A COMPARATIVE STUDY OF DRY GRAFT AND FRESHLY HARVESTED WET TEMPORALIS FASCIA GRAFT TO REPAIR TYMPANIC MEMBRANE PERFORATION IN CHRONIC MUCOSAL OTITIS MEDIA

By

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Dissertation submitted to the

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In partial fulfillment of the requirements for the degree of

MASTER OF SURGERY IN OTORHINOLARYNGOLOGY

Under the guidance of

Dr. KHAJA NASEERUDDIN, MBBS, MS

DEPARTMENT OF OTORHINOLARYNGOLOGY

SRI DEVARAJ URS MEDICAL COLLEGE

TAMAKA, KOLAR

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Date:

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LIST OF ABBREVIATIONS

COM	⇨	Chronic Otitis Media
AOM	⇨	Acute Otitis Media
TM	⇨	Tympanic Membrane
PTA	⇨	Pure Tone Average
TM	⇨	Tympanic Membrane
EAC	⇨	External Auditory Canal
EP	⇨	Epithelium
LP	⇨	Lamina Propria
DNS	⇨	Deviated Nasal Septum
DNE	⇨	Diagnostic Nasal Endoscopy
PO	⇨	Post Operative

ABSTRACT

Background:

Chronic otitis media (COM) is a chronic inflammation of the middle ear cleft causing permanent abnormality in the tympanic membrane. COM can be managed both medically and surgically. Medical treatment helps in the management of acute episodes in terms of controlling the infection, pain and discharge. However repeated episodes of COM cannot be controlled by medical line of management alone when surgery is the treatment of choice. There is a constant refinement in the surgical approach, method of grafting and grafting material used in the surgery due to improved understanding of the disease and advancement in technology. The temporalis fascia graft used in the surgery is believed to become the middle fibrous layer of the neo tympanic membrane. Considering this above hypothesis, vascularity of a freshly harvested graft maybe better than the dried graft which is conventionally used.

Objectives:

1) To document the success rate, improvement in hearing and operation time in tympanoplasty using dry temporalis fascia graft for closing the tympanic membrane perforation.
2) To document the success rate, improvement in hearing and operation time in tympanoplasty using a freshly prepared wet temporalis fascia graft for closing the tympanic membrane perforation.
3) To compare the results of the two procedures mentioned above.

Methods:

A total of 102 patients diagnosed to have mucosal type of COM were included in this study. The patients were subjected to microscopic ear examination, audiometric evaluation, mastoid radiography and haematological investigations. Patients were classified into groups depending on the size of the tympanic membrane perforation. In each group alternate patients will be taken up for the repair of tympanic membrane (Type 1 tympanoplasty) using dry temporalis fascia graft (Group A) or freshly prepared wet temporalis fascia graft (Group B). In both the groups the time taken for the surgery and time taken for placement of the graft were documented. All patients were followed up 3 and 6 months after surgery, when they were assessed for graft uptake and air bone gap closure. The significance of difference in the mean take up rate of the graft, mean air bone gap closure, mean surgical time and mean time taken to place the graft were assessed using independent t-test.

Results:

The 102 patients included in the study ranged from 18 to 70 years and 44% of the patients had a large size perforation. The mean preoperative PTA in Group A was 33.61dB and in Group B was 37.41dB.

The average time taken to place the graft was statistically significant with a p-value of 0.001, but the time taken to place the graft was not statistically significant.

At 3 months, 3.92% of patients belonging to group A had a residual perforation. The mean PTA for Group A was 15.5dB and for Group B was 15.39dB.

At 6 months, all patients achieved complete closure of the perforation. The mean PTA for Group A was 14.13dB and for Group B was 15.29dB.

Conclusion:

We found a significant difference in the time taken to place the graft (p-value = 0.001); but no significant difference was noted in the take up rates of the graft, outcome of hearing at end of 3 months or 6 months and duration of surgery between the two groups.

KEYWORDS:

Chronic Otitis Media, Tympanoplasty, Temporalis fascia graft

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INTRODUCTION:

Chronic otitis media (COM) is defined as a chronic inflammation of the middle ear cleft causing permanent abnormality in the tympanic membrane. It is most likely as a result of earlier Acute otitis media (AOM), Negative middle ear pressure or Otitis media with effusion.[1]

COM can be managed both medically and surgically. Medical treatment helps in the management of acute episodes in terms of controlling the infection, pain and discharge. However repeated episodes of COM cannot be controlled by medical line of management alone. In such cases surgery is the treatment of choice.

There is a constant refinement in the surgical approach, method of grafting and grafting material used in the surgery due to improvement in understanding about the disease and advancement in technology.

Currently even in expert hands, the failure rate of surgery ranges from 5 to 8%. However, when large numbers of surgeries in hands of many surgeons are considered, the failure rates are believed to be much higher than the quoted figures.[1]

Many grafting materials have been tried for repair of tympanic membrane perforations, however temporalis fascia graft has been preferred over the others. The temporalis fascia graft is believed to become the middle fibrous layer of the neo tympanic membrane, in which case the ability of the graft to get vascularised should be a predictive factor for successful repair of tympanic membrane.[2] Considering the above hypothesis the vascularity of the freshly harvested graft maybe better than the dried graft which is conventionally used.[3]

It would be interesting to compare the success rates between the dry and the wet grafts as there are a very few studies addressing this issue.

OBJECTIVES:

1) To document the success rate, improvement in hearing and operation time in tympanoplasty using dry temporalis fascia graft for closing the tympanic membrane perforation.

2) To document the success rate, improvement in hearing and operation time in tympanoplasty using a freshly prepared wet temporalis fascia graft for closing the tympanic membrane perforation.

3) To compare the results of the two procedures mentioned above.

REVIEW OF LITERATURE:

Histologically tympanic membrane comprises of 3 layers: outer epithelial, middle fibrous and inner mucosal. COM causes permanent necrosis of all the 3 layers leading to persistent perforation as one of the sequelae of the disease.[4]

Surgery in the form of tympanoplasty or myringoplasty has evolved as the most promising treatment option for mucosal COM. However the surgical approach, grafting technique and grafting material have not been standardised till date.

The common approaches for the tympanoplasty are post aural approach, end aural approach and endomeatal approach. Lately endoscopic approaches have also evolved. Of all these approaches, post aural approach is most widely practised by otologists considering the wider exposure this technique provides.[1]

Different techniques are available for graft placement like underlay, interlay and onlay based on the relation of the graft to the tympanic annulus. Of all these, the underlay technique is widely practised by otologists. The success rates are better by underlay technique because anterior blunting does not occur by this procedure, graft cannot get lateralised and there is no risk of secondary acquired cholesteatoma as no squamous epithelium can get entrapped.[1]

Many grafting materials are available for closure of tympanic membrane perforations like temporalis fascia, tragal perichondrium, cartilage, adipose tissue, vein graft, fascial lata etc. Of all these, temporalis fascia is preferred by most otologists considering its easy availability, low metabolic rate and suitable thickness.[1]

The temporalis fascia graft can either be obtained in the beginning of the surgery where it is dried or it can be freshly harvested and immediately grafted which is the wet graft.

A study conducted by Alkan S comparing the effect of use of dry or wet temporalis fascia graft suggests that, there were no significant differences between the two groups regarding recurrence of the disease, residual perforation and postoperative hearing results. However, the mean operation time was significantly less in the freshly harvested wet fascia group.[5]

Another study compared the fresh, dried and dried-then-rehydrated temporalis fascia graft and found no statistically significant difference between the three groups. But in none of these studies, has the size of the perforation been taken into account. Most of the studies cater to the western population and there is very limited literature on this topic in our country.[6]

Surgical anatomy:

External ear

It is involved primarily with transmission of sound from external source to middle ear. It consists of the pinna or auricle and the external acoustic meatus.

Development

The primordium of the external acoustic meatus is the dorsal end of the first external branchial cleft, in relation medially to the mesoderm separating it from the tubotympanic recess. The primitive meatus present at the fourth week is replaced by a solid core of ectodermal (epithelial cells) which persists from the 8^{th} until the 28^{th} week, when it undergoes canalization by dissolution of cells from within outwards.

The development of pinna commences at 4 weeks as tissue condensations of the mandibular and hyoid arches appear at the distal portion of the first branchial groove. Within 2 weeks, six ridges known as hillocks of His, arise from the tissue condensations. The tragus and the anterior external auditory canal arise of mandibular arch, while the rest of pinna from hyoid arch. Adult configuration is achieved by the 5^{th} month, independent of developmental progress in the middle and inner ears. The Darwinian tubercle, corresponding to the tip of pinna in lower mammals, is seen roughly at 6 months.[7]

Auricle

The shape of the auricle is formed by the thin, convoluted, continuous sheet of yellow elastic cartilage that curves forward to enclose the floor and anterior wall of the external cartilaginous meatus but not the roof. Superiorly the cartilage of the meatus is lacking, leaving a deep cleft, the incisura terminalis, utilized by the surgeon in making the extarcartilaginous endaural incision for surgical exposure of the temporal bone.[7]

The curved rim is helix and in its posterior superior aspect is a small auricular tubercle-Darwin's tubercle. Anterior to and parallel to the helix is the antihelix. Superiorly this divides into two crus, between which is the triangular fossa; the scaphoid fossa lies above the two crura. In front of the antihelix and partly encircled by it is the concha. The anterior superior part of the concha is usually covered by the descending part of the anterior superior portion of the helix. This is called the symba concha, which is in direct superior relation with the suprameatal triangle. Below the crus of helix and opposite to the concha, across the external auditory canal is tragus. The medial surface of auricle has elevation corresponding to the depressions on the lateral surface and possesses corresponding names. The cartilage depends on the perichondrium for supply of nutrients.[8]

The auricle is connected by two extrinsic ligaments to the temporal bone. The anterior ligament runs from tragus and from a cartilaginous spine on the anterior rim of the crus of the helix to the root of the zygomatic arch. Posterior ligament runs from the medial surface of the concha to the lateral surface of the mastoid prominence.[9]

Blood supply

It is derived from posterior auricular and superficial temporal arteries which form a network and communicate over the antihelix.[10]

Lymphatic drainage

The lymphatics drain into the preauricular, post auricular and superficial cervical lymph nodes.[11]

Nerve supply

Lateral surface of the auricle is supplied by the auriculotemporal nerve (upper $2/3^{rd}$) and greater auricular (lower $1/3^{rd}$) the medial surface, by the lesser occipital (upper $2/3^{rd}$) and great auricular nerve (lower $1/3^{rd}$); concha by the auricular branch of the vagus. [12]

External auditory canal

It is a communicating passage between the concha and tympanic membrane. In the adult the average length is 24 mm. It is composed of two portions, an outer cartilaginous portion which is around 8 mm in length and an inner bony portion which is around 16 mm long and it is constricted slightly in the middle by an isthmus. Since the tympanic membrane lies obliquely at the inner end of the meatus the anterior and inferior walls are longer than the posterior and superior walls.

At the junction of the inferior wall with the tympanic membrane there is a depression the inferior meatal recess. This recess can be difficult to see and contain an unsuspected reservoir of debris in an infected ear.

The cartilaginous portion is oval in section with a backward convexity continuous with the cartilage of the auricle. The direction is medially upwards and backwards, while that of the bony meatus is medial slightly downwards and forwards.

There are two constrictions in the canal one at the junction of cartilaginous and bony part and other in the osseous part 5 mm from the tympanic membrane where a prominence of the anterior canal wall reduces the diameter. The meatus may be partially straightened in the adult by pulling the auricle upwards, outwards and backwards. In neonate there is virtually no bony external meatus as the temporal bone is not yet developed and the tympanic membrane is more horizontally placed. The auricle must hence be pulled downwards and backwards for a view of the tympanic membrane.[13]

In cartilaginous part, the fissure of santorini provides a potential path of infection between the parotid gland and the superficial mastoid region. Foramen Huschke is the deficiency in the anteroinferior part of the bony part of the external auditory canal in adults.

The external auditory meatus is lined by skin continuous with the auricle and extends over the tympanic membrane. In cartilaginous part, it contains hair follicles, sebaceous and ceruminous glands, in which are absent in bony part.

In the bony portion the skin is firmly attached to the periosteum and is very thin whereas in the cartilaginous portion the subcutaneous tissue attaches the skin firmly to the perichondrium, which accounts for the pain and tenderness of the furuncle in the cartilaginous portion.

Blood supply

The auricular branches of the superficial temporal artery supply the roof and anterior portion of the canal. The deep auricular branch of the first part of the maxillary artery arises in the parotid gland in the temporomandibular joint, pierces the cartilage or bone of the external meatus and supplies the anterior meatal wall skin.[9]

The auricular branches of the posterior auricular artery pierce the cartilage of the auricle and supply the posterior portions of the canal.

Venous drainage

Veins drain into the external jugular vein, the maxillary vein and the pterygoid plexus.[9]

Lymphatic drainage

The lymphatics of the tragus and anterior external portion of the auricle drain into the superficial parotid lymph nodes, the posterior external and medial aspect of the auricle into the retroauricular lymph nodes and of the lobule and inferiorly of the external auditory canal drains into the superficial cervical group of nodes.[13]

Tympanic membrane

It is an elliptical disc stretched obliquely across the medial end of external auditory canal. It is broader above than below forming an angle of 55° with the floor of the external auditory canal. It forms the lateral wall of the mesotympanum and small part of the epitympanum, separates the tympanic cavity from the external auditory canal. It is convex towards the tympanic cavity. The diameter from posterosuperior to anteroinferior is 9-10 mm, perpendicular to this is 8-9 mm. The circumference is thickened to form a fibro cartilaginous ring, the tympanic annulus which sits in a groove in the temporal bone, the tympanic sulcus. This sulcus does not extend to the roof of the canal, which is formed by squamous portion of the temporal bone. Form the superior limits the annulus becomes fibrous bands which run centrally as anterior and posterior malleolar folds to the lateral process of malleus. The malleolar folds divide the tympanic membrane into pars flaccida and pars tensa. Pars flaccida is a triangular region of tympanic membrane above the malleolar folds, while pars tensa forms rest of tympanic membrane. The handle of malleus lies within the layers of the tympanic membrane.[9,13]

Blood supply

Vessels supplying the tympanic membrane lie in connective tissue layer of the lamina propria. This layer has peripheral rim of arteries connected by radial anastomosis.

The arteries involved are:

Lateral surface: Deep auricular branch of maxillary artery.

Medial surface:

(a) Posteriorly – stylomastoid branch of the posterior auricular artery.

(b) Anteriorly: Tympanic branch of maxillary artery.

(c) Twigs from middle meningeal artery.

Nerve supply

Lateral surface:

(i) Anterior half by auriculotemporal branch of the fifth cranial nerve.

(ii) Posterior half by auricular branch of vagus nerve. Medial surface is supplied by tympanic branch of the glossopharyngeal nerve.

Venous drainage

Veins drain into external jugular vein, traverse sinus, dural sinus and venous plexus around the eustachian tube.

Histology of the tympanic membrane

Tympanic membrane contains three layers:

(a) Outer epidermal layer

(b) Middle fibrous layer – lamina propria

(c) Inner mucosal layer

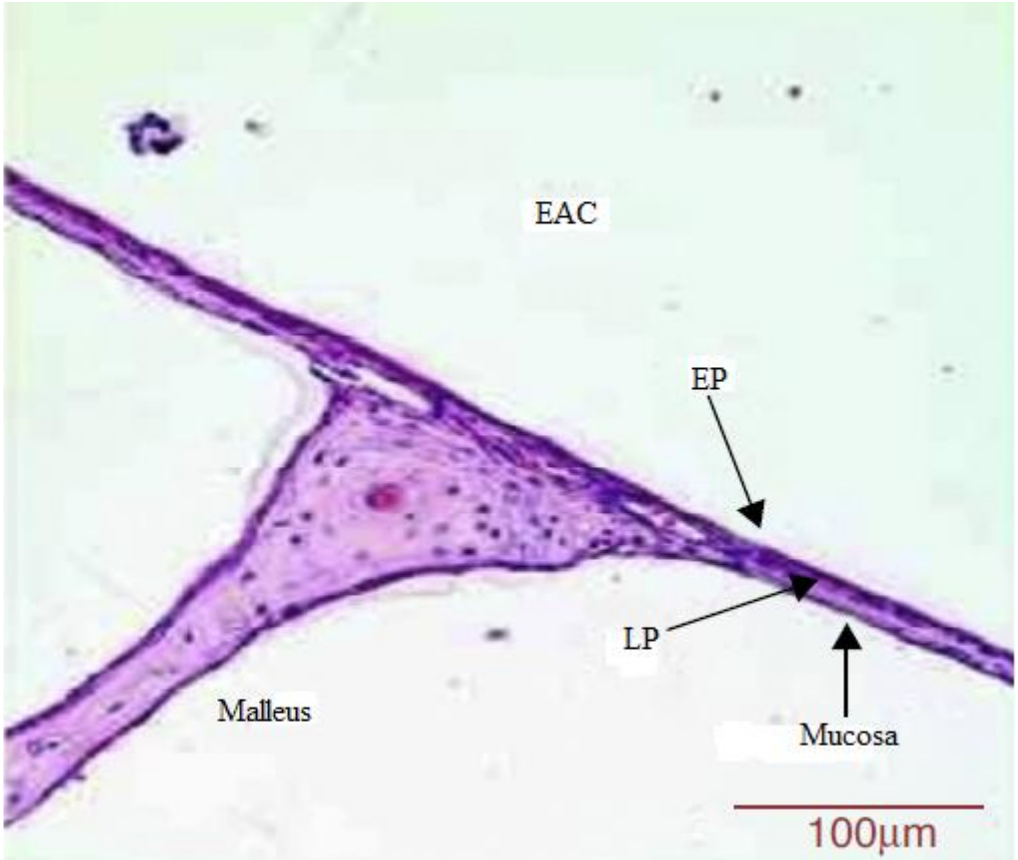


Figure 1: Histology of tympanic membrane

(a) Outer epidermal layer

It is continuous with the skin of the external auditory canal, it contains four layers.

Stratum corneum: Outermost layer contains 1-6 compressed layer of cellular structure.

Stratum granulosum: Contains 1-3 layers of cells with smooth borders and inter connecting desmosomes, keratohyaline granules, lamellar granules and occasionally tonofilaments are present.

Stratum spinosum: Contains 2-3 layers of cells. It has prominent interdigitations with neighbouring cells. Cells contain fewer bundles of tonofilaments with mitochondria and ribosomes.

Stratum basale: Contains single layer of cells separated by lamina propria, cells are polyhedral in shape or elongated parallel to the basement membrane.[14]

(b) Lamina propria

This is more marked in pars tensa. It contains subepithelial connective tissue layer, outer radiate collagenous layer, inner circular collagenous layer and submucosal connective tissue layer. In pars tensa the lateral fibres are radially arranged and deeper fibres are arranged in circular or parabolic or transverse fashion.

But in case of pars flaccida it is random.[14]

(c) Mucosal layer

It is the inner most layer. The cells are low simple squamous or cuboidal or columnar ciliated type of epithelium in pars tensa, whereas in pars flaccida taller ciliated cells are not found.[14]

Middle ear cleft

It consists of the eustachian tube, the tympanic cavity, the aditus, and the mastoid air cell system. It is lined by a continuous layer of epithelium of respiratory type. Near the eustachian tube and anteroinferior part of the tympanic cavity it is columnar epithelium. Above and behind this level the epithelium is flattened.

Development[15]

The tympanomastoid compartment appears at three week stage as an out pouching of the first pharyngeal pouch known as the tubotympanic recess. The endodermal tissue of the dorsal end of this pouch eventually becomes the Eustachian tube and tympanic cavity. By 7 weeks, concomitant growth of second branchial arch constricts the midportion of the tubotympanic recess, the primary tympanic cavity lies lateral and primordial eustachian tube lies medial to this constriction. The terminal end of the first pharyngeal pouch buds into four sacci (anticus, posticus, superior and medius) which expand progressively to pneumatise the middle ear and the epitympanum. Expansion of the sacci envelops the ossicular chain and lines the tympanomastoid compartment, whereas the interface between two sacci gives rise to mesentry like mucosal folds, transmitting blood vessels.

By 21 week, pneumatisation reaches the antrum. The tympanic cavity is essentially complete by 30 weeks. Mastoid pneumatisation is evident as early as 33 weeks and proceeds by well established tracts.

By birth, the antrum approximates that of the adult. Mesenchymal resolution continues as late as one year post-natally. Similarly, mastoid continues to grow for up to 19 years after birth. The first evidence of ossicular development in the humans occurs at approximately 4 weeks. The first arch (Meckel's cartilage) through cartilaginous differentiation gives rise to primordial malleus and incus. Stapes is derived from 2nd arch (Reichert's cartilage) except for the medial surface of footplate and the annular ligament, which are of otic capsular origin.

The ossicular chain has enchondral bone development. The anterior process of the malleus is unique in that it develops as membranous bone without a cartilaginous model. Development of stapes blasteoma involves progressive encirclement of the stapedial artery. The obturator foramen represents the complete ring left empty after the stapedial artery involutes.

By 15 weeks, the ossicles attain adult size and ossification soon begins, first in incus, then in the malleus and finally in the stapes.

The tensor tympani and stapedius muscle develop from the mesenchyma of first and second branchial arches. The ossicles assume adult configuration by 20 weeks.

Eustachian tube

It is named after Bartholomeus Eustachius. The tube is about 36 mm long in the average adult, it connects the tympanic cavity with the nasopharynx runs downwards, forwards and medially from the middle ear. There are two parts, a lateral bony posterior part arising from the anterior wall of the tympanic cavity and a medial fibro cartilaginous part entering the nasopharynx. The tube is lined by respiratory mucosa. The bony portion is 12 mm long. Isthmus is the narrowest portion which is only 2 mm in diameter. The cartilaginous portion of tube is about 24 mm. the lower opening lies behind and on a level with the posterior end of the inferior turbinate. In infants the tube is more horizontal and relatively wider and shorter than in adults. The tensor palate muscle helps in opening the tubal end on swallowing and yawning. [9,13]

Blood supply

It is supplied by ascending pharyngeal and middle meningeal arteries.

Venous drainage

Veins drain into pterygoid venous plexus.

Lymphatic drainage

Lymphatics drain into retropharyngeal nodes.

Nerve supply

Pharyngeal branch of the sphenopalatine ganglion (Vb) for the ostium, the nervus spinosus (Vc) for the cartilaginous portion and from the tympanic plexus (IX) for the bony part.[9]

Middle ear cavity

It lies between the external ear and inner ear and measures about 15 mm above downwards and 13 mm from behind forwards. It is very narrow in its transverse diameter measuring 6 mm across in the upper part, 4 mm in its lower part and 2 mm at its centre which is the narrowest part.

It has 6 walls, floor, roof, medial, lateral anterior and posterior walls. It is divided into 3 compartments.

The epitympanum or attic lies above the level of the anterior and posterior malleolar folds.

Mesotympanum lies medial to the tympanic membrane.

Hypotympanum, lies below the level of the inferior part of the tympanic sulcus medially.

Roof

It is formed by Tegmen tympani which are formed partly by petrous part of the temporal bone and partly by the squamous portion of the temporal bone. This wall separates the middle ear cavity, mastoid antrum and canal of tensor tympani from middle cranial cavity. Incomplete ossification of the petrosquamous suture may allow passage of infection from the middle ear cavity or mastoid antrum to the middle cranial fossa. Similarly venous channels passing through this fissure may allow infection to reach the superior petrosal sinus.[16]

Floor

It is formed by a thin plate of bone which separates it from the dome of jugular bulb. This floor may be deficient and thus jugular bulb may project into the tympanic cavity.[17] Anteromedial to the vein the tympanic branch of the glossopharyngeal nerve pierces the floor on its way to arborize over the promontory in the formation of the tympanic plexus.

Anterior wall

The anterior wall which is vertical is angulated acutely with the floor and forms a hypotympanic recess where inflammatory secretions accumulate. The portion of the recess is indicated by the 'cone of light' on the membrane, whose base points towards it.

This wall has '4' openings. The eustachian tube opening is seen in the lower part of the anterior wall. A thin plate of bone separates the eustachian tube and the middle ear from the internal carotid artery, which is perforated by caroticotympanic nerves derived from the sympathetic plexus on the internal carotid artery sheath. The canal for tensor tympani muscle is above the opening for eustachian tube. Canal of Huguier is a small opening in upper part which transmits chorda tympani nerve. Glasserian fissure is the 4^{th} opening, which transmits tympanic artery and anterior ligament of malleus.

Posterior wall

It is wider above than below and has in its upper part the opening (aditus) into the mastoid antrum. This is a large irregular hole that leads back from the posterior epitympanum. Below the aditus is a small depression, the fossa incudis, which houses the short process of the incus and the ligament connecting the two. Below the fossa incudis is the pyramid, a small hollow conical projection with its apex pointing anteriorly. It contains stapedius muscle, the tendon of which passes forward to be inserted into the neck and posterior crura of the stapes. Between the pyramid and the tympanic annulus is the facial recess. This is bounded medially by the facial nerve and laterally by the tympanic annulus, the chorda tympani runs between the facial nerve and tympanic annulus. This nerve always runs medial to tympanic membrane, which means that the angle between the facial nerve and the chorda allows access to the middle ear from the mastoid without disruption to the tympanic membrane.

Sinus tympani is the posterior extension of mesotympanum deep to the pyramid and the facial nerve. This extension of air cells into the posterior wall can be extensive when measured from tip of the pyramid, the sinus can extend as far as 9 mm into the mastoid bone.[18] The medial wall of the sinus tympani becomes continuous with the posterior portion of the medial wall of the tympanic cavity.

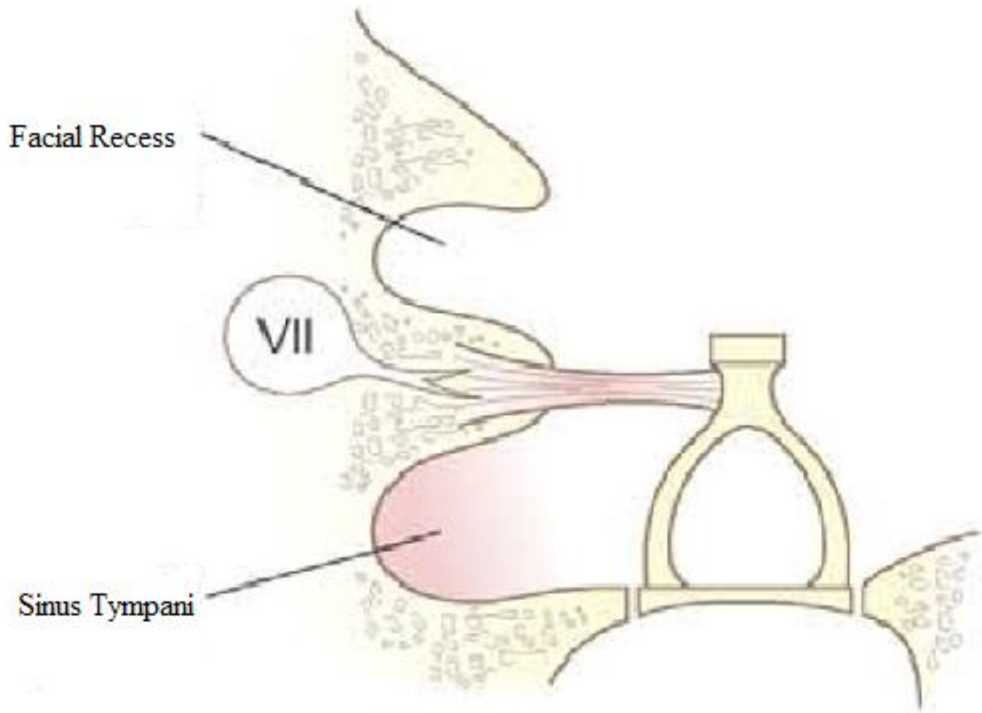


Figure 2: Sinus tympani

Medial wall of tympanic cavity

The medial wall separates the tympanic cavity from the inner ear. Its surface possesses several prominent features and two openings. The promontory is a rounded elevation occupying much of central portion of the medial wall, over whose surface is the nerves which form the tympanic plexus. The promontory covers part of the basal coil of cochlea and in front merges with the anterior wall of the tympanic cavity.

Behind and above the promontory is the fenestra vestibuli (oval window), a kidney shaped opening that connects the tympanic cavity with the vestibule, which in life is closed by the foot plate of the stapes and its surrounding annular ligament. The long axis of fenestra vestibuli is horizontal. The size is 3.25 mm long and 1.75 mm wide. Above the fenestra vestibuli is the facial nerve and below is the promontory.

The fenestra cochlea (round window) which is closed by the secondary tympanic membrane (round window membrane) lies below and a little behind the fenestra vestibuli from which it is separated by a posterior extension of the promontory called the subiculum. Occasionally a spicule of bone extends from promontory above the subiculum and runs to the pyramid on the posterior wall of the cavity. This spicule is called the ponticulus.

The round window niche is triangular in shape, with anterior, posterosuperior and posteroinferior walls. The latter two meet posteriorly and lead to the sinus tympani. The average lengths of the walls are: anterior – 1.5 mm, superior – 1.3 mm and posterior – 1.6 mm. The shape of the round window membrane varies from round through oval and kidney shaped the spatulate, with the average longest and shortest diameters of 2.30 mm and 1.87 mm respectively.

The round window membrane consists of three layers: outer mucosal, middle fibrous and inner mesothelial layer. The mucosal layer contains the capillaries and nerves.

The membrane of the fenestra cochlea forms part of its floor. The scala tympani terminate posterior and medial to the membrane. The ampulla of the posterior semicircular canal is the closest vestibular structure to the membrane and its nerve (singular nerve) runs almost parallel to and 1 mm away from its medial attachment. The membrane is thus a surgical landmark for singular nerve.

The facial nerve canal runs above the promontory and fenestra vestibuli in an anteroposterior direction. It is marked anteriorly by processus cochleariformis, which is a curved projection of bone, concave anteriorly and houses the tendon of tensor tympani muscle as it turns laterally to the handle of malleus. Behind the fenestra vestibuli, the facial canal starts to turn inferiorly as it begins its descent in the posterior wall of the tympanic cavity.

The dome of lateral semicircular canal extends a lateral to facial canal and is the major feature of the posterior portion of the epitympanum.

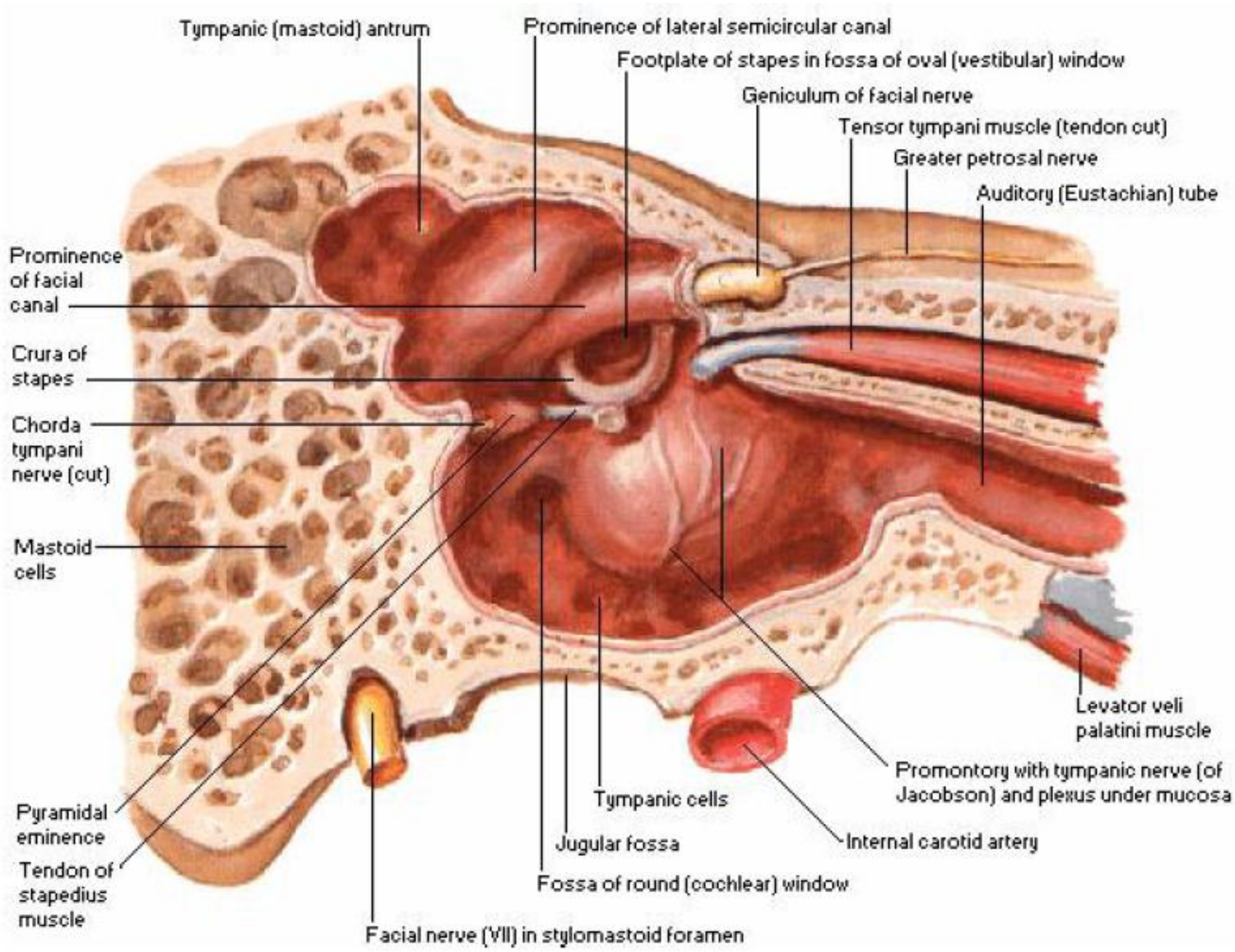


Figure 3: Medial wall of the tympanic cavity

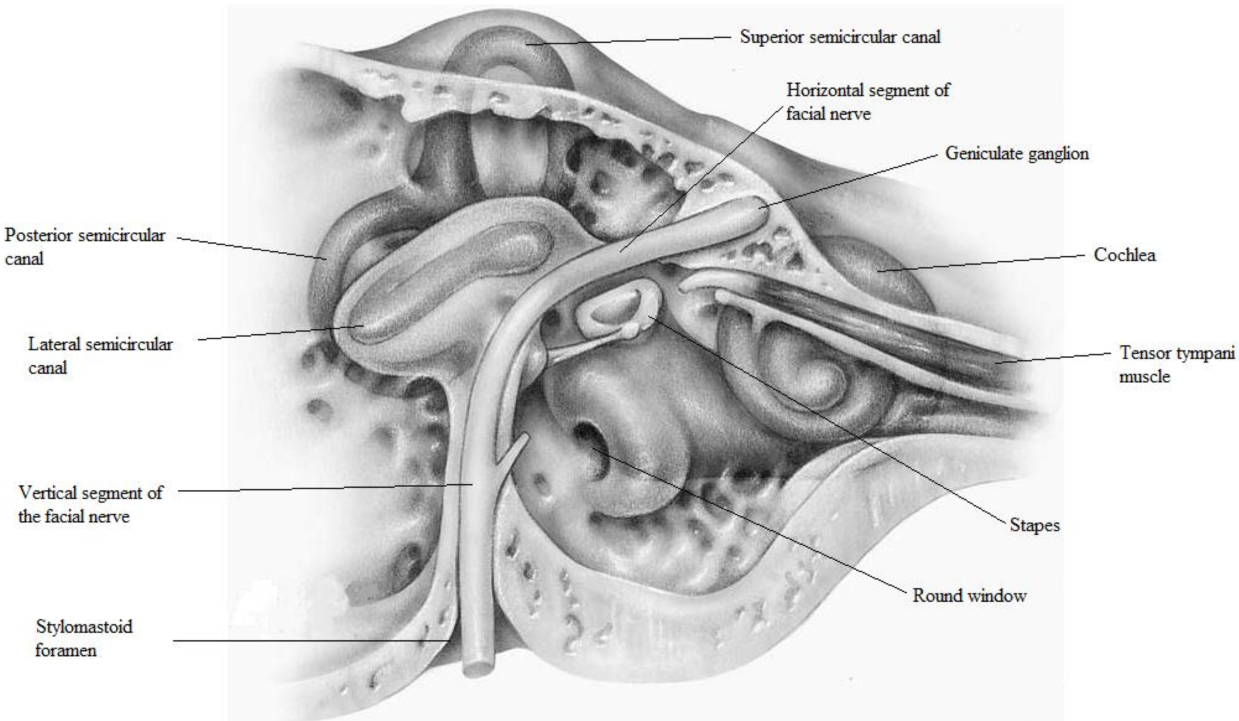
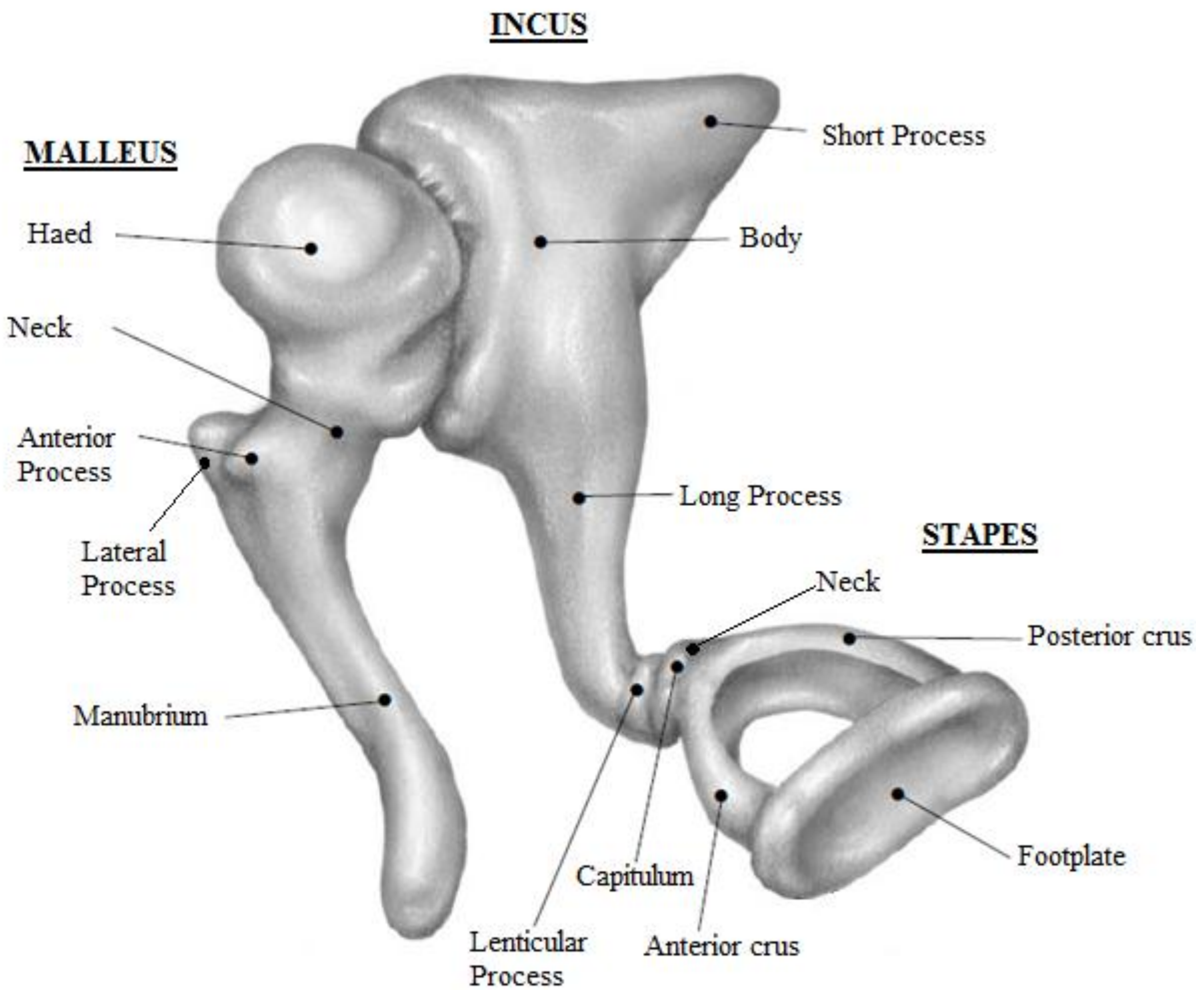


Figure 4: Facial nerve in its vertical and tympanic segment

Lateral wall

It is mainly composed of the tympanic membrane. Scutum or (outer) attic wall is party wall between the epitympanic recess and the roof of the external auditory meatus. The fibro cartilaginous circumference of the pars tensa of the tympanic membrane is fixed into the tympanic sulcus. The upper limits of the sulcus are marked behind by the posterior canaliculus and in front by the anterior canaliculus of the chorda tympani nerve. The anterior canaliculus is placed at the medial end of petrotympanic fissure, which lodges the anterior ligament of the malleus and admits the anterior tympanic branch of the maxillary artery. The contents of middle ear cavity are: auditory ossicles, muscles, chorda tympani nerve and facial nerve.

Ossicles



<u>Figure 5: Assembly of the ossicles</u>

1. Malleus

It is about 7.5 mm in length has a head, neck, anterior and lateral (short) process and a handle. The head is in the attic or in the epitympanic recess of the middle ear. The handle or manubrium is crescentic, concave laterally. The lower horn of the crescent terminates flatly at the umbo. The upper horn projects into the lumen of the external meatus as the lateral process. The neck is set at about 135° to the medial aspect of the handle, where the upper quarter joins the lower three quarter.

The anterior surface of the neck is thickened and drawn forwards into a small spicule known as the anterior process, which is connected to the petrotympanic fissure by ligamentous fibres, occasionally augmented by muscle fibres (luxator tympani muscle).

2. The incus

It consists of a body and two processes. The processes are set on to the body at right angles to each other. The long process is slender, and descends posteromedially and parallel to the slightly longer handle of malleus. The lower end of the long process is bent inwards and surmounted by a small tubercle covered with cartilage, the lentiform nodule, which articulates with the head of the stapes. The short process is thicker and shorter and passes horizontally backwards to obtain lodgement in and ligamentous attachment to fossa incudis.

A shallow saddle shaped depression in the anterior face of the head of the incus accommodates the convex facet on the posterior aspect of the head of the malleus. This joint allows a rotatory gliding movement. The excessive motion of the malleus on its outward swing is countered by the disengagement mechanism, while excessive inward swing is believed to be opposed by the mutual action of tensor tympani and stapedius muscle.

3. The stapes

The stapes consists of the head, neck, two crura (limbs) and a footplate. The footplate of the stapes is around 3mm x 1.4mm wide and covers the fenestra vestibule where it attaches to the bony labyrinth by an annular ligament. To the footplate is attached the two crura. The head of the stapes articulates with the lenticular process of the incus. The stapedius muscle is inserted into the posterior part of the neck and the upper portion of the posterior crura.

Auditory muscles

The two auditory muscles tensor tympani and stapedius muscle exert a dampening effect on the amplitude of the vibratory waves, thus protecting the cochlea from excessive stimulation by loud noise.[19]

Tensor tympani

It arises from cartilaginous portion of auditory tube, the adjoining portion of greater wing of the sphenoid, as well as from bony canal, above the auditory tube. It passes backwards in a tendon, round the processes cochleariformis and is inserted into the medial aspect of the upper end of the handle of malleus. It has got definite frequency selectivity for its contractions at 0.5 to 1 kHz resulting in decreased conductivity.

Nerve supply

Supplied by mandibular division of Vth nerve, via a branch leaving the nerve to the medial pterygoid muscle.

Stapedius

It is housed in a bony cavity. The tendon is seen issuing from the orifice of the pyramidal projection on the posterior wall at the posterior end of fenestra vestibuli. It is inserted into the posterior aspect of the neck of stapes.

Nerve supply

It is innervated by nerve to stapedius branch from facial nerve.

Vessels and nerves of the tympanic cavity

There are six arteries of the tympanic cavity:

1. Anterior tympanic branch of maxillary artery supplies the tympanic membrane.

2. Stylomastoid branch of posterior auricular artery supplies posterior part of the cavity and mastoid air cells.

3. Superficial petrosal branch of middle meningeal artery, which enters through the hiatus for the greater petrosal nerve.

4. Superior tympanic branch of middle meningeal artery enters via canal for tensor tympani.

5. Inferior tympanic branch from ascending pharyngeal artery accompanying the tympanic branch of the glossopharyngeal nerve.

6. Carotico tympanic branch of internal carotid artery passes directly into the cavity through the anterior wall.

Veins

Veins drain into pterygoid plexus and superior petrosal sinus.

Lymphatics drainage

The lymph vessels of the epithelial lining of the tympanum and mastoid antrum pass to the parotid and upper deep cervical lymph nodes.

Nerve supply

The nerves are contributory to or derivative from a plexus which ramifies over the promontory.

Tympanic plexus

It is formed by

1. Tympanic branch of glossopharyngeal nerve.

2. The superior and inferior caroticotympanic branches of the sympathetic plexus of internal carotid artery.

It supplies:

1. The lining membrane of the tympanic cavity, mastoid air cells and auditory tube.

2. A branch of greater superficial petrosal nerve.

3. Lesser superficial petrosal nerve. It is a continuation of the tympanic branch of the glossopharyngeal nerve which passes through the foramen ovale to the otic ganglion, from this post-ganglion secretomotor fibres are relayed via the auriculotemporal nerve to the parotid gland.

Mastoid air cell system[9,13]

In the majority of adult population a more or less extensive system of interconnecting air filled cavities arises from the walls of the mastoid antrum and sometimes even from the walls of the epitympanum and mesotympanum. These air cells like the mastoid itself are lined with a flattened non-ciliated squamous epithelium. Pneumatisation can be very extensive (cellular or well aerated).

Alternatively the mastoid antrum may be the only air filled space in the mastoid process when the name acellular or sclerotic is applied. This condition is noted in about 20% of adult temporal bones. In between these two forms are the so called diploeic or mixed types where air cells are present but are interspread with marrow containing space that have persisted from the late foetal life.

Temporalis fascia

Temporalis muscle is covered by deep temporal fascia which in turn is covered by superficial temporal fascia.[20] It is a strong aponeurosis overlapped by auricularis anterior and superior, the epicranial aponeurosis and part of orbicularis oculi. The superficial temporal vessels and the auriculotemporal nerve ascend over it. Above it is a single layer, attached to whole of the superior temporal line, below it has two layers, one attached to the lateral and other to the medial margin of the upper border of the zygomatic arch between these layers are the zygomatic branch of superficial temporal artery, zygomatic temporal branch of the maxillary nerve and small quantity of fat.

The deep surface of the fascia offers attachment to the superficial fibres of temporalis. The size of this fascia alters with its hydration.[21]

Physiology of conduction of sound[22]

Hearing is the vital basis for acquisition in speech and language and these skills in turn are most important tools of constructive thought. The sound conducting mechanism comprising the ossicles which forms a link extending from the pinna to the organ of corti. Its functions include:

1. Collection and transmission of sound energy involving impedance matching at every stage and particularly matching between the external air and cochlear fluids.

2. Protection of the inner ear from the excess loud sounds, a function carried out by the tympanic muscle sacrificing the sensitivity of low intensity sound levels.

Middle ear sound conduction[23]

The sound waves in air cannot be transmitted efficiently to the fluid medium which fills the cochlea without the help of some device to overcome the impedance mismatch. The role of middle ear is to match these impedances by acting as an acoustic sound pressure transformer. It also has to provide for acoustic separation of the round window from oval window if movement of stapedial foot plate is to be transmitted to the perilymph in the cochlea. The round window membrane provides the elasticity needed for the transmission of the sound wave into the fluid medium. If an incident sound wave falls on the oval and round windows simultaneously, the perilymph column will be unmoved, because the pressure exerted by the footplate at the oval window would be exactly resisted by pressure, acting in the opposite direction on the round window membrane. This difficulty is overcome by protection of the air cushion within the tympanum and by the preferential channeling of the sound waves from the tympanic membrane through the ossicular chain to the oval window. By these means the round window is acoustically isolated from the oval window.

Ossicular movement[22,23]

The vibrations of the tympanic membrane are conveyed to the malleus through its handle. The malleus and incus move as one functional unit, except at very high intensity, rotating in and out through a tiny arc, about an axis which passes from the anterior process of the malleus backwards to the end of the short process of the incus. The oscillating movement of the stapes in the oval window, received from the long process of the incus, is in and out, like that of a piston, when amplitude is low. At higher amplitude the footplate executes a rocking motion about a vertical axis through its posterior edge. When the stapedius muscle contracts, in response to sound pressure levels 80 dB or more above the threshold, the mode of stapes movement may change to one of longitudinal rotation about its long axis. This form of vibration attenuates sound levels reaching the cochlea, especially in the low frequencies.[19]

Sound pressure transformation

The problem of impedance matching, so that relatively light and inelastic air can impart its energy to relatively dense and highly elastic fluid, solved by two mechanisms – ossicular lever action and hydraulic action. The pressure of sound waves on the stapes footplate is almost twenty times greater than on the tympanic membrane as a result of the combined effect of these mechanisms.

Ossicular leverage

It is provided by the movement of the malleus – incus complex acting as a lever about its axis of rotation. The handle of the malleus is about 1.3 times longer than the long process of the incus, when each is measured from its tip to the fulcrum at the axis. This factor of 1.3 is the size of the mechanical gain provided by the lever action.

Hydraulic action

It depends on the relative surface areas of the tympanic membrane and the stapes footplate. Anatomically the surface area of the tympanic membrane is about 21 times that of the footplate. It is known that the central $2/3^{rd}$ of area of tympanic membrane moves as a unit and it is this central part which provides the area to relate to that of the footplate. The functional ratio of tympanic membrane surface area to footplate area is then $2/3^{rd}$ of 21:1 = 14:1, which is the mechanical advantage derived from the hydraulic action. The combined benefits of lever action and the hydraulic action provide an increase of pressure at the oval window of 14 x 1.3 or just over 18 times.

Auditory tube function

Effective sound transmission through the middle ear and into the cochlea requires that the air in the middle ear is maintained at a pressure level identical to that of the ambient air in the external acoustic meatus. Deviations from this ambient level of pressure, the impedance of middle ear increases. The pressure of air in the middle ear must at all times be kept at the ambient external level as a prerequisite for efficient middle ear function and inner ear sound conduction. Auditory tube maintains this pressure. Auditory tube obstruction raises the threshold of hearing by 30-40 dB. In normal individuals, the limits of variation for compliance and resistance are much narrower for female subject, but the average values are similar to both sexes.[24]

Sensorineural function

Air conducted sound waves are admitted to the cochlear perilymph through the oval window, and the information they convey emerges at the other end of the cochlea as nerve impulses in the afferent fibres of the cochlear nerve. The cochlea is a tube filled with perilymph, coiled on itself 2¾ times. Along the length this tube is divided into two channels by a cochlear partition. The upper channel is the scala vestibuli, into which the oval window opens. The lower channel is the scala tympani, which is sealed at its end by the round window membrane. These two perilymphatic channels communicate with each other only at the cochlear apex, through the helicotrema, scala media containing the endolymph is separated from scala vestibuli by Reissner's membrane and from scala tympani by basilar membrane supporting the organ of corti and associated structure. The basilar membrane is 35 mm long gradually increases in width from 0.08 mm at the base near the oval window to 0.5 mm at the apex. The progressive increase in mass and decrease in stiffness along the length of the membrane. An account of sensorineural function demands a description of movement of the cochlear partition by sound waves, of the conversion of the mechanical energy of movement to electrical energy (transduction) and of the electrical events induced in the fibres of cochlear nerve.

Movement of the cochlear partition[22]

1. Helmholtz in his 'place' theory suggested that, basilar membrane consist of a series of tuned resonators. In this theory, any segment of the basilar membrane is activated by a sound wave of

the resonant frequency of that segment, with high frequency waves exciting segments in the basal turn and low frequencies exciting the more apical regions.

2. Rutherford's telephone theory: According to this the frequency of activating sound wave is signaled by the rate of discharge in the cochlear nerve fibres. The latent period of nervous action limits this theory to the perception only of frequencies below 1000 Hz, if the relationship between sound wave frequency and nerve impulse has a simple ratio of 1:1.

3. Wever's volley theory: Combines both place and telephone principles postulating that:

a. High frequencies are perceived as per place theory (in the basal turn).

b. Low frequency (below 1000 Hz) stimulate nerve action potentials at a rate equal to the stimulus frequency.

c. Intermediate frequencies are represented in the auditory nerve by asynchronous discharges in groups of neurons, whose combined activity represents the frequency of the stimulus.

4. Von Bekesy's Travelling wave theory: Each wave increases in amplitude until it reaches a maximum at a place, which is specific for its frequency and then rapidly dies away. Successive trains of waves produced by a sustained tonal stimulus have an envelope with a maximal displacement at a site determined by the stimulus frequency. High frequency waves activate only the basal turn, which appears to move as one. Lower frequency waves travel farther along the whole length of the partition to the apex before reaching their maximum. Sharpening of this frequency sensitivity takes place partly in the cochlea and farther by neural mechanisms in the

brain. The traveling wave uniquely represents the frequency of excitation and many of its physical character may subsequently be used by brain for finer pitch assessment.

Cochlear transduction

Endolymph has a composition different from that of perilymph, which is an ultrafiltrate of plasma. Particularly the high potassium level of endolymph (150 mq/litre compared with 6 mEq/litre in perilymph) and the low endolymphatic sodium level (1.5 meq/litre compared with 150 meq/litre in the perilymph).

Electrically endolymph in the scala media has a positive potential of +80 mV relative to that of perilymph. This is endocochlear potential. The interior of hair cell has a potential negative relative to that of perilymph, of the order of -70 mV, so there is a potential difference of 150 mV between the endolymph and the interior of the hair cell.

Deformation of the cochlear partition by the traveling wave bends both the basilar membrane and the tectorial membrane, but since these pivot about different axes, the displacement ‘wipes’ the tectorial membrane with a shearing action, across the tops of hair cells. This changes the resistance of the surface of the hair cell in contact with the endolymph and so alters the amount of current flowing through the cell. In this way movements of the cochlear partition modulate the current flowing through the hair cell body. This causes the electrical excitation of the afferent nerve endings.

The stored electrical energy represented by the large potential differences, endows the cell with amplifier properties, so that tiny amounts of mechanical energy modulate the output of a greater electrical energy source. The endocochlear potential is changed by displacement of basilar membrane and resulting hair bending and the change is maintained as long as mechanical deformation persists. Movement upwards, which is the direction causing neural excitation, is associated with a reduction of the potential.

Cochlear nerve activity[22]

This nerves act on 'an all or none' basis, which implies that the nerve discharges only when its threshold of excitation is exceeded. A second action potential can follow only after a refractory period, during which the nerve regains its resting state. At rest all the cochlear nerve fibres are discharging. Each nerve fibre responds most readily to a stimulus of a particular frequency its characteristic frequency and less readily to stimuli of frequencies differing from that. The threshold for excitation increases the more the stimulus frequency differs from the characteristic frequency. Tuning curve of acoustic nerve fibres shows that frequency sensitivity is much finer or the tuning much sharper, than the mechanical response of the basilar membrane. The tuning curves overlap and broaden at high intensities, high intensity sounds excite fibres whose characteristic frequencies are more and more distant from the stimulus frequency.

The tuning curves of low frequency fibres are symmetrical but those of fibres with high characteristic frequencies are asymmetrical with a sharp high frequency cutoff. This means, at high intensity, all fibres with characteristic frequency below the test tone will be activated. Thus the intensity of a sound is indicated by the rate of spike discharge and the number of active fibres. Frequency information is available from the site of maximum excitation and from the spatial pattern and responses of excited fibres. At very low frequencies, periodicity of discharge is informative, while at higher pitches phase locked information in groups of fibres extends the potential of volley theory information. The frequency and intensity determinants of nerve fibre impulse rates are finally separated centrally by the activity of 10^7 neurons in the brain with which the auditory fibres eventually connect.

Cochlear microphonics

These are alternating potentials, originating in the hair cells, which accurately follow the pattern of the sound stimulus, and the movements of the cochlear partition. They persist after nerve conduction ceases and appear as responses in opposite senses with upward and downward movement of the partition. Summating potentials show as steady baseline shifts in the recording. They reflect steady changes in endocochlear potential.

Chronic otitis media (COM)

Otitis media is defined as “an inflammation of the middle ear without reference to aetiology or pathogenesis.”[25] Otitis media also implies concomitant inflammation, to a greater or lesser extent, of the mastoid air cell system, owing to its anatomic linkage to the middle ear cleft. Accordingly, otitis media is more correctly conceived of as an inflammatory disorder of the entire tympanomastoid compartment.

COM is a major global cause of hearing impairment and this may have serious long term effects on language, auditory, cognitive development and educational progress.

As per WHO, despite the shortage of accurate, standardized data, the prevalence of COM in Indian population is approximately 2% which is comparatively higher than that found in developed countries like that of USA and UK where the prevalence is <1%.[26] It is considered “Chronic” if the tympanic membrane defect is present for more than 3 months. Thus a draining middle ear cavity that is associated with a perforation from acute otitis media would not qualify for this diagnosis if it responds to treatment within 3 months. Histologically, COM is defined as irreversible mucosal changes within the middle ear cleft.[27] COM is characterized by intermittent or persistent chronic purulent drainage through a perforated tympanic membrane and can be associated with cholesteatoma. On occasion, a permanent, central perforation of the tympanic membrane can remain dry, with only rare intermittent drainage, that is, inactive COM. More typically, chronic or recurrent mucoid otorrhea, that is, active COM is provoked by exposure of the tympanic mucosa to bacteria of the external auditory canal as well as of the eustachian tube.

Clinical Classification

Table -1: Classification of Chronic Otitis Media[28]

COM Classification	Otoscopic findings
Healed COM	Thinning and/or localised or generalised opacification of the pars tensa without perforation or retraction
Chronic Inactive mucosal	Permanent perforation of the pars tensa but the middle ear mucosa is not inflamed
Chronic inactive squamous	Retraction of pars flaccid or tensa which has the potential to become active with retained debris
Chronic active mucosal	Permanent defect of the pars tensa with an inflamed middle ear mucosa which produces mucopus that may discharge
Chronic active squamous	Retraction of the pars flaccid or tensa that has retained squamous epithelial debris and is associated with inflammation and production of pus from the adjacent mucosa

Etiopathogenesis

A variety of underlying pathologies can cause COM including:

1. An acute episode of acute otitis media can result in a perforation of the ear drum and does not settle within two weeks;

2. Recurrent episodes of acute otitis media in an ear with a perforation from a previous episode of acute otitis media; or

3. An ear with a persistent perforation with active chronic otitis media with metaplastic changes to the mucosa of the middle ear and mastoid air cell system.[28]

In adults, the majority of patients are likely to have COM with a perforation that will not spontaneously heal. This results in associated hearing impairment and ear discharge. Hearing impairment due to otorrhea and a perforated eardrum will usually improve as the disease resolves.

However, untreated COM may result in permanent hearing loss due to damage to the ossicles which transmit sound vibrations from the eardrum to the cochlea. Since otitis media occurs mostly in children during pre-school years, the years in which the most dynamic phase of speech and language development occurs, there is concern that the associated hearing deficits may result in speech and language delays or permanent learning disabilities, as well as disturbances in behaviour.[29] Majority of the patients with otitis media do well with antimicrobial therapy but despite this there is a subset of the patients who develop serious complications from this otherwise self limiting disease.

There are various intratemporal and intracranial complications likely in patients with COM and the mortality rate of these remains substantial ranging from 10 – 31%.[30] In addition to hearing impairment (with its associated consequences), complications of otitis media can result in death or severe disability, which is especially more common in developing countries, where immunity, housing conditions and access to medical services are often poorer than in high income settings.[31] The infection may extend and spread to the head and neck structures and to the brain. Intracranial infections include meningitis, abscesses, hydrocephalus, or thrombosis of the lateral venous sinus (from suppuration within the mastoid causing thrombus occluding the lumen of the vessel).[32] Alternatively complications may be extracranial, such as subperiosteal abscess (superficial accumulations of pus that eroded the bony mastoid cortex), facial paralysis, cholesteatoma (a destructive formation of layers of keratinizing epithelium, accumulating in the middle ear and mastoid, also described as 'active squamous/epithelial chronic otitis media), labyrinthitis (extension to the labyrinth through the round window), or acute mastoiditis (spread of the infection to the mastoid air cells) which may spread further due to necrosis of the bony wall of the cells resulting in further life-threatening complications.[32,33,34] In view of the above it is imperative to treat patients with COM and the mainstay of therapy remains surgical. In 1965, the American Academy of Ophthalmology and Otolaryngology Subcommittee on Conservation of Hearing set forth a standard classification for surgery of chronic ear infection and defined tympanoplasty as "a procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting."[35]

The causes and risk factors associated with COM are unclear, and few studies have examined these for COM. Instead authors have extrapolated results of studies for AOM and otitis media with effusion to COM. However, these studies often have conflicting findings, and there is no proven correlation between the various host and environmental factors associated with COM and the factors associated with AOM and otitis media with effusion. Despite this, some important factors that may be associated with COM include: environmental factors such as inadequate treatment (of COM and acute otitis media), poor access to medical care, poor socioeconomic conditions, season, exposure to tobacco smoke, overcrowding, attendance at day care centre, lack of breastfeeding, or poor nutrition or hygiene; and host factors such as altered immunity and underlying diseases (e.g. HIV/AIDS, frequent upper respiratory tract infections), early onset of otitis media in the first months of life and family history of otitis media.[36,37]

Some populations are at increased risk of developing COM, and have high rates reported, including certain ethnic groups (such as Native American tribes of Apache and Navajo, Australian Aborigines, and Inuit of Canada, Greenland and Alaska), and individuals with anatomical defects (e.g. cleft palate or sub mucous cleft), altered physiological defences(Eustachian tube dysfunction) or Down's syndrome.[38] In the ethnic groups found to be at high risk for developing COM, there is some evidence that this may be due to their eustachian tubes being semi patulous (of low resistance) or larger in diameter than in other ethnic groups which allows easier reflux of nasopharyngeal secretions into the middle ear. In addition Australian aboriginal neonates have been shown to develop colonisation of the nasopharynx earlier and more rapidly than Caucasian neonates.

Individuals with cleft palate or Down's syndrome more readily develop otitis media and they have on average shorter eustachian tubes than age-matched individuals without these disorders.

Treatment Modalities

The aims of treatment are to stop the discharge (and to eradicate infection), to heal the tympanic membrane, improve hearing, prevent the common problems of recurrent or new infections and to prevent potentially life-threatening complications.

Treatment options for uncomplicated COM include dry mopping, ear wicking, gentle syringing, or suctioning, to clean the ear discharge (aural toilet); systemic antibiotics (e.g. oral antibiotic preparations, or intravenous antibiotics); and topical treatment with either antiseptics or antibiotics, sometimes with steroids. If complications develop, surgery is usually required to remove the infected tissue from the middle ear and mastoid air cells, and possibly repair the damaged eardrum and ossicles. The treatments modalities available are as follows:

- aural toilet
- systemic antibiotic treatment
- topical antiseptics
- topical antibiotics without steroids.[39]
- systemic versus topical treatments for COM
- systemic or topical steroids: steroids, as monotherapy or combination therapy.
- surgical treatment

Surgery of the TM dates back as far as the 17th century when Banzer (1640) described the first attempt at repair of a TM perforation with a pig's bladder. Over the next century, most of the advances in otologic surgery were focused on the mastoid to treat life threatening infections. In 1853, Toynbee placed a rubber disk attached to a silver wire over a perforation. He reported significant improvement in hearing with this method. Later Yearsley (1863) placed a cotton ball over a perforation and in 1877; Blake proposed the paper patch which is still used today for preoperative evaluation of potential hearing improvement. The earliest treatment of TM perforations with chemical cautery was performed by Roosa (1876) and Okneuff (1895). The term myringoplasty was coined by Berthold in 1878. He placed a court plaster against the tympanic membrane for 3 days to remove the epithelium, and then applied a thick skin graft. Despite success reported in two cases, little more was heard of myringoplasty until Schulhof and Valdez mentioned it in 1944. Wullstein and Zollner are given credit for ushering in the modern era of tympanoplasty in the 1950s. They placed split thickness skin grafts over the de-epithelialized TM remnant. Initially, good results were obtained; however, subsequent graft eczema, inflammation, and perforation were common. During this time, Wullstein (1956) described five types of tympanoplasty based on the relationship of the grafted TM to the middle ear structures. In 1961, Storrs reported a series of patients in which temporalis fascia was used as an outer surface graft. Over the next three years, this technique became wide spread and resulted in over 90% graft take. House (1961),Glasscock, and Sheehy (1967) further developed and refined techniques used for lateral graft tympanoplasty which are the same techniques used today. The first medial graft tympanoplasty was performed by Shea (1957). He was performing a stapedectomy and by chance, discovered that a medial vein graft was successful in repairing an accidental tear. Storrs later replaced the vein graft with temporalis fascia for use in medial grafting.

Over the past three decades temporal fascia has been the most commonly used grafting material in tympanoplasty operations, although tragal perichondrium, periosteum, loose overlay tissue, fat, vein, alloderm, homograft TM, and homologous dura are also employed.

Tympanoplasty

It is a procedure to eradicate the disease in the middle ear and reconstruct the hearing mechanism with or without tympanic membrane grafting as given by the American academy of ophthalmology and otolaryngology subcommittee on conservation of hearing in 1965.[35] This procedure can be combined with either an intact canal wall mastoidectomy or canal wall down mastoidectomy to eradicate the disease from the mastoid area.[40]

Principle of tympanoplasty[41,42]

1. To accomplish the sound protection for the round window by placement of a graft so that sound does not reach the oval window and round window at the same time and a phase difference is provided
2. To improve the sound pressure transformation by providing an increased surface after placement of the graft and reconstructing the hearing mechanism.

Types of tympanoplasty

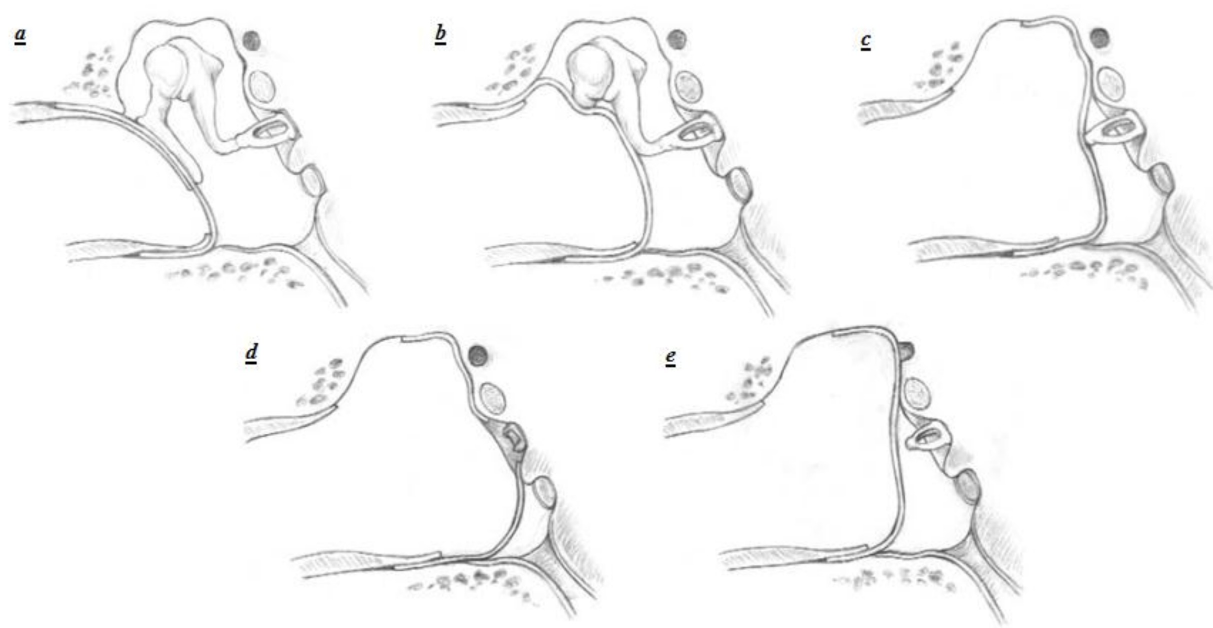


Figure 6: Types of tympanoplasty based on Wullstein and Zolner classification.

Tympanoplasty type I [Figure 06 (a)]:

Type I tympanoplasty is performed when all three ossicles are present and mobile and involves repair of a tympanic membrane perforation or retraction without ossicular chain reconstruction.

Tympanoplasty type II [Figure 06 (b)]:

Type II tympanoplasty is utilized when the malleus is eroded and involves grafting the tympanic membrane to an intact incus and stapes or remnant of the malleus

Tympanoplasty type III [Figure 06 (c)]:

A type III tympanoplasty is indicated when the lateral ossicles are eroded. The stapes must be intact and mobile. The tympanic membrane or graft or partial ossicular chain reconstruction prosthesis is placed in contact with the stapes superstructure.

Tympanoplasty type IV [Figure 06 (d)]:

Type IV describes an absent or eroded suprastructure with the graft or tympanic membrane overlying a mobile stapes footplate. The resulting middle ear consists of the hypotympanum and the eustachian tube orifice only.

Tympanoplasty type V [Figure 06 (e)]:

Type V tympanoplasty is used when the stapes footplate is fixed. Type Va involves grafting over a fenestration created in the horizontal semicircular canal. This technique has largely been abandoned in favour of the Type Vb which involves a stapedectomy.

Graft materials used in tympanoplasty

1. Autologous / Autografts

Temporalis fascia, tragal perichondrium with or without cartilage, periosteum, fat, vein and fascia lata.

2. Homologous / Homograft

Duramater, tympanomeatal graft, cornea, amniotic membrane.

3. Heterologous / Heterograft

Bovine jugular vein, calf caecal serosa.

Advantages of Temporalis fascia graft:[43]

1. It has a thickness comparable to the tympanic membrane
2. It has a low basal metabolic rate
3. Can be harvested in the same incision as the postaural or endaural incision
4. Also large amount of graft is available even if a revision tympanoplasty is planned

Types of graft placement

Overlay technique

This is a technique of placement of the graft where the connective tissue graft is placed lateral to the annulus tympanicus i.e. between the outer epithelial layer and the middle fibrous layer of the tympanic membrane. Overlay technique is best suited for a large central perforation in which minimal de-epithelialisation is required.

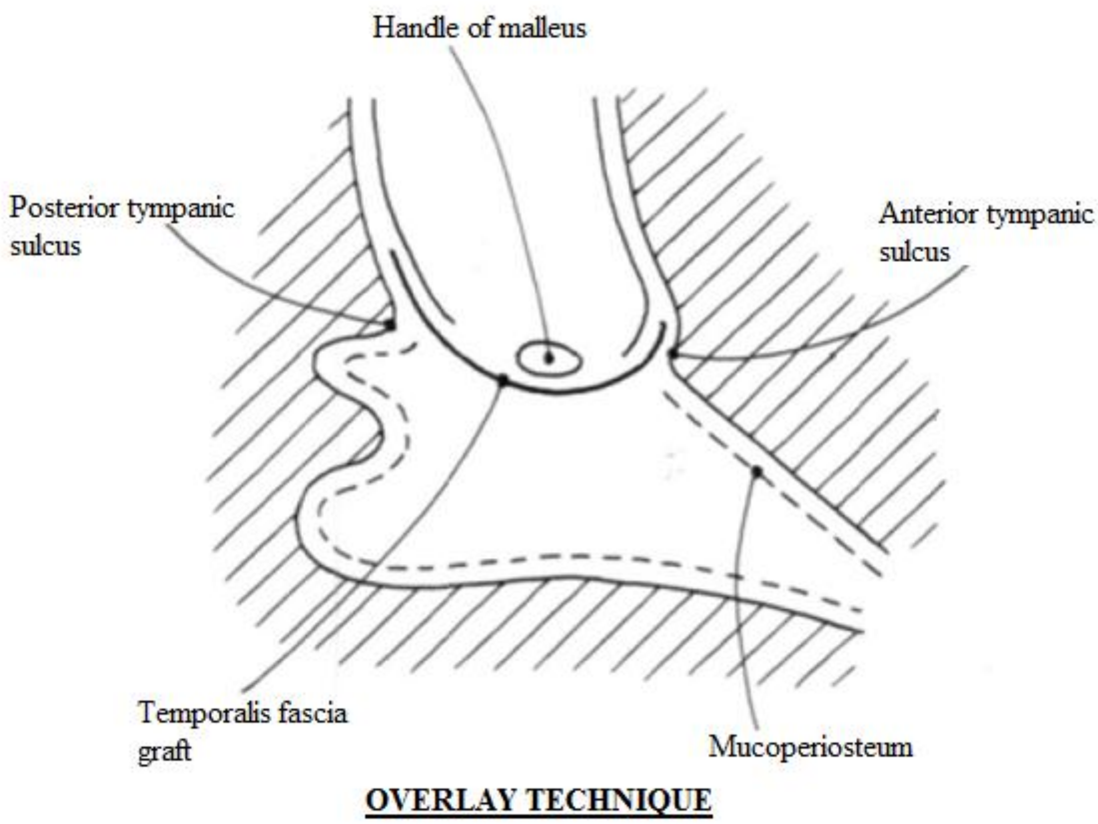


Figure 7: Overlay technique of grafting

Advantages of overlay technique:

1. Can be used in perforations of all sizes
2. Wide exposure
3. Anterior meatal recess can be visualized well
4. Higher success rate of graft take up
5. No reduction of middle ear space

Potential pitfalls of overlay tympanoplasty:

1. Anterior angle blunting
2. Epithelial pearl formation
3. Lateralisation of the graft
4. Prolonged healing as the canal skin is completely removed and replaced back as a free graft

Underlay technique

This is a technique where the connective tissue graft is placed medial to the remnant of the tympanic membrane i.e. the annulus tympanicus.

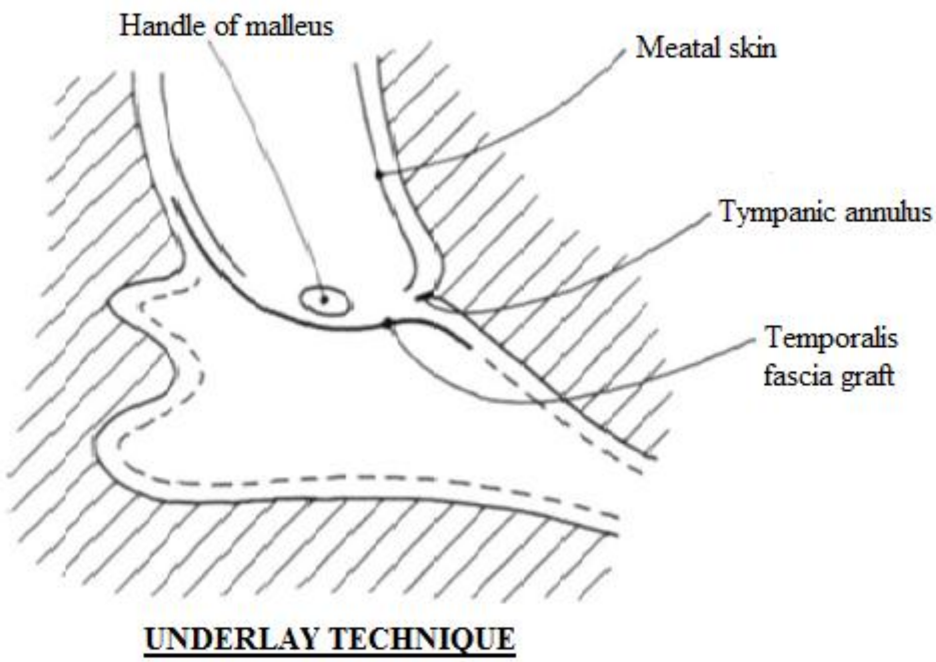


Figure 8: Underlay technique of grafting

Advantages of underlay technique:

1. Has a high take up rate
2. Ideal for small and easily visualized perforations
3. Technically less demanding compared to the overlay technique
4. Less time consuming
5. Graft lateralization, anterior blunting and epithelial pearl formation are not commonly encountered

Disadvantages of underlay technique:

1. Poor visibility of the anterior meatal recess
2. Reduction of the middle ear space
3. Not suited for large anterior perforations
4. Difficult in cases with small external auditory canal and may have to be combined with a canal plasty to overcome the same

Approaches for tympanoplasty

1. Transcanal approach:

It consists of a U- shaped incision, starting just lateral to the annulus tympanicus from the 12 o' clock position superiorly and meeting the inferior incision starting at 6 o' clock position at the bony cartilaginous junction which is around 5 to 7 mm from the annulus along the posterior meatal wall.

Advantages of transcanal approach

- Small posterior perforations and medium-size perforations when the ear canal anatomy is favorable and the entire perforation and an anterior tympanic membrane rim can be seen
- Post aural scar is avoided
- Less discomfort and better healing

Disadvantages of transcanal approach

- Poor exposure(especially of the anterior mesotympanum)
- Tympanomeatal flap obscures the vision
- Has a greater learning curve

2. Endaural approach

This technique was by Lempert in 1937. It consists of two parts-

Lempert 1- A curvilinear incision made from the 12 o'clock to 6 o'clock position around 5mm from the annulus along the posterior meatal wall

Lempert 2- starting from the first incision at 12 o'clock position a linear incision is made passing between the crus of the helix and the tragus. Hence, the incision does not cut through the cartilage.

Advantages of endaural approach

- Both hands free for instrumentation
- Fairly good exposure of the surgical field
- Absence of a visible surgical scar

Disadvantages of endaural approach

- Presence of postoperative discomfort
- Has a greater learning curve

3. Postaural approach

The canal incision consists of a curvilinear incision starting 5mm lateral to the annulus from 12 o'clock position to the 6 o'clock position along the posterior meatal wall. Vertical incisions are then taken at 12 o'clock and 6 o'clock positions which extend till the bony cartilaginous junction.

This is followed by a post auricular incision which is taken around 5mm from the postauricular groove starting from the highest point of the helix to the tip of the mastoid.

Advantages of postaural approach

- Both hands free for instrumentation
- Excellent exposure of the surgical field
- Can be combined with mastoidectomy in case it is planned along with tympanoplasty

Disadvantages of post aural approach

- Presence of Postoperative discomfort
- Delayed healing of the post aural wound
- Presence of a visible but hidden surgical scar

Indications for tympanoplasty

1. Improve healing

2. To prevent further infection of the ear via the eustachian tube and external auditory canal.

3. To prevent tympanosclerosis.

4. To enable proper fitting of the hearing aid.

5. To enable recruitment in certain professionals.

6. Prevent caloric effect

Contraindications for tympanoplasty

Absolute contraindications

1. Presence of cholesteatoma

2. Malignant neoplasm of the outer and middle ear.

3. Invasive life threatening infections with pseudomonas of outer and middle ear.

4. Suspected intracranial complications of chronic otitis media.

Relative contraindications

1. Dead ear or ear without cochlear reserve

2. Acute exacerbation of chronic otitis media

3. Allergic type of chronic otitis media

4. Chronic otitis externa

5. Non-functioning eustachian tube

6. Only hearing ear

7. Child < 10 years

Cortical mastoidectomy

Cortical mastoidectomy is the transcortical opening of the mastoid air cells and the antrum. It is also called simple mastoidectomy or Schwartze mastoidectomy. It forms the basic operation for several conditions of the middle ear as well as the initial stage surgery for the transmastoid surgery of the middle ear, inner ear, facial nerve, endolymphatic sac, labyrinth, internal auditory canal and removal of certain skull base tumours. The extent of the surgery depends on the disease process and the access required for the approach. It is generally combined with a tympanoplasty to clear the disease from the mastoid. However, it is not indicated in all patients.[44,45]

The aims of performing a cortical mastoidectomy are:

1. To exentrate all the mastoid air cells.
2. To widen the aditus and facilitate better ventilation of the mastoid antrum.
3. To clear the hypertrophied mucosa and infection from the middle ear.
4. Also as an approach to other surgeries like facial nerve decompression, endolymphatic sac decompression, excision of glomus tympanicus, etc.

Indications for cortical mastoidectomy

1. Chronic otitis media not responding to medical management.
2. Presence of a retroauricular subperiosteal abscess, zygomatic subperiosteal abscess, bezold's abscess.
3. Masked mastoiditis.

4. Sagging of the posterosuperior canal wall due to thickening of the periosteum near the antrum.
5. Associated intracranial complications like meningitis, encephalitis, extradural & subdural abscess with acute otitis media.
6. Persistence of ear discharge for more than four weeks in acute otitis media.
7. Recurrent acute otitis media.
8. Refractory secretory otitis media.
9. As an approach to facial nerve decompression, endolymphatic sac decompression, internal auditory canal surgeries, certain skull base tumours.

Procedure

1. Infiltration in the post aural region is done using 2% lignocaine with 1:80000 units of adrenaline.
2. William wilde’s incision is taken which is a curvilinear incision 5mm behind the post auricular groove from the root of the helix to the tip of the mastoid.
3. The skin incision is gradually deepened and the periosteum identified.
4. A horizontal cut is taken along the linea temporalis and the vertical cut is made along the external auditory canal over the periosteum covering the mastoid.
5. The periosteum is then stripped to reveal the landmarks over the mastoid.
6. Drilling is begun in the MacEven’s triangle. The mastoid antrum lies 1.5cms medial to this triangle.

7. The mastoid antrum is entered by drilling through the cortex and slowly the cavity is widened.
8. Drilling is continued till the tegmen plate superiorly; sigmoid sinus posteriorly; thin out the posterior canal wall anteriorly; digastric ridge inferiorly; lateral semicircular canal medially.
9. The disease in the aditus and mastoid antrum is cleared and patency is achieved.
10. The periosteum and the skin is closed in layers.

Complications of cortical mastoidectomy

1. Injury to the duramater, sigmoid sinus, facial nerve, lateral semicircular canal.
2. Subluxation of the incus or dislocation of the ossicular chain.
3. Sensorineural hearing loss caused due to the use of drill.
4. Meatal stenois.
5. Fixation of the malleus and the incus.

MATERIALS AND METHODS

Source of data

A minimum of 102 patients who have been diagnosed to have mucosal COM in the department of Otorhinolaryngology and Head and Neck Surgery of R L Jalappa Hospital and Research Centre, Tamaka, Kolar from December 2012 – March 2014 were included in this study.

Inclusion criteria

1) All patients above 18 years of age who are diagnosed to have Chronic mucosal otitis media.

Exclusion criteria

1) Patients having ossicular abnormalities.
2) Patients with tympanosclerosis.
3) Revision cases of tympanoplasty/ myringoplasty.
4) Patients unfit or not willing for surgery.

Methods of collection of data

A minimum of 102 patients above 18 years of age diagnosed as COM in the department of Otorhinolaryngology and Head and Neck Surgery of R L Jalappa Hospital And Research Centre, Tamaka, Kolar from December 2012 – March 2014 were included in this study.

The diagnosis of COM was based on clinical history (ear discharge, hearing loss and tinnitus) and routine ENT examination. Once the diagnosis was made, these patients were subjected to Microscopic ear examination. Patients were then subjected to Pure tone audiometric evaluation, mastoid radiography and haematological investigations. A written informed consent was taken to include the patient into the study and then surgically repair of the tympanic membrane perforation.

Patients with acute infection were treated with a course of antibiotics for a week for the infection to subside and were then planned for surgery.

The patients diagnosed to have mucosal COM were classified into groups depending on the size of the tympanic membrane perforation- small, moderate and large size central perforation. In each group alternate patients were taken up for the repair of tympanic membrane (Type 1 tympanoplasty) using dry temporalis fascia graft (Group A) or freshly prepared wet temporalis fascia graft (Group B).

Surgical preparation:

Pre-operative Evaluation:

The patients with mucosal type of chronic otitis media, were clinically evaluated in the out-patient department. The affected ear was thoroughly examined under operating microscope for discharge, site of tympanic membrane defect, retraction pockets, presence of squamous epithelium and keratin debris, disruption of ossicular chain, presence of inflammatory polyp, granulation tissue and osteitis. The lateral oblique radiographs of bilateral mastoids, preoperative pure tone audiometry and routine hematological investigations were done for all the patients.

Patients with retraction pocket, ossicular chain abnormalities and cholesteatoma were excluded from the study.

In case of presence of acute infection of the middle ear the patient was treated with a course of antibiotics and considered for surgery at a later date once the infection had subsided

Preparation of the patient:

- The patient was kept nil orally for a period of 6 hours prior to the surgery.
- Injection Tetanus toxoid 0.5cc intra muscular was given the previous day.
- Injection Lignocaine sensitivity test was done previous day (0.1ml intra dermal).
- Tablet Diazepam 10 mg oral, previous night and 5 mg early in the morning.
- Part preparation: The hair was shaved, about half an inch above and behind the auricle on the side of surgery for the purpose of good surgical field exposure.

Anaesthesia:

Patients were operated either under local anaesthesia or general anaesthesia.

Pre-medication for local anaesthesia:

- Pethidine: 1.0 – 1.5 mg/kg body weight, intra muscular (analgesic and sedative)
- Promethazine: 25 mg, intra muscular (antiemetic)
- Atropine: 0.6 mg, intra muscular (vagolytic and cardioprotective)

The premedication is given 30 minutes before surgery.

Surgical technique:

Preparation of part:

The patient was made to lie down in supine position with the operating ear facing upwards and towards the operating surgeon. Ear canal was instilled with 4% lignocaine. The ear and adjacent areas were painted with 5% povidone iodine solution. The patient was then draped with sterile surgical towels.

Infiltration:

It was done 10 minutes prior to the incision. Infiltration solution was prepared using 10 ml of 2% lignocaine, 10 ml of normal saline and 10 drops of 1:1000 adrenaline.

About 0.5 cc of the prepared solution was infiltrated each into the bony cartilaginous junction of the external auditory canal at 2, 4, 8 and 10 O’ clock positions, without creating blebs.

The auricular branches of the auriculotemporal nerve which supplies the upper part of the auricle and skin above the meatus are blocked by injection of 1 ml of solution at several points into the skin and periosteum of the incisura terminalis, upward to the upper attachment of the auricle.

The branches of the great auricular nerve to the auricle and meatus are blocked by injection of 1 ml of solution at several points behind the auricle over the mastoid process.

The auricular branch of the vagus nerve is blocked by injection of the periosteum of the anterior surface of the mastoid process and of the skin of the floor of the meatus.

Surgical technique:

1. **Canal Incisions and Elevation of Posterior Meatal Skin Flap**

The external auditory canal and the tympanic membrane were exposed using a Lemperts aural speculum. Through the external auditory meatus initial inferior vertical canal incision was made starting about 5 mm lateral to the fibrous annulus at about 7 o'clock position (5 o'clock position for left ear) using canal side knife. The medial ends of the incisions were joined by a horizontal incision using circular angled knife parallel to fibrous annulus. A rectangular posterior meatal skin flap between the above incisions was elevated laterally up to bony cartilaginous junction to develop a laterally based posterior meatal skin flap.

2. **Post aural incision**

Post-auricular William Wilde's incision was taken from the mastoid tip to the superior temporal line, the soft tissue and the loose areolar tissue was dissected out to reach the temporalis fascia.

3. **Harvesting temporalis fascia**

The areolar tissue over the temporalis fascia was stretched/teased by blunt dissection by artery forceps to identify the plane of temporalis fascia. The fascia was elevated from the underlying temporalis muscle by injecting saline underneath the fascia to facilitate easy removal of uniform thin fascia without underlying muscle or fat. The temporalis fascia was then harvested under direct vision by sharp dissection using 15 number blade and dissecting scissors

In patients belonging to group A, the fascia was harvested at the beginning of the surgery and was allowed to dry. In patients belonging to group B, the fascia was freshly harvested just before the placement of the graft.

Photo 1: Wet temporalis fascia graft

Photo 2: Dry temporalis fascia graft

4. **Exposure of the mastoid**

Two incisions were made over the subcutaneous tissue with the curvilinear vertical limb along the posterior

bony canal wall close to the meatal skin and the horizontal incision just above the spine of Henle along the linea temporalis. The soft tissue with periosteum over the mastoid was elevated posteriorly by Lempert's periosteal elevator. The cartilaginous canal along with posterior meatal skin flap was separated from its attachment at spine of Henle by Lempert's periosteal elevator. The posterior meatal skin flap was separated from the attachments along the tympanomastoid and tympanosquamous sutures by sharp dissection using periosteal elevator and a 15 number blade. The posterior meatal skin flap and subcutaneous tissue over the mastoid was retracted by modified Perkin's mastoid retractor.

5. **Cortical mastoidectomy**

The drilling was begun in the Mac Ewan's triangle (marked by linea temporalis superiorly, posterior bony meatus anteriorly and a line tangential to bony meatus perpendicular to linea temporalis posteriorly), till the mastoid antrum was reached. Drilling was continued till the demarcation of the tegmen plate superiorly, the posterior wall of the external auditory canal anteriorly, the sigmoid sinus posteriorly and lateral semicircular canal medially.

6. **Freshening the Margins of Perforation**

The mucosa in the undersurface of remnant tympanic membrane was scraped through the perforation using

Plester's side knife. The margins were excised by small sickle knife and micro scissors. Freshening the margins facilitates faster healing and epithelialization over the temporalis fascia in postoperative period and prevents formation of epithelial pearls between the undersurface of tympanic membrane and the graft.

7. **Elevation of the tympanomeatal flap and entry into the middle ear**

The tympanomeatal incision was extended superiorly and inferiorly based on the size and location of the perforation. The semicircular tympanomeatal flap was now elevated first from the posterior bony canal wall in a lateral to medial fashion till the fibrous annulus was reached using oval angulated canal elevator. The middle ear mucosa was entered below 9 o'clock position (3 o'clock for left ear) by separation of fibrous annulus using a sickle knife, with caution not to injure the underlying chorda tympani nerve. The handle of malleus was then skeletonised using a sickle knife.

8. **Assessment of the ossicular chain**

The status of ossicular chain was evaluated for continuity and mobility in each and every patient. It is important to confirm the mobility of each ossicle individually by palpating it with a smooth curved pick and finally by eliciting the round widow reflex.

9. **Placement of the graft using underlay grafting technique**

The graft bed was prepared by placing gel foam in the middle ear. The temporalis fascia was placed by holding it from the anterior end using a crocodile forceps and tucked anteriorly under the remnant of the anterior part of the tympanic membrane using a curved pick. The tympanomeatal flap was then repositioned. Gelfoam was placed in the external auditory canal.

10. Repositioning of the posterior meatal skin flap

The curled up posterior meatal skin was unfolded and repositioned in the external auditory canal. The canal was filled with gel foam soaked in antibiotic drops and plugged with a cotton ball impregnated with an antibiotic and steroid.

11. Closure of the wound

The subcutaneous tissue was closed using vicryl and skin was closed using ethilon. Mastoid dressing was then applied.

12. Postoperative care

In the immediate post operative period patient was checked for any facial nerve palsy, presence of nystagmus, bleeding and treated accordingly. All the patients were treated with a course of antibiotics, analgesics, and antihistaminics for a period of one week.

13. The mastoid dressing was removed after 4days and the suture removal done on the 7^{th} post operative day. External auditory canal pack was removed after 2 weeks.

Assessment of time taken to place the graft:

The time taken to place the graft, was assessed from the time the graft was placed over the posterior wall of the external auditory canal to the repositioning of the tympanomeatal flap.

Assessment of time of surgery:

The time taken for surgery, was assessed from the time of placement of the post aural skin incision to the application of the last skin suture.

Follow up:

All the patients were followed up at the end of 3 and 6 months after surgery.

During their visit, history regarding earache, ear discharge, ear trauma and subjective improvement in hearing were obtained.

Microscopic ear examination was performed to evaluate the graft uptake. In case of a residual perforation, the quality, quantity, colour and odour of the discharge; the size, shape, margins of the perforation; condition of the middle ear mucosa were noted.

The patients were then subjected to a pure tone audiogram to assess the improvement in hearing.

Statistical analysis

We used the IBM SPSS software (v.22) to perform the statistical analysis. The collected data were analysed using descriptive statistics like mean, standard deviation and proportions. The significance of difference in the mean take up rate of the graft, mean air bone gap and mean time consumption for the surgery and placement of the graft were done using independent t-test. P-value less than or equal to 0.05 was considered significant.

Observation and results

Table – 2

Age wise distribution of patients (n=102)

Age (years)	Group A	Group B
18-25	19	16
26-35	17	11
36-45	9	11
46-55	3	7
>56	3	6
Total	51	51

The age of the patients ranged from 18 to 60 years in Group A and it ranged from 18 to 70 in Group B. Majority of patients in both the groups belonged to the age group of 18-25 years.

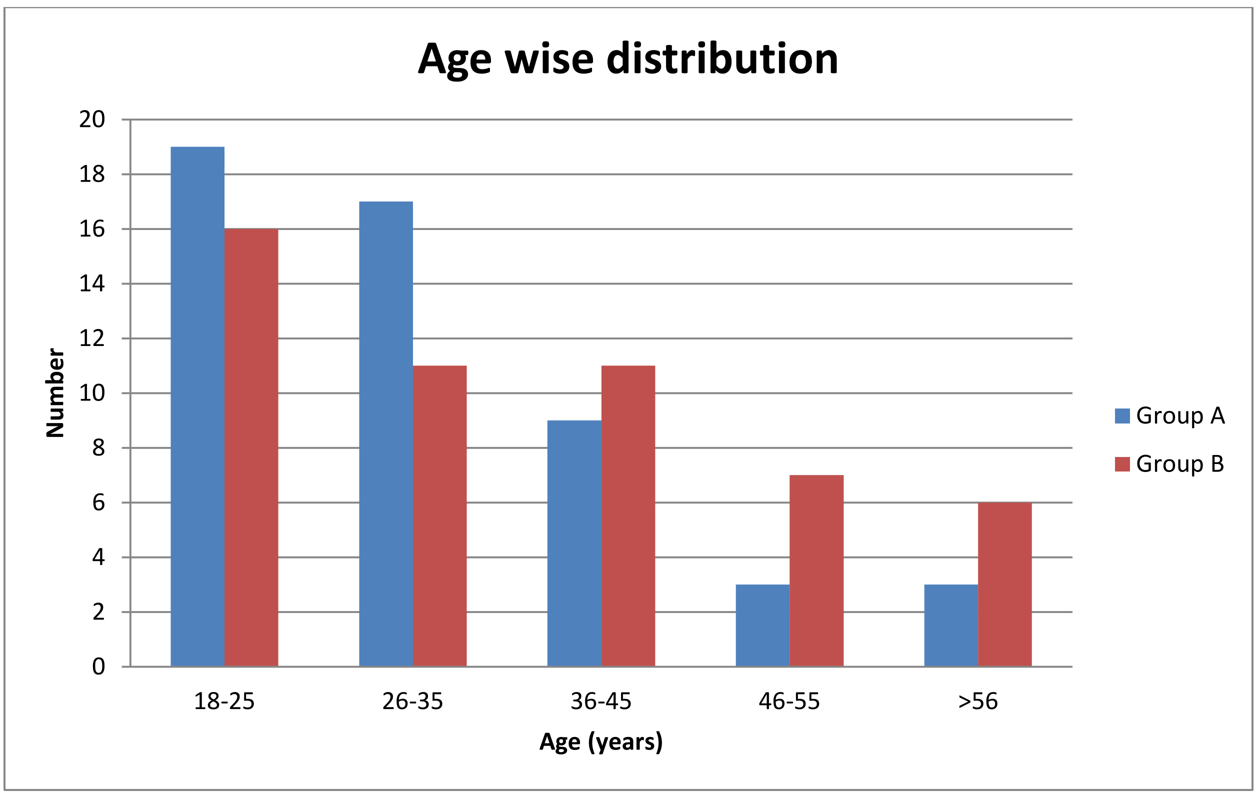


Figure 9: Age wise distribution of patients

Table – 3

Distribution of patients based on the size of tympanic membrane perforation

Size of tympanic membrane perforation	Number (n=102)	Percentage (%)
Small	23	22.5
Moderate	34	33.3
Large	45	44.1

The patients were divided into three groups based on the size of the perforation i.e Small, Moderate and Large central perforation. Most of the patients presented with large central perforation consisting of 44.1% followed by 33.3% of the patients having moderate size central perforation. 22.5% of the patients had a small central perforation.

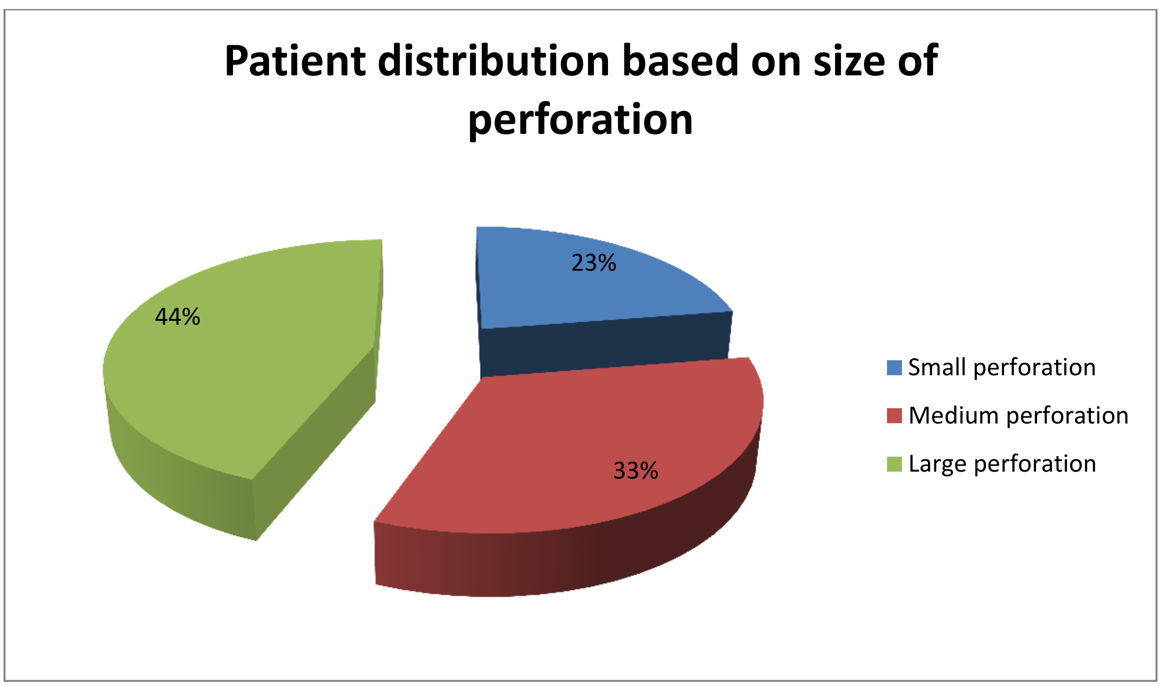


Figure 10: Distribution of patients based on the size of tympanic membrane perforation

Table – 4

Distribution of patients into groups based on the size of tympanic membrane perforation

Size of tympanic membrane perforation	Group A (n=51)	Group B (n=51)
Small	12	11
Moderate	17	17
Large	22	23

The patients in each group were alternately divided into groups. Group A received a dry temporalis fascia graft which was harvested in the beginning of the surgery and Group B received a freshly harvested wet temporalis fascia graft.

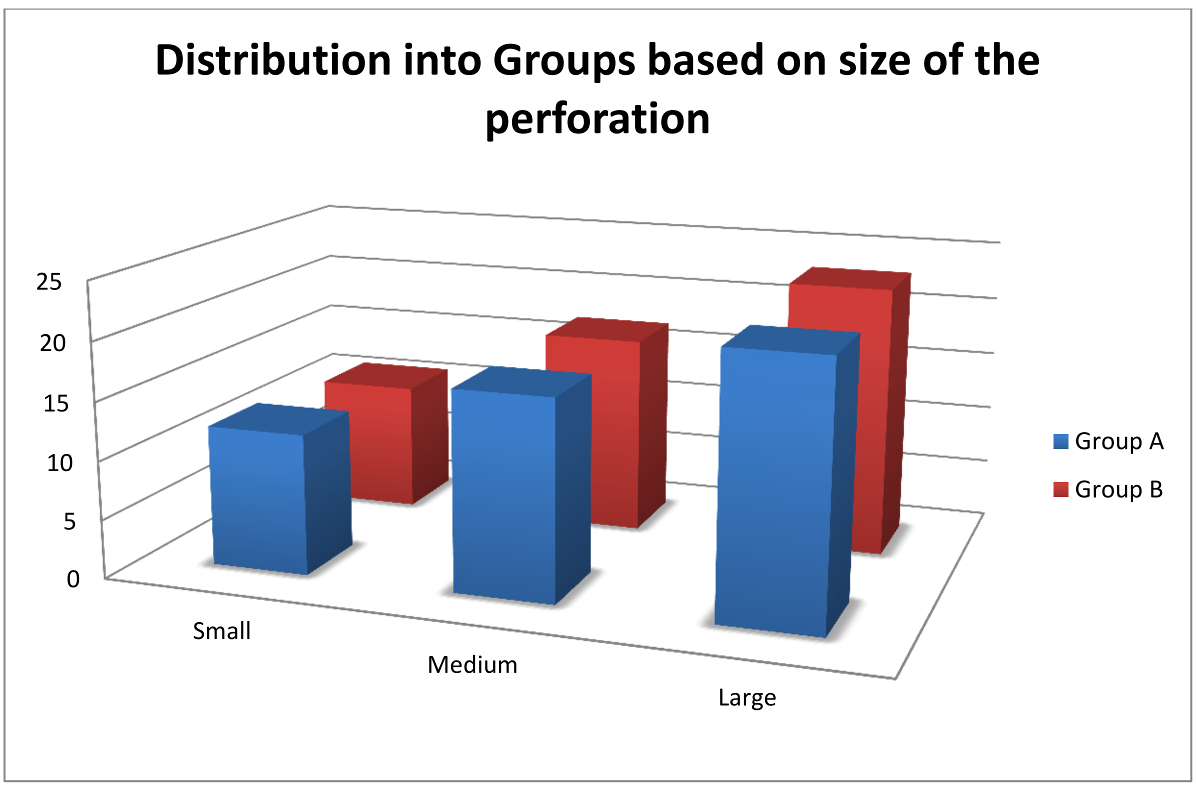


Figure 11: Distribution of patients into groups based on the size of tympanic membrane perforation

Table – 5

Preoperative Pure tone average in each group

Group	Pure tone average (dB)
A (n=51)	33.61
B (n=51)	37.41

The preoperative pure tone average of the patients belonging to Group A was 33.61 dB in comparison to 37.41 dB in patients belonging to Group B.

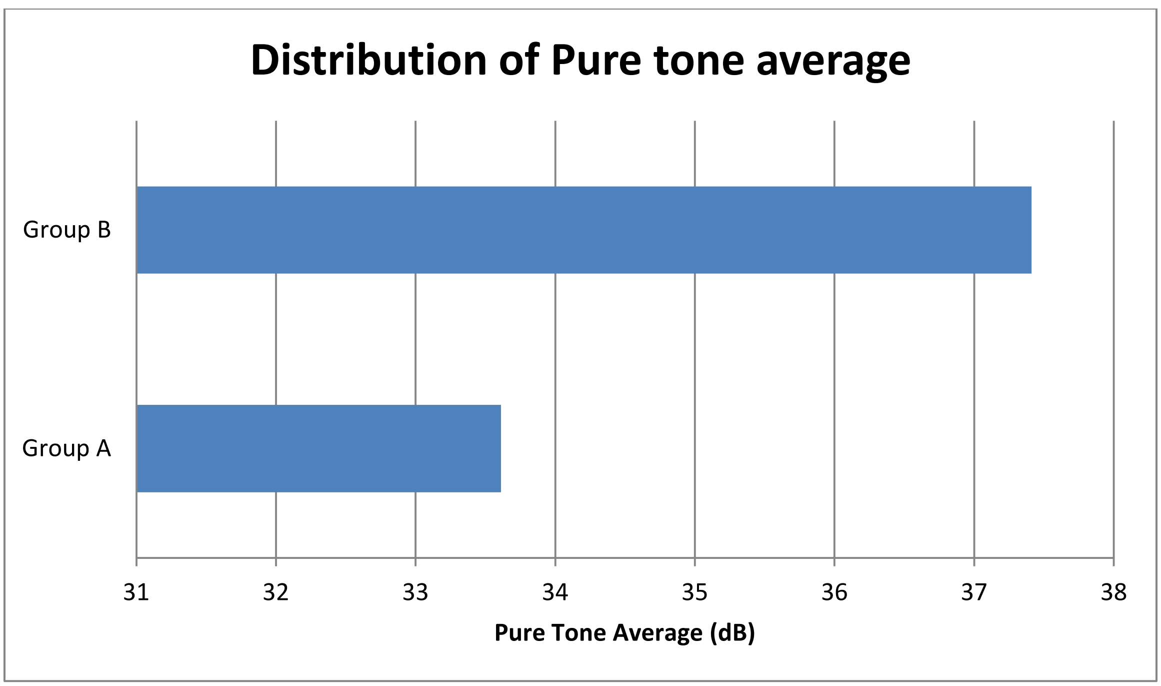


Figure 12: Preoperative Pure tone average in each group

Table – 6

Preoperative Pure tone Average in each subgroup

Size of the perforation	PTA in Group A (dB)	PTA in Group B (dB)
Small	20.42	26
Moderate	30.29	31.17
Large	43.36	47.47

In patients having a large central perforation the Group A patients had a 43.36 dB hearing loss in comparison to 47.47 dB in Group B. Patients with a moderate size perforation had 30.29 dB loss in Group A and 31.17 dB in Group B. Patients having a small perforation had a 20.42 dB loss in Group A to 26 dB loss in Group B.

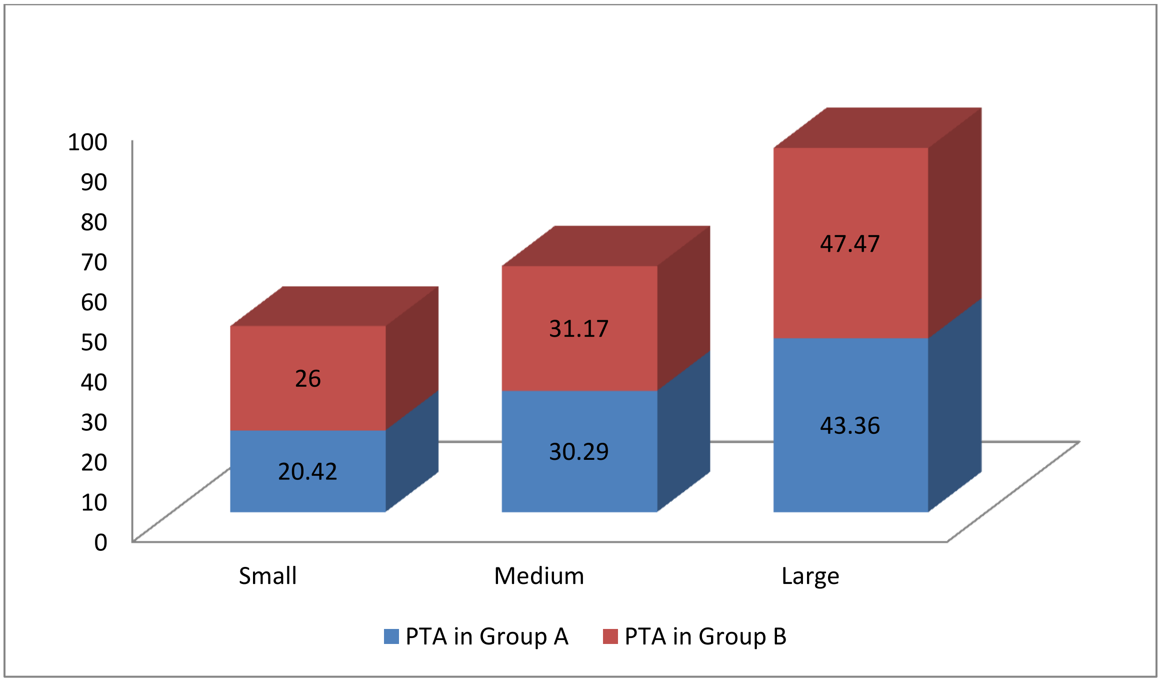


Figure 13: Preoperative Pure tone Average in each subgroup

Table – 7

Average time taken for placement of the graft

Group	Average time taken to place the graft (minutes)	p-value
A (n=51)	11.82	0.001
B (n=51)	14.13	

In Group A, the maximum time taken to place the graft was 20minutes and the minimum time was 6 minutes, average being 11.82 minutes.

In Group B the maximum time taken to place the graft was 25 minutes and the minimum time was 9 minutes, average being 14.13 minutes.

The difference in the time taken to place the graft, between two study groups was statistically significant

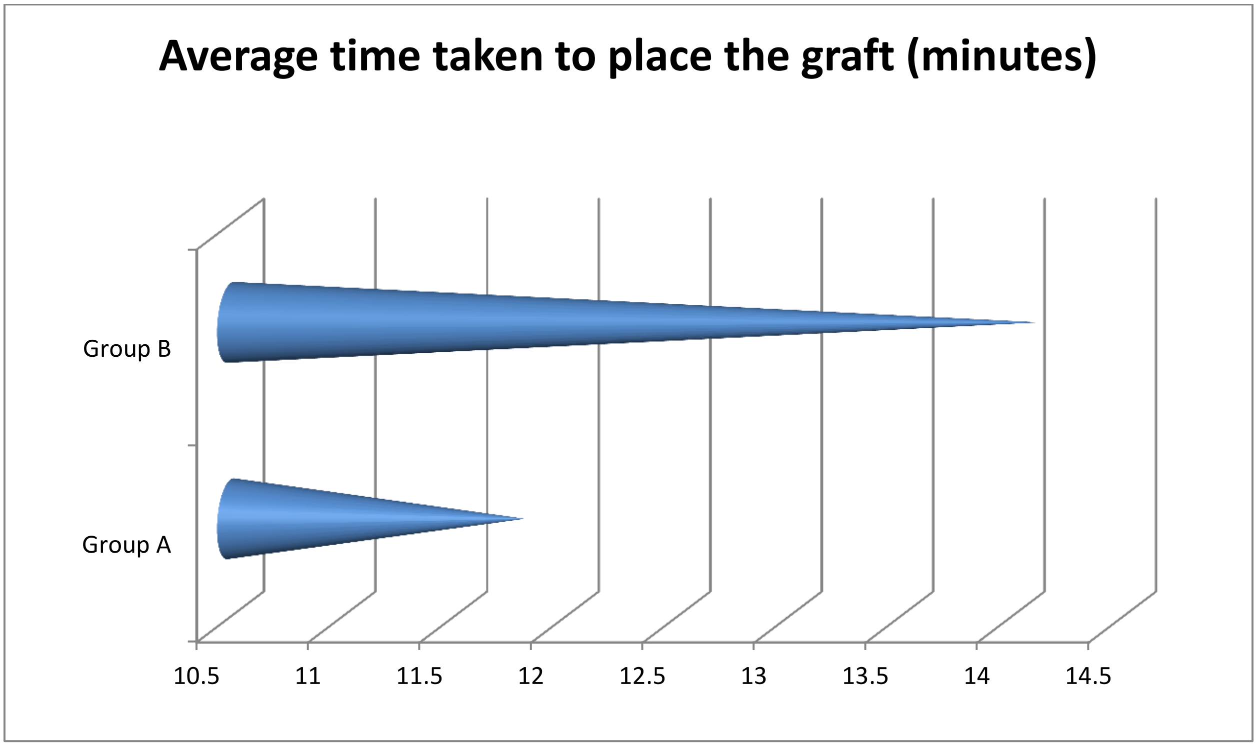


Figure 14: Average time taken for placement of the graft

Table – 8

Average time taken for the surgery

Group	Average time taken for surgery (hours)	p-value
A (n=51)	2.63	0.337
B (n=51)	2.75	

In Group A the maximum time taken for the surgery was 4.5 hours and minimum time taken was 1.5 hours the average being 2.63 hours. In Group B the maximum time taken for surgery was 5 hours and the minimum time was 1.5 hours the average being 2.75 hours. The difference in the time taken for the surgery was not statistically significant.

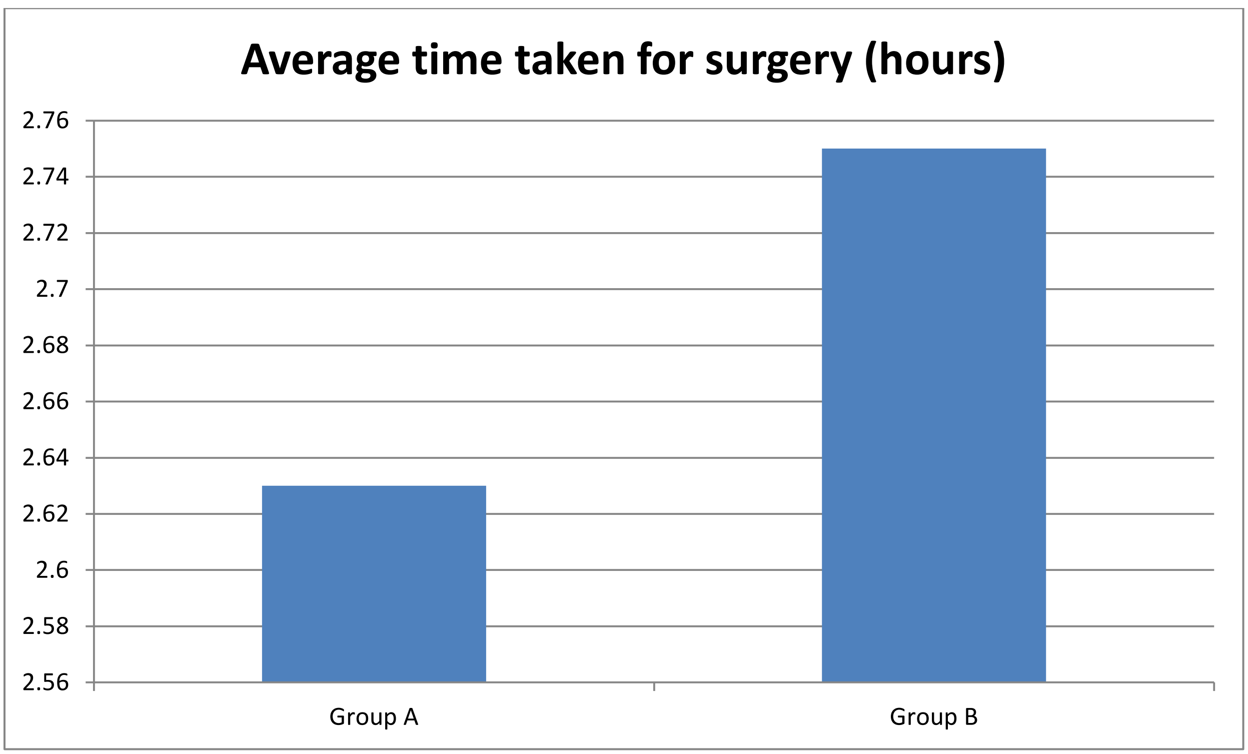


Figure 15: Average time taken for the surgery

Table – 9

Graft take up at 3 months follow up

Group	Total no of patients	No of patients with residual perforation	Percentage
A	51	2	3.92
B	51	0	0

Group A consisted of 51 patients, of which 49 patients achieved complete closure of the perforation and 2 patients had a residual perforation at the end of three months.

In Group B, all the 51 patients achieved complete closure of the perforation at the end of 3months.

For patients with residual perforation, since the size of the perforation was small, chemical cauterization of the margins was done.

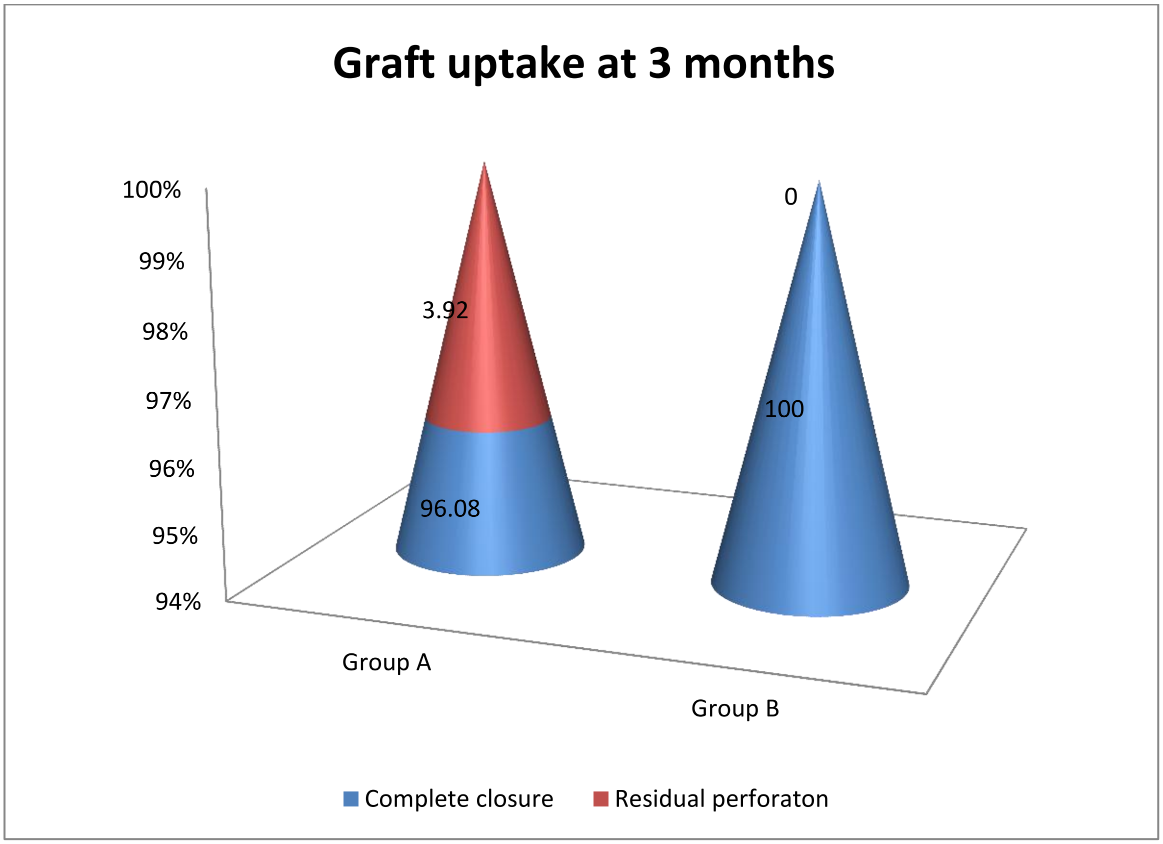


Figure 16: Graft take up at 3 months follow up

Table – 10

Outcome of hearing at 3 months

Size of tympanic membrane perforation	Group A (n=51)		Group B (n=51)	
	<=20dB HL (%)	>20dB HL (%)	<=20dB HL (%)	>20dB HL (%)
Small	100	0	91	9
Moderate	94.1	5.9	94	6
Large	68.2	31.8	78	22

The mean PTA at the end of 3months for Group A was 15.5 dB and for Group B it was 15.39 dB. In case of small perforations, 100% of the patients in Group A achieved <20 dB hearing to 91% in Group B. In case of moderate size perforations the results were similar in either group. In case of large size perforations 78% of patients in Group B achieved <20 dB hearing to 68.2% in Group A.

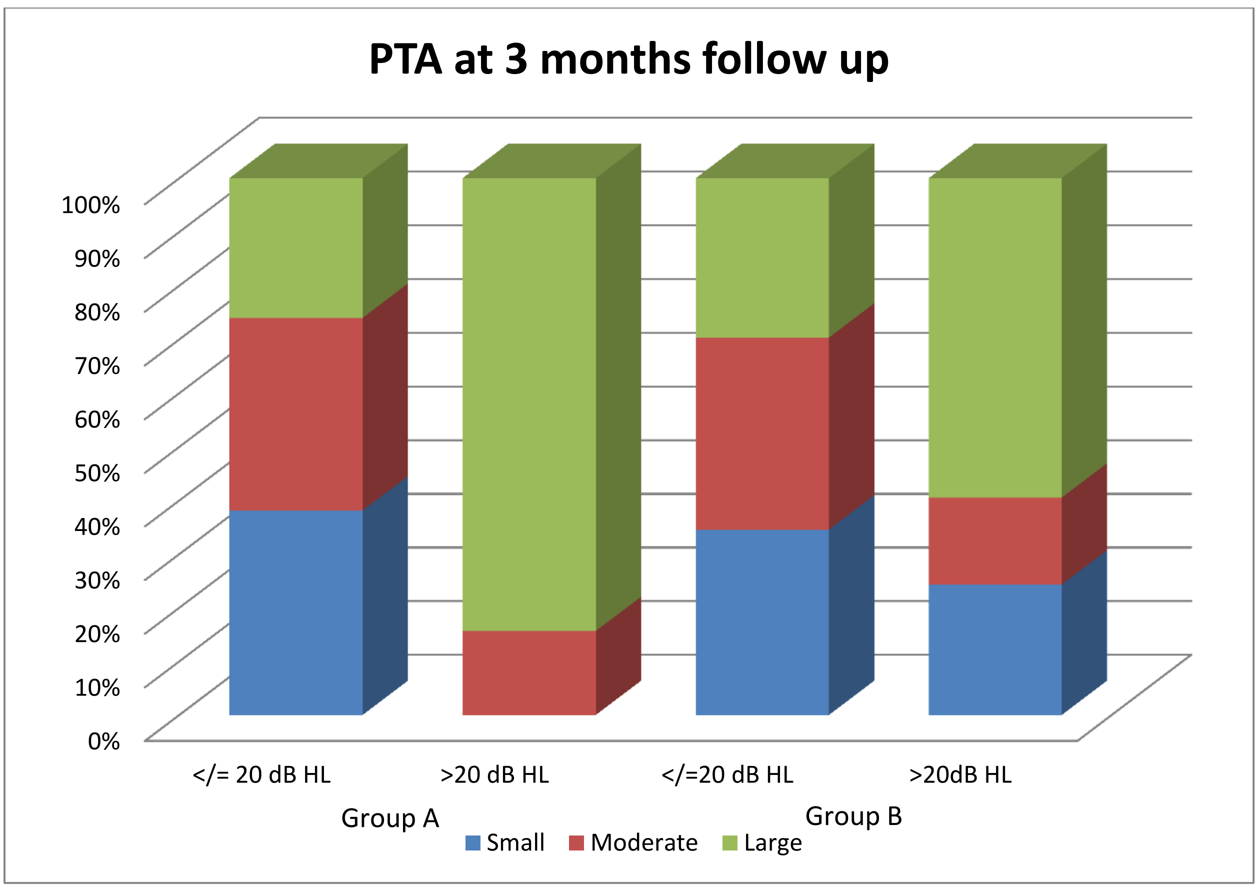


Figure 17: Outcome of hearing at 3 months

Table – 11

Graft take up at 6 months follow up

Group	Total no of patients	No of patients with residual perforation	Percentage
A	51	0	0
B	51	0	0

At the end of 6 months, all the patients belonging to both the groups had achieved complete closure of the perforation.

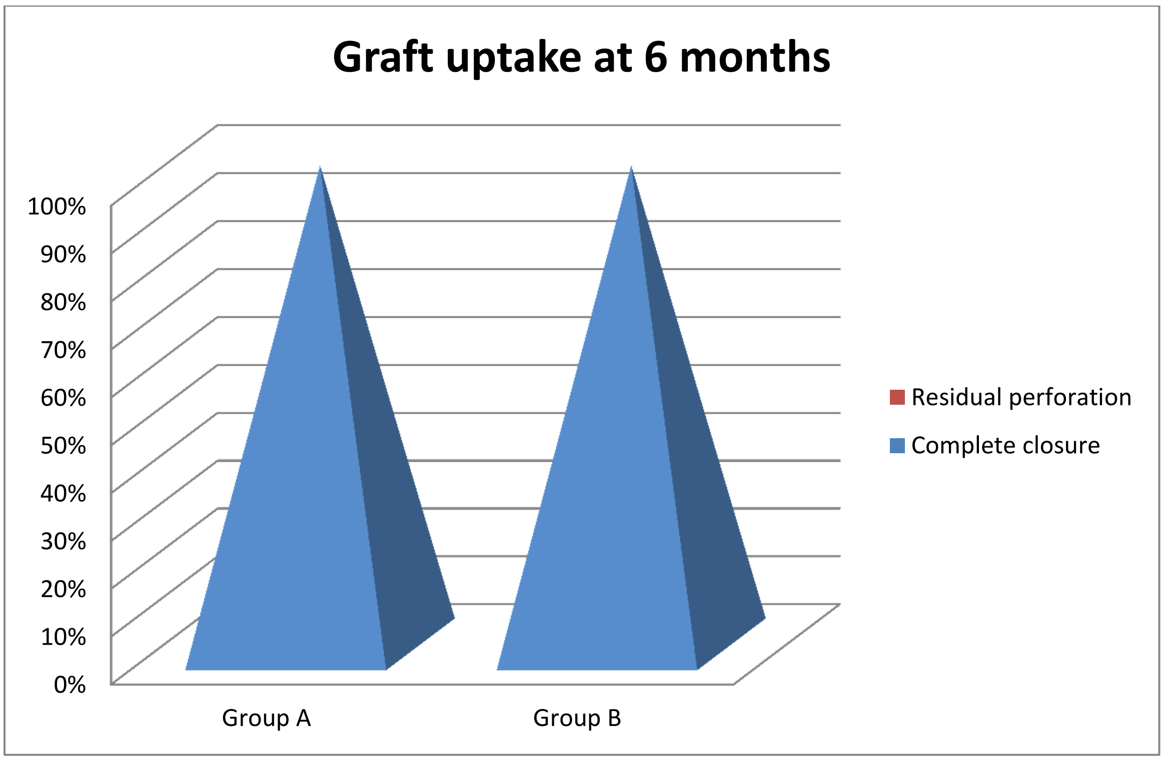


Figure 18: Graft take up at 6 months follow up

Table – 12

Outcome of hearing at 6 months

Size of tympanic membrane perforation	Group A (n=51)		Group B (n=51)	
	<=20dB HL (%)	>20dB HL (%)	<=20dB HL (%)	>20dB HL (%)
Small	100	0	91	9
Moderate	100	0	94	6
Large	72.7	27.3	83	17

At the end of 6 months the mean PTA for Group A was 14.13 dB and for Group B was 15.29 dB. In Group A, all patients having small and moderate perforations achieved a <20 dB hearing threshold and 72.2% of patients with large perforations achieved <20 dB hearing threshold. In Group B, 83% of patients with large perforations achieved <20 dB hearing threshold, whereas the results in case of small and moderate perforations the results were similar to the results at the end of 3 months.

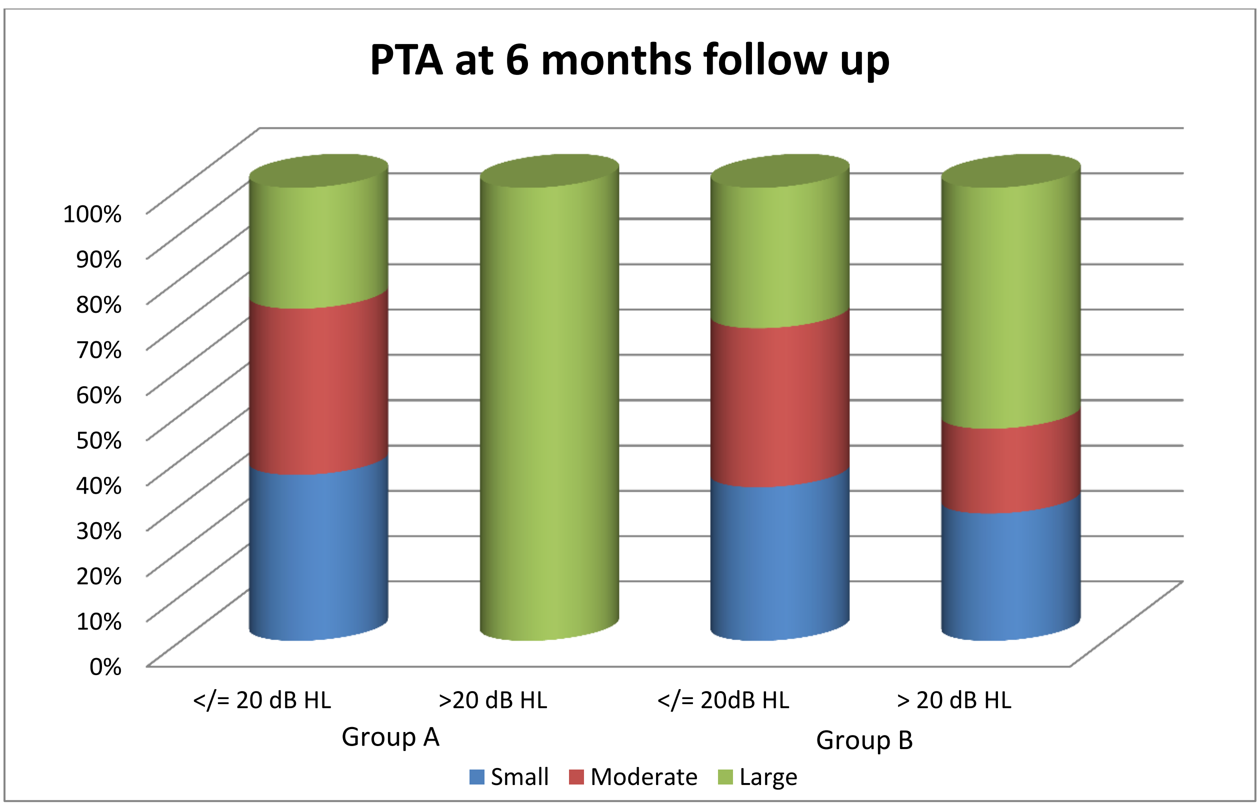


Figure 19: Outcome of hearing at 6 months

Photo 3: Tympanic membrane showing small size central perforation

Photo 4: Tympanic membrane showing moderate size central perforation

Photo 5: Tympanic membrane showing large size central perforation

Photo 6: X- ray mastoid Schullers' view showing diploic mastoid

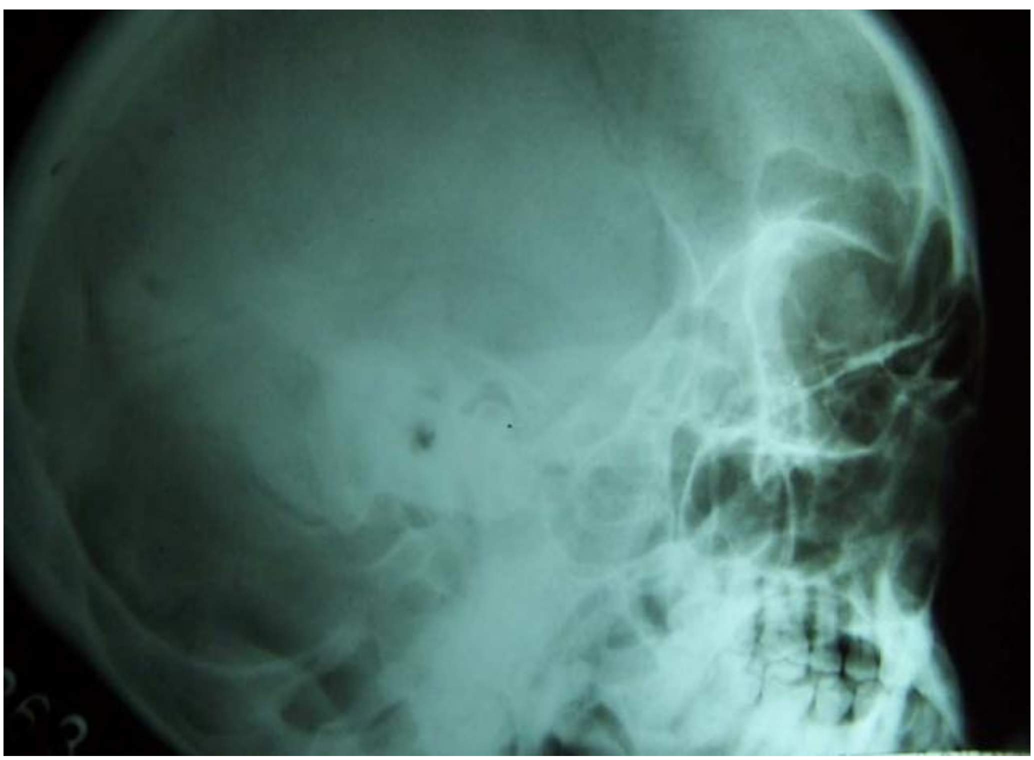


Photo 7: X – ray mastoid Schullers' view showing sclerotic mastoid

Photo 8: Pre-operative photograph of the tympanic membrane showing a medium size perforation in the anterosuperior quadrant

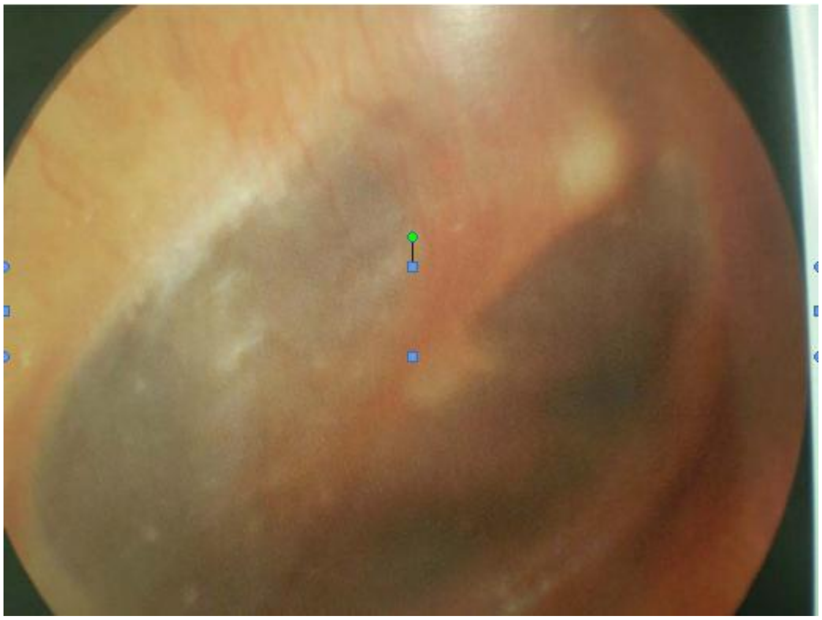


Photo 9: Post operative photograph of tympanic membrane of the same patient at 3 months follow up

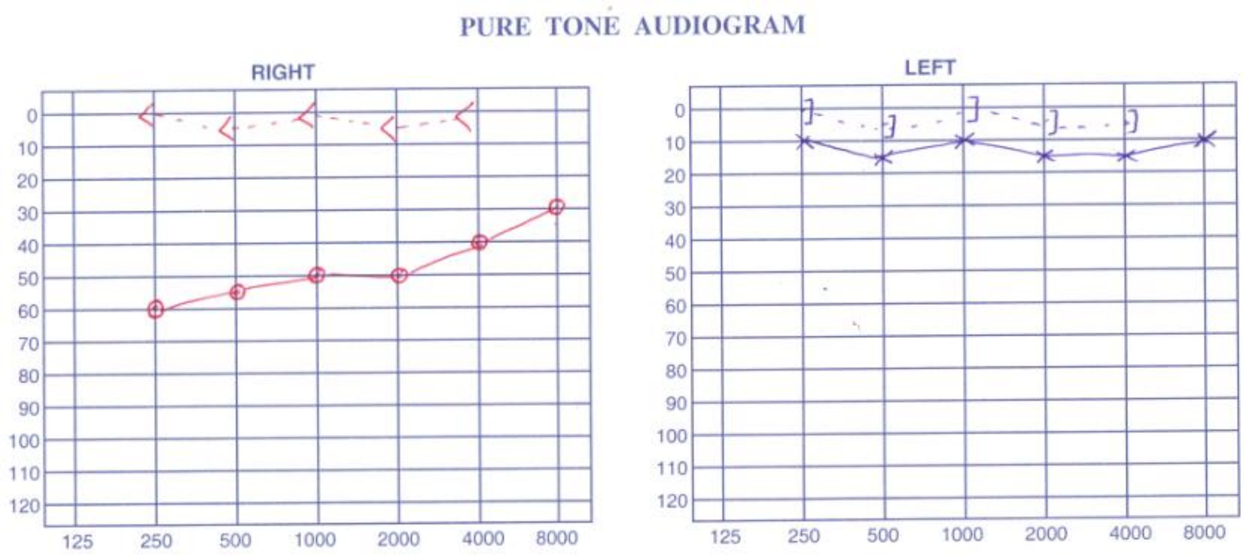


Photo 10: Pre operative Pure tone audiogram showing PTA of 51.66dB on the right side and 13.33dB on the left side

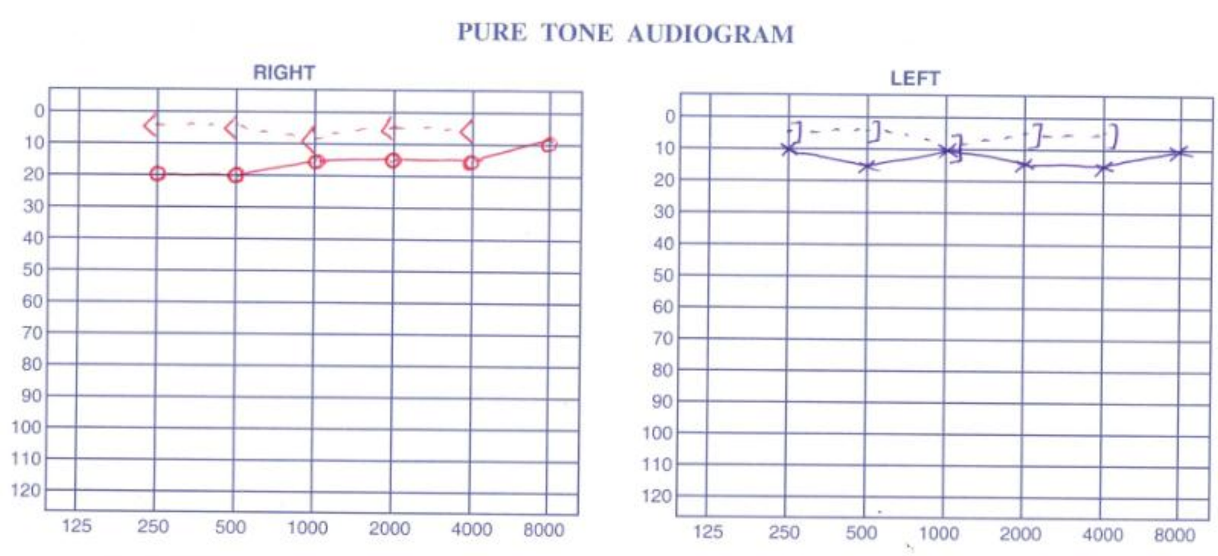


Photo 11: Post operative Pure tone audiogram of the same patient at 3 months follow up showing PTA of 16.66dB on the right side and 13.33dB on the left side

Discussion

Chronic otitis media (COM) is defined as a chronic inflammation of the middle ear cleft causing permanent abnormality in the tympanic membrane. It is most likely as a result of earlier Acute otitis media (AOM), Negative middle ear pressure or Otitis media with effusion. It is the major cause for hearing impairment in developing countries.[25]

Various modalities of treatment have been described in literature for the treatment of COM but surgery has remained the mainstay of treatment if the other modalities failed.

In a study conducted by Shrikrishna BH, the highest incidence of COM was noted in the age group of 21 to 30 years, followed by the age group of 10 to 20 years.[46]

In a study conducted by Glasscock in 1982, he found no association between the uptake rate of the graft and the age of the patient.[47]

In our study, 102 patients underwent Tympanoplasty for COM, who were in the range of 18 to 70 years. Most of these patients in both the groups (Group A and Group B) belonged to the age group of 18 to 25 years, followed by 26 to 30 years age group.

In a study conducted by Michael E Glasscock in 1982, temporalis fascia was grafted by post auricular approach and underlay technique, showed that the take up rate of the graft was 93%.[47] Also another study conducted by the same author in 1973, showed a take up rate of 96%.[48] In a study conducted by Albera R and team in 2006, of the 212 patients a successful uptake was obtained in 86% of the cases.[49]

In our study, among the patients who received a dry temporalis fascia graft (Group A), two patients had a residual perforation at the end of 3 months. One patient had a large central perforation and one patient with a medium size central perforation. Both these patients had a history of upper respiratory tract infection in the 2nd week of the surgery. Since, the size of the residual perforation were small in both the cases, the patients were planned for chemical cauterization on an outpatient basis. Here, silver nitrate was used to cauterize the margins of the residual perforation, cotton wick was placed in the external auditory canal and patient was prescribed antibiotic ear drops to apply over the cotton to keep the ear canal moist and thereby facilitating epithelial growth. The first patient with residual perforation required 3 sittings, done over three weeks to achieve a complete closure of the perforation. The second patient required 2 sittings, done over two weeks to achieve a complete closure of the perforation. At the end of 6 months, all the patients achieved a complete closure of the perforation.

The results of graft uptake in other studies are similar to the results obtained in our study where we have a 96% take up rate.

In a study conducted by Sudhakar Vaidya, he found no association between size of the perforation and the graft uptake. Also, the hearing improvement was similar among patients belonging to different groups.[50]

In our study, we noted residual perforation in two cases, both belonging to the subgroup A, who received a dry temporalis fascia graft for the repair of the perforation. One patient had a medium size perforation and the other had a large size perforation. Both the patients give history of an upper respiratory tract infection in the 2nd postoperative week. Hence, no association could be noted between the size of the perforation and the graft uptake. Thus, the results were similar to other studies.

In a study by Loock J W, who compared the graft uptake between dry and wet temporalis fascia graft found no significant difference in the graft uptake.[51] Similar results were obtained in our study where no significant difference was noted between the two groups.

There are two schools of thought regarding the fate of the graft. Some authors are of the opinion that the graft only acts as a scaffold over which epithelial growth occurs and hence, there is no association between the take up rates in dry and freshly harvested wet temporalis fascia graft.[51] In contrast to this, Schuknecht HF having followed up post tympanoplasty patients till death and performed autopsy has found that, the graft itself has undergone vascularisation and formed the middle fibrous layer of the tympanic membrane.[2]

In a study conducted by Riza Dundar, the operative time taken for a type 1 tympanoplasty ranged between 60-77 minutes with a mean operative time of 67 minutes.[52] However, no study calculating the time taken for cortical mastoidectomy along with a type 1 tympanoplasty was found.

In our study, the mean operative time in case of Group A patients was 2.63 hours and in Group B was 2.75 hours. However, no statistical significance was noted between the two groups.

In the study conducted by Alkan S, on the time taken to place the graft in case of a dry graft and a freshly harvested wet temporalis fascia graft, he found that wet temporalis fascia graft took a lesser time for harvesting and placement in comparison to the dry temporalis fascia graft. He found the time difference to be statistically significant.[5]

However, in our study, we found that, lesser time was taken to place a dry temporalis fascia graft than a freshly harvested wet temporalis fascia graft. The difference in the time taken to place the graft was statistically significant. The reduced time taken for placing the dry temporalis fascia graft was due to the stiff parchment like consistency of the dry fascia. In case of a wet graft, the graft was softer and more difficult to place. The surgical expertise of the surgeon contributed to the time taken for placement of the wet temporalis fascia graft .

In a study conducted by Bob Lerut, he found that, as the size of the perforation increased, there was an increase in hearing loss at each frequency. Hence, a linear correlation was observed.[53]

In our study, we found similar results, where the mean PTA among patients with small perforation was 20.42 dB in Group A and 26 dB in Group B; in moderate size perforations it was 30.29 dB in Group A and 31.17 dB in Group B; in large size perforations it was 43.36 dB in Group A and 47.47 in Group B. In both the groups, as the size of the perforation increased the PTA also increased.

In a study conducted by Brown C, consisting of 193 cases of myringoplasty, the mean preoperative PTA was found to be 35 dB while the postoperative PTA was 25 dB, with an average air conduction improvement by 10 dB.[54]

In our study, the preoperative PTA in Group A was 33.61 dB and in Group B was 37.41 dB. Following surgery, at the end of 3 months, all patients having a small central perforation belonging to Group A and 91% of patients belonging to Group B achieved <20 dB hearing level. In patients with moderate size perforation, 94.1% in Group A and 94% in Group B achieved <20 dB hearing level. In case of patients with large size perforations, 68.2% in Group A and 78% in Group B achieved a <20 dB hearing level. The mean postoperative PTA at the end of 3 months was 15.5 dB in Group A and 15.4 dB in Group B. Therefore, the average gain in hearing for patients belonging to Group A was 18.1 dB and for patients belonging to Group B was 22.01 dB. Though a mild improvement in hearing was noted in patients of Group B, the results were statistically insignificant.

At the end of 6 months, among patients with small size central perforation, all patients in Group A and 91% of patients in Group B achieved a <20 dB hearing level. In patients with moderate size perforations, 100% in Group A and 94 % in Group B achieved a <20 dB hearing level. In patients with large size perforations, 72.7% in Group A and 83% in Group B achieved < 20 dB hearing level. The mean post operative PTA at 6 months was 14.13 dB in patients of Group A and 15.3 in patients of Group B. Hence, mean gain in hearing among patients in Group A was 19.03 dB and among patients in Group B was 22.11 dB. The difference in the mean postoperative PTA between the two groups was statistically insignificant.

In a study conducted by Loock J W, he compared the outcome of hearing between patients receiving dry graft and freshly harvested wet temporalis fascia graft and noted no statistically significant difference between the two groups.[51] Also in the study conducted by Alkan S, no statistically significant difference was noted between the two groups.[5]

Conclusion

The conclusions drawn from my study are

- The take up rates of a dry graft and freshly harvested wet temporalis fascia graft are similar.
- The time taken for the placement of a dry temporalis fascia graft is significantly less compared to the time taken for the placement of a freshly harvested wet temporalis fascia graft.
- The duration of surgery is similar in patients receiving dry graft and freshly harvested wet temporalis fascia graft.
- The outcome of hearing is similar in patients receiving dry graft and freshly harvested wet temporalis fascia graft.
- The uptake of the graft does not depend on the size of the tympanic membrane perforation.

Since, no significant difference was noted in the graft uptake or hearing outcome between the two groups, both dry and wet temporalis fascia graft could be used during surgery based on the convenience of the surgeon.

Summary

A total of 102 patients diagnosed to have mucosal type of COM and meeting the inclusion criteria in the department of Otorhinolaryngology and Head and Neck Surgery of R L Jalappa Hospital And Research Centre, Tamaka, Kolar from December 2012 – March 2014 were included in this study.

Once the diagnosis of mucosal type COM was made on the basis of history and routine ENT examination, the patients were subjected to microscopic ear examination, pure tone audiometry, mastoid radiography and haematological investigations.

The patients were then categorised based on the size of the perforation into small, moderate and large size central perforation. In each category, alternate patients were taken up for the repair of the tympanic membrane perforation with dry temporalis fascia graft and freshly harvested wet temporalis fascia graft.

The time taken for placement of the graft and the time taken for the surgery were noted in each group and compared.

The patients were followed up at 3 months and 6 months where the graft uptake and PTA were assessed in all the patients and the results compared between the two groups.

We found a significant difference in the time taken to place the graft (p-value = 0.001); but no significant difference was noted in the take up rates of the graft, outcome of hearing at end of 3 months or 6 months and duration of surgery between the two groups.

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ANNEXURE - I

A COMPARATIVE STUDY OF DRY GRAFT AND FRESHLY HARVESTED WET TEMPORALIS FASCIA GRAFT TO REPAIR TYMPANIC MEMBRANE PERFORATION IN CHRONIC MUCOSAL OTITIS MEDIA

I. Personal details

Name: Age:Sex:
Occupation:Hospital number:
DOA: DOD:
Address:

Phone number:
Group: A / B Group A: patient receiving dry temporalis fascia graft.
Group B: Patient receiving freshly harvested wet temporalis fascia graft.

II. History of presenting complaints

a. Discharge: Y/N Duration:
Onset: Insidious/ sudden Progression: static/ progressive
Type: Intermittent/ continuous Quantity: copious/ scanty
Quality: watery/ thick & sticky/ pus Foul smell: present/ absent
Blood staining: Y/N
Aggravating factors:
Relieving factors:

b. Decreased hearing: Y/N Duration:
Onset: Insidious/ sudden Progression: static/ progressive

III. Past history

History of Hypertension/ Diabetes mellitus/ Tuberculosis/ Bronchial asthma
History of ear surgeries in the past: Y/N ; If yes:

IV. Family history

V. Personal history

Loss of appetite: Y/N Disturbed sleep: Y/N
Bowel & Bladder disturbances: Y/N
Smoker: Y/N ; If yes: Duration: Quantity: Type:

Examination

VI. General physical examination:

Temperature: Pulse: BP:
Pallor: Y/N Icterus: Y/N
Cyanosis: Y/N Clubbing: Y/N
Lymphadenopathy: Y/N Oedema: Y/N

VII. ENT examination

A. Ear examination:

Sl No	Ear	Right	Left
1	Preauricular area:		
2	Pinna:		
3	Postauricular area:		
4	External auditory canal:		
5	Tympanic membrane		
6	Middle ear mucosa Colour Oedematous Granulation tissue	 Pale/ congested Y/N Y/N	 Pale/ congested Y/N Y/N
7	Tuning fork tests Rinnes Webers ABC	 +ve/-ve R/L/C Normal/ reduced	 +ve/-ve R/L/C Normal/ reduced
8	Fascial nerve		

B. Nose examination:

Sl No	Nose	Findings
1	External framework:	
2	Vestibule	
3	Anterior rhinoscopy	
4	Diagnostic nasal endoscopy	

C. Throat examination:

Sl No	Throat	Findings
1	Oral cavity and oropharynx	
2	Indirect laryngoscopy	
3	Neck	

VIII. Examination

Cardiovascular system: Respiratory system:

Abdomen: Central nervous system:

IX. Clinical diagnosis

X. Investigation

Hb- TC- DC- BT- CT-

HIV- reactive/ non-reactive HbSAg- reactive/ non-reactive

X-ray mastoid-

PTA-

XI. Intra-operative findings:

Sl no		Findings
1	Size of perforation	
2	Type of canal incision	
3	Aditus patent	Y/N
4	Type of graft	Dry/ Wet
5	Canaloplasty	Performed / Not performed
6	Ossicular chain intact	Y/N
7	Handle of malleus denuded	Y/N
8	Anterior tucking done	Y/N
9	Eustachian tube area	Patent/ Blocked
10	Time taken to place the graft	
11	Time taken for surgery	
12	Complications	

XII. Immediate post-operative period

Sl no		Findings
1	Facial nerve	
2	Nystagmus	
3	Bleeding	
4	Any other complaints	

XIII. Follow up

Sl No		3 months	6 months
1	History of earache	Present/ absent	Present/ absent
2	History of ear discharge	Present/ absent	Present/ absent
3	History of trauma	Present/ absent	Present/ absent
4	Subjective improvement in hearing	Present/ absent	Present/ absent
5	Other complaints		
6	Graft taken up	Y/N ; If No Discharge: Size: Margin: Middle ear mucosa:	Y/N ; If No Discharge: Size: Margin: Middle ear mucosa:
7	Status of neotympanum		

Annexure – II

Informed consent

Title of the project: A comparative study of dry graft and freshly harvested wet temporalis fascia graft to repair tympanic membrane perforation in chronic mucosal otitis media.

I understand that I remain free to withdraw from the study at any time and this will not change my future care.

I have read the consent form / has been read to me and I understand the purpose of this study, the procedures that will be used, the risks and benefits associated with my involvement in the study and the confidential nature of the information that will be collected and disclosed during the study.

I have had the opportunity to ask questions regarding various aspects of this study and my question have been answered to my satisfaction.

I, the undersigned agree to participate in this study and authorize the collection and disclosure of my personal information as outlined in this consent form.

Subject's / Guardian's name and signature / thumb impression Date:

Name and signature of witness Date:

Name and signature of principle investigator Date:

Annexure III

KEY TO MASTERCHART

F	⇨	Female
M	⇨	Male
DOA	⇨	Date of Admission
DOD	⇨	Date of Discharge
URTI	⇨	Upper Respiratory Tract Infection
NA	⇨	Not Applicable
ABC	⇨	Absolute Bone Conduction
DNS	⇨	Deviated Nasal Septum
PO	⇨	Post Operative