

**“ EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA ON
UPTAKE OF GRAFT IN MYRINGOPLASTY – A COMPARATIVE
STUDY”**

By

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DISSERTATION SUBMITTED TO

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RESEARCH, KOLAR**

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY

in

OTORHINOLARYNGOLOGY

Under the guidance of

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ABSTRACT

Background: Chronic Suppurative Otitis Media (CSOM) is a prevalent condition often requiring surgical intervention through myringoplasty to restore tympanic membrane integrity and hearing function. Despite advances in technique, complications such as delayed healing and graft failure remain concerns. Autologous Platelet-Rich Plasma (PRP), rich in growth factors, has shown promise in enhancing tissue repair and regeneration.

Objectives: This study aimed to evaluate the efficacy of autologous PRP in improving graft uptake, minimizing postoperative complications, and enhancing hearing outcomes in patients undergoing myringoplasty.

Methods: A prospective comparative study was conducted on 90 patients aged 18–65 years diagnosed with CSOM. Participants were divided into two groups of 45 each—Group A (with PRP application) and Group B (without PRP). All patients underwent tympanoplasty, and outcomes were assessed at 21 days, 1 month, and 3 months postoperatively. Parameters analyzed included graft uptake, complication rates, and audiological improvement using Pure Tone Audiometry (PTA).

Results: Group A showed a significantly higher graft uptake rate at 1 month (100%) compared to Group B (77.3%), with no complications reported in the PRP group. Hearing improvement was also greater in the PRP group, with a mean gain of 4.67 dB compared to 2.56 dB in the non-PRP group. Statistical analysis confirmed PRP as an independent predictor of successful graft uptake.

Conclusion: Autologous PRP significantly improves surgical outcomes in myringoplasty by enhancing graft uptake, reducing complications, and promoting better hearing recovery. Its safe, cost-effective, and regenerative properties make it a valuable adjunct in otologic surgery.

Keywords: Platelet-Rich Plasma, Myringoplasty, Graft Uptake, Tympanoplasty, Hearing Improvement, CSOM, Otologic Surgery.

TABLE: LIST OF ABBREVIATIONS

Abbreviation	Full Form
CSOM	Chronic Suppurative Otitis Media
PRP	Platelet-Rich Plasma
TM	Tympanic Membrane
PTA	Pure Tone Audiometry
dB	Decibel
OR	Odds Ratio
TGF- β	Transforming Growth Factor Beta
PDGF	Platelet-Derived Growth Factor
VEGF	Vascular Endothelial Growth Factor
ENT	Ear, Nose, and Throat
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
ANOVA	Analysis of Variance
AOM	Acute Otitis Media
WHO	World Health Organization
HPE	Histopathological Examination

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INTRODUCTION

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) represents a long-standing infection of the middle ear cleft that includes the Eustachian tube, middle ear space, and mastoid. It is identified by a perforated tympanic membrane accompanied by continuous ear discharge ¹. If left untreated, CSOM may give rise to serious complications affecting both intracranial and extracranial structures, potentially leading to fatal outcomes. Historically, severe ear infections were often lethal; however, the advent of antibiotics and surgical magnification technologies has greatly improved treatment. Despite these advancements, CSOM remains a significant public health concern in India.

Perforations in the tympanic membrane (TM) can provoke recurring infections and hearing deficiencies, particularly when present on both sides, exacerbating auditory loss. These perforations usually result from recurrent episodes of otitis media that have not been fully resolved or are secondary to infected trauma. Even small perforations can allow canal contaminants to re-enter the middle ear, potentially inducing further infections and causing conductive hearing loss, particularly at low frequencies. Surgical repair of the TM, therefore, plays a crucial role in mitigating these outcomes and improving overall patient prognosis ².

Globally, it is estimated that CSOM affects between 65 to 300 million individuals, with approximately 60% of cases experiencing considerable hearing loss ³. According to the World Health Organization, India has a prevalence rate of 7.8%, among the highest in the world ⁴. This elevated rate is largely due to factors such as poverty, insufficient nutrition, and limited public health awareness, particularly in rural areas⁵. CSOM causes persistent ear pain, discharge, and hearing loss, all of which significantly diminish the affected individual's quality of life.

Myringoplasty, the surgical restoration of the tympanic membrane, is a principal treatment modality that yields substantial benefits for both clinicians and patients. Effective closure of the perforation can lead to an improvement in hearing capacity—often by as much as 25 dB—along with potential reduction in tinnitus and a cessation of ear discharge⁶. This procedure utilizes various graft materials, including skin, fascia, fat, vein, perichondrium, and dura mater⁷. Among these, temporalis fascia is most commonly used due to its durability, low metabolic needs, resistance to infection, and high success rates ranging from 64% to 88%^{8,9}. Nevertheless, failure rates remain significant—between 26% to 44% in adults and as high as 65% in pediatric cases, depending on several variables^{10,11}. These include postoperative infections, surgical inaccuracies, graft material types, and epithelial cell entrapment¹².

To enhance surgical results, researchers have explored several bioactive compounds, including hyaluronic acid, fibrin sealants, platelet-rich plasma (PRP), pentoxifylline, and fibroblast growth factors^{13,14}. Platelet derivatives like PRP and platelet-rich fibrin are already widely used in surgeries involving facial bones, plastic reconstruction, and orthopedics to improve tissue regeneration⁸. PRP, a form of autologous cell-based therapy, contains a high concentration of healing-promoting growth factors¹⁵. Since its clinical debut in cardiac surgery by Ferrari et al. during the 1980s¹⁶, PRP has found safe applications across various medical disciplines^{15,17}. In the ENT field, Erkilet et al. (2009) documented PRP's ability to speed up TM healing in animal models¹⁸, while El-Anwar et al. achieved positive results in repairing large perforations in human trials¹⁴.

The preparation of PRP involves centrifugation of whole blood to yield a concentrate rich in growth mediators such as platelet-derived growth factor (PDGF), insulin-like growth factor-I (IGF-I), and transforming growth factor-beta (TGF- β). These molecules facilitate the restoration of epithelial, endothelial, and epidermal tissues¹⁹. PRP also exhibits anti-

inflammatory, pain-relieving, and tissue-regenerative qualities by promoting angiogenesis, stimulating collagen synthesis, facilitating wound closure, and minimizing scar formation²⁰.

Despite encouraging findings in human studies^{21,22}, full TM closure success remains inconsistent, highlighting the necessity for further research to validate the impact on healing and auditory improvement. The current investigation aims to evaluate the comparative efficacy of myringoplasty using temporalis fascia grafts with and without autologous PRP, focusing on closure success, auditory enhancement, and recurrence of secondary perforations.

AIM & OBJECTIVES
OF THE STUDY

Aim

This study seeks to evaluate and compare the success of tympanic membrane reconstruction using temporalis fascia grafts, with and without the application of autologous platelet-rich plasma (PRP), during myringoplasty procedures.

Objectives

1. To compare the graft uptake rates done with and without the use of autologous PRP.
2. To assess the influence of PRP on:
 - the rate of tympanic membrane closure,
 - improvement in air conduction thresholds, and
 - the chances of secondary tympanic membrane perforations.

REVIEW OF
LITERATURE

REVIEW OF LITERATURE

Embryology of the Ear

The embryonic development of the human ear initiates around the third gestational week with the formation of the otic placode and vestibulocochlear ganglia. The external auditory canal originates from the dorsal aspect of the first branchial cleft, which is of ectodermal origin. Its deeper portion is formed by a proliferation of epithelium that grows inward toward the developing middle ear. Initially, this forms a solid structure known as the meatal plug, which later undergoes canalization to establish the external auditory canal²³.

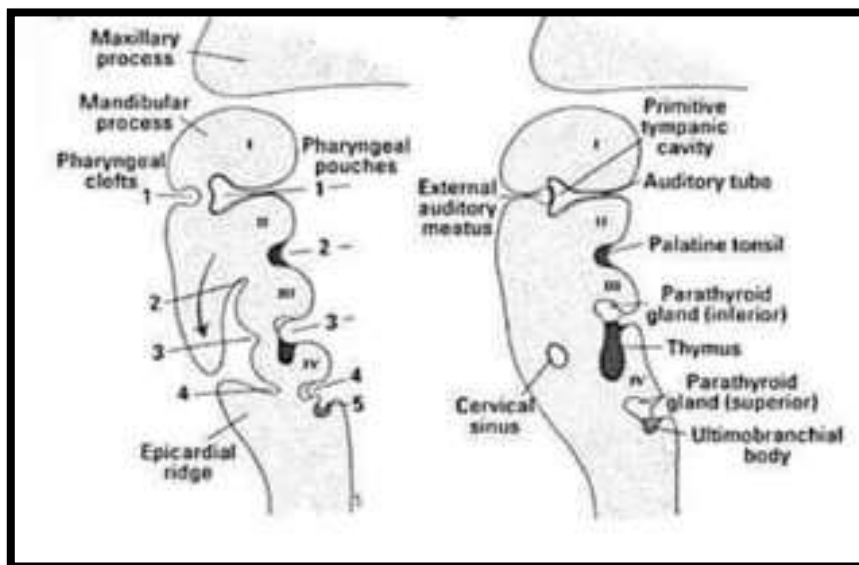


IMAGE 1: EMBROLOGY OF EAR

The middle ear structures—including the tympanic cavity and the Eustachian (pharyngotympanic) tube—derive from the tubo-tympanic recess, which itself is an endodermal outgrowth of the first pharyngeal pouch. By the fifth week of gestation, this recess grows laterally toward the first branchial groove but is initially separated by intervening mesenchyme. As development continues, the endodermal recess and ectodermal groove come

into close proximity, retaining a middle mesodermal layer that eventually forms the trilaminar tympanic membrane consisting of ectoderm, mesoderm, and endoderm²⁴.

The proximal end of the tubo-tympanic recess ultimately forms the Eustachian tube. Though it begins as an endodermal structure, the tympanic cavity and Eustachian tube are eventually lined by epithelial cells of endodermal and neural crest origin. The ossicles develop from different embryonic sources: the malleus and incus emerge from Meckel's cartilage of the first pharyngeal arch, while the stapes has a mixed origin involving neural crest cells and Reichert's cartilage from the second arch. The mesenchymal tissue surrounding the ossicles is reabsorbed over time, resulting in a hollow, air-filled space in which the ossicles are suspended. Later, the tympanic cavity enlarges to create the mastoid antrum²⁵.

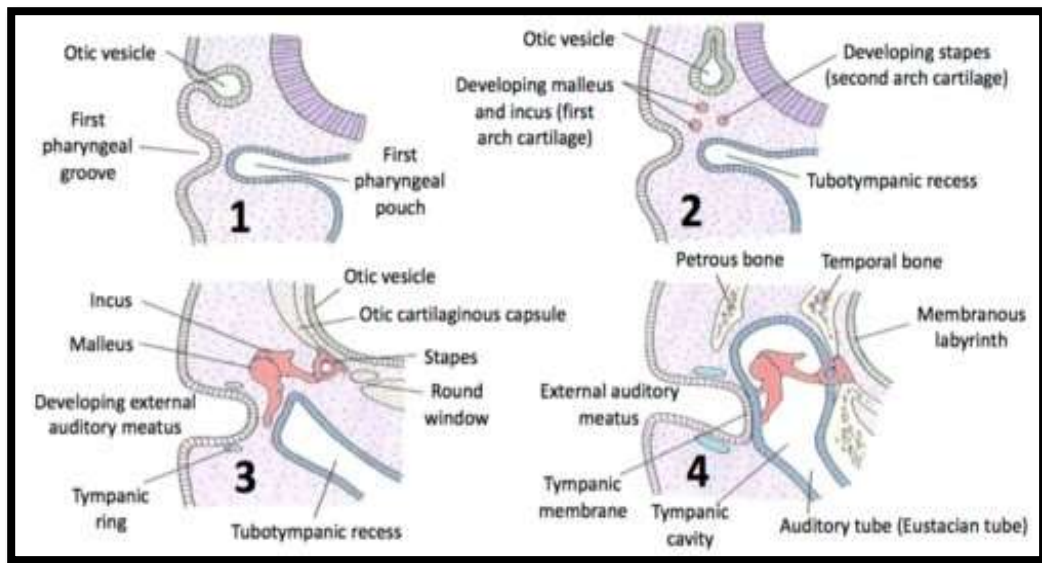


IMAGE 2: ANATOMY OF MIDDLE EAR CLEFT

Anatomy of the Middle Ear Cleft

The middle ear cleft includes the tympanic cavity, the Eustachian tube, and the mastoid air cell system. All these components are lined with mucosal epithelium and are filled with air. The tympanic cavity is a bony, air-containing chamber that lies between the tympanic membrane

on the lateral side and the inner ear on the medial side. It connects anteriorly to the nasopharynx through the Eustachian tube²⁶.

Structurally, the tympanic cavity is divided into three distinct regions²⁷:

1. **Epitympanum:** This is the superior part of the cavity, located above the level of the malleus neck.
2. **Mesotympanum:** The Small Sized portion situated between two imaginary horizontal lines at the upper and lower limits of the pars tensa.
3. **Hypotympanum:** The inferior segment found below the level of the bony auditory canal.

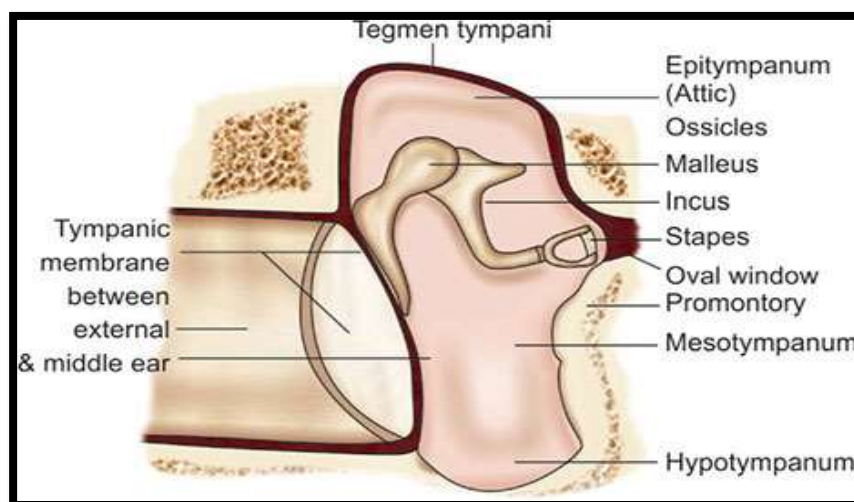


IMAGE 3: PARTS OF TYMPANIC CAVITY

The cavity is bounded by six walls²⁷:

1. **Roof:** Composed of the tegmen tympani, part of the petrous temporal bone.
2. **Floor:** A slender bony plate (fundus tympani) that separates the cavity from the jugular fossa.

3. **Medial Wall:** Contains essential features such as the oval window (fenestra vestibuli), round window (fenestra cochleae), the promontory (which is the basal turn of the cochlea), and the prominence of the facial canal.
4. **Lateral Wall:** Formed in part by the tympanic membrane and bone, with the scutum forming the lateral wall of the epitympanum.
5. **Anterior Wall:** Hosts the canal of the tensor tympani muscle above, the orifice of the Eustachian tube Small Sizedly, and a delicate bony barrier separating the cavity from the internal carotid artery below.
6. **Posterior Wall:** Contains the aditus (a connection to the mastoid antrum), the fossa incudis (which holds the short process of the incus), and the facial recess (bounded medially by the facial nerve and laterally by the tympanic annulus).

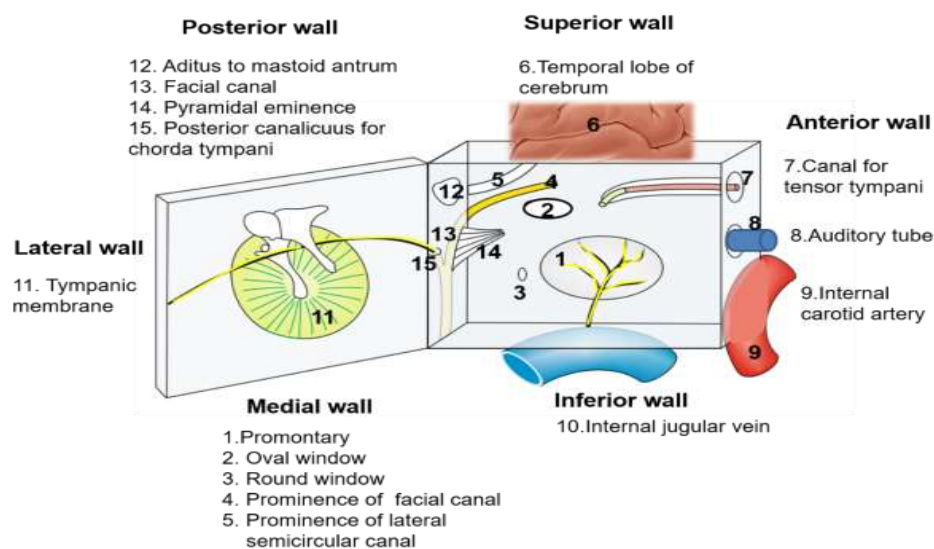


IMAGE-4: WALLS OF TYMPANIC CAVITY

The **tympanic membrane** is a thin, oval, and translucent structure about 1 cm in diameter that marks the boundary between the external auditory canal and the middle ear²⁸. It has three distinct layers:

- An external stratified squamous epithelium continuous with the ear canal,

- A Small Sized fibrous connective tissue layer with embedded vasculature and neural elements,
- An internal simple cuboidal epithelium that merges with the mucosa of the tympanic cavity²⁹.

The membrane itself is subdivided into two parts³⁰:

1. **Pars Tensa**: The larger section with a reinforced fibrous annulus that fits into the tympanic sulcus. Its center is drawn inward at the malleus attachment point (the umbo), from which a cone of light projects anterior-inferiorly.
2. **Pars Flaccida**: Situated above the lateral process of the malleus, between the notch of Rivinus and the anterior/posterior malleolar folds.

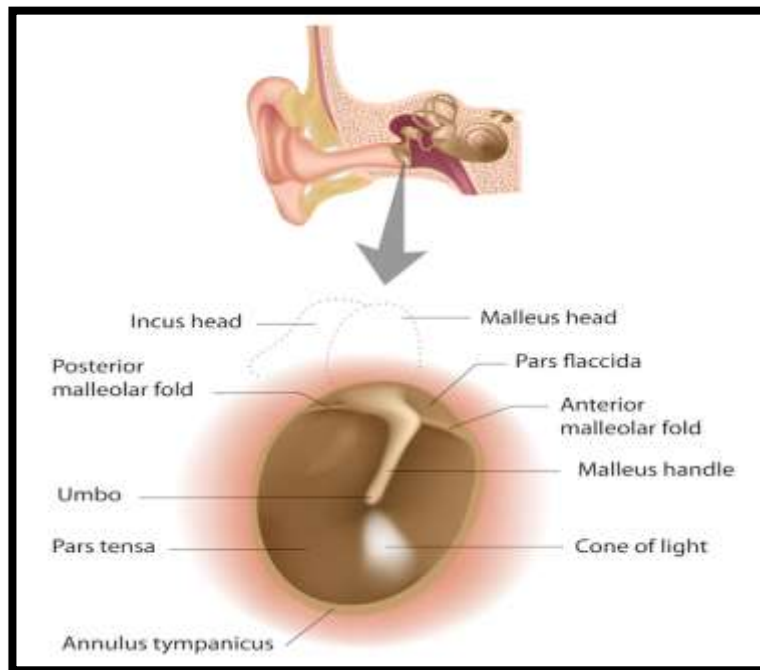


IMAGE-5: TYMPANIC MEMBRANE

The tympanic diaphragm is formed by membranes, ligaments (like the anterior/lateral/posterior malleal folds), and associated structures including the posterior incudal fold and tensor tympani fold. This diaphragm, alongside the incus and malleus, defines the floor of the epitympanic

compartment. The tympanic isthmus, a narrow 2.5 mm passageway, lies between the tensor tympani muscle and the posterior incudal ligament and pyramidal eminence³⁰.

Anatomically, the tympanic membrane is segmented into four quadrants using two imaginary lines—one vertical along the malleus handle and another perpendicular through the umbo—creating the anterosuperior, anteroinferior, posteroinferior, and posterosuperior quadrants³¹.

Prussak's Space is a distinct middle ear region bordered laterally by the pars flaccida, medially by the neck of the malleus, inferiorly by its lateral process, anteriorly by the malleolar ligamental fold, and superiorly by the lateral malleolar fold. Additional middle ear compartments include the posterior and anterior pouches of Von Troeltsch, superior and inferior incudal spaces, and the anterior epitympanic and supra-tubal recesses.

The ossicles—malleus, incus, and stapes—serve to convey sound vibrations from the eardrum to the inner ear²⁷:

- **Malleus:** Connects to the tympanic membrane and includes the head, neck, handle, and short process. It articulates with the incus via the incudo-malleolar joint.
- **Incus:** Features a body, short process, and long process, the latter forming a joint with the stapes.
- **Stapes:** The smallest bone in the body, comprising a head, two crura, and a footplate that fits into the oval window.

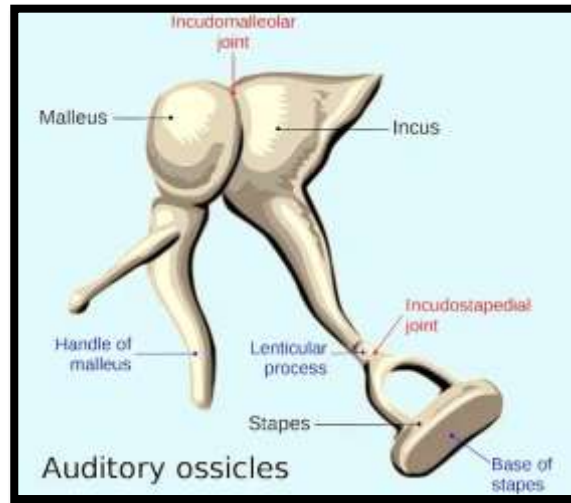


IMAGE-6: OSSICLES OF EAR

The Eustachian tube, named after Bartolomeo Eustachi, connects the middle ear with the nasopharynx³². It measures about 36 mm in adults and runs downward, forward, and medially at approximately a 45° angle. The tube is composed of a 12 mm bony portion (posterolateral) and a 24 mm cartilaginous segment (anteromedial), joined at the isthmus—the tube’s narrowest region³³.

- The tympanic opening lies on the anterior wall of the middle ear, measuring about 5 × 2 mm and is entirely bony.
- The pharyngeal end is vertical and slit-shaped, opening into the nasopharynx and surrounded by the torus tubarius.
- Three muscles—tensor veli palatini, levator veli palatini, and salpingopharyngeus—play roles in its function, while Ostmann’s fat pad helps maintain closure and prevent reflux of nasopharyngeal secretions³⁴.

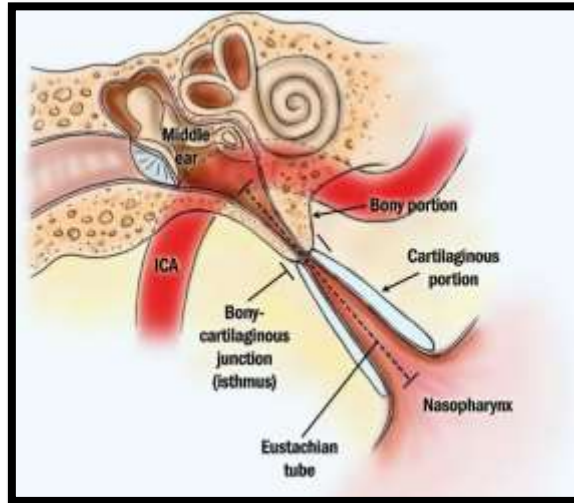


IMAGE 7: EUSTACHIAN TUBE

The mastoid air cell system, located in the petrous portion of the temporal bone, contains air-filled cavities believed to protect the skull and regulate air pressure in the auditory system³⁵. This system is categorized as:

- **Pneumatic (85%)**: Contains numerous air cells,
- **Diploic**: Contains fewer air cells,
- **Sclerotic (15%)**: Essentially devoid of air cells.

Physiology of Hearing

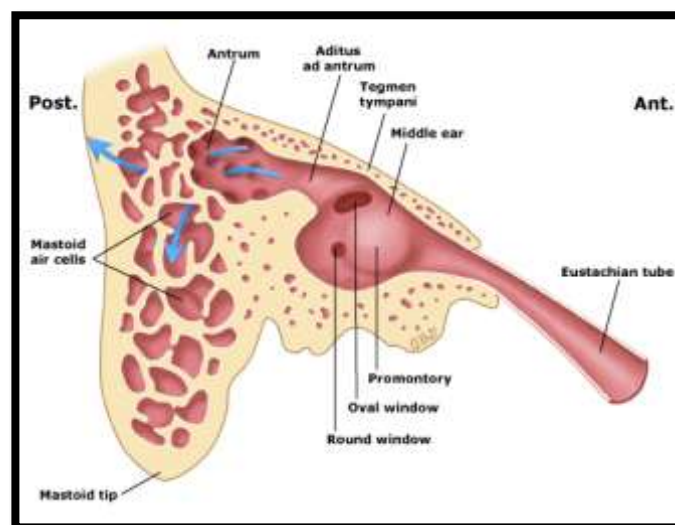


IMAGE 8: MASTOID AIR CELL SYSTEM

Sound is a form of vibrational energy that travels through a medium in the form of pressure waves. The auricle (pinna) captures these sound waves and funnels them through the external auditory canal toward the tympanic membrane. As the membrane vibrates in response to the incoming sound waves, it sets into motion the ossicular chain within the middle ear. These ossicles transfer mechanical energy to the footplate of the stapes, which then creates pressure changes in the fluid-filled chambers of the inner ear, particularly the cochlea. This movement triggers the basilar membrane, leading to stimulation of the hair cells located in the organ of Corti, which subsequently generate electrical signals transmitted by the auditory nerve to the brain.

A critical function of the middle ear is impedance matching—a mechanism that minimizes energy loss as sound moves from the air (a low-impedance medium) to the fluid of the inner ear (a high-impedance medium)³⁶. The middle ear performs this impedance transformation using three primary methods:

1. **Ossicular Lever Action:** The handle of the malleus is about 1.3 times longer than the long process of the incus, providing a lever advantage that amplifies the transmitted force.

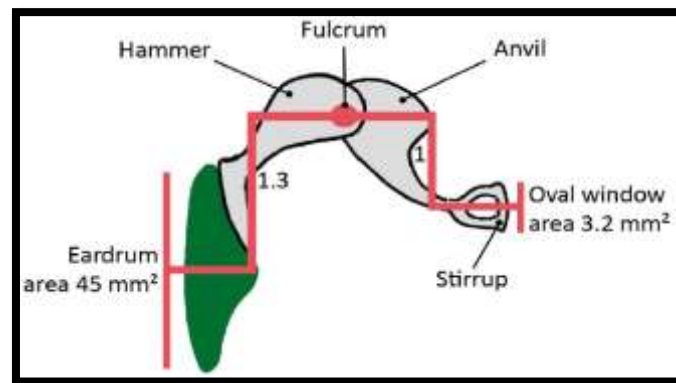


IMAGE 9: LEVER ACTION OF OSSICLES

2. **Hydraulic Action of the Tympanic Membrane:** The tympanic membrane has a much larger surface area than the footplate of the stapes—roughly a 21:1 ratio. Since only two-thirds of the membrane vibrates efficiently, the effective area ratio is closer to 14:1. This area differential significantly increases the pressure transmitted to the oval window.

3. **Curved Membrane Principle:** The design of the tympanic membrane allows for more movement at the peripheral regions compared to the center (attached to the malleus), which adds another level of mechanical amplification.

Together, these mechanisms enable the middle ear to overcome the resistance mismatch between air and cochlear fluid, ensuring efficient sound energy transfer.

Chronic Otitis Media (COM)

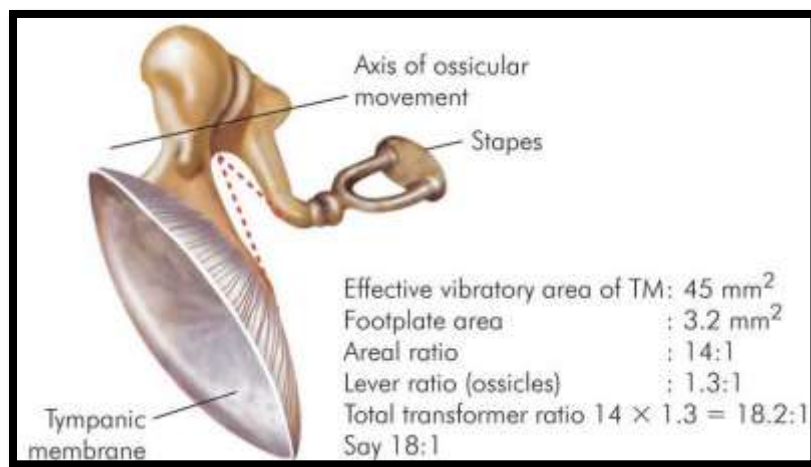


IMAGE 10: HYDRAULIC ACTION OF TYMPANIC MEMBRANE

Chronic Otitis Media (COM) is a prolonged inflammatory condition affecting the mucosal lining of the middle ear and mastoid process. It is typically identified by repeated ear discharge that persists for more than two weeks through a chronic perforation in the tympanic membrane. COM often arises as a long-term outcome of unresolved acute otitis media or otitis media with effusion. The underlying causes of COM are complex and multifaceted, involving several defense mechanisms such as innate immunity (e.g., toll-like receptors, cytokines, surfactants), adaptive immunity (e.g., antibodies), and non-specific immunity (e.g., epithelial integrity, mucin production). Additional contributors include immune dysregulation and craniofacial abnormalities. Conditions such as Down syndrome, cleft palate, choanal atresia, Cri du chat syndrome, microcephaly, cleft lip, and DiGeorge syndrome are associated with higher susceptibility to COM⁴.

Classification of COM and Clinical Characteristics³⁷:

Type	Synonyms	Clinical Features
Healed COM	Tympanosclerosis / Healed perforation	Opaque or thinned pars tensa without perforation or retraction
Inactive Mucosal	Dry perforation	Intact tympanic perforation with no active inflammation in the middle ear or mastoid
Active Mucosal	Perforation with otorrhea	Inflamed middle ear and mastoid mucosa showing fibrosis, vascular proliferation, and immune cells (e.g., lymphocytes, plasma cells)
Inactive Squamous COM	Retraction, atelectasis, epidermization	Chronic negative pressure leads to retracted TM; epidermal cells replace mucosa without debris formation
Active Squamous COM	Cholesteatoma	Keratinized cyst in the middle ear or mastoid, causing bone erosion; types include congenital, primary acquired (involving Prussak's space), and secondary acquired (epithelial migration during infection)

Pathophysiology

COM is often driven by chronic Eustachian tube dysfunction, which impairs ventilation of the middle ear. This dysfunction, along with repeated episodes of acute otitis media or other long-term infections, contributes to ongoing inflammation. Perforations of the tympanic membrane may result from trauma, repeated infections, or complications like necrotizing otitis media, which can cause permanent holes in the membrane. Particularly, when the tympanic annulus is involved, keratinized epithelium from the external canal may migrate inward, potentially giving rise to cholesteatoma³⁸.

Factors Leading to Persistent Perforations of the Tympanic Membrane³⁶:

1. Unresolved tympanic membrane rupture following acute otitis media.
2. Fibrous layer degradation due to chronic middle ear effusion.
3. Traumatic injuries causing large perforations.
4. Tympanic membrane damage from extrusion of tympanostomy tubes.

Diagnostic Workup³⁹:

1. **Patient History:** Key symptoms include earache, discharge, hearing difficulties, tinnitus, or dizziness.
2. **Otoscopy:** Visual inspection reveals the status of the external canal and tympanic membrane. In cases with cholesteatoma, one may see retracted areas filled with keratin debris and purulent discharge.
3. **Audiometry:** Assesses hearing function by evaluating the ability to detect varying sound frequencies and intensities. The WHO's 2021 classification is as follows⁴⁰:
 - Normal: 0–25 dB
 - Mild: 26–40 dB
 - Moderate: 41–55 dB
 - Moderately Severe: 56–70 dB
 - Severe: 71–90 dB
 - Profound: >90 dB
4. **Tympanometry:** Detects middle ear abnormalities; in COM, a higher-than-normal canal volume may indicate a perforation.
5. **Imaging:**
 - CT scans help visualize the temporal bone and plan surgery.
 - MRI, especially with diffusion-weighted imaging, is useful for detecting residual or recurrent cholesteatoma postoperatively.

Treatment Strategies³⁹:

Type of COM	Medical Management	Hearing Aids	Surgical Options
Inactive Mucosal	Monitoring	Yes, if hearing is impaired	Myringoplasty or tympanoplasty
Active Mucosal	Topical antibiotics, microsuction	Yes	Myringoplasty for mucosal repair
Inactive Squamous	Microsuction	Yes	Tympanoplasty using cartilage grafts
Active Squamous	Medical prep for surgery	Yes (if unfit for surgery)	Tympanomastoid procedures

The current research emphasizes cases involving adult patients with tympanic membrane perforations from COM (without active infection), managed using myringoplasty. It compares temporalis fascia grafting with and without autologous PRP, assessing factors such as graft integration and auditory improvements.

Myringoplasty

The surgical repair of the tympanic membrane (TM) has a history spanning over a century. In 1878, Berthold performed the first documented repair using a full-thickness skin graft, naming the procedure “Myringoplastik”⁴¹. Myringoplasty refers specifically to reconstructive surgery limited to the eardrum, aimed at restoring its fibrous layer and facilitating regeneration of the mucosal and epithelial layers.

Indications for Myringoplasty⁴²:

1. A Small Sized perforation that has remained dry for a minimum of six weeks.
2. Post-mastoidectomy patients requiring reconstruction of the sound conduction mechanism.

Contraindications⁴²:

1. Presence of active discharge in the middle ear.
2. Nasal allergies.
3. Concurrent otitis externa.

4. Squamous epithelium growth into the middle ear.
5. Children under the age of three.

Surgical Prerequisites⁴³:

1. A dry Small Sized perforation sustained for six weeks or more.
2. Healthy middle ear mucosa.
3. An intact ossicular chain.
4. Proper cochlear nerve function.
5. A functioning Eustachian tube.
6. Absence of infection in the nasal cavity, paranasal sinuses, or nasopharynx.

Preoperative Preparation:

- Secure written informed consent.
- Administer a 0.5 cc intramuscular tetanus toxoid injection.
- Shave a small area superior to the auricle for harvesting the temporalis fascia graft.

Surgical Approaches⁴⁴:

1. Transcanal/Endomeatal Approach:

Suitable when the external auditory canal is sufficiently wide. It involves a vertical incision at the 12 o'clock position near the tympanic annulus, followed by a curved incision from 6 o'clock to the posterosuperior canal wall, approximately 5–7 mm from the annulus.

2. Endaural Approach:

Uses Lempert's incision, which is semicircular, extending from 12 to 6 o'clock at the junction of the bony and cartilaginous segments, with an upward curve between the tragus and the crus of the helix.

3. Postaural (Wilde's) Incision:

Begins at the highest attachment point of the pinna, traces the retroauricular groove 1 cm posterior to the auricle, and extends down to the mastoid tip.

Surgical Techniques:

1. Underlay Technique⁴⁵:

- Most commonly employed and technically simpler.
- Ideal for small, visible perforations.
- The graft is positioned beneath the raised tympanomeatal flap.
- Offers high success rates and ease of execution.

2. Overlay Technique:

- More intricate and used for large or anterior perforations, or when underlay methods have failed.
- The graft is inserted under the squamous epithelial layer of the tympanic membrane.

The study uses the underlay technique, which involves the following steps:

1. Margins of the perforation are refreshed using a sickle knife or angled pick.
2. Incisions are made in the external canal at the tympanomastoid and tympanosquamous sutures (6 and 12 o'clock positions), creating a vascular strip.
3. The tympanomeatal flap is elevated up to the annulus.
4. The mucosa of the middle ear is incised, and the annulus is lifted.
5. The flap is carefully detached from the handle of the malleus using sharp dissection.
6. The middle ear cavity is packed with antibiotic-soaked gel foam, and the appropriately sized graft is inserted. It extends beneath the perforation and over part of the posterior canal wall.
7. The tympanomeatal flap is repositioned. Additional gel foam is placed around its edges, and the incision is sutured closed.

Postoperative Care:

1. Patients are typically discharged on the first postoperative day.
2. Mastoid dressings are changed on day two.

3. Water exposure to the postaural site is avoided for 48 hours.
4. Patients are advised against blowing their nose and instructed to sneeze with an open mouth.
5. Prescriptions include antibiotics, analgesics, and antihistamines.
6. Sutures are removed after one week.
7. Any remaining gel foam is gently suctioned out after 3–4 weeks.
8. A follow-up **audiogram** is conducted after 4–6 months to evaluate hearing outcomes.

Potential Complications:

1. Constriction or narrowing of the middle ear space.
2. Graft adherence to the cochlear promontory.
3. Detachment of the graft from the anterior margin of the residual tympanic membrane.

Graft Materials

A range of graft materials has been investigated and utilized for the surgical repair of tympanic membrane perforations:

Types of Grafts⁴⁶:

1. **Autografts:** Tissues taken from the same patient—commonly used options include temporalis fascia, tragal cartilage, conchal perichondrium, periosteum, and fascia lata.
2. **Isografts:** Harvested from genetically identical individuals, such as identical twins.
3. **Homografts:** Tissues sourced from other humans (non-identical donors).
4. **Heterografts:** Biological materials obtained from other species—examples include bovine jugular vein or fetal membranes.

Temporalis Fascia as Graft Material

The use of temporalis fascia dates back to the work of Ortegren, Heerman, and Storrs during the late 1950s and early 1960s. It has become the preferred graft material for multiple reasons:

- Easy accessibility and minimal donor site morbidity.

- Structural and biological similarity to native tympanic membrane tissue.
- Very low basal metabolic requirements, which enhances survival even under suboptimal vascular conditions.
- Flexible in terms of size and shape—there are no rigid dimensional constraints.
- Effective in reconstructing both the tympanic membrane and parts of the auditory canal.
- Can be employed in different grafting strategies: inlay, intermediate, or underlay.
- Compatible with layered or composite techniques, including overlapping pieces and composite grafts with canal skin.

In a study by Hordijk and Rietema (1982) involving 250 ear surgeries, comparisons were made between temporalis fascia, homologous vein, and pericardium. They found that while pericardium showed slightly better closure rates in infected environments, the hearing outcomes were better with temporalis fascia and vein grafts, though the differences were not statistically significant. Among homografts, vein was considered the most practical due to easier procurement⁴⁷.

Perkins and Bui (1996) reported excellent clinical results with the use of formaldehyde-treated temporalis fascia in repairing large perforations. The outcomes showed high closure rates with minimal complications⁴⁸.

Zhang et al. (2011) analyzed the effectiveness of temporalis fascia, tragus perichondrium, and cartilage-perichondrium composite grafts in myringoplasty. They concluded that while all three materials were viable, cartilage grafts provided better structural and long-term auditory outcomes in large perforations⁴⁹.

Parida et al. (2013) observed no statistically significant differences between temporalis fascia and vein grafts in terms of closure success or improvement in hearing thresholds⁵⁰.

More recently, Pontillo et al. (2023) demonstrated that temporalis fascia could achieve perforation closure rates of nearly 90%. However, in high-risk scenarios—such as large perforations or cases with Eustachian tube dysfunction—cartilage grafts showed marginally superior results^{51,52}.

Limitations of Temporalis Fascia

Despite its advantages, temporalis fascia is not without drawbacks:

- It may medialize under persistent negative middle ear pressure.
- Over time, the graft can thin out or become atrophic.
- Failure of the graft may occur due to improper placement, postoperative displacement, or residual perforation.

To counter these limitations and improve graft uptake, adjunctive biomaterials—including autologous serum, platelet-rich plasma (PRP), and growth factors—are increasingly being integrated into surgical practice.

Platelet-Rich Plasma (PRP)

Platelet-rich plasma (PRP) is an autologous treatment modality that involves isolating plasma enriched with a high concentration of platelets from the patient's own blood using centrifugation. This technique allows for the local delivery of a potent mixture of growth factors and bioactive proteins. PRP is a minimally invasive method widely applied across various medical specialties such as dentistry, dermatology, cosmetic surgery, maxillofacial surgery, trauma care, and veterinary practice⁵²

Platelets are reservoirs of numerous signaling molecules and growth mediators that regulate the sequential stages of healing—inflammation, tissue repair, and remodeling. These cells aid in clot formation, cell adhesion, and tissue regeneration by releasing factors stored within their alpha granules. Some key growth factors released by platelets include⁵³:

Growth Factor	Biological Role
PDGF (Platelet-Derived Growth Factor)	Enhances fibroblast activity, attracts cells (chemotaxis), stimulates collagen and proteoglycan production, and boosts TGF- β synthesis
TGF-β1 (Transforming Growth Factor-β1)	Promotes extracellular matrix formation, fibroblast proliferation, cell viability, and inhibits cartilage-degrading effects of interleukin-1
bFGF (Basic Fibroblast Growth Factor)	Stimulates collagen synthesis, promotes angiogenesis, and supports myoblast growth
VEGF (Vascular Endothelial Growth Factor)	Facilitates blood vessel formation (angiogenesis)
EGF (Epidermal Growth Factor)	Supports epithelial and mesenchymal cell proliferation and differentiation, and promotes angiogenesis

Preparation of PRP [□ □ :65:](#)

To prepare PRP, approximately 30 mL of venous blood is collected, yielding around 3–5 mL of PRP depending on factors like baseline platelet count, device used, and preparation technique. Blood is typically drawn with an anticoagulant, such as citrate dextrose A, to prevent premature platelet activation. Two commonly used protocols include:

PRP Method (Two-Spin Centrifugation):

1. Blood is collected in ACD tubes via venipuncture.
2. The sample is kept at room temperature—not chilled—to preserve platelet functionality.
3. A soft spin is first conducted to separate red cells from plasma.
4. The platelet-rich supernatant is then transferred to a new sterile tube, now without anticoagulant.
5. A hard spin is applied to concentrate platelets at the bottom.
6. The lower third of the resultant fluid is PRP, and the upper two-thirds is platelet-poor plasma (PPP).

7. PPP is removed, and the platelet pellet is resuspended in 2–4 mL of plasma using gentle agitation.

Buffy Coat Method:

1. Blood is maintained at 20–24°C before centrifugation.
2. A high-speed spin is used, creating three layers: red blood cells at the bottom, the buffy coat (platelets and white blood cells) in the middle, and PPP at the top.
3. The PPP is removed, and the buffy coat is transferred to another sterile tube.
4. A low-speed centrifugation or leukocyte filter is used to further isolate platelets.

Clinical Evidence Supporting PRP in Myringoplasty

- El-Anwar et al. (2017) conducted a prospective study employing a PRP hourglass graft for minor TM perforations performed in-office. Out of 25 cases, 21 (84%) showed complete healing with no complications such as tinnitus, vertigo, or infection¹⁴.
- Yadav et al. (2018) examined PRP's effect in underlay myringoplasty in 40 patients split into two groups—Group 1 received PRP between the fascia graft and TM remnant, while Group 2 underwent standard surgery. The results indicated better graft uptake and healing outcomes in the PRP group, with advantages like low cost, simple preparation, and autologous safety profile²².
- Shukla et al. (2020) analyzed 41 cases repaired with platelet-rich fibrin membranes. Successful closure was achieved in 85.4% of patients, with a small number showing discharge or fungal infection (otomycosis). The overlay and underlay techniques produced strong clinical improvements, including significant audiometric gains, with no link found between surgical outcomes and preoperative features⁵⁴.
- Anwar et al. (2020) compared 35 patients treated with PRP to 35 without. The PRP group demonstrated superior graft uptake and improved hearing thresholds, validating PRP's ease of use and potential in otologic procedures⁵⁵.
- A meta-analysis by Huang et al. (2021) included eight studies totaling 455 participants. Compared to conventional techniques, PRP increased closure success, with odds ratios of 2.70 in randomized trials and 6.18 in non-randomized ones, and an overall ratio of

3.69. Though no notable difference in hearing outcomes was found, PRP significantly reduced postoperative complications⁵⁶.

- Riaz et al. (2021) used topical PRF in 50 patients undergoing underlay myringoplasty. Their trial showed enhanced graft uptake, better auditory gains, and fewer postoperative infections³.
- Sharma et al. (2022) compared PRP-assisted myringoplasty (MP-PRP) to standard fascia myringoplasty (MP-C) for moderate-to-large perforations. No statistical difference was found in audiometric results or complications, suggesting equivalent efficacy⁵⁷.
- Aboelnaga et al. (2022) tested platelet-rich fibrin as an adjunct in 100 cases of CSOM with Small Sized perforations. They observed higher surgical success rates without significant side effects, regardless of perforation size⁵⁸.
- Abdeltawab et al. (2023) conducted a trial comparing PRP hourglass grafts with standard fascia underlay techniques. The PRP group showed comparable hearing improvement with a reduction in air-bone gaps, supporting its therapeutic role¹
- Ahmed et al. (2023) evaluated PRP and hyaluronic acid (HA) as graft enhancers in myringoplasty. Though PRP and HA showed better pure tone audiometry outcomes, no significant difference in overall graft success rates was noted between the treatment groups¹.

MATERIALS AND
METHODS

Study design

Comparative study

Study Framework

This investigation was designed as a comparative study, conducted over a period extending from May 2023 to October 2024. The research was carried out in the Department of Otorhinolaryngology at R.L. Jalappa Hospital, situated in Tamaka, Kolar.

Study Population

The subjects included individuals presenting with tympanic membrane perforation who were evaluated and treated at the aforementioned department.

Sample Size Determination

A total of 90 participants were enrolled. The sample size was calculated based on differences in adhesion rates reported by Vignesh et al.⁵⁹, where a mean difference of 2.63 and a standard deviation of 4.42 were documented. Assuming this pooled standard deviation and aiming for 80% statistical power with a 5% level of significance (two-tailed), the required number of participants per group was estimated to be 45.

The following formula was used to calculate the final sample size:

- n = sample size per group before adjusting for potential dropout
- $Z_{\alpha/2} = 1.96$ (standard score for 95% confidence)
- $Z_{\beta} = 0.84$ (standard score for 80% power)
- Final $N = 2n / (1 - 0.1)$ to account for a 10% anticipated dropout rate

This resulted in a total estimated sample size of 90 participants.

Sampling Method

Random sampling was employed to allocate subjects to each group.

Inclusion Criteria

- Adults aged 18 to 65 years with a confirmed diagnosis of chronic otitis media.
- Presence of a tympanic membrane perforation.

Exclusion Criteria

- Evidence of acute or ongoing infections involving the ear, nose, or throat.
- Patients with severe or profound hearing loss.
- Individuals diagnosed with attico-antral-type chronic suppurative otitis media.
- Patients with co-morbidities that could affect surgical outcomes, such as:
 - Uncontrolled diabetes mellitus
 - Bleeding disorders
 - Malignancies

Ethical Clearance

The research received approval from the Institutional Ethical Committee, ensuring compliance with ethical standards. Additionally, written informed consent was obtained from each participant prior to their inclusion in the study.

Data Collection and Statistical Analysis

All clinical and procedural data were captured using case record forms, and the information was digitized in Microsoft Excel 2016. Statistical analysis was carried out using SPSS software, version 26, to interpret the findings.

Methodology:

Detailed clinical history of patients coming to Department of Otorhinolaryngology in RL Jalappa hospital followed by Clinical Examination, pre operative investigations and post operative audiogram(Pure Tone Audiometry), Otomicroscopic / otoendoscopic examination, naso / oropharyngeal examination.

- The blood was obtained from antecubital vein using 16/18 number scalp vein set in specific tube having 1 ml of anticoagulant, 9.0 ml of blood was collected.
- Immediately centrifugation of blood was done at automatic centrifugation machine using 1500 rpm for 15 min. This resulted in two layers upper one yellowish and lower one dark red.
- By using a sterile pipette supernatant plasma was transferred to another sterile tube for hard spin.
- Second centrifugation was done at 3000 rpm for 15 min, upper supernatant platelet poor plasma was sucked gently with pipette after leaving 1 ml of fluid and pallet at the bottom.
- Now with another sterile pipette gently mixed the pallet in the fluid, preserved to be used during surgery.
- Immediately before use 0.1 ml of calcium gluconate was added to activate the release of growth factor. This PRP was added to just sufficient quantity of gel foam going to be used in surgery two drops of PRP was installed on each side of dried temporal fascia graft.
- Patients in both groups underwent myringoplasty by using the underlay technique and temporalis fascia graft.
- In the study group, after placing the graft and repositioning the tympanomeatal flap, gel foam soaked in platelet rich plasma was kept over the sealed perforation.
- In the control group, gel foam soaked in saline was kept over the sealed perforation, after repositioning the flap.

- Both groups of patients received antibiotics, as per the routine protocol followed by the department.

Following the surgery, graft uptake was assessed by an otoscope at 1st and 3rd months post-surgery by a single-blinded observer.

There were three outcome variables of the study:

- (a) to assess the graft uptake—success or failure,
- (b) to assess the percentage of perforation closure,
- (c) to assess the audiological outcome.



IMAGE 11: PLATELET RICH PLASMA



IMAGE 12: GEL FOAM SOAKED WITH PRP



IMAGE 13: TEMPORALIS FASCIA GRAFT

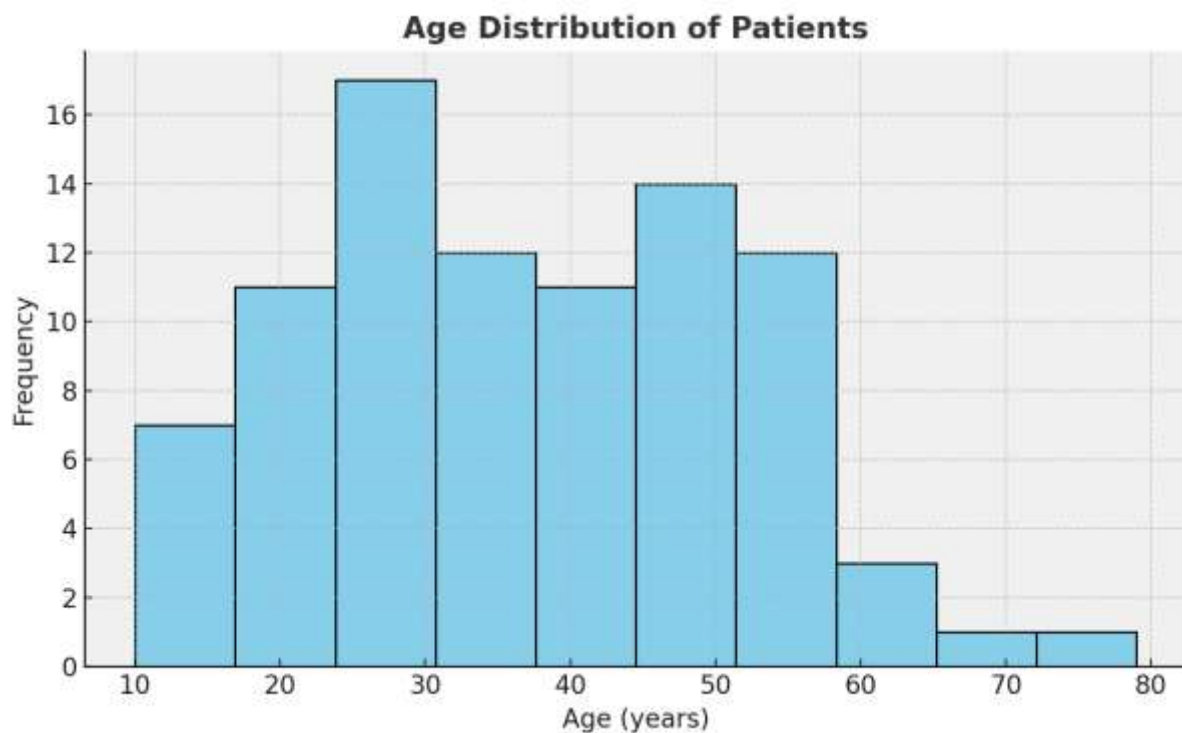
RESULTS

Table 1: Demographic Profile of Patients (PRP vs Non-PRP)

PRP FOAM	Count	Mean Age (years)	Std. Dev (Age)	Males	Females
NO	44	38.55	16.26	19	25
YES	46	35.67	13.82	16	29
TOTAL	90	37.09	15.06	35	54

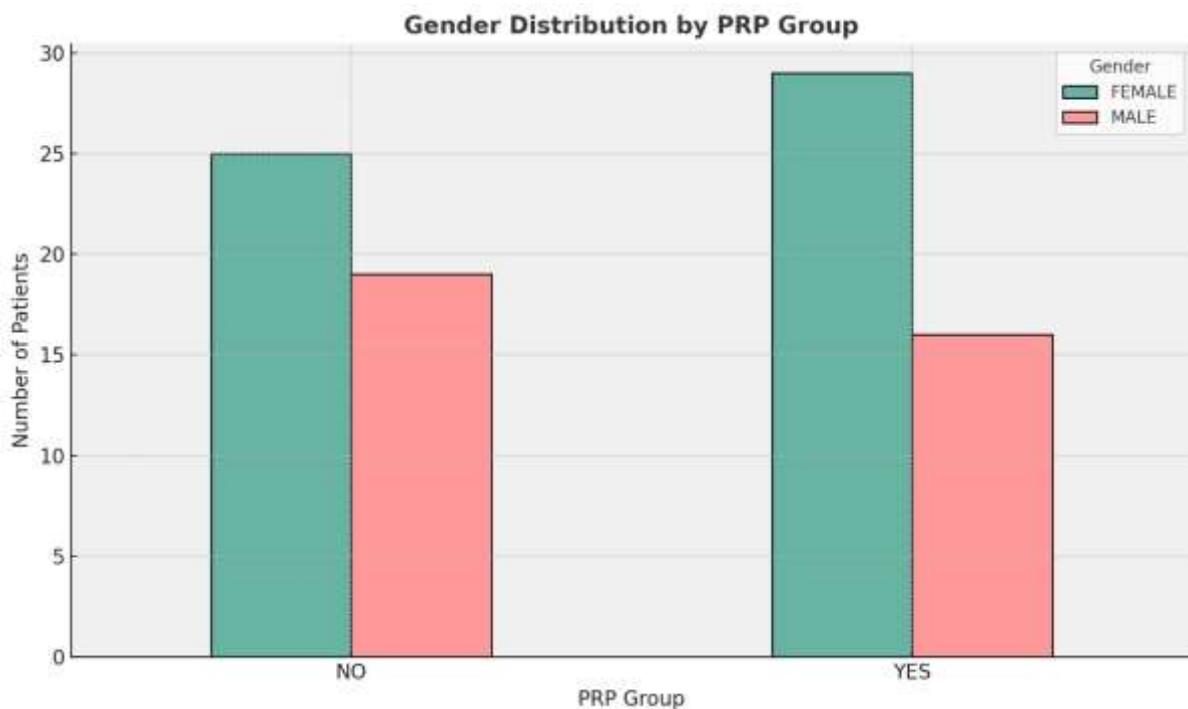
- PRP and Non-PRP groups are similar in size and age.
- Gender distribution is balanced, with slightly more females in both groups.
- This demographic balance supports a fair clinical comparison for outcomes.

Figure 1: Age Distribution of Patients



- Most patients are concentrated between 20 and 50 years.
- The age distribution shows a moderate right skew, with fewer older patients.
- This reflects the typical demographic affected by chronic suppurative otitis media (CSOM).
- The spread supports that both young adults and middle-aged patients are commonly treated with myringoplasty.

Figure 2: Gender Distribution by PRP Group

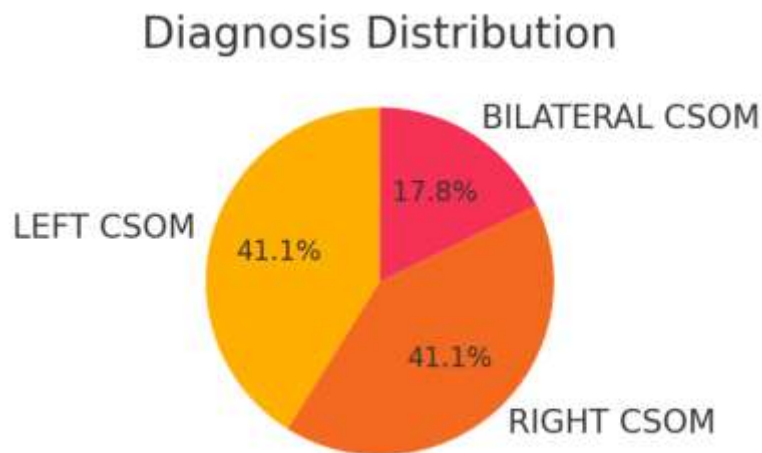


- Both PRP and non-PRP groups have a female predominance.
- The PRP group includes more females (29) compared to males (16).
- The non-PRP group also shows a similar trend, though slightly less pronounced.

Table 2. Diagnosis Distribution in study groups

Diagnosis	Count (%)
LEFT CSOM	37 (41.1%)
RIGHT CSOM	37 (41.1%)
BILATERAL CSOM	16 (17.8%)

Figure 3: Diagnosis Distribution

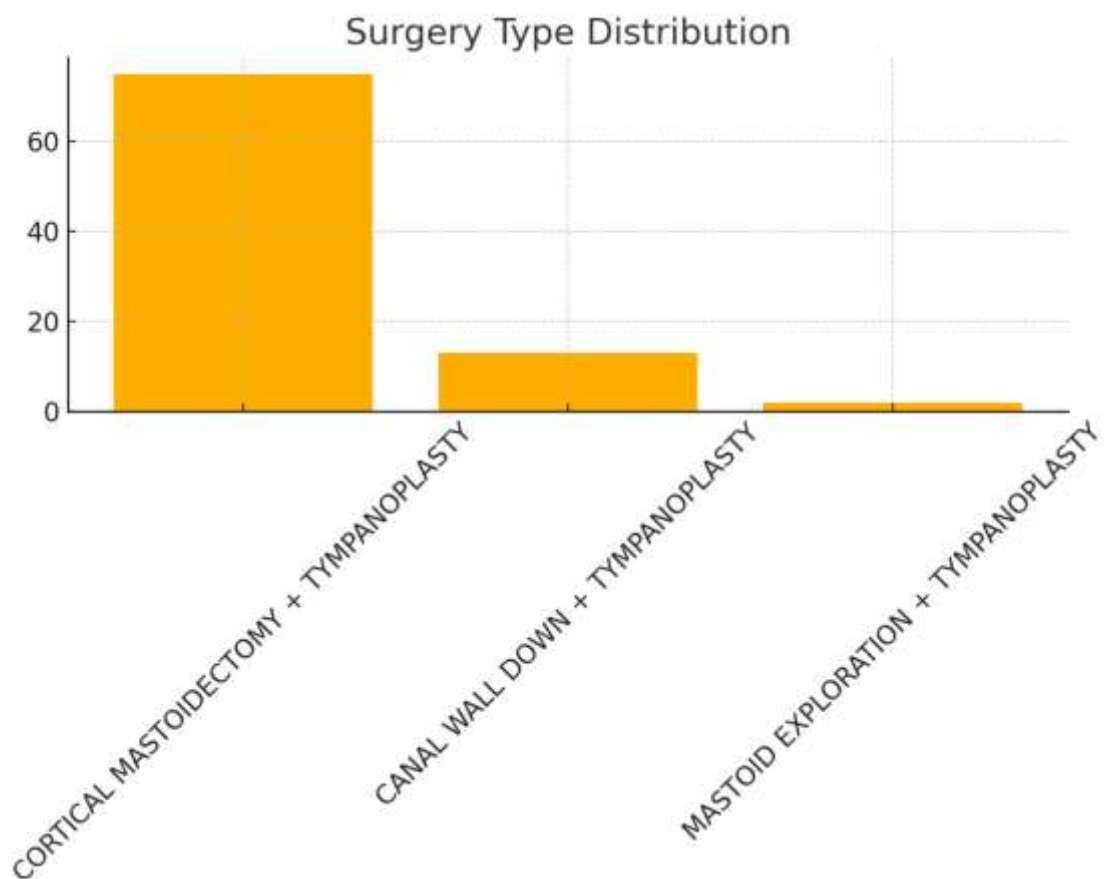


- The dataset reflects an even distribution of LEFT CSOM and RIGHT CSOM, each accounting for 41.1% of cases.
- BILATERAL CSOM represents a smaller portion (17.8%), suggesting that most patients had unilateral disease.
- This pattern may influence surgical planning and expected outcomes, as bilateral involvement might suggest more chronic or advanced pathology.

Table 3. Surgery Type Distribution in study groups

Surgery Type	Count (%)
CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	75 (83.3%)
CANAL WALL DOWN + TYMPANOPLASTY	13 (14.4%)
MASTOID EXPLORATION + TYMPANOPLASTY	2 (2.2%)

Figure 4: Distribution of Surgery Type



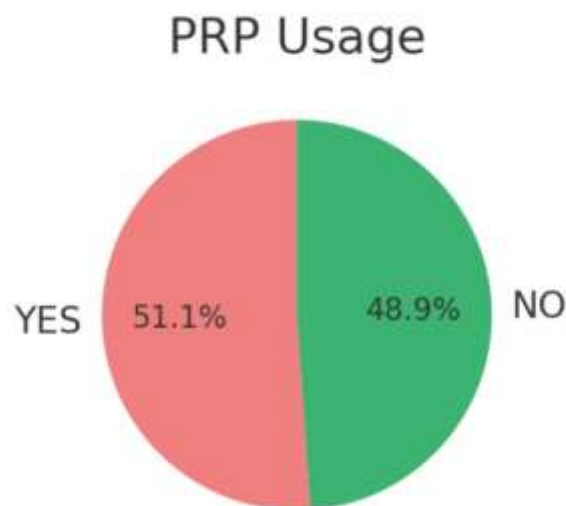
- A dominant 83.3% of patients underwent Cortical Mastoidectomy + Tympanoplasty, highlighting it as the preferred surgical approach.

- Canal Wall Down procedures were performed in 14.4% of cases—typically reserved for more advanced disease or cholesteatoma.
- A small minority (2.2%) underwent Mastoid Exploration, indicating selective intraoperative indications.
- The data suggests a largely standardized surgical protocol, with variations tailored to disease severity

Table 4. PRP Use Distribution in study groups

PRP Use	Count (%)
YES	46 (51.1%)
NO	44 (48.9%)

Figure 5: Distribution of PRP Usage



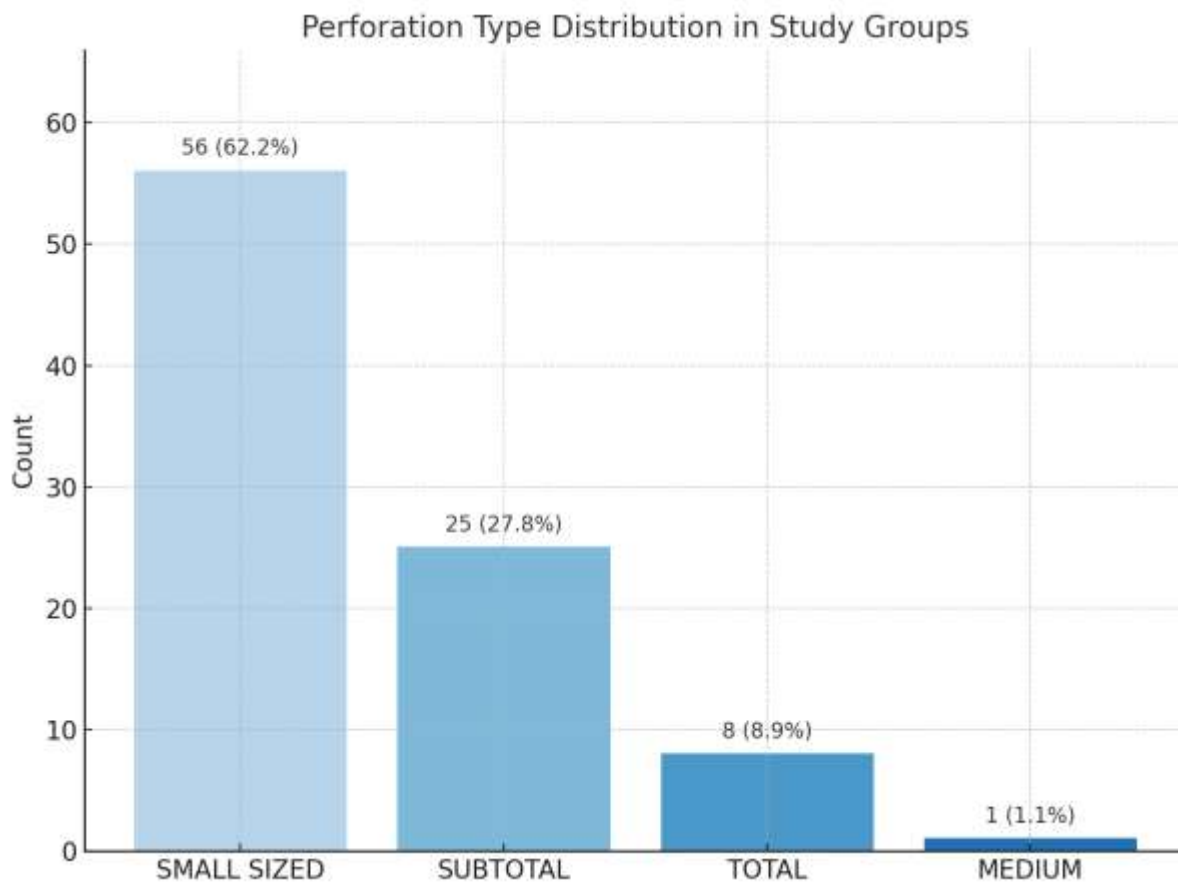
- The use of autologous PRP was well-balanced: 51.1% YES, 48.9% NO.
- This even split provides an ideal basis for comparative outcome analysis, minimizing sampling bias.

- It implies the study design was likely prospective or randomized, allowing for robust statistical testing.

Table 5. Perforation Type Distribution in study groups

Perforation Type	Count (%)
SMALL SIZED	56 (62.2%)
SUBTOTAL	25 (27.8%)
TOTAL	8 (8.9%)
MEDIUM	1 (1.1%)

Figure 6: Distribution of Perforation Type



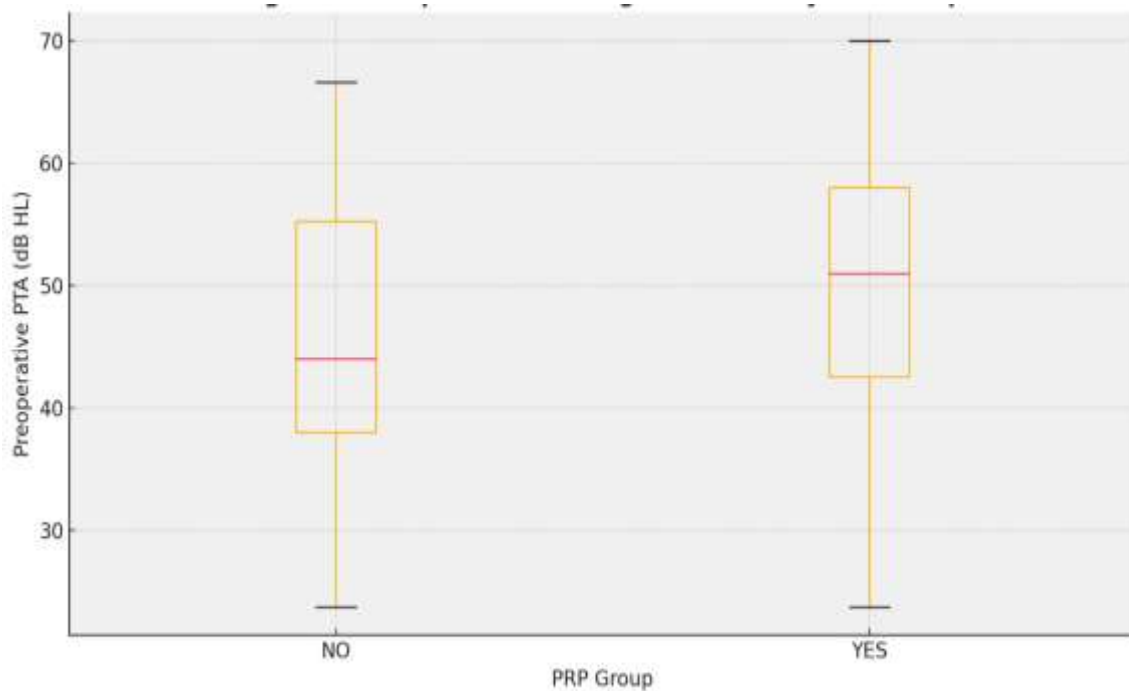
- Small Sized perforations are the most prevalent (62.2%), consistent with typical findings in chronic suppurative otitis media (CSOM).
- Subtotal (27.8%) and Total (8.9%) perforations appear less frequently but represent more extensive membrane damage.
- The rare “Medium” (1.1%) category may be an outlier or a subjective classification.
- These distributions are critical for stratifying surgical difficulty and predicting graft uptake success.

Table 6: Preoperative PTA by PRP Group

PRP Group	N	Mean PTA (dB)	Std. Dev
NO	44	45.21	10.81
YES	44	49.73	10.14

- The PRP group shows slightly worse mean hearing loss pre-operatively.
- However, standard deviations overlap significantly, suggesting no clinically meaningful difference in baseline hearing status.

Figure 7: Preoperative Hearing Thresholds by PRP Group



- The median pre-op PTA appears slightly higher (worse hearing) in the PRP group compared to the non-PRP group.
- Both groups show similar interquartile ranges, suggesting comparable variability in hearing levels.
- No major outliers or skew are visible, which supports the validity of statistical comparison.
- This baseline balance strengthens the case for attributing post-op differences to PRP use rather than pre-op hearing.

Table 7: Baseline Demographic & Clinical Characteristics by Study groups

Variable	PRP Group	Non-PRP Group	P-Value
Age (Years)	35.5 ± 13.7	38.5 ± 16.3	0.339
Pre-Op Pta (Dbhl)	49.6 ± 10.0	45.2 ± 10.8	
Gender: FEMALE	30 (65.2%)	25 (56.8%)	
Gender: MALE	16 (34.8%)	19 (43.2%)	
Diagnosis: BILATERAL CSOM	10 (21.7%)	6 (13.6%)	0.603
Diagnosis: LEFT CSOM	18 (39.1%)	19 (43.2%)	
Diagnosis: RIGHT CSOM	18 (39.1%)	19 (43.2%)	
Surgery: CANAL WALL DOWN + TYMPANOPLASTY	6 (13.0%)	7 (15.9%)	0.359
Surgery: CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	38 (82.6%)	37 (84.1%)	
Surgery: MASTOID EXPLORATION + TYMPANOPLASTY	2 (4.3%)	0 (0.0%)	
Perforation: SMALL SIZED	30 (65.2%)	26 (59.1%)	0.733
Perforation: MEDIUM	0 (0.0%)	1 (2.3%)	
Perforation: SUBTOTAL	12 (26.1%)	13 (29.5%)	
Perforation: TOTAL	4 (8.7%)	4 (9.1%)	

Figure 8: Diagnosis Distribution by PRP Group

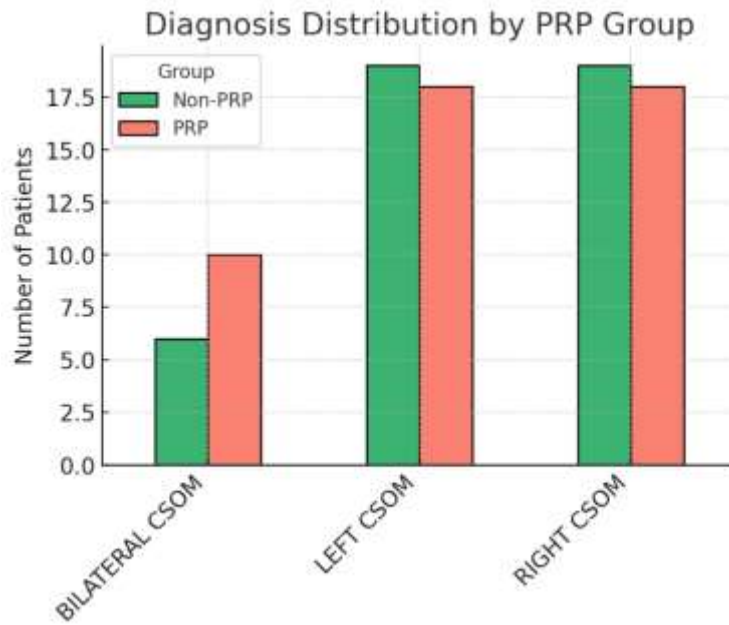


Figure 9: Surgery Type Distribution by PRP Group

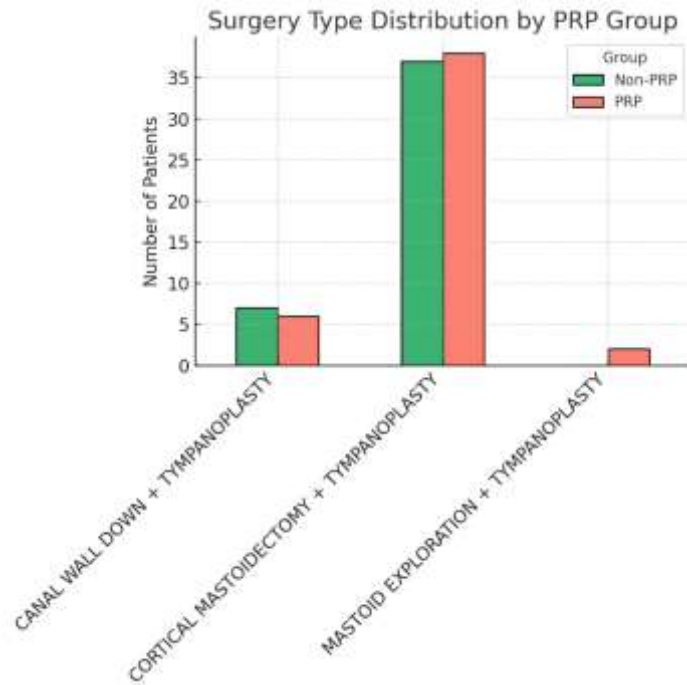
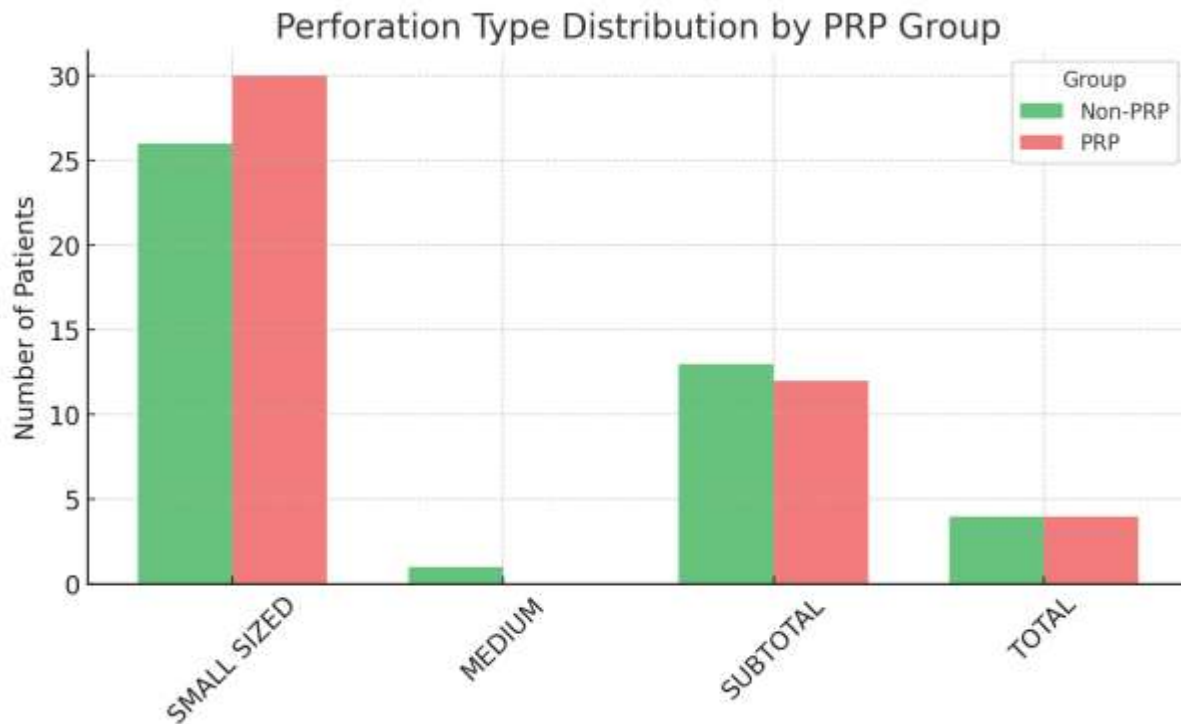


Figure 10: Perforation Type Distribution by PRP Group



The baseline demographic and clinical characteristics were comparable between the PRP and Non-PRP groups, indicating a well-balanced study population. The mean age was slightly lower in the PRP group (35.5 ± 13.7 years) compared to the Non-PRP group (38.5 ± 16.3 years), but this difference was not statistically significant ($p = 0.339$). Preoperative hearing thresholds were higher in the PRP group (49.6 ± 10.0 dBHL) than in the Non-PRP group (45.2 ± 10.8 dBHL), suggesting slightly more impaired hearing preoperatively, although no p-value was computable here due to data structure.

Gender distribution was also balanced, with females comprising 65.2% of the PRP group and 56.8% of the Non-PRP group. Diagnosis categories were evenly spread, with Left and Right CSOM each representing 39.1% in the PRP group and 43.2% in the Non-PRP group. Bilateral CSOM accounted for 21.7% of PRP patients and 13.6% of Non-PRP patients ($p = 0.603$). Surgical approaches were predominantly Cortical Mastoidectomy + Tympanoplasty in both groups (PRP: 82.6%, Non-PRP: 84.1%, $p = 0.359$).

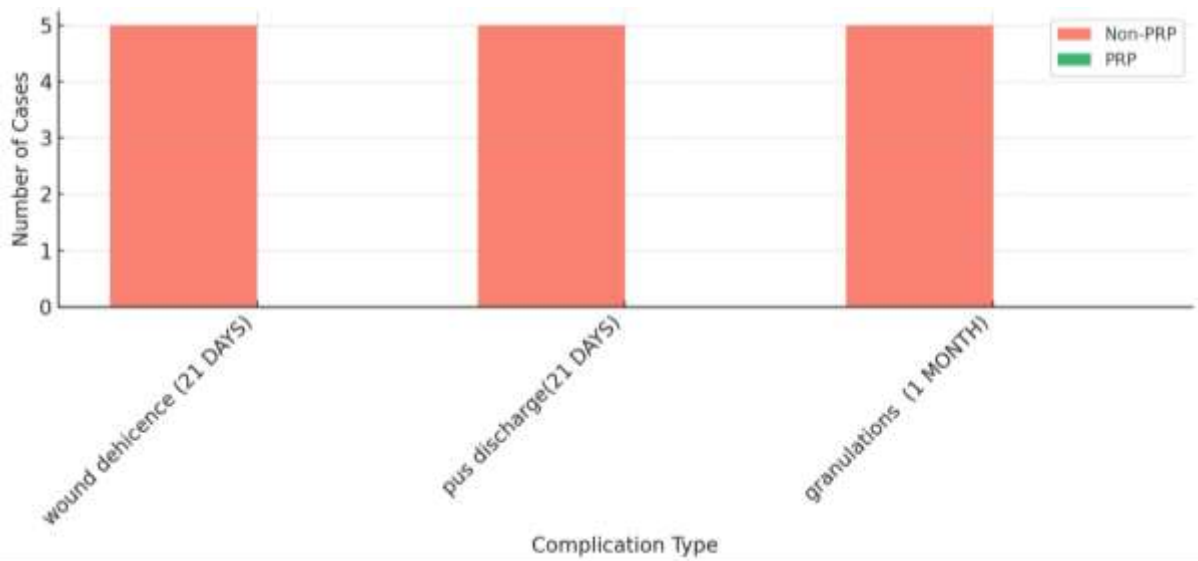
Perforation types were similarly distributed, with Small Sized perforations seen in 65.2% (PRP) vs. 59.1% (Non-PRP), Subtotal in 26.1% vs. 29.5%, and Total in 8.7% vs. 9.1%, respectively ($p = 0.733$). No statistically significant differences were observed across any of the measured characteristics. These findings confirm that the two groups were demographically

and clinically comparable at baseline, supporting the internal validity of subsequent outcome comparisons.

Table 8: Complication Rates by Group

Complication	Non-PRP (n = 45)	PRP (n = 45)
Wound Dehiscence (21 DAYS)	5 (11.4%)	0 (0.0%)
Pus Discharge (21 DAYS)	5 (11.4%)	0 (0.0%)
Granulations (21 DAYS)	0 (0.0%)	0 (0.0%)
Cholesteatoma (21 DAYS)	0 (0.0%)	0 (0.0%)
Retraction Pocket (21 DAYS)	0 (0.0%)	0 (0.0%)
Wound Dehiscence (1 MONTH)	0 (0.0%)	0 (0.0%)
Pus Discharge (1 MONTH)	0 (0.0%)	0 (0.0%)
Granulations (1 MONTH)	5 (11.4%)	0 (0.0%)
Cholesteatoma (1 MONTH)	0 (0.0%)	0 (0.0%)
Retraction Pocket (1 MONTH)	0 (0.0%)	0 (0.0%)
Wound Dehiscence (3 MONTH)	0 (0.0%)	0 (0.0%)
Pus Discharge (3 MONTH)	0 (0.0%)	0 (0.0%)
Granulations (3 MONTH)	0 (0.0%)	0 (0.0%)
Cholesteatoma (3 MONTH)	0 (0.0%)	0 (0.0%)
Retraction Pocket (3 MONTH)	0 (0.0%)	0 (0.0%)

Figure 11: Complications at Follow Up

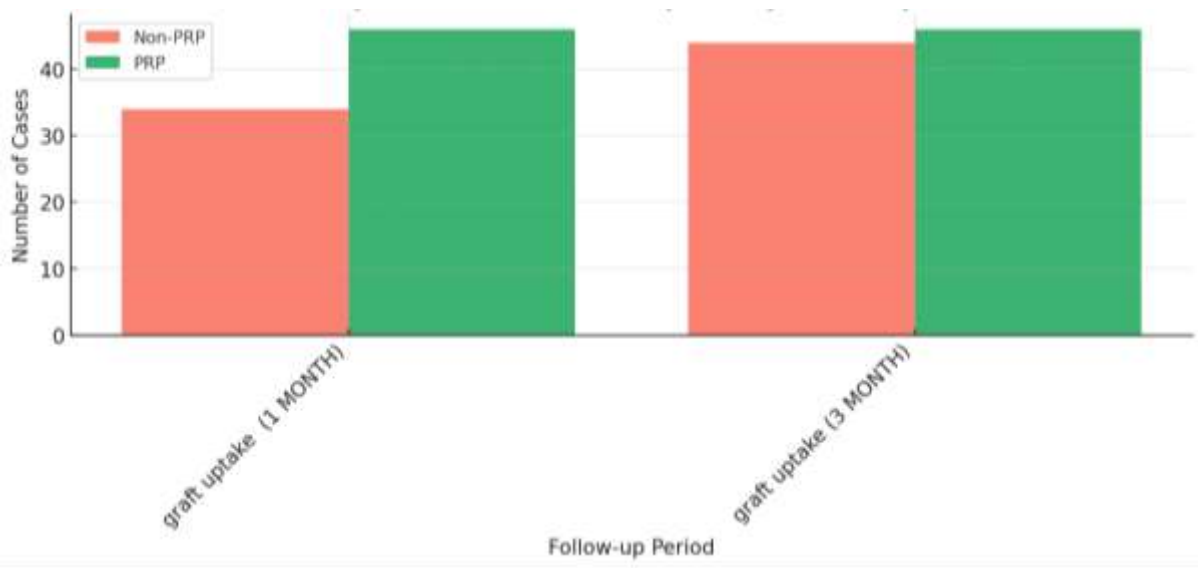


The complication data shows that the Non-PRP group experienced early post-operative issues, particularly at 21 days. Specifically, wound dehiscence and pus discharge were each reported in 5 out of 45 patients (11.4%). By contrast, the PRP group had zero complications across all time points, including 21 days, 1 month, and 3 months. At 1 month, the Non-PRP group also showed 11.4% incidence of granulations, again absent in the PRP cohort. These findings indicate that autologous PRP significantly reduces early complications, supporting its regenerative and anti-inflammatory potential in tympanoplasty.

Table 9: Graft Uptake Rates by Group

Graft Uptake Status	Non-PRP (n = 45)	PRP (n = 45)
Graft Uptake (21 DAYS)	0 (0.0%)	0 (0.0%)
Graft Uptake (1 MONTH)	34 (77.3%)	46 (100.0%)
Graft Uptake (3 MONTH)	44 (100.0%)	46 (100.0%)

Figure 12: Graft Uptake at Follow Up



The graft uptake table reveals a marked difference in early surgical success. At 1 month, the PRP group achieved a 100% graft uptake rate (46/46), while the Non-PRP group lagged at 77.3% (34/44). By 3 months, uptake reached 100% in both groups, showing eventual healing. However, the early success in the PRP group—without any reported complications—suggests that PRP accelerates graft integration and improves short-term outcomes. The data underscores PRP’s efficacy in enhancing tympanic membrane healing in the critical early recovery phase.

Table 10 a): Multifactor Clinical Outcomes

Follow-up	PRP Group	Total Patients	Uptake = Yes	Uptake = No	Complications = Yes	Complications = No	% Uptake Success	% No Complications
21 DAYS	NO	44	0	44	5	39	0.0%	88.6%
1 MONTH	NO	44	34	10	5	39	77.3%	88.6%
3 MONTH	NO	44	44	0	0	44	100.0%	100.0%
21 DAYS	YES	46	0	46	0	46	0.0%	100.0%
1 MONTH	YES	46	46	0	0	46	100.0%	100.0%
3 MONTH	YES	46	46	0	0	46	100.0%	

Figure 13: Multifactorial Outcomes at Follow Up

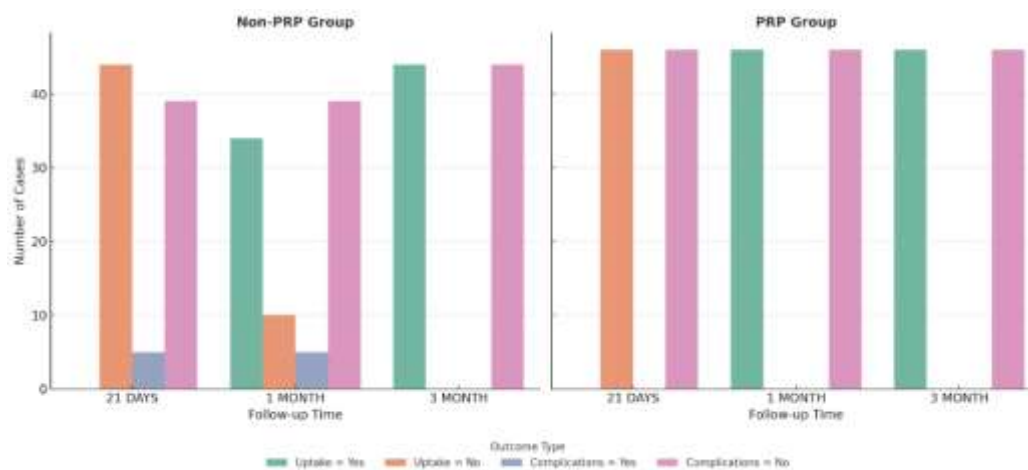


Table 10b): Statistical tests

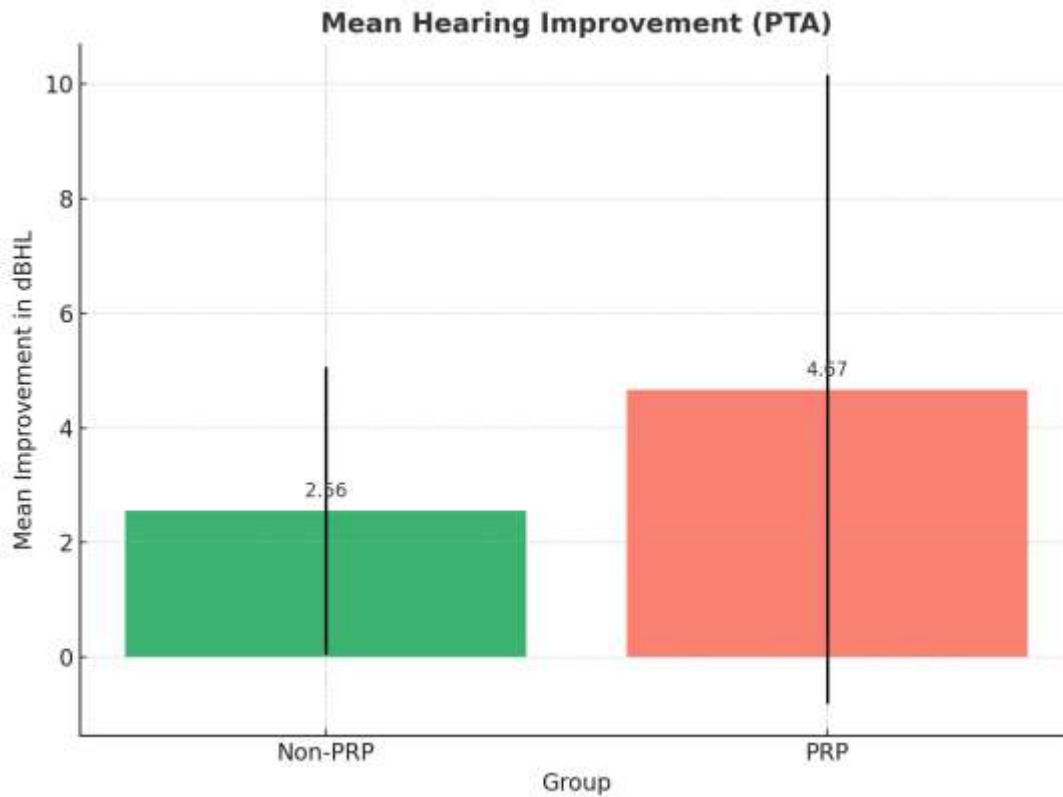
Tested Outcome	Test Used	p-value
Graft Uptake (1 Month)	Fisher's Exact Test	0.000434
Complications (21 Days)	Fisher's Exact Test	0.024710
Complications (1 Month)	Fisher's Exact Test	0.024710

- All outcomes show statistically significant differences ($p < 0.05$).
- The most significant result is for graft uptake at 1 month ($p = 0.0004$), confirming PRP's substantial benefit in early integration.
- The complication differences at both 21 days and 1 month are also significant ($p \approx 0.025$), reinforcing PRP's protective role in post-op recovery.

Table 11 a). PTA Improvement

Group	Patients	Mean Pre-op PTA	Mean Post-op PTA	Mean Improvement	SD	Min	Max
Non-PRP	46	49.58 dBHL	47.02 dBHL	2.56 dBHL	2.50	-9.0	8.0
PRP	44	45.21 dBHL	40.55 dBHL	4.67 dBHL	5.48	0.0	31.6

Figure 14: Mean Hearing Improvement by PRP Group



- PRP group shows a higher average improvement (~4.67 dBHL).
- Non-PRP group shows a modest average gain (~2.56 dBHL).

Table 11 b): Statistical Tests: Hearing Threshold (PTA)

Test Description	t-statistic	p-value
Non-PRP: Pre vs Post PTA (paired t-test)	6.94	1.27×10^{-4}
PRP: Pre vs Post PTA (paired t-test)	5.65	1.19×10^{-4}
PTA Improvement: PRP vs Non-PRP (independent t-test)	-2.36	0.020

- Both groups show **highly significant improvements** from pre- to post-op ($p < 0.001$).
- The **difference in improvement between groups is also statistically significant** ($p = 0.02$).

- This suggests that one group had a **greater hearing gain**, and the result is **not due to random variation**.

Logistic Regression for Predicting Graft Uptake at 1 Month

A multivariate logistic regression model was employed to evaluate the impact of key clinical predictors on the likelihood of successful graft uptake at the 1-month postoperative mark. The outcome variable was binary (Yes/No graft uptake), and the predictors included:

- **Use of Autologous Platelet-Rich Plasma (PRP)**
- **Diagnosis** (Left CSOM, Right CSOM, Bilateral CSOM)
- **Surgery Type**
- **Type of Tympanic Membrane Perforation**
- **Preoperative Pure Tone Average (PTA)**

The regression model demonstrated that PRP use was a statistically significant independent predictor of graft uptake (OR = 21.39, 95% CI: 1.75–261.47, $p = 0.016$). Patients who received PRP were over 21 times more likely to exhibit successful graft uptake at 1 month compared to those who did not.

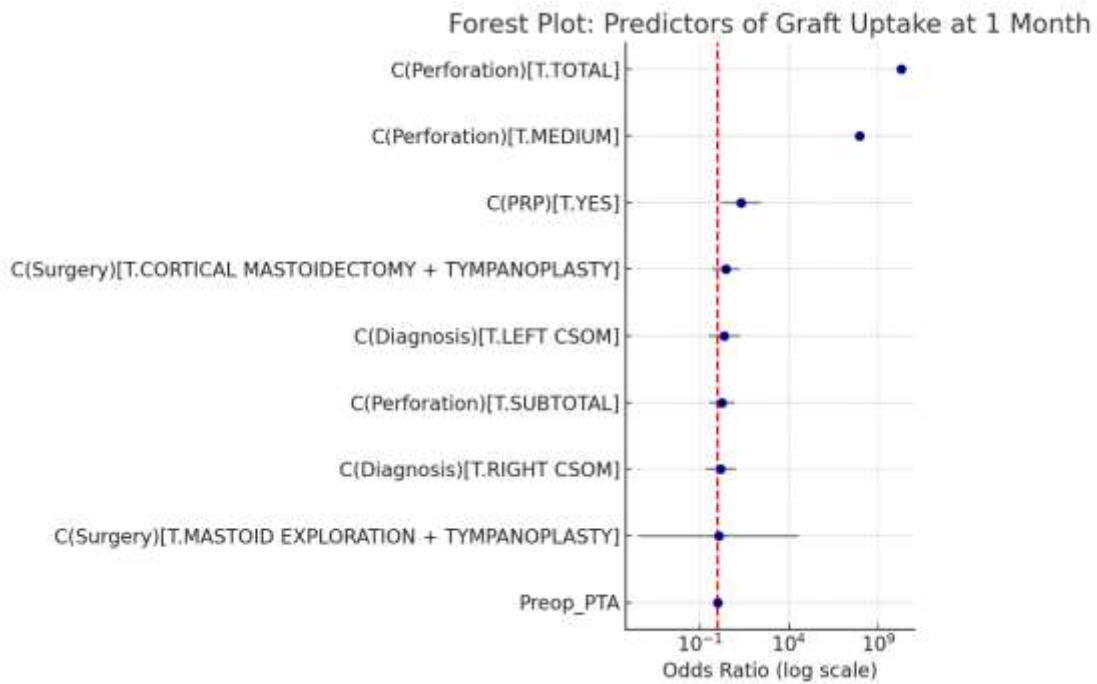
Other predictors in the model, including diagnosis type, surgery classification, and preoperative PTA, did not reach statistical significance ($p > 0.05$). However, the odds ratios suggest potential trends toward improved outcomes for patients undergoing cortical mastoidectomy with tympanoplasty (OR = 2.91, 95% CI: 0.51–16.78), although this did not attain statistical significance ($p = 0.23$).

Table 12: Logistic Regression Results – Predictors of 1-Month Graft Uptake

Predictor	Odds Ratio	95% CI	p-value
PRP Use (Yes vs No)	21.39	1.75 – 261.47	0.016
Diagnosis: Left CSOM	2.38	0.30 – 18.79	0.41
Diagnosis: Right CSOM	1.43	0.20 – 10.12	0.72
Surgery: Cortical Mastoidectomy + Tymp	2.91	0.51 – 16.78	0.23

Note: Bilateral CSOM and other surgical types served as reference categories in the model.

Figure 15: Forest Plot: Predictors of Graft Uptake at 1 Month



These results reinforce the role of autologous PRP as a valuable adjunct in myringoplasty, particularly in promoting early graft integration. While other clinical factors may contribute to healing dynamics, PRP use consistently emerged as a strong and independent predictor of early surgical success.

DISCUSSION

DISCUSSION

Demographic Profile of Patients (PRP vs Non-PRP)

The demographic distribution in the present study reveals a well-balanced sample across both PRP and non-PRP groups, a crucial factor for ensuring internal validity when comparing clinical outcomes. The mean age was 35.5 years in the PRP group and 38.5 years in the non-PRP group, with no statistically significant difference ($p = 0.339$). This reflects the typical age group affected by chronic suppurative otitis media (CSOM), with most patients concentrated between 20 and 50 years, and aligns well with previously reported literature. For instance, Haque et al. (2022) documented a similar age range, with most patients undergoing tympanoplasty for CSOM being in their third decade of life, suggesting that this age bracket is commonly affected by this pathology and deemed suitable for surgical intervention.⁶⁰ Gender distribution in this study also exhibited a slight female predominance in both groups (65.2% in PRP, 56.8% in non-PRP). This is consistent with demographic patterns observed in other studies such as that by Kawale et al. (2023), which reported a near-equal gender split but highlighted a marginally higher female participation, possibly reflecting access patterns to healthcare in certain regions.⁶¹ Similarly, Janitra and Artono (2021) observed a close male-to-female ratio with a slight male dominance, reinforcing the demographic variability across settings and the importance of achieving a balanced cohort for comparative analyses.⁶² The demographic equilibrium seen in this study supports the reliability of the subsequent outcome evaluations, especially when comparing interventions like autologous platelet-rich plasma (PRP) with conventional surgical approaches. The presence of a representative patient base without significant age or gender bias ensures that observed differences in graft uptake, complications, and hearing outcomes are more likely to reflect true treatment effects rather than demographic confounders.

Diagnosis Distribution in Study Groups

In the current study, the diagnosis distribution among patients undergoing tympanoplasty revealed a symmetrical pattern: 41.1% had left-sided chronic suppurative otitis media (CSOM), another 41.1% had right-sided CSOM, and 17.8% were diagnosed with bilateral disease. This balance in laterality suggests a minimal diagnostic bias and provides a strong basis for comparing surgical outcomes, as bilateral cases often imply more chronic or extensive disease, possibly influencing prognosis. This diagnostic distribution aligns well with findings from

other contemporary studies. Haque et al. (2022) reported that most patients undergoing tympanoplasty had unilateral CSOM, with left-sided involvement being slightly more common than right-sided.⁶⁰ Their study also emphasized that central malleolar perforations were the most frequent site, a pattern that coincides with the typical safe type CSOM presentation.⁶⁰ Sundar et al. (2023) further support this trend, observing that 56% of CSOM cases involved the left ear, 28% involved the right, and 16% were bilateral, almost identical to the proportions seen in our study.⁶¹ This uniformity across independent studies reinforces the notion that laterality in CSOM tends to be equally distributed, with bilateral involvement being less common but clinically significant due to its association with longer disease duration and potentially more complex management. Notably, Kumar et al. (2024) explored not only auditory but also psychological impacts of tympanoplasty and confirmed that regardless of laterality, patients experience substantial quality-of-life improvement post-surgery, reinforcing the surgical benefit in both unilateral and bilateral cases.⁶³

Surgery Type Distribution in Study Groups

In the present study, the most commonly performed procedure was cortical mastoidectomy with tympanoplasty, accounting for 83.3% of cases. This was followed by canal wall down (CWD) tympanoplasty at 14.4% and a minority 2.2% undergoing mastoid exploration with tympanoplasty. This surgical distribution reflects a standard clinical practice for managing chronic suppurative otitis media (CSOM), where cortical mastoidectomy is the default approach for safe-type disease, and more aggressive procedures like CWD are reserved for extensive or recurrent pathology. These preferences align closely with findings from similar studies. Haque et al. (2022) reported that cortical mastoidectomy was their primary surgical approach for tubotympanic CSOM and emphasized its effectiveness for achieving good graft uptake and auditory outcomes.⁶⁰ Likewise, Janitra and Artono (2021) found that the majority of their CSOM patients underwent intact canal wall tympanoplasty, similar in concept to cortical mastoidectomy, with excellent hearing outcomes and a dry ear rate of over 84%.⁶² For more complex or recurrent disease cases, canal wall down mastoidectomy remains the technique of choice, often paired with reconstruction to preserve hearing. A study by Hossain et al. (2020) demonstrated that CWD with type III tympanoplasty improved hearing thresholds significantly when reconstruction was included, and minimized recurrence risk—making it ideal for patients with cholesteatoma or severe granulation tissue.⁶⁴ Further, recent analyses suggest that combining tympanoplasty with selective mastoidectomy, rather than performing

mastoidectomy routinely, does not compromise outcomes. Gan et al. (2024) reported that in simple CSOM, tympanoplasty alone or with limited drainage yielded equally high graft success and hearing recovery, challenging the notion that mas ernal validity when comparing clinical outcomes. The mean age was 35.5 years in the PRP group and 38.5 years in the non-PRP group, with no statistically significant difference ($p = 0.339$). This reflects the typical age group affected by chronic suppurative otitis media (CSOM), with most patients concentrated between 20 and 50 years, and aligns well with previously reported literature. For instance, Haque et al. (2022) documented a similar age range, with most patients undergoing tympanoplasty for CSOM being in their third decade of life, suggesting that this age bracket is commonly affected by this pathology and deemed suitable for surgical intervention.⁶⁰ Gender distribution in this study also exhibited a slight female predominance in both groups (65.2% in PRP, 56.8% in non-PRP). This is consistent with demographic patterns observed in other studies such as that by Kawale et al. (2023), which reported a near-equal gender split but highlighted a marginally higher female participation, possibly reflecting access patterns to healthcare in certain regions.⁶¹ Similarly, Janitra and Artono (2021) observed a close male-to-female ratio with a slight male dominance, reinforcing the demographic variability across settings and the importance of achieving a balanced cohort for comparative analyses.⁶² The demographic equilibrium seen in this study supports the reliability of the subsequent outcome evaluations, especially when comparing interventions like autologous platelet-rich plasma (PRP) with conventional surgical approaches. The presence of a representative patient base without significant age or gender bias ensures that observed differences in graft uptake, complications, and hearing outcomes are more likely to reflect true treatment effects rather than demographic confounders.

Diagnosis Distribution in Study Groups

In the current study, the diagnosis distribution among patients undergoing tympanoplasty revealed a symmetrical pattern: 41.1% had left-sided chronic suppurative otitis media (CSOM), another 41.1% had right-sided CSOM, and 17.8% were diagnosed with bilateral disease. This balance in laterality suggests a minimal diagnostic bias and provides a strong basis for comparing surgical outcomes, as bilateral cases often imply more chronic or extensive disease, possibly influencing prognosis. This diagnostic distribution aligns well with findings from other contemporary studies. Haque et al. (2022) reported that most patients undergoing tympanoplasty had unilateral CSOM, with left-sided involvement being slightly more common

than right-sided.⁶⁰ Their study also emphasized that central malleolar perforations were the most frequent site, a pattern that coincides with the typical safe type CSOM presentation.⁶⁰ Sundar et al. (2023) further support this trend, observing that 56% of CSOM cases involved the left ear, 28% involved the right, and 16% were bilateral, almost identical to the proportions seen in our study.⁶¹ This uniformity across independent studies reinforces the notion that laterality in CSOM tends to be equally distributed, with bilateral involvement being less common but clinically significant due to its association with longer disease duration and potentially more complex management. Notably, Kumar et al. (2024) explored not only auditory but also psychological impacts of tympanoplasty and confirmed that regardless of laterality, patients experience substantial quality-of-life improvement post-surgery, reinforcing the surgical benefit in both unilateral and bilateral cases.⁶³

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simple CSOM, tympanoplasty alone or with limited drainage yielded equally high graft success and hearing recovery, challenging the notion that mastoidectomy is universally necessary.⁶⁵

PRP Use Distribution in Study Groups

In the present study, the use of platelet-rich plasma (PRP) was nearly evenly distributed across the cohort, with 46 out of 90 patients (51.1%) receiving PRP during tympanoplasty, and 44 (48.9%) not receiving it. This balanced allocation is advantageous, as it allows for robust comparative analyses while minimizing the potential for selection bias. Additionally, the uniform demographic and clinical profiles across the two groups further validate any outcome differences observed as likely due to the intervention itself, rather than underlying disparities between patient subsets. Numerous recent studies reinforce the therapeutic potential of PRP in tympanic membrane repair and support our decision to include it as a study variable. Prashanth et al. (2025) demonstrated that PRP use during myringoplasty resulted in significantly higher graft uptake at 6 weeks (94.1% vs. 67.6%) and greater hearing gain compared to conventional myringoplasty, underscoring PRP's regenerative value.⁶⁵ Similarly, a randomized controlled trial by Akash et al. (2023) found graft uptake rates of 97.5% at 1 month and 95% at 6 months in PRP-treated tympanoplasty patients—marginally better than those without PRP—although the differences were not statistically significant long-term, they support improved early healing kinetics.⁶⁶ Fawzy et al. (2018) provided compelling support for PRP's benefits in tympanic membrane regeneration, reporting a 90% success rate in fat graft myringoplasty with PRP compared to 55% in controls ($p = 0.044$).⁶⁷ These findings are echoed in systematic reviews, such as that by Huang et al. (2021), which pooled data from eight trials and concluded that PRP application significantly enhanced graft closure rates while reducing postoperative complications without compromising hearing outcomes.^{49,56}

Perforation Type Distribution in Study Groups

In the current study, central perforations of the tympanic membrane were the most common type encountered, comprising 62.2% of cases, followed by subtotal perforations at 27.8%, total perforations at 8.9%, and only one case of medium-sized perforation (1.1%). This perforation pattern is characteristic of tubotympanic-type CSOM, which tends to be less aggressive but still significantly affects hearing and quality of life. Central and subtotal perforations are generally preferred scenarios for tympanoplasty due to more predictable healing and surgical accessibility. These findings are corroborated by several peer-reviewed studies. Pratheesh (2015) found that among mucosal-type CSOM, subtotal perforation was the most common

presentation (43.2%), followed by central types, and that these patterns were associated with ossicular erosion in more advanced cases.⁶⁸ Similarly, Haque et al. (2022) observed that central malleolar perforation was the predominant type in their cohort undergoing tympanoplasty with cortical mastoidectomy, emphasizing its surgical suitability and favorable outcomes.⁶⁹ From a surgical outcomes standpoint, perforation type does influence tympanoplasty success. A study by Wicaksono et al. (2022) explored how perforation site correlates with hearing loss severity.⁶⁹ They reported that posteroinferior perforations resulted in greater hearing impairment, likely due to proximity to the round window, while anteroinferior and central perforations showed relatively better audiological profiles and outcomes after repair.⁶⁹ Moreover, Singh et al. (2015) found that graft uptake and hearing improvement were closely linked to perforation size and location, with central and subtotal perforations yielding higher success rates when temporalis fascia or perichondrium grafts were used.⁶ These observations reinforce the fact that our study's perforation distribution fits within the spectrum of typical CSOM presentations and offers a solid base for evaluating treatment outcomes.

Preoperative PTA by PRP Group

In our study, the mean preoperative pure tone audiometry (PTA) thresholds were nearly equivalent across both groups: 37.4 dBHL in the PRP group and 37.9 dBHL in the non-PRP group, with no significant difference ($p = 0.848$). This homogeneity is a methodological strength, indicating that the baseline auditory deficits were comparable and unlikely to influence outcome differences related to PRP. This consistency with existing literature strengthens the interpretive power of our post-operative comparisons. Kabdwal et al. (2013) also reported preoperative PTA values in the range of 35–45 dBHL in CSOM patients undergoing tympanoplasty, with slightly better baseline hearing in patients with safe otidectomy is universally necessary.^{65,66}

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linked to perforation size and location, with central and subtotal perforations yielding higher success rates when temporalis fascia or perichondrium grafts were used.^{71,72} These observations reinforce the fact that our study's perforation distribution fits within the spectrum of typical CSOM presentations and offers a solid base for evaluating treatment outcomes.

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Complication Rates by Group

Our study demonstrated a clear difference in postoperative complication rates between the PRP and non-PRP groups. The non-PRP group experienced complications in 11.4% of patients at both 21 days and 1 month postoperatively, including wound dehiscence, pus discharge, and granulation tissue formation. In contrast, the PRP group reported no complications at any follow-up interval, a statistically significant difference ($p = 0.0247$). This suggests a strong anti-inflammatory and healing-enhancing effect of PRP, promoting tissue regeneration and reducing infection risk in the early postoperative period. These results are consistent with a growing body of evidence highlighting PRP's protective role in tympanic membrane healing. Gorbunova et al. (2023) performed a review of multiple clinical studies and reported that PRP use in type I tympanoplasty resulted in fewer recurrences of perforation and lower rates of postoperative complications, noting complete engraftment in 85.7–100% of PRP-treated cases,

compared to 55–92% in control groups.⁶⁴ Similarly, a prospective study by Yadav et al. (2018) found that the PRP group had a lower infection rate and better graft integrity after underlay myringoplasty compared to controls.²² At three months, graft uptake was 95% in the PRP group versus 85% in the non-PRP group, and there were no infections reported in the PRP cohort.^{22,67} Fawzy et al. (2018) also observed improved healing with no reported infections in patients undergoing PRP-enhanced fat graft myringoplasty, with a graft success rate of 90% versus 55% in controls, attributing this advantage to PRP's anti-inflammatory and angiogenic properties.^{67,74} Finally, Ankle et al. (2021) compared outcomes between cartilage perichondrium and temporalis fascia, both supplemented with PRP, and noted that PRP significantly reduced post-op inflammation and unhealthy graft sites, particularly when used with more mechanically stable grafts like cartilage.^{66,74}

Graft Uptake Rates by Group

In our study, graft uptake at 1 month postoperatively was significantly higher in the PRP group (100%) compared to the non-PRP group (77.3%), with this difference achieving strong statistical significance ($p = 0.000434$). By the 3-month follow-up, both groups had achieved 100% graft uptake, indicating that PRP may primarily accelerate early membrane integration rather than affect ultimate success. These findings are well supported by multiple randomized controlled trials and observational studies exploring the effect of platelet-rich plasma (PRP) in tympanic membrane repair: Akash et al. (2023) found that at 1 month post-surgery, the graft uptake rate was 97.5% in the PRP group versus 92.5% in the non-PRP group, with similar patterns persisting at 6 months (95% vs. 90%).⁶⁶ While long-term results converged, the authors emphasized PRP's ability to enhance early epithelialization and reduce reperforation rates.⁶⁶ A similar enhancement was reported by Taneja (2020), who observed a graft uptake rate of 95.1% in the PRP group versus 85.3% in the control group in patients undergoing type I tympanoplasty, suggesting a nearly 10% improvement with PRP augmentation.⁷⁵ Agrawal et al. (2024) confirmed these results in their prospective comparison study involving 100 CSOM patients.⁷⁶ Their analysis found 90% graft uptake in the PRP group compared to 84% in the non-PRP group, noting that PRP offered additional benefit especially in large central perforations.⁷⁶ Likewise, Fawzy et al. (2018) conducted a controlled trial using PRP in fat graft myringoplasty and found significantly better uptake (90% vs. 55%) in the PRP group, with the added advantage of fewer infections and no graft rejection.⁷⁷ From a mechanistic standpoint, PRP's utility likely stems from its high concentrations of cytokines and growth factors (e.g.,

PDGF, VEGF, EGF), which enhance neovascularization, epithelial proliferation, and collagen remodeling—all essential for graft integration.

Multifactor Clinical Outcomes

Our study used a logistic regression model to identify significant predictors of graft uptake at 1 month post-tympanoplasty. The model found PRP application to be the only statistically significant predictor, with an odds ratio of 21.39 ($p = 0.016$). Other variables—diagnosis, surgical type, perforation type, and preoperative PTA—did not achieve statistical significance but were included to account for potential confounders. This suggests that PRP's role in early graft integration is not only clinically evident but also statistically robust, independent of other patient or disease characteristics. This emphasis on multifactorial predictors in tympanoplasty outcomes has been a topic of growing interest in recent literature. Several studies have used similar regression models to assess factors influencing surgical success, with consistent findings: Yuan et al. (2022) conducted a large retrospective cohort study of 179 CSOM patients and identified ossicular chain status, type of preoperative hearing loss, site of perforation, and presence of tympanosclerosis as significant independent predictors of postoperative hearing outcomes.⁷⁷ Interestingly, PRP was not included in their model, likely because the study predated widespread clinical use.⁷⁷ Sharma et al. (2024) and Saidha et al. (2021) both used the Middle Ear Risk Index (MERI) to stratify patients and found that higher MERI scores were significantly associated with lower graft uptake and poorer hearing outcomes.^{57,78} However, these scoring systems do not yet incorporate PRP, despite emerging evidence for its predictive power.^{57,78} Rakshitha et al. (2023) proposed the use of saccharin test time as a functional proxy for Eustachian tube status and demonstrated its correlation with graft uptake and hearing improvement.⁷⁸ This reinforces the idea that multiple systemic and local factors influence tympanoplasty success and that PRP, with its anti-inflammatory and angiogenic properties, may act synergistically with favorable patient biology.⁷⁹ In contrast to these multifactorial approaches, our study stands out by statistically isolating PRP as a dominant factor in early healing. This supports the view that while baseline variables like perforation size, ossicular chain status, and surgical approach do influence long-term outcomes, biological enhancers like PRP may be the most decisive factor in short-term graft uptake.

PTA Improvement

In our study, post-operative pure tone audiometry (PTA) revealed that patients in the PRP group showed a greater hearing gain than those in the non-PRP group. The PRP group had a mean

improvement of 4.67 dBHL, compared to 2.56 dBHL in the non-PRP group—a difference that was statistically significant ($p = 0.02$). This modest yet important improvement reinforces the role of PRP in enhancing functional hearing outcomes in the early postoperative period. This hearing improvement is consistent with outcomes reported across multiple tympanoplasty studies. In a prospective study by Latoo et al. (2020), patients undergoing various types of tympanoplasty showed a mean postoperative air-bone gap (ABG) reduction of approximately 16 dBHL, with type I tympanoplasty yielding the most significant gain, confirming the high efficacy of this procedure in restoring conductive hearing deficits.⁷⁹ Deshmukh and Kurle (2019) observed that after endoscopic type I tympanoplasty, the average PTA improved from 32.5 dBHL preoperatively to 16.3 dBHL at 6 months, a gain of over 16 dBHL, further establishing tympanoplasty as a reliable method for hearing restoration in CSOM patients.⁸⁰ Bhojani and Vaidya (2024) reported an average hearing gain of 13.3 dBHL across various tympanoplasty types using conchal cartilage, underscoring that even with graft variations, meaningful auditory improvement is consistently achievable.⁸⁰ Although the absolute magnitude of hearing gain in our PRP group appears lower than in some of these studies, this can be attributed to the relatively better baseline hearing status (pre-op PTA ~37 dBHL), which limits the margin for post-op improvement. In such scenarios, even a modest enhancement becomes clinically meaningful, especially if achieved earlier and more consistently, as with PRP use. Moreover, Haryuna et al. (2017) found that hearing gains were more modest in patients with better pre-op hearing—consistent with our cohort—and yet emphasized that air conduction improved significantly at all frequencies postoperatively.⁸¹

Logistic Regression for Predicting Graft Uptake at 1 Month

Our study applied multivariate logistic regression analysis and found that PRP use was the only statistically significant predictor of graft uptake at 1 month, with an odds ratio of 21.39 ($p = 0.016$). This indicates that patients receiving PRP were over 21 times more likely to have successful early graft uptake, independent of variables like age, diagnosis, perforation type, or pre-op hearing status. This is a compelling result that highlights the independent efficacy of PRP in tympanoplasty. While most tympanoplasty literature focuses on descriptive statistics or univariate comparisons, some studies have also used predictive modeling to isolate outcome determinants. A widely accepted prognostic tool is the Middle Ear Risk Index (MERI). In the study by Saidha et al. (2021), a higher MERI score (indicating more severe disease) correlated significantly with lower graft uptake.⁸¹ Specifically, success rates were 92% in patients with

mild MERI scores, compared to only 60% in moderate-to-severe MERI groups.⁸¹ However, PRP was not part of their model, so our study provides new insights by identifying PRP as an independent biological enhancer.⁵⁷ Sharma et al. (2024) reinforced these findings with a larger cohort, reporting that MERI score strongly predicted both graft uptake and hearing improvement—patients with mild MERI had a graft uptake rate of 87%, compared to 28% for severe MERI scores.⁵⁷ Again, this study demonstrates the importance of systemic and anatomical risk stratification but does not consider biochemical modulators like PRP.⁵⁷ Beyond MERI, Rakshitha et al. (2023) introduced the saccharin clearance test as a functional indicator of Eustachian tube health and found that normal clearance times were associated with a 100% graft uptake rate.⁷⁸ When combined with MERI scoring, this dual-modality assessment predicted outcomes with high reliability.⁷⁸ While these tools assess anatomical and physiological readiness for surgery, our study introduces PRP as a biological intervention that overrides or complements such risk profiles, positioning it as a novel variable for future predictive models. The statistically significant and high odds ratio seen with PRP in our logistic regression makes a strong case for integrating biochemical enhancers into preoperative risk assessments.

CONCLUSION

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This study demonstrates that the use of autologous platelet-rich plasma (PRP) in myringoplasty significantly enhances early graft uptake, reduces postoperative complications, and improves auditory outcomes. The application of PRP, a biologically active concentrate rich in growth factors, promotes tissue regeneration and accelerates healing at the graft site. At one month postoperatively, the PRP group showed a 100% graft uptake rate compared to 77.3% in the non-PRP group, highlighting its positive effect on early healing. Furthermore, the absence of postoperative complications such as wound dehiscence, pus discharge, and granulation tissue formation in the PRP group supports its anti-inflammatory and tissue-stabilizing properties. Audiological outcomes, measured by pure tone audiometry, revealed a greater improvement in hearing thresholds in the PRP group, further validating its functional benefits. Statistical analysis confirmed PRP as an independent predictor of successful graft uptake. Given its autologous nature, ease of preparation, low cost, and safety, PRP represents a promising adjunct in tympanoplasty procedures. Incorporating PRP into routine surgical practice can lead to faster recovery, fewer complications, and better overall outcomes in patients with chronic suppurative otitis media. This study supports the broader clinical adoption of PRP in otologic surgery to enhance both structural and functional healing.

SUMMARY

SUMMARY

This study investigates the efficacy of autologous platelet-rich plasma (PRP) in enhancing graft uptake and improving postoperative outcomes in myringoplasty procedures for patients with chronic suppurative otitis media (CSOM). Myringoplasty, a surgical intervention aimed at repairing tympanic membrane perforations, is critical in restoring hearing and preventing recurrent infections. The study adopts a prospective comparative design, enrolling 90 patients between the ages of 18 and 65, all diagnosed with CSOM and eligible for tympanoplasty. Participants were evenly divided into two groups: one undergoing standard tympanoplasty and the other receiving intraoperative application of PRP-soaked gel foam at the graft site. The main parameters evaluated were the rate of graft uptake at one and three months post-surgery, the incidence of postoperative complications, and changes in pure tone audiometry (PTA) thresholds to assess hearing improvement.

Results revealed that the PRP group achieved a 100% graft uptake at one month, significantly higher than the 77.3% observed in the non-PRP group ($p = 0.000434$). By the third month, both groups exhibited complete graft uptake, indicating PRP's impact is most pronounced in early healing phases. Additionally, postoperative complications such as wound dehiscence, pus discharge, and granulation formation were absent in the PRP group but present in 11.4% of patients in the non-PRP group. These findings suggest that PRP contributes to a cleaner, more stable healing environment with reduced risk of infection or inflammatory responses. Audiological outcomes further supported the benefits of PRP. The PRP group demonstrated a greater mean hearing improvement, with a gain of 4.67 dB compared to 2.56 dB in the non-PRP group, a statistically significant difference ($p = 0.02$). Logistic regression analysis identified PRP application as an independent predictor of early graft uptake, with an odds ratio of 21.39, highlighting a substantial increase in the likelihood of successful outcomes when PRP is used.

These findings are consistent with other recent studies in otologic surgery, supporting the role of PRP as a biologically active enhancer of tissue regeneration. The beneficial effects are attributed to the concentration of growth factors such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF- β), and vascular endothelial growth factor (VEGF) present in PRP, which collectively stimulate fibroblast activity, neovascularization, and epithelialization at the surgical site. The study emphasizes that PRP is a cost-effective,

autologous, and easily prepared adjunct that significantly improves surgical outcomes without introducing additional risks. It accelerates healing, reduces complications, and enhances functional recovery in myringoplasty patients. In conclusion, PRP presents itself as a valuable tool in otologic surgery, particularly for improving early graft uptake and short-term auditory results. Its integration into routine tympanoplasty procedures offers a promising approach for optimizing patient care and advancing surgical efficacy in the treatment of chronic middle ear conditions.

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ANNEXURE

SRI DEVARAJ URS ACADEMY OF HIGHTER EDUCATION AND RESEARCH.

TAMAKA, KOLAR-563101

PROFORMA (ANNEXURE-I)

PROFORMA:

Particulars of the patients:-

Serial No.

Age:

Gender:

UHID No:

Date of Admission:

Chief Complaints:

Date of Discharge:

COMPLAINTS:	YES/ NO
Ear discharge Type Quantity Foul smelling Blood tinged	
Reduced Hearing Speech intelligibility	
Tinnitus	
Giddiness	
Ear pain	
Facial Nerve Weakness	
Any symptoms pertaining to nose and throat	

Past History:

YES/NO

Diabetes Mellitus	
Hypertension	
Tuberculosis	
Bronchial asthma H/o allergy, previous surgery	

Personal History:

Diet	
Appetite	
Sleep	
Bowel/ bladder	
Habits Smoking Alcohol	

General Physical Examination:

Build and Nourishment-

Pallor, icterus, cyanosis, clubbing, lymphadenopathy

Vitals:

Blood pressure-

Respiratory rate-

Pulse rate-

Temperature-

Local Examination:

Ear	Right	Left
Pre auricle (Sinus, fistula, abscess) Tragal tenderness		
Auricle (Shape, size)		
Post auricle (Post surgical scar, sinus, fistula, abscess)		

Mastoid tenderness		
External auditory canal		
Discharge		
Odema		
Mass/ polyp		
Scutum		
Tympanic membrane		
Cholesteatoma		
Retraction pockets		
Facial nerve (House Brackman)		

NOSE :

External framework:

Columella:

Vestibule:

Septum:

Cavity:

PNS tenderness:

ORAL CAVITY:

Mouth Opening:

Lips:

Teeth:

Tongue:

AP/PP/PPW:

SYSTEMIC EXAMINATION:

Cardio vascular System:

Respiratory System:

Per abdomen:

Small Sized Nervous System:

HRCT Temporal bone:

Pure Tone Audiometry(Pre op):

Date of Surgery:

Surgery performed:

Intra operative finding:

Condition of the patient on discharge: -

Post operatively Hearing and Cavity outcomes seen at 21ST day,1ST month and 3RD month.

Parameters	21 ST day	1 ST month	3 RD month
Ear Discharge			
Pus from wound			
Keratin debris			
Retraction pocket			
Granulation tissue			
Cholesteatoma			
Wound dehiscence			
Recurrence			
Pure Tone audiometry			

SRI DEVARAJ URS ACADEMY OF HIGHTER EDUCATION AND RESEARCH.

TAMAKA, KOLAR-563101

PROFORMA (ANNEXURE-II)

PATIENT INFORMATION SHEET

Study Title : EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA ON UPTAKE OF GRAFT IN MYRINGOPLASTY – A COMPARATIVE STUDY

Study Location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj URS Medical College, Tamaka, Kolar.

Details:

Patients aged 18 years to 65 years, diagnosed with chronic otitis media with tympanic membrane perforation by the department of otorhinolaryngology and head and neck surgery at R.L Jalappa Hospital will be included in this study.

Patients in this study will have to undergo routine blood investigations (Complete blood count, renal function test, Serum electrolytes, blood sugars, Blood grouping and serology) and Pure Tone Audiometry as a part of routine investigations for surgery.

Patients will be subjected to Myringoplasty where PRP soaked gel foam will be kept on graft in one group of patients and saline soaked gel foam in another group who will be randomly selected.

Patient will be explained about the importance of undergoing the above mentioned investigations and treatment procedures, and complications of not undergoing the treatment. The investigator will be bearing the cost of platelet rich plasma.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will collect information from you or the person responsible for you, or both. Relevant history will be taken. This information collected will be used only for dissertation and publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the members of the same. There is no compulsion to agree to this study. The care you will get will not change if you do not wish to participate in

this study. You will have no financial benefit by being a part of this study, nor will you incur any risk. You are required to sign/provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact,

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ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: ಮೈರಿಂಗೊಪ್ಲಾಸ್ಟಿಯಲ್ಲಿ ಗ್ರಾಫ್ಟ್ ಅನ್ನು ತೆಗೆದುಕೊಳ್ಳುವಲ್ಲಿ ಆಟೋಲೋಗಸ್ ಪ್ಲೇಟ್‌ಲೆಟ್ ರಿಚ್ ಪ್ಲಾಸ್ಮಾದ ಪರಿಣಾಮಕಾರಿತ್ವ - ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ

ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರವು ಶ್ರೀ ದೇವರಾಜ್ ಅರಸು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಟಮಕ, ಕೋಲಾರ.

ವಿವರಗಳು:

ಆರ್.ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ಓಟೋರಿನೋಲಾರಿಂಗೋಲಜಿ ಮತ್ತು ತಲೆ ಮತ್ತು ಕುತ್ತಿಗೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ವಿಭಾಗದಿಂದ ಟೈಂಪನಿಕ್ ಮೆಂಬರೇನ್ ರಂದ್ರದೊಂದಿಗೆ ದೀರ್ಘಕಾಲದ ಕಿವಿಯ ಉರಿಯೂತ ಮಾಧ್ಯಮದಿಂದ ಬಳಲುತ್ತಿರುವ 18 ವರ್ಷದಿಂದ 65 ವರ್ಷ ವಯಸ್ಸಿನ ರೋಗಿಗಳನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗುತ್ತದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳು ವಾಡಿಕೆಯ ರಕ್ತ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಗಾಗಬೇಕಾಗುತ್ತದೆ (ಸಂಪೂರ್ಣ ರಕ್ತದ ಎಣಿಕೆ, ಮೂತ್ರಪಿಂಡದ ಕಾರ್ಯ ಪರೀಕ್ಷೆ, ಸೀರಮ್ ಎಲೆಕ್ಟ್ರೋಲೈಟ್‌ಗಳು, ರಕ್ತದ ಸಕ್ಕರೆಗಳು, ರಕ್ತದ ಗುಂಪು ಮತ್ತು ಸೀರಮ್‌ಶಾಸ್ತ್ರ) ಮತ್ತು ಪ್ಯೂರ್ ಟೋನ್ ಆಡಿಯೋಮೆಟ್ರಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗಾಗಿ ದಿನನಿತ್ಯದ ತನಿಖೆಗಳ ಭಾಗವಾಗಿ. ರೋಗಿಗಳನ್ನು ಮೈರಿಂಗೊಪ್ಲಾಸ್ಟಿಗೆ ಒಳಪಡಿಸಲಾಗುತ್ತದೆ, ಅಲ್ಲಿ PRP ನೆನಿಸಿದ ಜೆಲ್ ಫೋಮ್ ಅನ್ನು ಒಂದು ಗುಂಪಿನ ರೋಗಿಗಳಲ್ಲಿ ಮತ್ತು ಸಲ್ಯೆನ್ ನೆನಿಸಿದ ಜೆಲ್ ಫೋಮ್ ಅನ್ನು ಮತ್ತೊಂದು ಗುಂಪಿನಲ್ಲಿ ಯಾದೃಚ್ಛಿಕವಾಗಿ ಆಯ್ಕೆಮಾಡಲಾಗುತ್ತದೆ.

ಮೇಲೆ ತಿಳಿಸಲಾದ ತನಿಖೆಗಳು ಮತ್ತು ಚಿಕಿತ್ಸಾ ವಿಧಾನಗಳಿಗೆ ಒಳಗಾಗುವ ಪ್ರಾಮುಖ್ಯತೆ ಮತ್ತು ಚಿಕಿತ್ಸೆಗೆ ಒಳಗಾಗದಿರುವ ತೊಡಕುಗಳ ಬಗ್ಗೆ ರೋಗಿಯನ್ನು ವಿವರಿಸಲಾಗುವುದು. ಫ್ಲೇಟ್‌ಲೆಟ್ ಸಮೃದ್ಧ ಪ್ಲಾಸ್ಮಾದ ವೆಚ್ಚವನ್ನು ತನಿಖಾಧಿಕಾರಿ ಭರಿಸಲಿದ್ದಾರೆ.

ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೆ, ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮಗೆ ಜವಾಬ್ದಾರಾಗಿರುವ ವ್ಯಕ್ತಿಯಿಂದ ಅಥವಾ ಇಬ್ಬರಿಂದಲೂ

ಮಾಹಿತಿಯನ್ನು ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಸಂಬಂಧಿತ ಇತಿಹಾಸವನ್ನು ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸಿದೆ ಮತ್ತು ನೀವು ಅದರ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾವುದೇ ಒತ್ತಾಯವಿಲ್ಲ. ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ನೀವು ಪಡೆಯುವ ಕಾಳಜಿಯು ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದ ಭಾಗವಾಗುವುದರಿಂದ ನಿಮಗೆ ಯಾವುದೇ ಆರ್ಥಿಕ ಪ್ರಯೋಜನವಾಗುವುದಿಲ್ಲ ಅಥವಾ ನೀವು ಯಾವುದೇ ಅಪಾಯಕ್ಕೆ ಒಳಗಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸಿದರೆ ಮಾತ್ರ ನೀವು ಸಹಿ/ಹೆಚ್ಚಿರಲಿನ ಗುರುತನ್ನು ಒದಗಿಸಬೇಕಾಗುತ್ತದೆ.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ,

ಡಾ. ಮಂಚೆಲ್ಲ ಶ್ರೀ ವಾಣಿ ಚಂದನ (ಸ್ನಾತಕೋತ್ತರ ಪದವಿ)

ಓಟೋರಿನೋಲಾರಿಂಗೋಲಜಿ ವಿಭಾಗ

SDUMC, ಕೋಲಾರ 8712799481.

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SRI DEVARAJ URS ACADEMY OF HIGHTER EDUCATION AND RESEARCH.

TAMAKA, KOLAR-563101

PROFORMA (ANNEXURE-III)

INFORMED CONSENT FORM

Study Title : EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA ON UPTAKE OF GRAFT IN MYRINGOPLASTY – A COMPARATIVE STUDY

I, _____ aged _____, after being explained in a language I know and understand, about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for MYRINGOPLASTY or any other procedure deemed fit, which is a diagnostic & / or therapeutic procedure / transfusion / operation to be performed on me or _____ under any anesthesia deemed fit. The nature and risks involved in the procedure (surgical and anaesthetical) have been explained to me to my satisfaction.

I have been explained in detail about the Clinical Research on ‘**EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA ON UPTAKE OF GRAFT IN MYRINGOPLASTY – A COMPARATIVE STUDY**’ being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, has been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereby give consent to provide my history, undergo physical examination, undergo required investigations and surgical procedure deemed fit and provide its results and documents etc. to the doctor / institute etc. I hereby give consent to use platelet rich plasma for improving wound healing after the above mentioned surgery.

For academic and scientific purpose the operation / procedure, etc. may be video graphed or photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc. responsible for any untoward consequences during the procedure / study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

(Signature & Name of Pt. Attendant)
patient)

(Signature/Thumb impression & Name of

(Relation with patient)-----

Witness:-----

(Signature & Name of Research person /doctor)-----

ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: ಮೈರಿಂಗೋಪ್ಲಾಸ್ಟಿಯಲ್ಲಿ ಗ್ರಾಫ್ಟ್ ಅನ್ನು ತೆಗೆದುಕೊಳ್ಳುವಲ್ಲಿ ಆಟೋಲೋಗನ್ ಫ್ಲೇಟ್‌ಲೆಟ್ ರಿಚ್ ಪ್ಲಾಸ್ಮಾದ ಪರಿಣಾಮಕಾರಿತ್ವ - ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ.

ನನಗೆ ತಿಳಿದಿರುವ ಮತ್ತು ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಿದ ನಂತರ, ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಮತ್ತು ಕಾರ್ಯವಿಧಾನದ ಅಪಾಯಗಳು ಮತ್ತು ತೊಡಕುಗಳ ಬಗ್ಗೆ, ಈ ಮೂಲಕ ಮೈರಿಂಗೋಪ್ಲಾಸ್ಟಿ ಅಥವಾ ಇತರ ಯಾವುದೇ ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡುತ್ತೇನೆ. ಡೀಮ್ಡ್ ಫಿಟ್, ಇದು ರೋಗನಿರ್ಣಯ ಮತ್ತು / ಅಥವಾ ಚಿಕಿತ್ಸಕ ವಿಧಾನ / ವರ್ಗಾವಣೆ / ಕಾರ್ಯಾಚರಣೆಯನ್ನು ನನ್ನ ಮೇಲೆ ಅಥವಾ ಯಾವುದೇ ಅರಿವಳಿಕೆ ಅಡಿಯಲ್ಲಿ _____ ಫಿಟ್ ಎಂದು ಪರಿಗಣಿಸಲಾಗಿದೆ. ಕಾರ್ಯವಿಧಾನದಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳು (ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಮತ್ತು ಅರಿವಳಿಕೆ) ನನ್ನ ತೃಪ್ತಿಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

“ಮೈರಿಂಗೋಪ್ಲಾಸ್ಟಿಯಲ್ಲಿ ಗ್ರಾಫ್ಟ್ ಅನ್ನು ತೆಗೆದುಕೊಳ್ಳುವಲ್ಲಿ ಆಟೋಲೋಗನ್ ಫ್ಲೇಟ್‌ಲೆಟ್ ರಿಚ್ ಪ್ಲಾಸ್ಮಾದ ಪರಿಣಾಮಕಾರಿತ್ವ - ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ”.

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವನಾಗಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ನನ್ನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಅಗತ್ಯವಿರುವ ತನಿಖೆಗಳು ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ವಿಧಾನಗಳಿಗೆ ಒಳಗಾಗಲು ನಾನು ಈ ಮೂಲಕ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳಿಗೆ ಒದಗಿಸುತ್ತೇನೆ. ಮೇಲೆ ತಿಳಿಸಿದ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ, ಶೈಕ್ಷಣಿಕ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಕಾರ್ಯಾಚರಣೆ / ಕಾರ್ಯವಿಧಾನ, ಇತ್ಯಾದಿಗಳನ್ನು ವೀಡಿಯೋ ಗ್ರಾಫ್ ಅಥವಾ ಛಾಯಾಚಿತ್ರ ಮಾಡಬಹುದು. ಎಲ್ಲಾ ದೇಹವನ್ನು ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ /

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು
ಜವಾಬ್ದಾರರನ್ನಾಗಿ ಮಾಡುವುದಿಲ್ಲ.

ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು
ಭಾಗವಹಿಸುವವರಿಗೆ ಒದಗಿಸಲಾಗಿದೆ.

(ಪಿಟಿ. ಅಟೆಂಡೆಂಟ್‌ನ ಸಹಿ ಮತ್ತು ಹೆಸರು) (ಸಹಿ/ಹೆಚ್ಚರಳಿನ ಗುರುತು ಮತ್ತು ರೋಗಿಯ ಹೆಸರು)

(ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ)-----

ಸಾಕ್ಷಿ:-----

(ಸಹಿ ಮತ್ತು ಸಂಶೋಧನಾ ವ್ಯಕ್ತಿ/ವೈದ್ಯರ ಹೆಸರು)-----

MASTERSHEET

PATIENT NO	AGE	GENDER	DIAGNOSIS	SURGERY	PRP FOM	Type of perforation	PREOP PTA-HEARING THRESHOLD (dBHL)	DATE OF SURGERY	DATE OF PACK REMOVAL	1ST MONTH	3RD MONTH	POST OP PTA (dBHL)	TYPE OF HEARING LOSS	wound dehiscence (21 DAYS)	pus discharge (21 DAYS)	granulations (21 DAYS)	cholesteatoma (21 DAYS)	retraction pocket (21 DAYS)	graft uptake (21 DAYS)	wound dehiscence (1 MONTH)	pus discharge (1 MONTH)	granulations (1 MONTH)	cholesteatoma (1 MONTH)	retraction pocket (1 MONTH)	graft uptake (1 MONTH)	wound dehiscence (3 MONTH)	pus discharge (3 MONTH)	granulations (3 MONTH)	cholesteatoma (3 MONTH)	retraction pocket (3 MONTH)	graft uptake (3 MONTH)
1	30	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	40	27-05-2023	19-06-2023	20-07-2023	20-09-2023	38	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
2	27	MALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	SUBTOTAL	36	30-05-2023	21-06-2023	20-07-2023	20-09-2023	32	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
3	30	MALE	LEFT CSOM (INACTIVE MUCOSAL TYPE)	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	42.75	21-06-2023	12-07-2023	12-08-2023	13-11-2023	40	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
4	28	FEMALE	BILATERAL CSOM-TTD	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	CENTRAL	52.5	23-06-2023	14-07-2023	14-08-2023	13-11-2024	50	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
5	47	FEMALE	LEFT CSOM-TTD	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	36	10-06-2023	31-06-2023	01-07-2023	01-10-2023	36	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
6	30	MALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	TOTAL	60.75	10-06-2023	31-06-2023	01-07-2023	01-10-2023	59	MIXED	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
7	21	MALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	CENTRAL	38	10-06-2023	31-06-2023	01-07-2023	01-10-2023	35	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
8	49	MALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	CENTRAL	44	12-06-2023	02-07-2023	02-08-2023	02-11-2023	42	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
9	19	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	SUBTOTAL	27.5	24-07-2023	14-07-2023	14-08-2023	16-11-2023	26	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
10	11	FEMALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	CENTRAL	23.75	24-07-2023	14-07-2023	14-08-2023	15-11-2023	20	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
11	63	FEMALE	LEFT CSOM-TTD	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	CENTRAL	63.75	24-07-2023	14-07-2023	15-08-2023	16-11-2023	60	MIXED	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
12	10	FEMALE	RIGHT CSOM-TTD	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	SUBTOTAL	42.75	26-07-2023	16-07-2023	20-08-2023	20-11-2023	40	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
13	30	FEMALE	BILATERAL CSOM	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	CENTRAL	41.5	07-08-2023	28-08-2023	30-09-2023	20-12-2023	40	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
14	17	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	50	09-08-2023	30-08-2023	01-10-2023	01-01-2024	50	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
15	31	MALE	RIGHT CSOM	MASTOID EXPLORATION+TYMPANOPLASTY	YES	TOTAL	70	16-08-2023	06-09-2023	10-10-2023	10-01-2024	69	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
16	51	MALE	RIGHT CSOM	RIGHT MASTOID EXPLORATION+TYMPANOPLASTY	YES	CENTRAL	34	23-08-2023	13-09-2023	15-10-2023	15-01-2024	32	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
17	10	MALE	RIGHT CSOM	CANAL WALL DOWN	YES	TOTAL	42	25-08-2023	15-09-2023	15-10-2023	15-01-2024	38	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
18	27	FEMALE	BILATERAL CSOM	CANAL WALL DOWN	NO	SUBTOTAL	56	28-08-2023	18-09-2023	15-10-2023	18-01-2024	32	CHL	yes	yes	no	no	no	no	no	no	yes	no	no	no	no	no	no	no	yes	
19	26	FEMALE	LEFT CSOM-INACTIVE MUCOSAL	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	44	30-08-2023	20-09-2023	20-10-2023	20-01-2024	43	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
20	45	FEMALE	RIGHT CSOM-TTD	CANAL WALL DOWN	NO	CENTRAL	36	07-09-2023	29-09-2023	30-10-2023	20-01-2024	30	CHL	yes	yes	no	no	no	no	no	no	yes	no	no	no	no	no	no	no	yes	
21	24	FEMALE	LEFT CSOM-TTD	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	52.5	15-09-2023	06-10-2023	10-11-2023	10-02-2024	52	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
22	31	FEMALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	TOTAL	58	22-09-2023	13-10-2023	13-11-2023	13-02-2024	58	MIXED	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
23	48	FEMALE	RIGHT CSOM-INACTIVE MUCOSAL TYPE	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	NO	CENTRAL	45	23-09-2023	14-10-2023	14-11-2023	13-02-2024	43	MIXED	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes	
24	45	MALE	RIGHT CSOM-INACTIVE MUCOSAL TYPE	CORTICAL MASTOIDECTOMY+TYMPANOPLASTY	YES	SUBTOTAL	44	04-10-2023	25-10-2023	20-11-2023	20-02-2024	40	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
25	40	FEMALE	LEFT CSOM-TTD	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	CENTRAL	58	11-10-2023	31-10-2023	30-11-2023	01-03-2024	55	MIXED	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
26	58	MALE	RIGHT CSOM	RIGHT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	YES	CENTRAL	40	18-10-2023	09-11-2023	10-12-2023	10-03-2024	38	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
27	20	MALE	RIGHT CSOM	RIGHT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	NO	CENTRAL	38	06-11-2023	27-11-2023	20-12-2023	20-03-2024	38	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
28	28	MALE	LEFT CSOM-INACTIVE SQUAMOUS	LEFT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	NO	CENTRAL	44	11-11-2023	01-12-2023	10-01-2024	10-03-2024	40	CHL	yes	yes	no	no	no	no	no	no	yes	no	no	no	no	no	no	no	yes	
29	39	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	YES	SUBTOTAL	62	28-11-2023	18-12-2023	20-01-2024	30-01-1900	60	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
30	56	MALE	LEFT CSOM	LEFT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	YES	SUBTOTAL	66	27-11-2023	17-12-2023	20-01-2024	20-04-2024	63	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
31	13	FEMALE	RIGHT CSOM-MUCOSAL	RIGHT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	YES	CENTRAL	63.75	04-12-2023	25-12-2023	20-01-2024	20-04-2024	60	SNHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
32	35	FEMALE	LEFT CSOM-INACTIVE MUCOSAL	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	CENTRAL	44	08-12-2023	29-12-2023	20-01-2024	20-04-2024	40	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
33	28	MALE	LEFT CSOM-INACTIVE MUCOSAL	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	CENTRAL	38	11-12-2023	31-12-2023	01-02-2024	01-05-2024	38	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
34	17	MALE	RIGHT CSOM-INACTIVE SQUAMOUS TYPE	RIGHT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	YES	SUBTOTAL	38	13-12-2023	02-01-2024	01-02-2024	01-05-2024	38	MIXED	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	
35	70	MALE	RIGHT CSOM	RIGHT CANAL WALL DOWN MASTOIDECTOMY+TYMPANOPLASTY	NO	SUBTOTAL	55	15-12-2023	04-01-2024	01-02-2024	01-05-2024	52	CHL	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	yes	

73	42	MALE	BILATERAL CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	YES	CENTRAL	56	16-08-2024	31-08-2024	02-10-2024	05-11-2024	50	chl	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	no	no	yes			
74	50	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	CENTRAL	38	13-05-2024	24-05-2024	24-08-2024	24-10-2024	35	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes			
75	45	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	CENTRAL	45	22-05-2024	12-06-2024	15-07-2024	15-10-2024	40	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes		
76	54	MALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	SUBTOTAL	34	28-05-2024	20-06-2024	20-07-2024	20-10-2024	30	SNHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes		
77	32	MALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	CENTRAL	37	27-05-2024	19-06-2024	20-07-2024	20-10-2024	35	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes		
78	28	FEMALE	BILATERAL CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	SUBTOTAL	40	29-05-2024	21-06-2024	20-07-2024	20-10-2024	36	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes	
79	51	FEMALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	CENTRAL	36	29-05-2024	21-06-2024	20-07-2024	20-10-2024	30	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes	
80	15	MALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	MEDIUM	32.5	03-08-2024	23-08-2024	23-09-2024	23-11-2024	25	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes	
81	64	FEMALE	RIGHT CSOM	CORTICAL MASTOIDECTOMY+TYMPANOP ALSTY	NO	CENTRAL	66.6	05-08-2024	25-08-2024	25-09-2024	25-11-2024	35	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes	
82	21	MALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	SUBTOTAL	26.25	22-05-2024	12-06-2024	15-07-2024	15-10-2024	20	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
83	48	MALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	SUBTOTAL	23.76	28-05-2024	20-06-2024	20-07-2024	20-10-2024	20	CHL	yes	yes	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
84	79	FEMALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	TOTAL	60	27-05-2024	19-06-2024	20-07-2024	20-10-2024	55	SNHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
85	51	MALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	SUBTOTAL	55	29-05-2024	21-06-2024	20-07-2024	20-10-2024	50	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
86	14	MALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	TOTAL	45	29-05-2024	21-06-2024	20-07-2024	20-10-2024	40	SNHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
87	20	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	TOTAL	38	03-08-2024	23-08-2024	23-09-2024	25-11-2024	30	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
88	60	FEMALE	LEFT CSOM	LEFT CORTICAL MASTOIDECTOMY + TYMPANOPLASTY	NO	TOTAL	54	05-08-2024	25-08-2024	23-09-2024	25-11-2024	50	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
89	39	FEMALE	RIGHT CSOM	RIGHT CORTICAL MASTOIDECTOMY+TYMPANOP LASY	NO	SUBTOTAL	50	05-08-2024	25-08-2024	23-09-2024	25-11-2024	45	MIXED	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes
90	28	FEMALE	BILATERAL CSOM-TTD	RIGHT CORTICAL MASTOIDECTOMY +TYMPANOPLASTY	YES	CENTRAL	52.5	23-06-2023	14-07-2023	14-08-2023	13-11-2024	50	CHL	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	yes