomy as a single stage procedure, thus avoiding staged reconstruction.

4. Hydroxyapatite being similar in composition to the human bone, has good osseointegrative properties, biocompatible and nil adverse reactions.
5. It showed significant gain in the air bone gap.
6. No Post operative complications were recorded in the study group.
7. Long term results are awaited.

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PROFORMA

Name Age / Sex:

IP No: Address :

DOA : DOS :

H/o Present illness:

Details of complaints:

H/o Ear discharge
H/o Hard of hearing
H/o Itching
H/o Earache
H/o Headache, convulsions
H/o Tinnitus
H/o Vertigo
H/o Fever
H/o recurrent Cold and Cough
H/o Trauma
H/o Any drug intake
H/o Noise exposure
H/o Nasal Discharge/ Blockage/ Bleeding

PAST HISTORY

H/o Similar complaints in the past

TREATMENT HISTORY

H/o any ototoxic drugs intake
H/o any operations on the ear

PERSONAL HISTORY

FAMILY HISTORY

EXAMINATION

GENERAL EXAMINATION:

LOCAL EXAMINATION

EXAMINATION OF EAR

	RIGHT	LEFT
Preauricular area		
Pinna		
External Auditory Canal		
Tympanic membrane		
Post auricular area		
Facial nerve		

EXAMINATION OF NOSE AND THROAT:

Otoscopy/ Microscopic examination

Tuning Fork Test

Pure Tone Audiometry

Impedance audiometry

CT Temporal Bone

Routine blood investigations

Observation

	Preoperative values	Postoperative values (at the end of 12 months)
AC PTA		
BC PTA		
ABG		

TYPE OF PERFORATION	**SIDE OF DISEASE**	**DURATION OF DISEASE in years**	DIAGNOSIS	PRE OPERATIVE (DB SD)			POST OPERATIVE PTA (DB SD)			PRE OP AC PTA - POST OP AC PTA **HEARING GAIN**	PRE OP BC PTA - POST OP BC PTA	PRE OP ABG - POST OP ABG ABG REDUCTION
				AC PTA	**BC PTA**	**ABG**	ACPTA	BCPTA	ABG			
LARGE CP	R	5	LEFT COM WITH LARGE CP	43.3	9.3	34	30	9.3	20.7	13.3	0	13.3
LARGE CP	R	10	RIGHT COM WITH LARGE CP	41.6	10.6	31	30	10.6	19.4	11.6	0	11.6
SUB TOTAL CP	L	10	LEFT COM WITH PSRP	48.3	6.6	41.7	38.3	6.6	31.7	10	0	10
MEDIUM CP	R	6 MONTHS	RIGHT COM ATTICO ANTRAL	50	10	40	41.6	8.3	33.3	8.4	1.7	6.7
LARGE CP	R	1	RIGHT COM WITH LARGE CP	45	11.6	33.4	36.6	10	26.6	8.4	1.6	6.8
LARGE CP	R	2	LEFT ATTIC CHOLESTEATOMA	46.6	10	36.6	41.6	10	31.6	5	0	5
SUB TOTAL CP	L	10	RIGHT COM WITH PSRP	51.6	11.6	40	45	11.6	33.4	6.6	0	6.6
MEDIUM CP	L	8	RIGHT COM WITH SUB TOTAL CP	48.3	10	38.3	38.3	10	28.3	10	0	10
LARGE CP	R	3	LEFT ATTIC CHOLESTEATOMA	50	11.6	38.4	48.3	15	33.3	1.7	-3.4	5.1

LARGE CP	L	10	RIGHT PSRP/CHOLESTEATOMA	53.3	11.6	41.7	31.6	6.6	25	21.7	5	16.7
LARGE CP	R	10	RIGHT COM WITH LARGE CP	46.6	13.3	33.3	28.3	11.6	16.7	18.3	1.7	16.6
LARGE CP	R	1	LEFT COM WITH PSRP	48.3	11.6	36.7	33.3	11.6	21.7	15	0	15
LARGE CP	R	4	LEFT ATTIC CHOLESTEATOMA	43.3	10	33.3	33.3	10	23.3	10	0	10
LARGE CP	L	10	RIGHT PSRP WITH CHOLESTEATOMA	55	10	45	43.3	10	23.3	11.7	0	21.7
LARGE CP	L	1	LEFT COM WITH SMALL CP	41.6	3.3	38.3	36.6	3.3	33.3	5	0	5
LARGE CP	L	14	LEFT ATTIC CHOLESTEATOMA	48.3	5	43.3	30	5	25	18.3	0	18.3
LARGE CP	R	5	RIGHT ATTIC CHOLESTEATOMA	45	6.6	38.4	40	6.6	33.4	5	0	5
LARGE CP	L	2	RIGHT COM WITH LARGE CP	46.6	6.6	40	38.3	6.6	31.7	8.3	0	8.3
LARGE CP	R	7	LEFT COM WITH PSRP	51.6	11.6	40	40	11.6	28.4	11.6	0	11.6
LARGE CP	R	10	LEFT ATTIC CHOLESTEATOMA	48.3	6.6	41.7	30	6.6	23.4	18.3	0	18.3
LARGE CP	R	7	RIGHT ATTIC CHOLESTEATOMA	53.3	11.6	41.7	48.3	10	38.3	5	1.6	3.4

LARGE CP	R	12	RIGHT ATTIC CHOLESTEATOMA	48.3	8.3	40	50	11.6	38.4	-1.7	-3.3	1.6
LARGE CP	L	10	RIGHT COM WITH SUBTOTAL CP	45	11.6	33.4	30	8.3	21.7	15	3.3	11.7
SUB TOTAL CP	L	10	LEFT ATTIC CHOLESTEATOMA	48.3	11.6	36.7	33.3	10	23.3	15	1.6	13.4
LARGE CP	R	10	RIGHT COM WITH PSRP	41.6	3.3	38.3	30	3.3	26.7	11.6	0	11.6
LARGE CP	L	10	RIGHT ATTIC CHOLESTEATOMA	50	13.3	36.7	33.3	11.6	21.7	16.7	1.7	15
LARGE CP	R	5	LEFT PSRP /CHOLESTEATOMA	51.6	10	41.6	41.6	10	31.6	10	0	10
LARGE CP	R	5	LEFT ATTIC CHOLESTEATOMA	41.6	15	26.6	36.6	15	21.6	5	0	5
SUB TOTAL CP	L	15	RIGHT ATTIC CHOLESTEATOM	46.6	6.6	40	28.3	6.6	21.7	18.3	0	18.3
SUB TOTAL CP	R	10	RIGHT COM WITH LARGE CP	45	8.3	36.7	40	10	30	5	-1.7	6.7

ஆராய்ச்சி தகவல் அறிக்கை

மதுரை அரசு இராசாசி மருத்துவமனையில் வரும் நோயாளிக்கு ஒரு ஆராய்ச்சி இங்கு நடை பெற்று வருகிறது. நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க விரும்பிகிறோம் .

உங்களை சில சிறப்பு பரிசோதனைக்கு உட்படுத்தி அதன் தகவல்களை ஆராய்வோம். அதனால் தங்களது நோயின் ஆய்வரிகையோ அல்லது சிகிச்சையோ பாதிப்பு ஏற்படாது என்பதைதெரிவித்து கொள்கிறேன் .

முடிவுகளை வெளியிடும் போது அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரோ அல்லது அடையாளங்களோ வெளியிடமாட்டோம் என்பதை தெரிவித்துகொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் நடக்கும். மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின் வாங்கலாம் என்பதையும் தெரிவித்து கொள்கிறோம்.

இந்த சிறப்பு பரிசோதனை முடிவுகளை ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துகொள்கிறோம்.

பங்கேற்பாளர்   கையொப்பம்

PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled **"AN OBSERVATIONAL STUDY TO EVALUATE THE HEARING EFFICACY OF BONE CEMENT OSSICULOPLASTY FOR INCUDOSTAPEDIAL REBRIDGING"** of the candidate Dr.R.M.MONISHA with registration number 221914103 for the award of M.S. OTORHINOLARYNGOLOGY in the BRANCH IV. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion and results show 3 percentage of plagiarism in the dissertation.

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INSTITUTIONAL ETHICS COMMITTEE
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Study Title	:	An observational study to evaluate the hearing efficacy of bone cement ossiculoplasty for incudostapedial rebridging
Principle Investigator	:	Dr.R.M.Monisha
Designation	:	PG in MS., Otorhinolaryngology (2019 – 2022)
Guide	:	Dr.N.Dhinakaran, MS., ENT Professor and Head of ENT
Department	:	Department of ENT Govt. Rajaji Hospital & Madurai Medical College, Madurai.

The request for an approval from the Institutional Ethics Committee (IEC) was considered on the IEC meeting held on **03.03.2021** at Auditorium, Govt. Rajaji Hospital, Madurai at 10.00 AM.

The Members of the committee, the Secretary and the Chairman are pleased to inform you that your proposed project mentioned above is **Approved.**

You should inform the IEC in case of any changes in study procedure, methodology, sample size investigation, Investigator or guide or any other changes.

1. You should not deviate from the area of work for which you had applied for ethical clearance.

2. You should inform the IEC immediately, in case of any adverse events or serious adverse reactions. If encountered during from study.

3. You should abide to the rules and regulations of the institution(s)

4. You should complete the work within the specific period and if any extension is required, you should apply for the permission again for extension period.

5. You should submit the summary of the work to the ethical committee on completion of the study.

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