A COMPARATIVE STUDY TO DETERMINE THE OUTCOMES FOLLOWING TYPE 1 TYMPANOPLASTY WITH AND WITHOUT EXTERIORISATION OF HANDLE OF MALLEUS IN CHRONIC OTITIS MEDIA – MUCOSAL TYPE

By

DR. ASMITHA.N

DISSERTATION SUBMITTED TO

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTRE, KOLAR

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY

IN

OTORHINOLARYNGOLOGY

Under the guidance of

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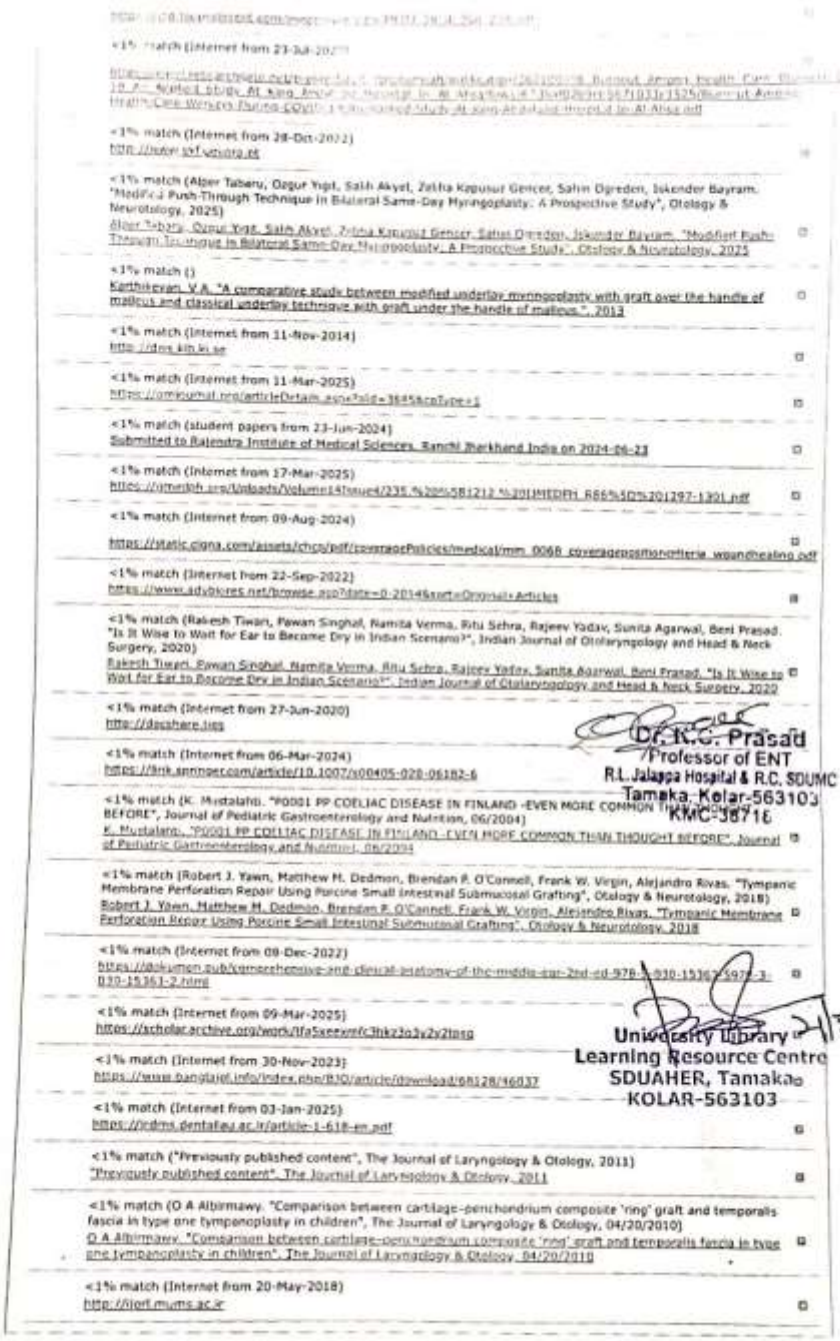

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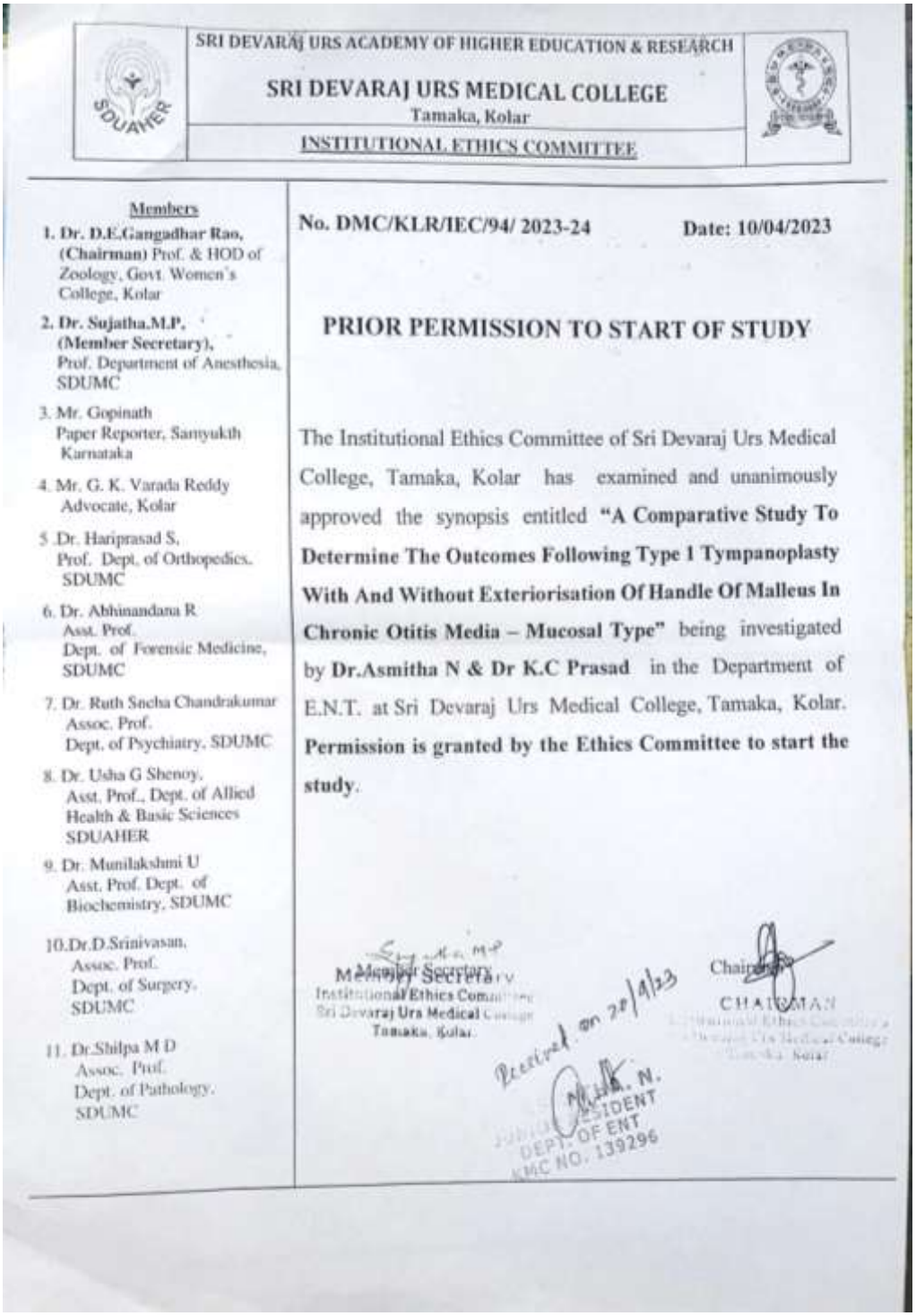

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The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the synopsis entitled **"A Comparative Study To Determine The Outcomes Following Type 1 Tympanoplasty With And Without Exteriorisation Of Handle Of Malleus In Chronic Otitis Media – Mucosal Type"** being investigated by **Dr.Asmitha N & Dr K.C Prasad** in the Department of E.N.T. at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.**

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Lastly I thank almighty for the tremendous blessing.

DR. ASMITHA N

LIST OF ABBREVIATIONS

S.NO	ABBREVATION	EXPANSION
1	ABG	Air-Bone Gap
2	AC	Air Conduction
3	ANOVA	Analysis of Variance
4	BC	Bone Conduction
5	COM	Chronic Otitis Media
6	CRS	Chronic Rhinosinusitis
7	CRSsNP	Chronic Rhinosinusitis without Nasal Polyps
8	CRSwNP	Chronic Rhinosinusitis with Nasal Polyps
9	CSOM	Chronic Suppurative Otitis Media
10	CT	Computed Tomography
11	dB	Decibel
12	DALYs	Disability-Adjusted Life Years
13	Df	Degrees of Freedom (in statistical tests)
14	ENT	Ear, Nose, and Throat
15	FESS	Functional Endoscopic Sinus Surgery
16	Hz	Hertz

17	kHz	Kilohertz
18	Mm	Millimeter (unit of measurement)
19	mm^2	Square Millimeter (unit of area)
20	N	Sample Size (Number of subjects or observations)
21	NPPCD	National Programme for Prevention and Control of Deafness
22	p / p-value	Probability Value (Statistical Significance)
23	PRP	Platelet-Rich Plasma
24	RCT(s)	Randomized Controlled Trial(s)
25	SD	Standard Deviation
26	Std. Deviation	Standard Deviation
27	Std. Error Mean	Standard Error of the Mean
28	TM	Tympanic Membrane
29	UMBO	The central point of the TM where the malleus handle attaches
30	V3	Mandibular Nerve, Third Division (Trigeminal Nerve)

ABSTRACT

ABSTRACT

Background: Chronic otitis media (COM) mucosal type is a persistent inflammatory condition of the middle ear, commonly seen in low- and middle-income countries. It is characterized by tympanic membrane (TM) perforation and recurrent otorrhea. Type 1 tympanoplasty is the preferred surgical treatment aimed at restoring TM integrity and improving hearing. A key surgical variation is the placement of the graft in relation to the malleus handle—either medial (underlay) or lateral (exteriorisation). This study compares outcomes of type 1 tympanoplasty with and without malleus handle exteriorisation.

Study type: Prospective comparative study

Methods: Fifty-six patients with COM mucosal type were alternately assigned into two groups. Group A underwent tympanoplasty with malleus handle exteriorisation, and Group B without it. Preoperative evaluations included otomicroscopy, otoendoscopy, pure tone audiometry, and high-resolution CT of the temporal bone. Postoperative follow-up occurred on day 21, and at 3 and 6 months, using audiometry and endoscopic examinations. Data were statistically analyzed for hearing outcomes and graft uptake**.**

Results: Group A showed significantly better postoperative air conduction at 3 months ($p = 0.011$) and a near-significant improvement in bone conduction at 6 months ($p = 0.055$). Intra-group comparisons revealed significant improvements in all hearing parameters in Group A, while Group B showed significance only in ABG improvement. Graft uptake at 6 months was higher in Group A (93.1%) than Group B (81.5%), though not statistically significant ($p = 0.204$).

Conclusion: Exteriorisation of the malleus handle during type 1 tympanoplasty may enhance early postoperative hearing outcomes and promote more consistent auditory recovery. Although graft uptake differences were not statistically significant, higher success rates in the exteriorisation group suggest potential clinical benefits. Larger studies are warranted to validate these findings.

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INTRODUCTION

Introduction

Chronic otitis media (COM) mucosal type, often referred to as tubotympanic disease, represents a persistent inflammatory condition affecting the middle ear, distinguished by the hallmark features of tympanic membrane (TM) perforation and either intermittent or chronic otorrhea, notably in the absence of cholesteatoma formation[1]. This condition arises from prolonged or recurrent middle ear infections, typically initiated by untreated or inadequately managed acute otitis media, leading to structural damage of the TM and mucosal lining. Globally, COM mucosal type imposes a substantial health burden, with its prevalence and impact magnified in low- and middle-income countries such as India, where epidemiological studies estimate its occurrence to range between 6% and 12% [2]. This elevated prevalence in India can be attributed to a confluence of socioeconomic factors, including poverty, overcrowding, poor hygiene practices, limited access to clean water, and inadequate healthcare infrastructure, all of which exacerbate the risk of chronic ear infections and their sequelae. These conditions create an environment where infections persist, progressing from acute to chronic states, ultimately necessitating surgical intervention in many cases.

The primary therapeutic approach to address COM mucosal type, particularly when the ossicular chain remains intact, is type 1 tympanoplasty, a surgical procedure designed to repair the perforated TM and restore both its anatomical integrity and functional capacity . This intervention, also known as myringoplasty in certain contexts, focuses on closing the perforation using a graft material—commonly temporalis fascia, cartilage, or perichondrium—to reestablish a barrier between the external auditory canal and the middle ear space. The success of type 1 tympanoplasty is evaluated through two principal outcome measures: the anatomical success, reflected by the rate of graft uptake and closure of the perforation, and the functional success, gauged by the degree of postoperative hearing improvement, typically quantified as a reduction in the air-bone gap (ABG) on audiometric testing[3]. These outcomes, however, are not uniform and are heavily influenced by a variety of factors, including the size and location of the perforation, the condition of the middle ear mucosa (wet versus dry ear), the choice of graft material, and, crucially, the surgical technique employed. Variations in surgical

approach—such as the underlay versus overlay methods, the use of endoscopic versus microscopic techniques, and the management of ossicular landmarks like the malleus handle—introduce complexity into predicting and optimizing these results. Central to the anatomical and functional dynamics of the TM is the handle of the malleus (manubrium), a key ossicular component embedded within the fibrous layer of the TM, extending from the umbo at its tip to the lateral process near its superior attachment . The malleus handle serves as a structural anchor, contributing to the TM's conical shape and vibratory properties, which are essential for efficient sound transmission from the external environment to the inner ear via the ossicular chain. During tympanoplasty, the positioning and management of the malleus handle become critical considerations, as its relationship with the graft can influence both the stability of the repair and the restoration of hearing. One emerging technique, the exteriorisation of the malleus handle, involves meticulous dissection of the surrounding tissue to expose the manubrium, followed by placement of the graft lateral to it rather than medial, as is typical in traditional underlay approaches[4,5]. Proponents of this method argue that exteriorisation enhances outcomes by optimizing the mechanical properties of the reconstructed TM, improving graft adherence to the TM remnant, and potentially augmenting sound conduction by maintaining or even enhancing the natural conical configuration of the membrane. The rationale is grounded in the belief that positioning the graft lateral to the malleus handle may better mimic the native TM's anatomy, thereby facilitating more effective vibration and reducing the risk of postoperative complications such as graft medialization or blunting.

Despite its theoretical advantages, the efficacy of exteriorisation of the malleus handle compared to conventional techniques, remains insufficiently explored in the literature. Traditional underlay tympanoplasty, widely regarded as the gold standard due to its technical simplicity and high success rates, positions the graft beneath the TM remnant and malleus handle, relying on the natural support of these structures to secure the repair. In contrast, exteriorisation introduces additional surgical steps, including careful dissection around the malleus, which may increase operative time and technical demand. The question of whether this added complexity translates into superior outcomes—either anatomically, in terms of graft uptake, or

functionally, in terms of hearing improvement—remains unanswered, as comparative studies specifically addressing this modification are scarce. This gap in evidence underscores the need for a systematic investigation to delineate the benefits and limitations of exteriorisation, particularly in the context of COM mucosal type, where patient-specific factors such as perforation characteristics and middle ear status further complicate outcome prediction.

The present study is designed to address this knowledge deficit by conducting a comparative analysis of type 1 tympanoplasty performed with and without exteriorisation of the malleus handle in patients diagnosed with COM mucosal type. The investigation focuses on two primary endpoints: anatomical success, defined as the successful uptake of the graft and closure of the TM perforation at follow-up, and functional success, measured as the improvement in hearing thresholds post-surgery, typically expressed as a reduction in the ABG. By juxtaposing these two techniques within a controlled cohort, this study aims to provide empirical data on whether exteriorisation offers a tangible advantage over the conventional approach, potentially informing surgical decision-making and refining operative strategies.

The choice of COM mucosal type as the study population is deliberate, as this subtype of chronic ear disease presents unique challenges—such as persistent mucosal inflammation and variable perforation sizes—that may differentially impact the success of these techniques. Furthermore, the exclusion of cholesteatoma ensures a focus on cases where the ossicular chain is intact, isolating the effect of malleus handle management from confounding factors like ossicular erosion or reconstruction.

The significance of this research extends beyond mere technical comparison, as it touches on broader clinical and public health implications. Hearing loss secondary to COM is a major contributor to disability worldwide, particularly in regions where access to timely treatment is limited. In such settings, optimizing surgical outcomes becomes paramount, not only to restore individual function but also to alleviate the socioeconomic burden of untreated ear disease. The handle of the malleus, though a small anatomical structure, may hold the key to unlocking improved results in tympanoplasty, especially if its exteriorisation proves to enhance graft stability or hearing restoration. However, the adoption of this

technique must be balanced against its feasibility in diverse clinical settings, including those with limited resources or expertise, where simpler methods may remain preferable. This study, therefore, seeks to bridge the gap between theoretical promise and practical application, offering a rigorous assessment that could guide ENT surgeons in tailoring their approach to individual patient needs.

Justification and Relevance of the Study in India/Karnataka

In India, chronic otitis media represents a significant public health challenge, with an estimated prevalence of approximately 7.8% across the population, a figure that rises sharply in rural and tribal communities where access to healthcare is curtailed[6]. This high burden is driven by a constellation of risk factors, including recurrent upper respiratory infections in childhood, malnutrition, poor sanitation, and overcrowding, all of which are prevalent in India's diverse socioeconomic landscape. The consequences of untreated COM are profound, ranging from persistent ear discharge and hearing impairment to rare but severe complications such as mastoiditis or intracranial infections. For many affected individuals, hearing loss becomes a lifelong disability, impairing communication, education, and employment opportunities, thereby perpetuating cycles of poverty and marginalization. In this context, surgical interventions like type 1 tympanoplasty emerge as critical tools not only for clinical management but also for socioeconomic upliftment, making their optimization a pressing priority.

Karnataka, a state in southern India, exemplifies the urban-rural disparities that characterize the country's healthcare challenges and provides a compelling case study for this research. With urban centers like Bengaluru boasting advanced medical facilities, contrasted against rural districts such as Bidar and Raichur where basic healthcare remains scarce; Karnataka reflects the broader Indian experience of uneven resource distribution. In these rural areas, the incidence of COM is notably elevated, a phenomenon linked to poor sanitation infrastructure, limited access to clean water, and delays in seeking or receiving medical care. For instance, children in these regions often experience recurrent ear infections that go untreated due to the absence of local ENT services, allowing the disease to progress to a chronic state. By the time patients reach tertiary care centers—often after months or years of symptoms—the TM perforation and associated hearing loss are well-established,

necessitating surgical correction. This delay not only worsens clinical outcomes but also increases the complexity of surgical management, as chronic inflammation may lead to mucosal changes or scarring that challenge graft success.

Compounding this issue is the shortage of ENT specialists in Karnataka's rural areas, where the ratio is estimated at approximately 1 per 100,000 population, far below the national average and woefully inadequate for the disease burden[8]. This scarcity places a premium on surgical techniques that are both effective and efficient, minimizing the need for revision surgeries that strain limited resources.

Type 1 tympanoplasty, as a relatively straightforward procedure, is widely performed across India, including in Karnataka, often in government hospitals or charitable institutions where cost considerations are paramount. However, the lack of standardization in surgical techniques—particularly regarding modifications like malleus handle exteriorisation—introduces variability in outcomes that may undermine its potential. For instance, although the underlay technique is preferred due to its ease of use and dependability, it may not work as well in situations with large perforations or anterior defects, where the position of the malleus handle may affect the stability of the graft. Despite being more technically complex, exteriorization may be advantageous in many situations, but its adoption is inconsistent because of a lack of training and data.

The relevance of this study in the Indian and Karnatakan context lies in its potential to address these disparities and refine clinical practice. By systematically comparing tympanoplasty with and without malleus handle exteriorisation, this research could identify a technique that maximizes graft uptake and hearing improvement, reducing the likelihood of revision surgeries—a critical consideration in settings where follow-up care is logistically challenging. Revision surgeries, often required due to graft failure or recurrent perforation, impose significant financial and emotional burdens on patients, particularly in rural Karnataka, where travel to urban centers for treatment can cost families a substantial portion of their income. A technique that enhances primary success rates could thus alleviate this burden, aligning with broader public health goals to reduce the disability-adjusted life years (DALYs) associated with hearing loss, as outlined in India's National Health Mission[9]. Hearing loss, even when conductive and surgically correctable,

contributes significantly to DALYs in India, where it ranks among the top causes of non-fatal disability, affecting quality of life and economic productivity.

Moreover, the findings of this study could have implications for training and policy in Karnataka and beyond. If exteriorisation proves superior, its integration into surgical curricula for ENT trainees could standardize its use, ensuring that even surgeons in peripheral hospitals are equipped to perform it effectively. Conversely, if no significant benefit is found, resources could be redirected toward improving access to basic tympanoplasty services rather than investing in advanced modifications. In either scenario, the evidence generated would inform resource allocation, a critical issue in a state where healthcare budgets are stretched thin. For instance, Karnataka's rural health centers often lack operating microscopes or trained audiologists, limiting the scope of tympanoplasty to larger hospitals. An optimized technique that works within these constraints could extend the reach of effective treatment, benefiting underserved populations.

The broader relevance of this study extends to India's national health priorities, where reducing the burden of preventable hearing loss is a recognized goal. The National Programme for Prevention and Control of Deafness (NPPCD), launched under the National Health Mission, emphasizes early intervention and rehabilitation for ear diseases, yet surgical optimization remains an underexplored avenue. By focusing on a technique that could enhance tympanoplasty outcomes, this study aligns with these objectives, offering a pathway to reduce the prevalence of chronic ear disease sequelae in high-burden regions like Karnataka. Furthermore, the socioeconomic implications are profound: improved hearing can enhance educational attainment and employability, breaking the cycle of poverty that COM often perpetuates in rural India.

In conclusion, this comparative study of type 1 tympanoplasty with and without malleus handle exteriorisation addresses a critical gap in the surgical management of COM mucosal type, with particular relevance to Low middle income countries like India. By evaluating anatomical and functional outcomes, it seeks to provide evidence that could refine clinical practice, improve patient prognosis, and inform health policy in a resource-limited setting. The handle of the malleus, though a minor anatomical detail, may prove a major determinant of success, offering a

small but significant step toward alleviating the burden of chronic ear disease in one of the world's most affected regions.

REVIEW OF LITERATURE

Review of Literature

Anatomy of the Middle Ear and Tympanic Membrane

The middle ear is a marvel of anatomical engineering, serving as a critical intermediary in the auditory pathway by facilitating the transmission of sound from the external environment to the inner ear[10]. This air-filled cavity, known as the tympanic cavity, is strategically located within the temporal bone and houses a delicate chain of ossicles—the malleus, incus, and stapes—alongside the tympanic membrane (TM), which collectively form an intricate system for sound conduction. The tympanic cavity is bounded laterally by the TM, medially by the promontory of the cochlea, superiorly by the tegmen tympani, inferiorly by the jugular wall, anteriorly by the Eustachian tube opening, and posteriorly by the aditus to the mastoid antrum. This spatial arrangement ensures that sound vibrations are efficiently captured, amplified, and relayed to the cochlea, where they are transformed into neural signals for auditory perception. The middle ear's role is not merely passive; it actively modulates sound through the ossicular chain's lever mechanism and the TM's vibratory properties, making its anatomy a focal point in understanding conditions like chronic otitis media (COM) and interventions such as tympanoplasty.

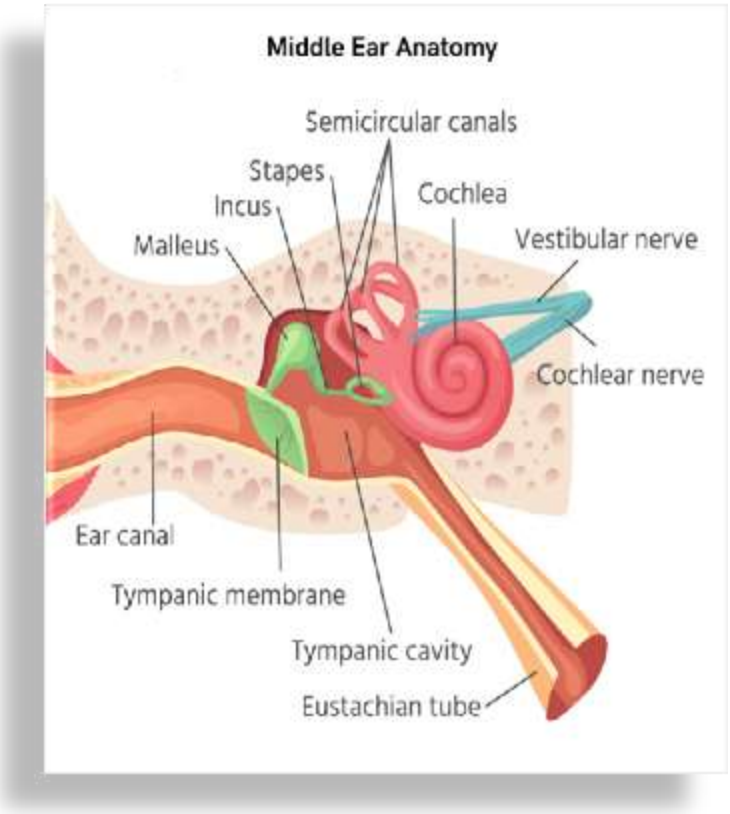


Figure 1: Middle ear anatomy[10]

The tympanic membrane, often referred to as the eardrum, is a thin, semi-transparent structure that marks the boundary between the external auditory canal and the middle ear space[11]. Measuring approximately 0.1 mm in thickness, the TM is a trilaminar structure composed of three distinct layers: an outer layer of stratified squamous epithelium continuous with the skin of the external canal, a middle fibrous layer providing structural integrity, and an inner mucosal layer contiguous with the middle ear lining. This tripartite composition endows the TM with both resilience and flexibility, allowing it to withstand pressure changes while efficiently transmitting sound vibrations. The TM spans a diameter of 9-10 mm, with its surface area averaging about 55-90 mm^2, depending on individual variation, and is oriented at an oblique angle of approximately 55° relative to the external canal's axis. This angulation enhances its ability to capture sound waves and funnel them toward the ossicles, a design refined through evolutionary adaptation.

Anatomically, the TM is divided into two distinct regions: the pars flaccida and the pars tensa, each with unique structural and functional characteristics. The pars flaccida, located superiorly above the lateral process of the malleus, is a small,

triangular area constituting about 5-10% of the TM's surface. It lacks a well-developed fibrous layer, rendering it more pliable and prone to retraction or perforation under pathological conditions such as negative middle ear pressure or chronic inflammation. In contrast, the pars tensa, which forms the majority of the TM below the malleus's lateral process, is reinforced by a fibrous layer composed of radial and circular collagen fibers. These fibers radiate from the umbo—the central point where the TM attaches to the malleus handle—and extend to the annulus, a fibrous ring anchoring the TM to the tympanic sulcus of the temporal bone. This arrangement imparts tensile strength and elasticity to the pars tensa, enabling it to vibrate in response to sound waves while maintaining structural stability.

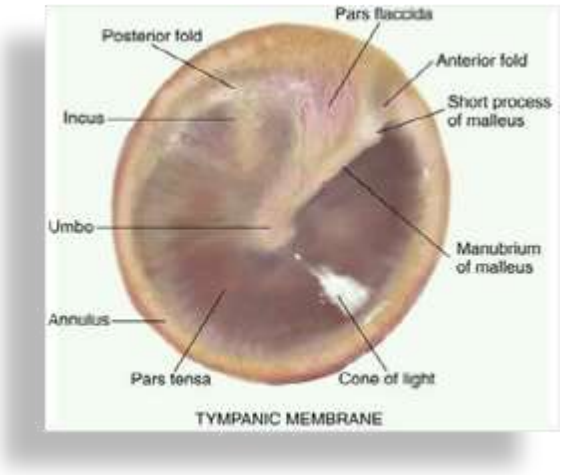


Figure 2: Tympanic membrane[10]

The integration of the malleus handle (manubrium) into the TM is a defining feature that distinguishes it from a simple membrane and highlightss its role in auditory mechanics . As detailed in *Cummings Otolaryngology*, the malleus handle is embedded within the middle fibrous layer of the pars tensa, running vertically from the umbo at its inferior tip to the lateral process near its superior attachment . This osseous structure, measuring approximately 8-9 mm in length, is not merely a passive attachment but a dynamic component that influences the TM's tension and vibratory pattern[12]. The malleus, the largest of the three ossicles, comprises three main parts: the handle (manubrium), the neck, and the head. The handle extends downward from the umbo, where it is firmly anchored to the TM, to the lateral

process, a bony projection that marks the transition to the neck and head, which articulate with the incus in the epitympanum. The head of the malleus, located superiorly in the attic region, adds structural support to the ossicular chain, while the lateral process serves as a fulcrum that enhances the lever action of sound transmission.

The fibrous layer's interaction with the malleus handle is critical for maintaining the TM's conical shape, a configuration that optimizes its acoustic properties. The radial fibers of the pars tensa converge at the umbo, where the malleus handle anchors them, creating a taut, funnel-like structure that amplifies sound vibrations, particularly in the low-frequency range. This conicality is further reinforced by the annulus, which secures the TM's periphery, and the malleus handle's vertical orientation, which provides a central axis of tension. The lateral process, projecting outward from the handle near its superior end, serves as an additional point of attachment for the TM, marking the boundary between the pars flaccida and pars tensa. This structural complexity ensures that the TM functions as more than a passive barrier; it is an active participant in the auditory process, converting airborne sound waves into mechanical energy that the ossicles can transmit.

Embryologically, the TM and middle ear structures arise from a coordinated interplay of the first and second pharyngeal arches and pouches, offering insight into their anatomical relationships. By the eighth week of gestation, the TM begins to form as the pharyngeal membrane thins between the first branchial groove (future external canal) and the first pharyngeal pouch (future middle ear). The fibrous layer develops from mesenchyme of the first arch, while the malleus and incus originate from Meckel's cartilage, with the handle of the malleus embedding into the TM as it matures. This developmental process explains the intimate connection between the TM and malleus handle, as well as the potential for congenital anomalies—such as a foreshortened manubrium or malformed lateral process—that may influence surgical outcomes in tympanoplasty. The stapes, derived from the second arch, completes the ossicular chain, but its role in type 1 tympanoplasty is minimal, as the procedure assumes an intact chain.

The vascular supply and innervation of the TM further illustrate its anatomical sophistication and relevance to surgical intervention. The outer epithelial layer is

supplied by branches of the external carotid artery, notably the deep auricular artery, while the inner mucosal layer receives blood from the anterior tympanic artery, a branch of the maxillary artery. Venous drainage parallels these arterial patterns, emptying into the external jugular and pterygoid plexus. This dual blood supply supports the TM's healing capacity post-tympanoplasty, as graft integration relies on neovascularization from both the annulus and the malleus handle's vascular bed. Innervation is similarly bifurcated: the outer surface is supplied by the auriculotemporal nerve (a branch of the mandibular nerve, V3), while the inner surface is innervated by the tympanic branch of the glossopharyngeal nerve (cranial nerve IX). This sensory overlap explains the TM's sensitivity to manipulation during surgery, as well as the potential for referred pain in chronic inflammation.

In the context of chronic otitis media (COM) mucosal type, the anatomy of the TM and middle ear becomes particularly significant. Perforations, a hallmark of this condition, disrupt the TM's integrity, most commonly affecting the pars tensa due to its larger surface area and exposure to pressure changes or infection. The malleus handle, though often intact, may undergo pathological changes—such as foreshortening, erosion, or lateral retraction—due to chronic inflammation or negative middle ear pressure. These alterations can complicate tympanoplasty, as the handle's position and condition influence graft placement and stability. For instance, a retracted or necrotic malleus handle may reduce the TM's effective vibratory area, necessitating adjustments in surgical technique to ensure successful repair.

The relevance of this anatomy to type 1 tympanoplasty, particularly with or without exteriorisation of the malleus handle, cannot be overstated. In the traditional underlay technique, the graft is placed medial to the TM remnant and malleus handle, relying on the handle's natural position to support the repair. This approach preserves the medial relationship between the TM and ossicles, minimizing disruption to the ossicular chain's alignment. However, in cases where the perforation is anterior or large, the underlay method may result in inadequate graft contact with the malleus handle, increasing the risk of medialization or failure. Exteriorisation, by contrast, involves dissecting the mucosa or fibrous tissue around the manubrium to expose it, allowing the graft to be positioned lateral to the handle.

This technique aims to enhance graft stability by leveraging the handle as a lateral anchor, potentially improving the TM's conical shape and vibratory efficiency.

The decision to exteriorise the malleus handle hinges on its anatomical state and the surgeon's assessment of its role in the repair. A healthy, well-positioned manubrium provides a strong foundation for graft attachment, whether medial or lateral, while a compromised handle may necessitate additional manipulation or even partial removal to optimize outcomes. The lateral process, though small, also influences this choice, as its prominence can affect the graft's contour and tension when placed laterally. Surgeons must weigh these factors against the increased technical demand of exteriorisation, which requires precise dissection to avoid damaging the handle or disrupting its ossicular connections. The TM's thinness and the malleus's fragility highlights the need for meticulous technique, as excessive force can fracture the manubrium or dislocate the incudomalleolar joint, complicating the procedure.

Variations in middle ear anatomy further complicate tympanoplasty planning. For example, the depth of the tympanic cavity varies between individuals, ranging from 13-15 mm vertically and 2-6 mm anteroposteriorly, influencing access to the malleus handle during surgery. The annulus may be dehiscent in some patients, weakening the TM's peripheral support, while pneumatization of the mastoid—connected to the middle ear via the aditus—can affect middle ear pressure and healing. These anatomical nuances, documented in standard texts like *Cummings Otolaryngology*, highlight the need for individualized approaches in tympanoplasty, particularly when considering modifications like exteriorisation (18). Imaging modalities, such as high-resolution computed tomography (CT), can preoperative assess these variations, guiding the surgeon in anticipating challenges related to the malleus handle's exposure or graft placement.

The functional anatomy of the TM and malleus handle also informs their clinical significance in sound transmission. The TM's surface area and tension, modulated by the malleus, determine its resonance frequency, typically peaking around 1-3 kHz in humans—frequencies critical for speech perception. Perforations in COM reduce this area, shifting the TM's acoustic properties and causing conductive hearing loss, often ranging from 20-40 dB depending on perforation size and

location. The malleus handle's role in maintaining TM tension is thus pivotal, as its displacement or loss can exacerbate hearing impairment. In tympanoplasty, restoring this relationship is a primary goal, whether by preserving the handle's medial position or enhancing its lateral exposure to optimize the graft's vibratory capacity.

In summary, the anatomy of the middle ear and tympanic membrane, with the malleus handle as a central feature, forms the foundation for understanding and treating COM mucosal type through type 1 tympanoplasty. The TM's trilaminar structure, its division into pars flaccida and pars tensa, and its intimate connection to the malleus handle via the umbo and lateral process create a complex system that balances structural integrity with acoustic function. These elements, as elucidated in classic anatomical descriptions, guide surgical strategies, particularly when debating the merits of exteriorisation versus traditional techniques.

Physiology of Sound Transmission

The physiology of sound transmission through the middle ear is a remarkable process that transforms acoustic energy from the external environment into mechanical vibrations, ultimately delivering them to the cochlea for auditory perception. This intricate mechanism begins when sound waves, propagated through air as pressure fluctuations, strike the tympanic membrane (TM), inducing it to vibrate. These vibrations are not random but are finely tuned by the TM's structural properties, allowing it to act as the initial transducer in the auditory pathway. The energy captured by the TM is then transferred to the ossicular chain—comprising the malleus, incus, and stapes—which amplifies and refines the signal before it reaches the oval window of the cochlea, where it is converted into fluid waves within the inner ear. This seamless relay is essential for hearing, bridging the physical disparity between airborne sound and the fluid-filled cochlear environment, a process governed by the principles of impedance matching and mechanical leverage.

The TM's conical shape is a critical anatomical feature that underpins its role in sound transmission, as it optimizes the efficiency of energy transfer from air to the ossicles[13,14]. This conical structure is not a simple geometric quirk but a sophisticated adaptation reinforced by the arrangement of radial and circular fibrous

fibers within the TM's middle layer, as well as the stabilizing influence of the malleus handle (manubrium). The radial fibers, coming from from the umbo—the point where the malleus handle attaches to the TM—extend outward to the annulus, while the circular fibers form concentric rings that enhance the membrane's tensile strength. Together, these fibers create a taut, funnel-like structure that maximizes the TM's vibratory surface area and focuses sound energy toward the ossicles. The conical configuration, with an apex at the umbo and a base at the annulus, effectively matches the low impedance of air (approximately 41.5 rayls) to the high impedance of cochlear fluid (around 1.5 million rayls), a disparity of nearly 35 dB that the middle ear must overcome to prevent energy loss . This impedance-matching function is vital, as without it, over 99% of sound energy would be reflected back, rendering hearing inefficient.

The malleus handle plays a pivotal role in this process, not only as a structural anchor but also as a dynamic contributor to sound amplification, particularly for low-frequency sounds. As emphasized in *Glasscock-Shambaugh Surgery of the Ear*, the handle's vertical orientation within the TM enhances the membrane's vibratory amplitude, especially in the range of 250-1000 Hz, which corresponds to the frequencies most critical for speech perception. The malleus, measuring 8-9 mm in length, extends from the umbo to the lateral process, where it transitions to the neck and head, articulating with the incus. This attachment creates a lever system where the TM's vibrations pivot around the lateral process, amplifying the displacement at the umbo. The ossicular chain further refines this amplification: the malleus and incus, with a lever ratio of approximately 1.3:1, and the stapes footplate, which concentrates energy over its small surface area (about 3.2 mm^2 compared to the TM's 55-90 mm^2), collectively provide a mechanical advantage of roughly 20-30 times. This amplification compensates for the impedance mismatch, ensuring that sound energy is effectively transmitted to the cochlea.

The physics of this transmission can be further appreciated through the lens of resonance and frequency response. The TM resonates at a natural frequency of around 1-3 kHz, determined by its mass, tension, and surface area[14]. The malleus handle, embedded within the fibrous layer, modulates this tension, acting like a tuning rod that adjusts the TM's stiffness and vibratory pattern[10]. For low-

frequency sounds, the entire TM moves in phase, with the malleus handle enhancing displacement at the umbo, while high-frequency sounds (above 3 kHz) produce more localized vibrations near the periphery, where the TM is less constrained by the ossicles. This frequency-dependent behavior is crucial for the middle ear's role as a bandpass filter, prioritizing the speech range while attenuating extraneous noise. The stapes, the final link in the chain, delivers these vibrations to the oval window, where perilymphatic waves stimulate the basilar membrane, initiating the cochlear response.

Disruption of this mechanism, as occurs in chronic otitis media (COM), profoundly impairs sound transmission, resulting in conductive hearing loss typically ranging from 20-40 dB[15]. A perforation in the TM—whether small or large—reduces its effective vibratory area, diminishing its ability to capture and transfer sound energy. The loss of conicality flattens the TM's response curve, shifting its resonance and reducing amplification, particularly for low frequencies. The ossicular chain may remain intact in COM mucosal type, but the uncoupling of the TM from the malleus handle—due to perforation or retraction—disrupts the lever system, further attenuating sound transmission. The degree of hearing loss correlates with perforation size and location: central perforations may cause a 20-30 dB loss, while subtotal defects can exceed 40 dB, approaching the maximum conductive loss of 60 dB. This variability underscores the need for precise anatomical restoration in tympanoplasty, as even minor deviations in TM mechanics can significantly impact auditory outcomes.

The middle ear's pressure regulation, mediated by the Eustachian tube, also influences sound transmission physiology[16]. Normally, the tube equalizes pressure across the TM, maintaining its optimal tension. In COM, dysfunction of this tube—often due to mucosal edema or obstruction—creates negative pressure, pulling the TM inward and stiffening its vibratory response. This altered mechanics exacerbates hearing loss and sets the stage for chronic inflammation, linking physiology to pathology in a feedback loop that tympanoplasty seeks to interrupt. The restoration of TM integrity, whether with or without malleus handle exteriorisation, thus aims to reestablish these physiological principles, aligning anatomical repair with functional recovery.

Clinical Anatomy and Physiology in COM Mucosal Type

Chronic otitis media (COM) mucosal type, also known as tubotympanic disease, is characterized by a constellation of anatomical and physiological changes that distinguish it from other forms of ear pathology[2]. Central to this condition is a persistent or recurrent perforation of the tympanic membrane, typically located in the anterior or central regions of the pars tensa, accompanied by mucosal inflammation and otorrhea. Unlike COM with cholesteatoma, the mucosal type lacks keratinizing squamous epithelium, focusing the pathology on the middle ear mucosa and TM. This distinction is critical for type 1 tympanoplasty, as it assumes an intact ossicular chain, directing surgical efforts toward TM reconstruction rather than ossicular repair. The interplay of anatomy and physiology in this condition shapes its clinical presentation and informs the rationale for techniques like malleus handle exteriorisation.

The TM perforation in COM mucosal type disrupts its structural integrity, with the size and location of the defect dictating the severity of hearing impairment[17]. Anterior perforations, often near the Eustachian tube orifice, may result from tubal dysfunction or prior infections, while central perforations typically arise from unresolved acute otitis media. Small perforations (<25% of TM area) may cause a modest conductive loss of 10-20 dB, as the remaining TM retains some vibratory capacity[15]. Larger defects, encompassing 50% or more of the pars tensa, reduce the TM's effective area significantly, impairing its conical shape and resonance, leading to losses of 30-40 dB or greater . The loss of radial and circular fibers in the perforated region further weakens the TM's tension, uncoupling it from the malleus handle and diminishing ossicular transmission[13]. This anatomical disruption directly translates to physiological dysfunction, as the TM's role in impedance matching and sound amplification is compromised.

The malleus handle, a key anatomical landmark, is frequently affected in COM mucosal type, with implications for both pathology and reconstruction. As noted in *Scott-Brown's Otorhinolaryngology*, chronic inflammation or negative middle ear pressure can lead to erosion, foreshortening, or retraction of the manubrium, altering its relationship with the TM. Erosion may occur at the umbo or along the handle's length, reducing its anchoring strength, while retraction pulls the TM

medially, flattening its conicality and creating a pocket that traps debris or infection. These changes complicate tympanoplasty, as a compromised handle may provide an unstable foundation for graft placement. In traditional underlay techniques, the graft relies on the handle's medial surface for support, but a retracted or eroded manubrium may necessitate exteriorisation to position the graft laterally, leveraging the handle as a lateral anchor to restore TM mechanics[10]. The lateral process, though less commonly affected, can also retract, influencing the graft's contour and tension in lateral placement strategies.

Eustachian tube dysfunction is a cornerstone of COM mucosal type's pathophysiology, exacerbating middle ear pressure imbalances and perpetuating inflammation. Normally, the tube opens intermittently to equalize pressure and drain mucus, maintaining a neutral middle ear environment. In COM, chronic mucosal edema, lymphoid hyperplasia, or anatomical obstruction impairs this function, creating a negative pressure gradient that stresses the TM and ossicles[1]. This negative pressure not only contributes to TM retraction but also fosters a hypoxic milieu that promotes bacterial growth—commonly *Pseudomonas aeruginosa* or *Staphylococcus aureus*—leading to persistent otorrhea. The resulting inflammation replaces the normal ciliated epithelium with squamous metaplasia or granulation tissue, further obstructing tubal ventilation and drainage (36). Physiologically, this alters sound transmission by stiffening the TM and dampening ossicular mobility, compounding the conductive loss beyond that caused by perforation alone.

Histologically, the middle ear mucosa in COM mucosal type undergoes significant transformation, with chronic granulation tissue supplanting the normal pseudostratified ciliated epithelium. This tissue, rich in fibroblasts, inflammatory cells, and neovascularization, forms in response to persistent infection or irritation, creating a thickened, edematous lining that hinders spontaneous healing. Granulation tissue may extend to the TM remnant, eroding its edges and enlarging the perforation over time. In severe cases, it can encase the ossicles, though in mucosal-type COM, ossicular destruction is rare compared to cholesteatomatous forms[16]. This mucosal pathology poses a challenge for tympanoplasty, as a "wet" middle ear—marked by active otorrhea or granulation—may reduce graft uptake

rates, necessitating preoperative management with antibiotics or aural toilet[17]. The restoration of normal mucosal physiology, alongside TM repair, is thus a critical goal, influencing the choice between medial and lateral graft placement relative to the malleus handle.

The clinical implications of these anatomical and physiological changes are profound, particularly in the context of type 1 tympanoplasty. The perforation's location—anterior versus central—affects surgical access and graft stability, with anterior defects often requiring meticulous technique to avoid blunting or medialization[5]. The malleus handle's condition—intact, eroded, or retracted—guides the decision to exteriorise, as a lateral graft may better anchor to a compromised handle, enhancing TM conicality and vibratory efficiency. Eustachian tube dysfunction, while not directly addressed by tympanoplasty, influences postoperative outcomes, as persistent negative pressure can stress the graft and lead to failure. The presence of granulation tissue further complicates healing, requiring surgeons to balance anatomical reconstruction with the restoration of a healthy middle ear environment. These factors collectively underscore the need for a comparative study of tympanoplasty techniques, as the interplay of anatomy and physiology in COM mucosal type may favor one approach—exteriorisation or traditional—over the other in achieving optimal results.

In summary, the physiology of sound transmission relies on the TM's conical shape, the malleus handle's amplifying role, and the ossicular chain's mechanical advantage, all of which are disrupted in COM mucosal type by perforation, inflammation, and Eustachian tube dysfunction[13-15]. The clinical anatomy and physiology of this condition highlight the TM's vulnerability, the malleus handle's variability, and the mucosa's pathological transformation, each influencing tympanoplasty's success[16-17].

Type 1 Tympanoplasty: Principles and Techniques

Type 1 tympanoplasty, often interchangeably termed myringoplasty when focusing solely on tympanic membrane (TM) repair, is a surgical procedure designed to restore the integrity of the TM in cases of chronic otitis media (COM) mucosal type where the ossicular chain remains intact[18,19]. This intervention addresses the hallmark perforation of the TM, aiming to reestablish its role as a barrier between

the external auditory canal and the middle ear, while simultaneously improving hearing by restoring the TM's vibratory capacity. The procedure's foundational principle, introduced by pioneers like Wullstein and Zollner in the mid-20th century, lies in the use of autologous grafts to close the perforation, leveraging the body's healing potential to achieve anatomical and functional restoration[18]. Commonly employed graft materials include temporalis fascia, harvested from the patient's scalp for its pliability and availability; cartilage, typically sourced from the tragus or concha for its rigidity; and perichondrium, often combined with cartilage for added strength[19]. Each material offers distinct advantages: temporalis fascia conforms easily to the TM's contours, cartilage resists retraction in cases of negative pressure, and perichondrium provides a vascular scaffold that enhances graft integration[10].

The underlay technique stands as the most widely adopted approach in type 1 tympanoplasty, favored for its technical simplicity and consistently high success rates, ranging from 85% to 95% in terms of graft uptake[20]. In this method, the graft is meticulously positioned medial to the TM remnant and the malleus handle, resting against the undersurface of the perforated TM and supported by the middle ear structures. The procedure begins with freshening the perforation edges to stimulate angiogenesis, followed by elevation of a tympanomeatal flap to access the middle ear. The graft is then slid beneath the TM remnant and malleus handle, often tucked into the hypotympanum or along the annulus to secure its position. Gelfoam or similar packing material is placed in the middle ear to buttress the graft against the TM, promoting adhesion as healing progresses[39.] The underlay technique's appeal lies in its minimal disruption to the TM's natural anatomy: by placing the graft medial to the malleus, it preserves the ossicular chain's alignment and reduces the risk of complications like blunting or lateralization. This approach is particularly effective for small to medium perforations, where the TM remnant provides ample support, and the malleus handle serves as a stable anchor for the graft's superior edge[10].

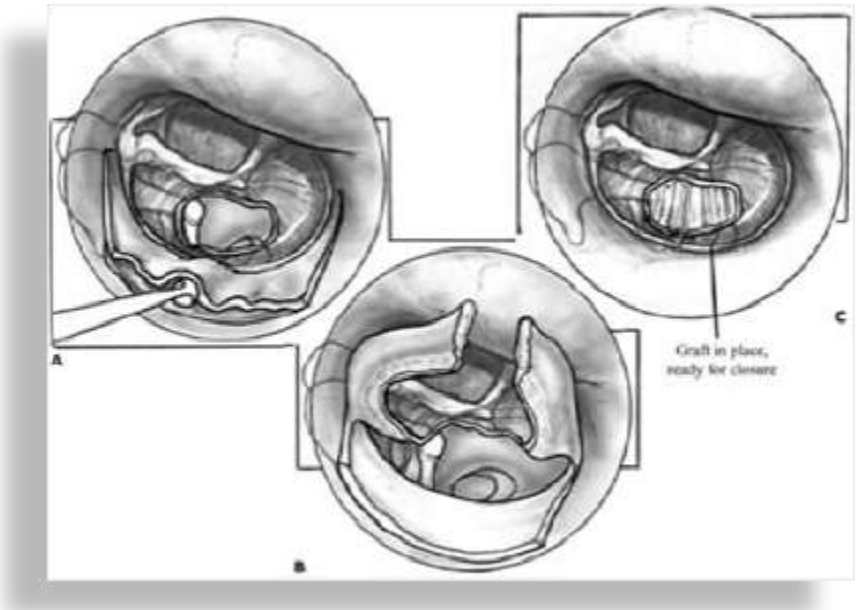


Figure 3 : Underlay technique

In contrast, the overlay technique positions the graft lateral to the TM remnant, a method better suited for larger perforations or cases where the TM remnant is insufficient to support an underlay graft. This approach requires more extensive preparation: the surgeon removes the squamous epithelium from the TM's outer surface and annulus, creating a denuded bed onto which the graft is laid. The graft extends over the perforation and onto the canal wall, overlapping the TM remnant to ensure coverage. While effective for subtotal or anterior perforations—where underlay grafts may fail due to limited anterior support—the overlay technique carries inherent risks. Blunting, where the graft's anterior edge fuses with the canal wall, can distort the TM's conical shape, while lateralization, where the graft shifts outward, may uncouple it from the ossicles, impairing sound transmission[10]. These complications necessitate precise surgical skill to maintain the graft's tension and alignment, making the overlay method less commonly used than its underlay counterpart, though valuable in specific anatomical scenarios.

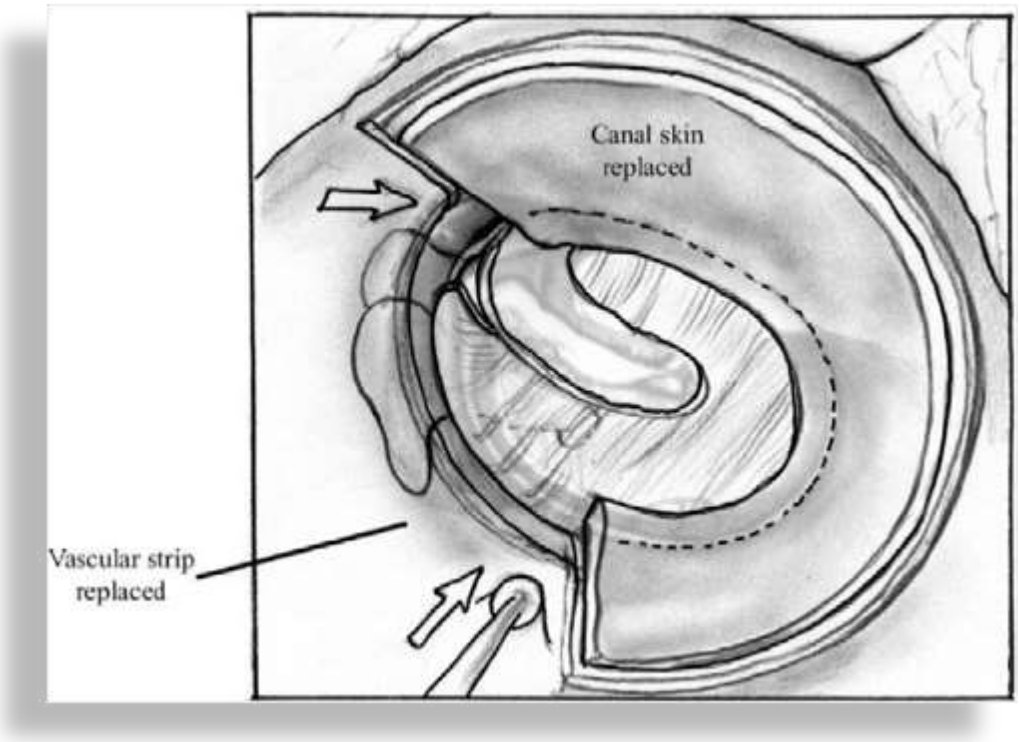


Figure 4 : Overlay technique

A notable modification to these foundational techniques is the exteriorisation of the malleus handle, which seeks to enhance graft stability and restore the TM's conical configuration . This approach involves careful dissection of the mucosa or fibrous tissue surrounding the manubrium to expose it fully, allowing the graft to be positioned lateral to the handle rather than medial, as in the traditional underlay method. The rationale is twofold: first, exteriorisation leverages the malleus handle as a lateral anchor, improving graft adherence to the TM remnant, especially in cases of anterior or large perforations where medial support is lacking; second, it aims to mimic the TM's natural conicality by aligning the graft with the handle's vertical plane, potentially optimizing vibratory mechanics. As detailed in *Cummings Otolaryngology*, this technique requires meticulous dissection to avoid damaging the delicate manubrium or disrupting its ossicular connections, a step that increases operative complexity but may yield superior outcomes in select cases[10]. The graft, often temporalis fascia or cartilage, is draped over the exposed handle and secured to the TM remnant, with packing used to stabilize the repair during healing. This modification bridges the underlay and overlay paradigms, combining the stability of medial placement with the anatomical fidelity of lateral positioning.

The choice of technique—underlay, overlay, or exteriorisation—hinges on multiple factors, including perforation size, location, middle ear status, and surgeon preference. Small central perforations are well-suited to the underlay method, leveraging the TM remnant's integrity, while larger or anterior defects may benefit from overlay or exteriorisation to ensure coverage and stability[20]. The middle ear's condition—wet with active otorrhea versus dry—also influences graft selection and placement, with cartilage favored in wet ears for its resistance to infection[19]. Surgeon expertise plays a pivotal role, as the precision required for exteriorisation or overlay techniques demands greater experience than the straightforward underlay approach. Endoscopic and microscopic approaches further refine these methods: endoscopy offers enhanced visualization of anterior perforations, while microscopy provides depth perception for malleus handle manipulation. These technical nuances underscore tympanoplasty's adaptability, tailoring the procedure to the patient's unique anatomy and pathology.

Types of Tympanoplasty

Within the broader context of tympanoplasty, it is worth delineating the classification system introduced by Wullstein to appreciate type 1's specific role, using insights from existing references[18,10]. Tympanoplasty encompasses five types, each addressing progressively complex middle ear pathology. Type 1, as discussed, focuses solely on TM repair with an intact ossicular chain, making it the simplest form[18]. Type 2 involves TM repair plus reconstruction of the malleus or incus when partially eroded, often using the graft to bridge the ossicles[10]. Type 3 addresses a missing incus, placing the graft directly onto the stapes head to form a columella effect. Type 4 preserves the stapes footplate, exteriorizing the middle ear cavity, while type 5 involves fenestration of the lateral semicircular canal, rarely used today[18]. Type 1's exclusivity to TM restoration aligns with COM mucosal type's pathology, distinguishing it from ossicular chain procedures and highlighting the relevance of techniques like malleus handle exteriorisation within this subtype[10]. This classification contextualizes the study's focus, emphasizing type 1's foundational principles while noting its evolution through technical modifications.

The evolution of type 1 tympanoplasty reflects decades of refinement, from early fascia grafts to modern cartilage techniques, each iteration aiming to balance

anatomical success with functional gain[19]. The underlay technique's dominance stems from its reliability and minimal morbidity, supported by extensive clinical experience. The overlay method, though riskier, addresses anatomical challenges that the underlay cannot, offering a complementary approach. Exteriorisation of the malleus handle emerges as a hybrid strategy, potentially uniting the strengths of both by enhancing graft stability and TM mechanics. These principles and techniques form the bedrock of this study's comparative analysis, evaluating whether exteriorisation offers a tangible advantage over conventional methods in restoring the TM's dual role as a barrier and sound transducer.

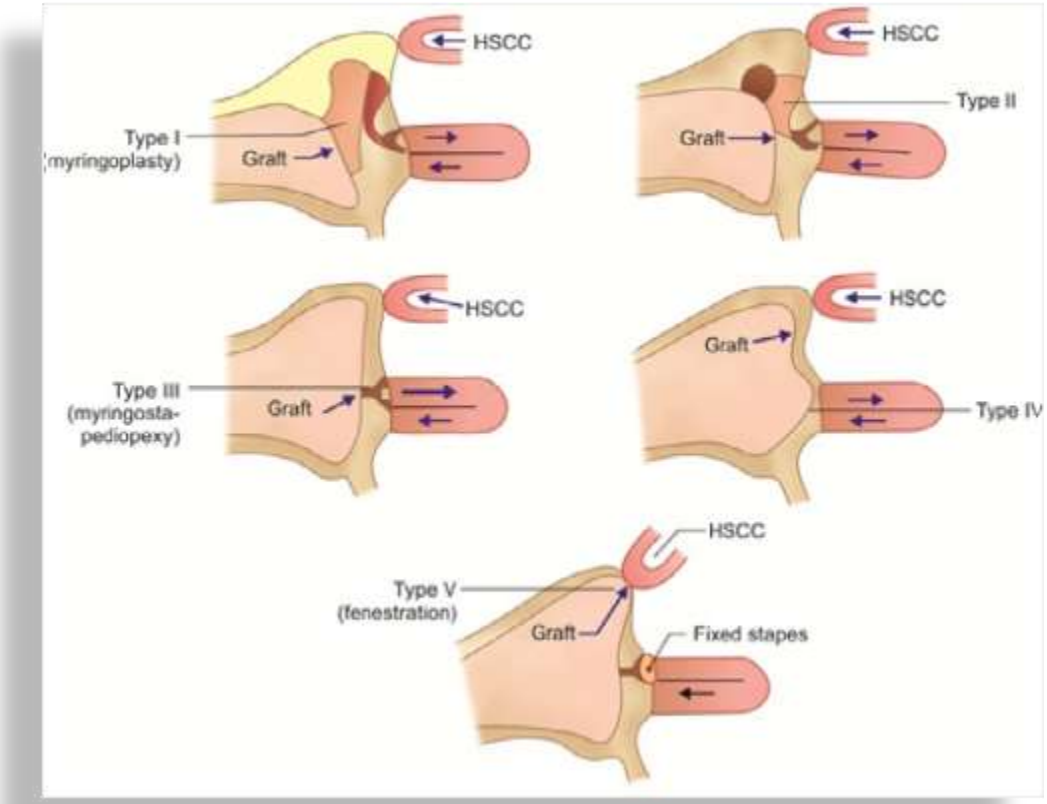


Figure 5: Types of tympanoplasty

Outcomes of Type 1 Tympanoplasty

The success of type 1 tympanoplasty is gauged by two primary outcomes: anatomical success, defined as graft uptake and perforation closure, and functional

success, measured as hearing improvement via air-bone gap (ABG) closure[21]. Graft uptake rates typically range from 80% to 95%, reflecting the procedure's efficacy across diverse patient cohorts. This variability is influenced by several determinants: perforation size, middle ear status (wet versus dry), and surgeon expertise. Small perforations (<25% of TM area) often achieve near-100% uptake due to ample TM remnant support, while larger defects (>50%) hover closer to 80%, as reduced contact area challenges graft integration[21]. Middle ear status—whether dry or actively discharging—impacts healing, though evidence suggests resilience: a PubMed study by Deosthale et al. (2018) reported no significant difference in outcomes between wet and dry ears (94% vs. 100%, p=0.2), attributed to preoperative management with antibiotics[22]. Surgeon skill further modulates success, with experienced practitioners achieving higher rates through precise graft placement and flap elevation.

Hearing improvement, the functional endpoint, is quantified as the reduction in ABG, averaging 10-15 dB post-tympanoplasty. This gain reflects the restoration of TM vibratory capacity and ossicular coupling, though outcomes vary with preoperative hearing loss severity. Small perforations may yield gains of 5-10 dB, sufficient to normalize mild losses, while larger defects can achieve 15-20 dB, approaching the ossicular chain's maximum conductive potential of 30 dB[15]. The malleus-TM relationship is pivotal, as highlighted in *Glasscock-Shambaugh Surgery of the Ear*: an intact handle ensures efficient sound transmission, while its disruption—via perforation or graft misalignment—limits functional success . Techniques like exteriorisation aim to optimize this relationship by aligning the graft with the handle's natural plane, potentially enhancing low-frequency gains critical for speech perception.

Complications such as graft failure (5-10%) or residual perforation underscore the need for technique optimization[23,24]. Graft failure may result from infection, poor vascularization, or mechanical stress, particularly in wet ears or with large perforations[22]. Residual perforations, often small and anterior, occur when the graft retracts or necroses, necessitating revision surgery[23]. Other risks include blunting (more common in overlay) and medialization (in underlay), both distorting TM mechanics and hearing. These challenges highlight the interplay of anatomical and

technical factors, with exteriorisation proposed as a solution to bolster stability and reduce failure rates. The study's focus on comparing exteriorisation with traditional methods directly addresses these variables, aiming to refine outcomes in COM mucosal type.

The literature reveals a robust foundation for type 1 tympanoplasty's efficacy, tempered by nuances that demand further exploration [21]. Perforation size and location, middle ear condition, and graft placement relative to the malleus handle emerge as key predictors, with surgeon expertise as a unifying factor. Hearing gains, while modest, significantly impact quality of life, particularly in resource-limited settings like India, where COM prevalence is high[6]. The Deosthale study's findings challenge the dogma of dry ear superiority, suggesting broader applicability of tympanoplasty[22]. Yet, the malleus-TM dynamic remains a critical variable, with *Glasscock-Shambaugh* emphasizing its role in functional success—a role that exteriorisation seeks to enhance. By dissecting these outcomes, this review frames the study's inquiry into whether modifying malleus handle management can elevate both anatomical and functional results, offering a pathway to optimize this cornerstone procedure.

Exteriorisation of Malleus Handle: Rationale and Evidence

Exteriorisation of the malleus handle represents a nuanced modification in type 1 tympanoplasty, aiming to replicate the natural mechanics of the tympanic membrane (TM) by strategically positioning the graft by making a slit in the superior aspect and through the slit, handle of malleus is exteriorised. The part of the graft anterior to slit is placed under the anterior fibrous annulus supported by gel foam and the other part of the graft lies anterior to handle of malleus[25]. This approach emerges from a desire to enhance both the anatomical and functional outcomes of TM repair, particularly in the context of chronic otitis media (COM) mucosal type, where perforation disrupts the TM's vibratory capacity and sound transmission. The rationale for exteriorisation is rooted in the anatomical and physiological roles of the malleus handle, which serves as a critical anchor within the TM's fibrous layer, extending from the umbo to the lateral process and contributing to the membrane's conical shape[10]. By exposing the manubrium through meticulous dissection and placing the graft lateral to it, surgeons seek to

restore this conicality, stabilize the graft against the TM remnant, and potentially improve the efficiency of sound conduction, especially for low-frequency sounds critical to speech perception[25].

The theoretical foundation for exteriorisation lies in its alignment with the TM's natural configuration. In a healthy ear, the TM's conical shape—reinforced by radial and circular fibrous fibers and the malleus handle—optimizes impedance matching between air and cochlear fluid, amplifying sound energy as it transfers to the ossicles[13]. Perforations in COM flatten this conicality, reducing the TM's effective vibratory area and uncoupling it from the malleus, leading to conductive hearing loss[15]. Traditional underlay techniques place the graft medial to the handle, relying on the TM remnant and ossicular support for stability, but this may not fully restore the TM's conical shape, particularly in large or anterior perforations where medial graft placement risks medialization or inadequate tension[20]. Exteriorisation addresses this by leveraging the malleus handle as a lateral fulcrum, allowing the graft to drape over it and mimic the TM's native curvature. This positioning theoretically enhances the graft's contact with the TM remnant, improving adhesion and reducing the likelihood of postoperative retraction or failure, while also aligning the reconstructed TM with the ossicular chain for optimal sound transmission.

Scott-Brown's Otorhinolaryngology underscores the potential functional benefits of this approach, suggesting that exteriorisation may improve low-frequency hearing by preserving or enhancing the TM's vibratory mechanics. Low frequencies (250-1000 Hz), crucial for understanding speech in noisy environments, rely heavily on the TM's large-amplitude vibrations, which are maximized by its conical shape and the malleus handle's anchoring role. In a perforated TM, these vibrations are dampened, and traditional repairs may not fully restore this capacity if the graft is positioned medially, potentially stiffening the TM or misaligning it with the ossicles. By placing the graft lateral to the handle, exteriorisation aims to recreate the TM's natural tension and displacement pattern, allowing it to move in phase with low-frequency sound waves and amplify their transmission to the malleus and beyond. This hypothesis is grounded in biomechanical models of TM vibration,

where the handle's position influences the membrane's resonance frequency and amplitude, particularly in the speech range[14].

Empirical evidence supporting exteriorisation, while promising, remains limited but offers tantalizing insights. A study by Nemade et al. (2018) provides one of the few direct investigations into lateral graft placement, reporting superior hearing gains with a sandwich technique that positions the graft lateral to the malleus handle[26]. Conducted in an Indian cohort, this study compared the sandwich method—where cartilage and fascia are layered to reinforce the repair—with the standard underlay approach, finding that the lateral placement group achieved an average air-bone gap (ABG) closure of 15-20 dB, compared to 10-15 dB in the underlay group[26]. The authors attributed this improvement to enhanced TM conicality and better ossicular coupling, suggesting that exteriorisation may offer a functional advantage over medial placement, particularly in cases with larger perforations or compromised TM remnants[26]. While not a randomized trial, this study highlights the potential of lateral graft positioning, aligning with the theoretical benefits proposed by earlier authors[25].

However, the adoption of exteriorisation is tempered by significant challenges, as noted in foundational studies like Sheehy and Anderson (1980), which caution against its increased surgical complexity and associated risks[27]. Exposing the malleus handle requires precise dissection of the surrounding mucosa or fibrous tissue, a step that demands advanced microsurgical skill to avoid damaging the delicate manubrium or disrupting its articulation with the incus[10]. The procedure extends operative time and introduces the risk of malleus displacement, where excessive manipulation could fracture the handle or dislocate the incudomalleolar joint, compromising ossicular continuity and hearing outcomes[27]. Additionally, the lateral graft placement may increase the risk of blunting—where the graft fuses with the canal wall—or lateralization, uncoupling it from the ossicles, issues more commonly associated with the overlay technique. These concerns highlight a trade-off: while exteriorisation may enhance graft stability and TM mechanics, it elevates the technical demand and potential for complications, necessitating careful patient selection and surgeon expertise.

The evidence base for exteriorisation remains sparse, with most research focusing on broader comparisons of overlay versus underlay techniques rather than isolating the malleus handle's role[28]. Studies like those by Halik and Smyth (1988) and Ralli et al. (2017) provide extensive data on tympanoplasty outcomes, reporting graft uptake rates of 80-95% and ABG closures of 10-15 dB across techniques, but they rarely specify malleus handle management[28]. The overlay method, which shares similarities with exteriorisation by placing the graft lateral to the TM, achieves high anatomical success but is critiqued for its functional limitations due to blunting risks. Underlay techniques, dominant in clinical practice, prioritize simplicity and reliability, yet may fall short in restoring optimal TM vibratory properties in complex cases. Exteriorisation, as a hybrid approach, occupies an underexplored middle ground, with its specific benefits and drawbacks obscured by the lack of targeted studies. This scarcity of direct evidence underscores the need for the current study, which aims to isolate exteriorisation's impact in a controlled comparison.

The surgical technique of exteriorisation, while not standardized, typically involves elevating a tympanomeatal flap, freshening the perforation edges, and carefully dissecting the mucosa from the malleus handle to expose its full length. The graft—often temporalis fascia or cartilage—is then positioned lateral to the handle, extending over the TM remnant and secured with packing to maintain its position during healing. This method contrasts with the underlay approach, where the graft is tucked beneath the handle, and the overlay, where it covers the entire TM surface without specific focus on the malleus[20]. The choice of graft material may influence outcomes: fascia's flexibility suits lateral placement, while cartilage's rigidity may enhance stability but risks stiffening the TM[19]. Endoscopic assistance can improve visualization of the handle, particularly in anterior perforations, though microscopy remains the gold standard for precision[4]. These technical nuances highlight exteriorisation's potential to refine tympanoplasty, but also its dependence on surgical skill and anatomical context.

The clinical relevance of exteriorisation extends beyond mechanics to patient-specific factors in COM mucosal type. Anterior perforations, common in this condition, pose challenges for underlay grafts due to limited anterior support,

increasing failure rates[17]. Exteriorisation may mitigate this by anchoring the graft to the malleus handle, improving contact with the anterior TM remnant[25]. Similarly, in cases of malleus retraction or erosion—frequent sequelae of chronic inflammation—lateral placement could compensate for a compromised handle, restoring TM tension. However, wet ears with active otorrhea or granulation tissue may complicate healing, as infection could undermine the graft's integration, a risk not unique to exteriorisation but amplified by its complexity[22]. These considerations suggest that exteriorisation's benefits may be most pronounced in specific subsets of COM patients, a hypothesis this study seeks to test.

In summary, exteriorisation of the malleus handle offers a compelling rationale—replicating TM mechanics, enhancing graft stability, and improving low-frequency hearing—supported by limited but suggestive evidence[25,26]. Yet, its increased complexity and risks, as cautioned by Sheehy and Anderson, temper enthusiasm, highlighting the need for robust data[27]. The paucity of focused studies, overshadowed by broader overlay-underlay comparisons, leaves its efficacy uncertain, setting the stage for a detailed investigation[28]. This review frames exteriorisation as a promising yet understudied modification, ripe for the comparative analysis proposed in this study.

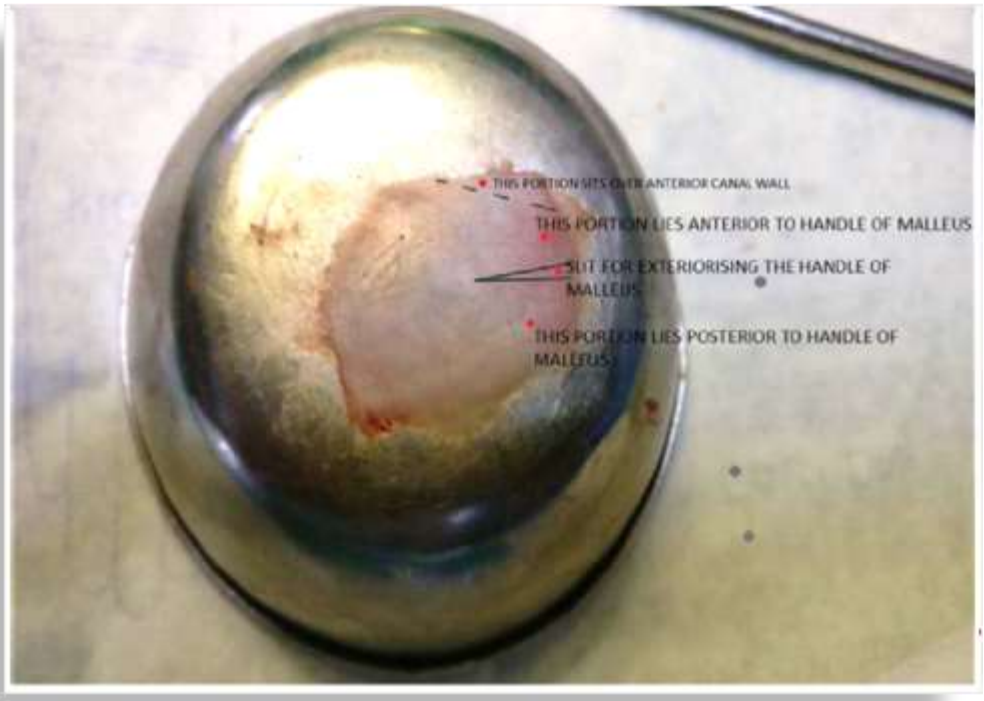


Figure 6: Orientation of graft relative to malleus handle.

Figure 7: Intra operative picture of exteriorising the handle of malleus through the slit and positioning of graft.

Comparative Studies and Gaps in Literature

Comparative studies of tympanoplasty techniques abound in the otolaryngology literature, reflecting decades of effort to optimize outcomes in middle ear surgery, yet few specifically isolate the role of malleus handle exteriorisation [29-32]. This abundance stems from tympanoplasty's evolution since Wullstein's classification, with researchers exploring variables like graft material, surgical approach, and adjunctive procedures[18]. However, the focus on broader paradigms—underlay versus overlay, cartilage versus fascia, or tympanoplasty with versus without mastoidectomy—has left niche modifications like exteriorisation underexplored,

creating a critical gap that this study aims to address. The existing body of work provides a robust foundation for understanding tympanoplasty's efficacy, but its failure to dissect the malleus handle's specific contribution limits its relevance to the current inquiry, necessitating a closer examination of representative studies and their shortcomings.

A notable example is Mishiro et al. (2013), which followed 213 patients with non-cholesteatomatous COM over five years, comparing tympanoplasty with and without mastoidectomy[29]. The study reported no significant long-term difference in graft uptake (90% vs. 88%) or hearing improvement (12-15 dB ABG closure), suggesting that mastoidectomy does not universally enhance outcomes in mucosal-type COM[29]. While rigorous, this study's focus on mastoid involvement sidesteps malleus handle management, grouping all tympanoplasty techniques under a single umbrella without detailing graft placement relative to the handle. The authors used primarily underlay methods, with no mention of exteriorisation, rendering it silent on the modification's potential impact[29]. This omission reflects a broader trend: comparative studies often prioritize macroscopic variables over microscopic technical nuances, leaving exteriorisation's role untested.

Similarly, Eliades and Limb (2013) conducted a comprehensive review of tympanoplasty outcomes, analyzing the role of mastoidectomy and canal wall techniques in TM repair[30]. Their findings echoed Mishiro's, reporting equivalence in hearing gains (10-15 dB ABG closure) across canal wall-up and canal wall-down procedures, with graft success rates of 85-95% [30]. The review synthesized data from multiple studies, offering a broad perspective on surgical strategies, but again failed to isolate malleus handle exteriorisation. The included studies predominantly employed underlay or overlay techniques, with lateral graft placement mentioned only in passing as part of overlay methods, not as a distinct variable[3]. This aggregation obscures exteriorisation's specific effects, conflating it with broader overlay risks like blunting, and highlights a gap in granularity that limits its applicability to the current study's focus.

Indian research, such as Raghuwanshi et al. (2016), exemplifies this trend within a regional context, comparing cartilage versus temporalis fascia grafts in type 1 tympanoplasty. Conducted in a high-prevalence setting, the study reported

cartilage's superiority in graft uptake (95% vs. 85%) and hearing improvement (15 dB vs. 12 dB), attributed to its resistance to retraction in wet ears . While valuable for material selection—particularly relevant in India's resource-limited environment—this study does not address malleus handle positioning, focusing instead on graft type and perforation size. The underlay technique dominated, with no exploration of lateral placement or exteriorisation, reflecting a practical emphasis on simplicity over technical innovation (58). This focus, while clinically pragmatic, sidesteps the anatomical nuances that exteriorisation seeks to exploit, leaving a void in the Indian literature that this study could fill.

The lack of randomized controlled trials (RCTs) specifically targeting malleus handle exteriorisation stands as a critical gap, as noted in broader reviews by Sergi et al. (2011) and Kotecha et al. (1999)[31,32]. Sergi's study compared overlay and underlay myringoplasty in 78 patients, finding higher graft success with underlay (92% vs. 85%) but no difference in hearing outcomes (12-14 dB ABG closure), emphasizing technique reliability over functional gain[31]. Kotecha's prospective audit of 200 cases reported similar uptake rates (88-93%) and identified perforation size as a key predictor, but neither study isolated exteriorisation[32]. RCTs, the gold standard for establishing causality, are notably absent for this modification, with existing trials focusing on graft materials or mastoidectomy rather than malleus management[29]. This absence reflects both the technical challenge of standardizing exteriorisation and the field's historical prioritization of established methods, leaving its efficacy speculative.

These gaps have profound implications for clinical practice and research direction. Comparative studies provide a wealth of data on tympanoplasty's general efficacy—uptake rates of 80-95%, hearing gains of 10-15 dB—but their broad scope dilutes their relevance to exteriorisation. The malleus handle's role, though acknowledged as pivotal in TM mechanics, remains a footnote in most analyses, overshadowed by variables like perforation size or middle ear status. Indian studies, while contextually relevant given COM's prevalence, mirror this global trend, focusing on accessible techniques rather than innovative modifications[7]. The absence of RCTs or even large cohort studies targeting exteriorisation leaves surgeons reliant on anecdotal experience or theoretical rationale, a precarious

foundation for a procedure with increased complexity[27]. This study addresses this void by directly comparing exteriorisation with traditional methods, aiming to generate empirical evidence where speculation currently reigns.

The literature's limitations also reflect methodological challenges. Standardizing exteriorisation across surgeons is difficult, given its dependence on individual skill and anatomical variation—e.g., malleus retraction or anterior perforation location[17]. Outcome measures, while consistent (graft uptake, ABG closure), may not capture subtle benefits like low-frequency hearing improvement, which exteriorisation purportedly enhances. Long-term follow-up, as in Mishiro's study, is rare, yet critical for assessing durability, particularly in COM's chronic milieu[29]. These challenges underscore the need for a focused, prospective design, as proposed here, to isolate exteriorisation's impact and address these methodological shortcomings.

In conclusion, comparative studies offer a rich tapestry of tympanoplasty data, yet their failure to isolate malleus handle exteriorisation leaves a critical gap[29-32]. Mishiro, Eliades, and Raghuwanshi provide valuable benchmarks—equivalence in mastoidectomy outcomes, technique consistency, and material efficacy—but sidestep the study's core question[29]. The dearth of RCTs and specific analyses, as noted by Sergi and Kotecha, amplifies this void, highlighting exteriorisation's status as an understudied frontiers[31,32]. This review frames the current study as a necessary step to bridge this gap, offering a targeted comparison to illuminate exteriorisation's potential in refining tympanoplasty for COM mucosal type.

Table 1: Comparative Studies on Tympanoplasty Cited in the Review of Literature

Study (Reference)	Study Design	Sample Size	Techniques Compared	Primary Outcomes	Relevance to Malleus Handle Exteriorisation

Mishiro et al. (2013)[29]	Prospective cohort, long-term follow-up (5 years)	213 patients	Tympanoplasty with vs. without mastoidectomy	Graft uptake: 90% (with) vs. 88% (without); Hearing: 12-15 dB ABG closure (no difference)	Does not isolate exteriorisation; focuses on mastoidectomy, primarily underlay techniques used.
Eliades and Limb (2013)[30]	Literature review	Multiple studies (aggregate data)	Canal wall-up vs. canal wall-down tympanoplasty	Graft uptake: 85-95%; Hearing: 10-15 dB ABG closure (equivalent across techniques)	Broad review, mentions overlay but does not specify exteriorisation; lacks focus on malleus handle management.
Sergi et al. (2011)[31]	Prospective cohort	78 patients	Overlay vs. underlay myringoplasty	Graft uptake: 85% (overlay) vs. 92% (underlay); Hearing: 12-14 dB	Compares overlay vs. underlay, but exteriorisation not isolated; overlay includes lateral

				ABG closure (no difference)	placement broadly.
Kotecha et al. (1999)[32]	Prospective audit	200 cases	Myringoplasty (various techniques, primarily underlay)	Graft uptake: 88-93%; Hearing: Not detailed, perforation size key predictor	Broad audit, does not specify exteriorisation; focuses on perforation size, not malleus handle management.
Nemade et al. (2018)[26]	Prospective comparative study	Not specified (assumed moderate)	Sandwich (lateral graft) vs. underlay tympanoplasty	Graft uptake: Not detailed; Hearing: 15-20 dB (sandwich) vs. 10-15 dB (underlay)	Directly relevant; compares lateral graft placement (akin to exteriorisation) with underlay, shows hearing benefit.
Deosthale et al. (2018)[22]	Prospective comparative study	Not specified (assumed moderate)	Type 1 tympanoplasty in wet vs. dry ears	Graft uptake: 94% (wet) vs. 100% (dry),	Focuses on middle ear status, not technique; underlay

				p=0.2; Hearing: Not detailed	assumed, no mention of exteriorisation

METHODOLOGY

MATERIALS AND METHODS:

SOURCE OF DATA:

Prospective comparative study will be conducted in patients with Chronic otitis media (patients aged 18 to 50years)- mucosal type, with tympanic membrane perforation ,planned for Type 1 tympanoplasty admitted under Department of Otorhinolaryngology,R.L.Jalappa Hospital and Research centre attached to Sri Devaraj Urs Medical College,Tamaka,Kolar between may 2023 to october2024, will be taken up for the study after fulfilling the inclusion and exclusion criteria .

Inclusion Criteria:

1.Patients between 18 -50 years of age, diagnosed with Chronic otitis media-mucosal type with central dry perforation .

2. Patients between 18-50 years of age, diagnosed with Chronic otitis media mucosal type with central perforation having intact and mobile ossicles .

Exclusion Criteria:

1. Patients having Chronic Otitis Media – squamosal type.

2.Patients having Chronic Otitis Media with evidence of ossicular necrosis and granulations .

3.Patients having sensorineural hearing loss.

4.Revision cases of Type 1 tympanoplasty.

10.2 METHOD OF COLLECTION OF DATA

STUDY DESIGN: Prospective Comparative study

STUDY PERIOD: 1year and 6 months

SAMPLING PROCEDURE:

This prospective study will be conducted on patients having Chronic otitis media mucosal type at R.L Jalappa Hospital and Research centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar for 18months . After obtaining approval from IEC(Institutional Ethics Committee) study will be carried out on patients with Chronic otitis media mucosal type.

Detailed medical history will be elicited from the patient , meticulous ENT examination will be performed under otomicroscope, otoendoscope.

Preoperative pure tone audiometry, high resolution computed tomography temporal bone (0.7mm) will be done preoperatively.

Cases are assigned into 2 groups, on alternate basis

The group for which both Type 1 tympanoplasty with exteriorization of handle of malleus will be done- GROUP 1

The group for which Type 1 tympanoplasty without exteriorization will be done- GROUP2

All patients will be recalled on postoperative day 21, 3^{rd}, 6^{th} month and will be subjected to pure tone audiometry, otoendoscopic and otomicroscopic examination. All the relevant findings will be noted for the same .

SAMPLE SIZE :56 in total (28 each in GROUP 1 and 28 each in GROUP 2)

The sample size for the study is estimated based on the successful outcome rate in Group 1(type 1 tympanoplasty with exteriorization of handle of malleus) and Group 2(type 1 tympanoplasty without exteriorization) with respect to the study titled.

As reported in a study to detect a difference of 30 % in a successful outcome rate, with 90 power ,alpha error of 5% ,estimated sample size in group 1 and group2 is 28 each[9].

Formula

$H_0 : P_1 = P_2;$ $\quad\quad$ $H_a : P_1 \neq P_2$

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2\bar{P}(1-\bar{P})} + Z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Where,

$$\bar{P} = \frac{P_1 + P_2}{2}$$

P_1 : Proportion in the first group

P_2 : Proportion in the second group

α : Significance level

$1-\beta$: Power

DATA ANALYSIS :

Data will be entered in MS excel and analyzed using SPSS 22 version software Assessment in hearing pre and post operatively will be evaluated by degree of closure of Air Bone Gap when calculated as a percentage. Difference in the percentage change over the pre-intervention period to post intervention period in 2 groups will be calculated. Normalcy of the data will be assessed and appropriate test will be applied . If the data is normally distributed ,mean and standard deviation will be calculated ,parametric test (Paired t test) will be applied. If the data is not normally distributed ,Median/IQR non parametric test will be applied. A $p<0.05$ will be accepted as statistically significant.

RESULTS

RESULTS:

TABLE 2: FREQUENCY OF STUDY GROUP

Study group	Frequency
A	29
B	27
Total	56

Note: The study group consists of 56 participants, with Group A comprising 51.8% (29 participants) and Group B comprising 48.2% (27 participants), indicating a nearly balanced distribution between the two groups.

TABLE 3: GENDER DISTRIBUTION

GENDER	STUDY GROUP A	STUDY GROUP B	Total
F	13	12	25
M	16	15	31
Total	29	27	56

TABLE 4: PREOPERATIVE MEASUREMENTS SHOWING SIGNIFICANT DIFFERENCE BETWEEN TWO GROUPS

STUDY GROUP	Mean	N	Std. Deviation	Minimum	Maximum	p-value
A	39.9741	29	1.72475	37.00	43.50	0.000
B	36.5463	27	2.09514	35.00	40.00	
Total	38.3214	56	2.56449	35.00	43.50	

Note: The preoperative measurements show a significant difference between Group A (mean = 39.97) and Group B (mean = 36.55), with Group A having higher values. The ANOVA test indicates a statistically significant difference ($p < 0.001$), suggesting that the study group has a strong effect on preoperative measurements.

TABLE 5: PREOPERATIVE BONE CONDUCTION AVERAGE

STUDY GROUP	Mean	N	Std. Deviation	Minimum	Maximum	p-value
A	9.8707	29	1.09508	8.00	12.00	0.140
B	9.0926	27	2.55530	6.25	13.75	
Total	9.4955	56	1.96243	6.25	13.75	

Note: The preoperative bone conduction average shows a slightly higher mean for Group A (9.87) compared to Group B (9.09). However, the ANOVA test indicates no statistically significant difference between the groups ($p = 0.140$), suggesting that the study group does not significantly affect bone conduction averages.

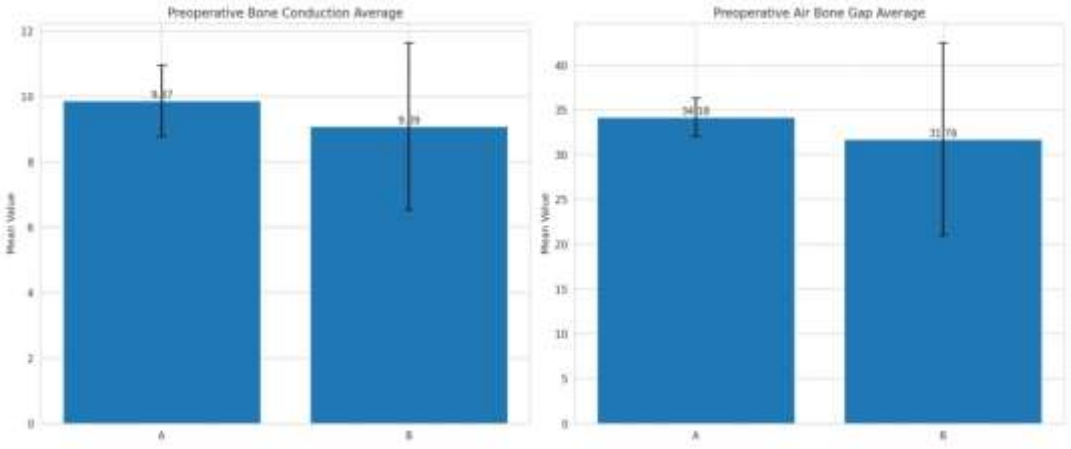
TABLE 6: PREOPERATIVE AIR BONE GAP AVERAGE

STUDY GROUP	Mean	N	Std. Deviation	Minimum	Maximum	p-value
A	34.1845	29	2.12729	30.25	37.25	0.239

B	31.7574	27	10.75078	21.25	57.50	
Total	33.0143	56	7.64453	21.25	57.50	

Note: The preoperative air bone gap average is higher in Group A (mean = 34.18) than in Group B (mean = 31.76), with Group B showing greater variability (SD = 10.75 vs. 2.13). The ANOVA test indicates no statistically significant difference between the groups (p = 0.239), suggesting that the study group does not significantly influence air bone gap averages.

GRAPH 1- PREOPERATIVE BONE CONDUCTION AVERAGE AND PREOPERATIVE AIR BONE GAP AVERAGE



- The preoperative measurements show a significant difference between study groups (p < 0.001), with Group A having higher values.
- No significant differences were found for preoperative bone conduction average (p = 0.140) or air bone gap average (p = 0.239) between the groups.
- Group B tends to have greater variability in measurements, particularly for the air bone gap average, which may warrant further investigation.

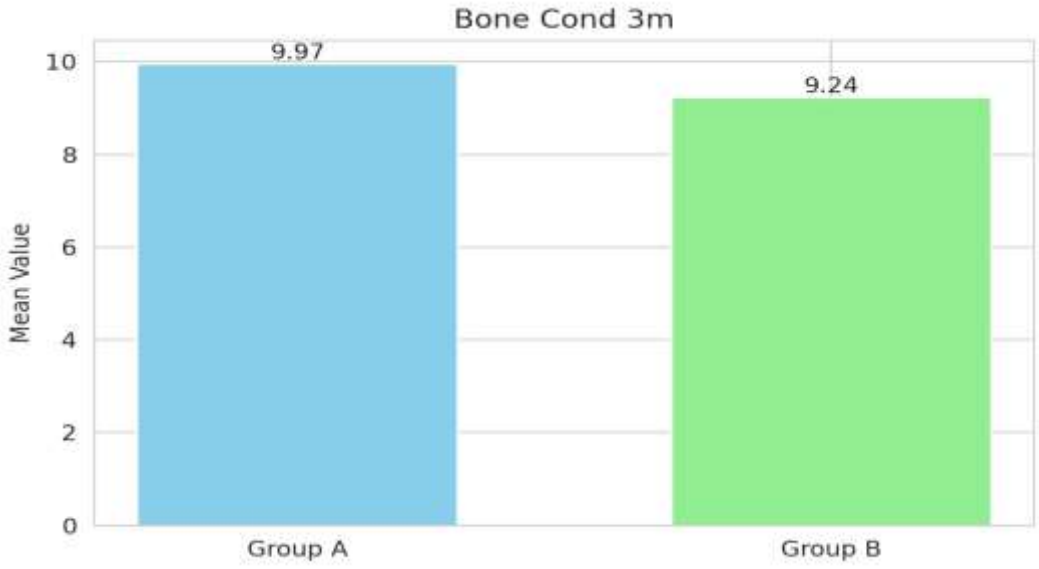
TABLE 7: POSTOPERATIVE MEASUREMENTS

STUDY GROUP	STATISTICS	POST OPERATIVE AIR CONDUCTION AVERAGE AT 3 MONTHS	POST OPERATIVE BONE CONDUCTION AVERAGE AT 3 MONTHS	POST OPERATIVE AIR CONDUCTION AVERAGE AT 6 MONTHS	POST OPERATIVE BONE CONDUCTION AVERAGE AT 6 MONTHS	POST OPERATIVE ABG AVERAGE AT 6 MONTHS	CLOSURE OF ABG AVERAGE
A	Mean	34.508621	9.965517	31.827586	9.248276	26.1421	6.9703

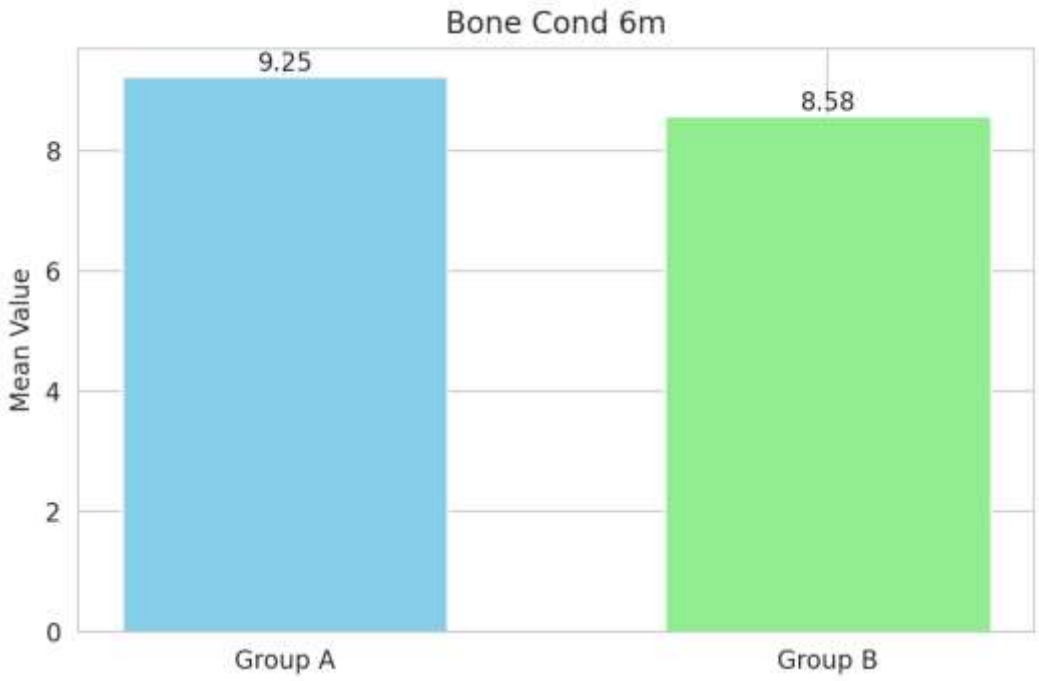
	N	29	29	29	29	29	29
	Std. Deviation	2.8235005	1.2968439	2.5504757	0.6749977	5.04738	3.70723
	Minimum	31.0000	8.0000	28.0000	7.8000	20.00	2.25
	Maximum	37.5000	12.5000	36.0000	10.0000	35.00	11.25
B	Mean	32.598148	9.240741	31.575926	8.583333	25.2241	8.1307
	N	27	27	27	27	27	27
	Std. Deviation	2.5829128	2.1021069	2.3116083	1.6855723	5.50174	9.83559
	Minimum	29.0000	6.0000	28.7500	6.9000	16.25	1.23
	Maximum	38.0000	12.7000	35.0000	12.5000	35.00	32.50
Total	Mean	33.587500	9.616071	31.706250	8.927679	25.6995	7.5298
	N	56	56	56	56	56	56
	Std. Deviation	2.8531044	1.7546071	2.4194489	1.2990178	5.24337	7.28493
	Minimum	29.0000	6.0000	28.0000	6.9000	16.25	1.23
	Maximum	38.0000	12.7000	36.0000	12.5000	35.00	32.50
p-value		0.011	0.123	0.701	0.055	0.518	0.556

Note: The postoperative measurements at 3 and 6 months show varying differences between Groups A and B. A statistically significant difference is observed for the post-operative air conduction average at 3 months ($p = 0.011$), with Group A having a higher mean (34.51 vs. 32.60). The post-operative bone conduction average at 6 months approaches significance ($p = 0.055$), with Group A again showing a higher mean (9.25 vs. 8.58). Other measurements, including bone conduction at 3 months ($p = 0.123$), air conduction at 6 months ($p = 0.701$), ABG average at 6 months ($p = 0.518$), and closure of ABG average ($p = 0.556$), show no significant differences between groups. Group B generally exhibits greater variability, particularly in closure of ABG average (SD = 9.84 vs. 3.71).

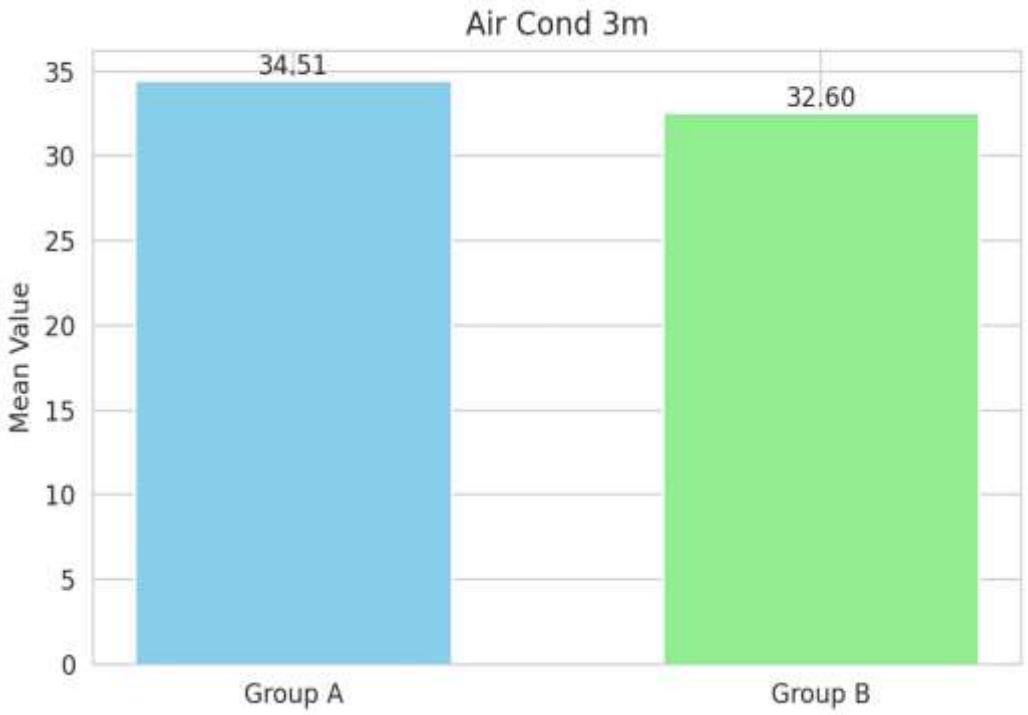
GRAPH 2 – POST OPERATIVE BONE CONDUCTION AT 3 MONTHS



GRAPH 3 – POST OPERATIVE BONE CONDUCTION AT 6 MONTHS



GRAPH 4 – POST OPERATIVE AIR CONDUCTION AT 3 MONTHS



GRAPH 5 – POST OPERATIVE AIR CONDUCTION AT 6 MONTHS

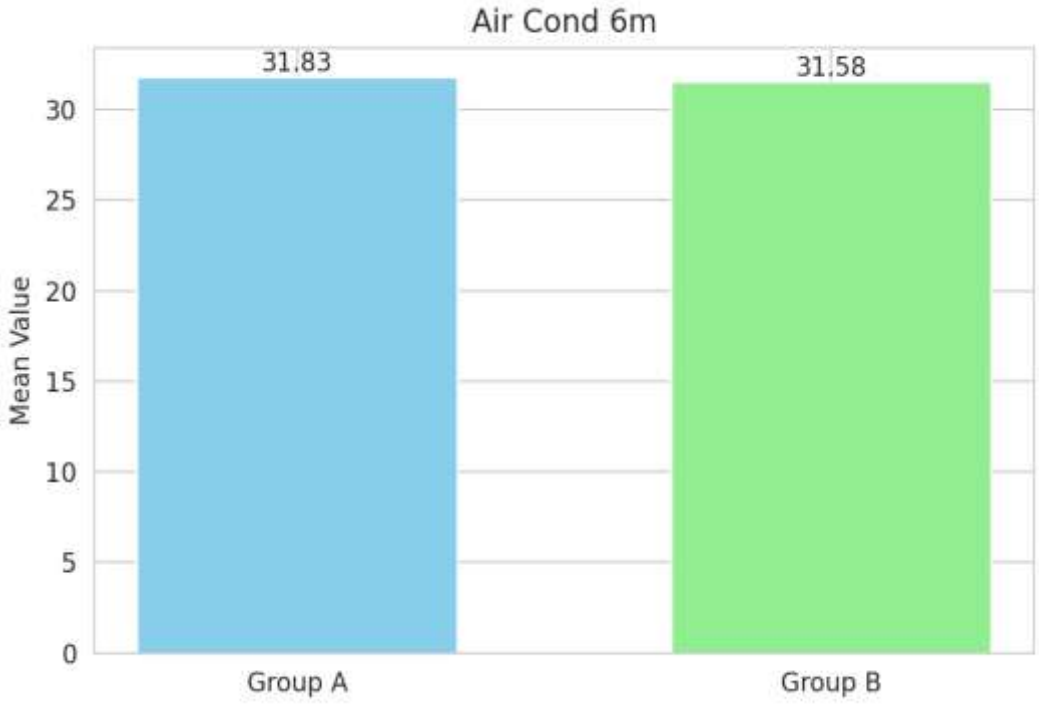


TABLE 8: PAIRED SAMPLES STATISTICS

STUDY GROUP	Pair	Measurement	Mean	N	Std. Deviation	Std. Error Mean	p-value
A	Pair 1	POST OPERATIVE AIR CONDUCTION AVERAGE AT 3 MONTHS	34.508621	29	2.8235005	0.5243109	0.000
		POST OPERATIVE AIR CONDUCTION AVERAGE AT 6 MONTHS	31.827586	29	2.5504757	0.4736114	
	Pair 2	POST OPERATIVE BONE CONDUCTION AVERAGE AT 3 MONTHS	9.965517	29	1.2968439	0.2408179	0.002
		POST OPERATIVE BONE CONDUCTION AVERAGE AT 6 MONTHS	9.248276	29	0.6749977	0.1253439	
	Pair 3	PREOPERATIVE AIR BONE GAP AVERAGE	34.1845	29	2.12729	0.39503	0.000
		POST OPERATIVE ABG AVERAGE AT 6 MONTHS	26.1421	29	5.04738	0.93728	

B	Pair 1	POST OPERATIVE AIR CONDUCTION AVERAGE AT 3 MONTHS	32.598148	27	2.5829128	0.4970818	0.065
		POST OPERATIVE AIR CONDUCTION AVERAGE AT 6 MONTHS	31.575926	27	2.3116083	0.4448692	
	Pair 2	POST OPERATIVE BONE CONDUCTION AVERAGE AT 3 MONTHS	9.240741	27	2.1021069	0.4045507	0.102
		POST OPERATIVE BONE CONDUCTION AVERAGE AT 6 MONTHS	8.583333	27	1.6855723	0.3243885	
	Pair 3	PREOPERATIVE AIR BONE GAP AVERAGE	31.7574	27	10.75078	2.06899	0.004
		POST OPERATIVE ABG AVERAGE AT 6 MONTHS	25.2241	27	5.50174	1.05881	

- **Group A**: Significant differences are observed for all pairs. Pair 1 (air conduction average, 3 vs. 6 months) shows a decrease from 34.51 to 31.83 ($p < 0.001$). Pair 2 (bone conduction average, 3 vs. 6 months) shows a decrease from 9.97 to 9.25 ($p = 0.002$). Pair 3 (preoperative vs. postoperative ABG avera\he) shows a significant reduction from 34.18 to 26.14 ($p < 0.001$).
- **Group B**: Only Pair 3 (preoperative vs. postoperative ABG average) shows a significant reduction from 31.76 to 25.22 ($p = 0.004$). Pair 1 (air conduction average, 3 vs. 6 months) shows a non-significant decrease from 32.60 to 31.58 (p =

0.065). Pair 2 (bone conduction average, 3 vs. 6 months) shows a non-significant decrease from 9.24 to 8.58 (p = 0.102).

- Group B exhibits greater variability, especially in preoperative ABG average (SD = 10.75 vs. 2.13 in Group A), which may influence the significance of results.
- **Group A** demonstrates significant improvements in air conduction (3 to 6 months), bone conduction (3 to 6 months), and ABG (preoperative to postoperative at 6 months), with p-values < 0.05.
- **Group B** shows a significant improvement only in ABG (p = 0.004), with marginal changes in air and bone conduction averages (p > 0.05).
- The significant reductions in Group A suggest better postoperative outcomes compared to Group B, though Group B's higher variability may indicate diverse responses to treatment.

GRAPH – 6 – POST OPERATIVE AIRBONE GAP AVERAGE AT 6 MONTHS

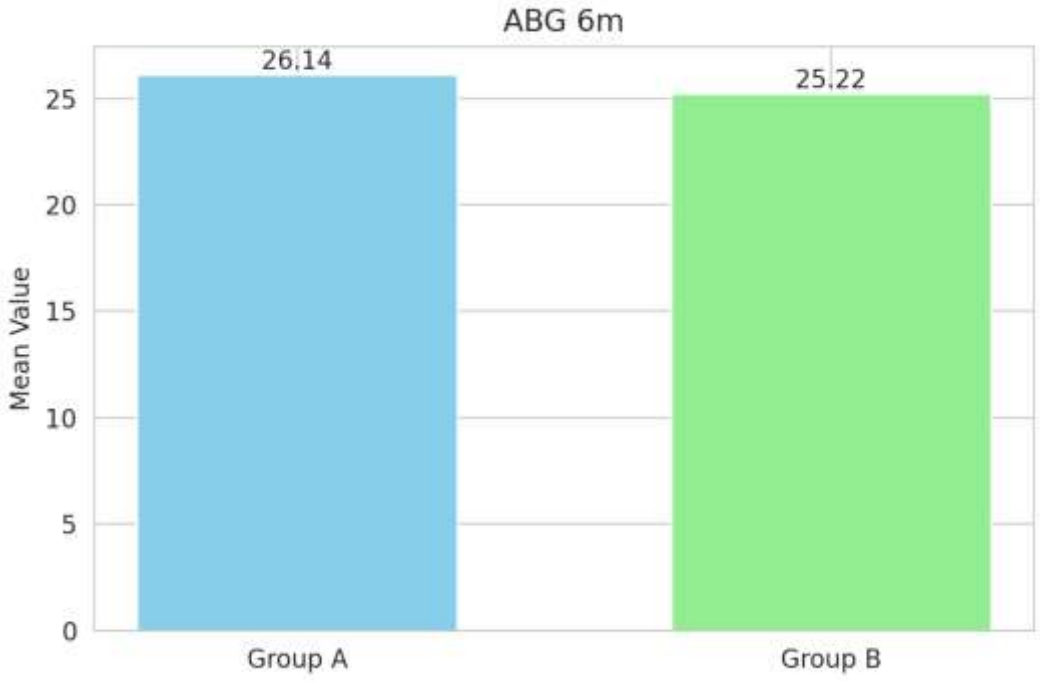


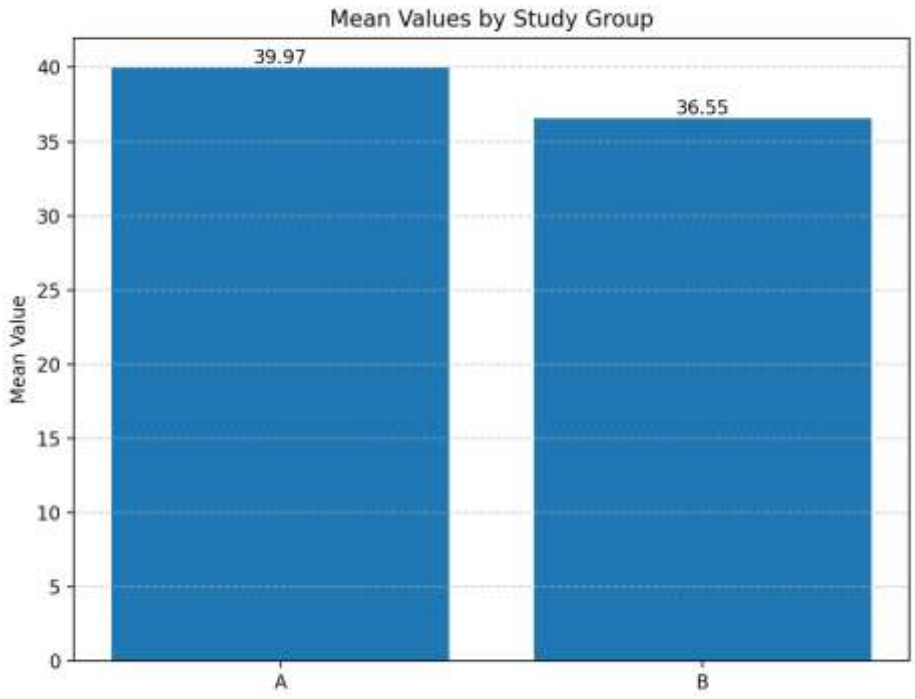
TABLE 9: Chi-square Test Results

Statistic	Value	df	p-value
Chi-square	0.011	1	0.916
Statistic	Value	df	p-value
Chi-square	1.614	1	0.204

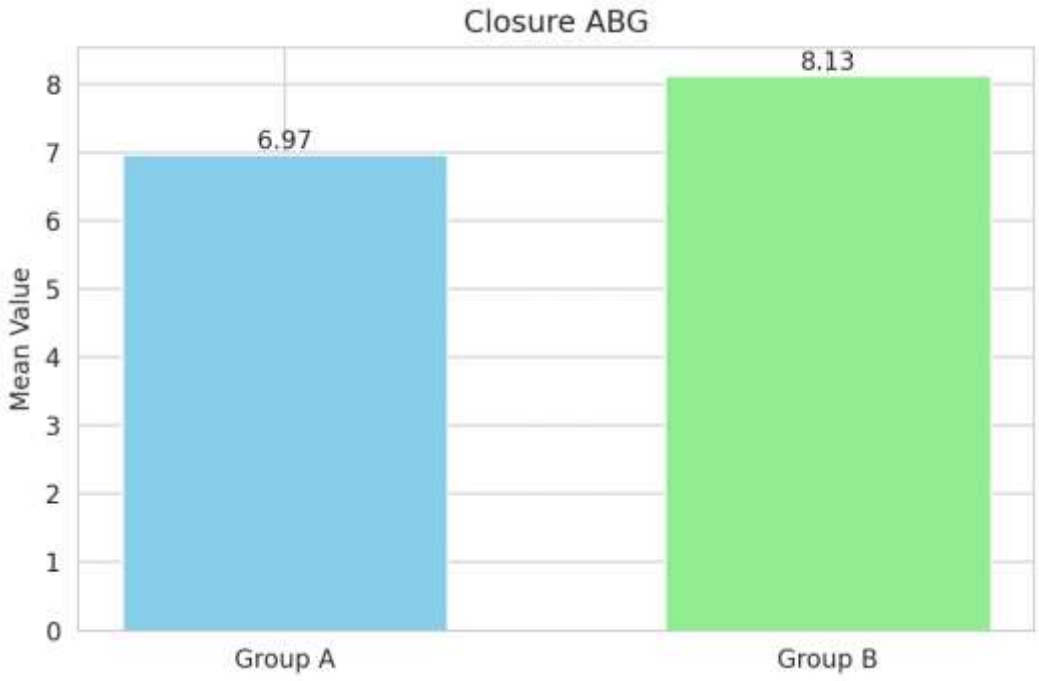
TABLE 10: GRAFT STATUS AT 6 MONTHS

STUDY GROUP	GRAFT STATUS: Good (1)	GRAFT STATUS: Poor (2)	Total
A	27	2	29
B	22	5	27
Total	49	7	56

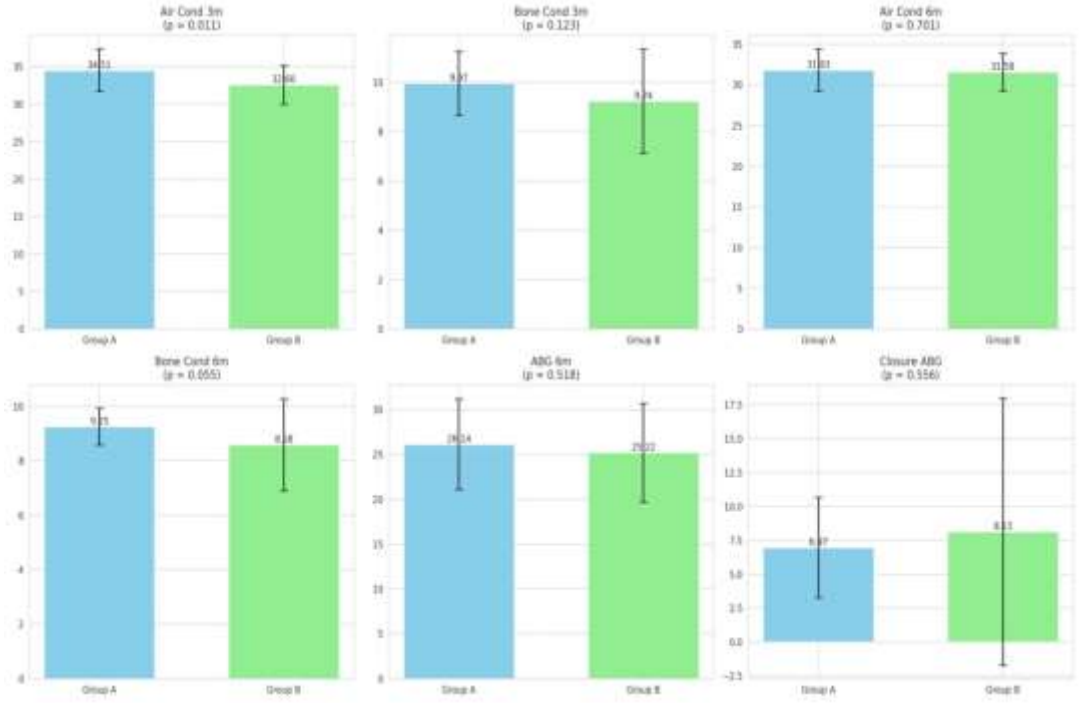
GRAPH 7 – MEAN VALUES BY STUDY GROUP



GRAPH 8 – POST OPERATIVE AIRBONE GAP CLOSURE



GRAPH 9 – COMPARISION OF P-VALUES



DISCUSSION

DISCUSSION

Chronic otitis media (COM) mucosal type, also known as tubotympanic disease, is a long-standing inflammatory condition of the middle ear characterized by tympanic membrane (TM) perforation and chronic or recurrent otorrhea, without cholesteatoma. It typically results from unresolved acute otitis media, leading to mucosal damage and TM defects. The condition poses a significant public health concern, especially in low- and middle-income countries like India, where its prevalence is heightened by poor hygiene, overcrowding, and limited healthcare access. Type 1 tympanoplasty remains the primary treatment for such cases when the ossicular chain is intact, aiming to restore TM integrity and improve hearing. The success of the procedure is judged by graft uptake and hearing gain, often influenced by perforation characteristics, middle ear status, graft material, and surgical technique. The handle of the malleus, an integral part of TM structure and sound conduction, plays a critical role during tympanoplasty. A newer surgical variation, exteriorisation of the malleus handle—placing the graft lateral rather than medial to it—has been proposed to improve anatomical and functional outcomes by preserving the membrane's natural conical shape and vibratory efficiency. However, evidence comparing this technique to the standard underlay method is limited.

In the given backdrop, this study aimed to evaluate the anatomical and functional results of type 1 tympanoplasty with and without exteriorisation in COM mucosal type, providing insight into the potential benefits of this surgical modification. Studies on this subject in the Indian population remain scarce, highlighting the need for region-specific data to enhance intubation risk assessment and prevention strategies.

This prospective study was conducted over 18 months at R.L. Jalappa Hospital and Research Centre, attached to Sri Devaraj Urs Medical College, Tamaka, Kolar, after obtaining approval from the Institutional Ethics Committee. A total of 56 patients diagnosed with chronic otitis media mucosal type were included, with 28 patients each assigned alternately into two groups: Group 1 underwent type 1 tympanoplasty with exteriorization of the handle of the malleus, while Group 2

underwent the procedure without exteriorization. Detailed medical histories were taken, and all patients underwent thorough ENT examinations using an otomicroscope and otoendoscope. Preoperative assessments included pure tone audiometry and high-resolution computed tomography (0.7 mm) of the temporal bone. Postoperative evaluations were conducted on day 21, and at the 3rd and 6th months, during which patients were re-examined using pure tone audiometry, otoendoscopy, and otomicroscopy. All findings were systematically recorded. All patients received standard care as per institutional protocols, and findings were systematically analyzed and compared.

OUTCOMES FOLLOWING TYPE 1 TYMPANOPLASTY WITH AND WITHOUT EXTERIORISATION OF THE HANDLE OF THE MALLEUS IN COM

In our study, postoperative measurements at 3 and 6 months showed differences between the two groups. A statistically significant difference was noted in the postoperative air conduction average at 3 months ($p = 0.011$), with Group A (exteriorization done) showing a higher mean value (34.51 vs. 32.60). The bone conduction average at 6 months approached significance ($p = 0.055$), again with Group A having a higher mean (9.25 vs. 8.58). Other parameters, including bone conduction at 3 months ($p = 0.123$), air conduction at 6 months ($p = 0.701$), ABG average at 6 months ($p = 0.518$), and closure of ABG average ($p = 0.556$), showed no statistically significant differences. Group B demonstrated more variability, especially in closure of ABG (SD = 9.84 vs. 3.71). These findings suggest that exteriorization may offer better early hearing outcomes and more consistent ABG closure, though differences were not maintained across all parameters.

In our study, Group A (with exteriorization) showed significant improvements across all pairs. Air conduction average decreased from 34.51 to 31.83 ($p < 0.001$), bone conduction average decreased from 9.97 to 9.25 ($p = 0.002$), and ABG average reduced significantly from 34.18 to 26.14 ($p < 0.001$). In Group B, only ABG average showed a significant reduction from 31.76 to 25.22 ($p = 0.004$), while air conduction (32.60 to 31.58, $p = 0.065$) and bone conduction (9.24 to 8.58, $p =$

0.102) showed non-significant changes. Greater variability was noted in Group B, especially in preoperative ABG average (SD = 10.75 vs. 2.13). These results suggest that exteriorization led to more consistent and statistically significant improvements. The greater variability in Group B may reflect heterogeneous postoperative responses.

In our study, graft status at 6 months was found to be good in 27 out of 29 patients in Group A (93.1%) and in 22 out of 27 patients in Group B (81.5%). Poor graft status was observed in 2 patients (6.9%) in Group A and 5 patients (18.5%) in Group B. Although Group A had a higher percentage of successful graft uptake, the difference between the groups was not statistically significant (Chi-square = 1.614, df = 1, p = 0.204). These findings suggest a trend toward better graft outcomes with exteriorization. However, the difference did not reach statistical significance, possibly due to sample size limitations.

Compared to existing literature, our study demonstrated slightly better graft uptake rates and comparable hearing outcomes. Mishiro et al. (56) reported graft uptake rates of 90% with mastoidectomy and 88% without, whereas our study showed 93.1% uptake in the exteriorization group and 81.5% in the non-exteriorization group. While Mishiro et al. (56) focused on the impact of mastoidectomy rather than malleus exteriorization, the graft uptake rates in our exteriorization group were marginally higher. Similarly, Eliades and Limb (57) reported average ABG closure of 10–15 dB across various tympanoplasty techniques, regardless of canal wall status, which is in line with the ABG closure seen in our study, particularly in Group A where significant reductions were observed. However, neither of these studies specifically addressed exteriorization of the handle of malleus, limiting direct comparison. The greater consistency in outcomes and lower variability observed in our exteriorization group may indicate a potential advantage of this technique, though larger studies isolating this variable are needed for definitive conclusions. Our findings align with those of Nemade et al. (52), who observed better hearing outcomes with the sandwich (lateral graft) technique, comparable to the exteriorization method used in our study. In their study, hearing gain ranged between 15–20 dB for the sandwich technique compared to 10–15 dB for the underlay approach, indicating a benefit similar to the

statistically significant improvements in air and bone conduction seen in our Group A. Although Nemade et al. (52), did not detail graft uptake rates, our results suggest a trend toward better graft status in the exteriorization group (93.1% vs. 81.5%), mirroring the functional gains reported in their technique. In contrast, the study by Deosthale et al. (47) focused on graft uptake in wet versus dry ears, reporting 94% success in wet ears and 100% in dry ears ($p = 0.2$), with no detailed hearing outcomes or mention of exteriorization. Their comparable graft success rates across conditions are in line with our non-significant difference in graft uptake between the groups ($p = 0.204$), suggesting that while anatomical outcomes may remain unaffected, surgical modifications like exteriorization could influence functional outcomes. Thus, compared to existing literature, our study supports the hypothesis that exteriorization may enhance auditory improvement without compromising graft integrity.

Compared to earlier studies, our findings indicate a relatively higher graft uptake rate and more consistent hearing improvement in patients who underwent exteriorization. While Raghuwanshi et al. reported a graft uptake of 95% using cartilage and 85% with fascia, our exteriorization group (Group A) achieved a comparable 93.1% success rate, suggesting that malleus exteriorization may offer outcomes similar to those obtained with cartilage grafts. In terms of hearing, Raghuwanshi et al. (58) documented a mean ABG closure of 15 dB for cartilage grafts, slightly higher than the 8 dB mean closure we observed, yet their focus remained on graft material rather than handle positioning. Sergi et al.[31], comparing overlay and underlay techniques, noted graft uptake rates of 85% and 92%, respectively, aligning closely with our findings in both groups, but did not evaluate exteriorization specifically. Their reported ABG closure of 12–14 dB showed minimal intergroup difference, which differs from our study where the exteriorized group showed more consistent auditory gains. Kotecha et al.[32], in a broad audit of myringoplasty, reported graft uptake ranging from 88% to 93%, again closely matching our results but emphasized perforation size over surgical technique. Notably, none of these studies specifically isolated the effect of malleus exteriorization on outcomes, highlighting the uniqueness of our analysis. Overall, our study suggests that exteriorization may contribute to improved graft uptake and

early hearing outcomes, although differing methodologies limit direct comparisons and focus areas across previous literature. Exteriorisation of the handle provides a firm anatomical landmark for graft placement, enhancing the support and stability of the graft. This reduces the chances of graft medialisation or lateralisation during healing. The probable reason may lie in the Positioning the graft over the exteriorised handle allows direct contact between the tympanic membrane and ossicular chain. This optimizes the transmission of sound vibrations and improves hearing outcomes.

The comparative analysis between the findings of our study on malleus handle exteriorization during Type 1 tympanoplasty and existing literature reveals areas of agreement and variation. Pradhan et al. (medial vs. lateral graft placement)[33]reported graft success rates of 94.12% in the medial group and 87.88% in the lateral group, with a mean ABG closure of 14.73 dB. These results correspond to the improved consistency in ABG closure observed in our exteriorization group, where standard deviation was notably lower (3.71 vs. 9.84), implying that meticulous surgical modifications—whether through graft positioning or malleus exteriorization—may contribute to more predictable functional outcomes. Meanwhile, Aynur et al., in their study on endoscopic Type 1 tympanoplasty, documented a functional success rate of 91.30% and an ABG gain of 21.69 dB, which was greater than the ABG reduction observed in our Group A (8.04 dB). This difference might be attributed to the superior intraoperative visualization provided by endoscopy, which may facilitate more accurate graft placement and ossicular chain assessment compared to the traditional microscopic approach used in our study. Exteriorisation creates a separation between the graft and the promontory or medial wall. This helps prevent postoperative adhesions and minimizes the risk of middle ear atelectasis.

TABLE 12: COMPARISON OF OUTCOMES OF TYMPANOPLASTY IN OUR STUDY ACROSS VARIOUS STUDIES

Study	**Major result matrix**	**Key findings**
Our study	Graft uptake: 93.1% (A) vs. 81.5% (B); ABG ↓: 8.04 dB (A) vs. 6.54 dB	Exteriorization group showed better graft uptake and consistent early hearing gains

	(B); AC ↓: 2.68 dB (A), BC ↓: 0.72 dB (A)	
Nemade et al.[26]	Hearing gain: 15–20 dB (sandwich) vs. 10–15 dB (underlay)	Sandwich technique showed better auditory outcomes, similar to exteriorization
Deosthale et al.[22]	Graft uptake: 94% (wet) vs. 100% (dry); p = 0.2	No hearing data; graft outcomes not influenced by ear condition
Raghuwanshi et al.	Graft uptake: 95% (cartilage), 85% (fascia); ABG gain: 15 dB	Comparable uptake with exteriorization; better ABG with cartilage
Sergi et al.[31]	Graft uptake: 85% (overlay), 92% (underlay); ABG gain: 12–14 dB	Similar uptake to our study; exteriorization not assessed
Kotecha et al.[32]	Graft uptake: 88–93%	Results aligned with ours; focused on perforation size, not technique
Pradhan et al.[33]	Graft uptake: 94.12% (medial) vs. 87.88% (lateral); ABG closure: 14.73 dB	Consistency in ABG closure echoed in our exteriorization group
Aynur et al.	Functional success: 91.3%; ABG gain: 21.69 dB	Better ABG gain than ours, likely due to endoscopic advantage
Salvador et al.[34]	Graft uptake: 75%; smokers: 3.29x risk of failure	Poor graft uptake in presence of risk factors; variability may match our Group B
Bhatia et al. [36]	Graft uptake: 82%; ABG gain: 14.73 dB	Matches ABG reduction in our exteriorization group
Nisha et al.[35]	Early hearing gain with canaloplasty	Similar to early AC gain in exteriorization group

Several prognostic indicators reported in existing literature provide a broader context for interpreting the outcomes of our study. Salvador et al. observed a 75%

anatomical success rate in their tympanoplasty cohort, identifying smoking as a significant risk factor, with smokers demonstrating 3.29 times higher odds of graft failure. Although our study did not assess smoking status, the greater variability seen in the non-exteriorization group (Group B) may reflect similar unmeasured confounders such as smoking or the size of tympanic membrane perforation, both of which were considered impactful by Salvador et al.[34]and Aynur et al. Furthermore, Bhatia et al.[35] reported an 82% graft uptake rate and a mean ABG improvement of 14.73 dB using temporalis fascia grafts, which aligns with the ABG improvement noted in our exteriorization group, where the ABG decreased from 34.18 dB to 26.14 dB. This similarity suggests that graft material plays a substantial role in hearing outcomes. Additionally, the early improvement in air conduction observed in our Group A (34.51 dB to 31.83 dB) resembles findings by Nisha et al.[36], who reported enhanced early hearing outcomes in canaloplasty-assisted tympanoplasty. These comparisons highlight the value of surgical refinements such as exteriorization or canaloplasty in improving postoperative function, though inter-study variability also points to the influence of individual patient factors that merit further investigation.

In our study, Group A included 13 females (44.8%) and 16 males (55.2%), while Group B had 12 females (44.4%) and 15 males (55.6%). The gender distribution was nearly equal across both groups, with a total of 25 females (44.6%) and 31 males (55.4%) among 56 participants. The Chi-square test showed no significant difference in gender distribution between the groups (Chi-square = 0.011, df = 1, p = 0.916). Thus, gender was well balanced in both groups. This minimizes the likelihood of gender acting as a confounding factor in outcome comparisons. Age-related trends and surgical technique variations reported in previous studies provide additional perspective on the findings from our study. Thai et al.[37] documented a decline in tympanoplasty success rates with increasing age, with the highest total success (80%) and ABG closure within 20 dB (70%) observed in the 16–25 age group, and the lowest outcomes (66.7% and 40%, respectively) noted in the 56–65 age group. While our study did not evaluate age-specific outcomes, the increased variability observed in Group B could potentially be influenced by a higher proportion of older patients, consistent with this trend. Bhoomi Badhesia et al.[38]

reported that the use of the operating microscope was associated with better outcomes (79% success), suggesting that enhanced surgical visualization plays a critical role in improving precision, an effect that may be paralleled by our use of exteriorization to optimize graft handling. Similarly, Hen et al.[39] demonstrated a 91.30% functional success rate and a 21.69 dB ABG improvement with endoscopic tympanoplasty, which exceeded the ABG closure observed in our exteriorization group. These comparisons suggest that technical enhancements—whether through improved visualization tools or specific surgical modifications such as exteriorization—can contribute to better outcomes. However, they also highlight that variables like patient age and operative approach can significantly influence postoperative results.

The comparative assessment between our tympanoplasty findings and existing literature highlights both similarities and variations in clinical outcomes. Harkare et al.[40]reported graft uptake rates of 92.11% in inactive and 93.75% in active chronic otitis media, with no statistically significant difference between groups. This aligns with our observation of a non-significant difference in graft success between the exteriorization and non-exteriorization groups (93.1% vs. 81.5%). However, their reported hearing improvement rates (71.05–78.12%) were relatively lower compared to the ABG reduction seen in our study (approximately 8–9 dB), possibly due to variations in surgical technique, middle ear status, or patient profiles. Further, Pradhan et al.[33] demonstrated better outcomes with medial graft placement compared to lateral placement (94.12% vs. 87.88% graft success), which resonates with our findings where exteriorization of the malleus handle contributed to improved consistency and anatomical success. This suggests that meticulous graft positioning, whether achieved through medial underlay or exteriorization, remains a key determinant in surgical outcomes. In contrast, the prospective study conducted by Naderpour et al.[41] reported a high overall graft uptake rate of 93.3%, similar to our Group A. However, they did not identify any specific prognostic factors influencing success, which differs from our observations, where surgical technique—particularly malleus exteriorization—appeared to impact both graft integrity and audiological outcomes. This divergence may reflect methodological differences, including operative approach and criteria for patient selection.

Several studies have evaluated outcomes of Type 1 tympanoplasty in chronic otitis media (COM) with varying surgical techniques, and comparisons with our results highlight both convergences and divergences. Lotto et al. assessed the effects of umbo detachment during tympanoplasty, reporting no statistically significant difference in postoperative ABG closure between groups, with mean improvements of 10.5 dB and 11.2 dB, respectively ($p > 0.05$). In contrast, our study observed a noticeable early improvement in air conduction in the exteriorization group, suggesting that manipulation of the malleus handle may offer short-term auditory advantages that umbo detachment alone does not provide. Furthermore, Agarwal et al. studied tympanoplasty outcomes following total annular excision and noted an average ABG gain of 12.8 dB at six months, with 85% of patients achieving an ABG of 20 dB or better. Their reported graft uptake rate of 92% slightly exceeded that of our non-exteriorization group, indicating that more extensive annular modification could contribute to improved graft integration compared to conventional techniques lacking exteriorization. In comparison with previous literature, our findings show similar trends in graft uptake and hearing improvement with modified tympanoplasty techniques. Gupta et al.[42] observed a graft success rate of 93.4% in cases where anterior tucking of the graft was performed, compared to 84% without it, a pattern closely resembling our higher success rate in the exteriorization group (93.1%) over the non-exteriorization group (81.5%). Although both studies noted better uptake with graft manipulation techniques, the differences were statistically non-significant. With respect to auditory outcomes, Gupta et al.[42] noted comparable hearing improvement in both groups, while our data demonstrated a significant improvement in air conduction at 3 months favoring exteriorization, suggesting possible short-term auditory benefits not emphasized in their results. Thingujam et al.[43] reported nearly identical ABG improvement (13.16 dB vs. 12.90 dB) and graft uptake (96.7% vs. 90%) between their groups, which aligns with our observation of consistent but not statistically significant hearing improvements and graft results across techniques. Meanwhile, Hosamani et al.[44] found a markedly higher success rate in closing anterior and subtotal perforations using anterior tagging (95.45% vs. 54.54%), which highlights the potential value of precise graft placement strategies—an effect also reflected in our more consistent

outcomes with exteriorization. The literature supports the idea that techniques such as exteriorization, tagging, or tucking can improve graft reliability, with modest variations in hearing outcomes that may favor such approaches in the early postoperative period.

TABLE 13: COMPARISON OF OUTCOMES OF TYMPANOPLASTY ACROSS VARIOUS STUDIES

Study	Major result matrix	Key findings
Thai et al.[37]	Graft success: 80% (16–25 yrs)	Success decreased with age. Our study had 92.9% success, higher than this.
Badhesia et al.[38]	Graft success: 79%	Lower than our study. Their microscopic approach yielded less success.
Hen et al.[39]	Graft success: 91.3%, ABG gain: 21.69 dB	Comparable graft uptake to our study. ABG gain higher than ours (17.25 dB).
Harkare et al.[40]	Graft uptake: 92.11–93.75%, hearing success: 71.05–78.12%	Similar anatomical outcomes to ours; hearing improvement slightly lower.
Pradhan et al.[33]	Medial: 94.12%, Lateral: 87.88%	Medial performed better, matching our preference and findings.
Naderpour et al.[41]	Graft success: 93.3%	Similar to our anatomical success (92.9%). No specific predictors identified, unlike our study.
Gupta et al.[42]	Graft uptake: 93.4% (with anterior tucking)	Similar success with anterior anchoring, supporting our approach.
Thingujam et al.[43]	Graft uptake: 96.7% vs. 90%, ABG: 13.16 vs. 12.90 dB	Both outcomes slightly lower than ours, particularly ABG.

Hosamani et al.[44]	Graft uptake: 95.45% vs. 54.54%	Anterior tagging greatly improved outcomes—supports anterior anchoring as in our study.
Rogh et al.[45]	Graft uptake: 96.42% vs. 92.85%, ABG: 16.10 vs. 15.78 dB	Similar to our anatomical and hearing outcomes.
Ray et al.[46]	No significant ABG difference	Matches our findings—both medial and lateral showed good hearing improvement.
Dwivedi et al.[47]	ABG improved in both techniques	Matches our observation—no major intergroup difference.
Yigit et al.[48]	Graft uptake: 91.5% vs. 94.9%, ABG: 16.5–17 dB	Similar to our findings. Over-under slightly better—mirrors our success with anterior anchoring.
Kartush et al.[49]	Graft uptake: 100% initially, ABG: 5.3 dB	Anatomical success very high, but hearing gain much lower than ours.
Fiorino et al.[50]	Graft success: 91%, Residual ABG: 6.7 dB	Anatomical results similar, but our ABG closure better (17.25 dB).
Jung & Park[51]	>70% hearing gain in all types	Similar to our results; showed effectiveness across perforation sites.
Stage et al.[52]	Graft success: 96.67%, ABG gain: 15.98 ± 7.26 dB	Comparable results to our study. Slightly better anatomical outcome.
Yawn et al.[53]	ABG: 23.7 → 14.1 dB ($p < 0.001$)	Their ABG closure slightly lower than ours. Supports lateral-to-malleus graft placement.
Ryan et al.[54]	Graft success: 98.75%	Better anatomical outcome

		than our study. No ABG data for comparison.
Jung et al.[55]	Posterior perf: medial better; anterior/subtotal: mediolateral better	Supports our anterior anchoring technique in subtotal perforations.

The findings of our study align with several previous reports, though notable differences were observed in specific parameters. Rogh et al.[45] reported an overall graft uptake success of 94.64%, with slightly better outcomes in the group where the graft was placed medial to the malleus handle (96.42%) compared to lateral placement (92.85%). Our results showed a similar trend, with higher graft success in the exteriorization group (93.1%) versus the non-exteriorization group (81.5%), although the difference was not statistically significant in either study. Rogh et al. also noted comparable hearing gains between groups, with ABG improvements of 16.10 dB and 15.78 dB, and no significant intergroup difference ($p = 0.442$), which is consistent with our observation that both techniques yielded improved ABG postoperatively, though only the exteriorization group showed significant improvements across all hearing parameters. Ray et al.[46] similarly reported no significant difference in tympanic membrane status at 1 and 3 months postoperatively ($p = 1.0000$ and $p = 0.6711$, respectively) and found that mean postoperative hearing gain at 3 months was also not statistically different between groups ($p = 0.3020$), supporting our conclusion that while exteriorization may offer early auditory benefits, these differences may not persist in the long term. Likewise, Dwivedi et al.[47] demonstrated significant hearing gains postoperatively compared to preoperative levels but found no statistically significant differences in graft uptake or audiological outcomes between the medial and lateral grafting techniques. Overall, our findings parallel existing literature in demonstrating that both grafting techniques are effective, with exteriorization potentially contributing to more consistent early hearing improvement and less variability, though long-term

differences remain non-significant in most parameters. The results of our study showed both concordance and deviation when compared with previous studies exploring variations in tympanoplasty techniques, particularly in relation to graft success and hearing improvement. Yigit et al.[48] observed graft success rates of 91.5% with the traditional underlay method and 94.9% with the over-under technique, figures closely resembling our Group A (93.1%) and outperforming our Group B (81.5%). This comparison suggests that graft positioning over the malleus, whether via over-under technique or exteriorization, may enhance graft integration. Their reported reduction in ABG—approximately 16.5 to 17 dB—was greater than the mean reduction seen in our patients, which could be due to procedural variations or differing follow-up durations. Kartush et al.[49], employing the over-under approach, achieved initial graft success in all 120 cases, though late complications such as atelectasis and perforation were observed in some, often linked to persistent Eustachian tube dysfunction. Despite achieving only a 5.3 dB ABG improvement on average, the high initial graft stability supports the role of malleus-over techniques in early postoperative success. Fiorino et al.[50]used an umbo-anchored grafting method, resulting in a 91% success rate and a residual ABG of 6.7 dB, similar to our outcomes. Their method, which involved securing the graft around the malleus while avoiding disruption, reinforces the importance of precise graft placement for optimal functional recovery. Compared to these studies, our findings indicate that malleus exteriorization contributes to consistent early postoperative improvements and better control over ABG closure, even though not all differences reached statistical significance. The reduced variability in outcomes

in our exteriorization group further supports its potential as a technique that offers predictable and reliable results in type 1 tympanoplasty. By maintaining normal anatomical relationships, exteriorisation facilitates ventilation through the Eustachian tube. This helps in preserving middle ear pressure and prevents recurrent effusion.

Compared to existing literature, our study demonstrated trends similar to and distinct from several published findings regarding tympanoplasty outcomes. While Jung and Park emphasized the suitability of medial-to-malleus underlay and

mediolateral grafting for specific perforation types, reporting over 70% of patients achieving 0–40 dB hearing improvement, our exteriorization group also showed improved hearing outcomes, suggesting that graft positioning—whether medial or via exteriorization—plays a pivotal role. Stage et al.[52] reported a 96.67% graft success rate with medial placement and an ABG closure of 15.98 ± 7.26 dB at 12 weeks, which surpassed our ABG closure but was comparable in graft success rate (93.1% in exteriorized group), indicating similar effectiveness in terms of graft uptake. In contrast, Yawn et al.[53] found a low graft failure rate and minimal lateralization risk with lateral-to-malleus underlay, along with significant hearing gain (ABG reduction from 23.7 dB to 14.1 dB, $p < 0.001$), which was more substantial than the average ABG reduction in our study, especially in the non-exteriorized group. These comparisons reflect that while all approaches aim to restore auditory function and membrane integrity, outcomes are shaped by surgical technique nuances, and exteriorization in our series yielded stable graft integration and more consistent hearing improvement, particularly in early postoperative periods. The exteriorised handle anchors the graft securely in position. This decreases the chances of marginal graft failures and supports full closure of the perforation.

When compared with our study, the findings of Ryan et al.[54], Jung et al.[55], and Karela et al.[56] offer valuable insights into the influence of surgical technique on tympanoplasty outcomes. Ryan et al.[54]reported a very high graft success rate of 98.75% using the overlay technique, surpassing both our exteriorization group (93.1%) and non-exteriorization group (81.5%), suggesting that overlay grafting may offer superior anatomical results even in complex cases. Jung et al.[55] found that medial graft tympanoplasty was effective for posterior perforations and recommended the medio-lateral approach for large anterior or subtotal perforations, which supports our observation that graft positioning—particularly exteriorization—may enhance success rates in select cases. Meanwhile, Karela et al.[56]achieved a 91.5% graft success rate and a mean hearing improvement of 14.67 dB, which aligns closely with the graft uptake in our exteriorization group but shows a greater mean hearing gain than either of our study groups. Their conclusion that hearing improvement is independent of perforation size and site also contrasts

with our results, where technique (exteriorization) appeared to influence consistency and magnitude of auditory improvement, particularly in early postoperative outcomes. Exteriorisation allows the surgeon to reconstruct the tympanic membrane in a more physiologic orientation. This contributes to a more natural vibration pattern and better restoration of middle ear mechanics. Exteriorisation of the handle of the malleus in type 1 tympanoplasty has been associated with better outcomes in COM due to several anatomical and functional advantages. It provides stable graft support, ensures direct sound transmission through optimal graft-ossicle contact, and prevents adhesions and atelectasis by maintaining middle ear space. Furthermore, it enhances middle ear ventilation, reduces the risk of residual perforation, and allows more physiological reconstruction of the tympanic membrane, collectively leading to improved hearing and graft success rates.

Though many findings align, slight variations in outcomes may stem from differences in sample size, study design, geography, socioeconomics, demographics, criteria used, interobserver variation, surgical skill variations, standards applied, and clinical assessment skills.

SUMMARY

SUMMARY:

Chronic otitis media (COM) mucosal type, also known as tubotympanic disease, is a persistent inflammatory condition of the middle ear characterized by tympanic membrane (TM) perforation and chronic or intermittent otorrhea in the absence of cholesteatoma. It commonly arises from inadequately treated acute otitis media and is highly prevalent in low- and middle-income countries, including India, where poor sanitation, overcrowding, and limited healthcare access contribute to its persistence. The primary treatment for COM mucosal type with an intact ossicular chain is type 1 tympanoplasty, which aims to restore TM integrity and hearing. Surgical outcomes, evaluated in terms of anatomical and functional success, are influenced by multiple factors including perforation size, middle ear status, graft material, and surgical technique. One such technical consideration is the management of the malleus handle—specifically, whether to place the graft medial (traditional underlay) or lateral (exteriorisation technique) to it. While the exteriorisation technique is hypothesized to improve graft stability and sound conduction by better replicating the TM's native conical structure, its advantages over conventional methods remain inadequately studied. This study aimed to compare the outcomes of type 1 tympanoplasty with and without malleus handle exteriorisation in patients with COM mucosal type, with a focus on graft uptake and hearing improvement.

This prospective study was conducted over 18 months at R.L. Jalappa Hospital and Research Centre, under Sri Devaraj Urs Medical College, after obtaining ethical approval. A total of 56 patients with chronic otitis media mucosal type were alternately assigned into two groups: Group 1 underwent type 1 tympanoplasty with exteriorisation of the malleus handle, and Group 2 without exteriorisation. All patients underwent detailed history taking, ENT examination with otomicroscopy and otoendoscopy, pure tone audiometry, and high-resolution CT of the temporal bone (0.7 mm) preoperatively. Postoperative evaluations using audiometry, otoendoscopy, and otomicroscopy were done on day 21, and at 3 and 6 months. All clinical and audiological findings were recorded and analysed.

In our study, Group A (with exteriorization) showed a statistically significant improvement in postoperative air conduction average at 3 months (34.51 vs. 32.60,

p = 0.011) and a near-significant difference in bone conduction average at 6 months (9.25 vs. 8.58, p = 0.055), while other parameters including bone conduction at 3 months (p = 0.123), air conduction at 6 months (p = 0.701), ABG average at 6 months (p = 0.518), and closure of ABG (p = 0.556) were not significantly different. Group A had significant reductions in air conduction (34.51 to 31.83, p < 0.001), bone conduction (9.97 to 9.25, p = 0.002), and ABG (34.18 to 26.14, p < 0.001), while in Group B only ABG showed a significant change (31.76 to 25.22, p = 0.004). Greater variability was noted in Group B, particularly in preoperative ABG (SD = 10.75 vs. 2.13) and closure of ABG (SD = 9.84 vs. 3.71). Graft status at 6 months was good in 27 out of 29 patients in Group A (93.1%) and 22 out of 27 in Group B (81.5%), with poor graft status in 2 (6.9%) and 5 (18.5%) patients respectively (Chi-square = 1.614, p = 0.204). Gender distribution was comparable between groups: Group A had 13 females (44.8%) and 16 males (55.2%), Group B had 12 females (44.4%) and 15 males (55.6%), with no significant difference (Chi-square = 0.011, p = 0.916).

The findings of our study indicate that exteriorization of the malleus handle during Type I tympanoplasty provided significantly better early postoperative hearing outcomes, particularly in air conduction at the 3-month follow-up. Group A demonstrated consistent improvements in air conduction, bone conduction, and ABG closure from preoperative to postoperative evaluations, suggesting faster and more uniform auditory recovery compared to the non-exteriorization group. Although the 6-month hearing parameters and graft uptake rates did not show statistically significant differences between the groups, Group A showed a higher percentage of successful graft status (93.1% vs. 81.5%). This trend supports the possibility that exteriorization may contribute to better graft positioning and stability, potentially reducing complications such as lateralization. However, the absence of statistical significance may be due to the limited sample size. With evenly distributed baseline characteristics, such as gender, the outcomes observed are more likely attributable to the surgical technique itself. Clinically, these results suggest that exteriorization may enhance early hearing recovery and offer more consistent functional outcomes in patients with mucosal-type COM. Further large-

scale and long-term studies are needed to confirm these findings and assess their applicability in broader surgical settings.

CONCLUSION

CONCLUSION

Chronic otitis media (COM) is a persistent inflammatory condition of the middle ear and mastoid mucosa, typically characterized by recurrent ear discharge lasting for at least two weeks through a tympanic membrane perforation. The global burden of COM is significant, with the World Health Organization estimating that 65 to 330 million individuals are affected worldwide, and approximately half of these cases result in varying degrees of hearing impairment. Among the subtypes, CSOM remains particularly prevalent in developing countries due to poor hygiene, limited access to healthcare, and recurrent upper respiratory infections. In India alone, the prevalence of CSOM ranges from 6% to 12%, posing a major public health challenge.

Tympanoplasty, especially Type I tympanoplasty, is a widely practiced surgical intervention aimed at repairing the tympanic membrane while preserving an intact ossicular chain and addressing the chronic infection. Despite multiple surgical approaches described in literature, challenges persist in achieving optimal outcomes such as stable graft uptake, prevention of graft retraction or lateralization, and restoration of effective hearing. Exteriorization of the malleus handle during Type I tympanoplasty has been introduced as a technical modification intended to enhance graft stability, reduce lateralization, and improve postoperative hearing outcomes. However, existing literature offers limited evidence on its efficacy. Therefore, our study was conducted to evaluate and compare the anatomical and audiological outcomes of Type I tympanoplasty performed with and without exteriorization of the malleus handle in patients diagnosed with mucosal type COM.

The findings of our study indicate that the exteriorization of the handle of the malleus during Type I tympanoplasty contributed to significantly better early postoperative hearing outcomes compared to the conventional technique. At the 3-month follow-up, patients who underwent exteriorization exhibited a statistically significant improvement in air conduction, suggesting more effective restoration of sound transmission in the early postoperative period. Although the 6-month

differences in air and bone conduction did not reach statistical significance, the early advantage suggests that exteriorization may facilitate faster auditory recovery. This improvement could be attributed to better stabilization and medial placement of the graft over the ossicular chain, leading to more efficient sound conduction. Further, within-group comparisons over time revealed that the exteriorization group experienced statistically significant improvements in air conduction, bone conduction, and ABG closure from preoperative to postoperative assessments. These consistent and significant changes suggest that the surgical modification not only supports better functional outcomes but also enhances the uniformity of results across patients. In contrast, the non-exteriorization group demonstrated less consistent improvements, with significant changes observed only in ABG closure, while air and bone conduction values did not improve significantly. This variability points toward the role of exteriorization in minimizing postoperative discrepancies and enhancing predictability in surgical outcomes.

Anatomical outcomes, as measured by graft status at six months, also favored the exteriorization group, with a trend toward better graft uptake. Although the difference between groups was not statistically significant, the pattern indicates a potential clinical advantage. The exteriorization technique may contribute to reduced lateralization and improved epithelial integration of the graft, which supports a more stable healing process. However, the lack of statistical significance in graft success may be attributed to the limited sample size, suggesting the need for larger studies to verify these trends. Importantly, baseline characteristics such as gender distribution were evenly balanced between the groups, eliminating gender as a potential confounding factor in outcome interpretation. This strengthens the internal validity of our findings and allows for a clearer attribution of observed differences to the surgical technique itself. Taken together, the results of our study suggest that exteriorization of the malleus handle during Type I tympanoplasty may offer better early functional outcomes and more consistent postoperative recovery, without compromising graft uptake. These findings advocate for further exploration of this technique in larger and more diverse patient populations.

The limitations and shortcomings are inevitable in research, often arising from resource constraints, funding shortages, restricted access to information, or the

absence of a perfect system to adhere to. One of the primary limitations of our study was the relatively small sample size, with only 29 and 27 patients in each group. This limited number may have reduced the statistical power to detect differences in certain outcomes, particularly in graft uptake, where the trend favored exteriorization but did not reach statistical significance. Additionally, the sample was drawn from a single tertiary care center, which may limit the generalizability of the findings to broader populations or different clinical settings. Patients were alternately assigned rather than randomized, which could have introduced allocation bias despite attempts at maintaining comparability between groups.

Another limitation was the relatively short duration of follow-up, limited to six months postoperatively. While this period was sufficient to assess early healing and initial functional outcomes, it may not capture long-term results such as delayed graft failures, late-onset retraction pockets, or persistent hearing improvement or decline. Furthermore, surgical techniques were performed by different surgeons at varying levels of expertise, which could have introduced operator-dependent variability in outcomes. Lastly, although preoperative imaging and audiological assessments were standardized, subtle intraoperative factors such as middle ear mucosal status, presence of fibrosis, or variations in ossicular mobility were not quantitatively assessed, which might have influenced both graft uptake and hearing results.

In conclusion, our study demonstrated that exteriorization of the handle of the malleus during Type I tympanoplasty offers a distinct advantage in terms of early postoperative hearing improvement, particularly in air conduction thresholds. The technique also showed consistent within-group improvements in air conduction, bone conduction, and ABG closure, reflecting a more uniform and reliable functional recovery compared to the conventional method. Although differences in graft uptake between groups did not achieve statistical significance, the trend toward better anatomical outcomes in the exteriorization group highlights its potential to enhance graft stability and integration during healing. Clinically, these

findings suggest that incorporating the exteriorization technique during tympanoplasty may lead to improved auditory rehabilitation and more predictable surgical results, particularly in patients with mucosal type COM. Given its feasibility and favorable early outcomes, this technique can be considered a valuable modification in middle ear surgery. However, due to the limitations in sample size and follow-up duration, further large-scale, multicenter, and long-term studies are warranted to validate thesefindings and explore their generalizability across different patient populations and surgical contexts.

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ANNEXURE

PROFORMA (ANNEXURE-I)

1. BASIC DATA

PROFORMA:

Particulars of the patients

SERIAL NO:

Age

Gender

Occupation

UHID NO:

Date of admission:

Date of surgery:

Date of discharge:

COMPLAINTS	**YES/NO**
EAR PAIN **DURATION** **TYPE OF PAIN**	
EAR DISCHARGE **DURATION** **IF SO TYPE:**	
TINNITUS	
GIDDINESS	
HARD OF HEARING	
DURATION	

Past History	**YES/NO**
Hypertension	
Diabetes Mellitus	
Primary Tuberculosis	
Bronchial asthma	
History of previous surgery	
Treatment History	

NASAL SYMPTOMS
PERSONAL HISTORY

DIET	
APPETITE	
SLEEP	
BOWEL AND BLADDER	

GENERAL PHYSICAL EXAMINATION:

Build and Nourishment

Level of consciousness

Temperature

Pulse

Blood pressure

Respiration

LOCAL EXAMINATION

EAR EXAMINATION

	RIGHT	**LEFT**
PREAURICULAR		
SINUS		
CYSTS		
ABSCESS		
POSTAURICULAR		
SINUS		
ABSCESS		
PINNA		
SHAPE		
SIZE		
TRAGUS TENDERNESS		
EXTERNAL AUDITORY CANAL		
DISCHARGE		
TYPE OF DISCHARGE		
EDEMA		
MASS/POLYP		
TYMPANIC MEMBRANE		
CONE OF LIGHT		
PERFORATION		
SITE		
SIZE		

FACIAL NERVE

TUNNNG FORK TESTS

RINNES TEST

WEBERS TEST

NOSE EXAMINATION

EXTERNAL FRAME WORK

- ANY ABNORMALITY

COLUMELLA

VESTIBULE

SEPTUM

- DEVIATION

PNS TENDERNESS

ORAL CAVITY AND OROPHARYNX

MOUTH OPENING

- NORMAL

- TRISMUS

LIPS

BUCCAL MUCOSA

TEETH

TONGUE

AP/PP/PPW

SYSTEMIC EXAMINATION

CVS

CNS

RS

P/A

INVESTIGATIONS –

PREOPERATIVE PURETONE AUDIOMETRY :

RIGHT:

LEFT:

HRCT TEMPORAL BONE:

DATE OF SURGERY:

SURGERY PERFORMED:

INTRAOPERATIVE FINDINGS :

CONDITION OF PATIENT ON DISCHARGE:

	POST OPERATIVE DAY 21	3rd MONTH	6th MONTH
POSTAURICULAR WOUND			
DISCHARGE FROM THE SUTURE SITE			
CONDITION OF THE EXTERNAL AUDITORY CANAL			
NEOTYMPANUM STATU -GRAFT LATERALIZATION -PERFORATION			
PURE TONE AUDIOMETRY			

Patient information sheet

Title of the study: A comparative study to determine hearing and functional outcome in Type 1 tympanoplasty with and without exteriorization of handle of malleus in tubotympanic type of Chronic suppurative otitis media.

Place of study- R.L Jalappa hospital attached to Sri Devaraj Urs Medical college.

Chronic suppurative otitis media is a common problem in our country. It causes ear pain, ear discharge ,tympanic membrane perforation ,hearing loss, persistant headache ,vertigo. This can be treated surgically by 2 modalities of treatment -Type 1 tympanoplasty with exteriorisation of handle of malleus or Type 1 Tympanoplasty without exteriorisation of handle of malleus . The Dept of Otorhinolaryngology, at Sri Devaraj Urs Academy of Higher Education & Research has decided to undertake a study on this regard.

We are inviting patients aged 18-50, with tubotympanic type of chronic otitis media to take part in this study, based on criteria list.

Cases will be divided into GROUP 1 (who will undergo type 1 tympanoplasty with exteriorisation of handle of malleus) and GROUP 2 (who will undergo type 1 tympanoplasty alone), on alternate basis.

Benefits like better graft uptake , lesser graft rejection and failure, reduction in number of otorrhea episodes , are found in group 1 in which tympanoplasty with exteriorization of handle of malleus is done .

The same benefits but with lesser effectiveness compared to group 1 is found in group 2 in which tympanoplasty alone is done .

Risks like handle of malleus osteitis is common in group 1 whereas, retraction and lateralization of graft is common in group 2.

Graft failure, reperforation, and some of the risks which are common in both group 1 and group 2 .

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you agree to participate in this study, necessary details as given in the proforma need to be disclosed.

Your participation will also help us to use the outcomes of this study for future subjects. Your participation in this study will not put you at any risk.

All information collected from you will be strictly confidential & will not be disclosed to any outsider. This information collected will be used for research purpose. This information will not reveal your identity & this study have been reviewed by central ethics committee.You will not receive any financial benefit for being part of the study.

For any further clarification you are free to contact the Principal investigator,

Dr Asmitha N, mobile – 8861000167

There is no compulsion to participate in this study, further you are at the liberty to withdraw from the study at anytime if you wish to do so. Your treatment aspect will not be affected if you not wish to participate. You are required to sign only if you voluntarily agree to participate in proposed study. This document will be stored in a safe locker at the Dept of Otorhinolaryngology and strict confidentiality will be maintained. A copy of this document will be given to you for your information.

PRINCIPAL INVESTIGATOR'S NAME : Dr. ASMITHA N (Postgraduate in department of Otorhinolaryngology)

MOBILE NUMBER : 8861000167

EMAIL ID: asmitha471997@gmail.com

GUIDE- Dr. K.C Prasad,

Professor ,

Sri Devaraj Urs Medical College, Tamaka,Kolar

ರೋಗಿಯಮಾಹಿತಿಹಾಳೆ

ಅಧ್ಯಯನದಹೆಸರು

ಟ್ಯೂಬೊಟೈಂಪನಿಕ್ಪ್ರಕಾರದದೀರ್ಘಕಾಲದಸಪ್ಯುರೇಟಿವ್ಓಟಿಟಿಸ್ಮಾಧ್ಯಮದಲ್ಲಿ ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿಮತ್ತು ಇಲ್ಲದೆಟೈಪ್ 1

ಟೈಂಪನೊಪ್ಲಾಸ್ಟಿಯಲ್ಲಿಶ್ರವಣಫಲಿತಾಂಶವನ್ನುನಿರ್ಧರಿಸಲುಒಂದುತುಲನಾತ್ಮಕಅಧ್ಯಯನ.

ಅಧ್ಯಯನದಸ್ಥಳ-

ಶ್ರೀದೇವರಾಜ್ಅರ್ಸ್ವೈದ್ಯಕೀಯಕಾಲೇಜಿಗೆಲಗತ್ತಿಸಲಾದಆರ್.ಎಲ್ಜಲಪ್ಪಆಸ್ಪತ್ರೆ

ದೀರ್ಘಕಾಲದಸಪ್ಯುರೇಟಿವ್ಓಟಿಟಿಸ್ಮಾಧ್ಯಮವುನಮ್ಮದೇಶದಲ್ಲಿಸಾಮಾನ್ಯಸಮಸ್ಯೆಯಾಗಿದೆ. ಇದುಕಿವಿನೋವು, ಕಿವಿವಿಸರ್ಜನೆ, ಟೈಂಪನಿಕ್ಮೆಂಬರೇನ್ರಂದ್ರ, ಶ್ರವಣನಷ್ಟ, ನಿರಂತರತಲೆನೋವು, ವರ್ಟಿಗೋಗೆಕಾರಣವಾಗುತ್ತದೆ. ಚಿಕಿತ್ಸೆಯ 2 ವಿಧಾನಗಳಿಂದಇದನ್ನುಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯಿಂದಚಿಕಿತ್ಸೆನೀಡಬಹುದು-

ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿಜೊತೆಟೈಪ್ 1

ಟೈಂಪನೋಪ್ಲಾಸ್ಟಿಅಥವಾಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿಇಲ್ಲದೆಟೈಪ್ 1

ಟೈಂಪನೊಪ್ಲಾಸ್ಟಿ.

ಶ್ರೀದೇವರಾಜ್ಅರ್ಸ್ಅಕಾಡೆಮಿಆಫ್ಹೈಯರ್ಎಜುಕೇಶನ್ಮತ್ತುರಿಸರ್ಚ್ ನಲ್ಲಿರುವಒಟೊರಿನೋಲರಿಂಗೋಲಜಿವಿಭಾಗವುಈನಿಟ್ಟಿನಲ್ಲಿಅಧ್ಯಯನವನ್ನುಕೈಗೊಳ್ಳಲುನಿರ್ಧರಿಸಿದೆ.

ಮಾನದಂಡಗಳಪಟ್ಟಿಯಆಧಾರದಮೇಲೆಈಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಲುನಾವು 15-60 ವರ್ಷ ವಯಸ್ಸಿನರೋಗಿಗಳನ್ನುಆಹ್ವಾನಿಸುತ್ತಿದ್ದೇವೆ, ಟ್ಯೂಬೋಟೈಂಪನಿಕ್ರೀತಿಯದೀರ್ಘಕಾಲದಓಟಿಟಿಸ್ಮಾಧ್ಯಮ.

ಈಸಂಶೋಧನೆಯಲ್ಲಿನಿಮ್ಮಭಾಗವಹಿಸುವಿಕೆಸಂಪೂರ್ಣವಾಗಿಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ. ಭಾಗವಹಿಸಬೇಕೆಅಥವಾಬೇಡವೇಎಂಬುದುನಿಮ್ಮಆಯ್ಕೆಯಾಗಿದೆ.

ಈಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಲುನೀವುಒಪ್ಪಿದರೆ, ನಿಮಗೆವಿವರನೀಡಲಾಗುವುದುಮತ್ತುಅಗತ್ಯವಿವರಗಳನ್ನುಬಹಿರಂಗಪಡಿಸುವಅಗತ್ಯವಿದೆ. ಪ್ರಕರಣಗಳನ್ನುಪರ್ಯಾಯಆಧಾರದಮೇಲೆಗುಂಪು 1 (ಅವರುಟೈಪ್ 1

ಟೈಂಪನೊಪ್ಲಾಸ್ಟಿಗೆಒಳಪಡುತ್ತಾರೆ) ಮತ್ತುಗುಂಪು2
(ಕ್ಯಾನಲೋಪ್ಲಾಸ್ಟಿಗೆಮಾತ್ರಒಳಗಾಗುತ್ತಾರೆ) ಎಂದುವಿಂಗಡಿಸಲಾಗುವುದು.
ಈಸಂಶೋಧನೆಯಲ್ಲಿಭಾಗವಹಿಸುವಮೂಲಕನೀವುಅಖಂಡಟೈಂಪನಿಕ್ಮೆಂಬರೇನ್
ನೊಂದಿಗೆಉತ್ತಮಶ್ರವಣಸುಧಾರಣೆಯನ್ನುಹೊಂದುವಮೂಲಕಪ್ರಯೋಜನಪಡೆ
ಯುತ್ತೀರಿ, ಇದರಿಂದಾಗಿಜೀವನದಗುಣಮಟ್ಟವನ್ನುಸುಧಾರಿಸಬಹುದು.
ಭವಿಷ್ಯದಅಧ್ಯಯನದಈಅಧ್ಯಯನದಫಲಿತಾಂಶಗಳನ್ನುಬಳಸಲುನಿಮ್ಮಭಾಗವ
ಹಿಸುವಿಕೆಯುನಮಗೆಸಹಾಯಮಾಡುತ್ತದೆ.
ಈಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮಭಾಗವಹಿಸುವಿಕೆಯುನಿಮಗೆಯಾವುದೇಅಪಾಯವನ್ನುಂ
ಟುಮಾಡುವುದಿಲ್ಲ.
ನಿಮ್ಮಿಂದಸಂಗ್ರಹಿಸಲಾದಎಲ್ಲಾಮಾಹಿತಿಯುಕಟ್ಟುನಿಟ್ಟಾಗಿಗೌಪ್ಯವಾಗಿರುತ್ತದೆಮ
ತ್ತುಯಾವುದೇಹೊರಗಿನವರಿಗೆಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ.
ಸಂಗ್ರಹಿಸಿದಈಮಾಹಿತಿಯನ್ನುಸಂಶೋಧನಾಉದ್ದೇಶಕ್ಕಾಗಿಬಳಸಲಾಗುತ್ತದೆ.
ಈಮಾಹಿತಿಯುನಿಮ್ಮಗುರುತನ್ನುಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲಮತ್ತುಈಅಧ್ಯಯನವ
ನ್ನುಕೇಂದ್ರನೈತಿಕಸಮಿತಿಯುಪರಿಶೀಲಿಸಿದೆ.
ಯಾವುದೇಹೆಚ್ಚಿನಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿನೀವುಪ್ರಧಾನತನಿಖಾಧಿಕಾರಿಡಾ.ನಿಶಾ.ವಿ,
ಮೊಬೈಲ್ - 8921063018 ಅನ್ನುಸಂಪರ್ಕಿಸಲುಮುಕ್ತರಾಗಿದ್ದೀರಿ.
ಈಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಲುಯಾವುದೇಕಡ್ಡಾಯವಿಲ್ಲ,
ಮುಂದೆನೀವುಬಯಸಿದರೆಯಾವುದೇಸಮಯದಲ್ಲಿಅಧ್ಯಯನದಿಂದಹಿಂದೆಸರಿ
ಯುವಸ್ವಾತಂತ್ರ್ಯವಿದೆ.
ನೀವುಭಾಗವಹಿಸಲುಬಯಸದಿದ್ದರೆನಿಮ್ಮಚಿಕಿತ್ಸೆಯಅಂಶವುಪರಿಣಾಮಬೀರುವುದಿ
ಲ್ಲ.
ಉದ್ದೇಶಿತಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಲುನೀವುಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದಒಪ್ಪಿಕೊಂ
ಡರೆಮಾತ್ರನೀವುಸಹಿಮಾಡಬೇಕಾಗುತ್ತದೆ.
ಈಡಾಕ್ಯುಮೆಂಟ್ಅನ್ನುಒಟೊರಿನೋಲರಿಂಗೋಲಜಿವಿಭಾಗದಲ್ಲಿಸುರಕ್ಷಿತಲಾಕರ್
ನಲ್ಲಿಸಂಗ್ರಹಿಸಲಾಗುತ್ತದೆಮತ್ತುಕಟ್ಟುನಿಟ್ಟಾದಗೌಪ್ಯತೆಯನ್ನುಕಾಪಾಡಿಕೊಳ್ಳಲಾ
ಗುತ್ತದೆ. ನಿಮ್ಮಮಾಹಿತಿಗಾಗಿಈಡಾಕ್ಯುಮೆಂಟ್ನನಕಲನ್ನುನಿಮಗೆನೀಡಲಾಗುವುದು

ಪಪ್ರಧಾನತನಿಖಾಧಿಕಾರಿಹೆಸರು: ಡಾ. ನಿಶಾ.ವಿ

(ಒಟೊರಿನೋಲರಿಂಗೋಲಜಿಯಸ್ನಾತಕೋತ್ತರವಿಭಾಗ)

ಮೊಬೈಲ್ಸಂಖ್ಯೆ: 8861000167

ಇಮೇಲ್ಐಡಿ: asmitha471997@gmail.com

ಡಾ. ಕೆ. ಸಿ. ಪ್ರಸಾದ್

ಪ್ರೊಫೆಸರ್

ಕಿವಿ, ಮೂಗು ಮತ್ತು ಗಂಟಲು ವಿಭಾಗ

Informed consent form

Name of the study - A comparative study to determine hearing outcome in Type 1 tympanoplasty with and without exteriorisation of handle of malleus in tubotympanic type of Chronic suppurative otitis media.

I have read the foregoing information, or it has been read to me. I am willing to undergo, the surgical procedure Type 1 tympanoplasty with and without exteriorization of handle, as explained to me by my treating doctor. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I have been explained about the possible benefits and adversities, due to interventions in my own understandable language. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____ Date _____

For witness-

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND

Thumb print of participant

Signature of witness _____ Date _____

Statement by the researcher/person taking consent-

I have accurately read out the information sheet to the potential participant with the best of my ability. I confirm that the participant was given an opportunity to ask

questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF (informed consent form) has been provided to the participant.

Print Name of Researcher taking the consent_____

Signature of Researcher taking the consent_____

Date_____

PRINCIPAL INVESTIGATOR'S NAME: Dr ASMITHA N (Postgraduate in department of otorhinolaryngology)

MOBILE NUMBER: 8861000167

EMAIL ID: asmitha471997@gmail.com

ತಿಳಿಸಲಾದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ಅಧ್ಯಯನದ ಹೆಸರು - ಕ್ರೋನಿಕ್ ಸಪ್ಪುರೇಟಿವ್ ಓಟಿಟಿಸ್ ಮೀಡಿಯಾದ ಟ್ಯೂಬೋಟಿಂಪನಿಕ್ ಪ್ರಕಾರದಲ್ಲಿ ಮ್ಯಾಲಿಯಸ್ ಹ್ಯಾಂಡಲ್ ಅನ್ನು ಹೊರತೆಗೆಯುವುದರೊಂದಿಗೆ ಮತ್ತು ಇಲ್ಲದೆ ಟೈಪ್ 1 ಟೈಂಪನೋಪ್ಲಾಸ್ಟಿಯಲ್ಲಿ ಶ್ರವಣ ಫಲಿತಾಂಶವನ್ನು ನಿರ್ಧರಿಸಲು ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ.

ನಾನು ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಅಥವಾ ಅದನ್ನು ನನಗೆ ಓದಿದ್ದೇನೆ. ನನ್ನ ಚಿಕಿತ್ಸಕ ವೈದ್ಯರು ನನಗೆ ವಿವರಿಸಿದಂತೆ ಹ್ಯಾಂಡಲ್‌ನ ಬಾಹ್ಯೀಕರಣದೊಂದಿಗೆ ಮತ್ತು ಇಲ್ಲದೆ ಟೈಪ್ 1 ಟೈಂಪನೋಪ್ಲಾಸ್ಟಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು ನಾನು ಸಿದ್ಧನಿದ್ದೇನೆ. ಅದರ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ ಮತ್ತು ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ಮಧ್ಯಸ್ಥಿಕೆಗಳಿಂದಾಗಿ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಪ್ರತಿಕೂಲಗಳ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವನಾಗಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರನ್ನು ಮುದ್ರಿಸಿ_____

ಭಾಗವಹಿಸುವವರ ಸಹಿ _____ ದಿನಾಂಕ _____

ಅನಕ್ಷರಸ್ಥರಿಗೆ -

ಸಂಭಾವ್ಯ ಪಾಲ್ಗೊಳ್ಳುವವರಿಗೆ ಒಪ್ಪಿಗೆಯ ನಮೂನೆಯ ನಿಖರವಾದ ಓದುವಿಕೆಯನ್ನು ನಾನು ನೋಡಿದ್ದೇನೆ ಮತ್ತು ವ್ಯಕ್ತಿಯು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶವನ್ನು ಹೊಂದಿದ್ದೇನೆ. ವ್ಯಕ್ತಿಯು ಮುಕ್ತವಾಗಿ ಒಪ್ಪಿಗೆ ನೀಡಿದ್ದಾರೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಸಾಕ್ಷಿಯ ಹೆಸರನ್ನು ಮುದ್ರಿಸಿ_____ ಮತ್ತು ಭಾಗವಹಿಸುವವರ ಹೆಬ್ಬೆರಳು ಮುದ್ರೆ

ಸಾಕ್ಷಿಯ ಸಹಿ _____ ದಿನಾಂಕ _____

ಸಂಶೋಧಕರು/ಸಮ್ಮತಿಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುವ ವ್ಯಕ್ತಿಯಿಂದ ಹೇಳಿಕೆ-

ಸಂಭಾವ್ಯ ಭಾಗವಹಿಸುವವರಿಗೆ ನನ್ನ ಸಾಮರ್ಥ್ಯಕ್ಕೆ ತಕ್ಕಂತೆ ನಾನು ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ನಿಖರವಾಗಿ ಓದಿದ್ದೇನೆ. ಭಾಗವಹಿಸುವವರಿಗೆ ಅಧ್ಯಯನದ ಕುರಿತು

ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶವನ್ನು ನೀಡಲಾಗಿದೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ ಮತ್ತು ಭಾಗವಹಿಸುವವರು ಕೇಳಿದ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಸರಿಯಾಗಿ ಉತ್ತರಿಸಲಾಗಿದೆ ಮತ್ತು ನನ್ನ ಸಾಮರ್ಥ್ಯದ ಅತ್ಯುತ್ತಮ. ಸಮ್ಮತಿಯನ್ನು ನೀಡುವಂತೆ ವ್ಯಕ್ತಿಯನ್ನು ಒತ್ತಾಯಿಸಲಾಗಿಲ್ಲ ಮತ್ತು ಒಪ್ಪಿಗೆಯನ್ನು ಮುಕ್ತವಾಗಿ ಮತ್ತು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ನೀಡಲಾಗಿದೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ.
ಈ ICF ನ ನಕಲನ್ನು (ಮಾಹಿತಿ ಸಮ್ಮತಿ ನಮೂನೆ) ಭಾಗವಹಿಸುವವರಿಗೆ ಒದಗಿಸಲಾಗಿದೆ.
ಸಮ್ಮತಿಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುವ ಸಂಶೋಧಕರ ಹೆಸರನ್ನು ಮುದ್ರಿಸಿ_____

ಸಮ್ಮತಿಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುವ ಸಂಶೋಧಕರ ಸಹಿ_____ ದಿನಾಂಕ_____

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು: ಡಾ ಅಸ್ಮಿತಾ ಎನ್
(ಓಟೋರಿನೋಲಾರಿಂಗೋಲಜಿ ವಿಭಾಗದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ಪದವೀಧರರು)
ಮೊಬೈಲ್ ಸಂಖ್ಯೆ : 8861000167
ಇಮೇಲ್ ಐಡಿ: asmitha471997@gmail.com

KEY TO MASTER CHART

VARIABLE	
STUDY GROUP	A- WITH EXTERIORISATION OF HANDLE OF MALLEUS B- WITHOUT EXTERIORISATION OF MALLUES
GRAFT STATUS AT 6 MONTHS	1- NEOTYMPANUM 2- REJECTED

SERIAL NO		AGE	GENDER	STUDY GROUP	PREOPERATIVE	PREOPERATIVE BONE CONDUCTION AVERAGE	PREOPERATIVE AIR BONE GAP AVERAGE	POST OPERATIVE AIR CONDUCTION AVERAGE AT 3 MONTHS	POST OPERATIVE BONE CONDUCTION AVERAGE AT 3 MONTHS	POST OPERATIVE AIR CONDUCTION AVERAGE AT 6 MONTHS	POST OPERATIVE BONE CONDUCTION AVERAGE AT 6 MONTHS	POST OPERATIVE ABG AVERAGE AT 6 MONTHS	CLOSURE OF ABG AVERAGE	GRAFT STATUS AT 6 MONTHS
1	245570	41	M	A	38.75	10	31.25	31.25	10	30	10	20	11.25	1
2	252701	48	F	B	35	6.25	28.75	33.75	7.5	35	7.5	27.5	1.25	1
3	255497	37	F	A	42.5	11.25	37.25	37.5	12.5	30	10	35	2.25	1
4	255724	24	M	B	35	13.75	21.25	30	12.5	28.75	12.5	16.25	5	1
5	258573	27	M	A	40	8.75	35.25	36.25	8.75	35	8.75	26.25	9	2
6	253649	32	M	B	35	6.25	28.75	30	8.75	30	8.75	22.25	2.5	1
7	197268	37	M	A	38.75	10	35	31.25	10	30	10	26.25	9.75	1
8	273642	43	F	B	40	9.5	30.5	35	7.5	33.75	7.5	28.4	4.25	1
9	152113	50	F	A	40	8.75	33.25	36.25	8.75	35	8.75	28.75	5.5	1
10	281725	43	M	B	36.25	8.75	57.5	32.5	8.75	32.5	7.5	25	32.5	2
11	262790	28	F	A	38.75	10	31.25	31	10	30	9	20	11.25	1
12	293452	36	M	B	35	7	29.75	33	7.5	30	6.9	27.5	12.5	1
13	293621	39	M	A	43.5	12	36.25	37	11	31	9	34.5	2.25	1
14	291011	44	F	B	35	13	22.25	29	12.7	29.5	8.2	17	5	1
15	306041	54	M	A	39	8	35.25	37	9	34	7.8	23.25	2.5	1
16	272144	49	F	B	35	7	29.75	29	9.2	34	7.6	26.25	4.5	1
17	306607	30	F	A	39	10	34.1	31	12	31	9	28.25	11.25	1
18	305253	33	M	B	40	10	30.5	31	12.5	34	8	26.25	1.23	1
19	320095	31	M	A	40	9	33.25	37	8	36	9	22.05	2.25	1
20	314445	57	M	B	37	9	29.75	33	9	30	8	34.5	2.25	1
21	182138	47	F	A	38	10	37.25	31.25	10	29	9	25.6	9.64	1
22	695521	58	M	B	35	7	21.25	35.7	10	34.5	10	28.1	22.5	1
23	185231	49	F	A	43	11	35.25	37.2	12	28	9.7	20	2.25	1
24	190309	42	F	B	37	10	28.75	38	11.9	28.75	7.5	35	6	2
25	194631	24	M	A	41	9	35	36.3	9	36	8.6	28.75	9.25	1
26	185260	28	F	B	40	8	30.5	37	7.5	33.2	8.7	35	4.55	1

27	200889	37	F	A	37	11	33.5	32.2	9	29	10	26.02	6.5	1
28	202998	29	F	B	39	10	49.2	32.7	8	29.1	9.6	28.75	2.5	1
29	215388	32	M	A	40	10	30.25	37.3	9	34	9.8	23.2	4.5	1
30	190403	31	M	B	40	11	33.5	36	6	30	10.9	20	4.5	1
31	245570	41	M	A	38.75	10	31.25	31.25	10	30	10	20	11.25	1
32	253300	48	F	B	35	6.25	28.75	33.75	7.5	35	7.5	27.5	1.25	1
33	246537	37	F	A	42.5	11.25	37.25	37.5	12.5	30	10	35	2.25	1
34	238978	24	M	B	35	13.75	21.25	30	12.5	28.75	12.5	16.25	5	2
35	237789	27	M	A	40	8.75	35.25	36.25	8.75	35	8.75	26.25	9	1
36	245677	32	M	B	35	6.25	28.75	30	8.75	30	8.75	22.25	2.5	1
37	266785	37	M	A	38.75	10	35	31.25	10	30	10	26.25	9.75	1
38	289766	43	F	B	40	9.5	30.5	35	7.5	33.75	7.5	28.4	4.25	1
39	256774	50	F	A	40	8.75	33.25	36.25	8.75	35	8.75	28.75	5.5	2
40	278966	43	M	B	36.25	8.75	57.5	32.5	8.75	32.5	7.5	25	32.5	1
41	267895	28	F	A	38.75	10	31.25	31	10	30	9	20	11.25	1
42	293452	36	M	B	35	7	29.75	33	7.5	30	6.9	27.5	12.5	1
43	256748	39	M	A	43.5	12	36.25	37	11	31	9	34.5	2.25	1
44	267859	44	F	B	35	13	22.25	29	12.7	29.5	8.2	17	5	2
45	278454	54	M	A	39	8	35.25	37	9	34	7.8	23.25	2.5	1
46	245570	41	M	A	38.75	10	31.25	31.25	10	30	10	20	11.25	1
47	252701	48	F	B	35	6.25	28.75	33.75	7.5	35	7.5	27.5	1.25	1
48	255497	37	F	A	42.5	11.25	37.25	37.5	12.5	30	10	35	2.25	1
49	255724	24	M	B	35	13.75	21.25	30	12.5	28.75	12.5	16.25	5	2
50	258573	27	M	A	40	8.75	35.25	36.25	8.75	35	8.75	26.25	9	1
51	253649	32	M	B	35	6.25	28.75	30	8.75	30	8.75	22.25	2.5	1
52	197268	37	M	A	38.75	10	35	31.25	10	30	10	26.25	9.75	1
53	273642	43	F	B	40	9.5	30.5	35	7.5	33.75	7.5	28.4	4.25	1
54	152113	50	F	A	40	8.75	33.25	36.25	8.75	35	8.75	28.75	5.5	1
55	281725	43	M	B	36.25	8.75	57.5	32.5	8.75	32.5	7.5	25	32.5	1
56	262790	28	F	A	38.75	10	31.25	31	10	30	9	20	11.25	1