DISSERTATION ON

"A COMPARATIVE STUDY TO EVALUATE TEMPORALIS FASCIA GRAFT VERSUS FASCIA WITH CARTILAGE GRAFT IN TYPE 1 TYMPANOPLASTY''

Dissertation submitted to

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This is to certify that this dissertation entitled **"A COMPARATIVE STUDY TO EVALUATE TEMPORALIS FASCIA GRAFT VERSUS FASCIA WITH CARTILAGE GRAFT IN TYPE 1 TYMPANOPLASTY"** is a Bonafide research work of **Dr.G.ANUJA** in partial fulfillment of the requirements for **M.S. OTORHINOLARYNGOLOGY** Examination of the Tamil Nadu Dr. M.G.R Medical University to be held in MAY - 2022, was carried out by her under our direct supervision and guidance.

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This to certify that the project work titled **A COMPARATIVE STUDY TO EVALUATE TEMPORALIS FASCIA GRAFT VERSUS FASCIA WITH CARTILAGE GRAFT IN TYPE I TYMPANOPLASTY** proposed by **Dr. G. ANUJA** in partial fulfilment of the requirement for the M.D /M.S course in the subject of **OTO-RHINO-LARYNGOLOGY** for the year **2020 – 2022** by The Tamilnadu Dr. MGR Medical University has been cleared by the Institutional Ethics Committee

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LIST OF ABBREVIATIONS

COM	-	Chronic otitis media
CSOM	-	Chronic suppurative otitis media
PTA	-	Pure tone Audiometry
dB	-	decibels
Hz	-	Hertz
CN	-	Cranial Nerve
TM	-	Tympanic membrane
DM	-	Diabetes Mellitus
WHO	-	World Health Organization
HRCT	-	High resolution Computerized Tomography
ABG	-	Air Bone Gap
CCPI	-	Composite Cartilage Perichondrium Island graft
ABC	-	Absolute bone conduction test
SPSS	-	Statistical package for Social Sciences

INTRODUCTION

Tympanoplasty is a procedure done to achieve a dry ear by eradicating middle ear disease and reconstructing the hearing mechanism. Type 1 Tympanoplasty involves the restoration of the perforated ear drum by grafting and also involves middle ear inspection and ensuring ossicular integrity[(1)]. The idea of tissue grafting is to replace the missing fibrous element of the tympanic membrane and to allow normal epidermis and mucosa to regenerate over the graft. The result of tympanoplasty is measured by achieving non discharge ear, satisfactory graft uptake and hearing improvement.

Various types of grafts are used such as Temporalis fascia graft, tragal and conchal perichondrium, tragal and conchal cartilage, vein graft,dura, fat etc[(2)]. The greatest advantage of cartilage graft is its low metabolic rate. It receives its nutrients by diffusion. It is easy to work with because of its pliability and its resistance to deformation from pressure variations.

It is very thick and stiff when compared with temporalis fascia graft. Perichondrium and cartilage are similar to fascia in the quality as they are also mesenchymal tissue.

It is preferred in case of large or anteriorly placed perforations or associated Eustachian tube dysfunction. Temporalis fascia is considered to be superior with respect to uptake rate or success rate. In conditions like subtotal perforations, adhesive otitis media and residual perforations after primary

tympanoplasty, cartilage along with the temporalis fascia graft has been used in recent years to attain the advantages of both. [(2)] This prevents sinking or shrinking of the graft. It splays and stays in place and provides firm support to the fascia graft. Other advantages of this are low metabolic rate, minimal inflammatory reaction, long duration of viability and long nutrition supply by diffusion.

There are many differences between biological and autologous graft materials in both advantages and disadvantages. The graft materials choice depends on their ease of harvesting, preparation time, viability, placement ease, graft uptake and hearing improvement. Such abundance of materials provides dilemma in making clear cut choice of graft on individual surgeon's preference. Although tragal and conchal cartilages are commonly used for tympanoplasty, conchal cartilage graft was selected in the current study.

With this backdrop, this study was carried out to compare the Temporalis fascia graft and Temporalis fascia graft with Conchal cartilage graft of Type I Tympanoplasty to manage safe type of Chronic Suppurative Otitis Media (CSOM) diagnosed patients attending OPD in Department of Otorhinolaryngology, KAPV government Medical College, Trichy.

OBJECTIVES

1. To compare the graft uptake in patients using temporalis fascia alone and using conchal cartilage support along with temporalis fascia graft.
2. To compare the improvement in conductive hearing loss, using temporalis fascia alone and using conchal cartilage support along with temporalis fascia graft.

REVIEW OF LITERATURE

The human ear is the organ of hearing. It is the transducer of sound mechanically.[3]The ear is divided into

1. External ear
2. Middle ear
3. Internal ear or Labyrinth.

THE EXTERNAL EAR

The external ear consists of the auricle or pinna, external acoustic canal and the tympanic membrane.

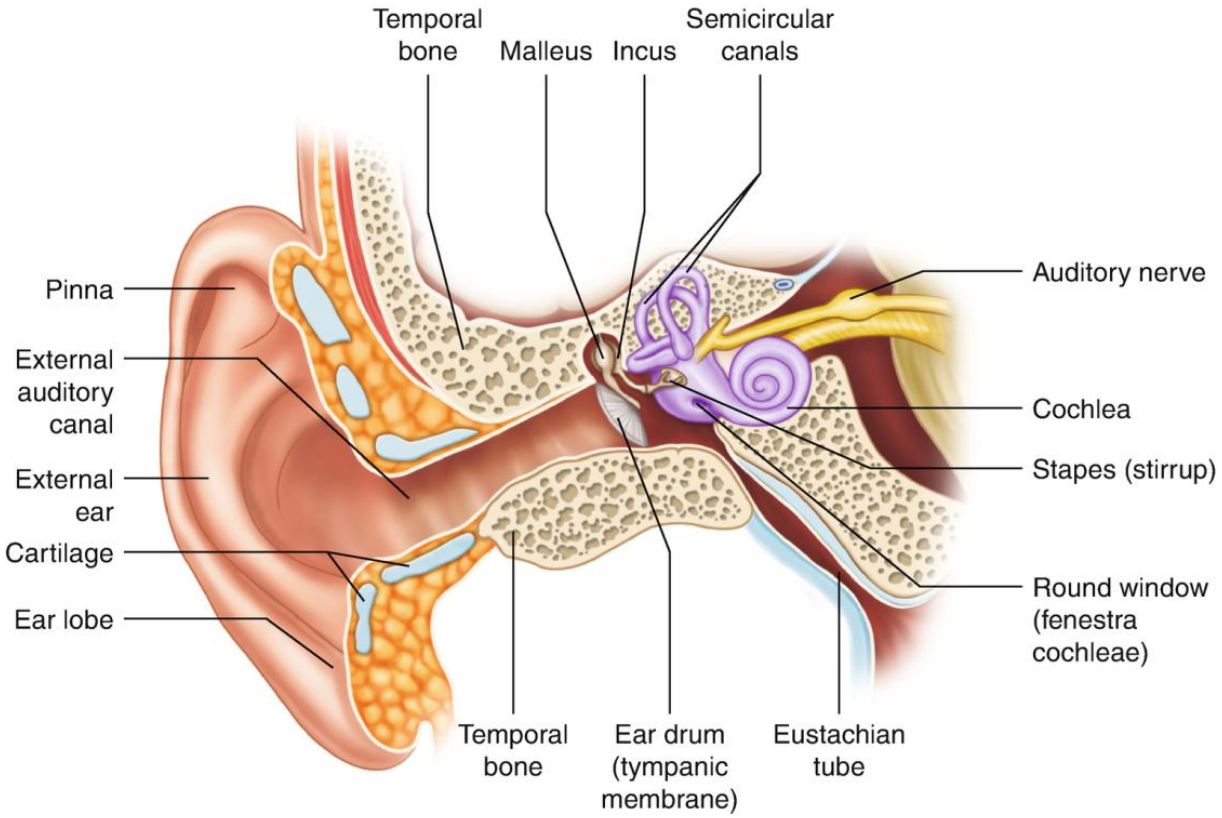


Figure 1 showing parts of external ear

External Acoustic Canal

It lengthens from the bottommost of the concha to the tympanic membrane and measures around 24 mm along its posterior wall. It is not a straight tube. Its outer part is focused upwards backwards and medially while its inner part is focused downwards forwards and medially. The canal is divided into two parts, the cartilaginous part and the Bony part. [3]

- **Cartilaginous part**

It forms the outer 8mm of the canal. It has two deficiencies; "fissures of Santorini" In this part of cartilage through them the superficial mastoid infections can appear in the meatus. The skin in the cartilaginous canal is thick and contains ceruminous and pilosebaceous glands which secrete the wax. Hair is only restricted to the outer canal.

- **Bony part**

It forms the inner 16 mm of the canal. Skin lining the bony Canal is thin and continuously over the tympanic membrane. It is lacking of hair and ceruminous glands. Around 6 mm lateral to the tympanic membrane, the Bony meatus presents a narrowing structure called the isthmus. The anterior recess is presented on the anteroinferior part of the deep meatus beyond the isthmus. It acts as a cesspool for discharge and debris.[4]

Tympanic Membrane or the Drum Head

It is the membrane separating the external acoustic canal and the middle ear. It is obliquely set. Its posterosuperior part is further lateral than its Anteroinferior part. It is 9 to 10 mm tall, 8 to 9 mm wide and 0.1 mm thick. Tympanic membrane can be separated into two parts: pars tensa and pars flaccida.

- **Pars tensa**

It forms most of the tympanic membrane. A fibrocartilaginous ring is formed in its periphery and is called the annulus tymphanicus which fits in the tympanic sulcus. Umbo is the chief part of pars tensa which is tilted inwardly at the level of the tip of malleus. A bright cone of light can be perceived radiating beginning from the tip of the malleus to the Margin in the anterior inferior quadrant. [(5)]

- **Pars flaccida (Shrapnel's membrane)**

This is located beyond the lateral process of the malleus between the anterior and posterior malleal folds and the notch of rivinus. It is not so rigid and may look somewhat pinkish.

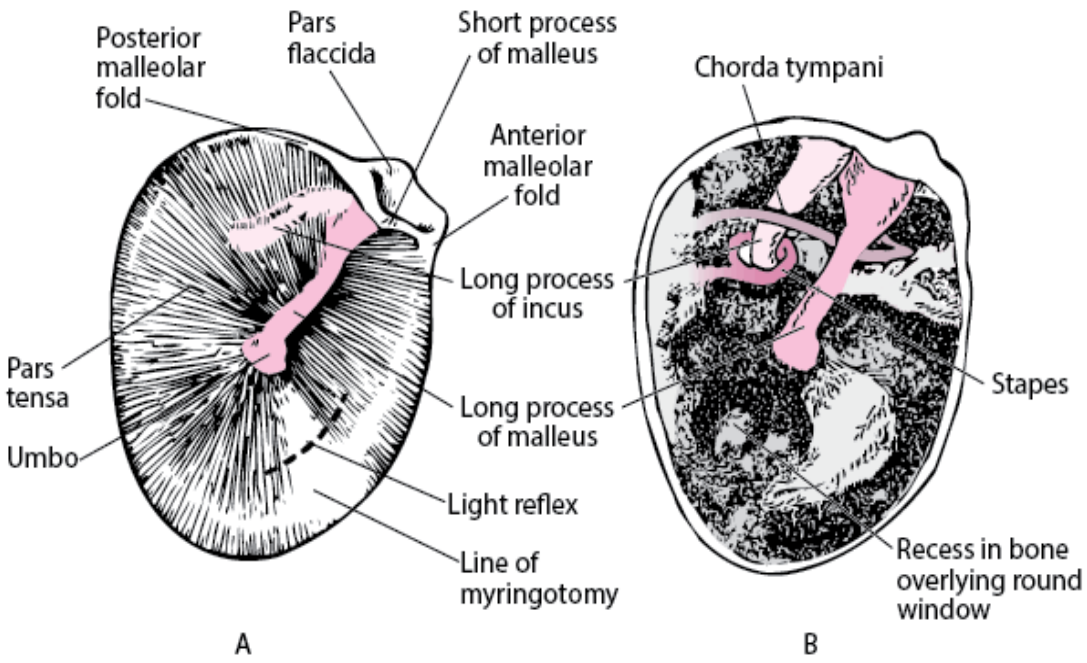


Figure 2 showing parts of Tympanic membrane

Layers of tympanic membrane

Tympanic membrane consists of three layers:

- Outer epidermal layer which is a continuous layer from the epidermis of external auditory canal.
- Inner mucosal layer which is continuous with that of the middle ear.
- Middle fibrous layer has outer radiating fibres and inner circular and tangential fibres.

Nerve supply of Tympanic Membrane

- Anterior half of lateral surface: Auriculotemporal nerve (V3).
- Posterior part of lateral surface: Vagus nerve auricular branch (CN X).
- Medial surface: tympanic branch of Cranial nerve IX (Jacobson's nerve).[6]

MIDDLE EAR

The middle ear together with the Eustachian tube, aditus, antrum and mastoid air cells is called the middle ear cleft. Mucous membrane lines the middle ear and contains air. [7,8]

The normal middle ear volume ranges from 2 to 20 ml. The middle ear is divided into

- Mesotympanum (lying opposite the pars tensa)
- Epitympanum or the Attic (lying medial to Shrapnel's membrane and the bony lateral attic wall and opposite the pars tensa)[9]
- Hypotympanum (lying below the level of pars tensa)
- Protympanum is also a portion of Middle ear around the tympanic orifice of the Eustachian tube.

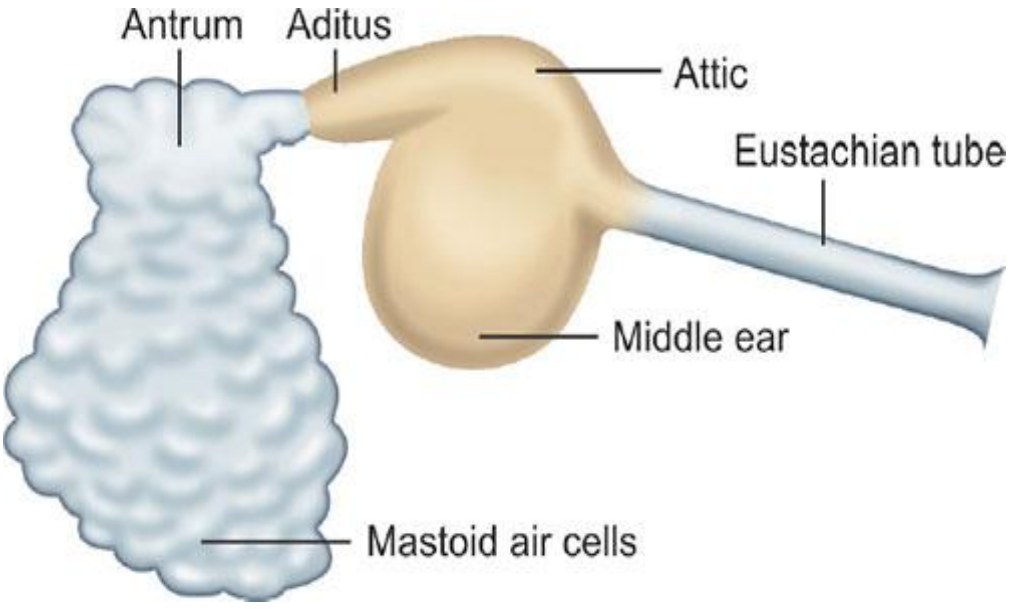


Figure 3 showing anatomy of middle ear cleft

Middle ear contains roof, floor, medial, lateral, anterior and posterior walls.

The roof was formed by a thin plate of bone called tegmen tympani. It forms the roof of the aditus and antrum by extending posteriorly. The tympanic cavity and the middle cranial fossa are separated by the roof.

The floor is a thin plate of bone. The tympanic cavity and the jugular bulb are separated by the floor. [10]

The anterior wall takes a thin plate of bone. The cavity and the internal carotid artery are separated by this thin plate of bone. There are two openings: one for the Eustachian tube and other for the canal of tensor tympani muscle.

The posterior wall is located near the mastoid air cells. It has a Bony projection called the pyramid. The tendon of stapedius muscle gets attached to the neck of stapes through the summit of pyramid. Aditus is an opening by which the attic connects with the antrum. It lies above the pyramid. Facial nerve goes through the posterior wall beneath the pyramid. There is a depression in the posterior wall lateral to the pyramid which is called Facial recess or the posterior sinus.[11]

The medial wall is formed by the Labyrinth. It presents a bulge called promontory which is due to the basal turn of cochlea; oval window into which is fixed the footplate of stapes; round window or fenestra cochlea. The secondary tympanic membrane covers it. Above the oval window is the Canal for the facial nerve. Above the canal for the facial nerve is the prominence of the lateral semicircular canal. Processus cochleariformisis a hook like projection located anterior to the oval window. The tendon of the tensor tympani takes a turn here

to get attachment to the neck of the malleus. Sinustympani is a recess which is located deep and medial to the pyramid. It is also bounded by the subiculum below and the ponticulus above.(12)

The lateral wall is formed by tymphanic membrane and to a lesser extent by the bony outer Attic wall called the scutum. The tympanic membrane is semitransparent.

Mastoid Antrum

It is a large air holding space in the upper portion of mastoid and interconnects with the attic via the aditus. Tegmentympani forms the roof and separates it from the middle cranial fossa. A small plate of bone forms the lateral wall of antrum and it is of 1.5 cm thick in the adult. Suprameatal (Mac Ewen's) Triangle is located externally on the surface of mastoid.(13)

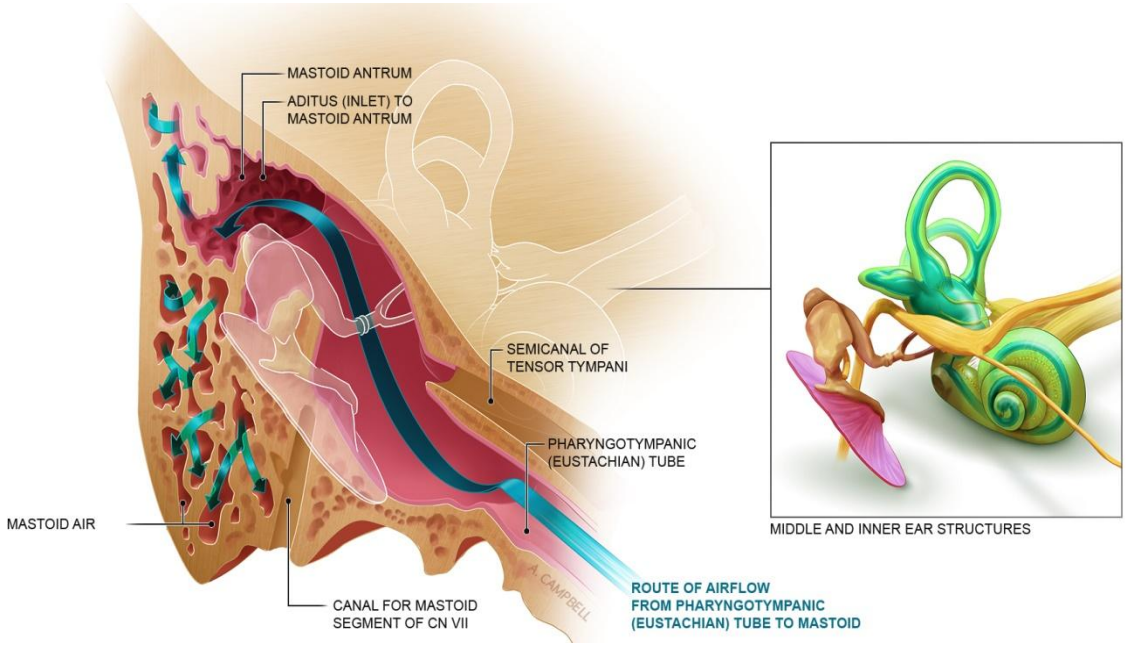


Figure 4 showing anatomy of mastoid antrum
Aditus and Antrum

Aditus is an opening via which the Attic connects with the antrum. The Bony prominence of the horizontal Canal lies on its medial side while the fossa incudis, to which is attached the short process of incus, lies laterally. Below the aditus runs the Facial nerve.

The Mastoid and Its Air Cell System

The mastoid comprises of a cortex of bone by means of a honeycomb of air cells below. Depending on air cell development three types of mastoid have been described.[14]

- Well pneumatized or cellular:
- Diploetic:
- Sclerotic or acellular:

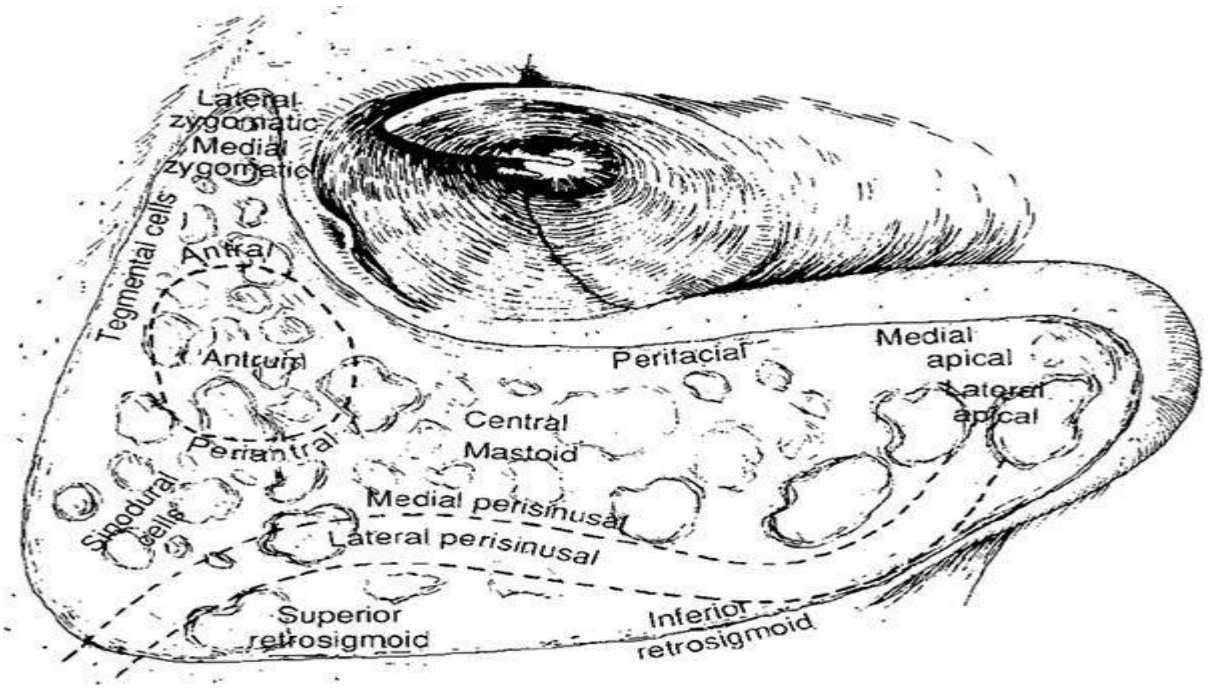


Figure 5 showing anatomy of mastoid air cells

Mastoid air cells are divided into:

1. zygomatic cells
2. tegmen cells
3. perisinus cells
4. Retrofacial cells
5. Perilabyrinthine cells
6. Peritubal cells
7. Tip cells
8. Marginal cells
9. Squamous cells

Development of the Mastoid

Mastoid develops from the squamous and petrous bones. The petrosquamous suture may persist as a Bony plate - the Korner ‘s septum, Separating superficial squamous cells from the deep petrosal cells. Mastoid antrum cannot be reached unless the Korner‘s septum has been removed.[15]

Ossicles of the Middle Ear

There are 3 ossicles in the Middle ear: the malleus, incus and the stapes.

The **malleus** has a head, neck, handle, lateral and an anterior process. The head and neck of malleus lie in the attic. Manubrium is embedded in the fibrous layer of tympanic membrane. Lateral process forms a knob like projection on the outer surface of the tympanic membrane and gives attachment to the anterior and posterior malleolar folds.[16]

The **incus** has a body and a short process both of which lie in the attic and a long process which hangs vertically and attaches to the head of the stapes.

The **stapes** has a head, neck, anterior and posterior crura and a foot plate. The foot plate is held in the oval window by an annular ligament.

The ossicles conduct the sound energy from the tympanic membrane to the oval window and then into the inner ear fluid.

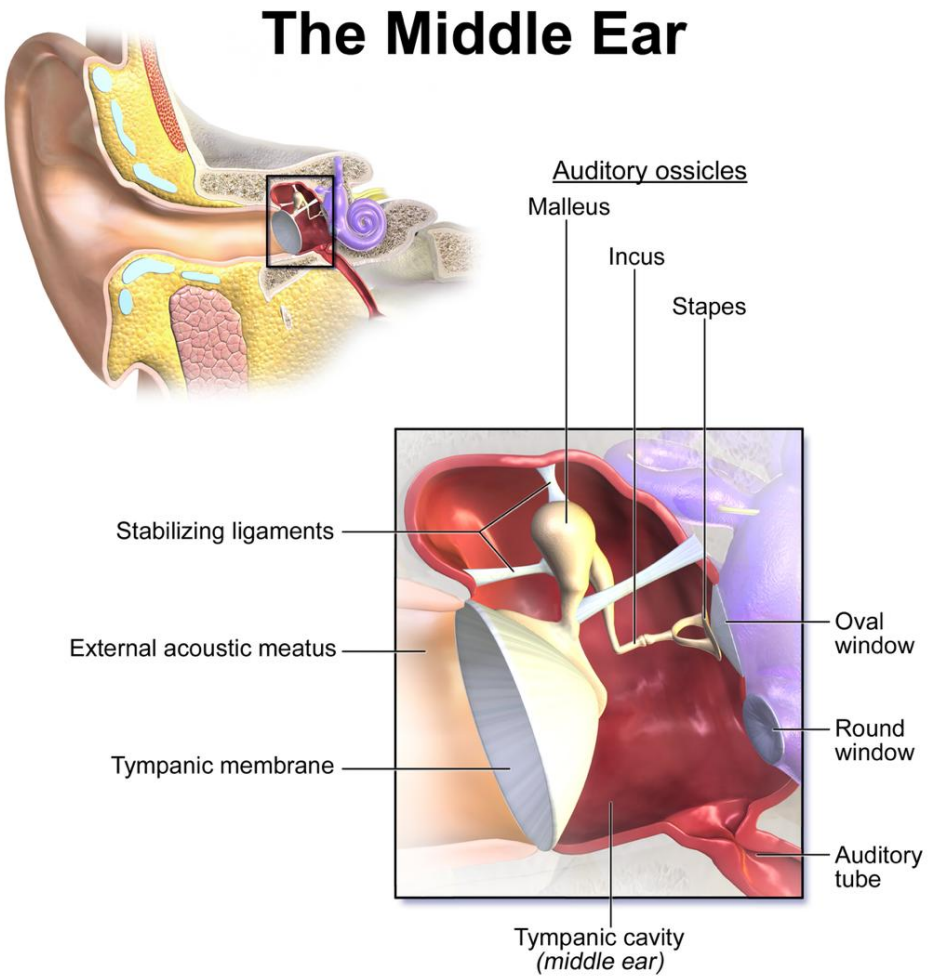


Figure 6 showing anatomy of ossicles of middle ear

Tympanic Plexus

It lies on the promontory and is formed by the tympanic branch of the glossopharyngeal nerve and sympathetic fibres from the plexus around the internal carotid artery. It gives nerve supply to the tympanic membrane on the medial surface, mastoid air cells, tympanic cavity, and the bony part of Eustachian tube. The secretomotor fibres goes for the parotid gland. [17]

Chorda Tympani Nerve

It is a branch of the facial nerve which enters a middle ear through posterior canaliculus and runs on the medial surface of the tympanic membrane between the handle of malleus and long process of incus above the attachment of the tendon of tensor tympani.

It carries taste from the anterior two thirds of tongue and secretomotor fibres to the submaxillary and sublingual salivary glands.

THE INTERNAL EAR OR LABYRINTH

The internal ear or Labyrinth is responsible of hearing and balance. It consists of two parts namely Bony and membranous Labyrinth. The second one is filled with clear fluid called endolymph while perilymph fills the space between membranous and the Bony Labyrinth.[18]

Bony Labyrinth

It consists of three parts the vestibule, semicircular canals and the cochlea.

Vestibule is the central Chamber of the Labyrinth. The oval window is located in its lateral wall. There are 2 recesses. First one is a spherical recess which contains the saccule and the second one elliptical recess which contains the utricle. There is the opening of aqueduct of vestibule below the elliptical recess. The endolymphatic duct passes through it. There are 5 openings of semicircular canals in the posterosuperior part of the vestibule.[19]

Semicircular canals are three in number, the lateral, the posterior and the superior. They are located at 90 degrees to one another. Each Canal has an ampullated end which opens independently into the vestibule and non ampullated end. The crus commune is a common channel formed by non-ampullated ends of posterior and superior canals. Thus the three canals open into the vestibule by 5 openings.[20]

The **Bony cochlea** is a coiled tube. It forms a 2.5 to 2.75 turning around a central pyramid of bone named the modiolus. The base of the modiolus is directed towards the internal acoustic meatus and transmits vessels and nerves to the cochlea. Around the modiolus and winding spirally like the thread of a screw, is a thin plate of bone called osseous spiral lamina. It divides the Bony cochlea and attaches to the basilar membrane.

The promontory is the bony bulge in the medial wall of the middle ear. It is created due to the basal coil of the cochlea. [21]

The bony cochlea contains three compartments:

1. Scala vestibuli
2. Scala tympani
3. Scala media or the membranous cochlea

The Scala vestibuli and the scala tympani are filled with perilymph. They communicate through an opening called helicotrema. Scala vestibuli is closed by the footplate of the stapes which separates it from the air filled middle ear.

The scala tympani is closed by a secondary tympanic membrane; it is also connected with the subarachnoid space through the aqueduct of cochlea.

Membranous Labyrinth

It consists of the cochlear duct, the utricle and the saccule, the three semicircular ducts and the endolymphatic duct and sac.[22]

Cochlear duct is also called membranous cochlea or the scala media. It appears triangular on cross section and its three walls are formed by

1. The basilar membrane which supports organ of corti
2. The Reissner's membrane which separates it from scala vestibuli
3. The stria vascularis which contains vascular epithelium and is concerned with secretion of endolymph.

It contains endolymph and divides the bony labyrinth into three compartments: scala vestibule above and scala tympani below with the scala media in between.

Organ of Corti is the organ of hearing and is situated on the basilar membrane. It has three main parts, namely the sensory hair cells, supporting cells and overlying gelatinous substance known as the Tectorial membrane.[23]

Utricle and saccule lie in the vestibule and are connected posteriorly with the three membranous semicircular canals.

Semicircular canals are three in number namely superior, lateral and posterior.

PHYSIOLOGY OF THE EAR

Hearing and equilibrium are the two functions of the ear.[24]

Sound Conducting Apparatus:

The sound waves are collected by the pinna and then passed to the external auditory Canal. The air pressure in the middle ear is maintained at atmospheric pressure by Eustachian tube which acts as a ventilating tube.

Sound pressure and protection of round window are the main functions of the middle ear. The hydraulic ratio of the middle ear and the lever factor play a major role in transformation of sound pressure.

Sound waves are conducted in the normal ear directly to the oval window and then to the inner ear. This process conserves a phase difference between oval and round window.

Sound waves are also conducted to the inner ear by bone conduction besides air conduction. These sound waves are conducted by the vibration of

skull bones and then through the basilar membrane. Low frequency sounds produce ossicular movement especially stapes movement with respect to the oval window. This is mechanism is referred to as 'translatory mechanism'. [24]

Conduction of sound waves

Middle ear: The following mechanisms are involved in conduction of sound waves.

1. Impedance matching mechanism
2. Attenuation reflex.
3. Phase differential between cochlear windows.
4. The natural resonance of external ear and middle ear.

1. Impedance matching mechanism also called as Transformation action

When sound waves travel from air into water, about 99.9% of sound waves are reflected away from the surface of the water. To compensate this loss, the tympanic membrane and the ear ossicles together convert the sound of greater amplitude but lesser force, to sound of lesser amplitude but greater force and this conversion serves as an impedance-matching device.

This task is accomplished by the following three mechanisms:

- Hydraulic action of the tympanic membrane and the lever action of ossicles.
- The handle of malleus is 1.3 times longer than the long process of incus, this provides a mechanical leverage advantage, due to which the middle ear ossicles increase the force of movement by 1.3 times.

- The area of the tympanic membrane is much larger than the area of stapes footplate. The average ratio between the two being 21:1. As the effective vibratory area of the tympanic membrane is only two-thirds of the surface area. The effective areal ratio is reduced to 14:1. This size differences between the tympanic membrane and stapes footplate provides the mechanical advantage. The product of areal ratio and lever action of ossicles is 18:1 (i.e., 18 folds).

According to some workers (Wever and Lawrence) out of a total of 90 mm2 area of the human tympanic membrane, only 55 mm sq is functional and given the area of stapes footplate (3.2 mm sq), the areal ratio is 17:1 and total transformer ratio (17× 1.3) is 22.1.

- Curved membrane effect. Movements of the tympanic membrane are more at the periphery than at the centre where malleus handle is attached. This too provides some leverage

2. Attenuation reflex (acoustic reflex) is a protective reflex. The muscles in the middle ear contract in response to ambient sounds >70-80 dB above hearing threshold, thereby tightening the tympanic membrane and restricting the movement of the ossicular chain. Hence the transmission of intense sound to the inner ear is stopped to protect the delicate sensory apparatus from damage. It is a slow reflex with a latent period of 40 milliseconds.

3. Phase differential between cochlear windows. Normally, the fluids in the inner ear are incompressible. The round window vibrates in opposite phase to

the oval window, in doing so it allows fluid in the cochlea to move. It means that when the oval window receives a wave of compression, the round window is at the phase of rarefaction. Phase differential between the windows contributes 4 dB when the tympano-ossicular system is intact. This acoustic separation of windows is attributed to the

- "Ossicular coupling" effect is produced by an intact tympano-ossicular system (preferential pathway to the oval window).
- "Acoustic coupling" effect is produced by a cushion of air in the middle ear around the round window also leads to phase difference.

Thus, if the sound waves were to strike both the windows at the same time and same phase, they would cancel each other effect with no movement of perilymph and no hearing.

4. Natural resonance of external and middle ear.

The external ear and middle ear, due to the inherent anatomic and physiologic properties, allows certain frequencies of sound to pass more easily to the inner ear. The natural resonance of important structures is:

- External auditory canal is 3000 Hz
- Tympanic membrane is 800–1600 Hz
- Middle ear is 800 Hz
- Ossicular chain is 500–2000 Hz

Thus, the greatest sensitivity of the sound transmission is between 500 and 3000 Hz, and used in daily talk and conversation.

- This is the reason, why human ear can perceive the pitch of sound between 16 and 20,000 Hz. Maximum sensitivity is between 1000 and 3000 Hz. This effect is depicted in the minimum audibility curve

C. Auditory transduction

The conversion of mechanical energy to nerve impulse occurring in the hair cells of the organ of Corti is termed ‘auditory transduction’.

Auditory transduction pathway

Process: Stapes footplate is attached to the oval window which is in close contact with scala vestibuli (containing perilymph). Movements of stapes footplate bring pressure changes in the perilymph which are transmitted to reissner’s membrane, causing compression of scala media (containing endolymph).

- Spiral ganglion (First-order neurons)
- Superior olivary nucleus complex, trapezoid nucleus and nucleus of lateral lemniscus (Second-order neurons)
- Inferior colliculus (Third-order neurons)
- Medial geniculate body (Fourth-order neurons)
- Auditory cortex. (Fifth-order neurons)

areas constituting auditory cortex present in the temporal lobe are: Primary auditory cortex (areas 42) and Auditory association areas (areas 22, 21 and 20)

Sound perception

The Foot plate of stapes causes movement of cochlear fluids. Movement is transmitted through perilymph in the scala vestibuli to the helicotrema and back down the Scala tympani to the round window. This compression wave in the perilymphatic fluid displaces there was basillar membrane resulting in a shearing movement between tectorial membrane and hair cells. This generates an electrical output in the afferent nerve fibres (cochlear microphonic). [25]

Chronic Suppurative Otitis Media (CSOM)

CSOM is the chronic suppurative inflammation of the mucoperiosteal layer of the middle ear cleft. It is also well-defined as a chronic inflammation of the middle ear and mastoid cavity. It is presented with recurrent ear discharges or otorrhoea over a tympanic perforation. Incidence of CSOM is higher in developing countries than in developed countries. It occurs commonly among low socio economic group of populations.[26]

Chronic Otitis Media (COM) equates the classic term Chronic Suppurative Otitis Media. Recent classification of COM includes Active Mucosal, Active Squamous, Inactive Mucosal, Inactive Squamous and Healed COM.

Predisposing factors

Some of the predisposing factors of CSOM are

- Repeated attacks of acute suppurative otitis media
- Poor Socioeconomic Status

- ❖ Upper respiratory Tract infections like nasopharyngitis, recurrent tonsillitis, adenoiditis and rhinosinusitis.
- ❖ Nasal allergy
- ❖ Swimming in contaminated water
- ❖ Previous perforation in the tympanic membrane can cause infection to spread from outside the middle ear causing CSOM (permanent perforation syndrome).[28]
- ❖ Poor nutrition
- ❖ Patients with comorbidities like Type 2DM etc

Etiology

The disease is common in that childhood age group. It is the sequel of acute otitis media typically succeeding exanthematous fever and causing central perforation. The perforation becomes everlasting and causes recurrent infection of the external ear. The middle ear mucosa gets visible to the environment and sensitized to particles like pollen, dust, and other allergens in the air. It further causes insistent otorrhoea. It can also be caused by referring infections from the tonsils, eustachian tube, adenoids and sinuses.[29]

Bacterial grounds

Many aerobic bacteria can cause CSOM namely

- ❖ Pseudomonas aeruginosa
- ❖ Escherichia coli
- ❖ S. aureus

- ❖ Streptococcus pyogenes
- ❖ Proteus mirabilis
- ❖ Klebsiella species

Anaerobic bacterial causes include

- ❖ Bacteroides
- ❖ Peptostreptococcus
- ❖ Proprionibacterium

Due to trauma or inflammation or lacerations or humidity, these bacteria may proliferate in the skin of the external canal. Then through a chronic perforation these bacteria enter the middle ear.

Among the above mentioned bacteria, the most serious type is P. aeruginosa. It goes deep, produces toxins and enzymes and destroys middle ear and mastoid structures progressively.[30]

Histopathology

The information is confined to the mucoperiosteum of the middle ear cleft which is chronically inflammed and infiltrated with chronic inflammatory cells. Hyperaemia and glandular (mucosal glands)hypertrophy occur, causing profuse discharge. In the early acute phase the Histopathological features are reversible whereas in late chronic phase CSOM shows intractable mucoperiosteal disease.

The recurrent episodes of CSOM lead to various changes in mucosa such as bony erosions, osteoneogenesis, and osteitis of temporal bone and ossicles.

Later on ossicular destruction and/or ankylosis occurs along with tympanic membrane perforation. This leads to the hearing loss. [31]

Disease burden

The disease burden is mainly measured by the indicator "prevalence of CSOM". Data obtained from various hospital and community based epidemiological studies revealed that the school children were the most common populations being infected and diagnosed with CSOM. The prevalence rate of different countries was based on regional classification of WHO.

The countries were classified based on prevalence rates of CSOM by WHO/CIBA workshop of otitis media experts in 1996. CSOM prevalence rates of 1–2% were measured as low and 3–6% were measured as high. [32]

Classification of countries based on prevalence of CSOM[32]

Group	Populations
Highest (>4%)	Tanzania, India, Solomon Islands, Guam, Australian Aborigines, Greenland
High (2–4%)	Nigeria, Angola, Mozambique, Republic of Korea, Thailand, Philippines, Malaysia, Vietnam, Micronesia, China, Eskimos
Low (1–2%)	Brazil, Kenya
Lowest (<1%)	Gambia, Saudi Arabia, Israel, Australia, United Kingdom, Denmark, Finland, American Indians

Symptoms

1. **Aural discharge:** discharge is profuse, mucopurulent and non-odorous. In the inactive stage no aural discharge is present.
2. **Deafness:** conductive deafness, degree of deafness depends upon the size and site of perforation and underlying middle ear ossicular involvement.

Classification of CSOM

CSOM is mainly classified into two groups.

1. Tubotympanic disease - 'safe ear' – is further classified as active mucosal, inactive mucosal, healed Chronic otitis media (COM).
2. Attico antral disease - 'unsafe ear'

Difference between Tubo-tympanic type and Attico antral type [33]

	Tubo-tympanic type	Attico antral type
Discharge	Profuse, mucoid, odorless	Scanty, purulent, foul smelling
Perforation	Central	Attic or marginal
Granulations	Uncommon	Common
Polyp	Pale	Red and fleshy
Cholesteatoma	Absent	Present
Complications	Rare	Common
Audiogram	Mild to moderate conductive deafness	Conductive or mixed deafness

Tubo-tympanic disease

It is the inflammation of the mucoperiosteal layer of the Middle ear cleft characterized by presence of Central perforation. There is no underlying osteitis or osteomyelitis. The disease is limited to the middle ear cleft. Complications are not common and hence it is called 'safe type'.

Perforations of tympanic membrane

There are three types of perforation:

1. Central perforation
2. Marginal perforation
3. Attic perforation

1. Central perforation:

Perforation is located in the pars tensa and all the margins are surrounded by pars tensa. For clinical purposes the portions of the tympanic membrane can be divided into four quadrants by two lines: One vertical line passing along the handle of the malleus and a horizontal line at the level of the umbo.

So, the location of Central perforation is anterosuperior, anteroinferior, posteroinferior and posterosuperior [(34)]. According to size, further classified into small, medium, large and subtotal.

The size of the perforation was determined in square millimeters by measuring the area occupied by the perforation. The perforation was classified into small if area is between 0 to 8 mm^2, medium if area is between 8.1 to 30 mm^2 and large area is above 30 mm^2.

2. Marginal perforation

It is located at the tympanic membrane margin with erosion of fibrous annulus and is characterized by bony boundaries. Posterio-superior marginal perforations are associated with cholesteatoma (secondary acquired variety).

3. Attic perforation

It occurs in the pars flaccida. It indicates primary acquired cholesteatoma.[35]

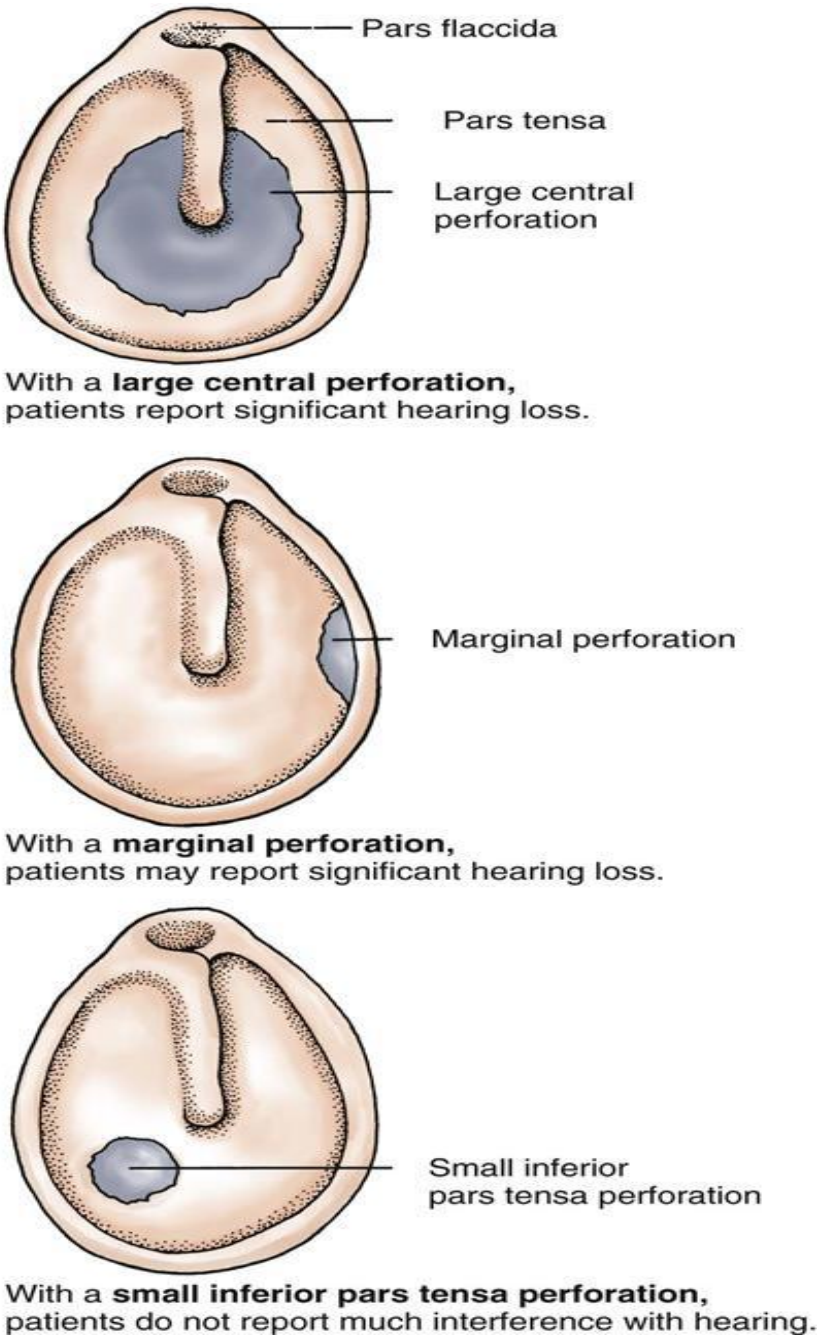


Figure 7 showing types of perforation

Clinical stages: two stages

1. **Active stage:** Patient complaints of profuse aural discharge. It is otherwise called ‘chronic discharging ear’.
2. **Inactive disease:** no discharge from the ear and Central perforation is present. Deafness is the main complaint.

Complications of CSOM

Infections spread from middle ear cleft to neighboring structures like facial nerve, inner ear, Dural venous sinuses, meninges, brain tissues and extra temporal soft tissue. This causes various intracranial and extracranial complications.[36]

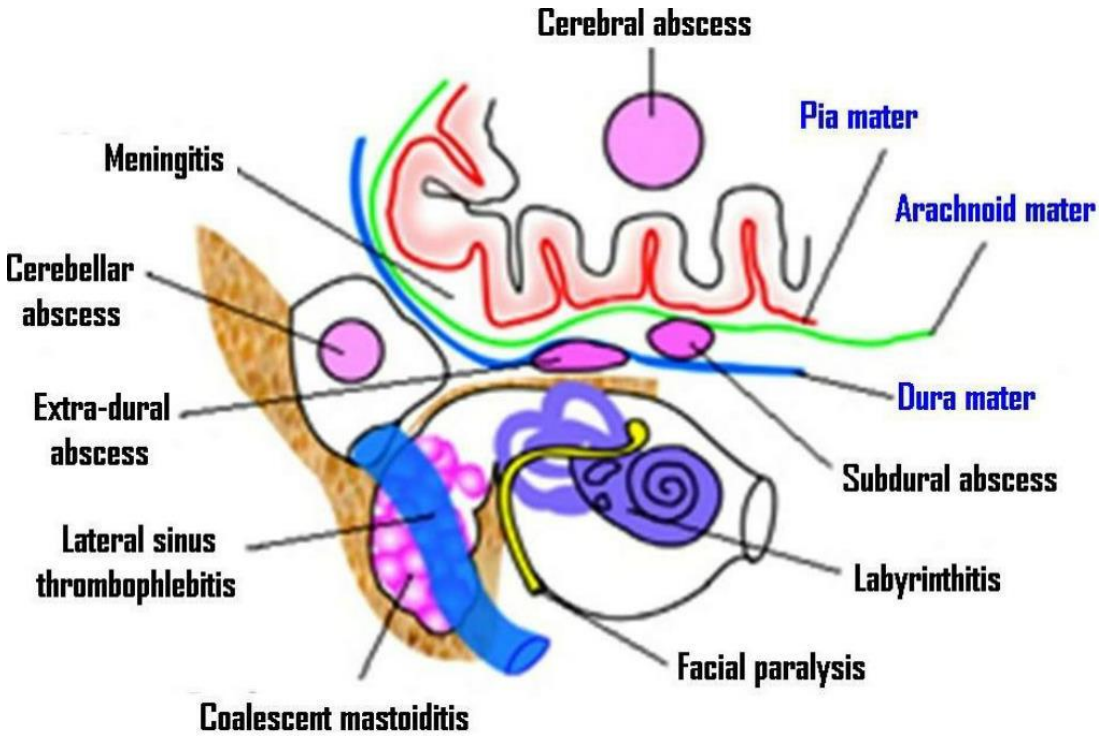


Figure 8 showing Complications of CSOM

Intracranial	Extracranial
Meningitis Extradural abscess Subdural empyema Lateral sinus thrombophlebitis Brain abscess Otitichydrocephalus CSF otorrhea	Subperiosteal abscess Mastoiditis Labyrinth involvement Petrous apicitis Facial nerve paralysis Sensorineural hearing loss

Examination of the ear

Discharge in the ear is mucopurulent in nature. After cleaning, the perforation is seen. In chronic perforation, the edges are epithelialized. Middle ear mucosa will be seen as Red, velvety, and edematous. Inflammatory middle ear mucosa protrudes through the perforation as a polyp. Tuning fork tests show conductive deafness.

Investigations:

1. Routine Blood Investigations
2. X Ray both mastoids lateral oblique view (Law's view) Cellular mastoids are seen in the majority of cases with clouding of cells.
3. Culture and sensitivity of the ear discharge
4. Pure tone Audiometry confirms conductive deafness and also shows the degree of deafness.
5. Microscopic ear examination
6. HRCT Temporal Bone

Management of CSOM

Active disease:

Aural cleaning: thorough cleaning of the ear is essential. This can be done by

- ❖ dry mopping with cotton buds
- ❖ Suction clearance under the operating microscope thorough cleaning of debris and secretions by suction is an ideal method

Antibiotics (based on culture and sensitivity report)

Local: in the form of ear drops, tobramycin, sulfisoxazole, sulfacetamide, tetracycline, polymyxin B, gentamicin, trimethoprim, norfloxacin, ofloxacin, chloramphenicol, ciprofloxacin and erythromycin.

Steroid drops such as hydrocortisone, fluocinolone and triamcinolone

Systemic antibiotics [37]

Types	Drugs
1. Penicillins	Carbenicillin, Piperacillin, Ticarcillin, Mezlocillin, Azlocillin, Methicillin, Nafcillin, Oxacillin, Ampicillin, Penicillin G
2. Cephalosporins	Cefuroxime, Cefotaxime, Cefoperazone, Cefazolin, Ceftazidime
3. Aminoglycosides	Gentamicin, Tobramycin, Amikacin
4. Macrolides	Clindamycin
5. Glycopeptide antibiotics	Vancomycin
6. Broad spectrum antibiotics	Chloramphenicol
7. Monobactem antibiotics	Aztreonam

Surgery:

Tympanoplasty is defined as "Procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism with or without tympanic membrane grafting".[38]

The major goals of surgery are to establish intact TM, to alleviate middle ear disease and create air containing middle ear space and to restore hearing by building a secure connection between the tympanic membrane and cochlea.

Wullstein in 1953 coined the term 'tympanoplasty'[39]. In 1956 he classified tympanoplasty into five different types as mentioned below:

Wullstein Classification of Tympanoplasty[40,41]

Type I Tympanoplasty

It involves reconstruction of a new tympanic membrane in situations with a normal ossicular chain with restoration of normal middle ear.

Type II Tympanoplasty

It involves reconstruction of a new tympanic membrane in situations where the malleus is partially eroded; skin graft placed against the ossicles after removal of bridge.

Type III Tympanoplasty

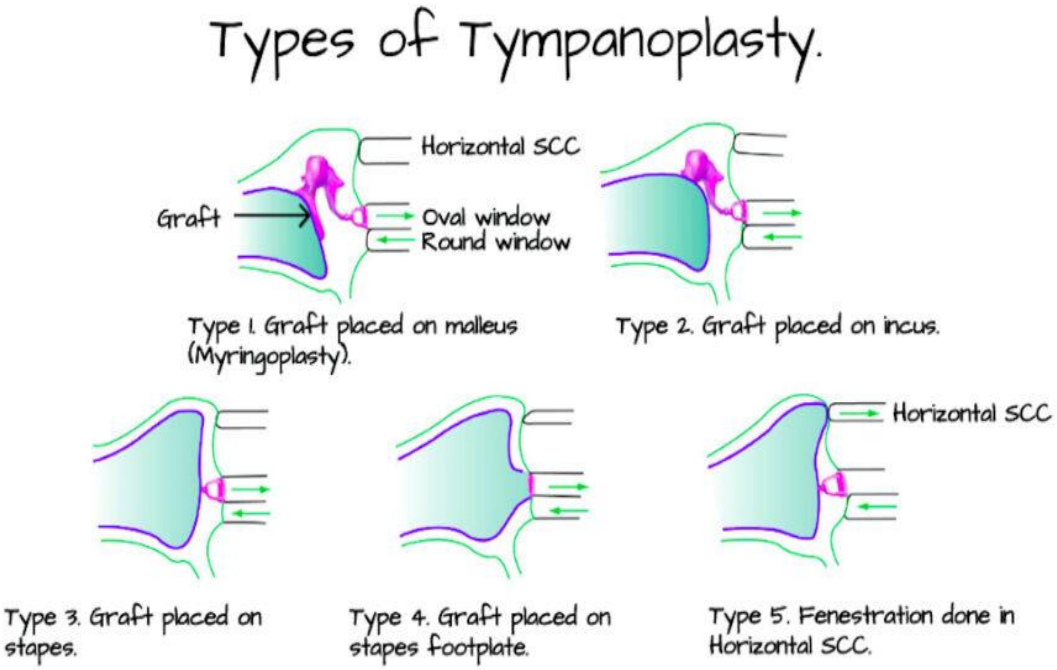
It involves reconstruction of a new tympanic membrane in situations involving defects of malleus and incus; graft is placed over stapes supra-structure producing a shallow middle ear and columella effect.

Type IV Tympanoplasty

Graft is placed to shield the round window membrane from sound with a small middle ear and mobile footplate left exposed.

Type V Tympanoplasty

It involves closed middle ear with round window protection and fenestra in the horizontal semicircular canal covered by a skin graft.



Minimalist Techniques:

There are certain clinical circumstances in which a minimalist approach to tympanoplasty is potential or desirable. This is mainly to manage small, uninfected, established perforations of 1- to 2-mmdiameter. First cauterization is done on the epithelium at the margins of the perforation followed by removal of plug which is some what bigger than the diameter of the perforation. It can be

used as a graft. It is positioned through the opening in a dumbbell manner and sheltered with a dressing such as Gelfoam or Gelfilm. Some may prefer trichloroacetic acid or phenol and apply a patch of Gelfoam, Gelfilm, cigarette paper, or a hyaluronic acid film.

Traumatic perforations also are often managed by patching which is to be done only after the perforation edges are freshened. Recently the use of a sealed tympanostomy tube is practiced when there are contradictions or refusal of surgery.

In 1964, Goodhill introduced Temporalis fascia - Tragal perichondrium into myringoplasty rather than its usage in stapedectomy as an oval window graft previously. [42]

Status of middle ear mucosa

The status of middle ear mucosa and occurrence of drainage are important prognosis factors of post operative hearing. Post-operative adhesions, fibrosis of middle ear mucosa are the factors which are detrimental to hearing ability.

TYMPANOPLASTY PROCEDURE

Indications

Tympanoplasty with or with mastoidectomy is the management for CSOM. Wullstein advises an empirical assessment of the attic and antrum in every case of CSOM before continuing with a tympanoplasty. The major indications [44] for tympanolasty are as follows

- ❖ Chronic or recurrent otitis media
- ❖ Conductive hearing loss due to TM perforation or ossicular dysfunction
- ❖ Perforation and associated hearing loss persistent for ≥ 3 months due to trauma, infection or surgery.
- ❖ Progressive hearing loss due to chronic middle ear pathology

Contraindications of tympanoplasty

Absolute

- ❖ Malignant neoplasm of the outer or middle ear
- ❖ Functionally dead ear
- ❖ Ear without residual cochlear function
- ❖ Malignant OE.
- ❖ Only Hearing Ear or significantly better hearing ear

Relative

- ❖ Allergic type of chronic tubotympanic type
- ❖ Acute exacerbation of CSOM
- ❖ Chronic otitis externa caused by pseudomonas, aspergillus, or staphyoloccous
- ❖ Dysfunction of Eustachian tube

Pre-operative evaluation and preparation:

Routine procedures like detailed complete history taking with general systemic examination and comprehensive otolaryngologic examination must be

done to all patients. Routine investigations, x ray both mastoids, tuning fork tests and Pure tone audiometry preoperatively and postoperatively are needed. The patency of the Eustachian tube is established by the Valsalva manoeuvre. Computed Tomographic scans may help to recognize the ossicular chain defect and extent of disease, mastoid pneumatization, intracranial involvement. Any generalized or localized infections must be treated before surgery. As in any surgical procedure, as informed written consent is important. Patient to be admitted 1-2 days before the date of surgery. Hair is clipped or shaved for a distance of 2" above and behind the ear on the operative side. Anxiolytic drug namely diazepam 5-10mg is given at bedtime on the preoperative day in adults; all patients are kept for fasting overnight. Pre-operative sedation: sedation should be sufficient to allay all anxiety but it should not depress the respiration or blood pressure. 30 minutes before surgery, patient receives pethidine 100mg, Promethazine 25mg andatropine 0.6mg by intramuscular injection.[45]

Anaesthesia for tympanoplasty:

Local and general anaesthesia can be used for middle ear surgery. However, both forms require the use of local injection to reduce intraoperative bleeding and intra- and postoperative pain. Local anaesthesia is achieved by the subcutaneous injection of 2% local Xylocaine with 1:100,000 adrenaline using a 2-mlsyringe. For this the auricle is pulled forward and a depot is placed in the postauricular fold. The needle is then proceeded further under permanent use of local anaesthetic in the direction of the posterior canal skin. The needle is then

pulled back and advanced superiorly and inferiorly to the prior injection site. Successively the ear canal is opened with a speculum, allowing subperiosteal injection at the 3, 6, 9 and 12o'clock positions. The bevelling of the needle is positioned against the bone and the anaesthetic is introduced until the ear canal skin goes white and develops noticeable. The ear canal is wrapped with a cotton ball erstwhile to disinfection to escape the penetration of possibly ototoxic constituents into the middle ear cavity if a perforation is existent.In some cases, the local anaesthesia is insufficient for the promontorial region innervated by the tympanic nerve. This can be overcome by the topical application4% xylocaine.[46]

General Anaesthesia

General anaesthesia is used for prolonged and long-lasting procedures, commonly in children and non-cooperative patients (mentally challenged or language-deficient).The decision as to implement transcanal, endaural or a retroauricular approach should be established on the preoperative assessment.

Transcanal Approach

This approach can be utilized for small central perforations especially when the size of ear canal is large. The use of self-retaining specula allows bimanual operations. Local anaesthesia should be constrained to avoid bulging and to warrant good access to the tympanic membrane.[47]

Endaural Approach

It was first described by Kessel in 1885 and was popularized by Lempert. The first incision in this approach is made along the entire posterior half of the ear canal at bony cartilaginous junction. A second vertical incision is made in the incisura and connects the previous incision and the area between the tragus ad the root of helix. Most central perforations in chronic otitis media can be managed using an endaural approach. Broadening of the ear canal and the fractional reduction of a protuberant anterior canal wall to uncover the anterior part of the drum may be essential.[48]

Postauricular Approach

The postauricular approach is preferable for large perforations necessitating total replacement of TM, especially when the ear canal is narrow. Even though mastoid surgery can be completed from an endaural incision, a retro auricular approach is favoured for most circumstances when surgery in the mastoidis anticipated.[49]

SIMILARSTUDIES

A study was conducted by **Dayanand et al**[50] among 75 cases of dry perforation of tympanic membrane in ENT department in Coimbatore between 2016 to 2018 where the study participants were divided into two groups. The group A consisting of 50 patients underwent Type I Tympanoplasty with temporalis fascia alone and group B consisting of 25 patients underwent Type I Tympanoplasty with combined temporalis fascia and conchal cartilage graft.

Postoperatively the study revealed that the mean hearing improvement in group A with temporalis fascia graft was 12.98 dB (better) whereas the mean hearing improvement in group B with temporalis fascia and conchal cartilage graft was 8.96 dB. The results of the study showed that small and medium perforations can be repaired better using temporalis fascia alone rather than conchal cartilage. In case of large and subtotal perforations, conchal cartilage graft can be used to repair but hearing improvement is comparatively low.

Another similar study was conducted by **Fernandes et al**[51] between 2014 to 2016 in Goa among 60 patients where the study participants were divided into two groups. The group 1 consisting of 30 patients underwent Type I Tympanoplasty with temporalis fascia alone and group 2 consisting of 30 patients underwent Type I Tympanoplasty with combined temporalis fascia and conchal cartilage graft.

After 8 weeks of postoperative period, the graft uptake was assessed. The average hearing improvement in group 1 and group 2 was 7 dB and 15 dB respectively. The study results advocated the use of cartilage as it reported better closure of perforation and hearing improvement.

A prospective study was conducted by **Gosavi et al**[52] in Miraj, Maharashtra over a period of 18 months from 2018 to 2020. The study included 100 patients who were divided into two groups where one group (50 patients) underwent Type I Underlay tympanoplasty by **using a reinforced temporalis fascia graft along with conchal cartilage**. The other group of another 50

patients underwent a similar procedure but with the use of temporalis fascia alone as grafting material. The patients were assessed post operatively at 6, 12 and 24 weeks. The graft uptake was 94% in group of patients who were grafted with a reinforced temporalis fascia with cartilage graft while in the other group the graft uptake was 86% in those patients who received exclusively with temporalis fascia. The mean air bone gap in patients of reinforced temporalis fascia with conchal cartilage was 9.72 dB whereas the mean air bone gap in patients of temporalis fascia alone was 9.70dB respectively. The difference was anyhow not statistically significant.

In Vishakhapatnam**, Gondela et al**[53] conducted a study among 60 patients to compare the use of temporalis fascia graft and tragal perichondrium graft material in view of graft uptake and hearing improvement. The patients were followed at 6, 12 and 24 weeks respectively. In first group who were grafted with tragal perichondrium, the successful graft uptake was 86.6% and hearing improvement < 10 dB was 83.33%. In the second group who were grafted with temporalis fascia graft showed 83.33% of graft uptake. The hearing improvement < 10dB was 80%.

A study by **Murugendrappa et al**[54] over a period of one year between 2014 - 2015 conducted among 50 patients attending OPD in Department of Otorhinolaryngology and Head and Neck Surgery, Davanagere revealed the following. Out of 50 patients, 25 had undergone conventional underlay technique and another 25 patients underwent circumferential subannular graft

technique. The results were calculated in terms of graft success rate and improvement in hearing after 3 months of postoperative period. The results were as follows: the success rate of graft uptake by circumferential subannular graft technique was 96% and by conventional underlay technique was 76% respectively. The mean difference in PTA (dB) Pure Tone Average Threshold was 11.05 and 7.96 in circumferential subannular graft technique and conventional underlay technique respectively. The study concluded that the circumferential grafting technique is superior when compared to conventional underlay technique.

In a hospital-based study in Mumbai in 2007 by **Dabholkar et al**[55], 50 patients were enrolled in randomized control trial to compare and evaluate the success of underlay tympanoplasty with temporalis fascia and tragal perichondrium. The results of graft take with temporalis fascia and tragal perichondrium were 84% and 80% respectively. Temporalis fascia achieved a satisfactory hearing improvement in 76% of patients while tragal perichondrium achieved 75% hearing gain. The study concluded that there was not much big difference between the two grafts.

Another study was conducted by **Nemade et al**[56] in 2017 among 144 patients of CSOM where 48 patients (Group A) underwent Type I tympanoplasty with modified sandwich graft – Temporalis fascia was underlaid and the areolar fascia was overlaid. The next 48 patients (Group B) underwent Type I tympanoplasty with underlay fascia technique. Another 48 patients

(Group C) underwent Type I tympanoplasty with underlay cartilage technique. After assessment postoperatively, the results revealed the following: successful graft intake was accomplished in 97.9% in Group A, 83.3% in Group B and 95.8% in Group C respectively. The average air bone gap closure achieved in Group A, Group B and Group C were 24.4dB, 22.5dB and 19.8dB respectively. The study concluded that modified sandwich graft maintained a perfect balance between sufficient stability and adequate acoustic sensitivity.

The study was conducted by **Mohanty et al**[57] in a tertiary care centre from 2012 – 2016. A total of 187 ear drums (n) in 168 patients with perforations involving anterior quadrant were included in the study. Tragal Composite Cartilage Perichondrium Island (CCPI) graft was used in 87 ears and temporalis fascia in 100 ears respectively. The results revealed that cartilage group had 91.95% success rate while fascia group had 79%. The mean improvements in ABG (Air Bone Gap) for both groups were 17.52 dB and 15.26 dB respectively. ABG closure ratios for both the groups were 62.84 and 53.6 respectively. The study concluded that the CCPI graft was an effective technique in managing perforations of anterior quadrant.

A retrospective study was conducted by **Cayir et al**[58] among 42 paediatric patients less than 18 years of age who underwent Type I Tympanoplasty using tragal cartilage perichondrium and temporalis fascia from 2013 – 2018. The graft success rate was significantly higher 95.2% for the perichondrium group compared with 71.4% for the fascia group. The post-

operative ABG <20 dB in perichondrium group was 90.4% and 85.7% in the fascia group respectively. The study concluded that the Tragal cartilage perichondrium was the first choice of graft material due to its high success rate.

Similar RCT study was conducted by **Bhardwaj et al**[59] from 2015 – 2017 on consecutive 40 patients of CSOM (safe type) in Amritsar. Among them 20 underwent Temporalis fascia type I tympanoplasty and rest 20 underwent Conchal cartilage graft. Hearing improvement was compared between two groups at 2 months and 6 months postoperatively. The ABG closure at 2 months postoperatively was 11.55 and 10.49 for conchal perichondrium group and temporalis fascia group respectively. The ABG closure at 6 months postoperatively was 14.98 and 11.41 for conchal perichondrium group and temporalis fascia group respectively. The study concluded that the conchal cartilage graft was better than temporalis fascia graft.

MATERIALS AND METHODS

STUDY SETTING

The study was conducted in Department of Otorhinolaryngology, KAPV Government Medical College, Mahatma Gandhi Memorial Government Hospital, Trichy.

STUDY POPULATION

The study was conducted among the patients diagnosed with safe type of CSOM and admitted in Department of Otorhinolaryngology, KAPV Government Medical College, Mahatma Gandhi Memorial Government Hospital, Trichy.

STUDY PERIOD

The data collection for the study was done between November 2020 to October 2021.

STUDY DESIGN

It was a Randomized Control Study Design.

SAMPLE SIZE & SAMPLING DESIGN

All patients diagnosed with CSOM safe type and admitted in Department of Otorhinolaryngology, KAPV Government Medical College, Mahatma Gandhi Memorial Government Hospital, Trichy during the study period were

considered for the study. Total of 50 patients were included in the study with 25 patients assigned to Group F and 25 patients to Group FC (described in the later part) according to the following criteria:

INCLUSION CRITERIA

Patients of age between 20 to 60 years of age presenting with

1. Perforated tympanic membrane due to Chronic Otitis media, Trauma, recurrent middle ear infection
2. Intact ossicular chain
3. Dry ear (atleast 6 weeks)
4. Patent Eustachian tube.
5. Adequate Cochlear Reserve

EXCLUSION CRITERIA

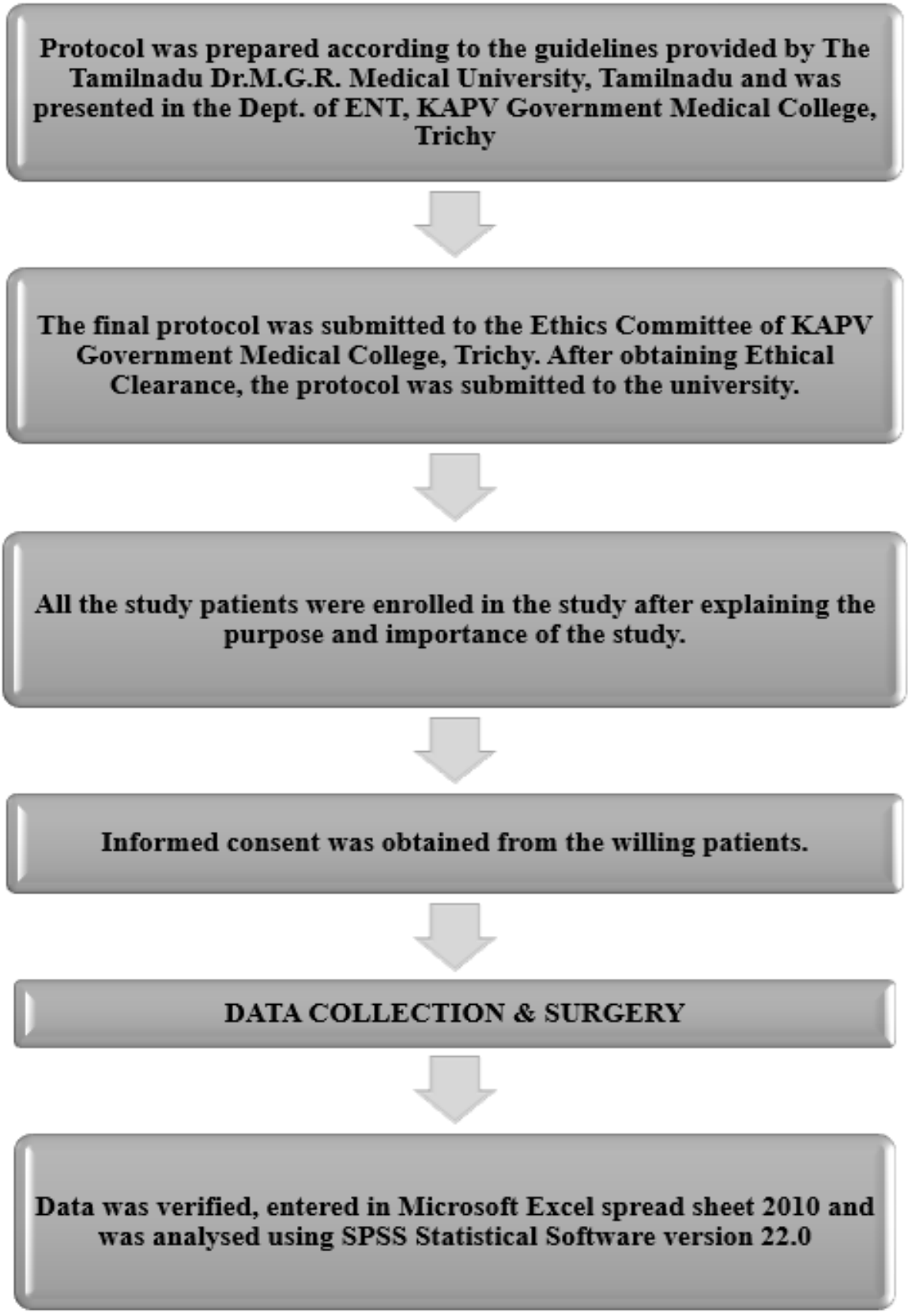
1. Patients with Sensory Neural Hearing Loss (SNHL) and mixed hearing loss
2. CSOM with Attico-Antral type of disease.
3. Patients with comorbidities such as uncontrolled diabetes, immunocompromised states etc.
4. Parent/guardian refusal

TIMELINE

The study work is termed in detail in the subsequent Henry Gantt chart from its initiation to the end.

Activity	2020												2021											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Protocol preparation, Submission																								
Questionnaire Preparation, Ethical clearance																								
Data Collection																								
Data Entry & Analysis																								
Thesis finalization																								

STUDY TECHNIQUE



STUDY PROCEDURE

This RCT study was conducted among 50 patients posted for elective type I tympanoplasty for safe type of Chronic Suppurative Otitis Media in Department of Otorhinolaryngology, KAPV Government Medical College, Mahatma Gandhi Memorial Government Hospital, Trichy. All the patients had undergone preanesthetic check-up with routine and specific investigations before surgery. Informed consent was obtained.

50 patients were divided as follows:

- 25patients were randomly assigned into **Group F** to receive temporalis **fascia graft alone** and
- Remaining 25 patients were randomly assigned into **Group FC** to receive **temporalis fascia graft with cartilage**.

Anesthesia was either local anaesthesia or general anaesthesia based on the patient status. During surgery, various parameters were noted down including duration of surgery and duration of hospitalization. Under strict aseptic precautions, antibiotic cover was given half an hour prior to surgery.

Position of the patient: The patient was placed in the supine position with the head partially rotated to the opposite side.

Infiltration: The post-auricular infiltration with 2% Xylocaine and 1: 100,000 adrenaline was done. The canal wall infiltration was done in four quadrants of canal wall using a 2ml syringe with 26-gauge lever lock needle with the terminal 1 cm angulated towards the bevel.

Approach: All the patients were subjected to microscope assisted tympanoplasty through post-aural approach.

Harvesting of graft: Post aural William Wilde's incision was given and then either temporalis fascia auto graft alone or with fascial graft with conchal cartilage was used for closure of tympanic membrane perforation. This was decided according to the group based on randomization. Temporalis fascia graft was harvested and prepared.

Through the same incision, conchal cartilage graft was harvested from the conchal bowl. Conchal cartilage was considered ideal as it was thin and had a smooth contour and was very elastic, so when it was placed medial to anterior rim, it splays and stays in place. The conchal cartilage was then cut into thin strips.

Inspection: The tympanic membrane with its perforation was visualized. Middle ear was examined through the perforation.

Incision and flap elevation: Freshening of the perforation margins was done using a wide curved pick. An 12 O'clock to 6 o'clock incision was taken in the posterior canal wall skin about 5mm away from the annulus. The tympano-meatal flap was being elevated.

Middle Ear Inspection: The middle ear and ossicles are inspected and checked for ossicular continuity. Middle ear disease if present was completely removed.

The round window reflex was visualized to confirm the continuity of the ossicular chain.

Graft placement: In underlay technique, the Temporalis fascia graft was placed medial to tympanic annulus hugging the handle of malleus. Strips of harvested conchal cartilage were placed over the promontory in a pallisade fashion medial to the fascia graft, supporting the anterior rim margin.

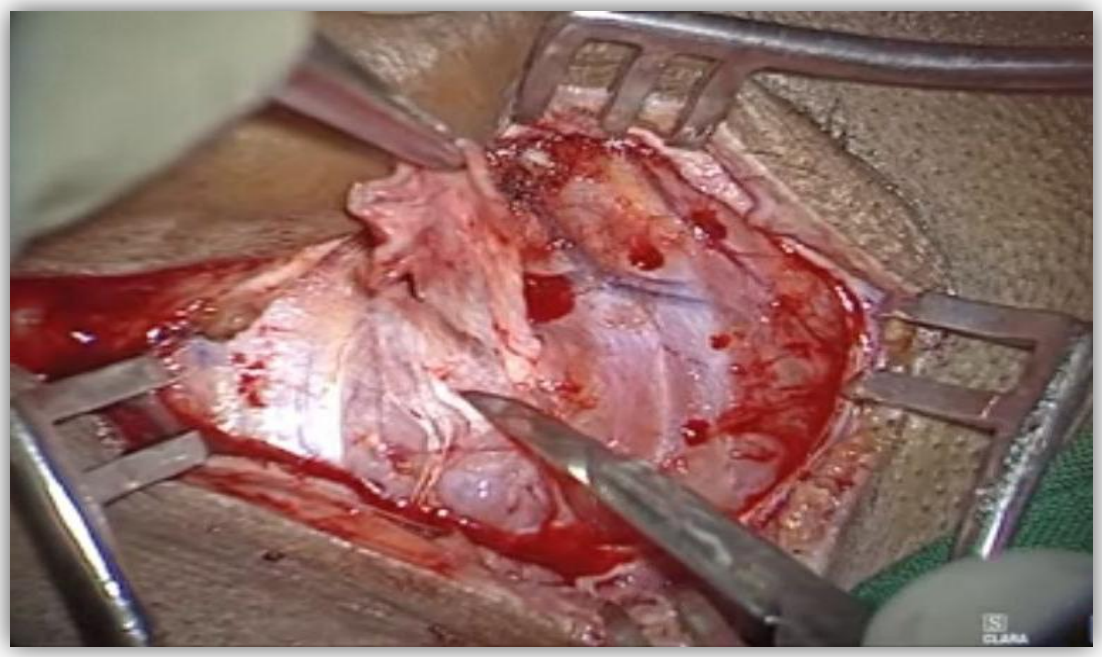
The strips were extended anterior to the malleus, and into the hypotympanum, making sure that the Eustachian tube opening was not closed. The strips of cartilage were placed in such a way that they did not impede the ossicular mobility.

Repositioning the tympano-meatal flap: The flap was repositioned to its' original position and then margins were approximated circumferentially. Gel foam pieces soaked in ointment were placed over the skin flap to keep the skin approximated to graft.

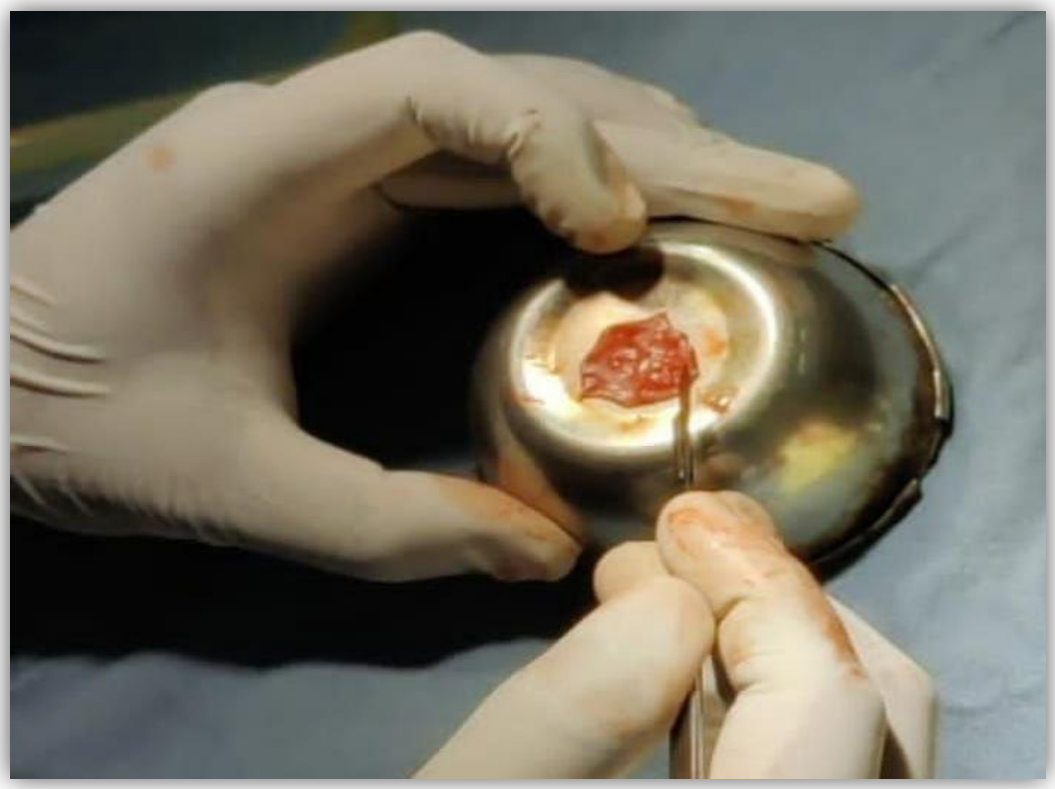
After the procedures, Mastoid Dressing was done. The patients were put on oral antibiotics and analgesics for one week. The post auricular sutures were removed after 1 week. Duration of surgery will be noted as from time of incision to final skin closure.

Post aural modified William Wilde incision

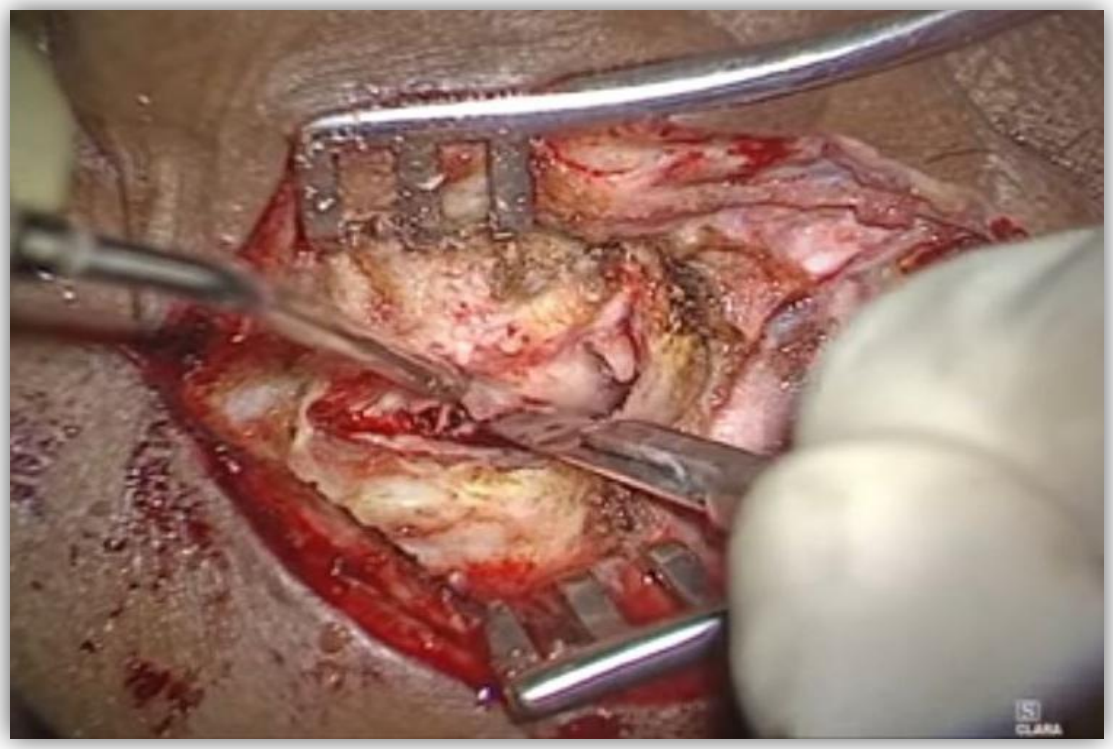
Temporalis fascia exposed



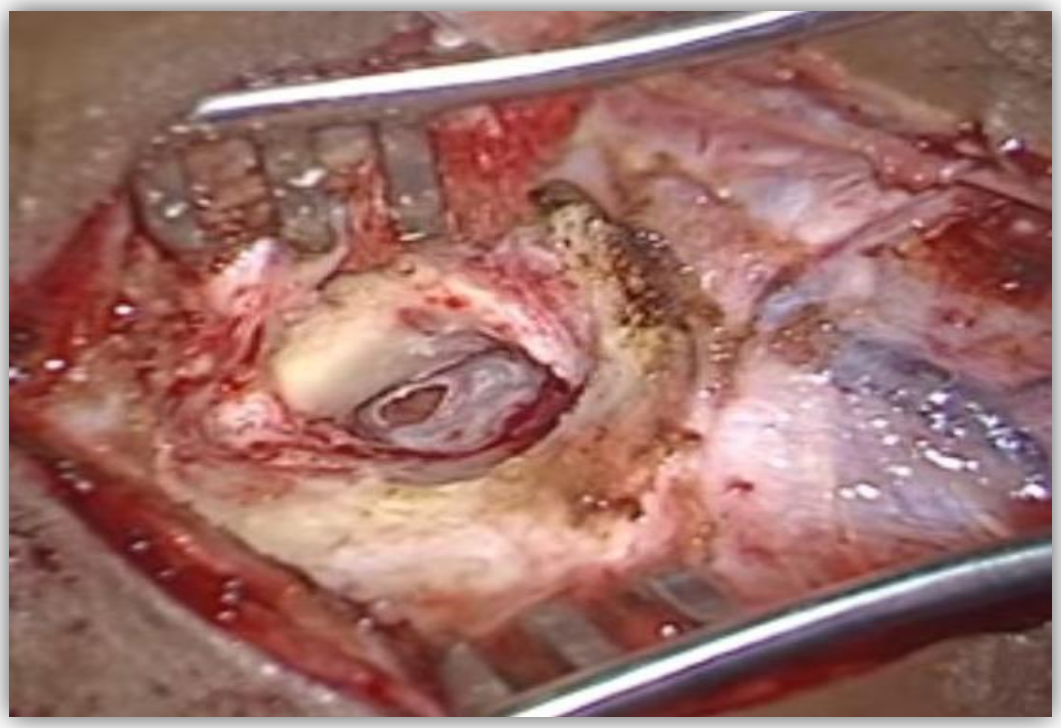
Harvesting of Temporalis fascia



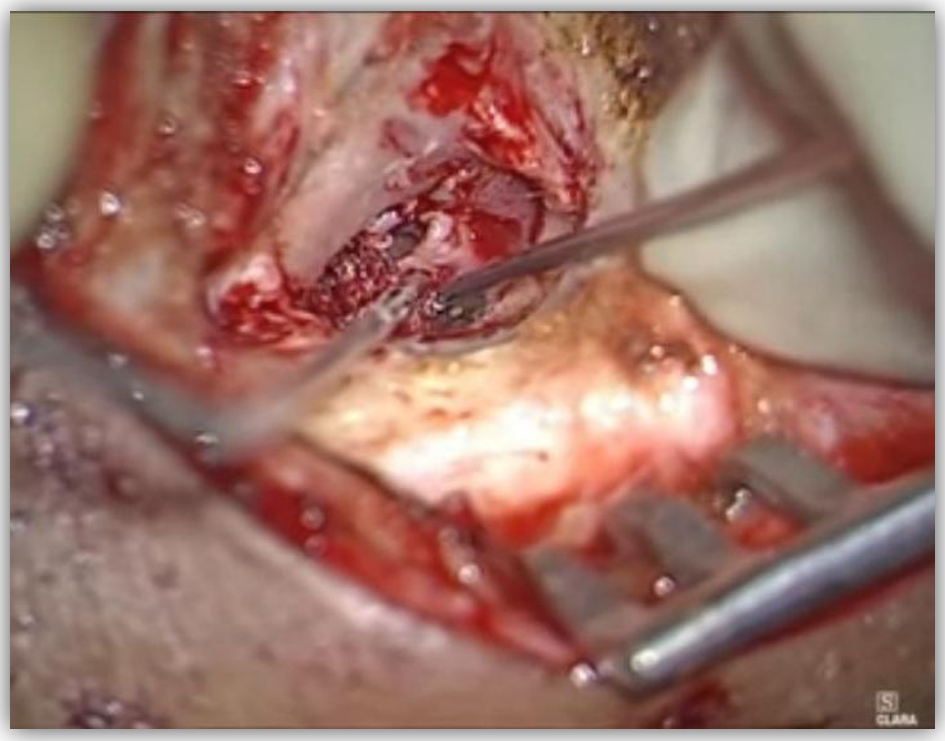
Preparation of Temporalis fascia



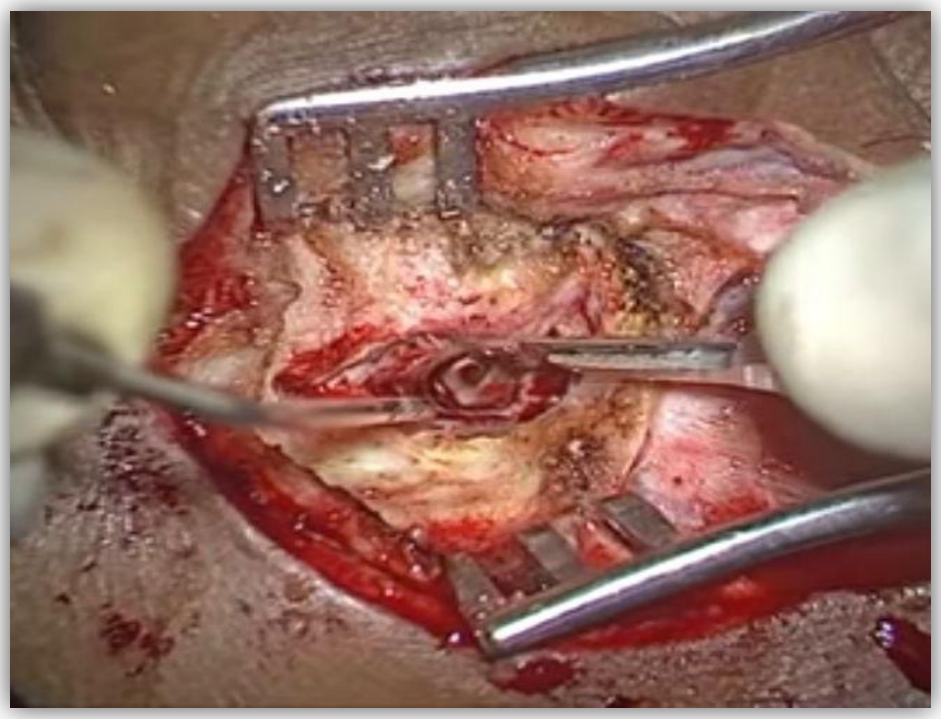
Posterior meatotomy



Tympanic membrane perforation margins freshened

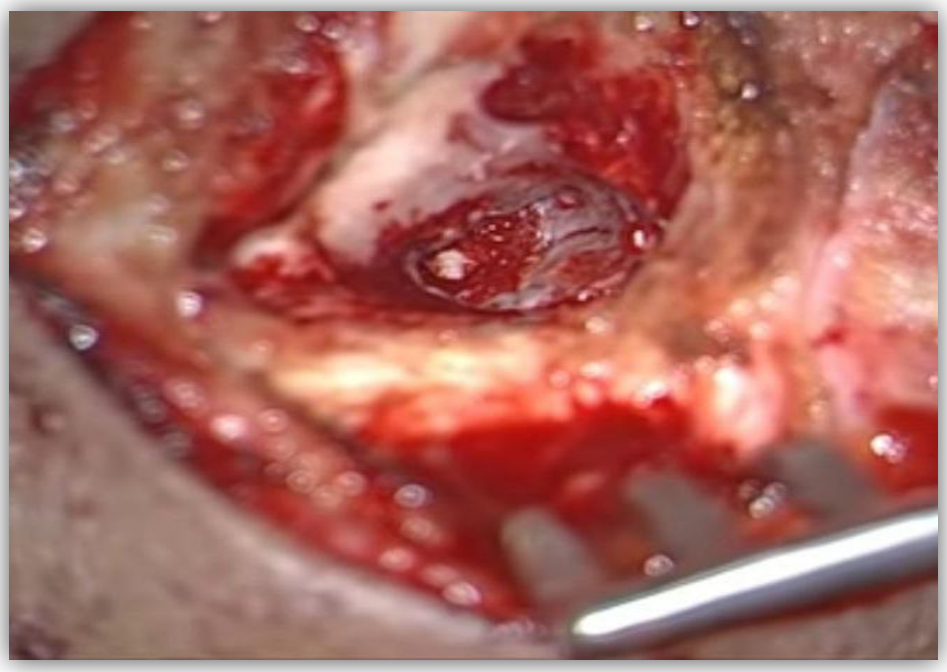


Tympano-meatal incision done from 12'o clock to 6'o clock



Tympano-meatal flap elevated

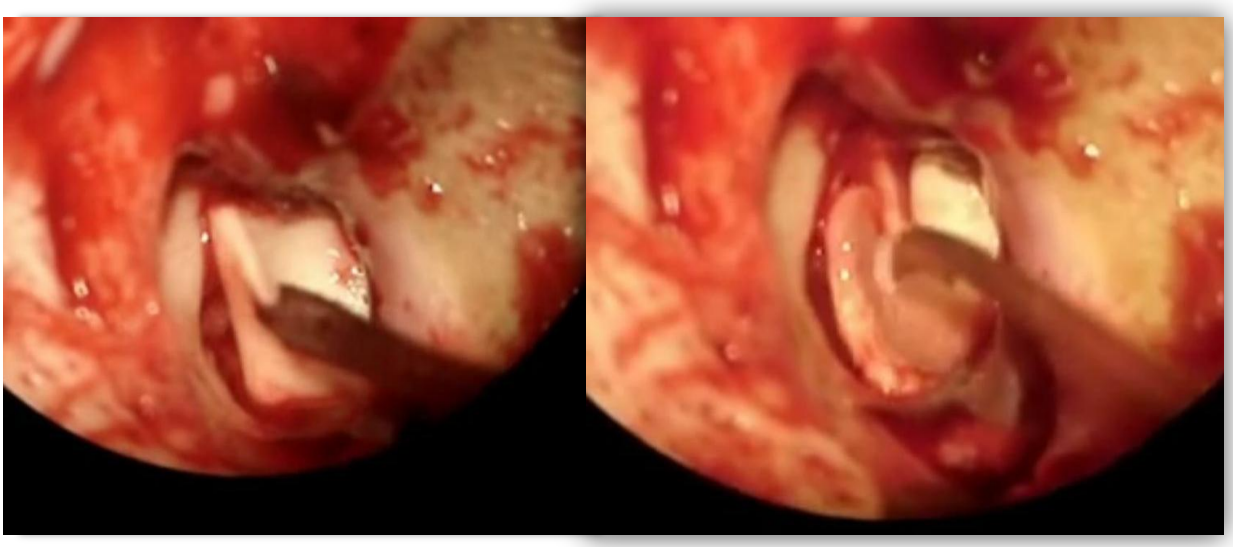
Temporalis fascia placed medial to tympanic annulus (after inspecting the ossicular continuity)



Tympano-meatal flap repositioned after placement of graft

Gel foams placed

Harvesting of conchal cartilage



Conchal cartilage placed in the middle ear & Positioning the cartilage graft in the media to tympanic annulus

Temporalis fascia positioned after placement of cartilage graft

Investigations done:

- **Routine blood investigations.**
- **X-Ray B/L mastoids**
- **Otoendoscopy/microscopic examination of ear**
- **Pure tone audiometry:**

  Before surgery (Pre-op) 1st PTA

  Post operatively in 6 weeks- 2nd PTA

  Post operatively in 12 weeks- 3rd PTA

  Post operatively in 24 weeks-4th PTA

- **HRCT temporal bone**
- **Post op monitoring:**

  Graft uptake after 8 weeks

  Improvement in hearing using Pure tone audiometry after 6weeks,12weeks and 24 weeks for air-bone (AB) Gap and improvement in decibels.

STATISTICAL ANALYSIS

The study data collected were initially entered to Microsoft Office Excel 2010 and later the spread sheets were exported to IBM SPSS (Statistical package for social sciences) version 22.0for all the sstatistical analysis.

1. **DESCRIPTIVE STATISTICS:**

   Descriptive statistics were calculated as frequency, percentage, mean and standard deviation, median and inter-quartile range. Descriptive data were represented using various tables, graphs, diagrams etc.

2. **INFERENTIAL STATISTICS:**

   For inferential statistics, various tests of significance were used according to the type of variables dealt with. For all the statistical tests of significance, p value of <0.05 was considered to reject the null hypothesis. Chi square test was used to compare the various categorical variables.

3. **TESTS FOR NORMALITY:**

   To determine whether the study data followed normal distributions or not, tests such as Shapiro–Wilk Test and Kolmogorov Smirnov Tests were used

4. **LEVEL OF SIGNIFICANCE USED:**

   Level of significance as given by the p value was fixed at<0.05 to reject the null hypothesis for all the statistical tests of significance.

RESULTS

Table 1 Age groups of all study subjects (n=50)

Age group	Frequency	Percent
<20 years	5	10.0
21 to 30 years	16	32.0
31 to 40 years	17	34.0
41 to 50 years	10	20.0
>50 years	2	4.0
Total	50	100.0

Mean: 33.9 years S.D: 9.3 years

Minimum age: 18 years Maximum: 52 years

Interpretation:

Majority of the study participants were in the age group of 31 to 40 years followed by 21 to 30 years.

Fig 1 Age groups of all study subjects (n=50)

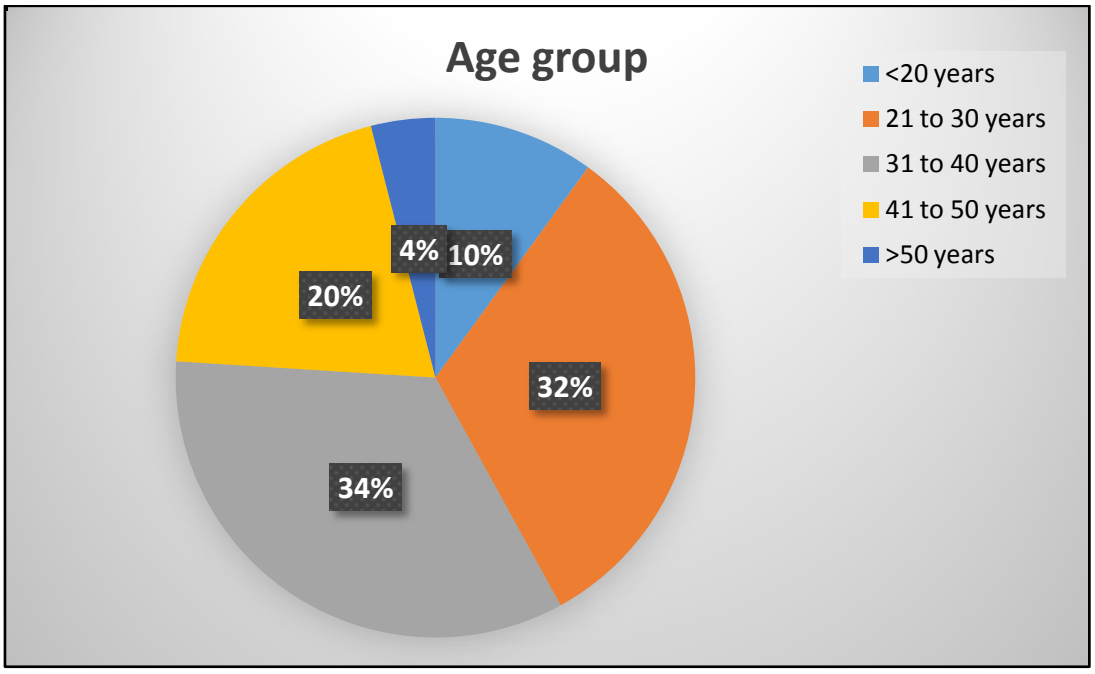


Table 2 Comparison of Age groups of 2 groups (n=50)

Age group	Group F N (%)	Group FC N (%)	Total N (%)
<20 years	4 (16)	1 (4)	5 (10)
21 to 30 years	7 (28)	9 (36)	16 (32)
31 to 40 years	9 (36)	8 (32)	17 (34)
41 to 50 years	4 (16)	6 (24)	10 (20)
>50 years	1 (4)	1 (4)	2 (4)
Total	25 (100)	25 (100)	50 (100)

Chi square value: 2.509 p value: 0.643

Interpretation:

There was no statistically significant difference between 2 groups with regards to distribution of age groups.

Fig 2 Comparison of Age groups of 2 groups (n=50)

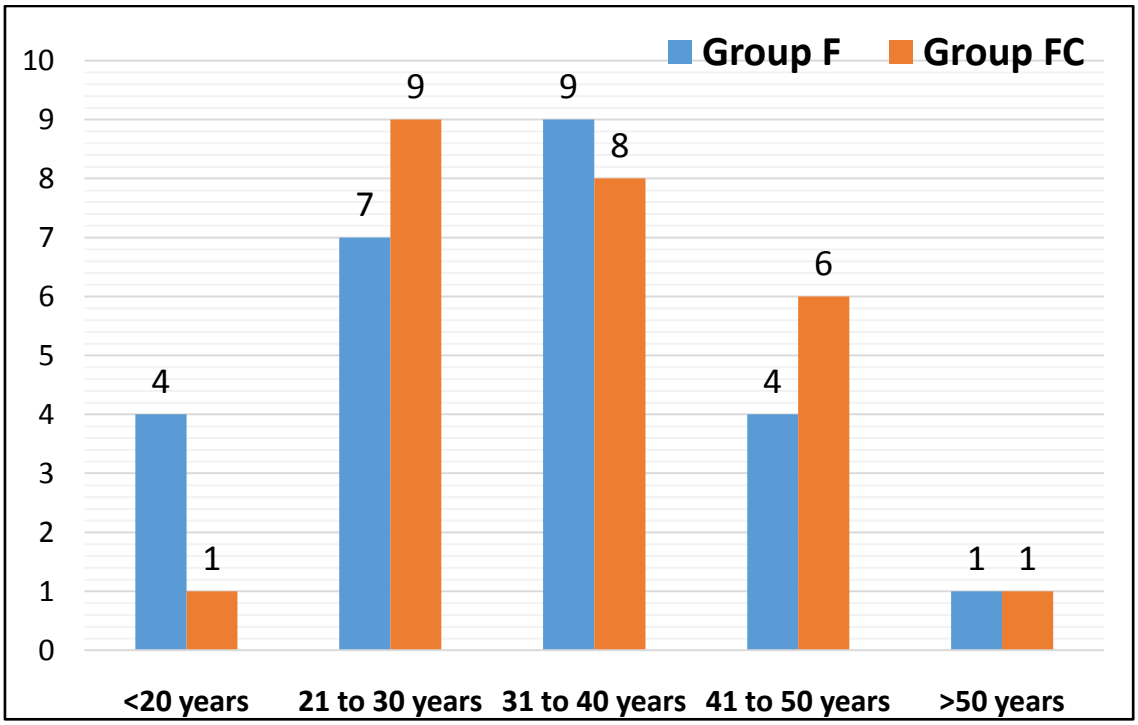


Table 3 Comparison of mean age of 2 groups (n=50)

Group	N	Mean age (years)	S.D	Mean difference	't' test p value
Fascia only	25	32.88	9.158	2.080	0.435
Cartilage + Fascia	25	34.96	9.533		

Interpretation:

There was no statistically significant difference between 2 groups with regards to mean age and hence both the groups were comparable.

Table 4 Comparison of gender of 2 groups (n=50)

Gender	**Group F N (%)**	**Group FC N (%)**	**Total N (%)**
Female	14 (56)	14 (56)	28 (56)
Male	11 (44)	11 (44)	22 (44)
Total	25 (100)	25 (100)	50 (100)

Chi-square value: 0.00 p value:1.000

Interpretation:

There was no statistically significant difference between 2 groups with regards to gender and hence both the groups were comparable.

Fig 3 Comparison of gender of 2 groups (n=50)

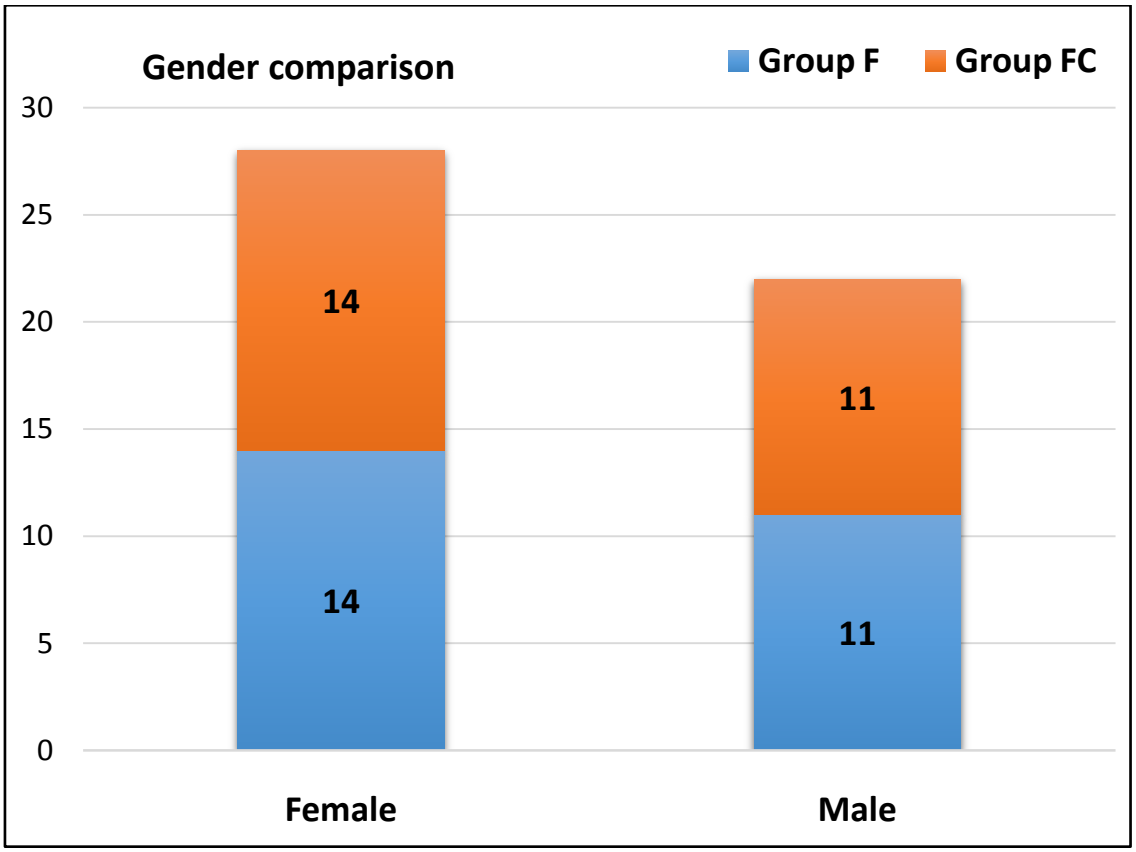


Table 5 Comparison of affected side of CSOM among the study groups (n=50)

Affected side	Group F N (%)	Group FC N (%)	Total N (%)
Left side	14 (56)	12 (48)	26 (52)
Right side	11 (44)	13 (52)	24 (48)
Total	25 (100)	25 (100)	50 (100)

Chi-square value: 0.321 p value: 0.571

Interpretation:

There was no statistically significant difference between 2 groups with regards to affected side as they were almost equally distributed.

Fig 4 Comparison of affected side of CSOM among the study groups (n=50)

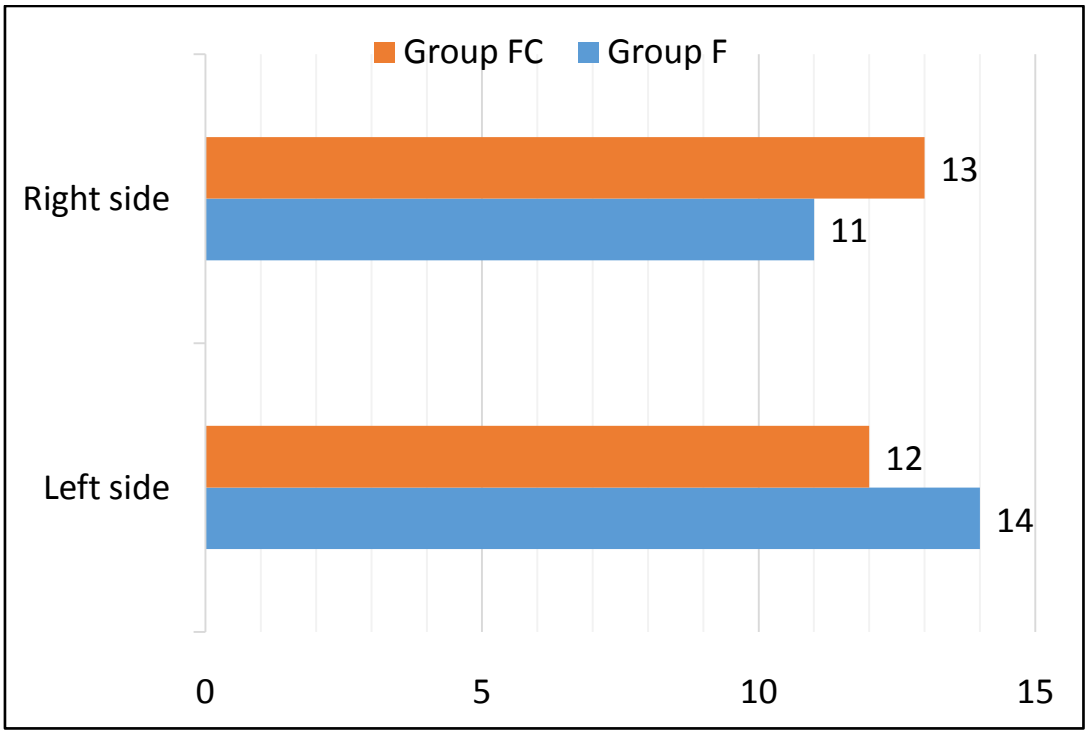


Table 6 Comparison of study groups according to size of the perforation (n=50)

Size of the perforation	Group F N (%)	Group FC N (%)	Total N (%)
Medium	10 (40)	9 (36)	19 (38)
Large	12 (48)	9 (36)	21 (42)
Subtotal	3 (12)	7 (28)	10 (20)
Total	25 (100)	25 (100)	50 (100)

Chi-square value: 2.081 p value:0.353

Interpretation:

There was no statistically significant difference between 2 groups with regards to size of the affected perforation.

Fig 5 Comparison of study groups according to size of the perforation (n=50)

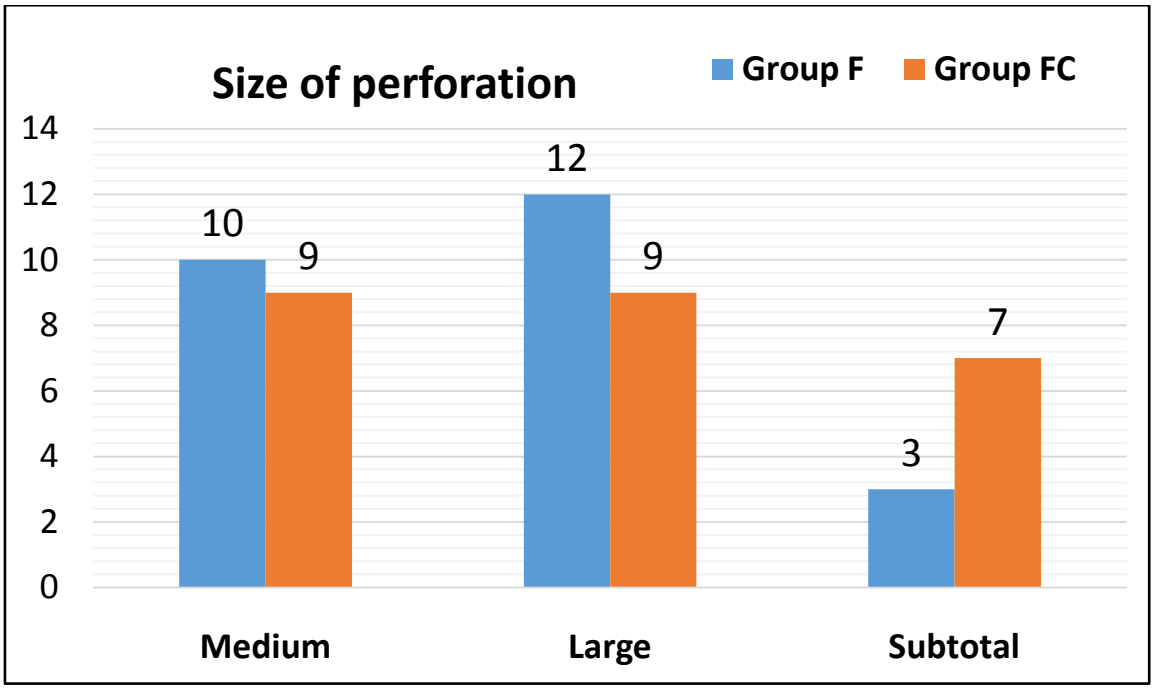


Table 7 Comparison of study groups according to graft uptake (n=50)

Graft uptake	Group F N (%)	Group FC N (%)	Total N (%)
Uptake	19 (76)	24 (96)	43 (86)
Failure	6 (24)	1 (4)	7 (14)
Total	25 (100)	25 (100)	50 (100)

Chi-square value: 4.153 p value: ***0.042***

Interpretation:

The graft failure rate was higher (24%) in fascia only group in comparison to subjects who received fascia and cartilage (4%) and this difference in graft uptake was statistically significant as p<0.05.

Fig 6 Comparison of study groups according to graft uptake (n=50)

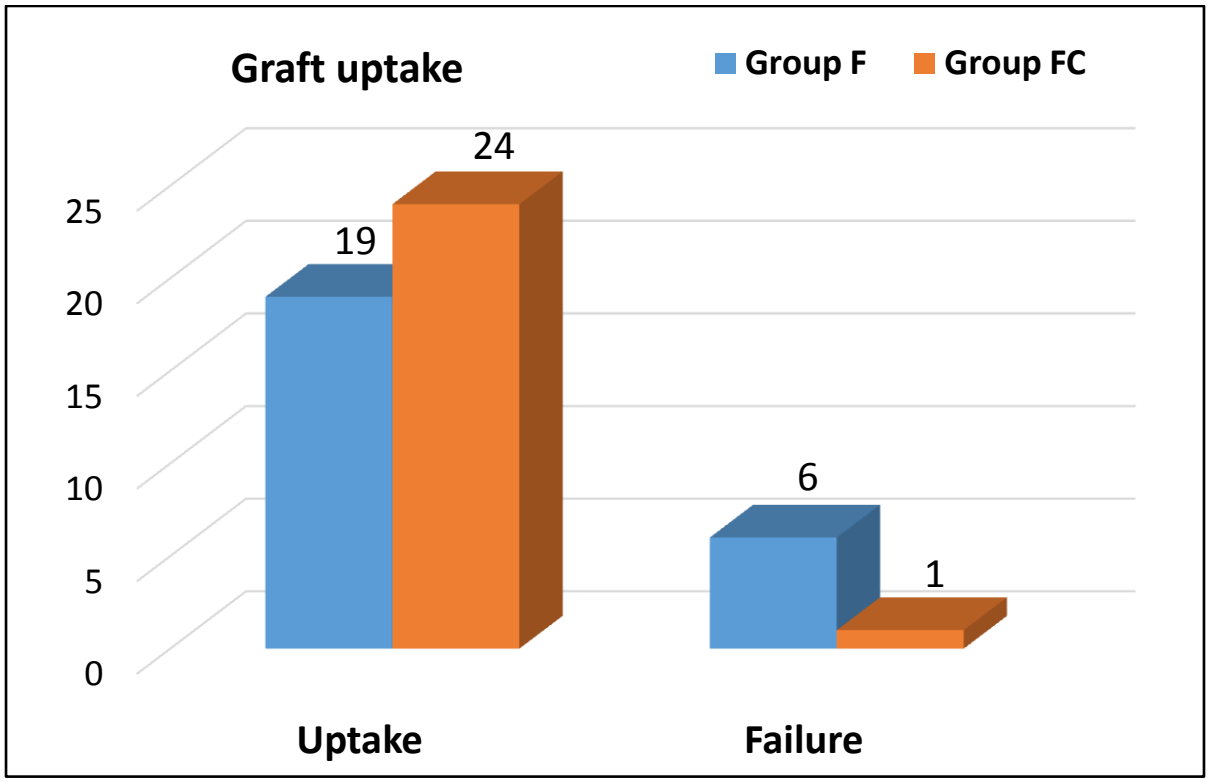


Table 8 Comparison of graft uptake according to size of the perforation in both the groups (n=50)

Size of the perforation	Group F		Group FC		Z test p value
	Uptake	Failure	Uptake	Failure	
Medium	10 (52.6)	0	9 (37.5)	0	0.322
Large	7 (36.8)	5 (83.3)	9 (37.5)	0	0.968
Subtotal	2 (10.5)	1 (16.7)	6 (25)	1 (100)	0.226
Total	19 (100)	6 (100)	24 (100)	1 (100)	

Interpretation:

Though the failure rate was higher among subjects with large and subtotal perforations in both the groups, there was no statistically significant association between the size of perforation and the graft uptake in both groups.

Fig 7 Comparison of graft uptake according to size of the perforation in both the groups (n=50)

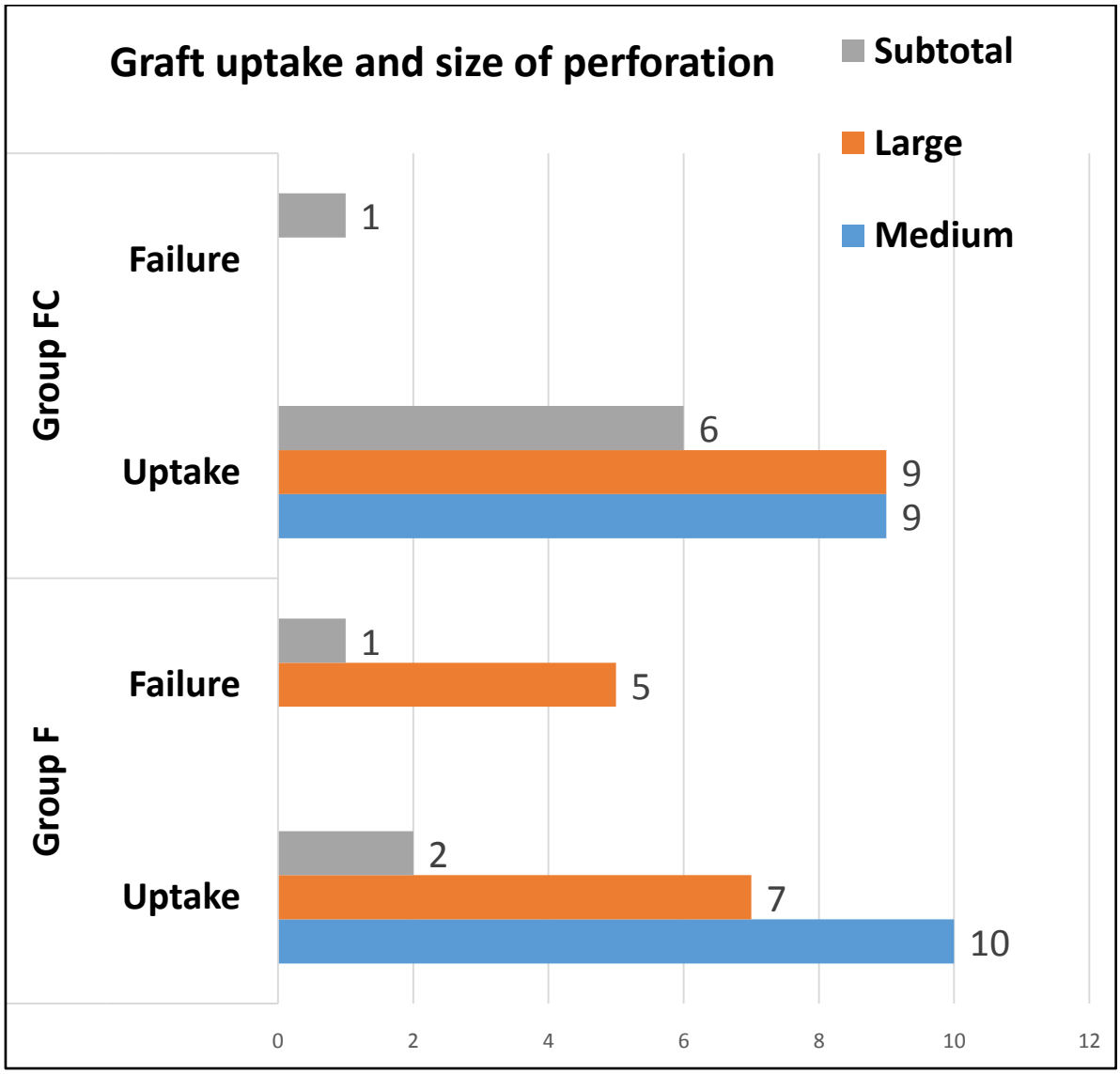


Table 9 Comparison of mean pre-operative pure tone audiometry (PTA) levels of 2 groups (n=50)

Group	N	Mean pre-operative PTA (dB)	S.D	Mean difference	't' test p value
Fascia only	25	38.9	6.14	0.801	0.649
Cartilage+Fascia	25	39.7	6.21		

Interpretation:

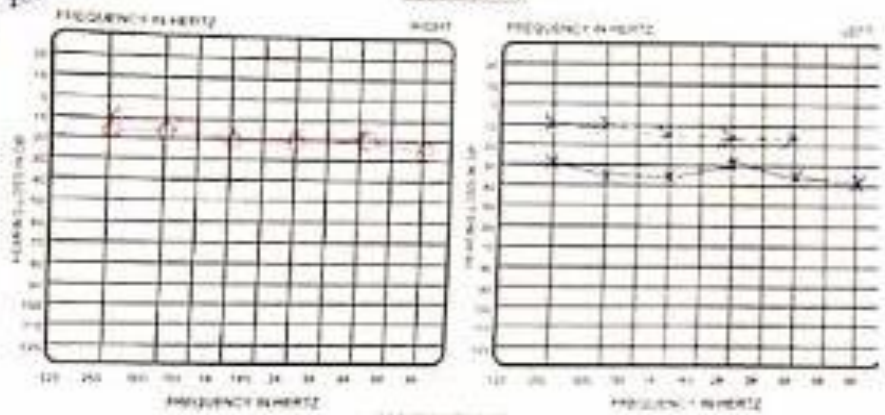
There was no statistically significant difference between 2 groups with regards to mean pre-operative pure tone audiometry (PTA) levels.

Doctor / Audiologist: J. SUBASHINI

Address: MANAGIRI, TRICHY

Tel No:

AUDIOGRAM



SYMBOL TABLE

Patient's Name: Sangeetha ID NO 25486

Age: 20yrs Date: Sex: F

Address:

Remarks: RE: Normal hearing Sensitivity

LE: mild Conductive hearing loss.

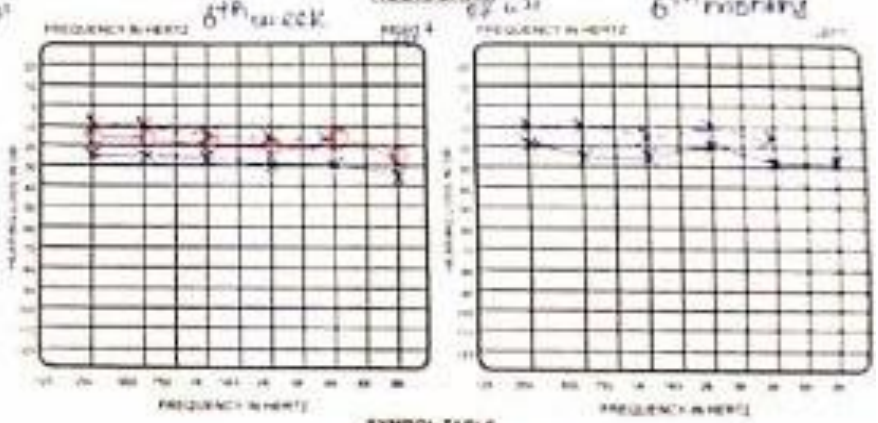
Audiologist

Doctor / Audiologist: J. SUBASHINI

Address: MANAGIRI, TRICHY

Tel No:

AUDIOGRAM 6th March 6th morning



SYMBOL TABLE

Patient's Name: Sangeetha ID NO: 25486

Age: 20yrs Sex: F

Address:

Remarks: RE: Normal hearing Sensitivity.

LE: Minimal hearing level.

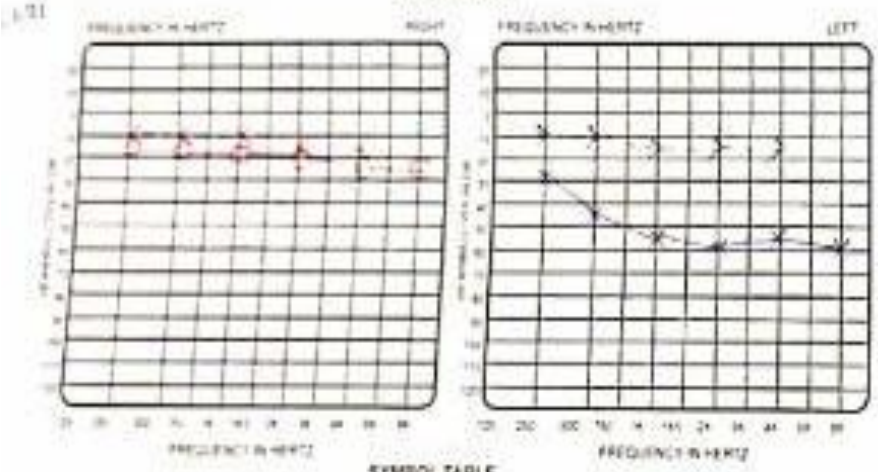
Audiologist

Doctor / Audiologist: SUBASHINI.J

Address: MANNARGUDI, TRICHY

Tel No:

AUDIOGRAM



SYMBOL TABLE

Patient's Name: Nanthakumar TP.NO 65724

Age: 28yrs Date: Sex: M

Address:

Remarks: RE: Normal hearing sensitivity.

LE: moderate conductive hearing loss

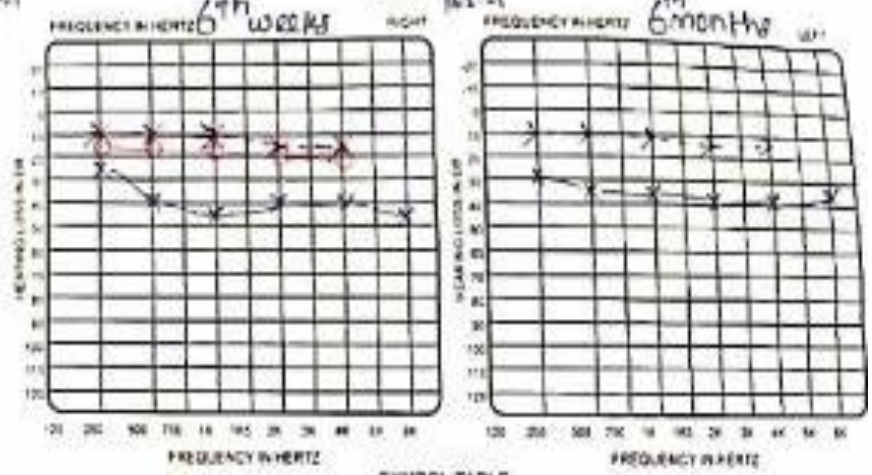
Audiologist

Doctor / Audiologist: SUBASHINI.J

Address: MANNARGUDI, TRICHY

Tel No:

AUDIOGRAM



SYMBOL TABLE

Patient's Name: Nanthakumar TP.NO: 65724

Age: 28yr Date: Sex: M

Address:

Remarks: RE: Normal hearing sensitivity

LE: Mild Conductive hearing loss

Audiologist

Table 10 Comparison of mean pure tone audiometry (PTA) levels of 2 groups in the post-operative period (n=50)

Post-operative PTA levels (dB)	Group F		Group FC		't' test p value
	Mean	S.D	Mean	S.D	
After 6 weeks	32.0	7.3	28.8	5.7	0.093
After 3 months	30.7	7.3	26.6	5.6	***0.033***
After 6 months	29.2	7.4	24.8	6.1	***0.029***

Interpretation:

- Though there was improvement in PTA levels after 6 weeks in both the groups, there was no statistically significant difference between the 2 groups as $p>0.05$.
- After 3 months: there was a statistically significant difference between the 2 groups with regards to PTA levels with subjects in 'FC' group having a lower PTA levels than subjects in 'F' group.
- After 6 months: there was a statistically significant difference between the 2 groups with regards to PTA levels with subjects in 'FC' group having a lower PTA level than subjects in 'F' group

Fig 8 Comparison of mean pure tone audiometry (PTA) levels of 2 groups (n=50)

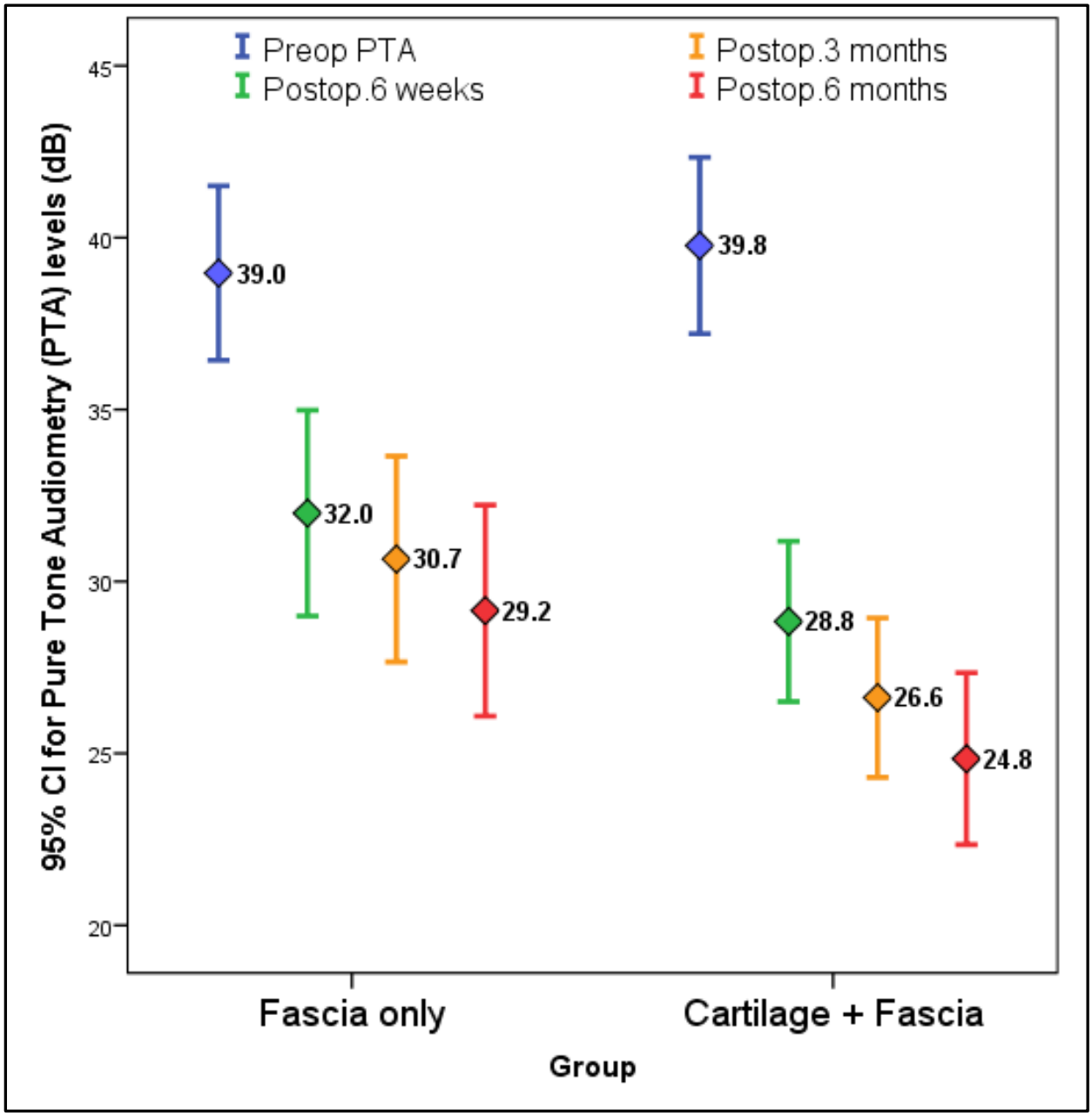


Table 11 Comparison of improvement in pure tone audiometry (PTA) levels of 2 groups in the post-operative period (n=50)

Improvement of PTA levels in post-operative period	Group F		Group FC		't' test p value
	Mean	S.D	Mean	S.D	
After 6 weeks	7.0	3.4	10.9	3.2	***<0.001***
After 3 months	8.3	3.8	13.2	3.6	***<0.001***
After 6 months	9.8	4.4	14.9	3.4	***<0.001***

Interpretation:

- There was a statistically significant improvement in PTA levels after 6 weeks in both the groups, as $p<0.05$.
- After 3 months: there was a statistically significant improvement in PTA levels in both groups when compared to pre-operative levels.
- After 6 months: there was a statistically significant improvement in PTA levels in both groups when compared to pre-operative levels.

Fig 9 Comparison of improvement in pure tone audiometry (PTA) levels of 2 groups in the post-operative period (n=50)

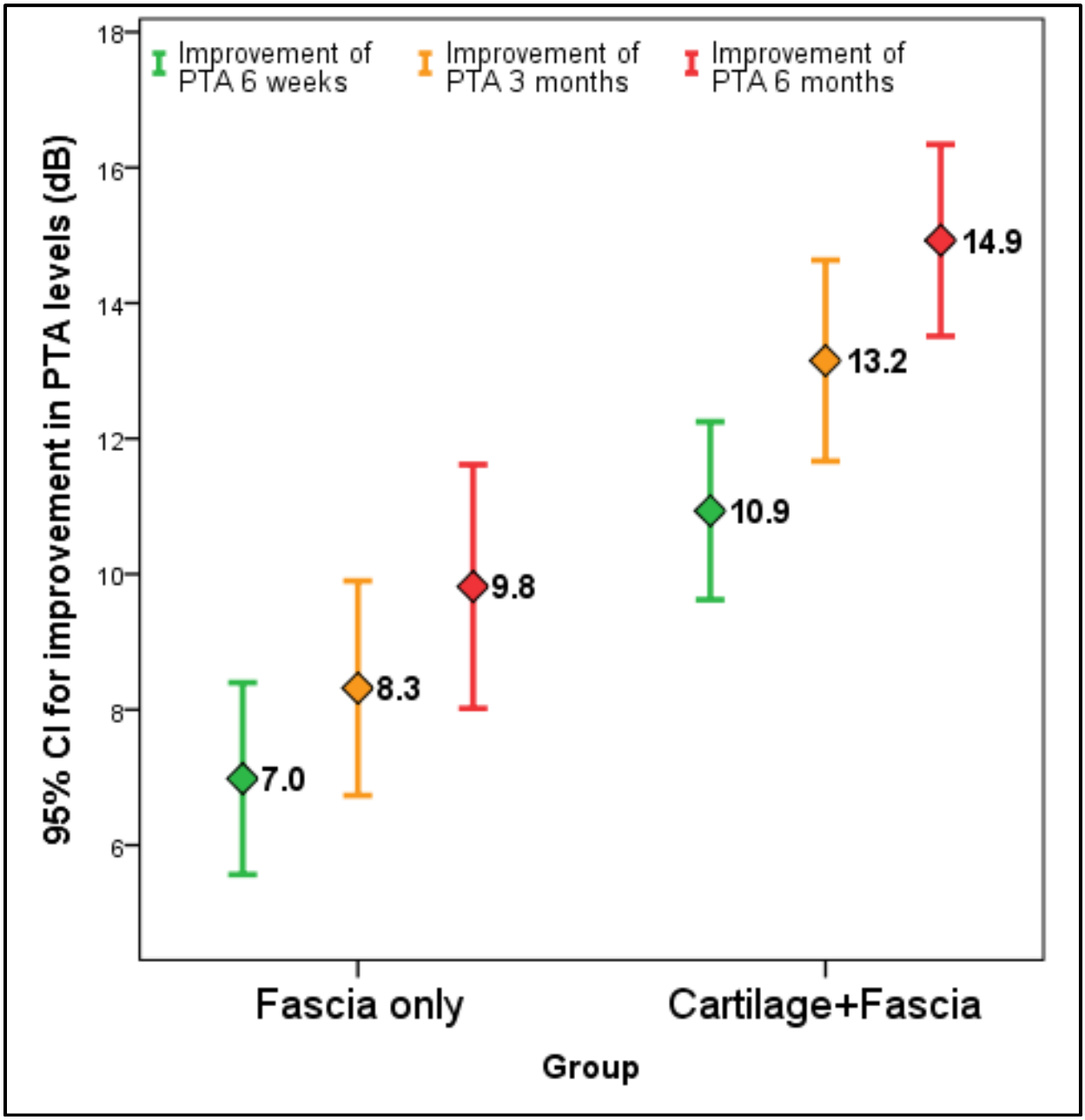


Table 12 Comparison of mean air bone gap (ABG) levels of 2 groups in the pre- and post-operative period (n=50)

mean air bone gap (ABG) (dB)	Group F		Group FC		't' test p value
	Mean	S.D	Mean	S.D	
Pre-operative ABG	25.2	3.0	26.8	3.1	0.071
Post-operative after 6 months	15.8	2.8	13.5	1.6	***<0.001***

Interpretation:

- There was no statistically significant difference in pre-operative mean air bone gap between the 2 groups as $p>0.05$.
- After 6 months of post-operative period: There was a statistically significant difference between the 2 groups with regards to air-bone gap levels with subjects in 'FC' group having a lower ABG levels than subjects in 'F' group. Though there was improvement in ABG levels in both the groups, subjects in 'FC' group had a higher fall in ABG levels when compared to subjects in 'F' group.

Fig 10 Comparison of mean air bone gap (ABG) levels of 2 groups in the pre- and post-operative period (n=50)

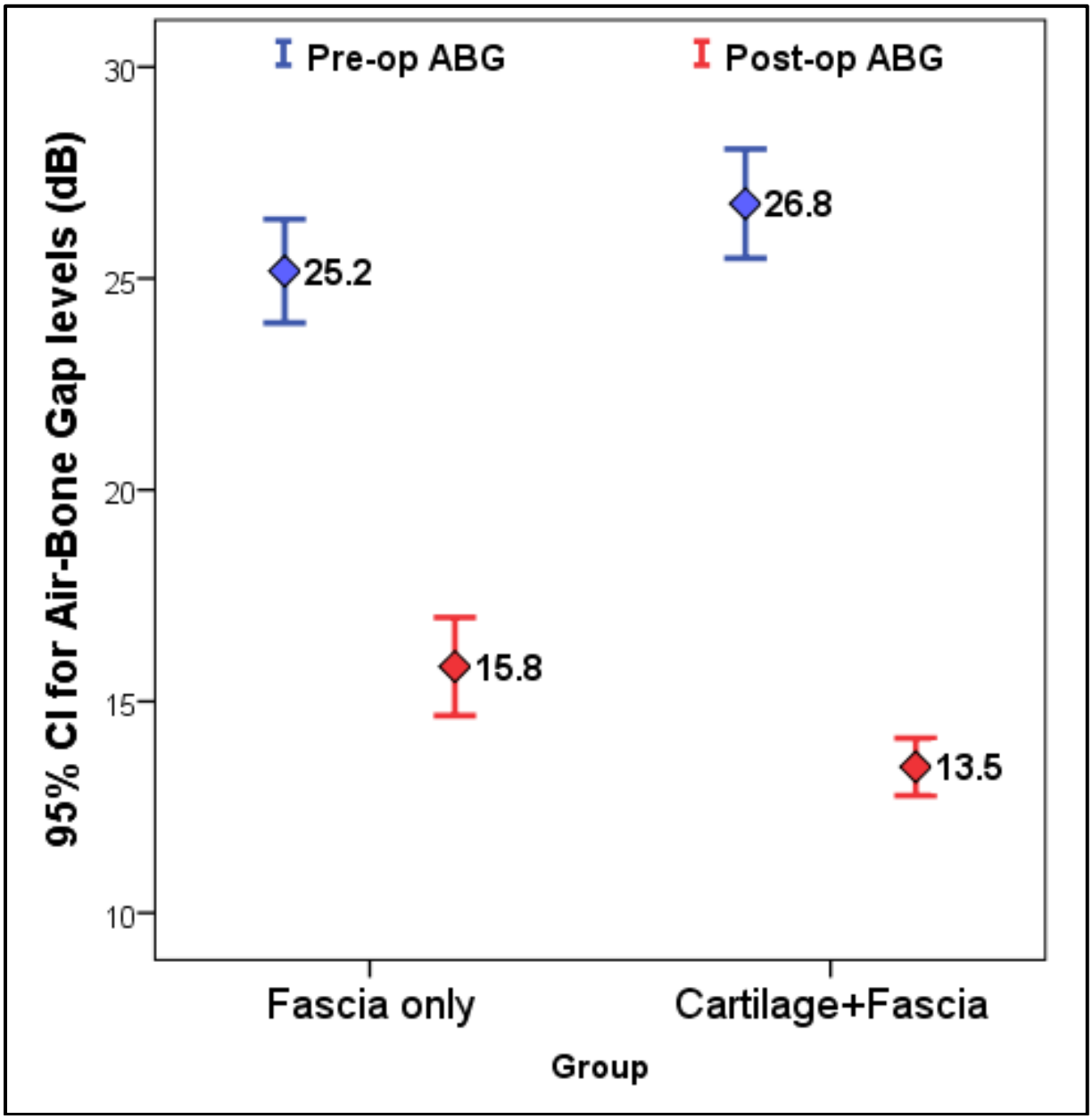


Table 13 Comparison of improvement in mean air bone gap (ABG) levels between 2 groups (n=50)

Mean air bone gap (ABG) (dB)	Group F		Group FC		't' test p value
	Mean	S.D	Mean	S.D	
Improvement in ABG levels after 6 months of post-operative period	9.4	2.2	13.3	2.8	***<0.001***

Interpretation:

- After 6 months of post-operative period: There was a statistically significant difference between the 2 groups with regards to improvement in air-bone gap levels with subjects in 'FC' group having a higher improvement in ABG levels than subjects in 'F' group.

Table 14 Comparison of mean air bone gap (ABG) levels between 2 groups according to size of perforation (n=50)

Perforation size	Air-Bone Gap (ABG)	Group				't' test p value
		Fascia only		Cartilage + Fascia		
		Mean	S.D	Mean	S.D	
Medium	Pre-op	22.3	1.1	23.9	2.6	0.091
	Post-op	13.6	1.7	12.3	0.7	**0.047**
	Improvement	8.7	2.2	11.6	3.0	**0.026**
Large	Pre-op	26.2	1.2	27.0	1.0	0.099
	Post-op	16.5	1.7	13.9	0.9	**0.001**
	Improvement	9.8	2.4	13.2	1.2	**0.001**
Subtotal	Pre-op	30.5	1.9	30.1	2.1	0.767
	Post-op	20.7	1.9	14.4	2.4	**0.004**
	Improvement	9.8	.6	15.7	2.6	**0.006**

Interpretation:

After 6 months of post-operative period, there was a statistically significant difference between the 2 groups with regards to improvement in air-bone gap levels among irrespective of the size of perforation with subjects in 'FC' group having a higher improvement in ABG levels than subjects in 'F' group and subjects with large and subtotal perforations showing higher improvement than subjects with medium size perforations.

DISCUSSION

GENERAL CONSIDERATIONS

The result of the present study describes the distribution of various factors like age, gender, clinical signs and symptoms, size of perforation, side of perforation, type of surgery done etc. of the study participants. The study also explains the outcomes of the surgeries such as graft uptake or graft success rate and hearing improvement.

COMPARISION OF GRAFTS

The current study compares the two methods of Tympanoplasty grafts: temporalis fascia graft alone and Conchal cartilage supported with Temporalis fascia graft in terms of Graft success rate and improvement in hearing (Air Bone Gap) using Pure tone audiometry. This similar comparision was applied in other studies like Bhardwaj et al, Dayanand et al, Gosavi et al and Fernandes et al. Another type of comparision of Temporalis fascia with Tragal cartilage with perichondrium was done in studies like Cayir et al, Dabholkar et al, Gondela et al and Mohanty et al. In another study by Murugendrappa et al, comparision was made between circumferential subannular grafting technique and conventional underlay technique.

In Nemale et al, comparision was made between tympanoplasty with modified sandwich graft (mediolateral double layer graft) ie tympanoplasty using temporalis fascia and areolar fascia and tympanoplasty with underlay cartilage technique.

AGE OF STUDY PARTICIPANTS

In the current study, majority of the study participants 34% belonged to age group of 31- 40 years of age followed by 32% under 21-30 years of age. The mean age of study participants was 33.9 years with the range between 18 – 52 years of age. There was no difference between two study groups with respect to age and hence their major differentiating study variable was easily comparable.

The study by Cayir et al was conducted among 8 – 18 years of age; Dabholkar et al conducted the same study among 13 – 56 years of age; Dayanand et al conducted the similar study among 20-60 years of age. Gondela et al conducted study among participants of 16 – 50 years of age. Gosavi et al, et al conducted study among participants of 16 – 50 years of age.

GENDER:

In the current study, 56% of study participants were females followed by males of 44% respectively. Similar results were seen in Fernandes et al (M – 43%, F – 57%), Gosavi et al (M – 41%, F – 59%) and Murugendrappa et al (M – 42%, F – 58%) where females were higher than males as study participants.

In contrast male patients were higher in studies by Cayir et al (M – 55%, F – 45%) and Dabholkar et al (M – 66%, F – 34%) respectively.

CSOM:

In the current study with regards to affected side of CSOM, 52% were of Left side and 48% of Right sided ears affected by CSOM. According to size of perforation, the current study revealed that large perforation was seen in 42% of patients followed by 38% in medium size and 20% in total perforation. Dayanand et al, majority of perforations were of small type (39%) followed by medium (34.67%) and then large type (30.66%) respectively.

GRAFT UPTAKE:

In the current study the graft uptake or graft success percentage was 86% and graft failure was 14 % respectively. The graft success rate was subsequently higher among patients in Conchal cartilage supported with Temporalis fascia graft than the Temporalis fascia graft alone. In Cayir et al study, the graft success rate was 83.3% overall. The graft success rate was significantly higher 95.2% for the perichondrium group compared with 71.4% for the fascia group. The results of graft take with temporalis fascia and tragal perichondrium were 84% and 80% respectively in study by Dabholkar et al. In Gondela et al study, the first group who were grafted with tragal perichondrium, the successful graft uptake was 86.6% and in the second group who were grafted with temporalis fascia graft showed 83.33% of graft uptake. In Gosavi et al, the graft uptake was 94% in group of patients who were grafted with a reinforced temporalis fascia

while in the other group the graft uptake was 86% in those patients who received exclusively with temporalis fascia.

In Mohanty et al study, the results revealed that cartilage group had 91.95% success rate while fascia group had 79%. In Murugendrappa et al study, the success rate of graft uptake by circumferential subannular graft technique was 96% and by conventional underlay technique was 76% respectively. In Nemade et al, successful graft intake was accomplished in 97.9% in Group A, 83.3% in Group B and 95.8% in Group C respectively.

PURE TONE AUDIOMETRY FINDINGS

In the current study, the mean pre-operative pure tone audiometry levels were 38.9 for Fascia only group and 39.7 for Cartilage plus fascia group repectively. The mean post-operative pure tone audiometry levels after 6 weeks, 3 months and 6 months were 32.0, 30.7 and 29.2 respectively for fascia only group and 28.8, 26.6 and 24.8 Cartilage plus fascia group respectively. Though there was improvement in PTA levels after 6 weeks in both the groups, there was no statistically significant difference between the 2 groups as $p>0.05$. After 3 months and 6 months there was a statistically significant difference between the 2 groups with regards to PTA levels with subjects in 'FC' group having a lower PTA level than subjects in 'F' group. There was a statistically significant improvement in PTA levels after 6 weeks, 3 months and 6 months in both the groups, when compared to pre-operative PTA levels as $p<0.05$.

In Bhardwaj et al study, The ABG closure at 2 months postoperatively was 11.55 and 10.49 for conchal perichondrium group and temporalis fascia group respectively. The ABG closure at 6 months postoperatively was 14.98 and 11.41 for conchal perichondrium group and temporalis fascia group respectively.

In Cayir et al, the post-operative ABG < 20 dB in perichondrium group was 90.4% and 85.7% in the fascia group respectively. In Dabholkar et al study, Temporalis fascia achieved a satisfactory hearing improvement in 76% of patients while tragal perichondrium achieved 75% hearing gain.

In Dayanand et al study, postoperatively the study revealed that the mean hearing improvement in group A with temporalis fascia graft was 12.98 dB (better) whereas the mean hearing improvement in group B with temporalis fascia and conchal cartilage graft was 8.96 dB. In Fernandes et al study, after 8 weeks of postoperative period, the graft uptake was assessed. The average hearing improvement in group 1 and group 2 was 7 dB and 15 dB respectively.

In Gondela et al study, In first group who were grafted with tragal perichondrium, hearing improvement < 10 dB was 83.33%. In the second group who were grafted with temporalis fascia graft, the hearing improvement < 10dB was 80%.

In Gosavi et al study, the mean air bone gap in patients of reinforced temporalis fascia with conchal cartilage was 9.72 dB whereas the mean air bone gap in patients of temporalis fascia alone was 9.70dB respectively. In Mohanty

et al study, the mean improvements in ABG (Air Bone Gap) for both groups were 17.52 dB and 15.26 dB respectively. ABG closure ratios for both the groups were 62.84 and 53.6 respectively. The study concluded that the CCPI graft was an effective technique in managing perforations of anterior quadrant.

In Murugendrappa et al study, the mean difference in PTA (dB) Pure Tone Average Threshold was 11.05 and 7.96 in circumferential subannular graft technique and conventional underlay technique respectively. In Nemade et al study, the average air bone gap closure achieved in Group A, Group B and Group C were 24.4dB, 22.5dB and 19.8dB respectively. The study concluded that modified sandwich graft maintained a perfect balance between sufficient stability and adequate acoustic sensitivity.

CONCLUSION

Although both temporalis fascia graft alone and cartilage supported with temporalis fascia graft are good options for closure of tympanic membrane perforation by providing good hearing improvement and graft uptake, based on the present study findings, we conclude that the cartilage with fascia graft is superior with respect to graft uptake rate and post-operative improvement in hearing when compared to temporalis fascia graft alone.

This study also emphasizes on the fact that the repair of tympanic membrane should be decided on size of the perforation and type of graft material to be used. Hence the study advocates the use of cartilage graft in combination with temporalis fascia over temporalis fascia graft alone especially for large and subtotal perforations.

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ANNEXURE I

STUDY PROFORMA

PATIENT NAME: **Unique ID:**

Group: F / FC

Age:

Gender:

Ip.no.

Address

Contact no.

Date of admission:

Presenting complaints:

Affected side-

Duration of symptoms:

Size of TM perforation:

Tuning fork test results:

Rinne’s test:

Weber’s test:

Absolute bone conduction test:

Comorbidities is any:

History of ear surgery:

Type of hearing loss:

Complications if any:

INVESTIGATIONS:

Routine blood investigations

X-ray B/L mastoids:

Microscopic examination of ear:

HRCT findings:

Pure tone audiometry (PTA):

Before surgery (Pre-op) 1st PTA:

Post operatively in 6 weeks- 2nd PTA:

Post operatively in 12 weeks- 3rd PTA:

Post operatively in 24 weeks-4th PTA:

Pre-op ABG:

Post-op ABG:

Graft uptake after 8 weeks:

Improvement in PTA after surgery:

Improvement in ABG after surgery:

ANNEXURE II

PATIENT INFORMATION SHEET

TITLE OF THE STUDY:

A COMPARATIVE STUDY TO EVALUATE TEMPORALIS FASCIA GRAFT VERSUS FASCIA WITH CARTILAGE GRAFT IN TYPE I TYMPANOPLASTY

Aim of the study:

To compare the surgical outcomes of Type 1 Tympanoplasty using temporalis fascia alone and using conchal cartilage support along with temporalis fascia graft for patients with mucosal type of chronic otitis media.

Objectives:

1. To compare the graft uptake in patients using temporalis fascia alone and using conchal cartilage support along with temporalis fascia graft.
2. To compare the improvement in conductive hearing loss, using temporalis fascia alone and using conchal cartilage support along with temporalis fascia graft.

Study Procedure:

This study compares the hearing outcomes of temporalis fascia graft alone and fascia with cartilage graft in Type I Tympanoplasty for mucosal type of chronic otitis media. On the day of surgery you will be shifted to the operating room and standard monitors will be connected. You will be randomised into a group among the two by simple randomization method to get operated with either temporalis fascia graft alone and fascia with cartilage graft. Your baseline clinical information and audiogram results will be recorded. You will be induced with either general anesthesia or local anesthesia. The appropriate surgical procedure will be completed and then maintenance and recovery of anaesthesia will be carried out as per routine protocol. The Graft uptake, Hearing improvement in PTA will be recorded.

Your rights in the study:

Your medical records will be maintained confidential. The results of the study may be published in journals, but will not disclose the identity of the participants. Your participation in this study is voluntary and not under any compulsion and you are free to withdraw from the study without giving any reasons, without affecting the medical care which will be provided to you normally. If in case any complication arises, you will be adequately taken care of by the medical crew.

Signature/thumb impression of the patient

Date:

Place: Tiruchirappalli Signature of the investigator

ANNEXURE III

PATIENT CONSENT FORM

Title of the study "A COMPARATIVE STUDY TO EVALUATE TEMPORALIS FASCIA GRAFT VERSUS FASCIA WITH CARTILAGE GRAFT IN TYPE 1 TYMPANOPLASTY"

Study Centre: Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli.

Patient's name: **Age/Sex:**
Parent/Guardian's Name:
Address:

- The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions about the assessment and the techniques to be administered to me.
- I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without affecting the medical care that will normally be provided by the hospital.
- I understand that the doctor involved in the study does not require my permission to monitor me and assess for various medical parameters
- I agree not to restrict the use of any data or results that arise from this study, provided such a use is only for scientific purpose(s).
- I understand that if in case any complication arises, I will be adequately taken care of by the medical crew.

Signature/Thumb impression of the patient:

Date:
Place: Trichy Signature of the investigator:

நோயாளியின் தகவல் அறிக்கை

ஆய்வின் தலைப்பு :

ஆய்வின் நோக்கம் :

ஆய்வு முறை :

ஆய்வில் உங்களது உரிமை உங்களது மருத்துவ சோதனைகள் இரகசியமாக வைக்கப்படும். சோதனையின் முடிவுகள் பத்திரிக்கையில் வெளியிடப்படும். ஆனால் யார் கலந்து கொண்டார் என்பது வெளியிடப்படாது. இந்த ஆய்வில் யாருடைய வற்புறுத்தலும் இல்லாமலும், நீங்களாகவே முன்வந்து கலந்து கொள்ளலாம். இந்த ஆய்வில் இருந்து எப்போது வேண்டுமானாலும், எந்தகாரணம் சொல்லாமலும் நீங்கள் விலகிக் கொள்ளலாம். இதனால் உங்களுக்கு எப்போதும் கொடுக்கப்படும் சிகிச்சையில் எந்த பாதிப்பும் இருக்காது. இந்த ஆய்வில் ஏதேனும் விளைவுகள் ஏற்பட்டால் எங்களது மருத்துவகுழுவினரால் நீங்கள் பராமரிக்கப்படுவீர்கள்.

நாள்:

நோயாளியின் கையொப்பம்

ANNEXURE IV
MASTER CHART

MASTER CHART																		
S.NO	NAME	IP.NO	Group	AGE	Agegroup	Gender	DIAGNOSIS	Perforation.size	Grad.Uptake	Preop PTA	Postop.PTA.6w	Postop.PTA.3m	Postop.PTA.6m	Improve.6w	Improve.3m	Improve.6m	Pre.op.ABG	Post.op.ABG	Improvement.ABG
1	SANGEETHA	25486	Fascia only	20	<20 years	Female	Left	Medium	Uptake	34.8	26.8	24.8	22.8	8.0	10.0	12.0	22.4	11.6	10.8
2	RAJI	68554	Fascia only	39	31 to 40 years	Female	Left	Large	Uptake	39.0	31	29	27	8.0	10.0	12.0	25.2	15.2	10.0
3	MANI	25484	Fascia only	27	21 to 30 years	Male	Right	Subtotal	Uptake	52.7	40.7	38.7	36.7	12.0	14.0	16.0	32.5	22.3	10.2
4	PALANIYAMMAL	29847	Fascia only	51	>50 years	Female	Right	Large	Failure	38.6	38.5	38	38	0.1	0.6	0.6	24.7	18.0	6.7
5	PRIYAKA	78638	Fascia only	26	21 to 30 years	Female	Right	Medium	Uptake	30.2	20.2	18.2	16.2	10.0	12.0	14.0	21.0	14.2	6.8
6	PRAVIN	25788	Fascia only	18	<20 years	Male	Left	Medium	Uptake	32.4	22.4	20.4	20.4	10.0	12.0	12.0	24.2	10.4	13.8
7	SUTHA	48657	Fascia only	30	21 to 30 years	Female	Left	Medium	Uptake	35.1	27.1	25.1	23.1	8.0	10.0	12.0	23.2	14.3	8.9
8	RANGASAMY	48657	Fascia only	42	41 to 50 years	Male	Right	Large	Failure	36.3	29.3	29.3	29.3	7.0	7.0	7.0	25.4	20.2	5.2
9	SWETHA	58697	Fascia only	18	<20 years	Female	Left	Medium	Uptake	29.8	19.8	19.8	17.8	10.0	10.0	12.0	23.2	16.2	7.0
10	MURUGESAN	89634	Fascia only	40	31 to 40 years	Male	Right	Large	Failure	38.5	38.5	38.2	37	0.0	0.3	1.5	26.4	17.2	9.2
11	MAHALAKSHMI	57893	Fascia only	37	31 to 40 years	Female	Left	Large	Uptake	42.6	34.6	32.6	30.6	8.0	10.0	12.0	27.2	14.5	12.7
12	MANIKANDAN	548312	Fascia only	48	41 to 50 years	Male	Left	Large	Failure	37.7	37.5	36.9	36.7	0.2	0.8	1.0	25.5	18.2	7.3
13	RANI	28763	Fascia only	29	21 to 30 years	Female	Right	Medium	Uptake	34.0	26	24	22	8.0	10.0	12.0	21.6	13.2	8.4
14	SURESH	48657	Fascia only	41	41 to 50 years	Male	Right	Large	Failure	45.4	44.6	43.6	43.2	0.8	1.8	2.2	27.2	16.0	11.2
15	LAKSHMI	39875	Fascia only	22	21 to 30 years	Female	Left	Large	Uptake	47.1	38.1	36.1	34.1	9.0	11.0	13.0	26.8	15.0	11.8
16	RANI	69832	Fascia only	40	31 to 40 years	Female	Left	Medium	Uptake	34.9	26.9	26.9	26.9	8.0	8.0	8.0	22.9	15.0	7.9
17	AJITH	98243	Fascia only	20	<20 years	Male	Right	Medium	Uptake	44.5	36.5	34.5	32.5	8.0	10.0	12.0	20.4	13.4	7.0
18	SARANYA	54731	Fascia only	32	31 to 40 years	Female	Right	Large	Uptake	41.0	33	33	31	8.0	8.0	10.0	25.2	16.3	8.9
19	MARIMUTHU	35784	Fascia only	30	21 to 30 years	Male	Left	Large	Uptake	35.1	27.1	25.1	23.1	8.0	10.0	12.0	25.1	15.2	9.9
20	NANTHAKUMAR	65724	Fascia only	28	21 to 30 years	Male	Left	Subtotal	Uptake	50.8	41.8	39.8	37.8	9.0	11.0	13.0	28.8	18.6	10.2
21	KANIMOZHI	36587	Fascia only	41	41 to 50 years	Female	Left	Large	Uptake	44.6	36.6	34.6	32.6	8.0	10.0	12.0	28.0	17.0	11.0
22	LOGESH	87563	Fascia only	38	31 to 40 years	Male	Right	Large	Uptake	38.1	31.1	29.1	27.1	7.0	9.0	11.0	27.8	14.6	13.2
23	SATISH	68572	Fascia only	33	31 to 40 years	Male	Right	Medium	Uptake	36.4	29.4	27.4	25.4	7.0	9.0	11.0	21.9	14.8	7.1
24	HARIPRIYA	68754	Fascia only	34	31 to 40 years	Female	Left	Medium	Uptake	31.2	21.2	21.2	19.2	10.0	10.0	12.0	22.6	13.1	9.5
25	SEETHA	65482	Fascia only	38	31 to 40 years	Female	Left	Subtotal	Failure	43.3	41	40	38.3	2.3	3.3	5.0	30.2	21.1	9.1
26	CHINNASAMY	78956	Cartilage+Fascia	23	21 to 30 years	Male	Right	Large	Uptake	36.1	25.6	22.1	20.1	10.5	14.0	16.0	28.1	14.2	13.9

27	RAJALAKSHMI	95842	Cartilage+Fascia	46	41 to 50 years	Female	Left	Medium	Uptake	29.2	21.6	18.2	15.1	7.6	11.0	14.1	26.7	11.9	14.8
28	RATHIGA	25873	Cartilage+Fascia	30	21 to 30 years	Female	Left	Large	Uptake	47.5	34.5	34.5	32.4	13.0	13.0	15.1	25.5	13.8	11.7
29	VENGAT	36971	Cartilage+Fascia	34	31 to 40 years	Male	Right	Large	Uptake	37.9	26.9	23.4	21.3	11.0	14.5	16.6	26.8	12.8	14.0
30	MONI	68745	Cartilage+Fascia	42	41 to 50 years	Female	Right	Subtotal	Failure	40.8	40.5	40.5	40	0.3	0.3	0.8	30.4	19.0	11.4
31	MURALI	98742	Cartilage+Fascia	38	31 to 40 years	Male	Left	Medium	Uptake	35.2	25.2	23.2	20.1	10.0	12.0	15.1	21.2	12.8	8.4
32	KALAIVANAN	36741	Cartilage+Fascia	52	>50 years	Male	Left	Medium	Uptake	32.0	25	21.9	18.8	7.0	10.1	13.2	26.8	12.2	14.6
33	SUNDARI	67845	Cartilage+Fascia	36	31 to 40 years	Female	Right	Subtotal	Uptake	41.7	29.2	29.2	27.1	12.5	12.5	14.6	32.0	13.2	18.8
34	RAMESH	67584	Cartilage+Fascia	25	21 to 30 years	Male	Right	Large	Uptake	40.0	28.6	22.8	22.4	11.4	17.2	17.6	28.1	13.8	14.3
35	KATHAYEE	75812	Cartilage+Fascia	50	41 to 50 years	Female	Right	Large	Uptake	39.0	28	28	25.9	11.0	11.0	13.1	28.0	14.8	13.2
36	NITHIYA	68754	Cartilage+Fascia	21	21 to 30 years	Female	Left	Large	Uptake	48.3	35.3	30.6	30.1	13.0	17.7	18.2	27.0	15.0	12.0
37	MARY	95751	Cartilage+Fascia	31	31 to 40 years	Female	Right	Medium	Uptake	33.2	20.2	20.2	18.6	13.0	13.0	14.6	26.5	12.6	13.9
38	NAGARAJ	98754	Cartilage+Fascia	27	21 to 30 years	Male	Left	Large	Uptake	38.2	27.2	24.1	21.6	11.0	14.1	16.6	25.9	14.8	11.1
39	RENGASAMY	54678	Cartilage+Fascia	47	41 to 50 years	Male	Right	Subtotal	Uptake	50.3	37	33	32.9	13.3	17.3	17.4	27.7	13.4	14.3
40	PUNITHA	65894	Cartilage+Fascia	39	31 to 40 years	Female	Right	Subtotal	Uptake	41.6	30.2	27.1	25.6	11.4	14.5	16.0	32.6	13.9	18.7
41	RAJI	65756	Cartilage+Fascia	29	21 to 30 years	Female	Left	Subtotal	Uptake	50.2	36.8	34.8	32.7	13.4	15.4	17.5	30.8	14.6	16.2
42	MANOKARAN	84592	Cartilage+Fascia	47	41 to 50 years	Male	Right	Subtotal	Uptake	39.1	27.7	26.7	24.6	11.4	12.4	14.5	27.0	11.2	15.8
43	SELAMBARASAN	57964	Cartilage+Fascia	29	21 to 30 years	Male	Left	Medium	Uptake	35.0	18.2	22.5	20.4	16.8	12.5	14.6	21.4	11.6	9.8
44	SAROJA	85476	Cartilage+Fascia	49	41 to 50 years	Female	Right	Large	Uptake	43.0	30.5	30.5	28.4	12.5	12.5	14.6	27.4	13.2	14.2
45	RANJITHA	35876	Cartilage+Fascia	19	<20 years	Female	Right	Medium	Uptake	37.7	27.2	24	23.6	10.5	13.7	14.1	22.4	12.4	10.0
46	SARANYA	39785	Cartilage+Fascia	35	31 to 40 years	Female	Left	Medium	Uptake	36.0	25.5	23.3	22.4	10.5	12.7	13.6	21.6	13.4	8.2
47	PALANISAMY	35889	Cartilage+Fascia	37	31 to 40 years	Male	Left	Subtotal	Uptake	51.7	38	31.1	31	13.7	20.6	20.7	30.0	15.3	14.7
48	PERIYASAMY	78623	Cartilage+Fascia	32	31 to 40 years	Male	Right	Large	Uptake	44.3	31.8	31.8	29.2	12.5	12.5	15.1	26.5	12.5	14.0
49	KALYANI	84661	Cartilage+Fascia	27	21 to 30 years	Female	Left	Medium	Uptake	35.5	25	23.5	20.4	10.5	12.0	15.1	26.4	11.0	15.4
50	JANIFER	64782	Cartilage+Fascia	29	21 to 30 years	Female	Left	Medium	Uptake	31.0	25.2	18.5	16.4	5.8	12.5	14.6	22.4	12.9	9.5