"THE ROLE OF CANALPLASTY IN TYMPANOPLASTY AND TO ASSESS ITS FUNCTIONAL AND SURGICAL OUTCOMES – A ONE YEAR COMPARATIVE STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE"

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Dr. RAJENDRA B. METGUDMATH M.S
Head of the Department
Department of Otorhinolaryngology
and Head & Neck Surgery,
KAHER's J.N.Medical College,
Nehru Nagar, Belagavi -590010

Date: 1/7/2024
Place: Belagavi

KAHER ★ BELAGAVI ★ J.N. MEDICAL COLLEGE

Dr. (Mrs)N. S. MAHANTASHETTI M.D(Peads)
Principal
KAHER's J.N.Medical College,
Nehru Nagar, Belagavi -590010

PRINCIPAL
J.N. Medical College,
BELAGAVI- 590 010

Date:
Place: Belagavi

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Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MoE (GoI)

Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA

0831 – 2471350 0831 – 2470759 www.jnmc.edu principal@jnmc.edu

Ref No: MDC/PG/ Date: 24-06-2024

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Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BE0121002
Postgraduate Student,
2021-22 Batch,
Department of E.N.T.
J. N. Medical College, Belagavi.

ETHICAL CLEARANCE CERTIFICATE

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JNMC INSTITUTIONAL ETHICS COMMITTEE
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref No.MDC/JNMCIEC/ 25 **Date: 27/09/2022**

To,

Reg.No.BE0121002

PG Student in Otorhinolaryngology and Head and Neck Surgery,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"THE ROLE OF CANALPLASTY IN TYMPANOPLASTY AND TO ASSESS ITS FUNCTIONAL AND SURGICAL OUTCOMES: A ONE YEAR COMPARATIVE STUDY IN DR PRABHAKAR KORE HOSPITAL AND MRC.",** is ethical and justifiable.

The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi

ABSTRACT

THE ROLE OF CANALPLASTY IN TYMPANOPLASTY AND TO ASSESS ITS FUNCTIONAL AND SURGICAL OUTCOMES

Aims and Objectives

1. To assess the post operative improvement in conductive hearing loss in patients who have undergone canalplasty with tympanoplasty, compared to tympanoplasty alone
2. To analyse the post operative enhancements in surgical outcomes (graft uptake) in patients who have undergone canalplasty with tympanoplasty, compared to tympanoplasty alone.

Methodology

This was an comparative study to evaluate the role of canalplasty in association with tympanoplasty in patients with COM requiring surgical intervention. All patients recruited in the study were followed up for 3 months post operatively.

Based on the selection criteria, a total of 50 patients were prospectively recruited in the study and all 50 patients were evaluable at the end of the study period.

Results

There was a significant decrease in mean PTA postoperatively and a significant improvement in mean hearing gain was reported in Group B patients undergoing canalplasty with tympanoplasty in comparison to Group A, who underwent tympanoplasty alone. The post operative mean hearing gain in Group A was 11.11, and in Group B was 15.39, which was statistically significant.

Superior surgical outcomes were reported for Graft uptake rate; in Group B patients, graft uptake was 100% (25/25) and in Group A, patients had a graft uptake of 92% (23/25).

At the end of the study, in Group B patients (canalplasty with tympanoplasty) post operative vertical dimensions were evaluated to be significantly superior to pre operative vertical dimensions, with pre operative mean of 6.56 (S.D. 0.78) and post operative mean of 10.64 (S.D. 0.91)

Conclusion

The addition of canalplasty to routine tympanoplasty enhances the overall efficacy and success rate of otological surgeries.

LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
COM	Chronic Otitis Media
AOM	Acute Otitis Media
TM	Tympanic membrane
OME	Otitis Media with Effusion
EAC	External Auditory Canal
EAM	External Auditory Meatus
MT	Microscopic tympanoplasty
SD	Standard Deviation
PTA	Pure Tone Audiometry

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INTRODUCTION

Tympanoplasty is a surgical procedure of choice with growing significance in the clinical management of Chronic Otitis Media (COM) and has revolutionized the management of tympanic membrane perforation and ear disorders.

Banzer [1]attempted the first recorded repair of tympanic membrane, Tympanoplasty has come a long way, and ongoing research continues to enhance its techniques.

Chronic Otitis Media (COM) continues to remain a public health challenge globally and in India, the estimated annual prevalence is estimated to be approximately 3.78% [2]. In a recent review, Chronic Suppurative Otitis Media (CSOM) was recognized as tympanic membrane perforation with current or recent otorrhoea. [3]

COM is characterized by a permanent anomaly affecting either the pars tensa or flaccida of the tympanic membrane and typically stemming from previous instances of Acute Otitis Media (AOM), negative middle ear pressure, or serous otitis media.[4] It is classified into mucosal and squamosal types, classically defined as safe and unsafe variety respectively.

The onset of COM is known to be related to Acute Otitis Media (AOM) or Otitis Media with Effusion (OME) experienced during infancy. OME may lead to the thinning of the tympanic membrane, thus resulting in hearing impairment, delayed speech development, and potential repercussions on the child's academic advancement. Histopathological characteristics associated with COM include the presence of granulation tissue, cholesterol granulomas, or the development of cholesteatoma [5]. Complications arising from perforations in the tympanic membrane

include hearing loss and recurrent ear infections, with persistent perforations often attributed to inadequate management of recurrent otitis media or traumatic perforations inflicted by infections. [6]

With the evolution of a number of techniques and surgical approaches, tympanoplasty has transformed the management of COM. Under current scrutiny, the role of canalplasty is being reviewed, with a premise to strengthen the surgical and functional outcomes, in tympanoplasty.

Sound Transmission in Tympanic membrane perforation:

The role of tympanic membrane in sound transmission has been extensively studied in various models. Tympanic membrane perforation is critical in disrupting the protective mechanism provided by the round window against sound transmission, allowing sound to reach both windows simultaneously, thereby nullifying the movements of the perilymph. [7]

The process of sound transmission from the external auditory canal to the cochlea involves ossicular and acoustic coupling. Middle ear aeration contributes to the maintenance of normal stapes-cochlear impedance and ossicular coupling. The presence of compressible air within the middle ear plays a crucial role in facilitating the movement of both the tympanic membrane and the ossicles, a movement that is primarily driven by the pressure differentials existing between the ear canal and the middle ear. [5]

Hearing impairment resulting from a tympanic membrane perforation is attributed to the reduction in the sound pressure differential across the membrane, leading to compromised ossicular coupling. The extent of hearing loss is directly correlated with the size of the perforation and exhibits variability across different

frequencies, being most prominent at lower sound frequencies (5). Studies have determined tympanic membrane perforations to affect the acoustic transmission and cause frequency-dependent loss based on the size of perforation, independent on location perforation[7]. Tympanic membrane has unique structural and physical properties that are vital for sound transmission and any variations from normal conditions will likely result in hearing loss. [8]

AIMS AND OBJECTIVES

Our study was designed with the following objectives

1. To assess the post operative improvement in conductive hearing loss in patients who have undergone canalplasty with tympanoplasty, compared to tympanoplasty alone
2. To analyse the post operative enhancements in surgical outcomes (graft uptake) in patients who have undergone canalplasty with tympanoplasty, compared to tympanoplasty alone.

REVIEW OF LITERATURE

Physiology of sound in External Auditory Canal:

Before sound waves reach the tympanic membrane, the waves undergo alteration via reflection and attenuation due to the external morphology of the body, the auricle, and the auditory canal. The auricle and the auditory canal combine to form a funnel with sealed ends alongside the tympanic membrane. The auditory canal and auricle exert the most significant impact on the resonance of the outer ear. [9]

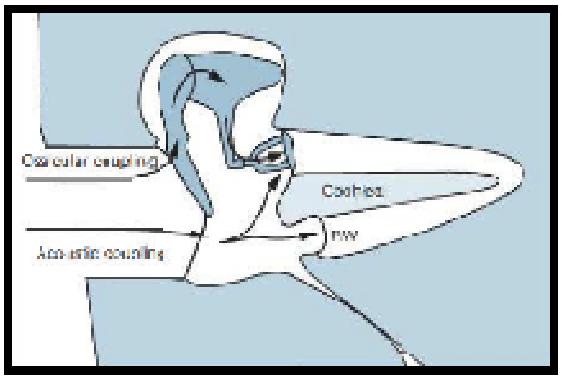
The ear canal assumes a critical role in modulating sound. The sharp anterior angle of the tympanomeatal junction can notably adjust the volume and inlet width of the ear canal, thereby influencing its resonance. A resonance-driven enhancement of sound pressure by up to 20 dB is observed in the typical ear canal at frequencies ranging from 2800 to 3000 Hz, contingent upon the canal's length and diameter. Essentially, a larger entrance of the external auditory meatus corresponds to a higher resonance frequency, while a greater cavity volume results in a lower resonance frequency. A decline of 10 dB in acoustic pressure amplification within the 3 to 4 kHz frequency range is linked to volume expansion. [9]

Surgical remodelling of the bony external auditory canal (EAC) leads to alterations in resonance acoustics. Research has demonstrated that crafting a wider bony EAC substantially reduces the resonant frequency and notably boosts the peak amplitude. [10]

The significance of a patent external auditory meatus (EAM) in facilitating the perception of higher frequency sounds, crucial for speech recognition, is underscored by finite element modeling of the ear. [8]

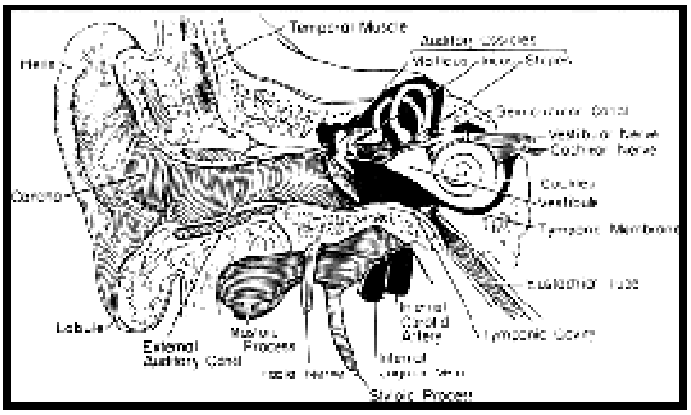
Lower frequencies with wavelengths exceeding the canal's dimensions remain unaffected by changes in canal diameter; however, at higher frequencies, variations in canal size visibly impact sound transmission. Notably, the canal segment nearest to the tympanic membrane plays a crucial role in transmitting high frequency sounds. [11]

Figure 1: Sound Transmission in Tympanic membrane perforation



Anatomy of External Auditory Canal(EAC)

Figure 2 : Anatomy of EAC



The external auditory canal has been extensively studied to have a sophisticated anatomy, contributing to the function of hearing. However, notable variations amongst individuals and racial groups have been documented. [12]

In a study to review and enhance awareness among otologists and radiologists regarding EAC variations and related dimensions of the EAC, Kelly and Mohs [13] explored the unique anatomy of the EAC**.** They observed that

1. At the entrance of the external auditory canal (EAC), the average vertical dimension (height) measured 7.75 ± 1 mm, while the average horizontal dimension (width) was 6.1 ± 0.8 mm.
2. At the junction where bone meets cartilage in the EAC, the average vertical dimension was 7.88 ± 1 mm, and the average horizontal dimension was 6.22 ± 0.9 mm.
3. Within the isthmus of the EAC, the average vertical dimension was 6.8 ± 0.97 mm, and the average horizontal dimension was 5.2 ± 0.76 mm.
4. At the innermost part of the EAC, the average vertical dimension was 7.1 ± 0.9 mm, while the average horizontal dimension was 5.4 ± 0.85 mm.

In a study by Anwar et al [14] , Computed Tomography (CT) scans were used to investigate the dimensions and characteristics of the external auditory canal (EAC).

Based on the current challenges to measure EAC diameter, Li et al [15] attempted to describe a method for EAC especially in congenital aural stenosis (CAS) and also proposed a method to measure the dimensions of the EAC, especially for CAS where the EAC is abnormally narrow.

Ahmad et al [16] conducted a study on utilizing silicon casting material in human cadaver ears to examine the narrowest point of the external auditory meatus. The isthmus, which is the narrowest part of the EAM, is located at the junction of the outer one third and inner two thirds of the canal length. This constriction predominantly occurs in the anteroposterior plane, displaying an oval or inverted pear shape.

A novel approach for measuring the dimensions of the osseous external auditory canal (OEAC) using CT (computed tomographic) images of the temporal bone was introduced by Mahboubi et al [17] who proposed a standardized method to measure OEAC dimensions. CT scans were used to assess the OEAC in axial and coronal planes, parallel to the tympanic membrane. The measurements focused on the medial-most aspect of the OEAC. The clinical significance of understanding OEAC dimensions is crucial for surgical planning and management, thus enhancing the accuracy in assessing the OEAC.

Chronic Otitis Media:

Chronic Otitis Media (COM) poses a considerable risk of inducing both conductive hearing loss (CHL) and sensorineural hearing loss (SNHL) in affected individuals. The diagnosis of chronic otitis media, primarily relies on otoscopic examination, with a comprehensive evaluation of presenting symptoms and prior treatment history. [4]

Etiology of COM:

The etiology of COM has been attributed to a number of factors, such as [18]

a. Eustachian tube dysfunction in children, such as those with cleft palate and Down's syndrome, alongside a patulous Eustachian tube that permits nasopharyngeal reflux

b. The presence of mucosal immune system deficiencies specific to the upper respiratory tract mucosa immunity, as well as atopy,

c. Systemic immune deficiency

d. Poor mastoid pneumatization

Factors affecting progression of CSOM

The failure of healing of a tympanic membrane perforation is owing to persistent infections in the middle ear cavities with continuous purulent otorrhea. Eustachian tube obstruction causes hypopressure in the tympanic cavity, leading to local secondary hypoxia and inflammation obstructing epithelial repair. Extensive perforations have also been linked to process of healing, as the spontaneous closure might be hindered by the size of the perforation and the migration patterns of epithelial cells. Further, the development of granulation tissue and polyps within the middle ear cavity in response to the host's immune reaction also complicates the healing process. [18]

When tympanic membrane perforation is evident without any signs of inflammation, it is called dry perforation, and is vital for ensuring suitable treatment strategies.

Hearing loss in COM

A number of studies have reviewed hearing loss subsequent to tympanic membrane perforation. The resultant lowering of pressure differential is known to compromise auditory function. [19 20 21]

Moreover, a larger size of perforations is strongly linked to a more noticeable decrease in the efficiency of the eardrum, due to a further decrease in pressure difference.

The level of hearing loss is directly related to the size of the perforation, rather than its location within the eardrum. [21]

Ossicular Bone Necrosis is connected to conductive hearing loss. When there is complete disconnection of the ossicular bones without any damage to the eardrum, there is a significant decrease in the transmission of sound in the middle ear, resulting in a reduction of 40-60 dB, depending on the specific frequency being evaluated. [22]

The correlation between the volume of the middle ear and mastoid and hearing loss is inversely related when there is tympanic membrane perforation. In cases where the perforation is consistent in size and position, the air-bone gap caused by the perforation could show fluctuations of about 35 decibels, influenced by the particular volumes of the middle ear and mastoid. [5]

Hearing Assessment

Modern otological practices for surgical interventions include a variety of diagnostic tools and methodologies that a are vital to guide decision-making process. Weber and Rinne tuning fork tests and 512-Hz tuning fork is a necessary aid to identify hearing loss to differentiate between conductive and sensorineural dysfunctions.

The significance of an audiogram is highly esteemed in the evaluation of conductive hearing loss and identification of varying air-bone gaps. The determination of the air-bone gap depends on several factors, such as the size of the tympanic membrane perforation, erosion of the ossicular chain (particularly the long process of the incus and sometimes the stapes superstructure), presence of granulation tissue around the ossicular chain affecting its movement, and the occurrence of tympanosclerosis around the ossicular chain area, which becomes crucial in situations of inconsistencies [5].Pure-tone audiometry has emerged as a fundamental tool for evaluating the extent of conductive hearing impairment associated with the underlying pathology. [4]

Other complications of COM

The reported prevalence rates for intracranial and extracranial complications of Chronic Otitis Media (COM) range between 0.69% and 5% [23].Moreover, complications within the temporal bone can impact the cochlea, labyrinth, and facial nerve, presenting in both extracranial and intracranial forms. Examples of extracranial complications include postauricular abscesses, facial palsy, petrous apicitis, and Bezold abscess. Conversely, intracranial complications encompass severe conditions like meningitis, brain abscess, extradural abscess, subdural abscess, lateral venous sinus thrombosis, and otitic hydrocephalus, highlighting the critical need for timely identification and intervention to prevent adverse outcomes. [4]

Studies by Singh and Maharaj [24] have highlighted the prevalence of squamous epithelial disease as opposed to mucosal disease when considering extracranial and intracranial complications.

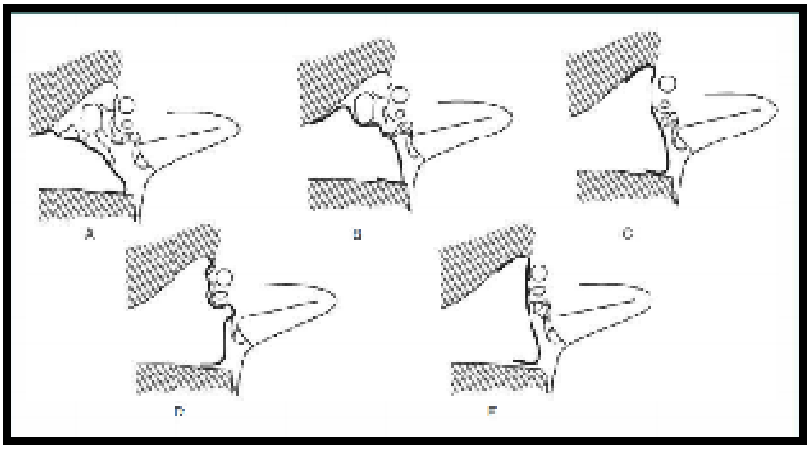
The onset of pain may potentially indicate the commencement of an acute infection, hinting at a potential accumulation of purulent material under pressure within the middle ear or mastoid region. Furthermore, it is worth noting that otogenic abscesses have the capability to manifest in ears that have previously undergone mastoidectomy procedures. [4]

Tympanoplasty

The primary goal of a tympanoplasty procedure is to restore sound to create an airtight, air-filled middle ear and reconstruct a connection from a large tympanic membrane to the stapes footplate through either an intact or reconstructed ossicular chain. [7]

The effectiveness of tympanoplasty is evaluated by the outcomes in terms of either the success or failure of graft-take, along with the degree of hearing improvement. [7]

Figure 3: Wullstein classification of Tympanoplasty



Wullstein proposed a categorization system for tympanoplasty, which relies on the residual of the middle ear following complete eradication of any pathological conditions and a method by which protection of round window is ensured. [5]

Types of tympanoplasty according to Wullstein.

- Type I Normal middle ear restoration.
- Type II. Ossicular chain partial destruction but preservation and restoration of the continuity. After removal of the bridge skin graft is laid against the ossicles.
- Type Ill. Myringostapediopexy producing a shallow middle ear and a columella effect.
- Type IV. Small middle ear mobile footplate being left exposed with round window protection
- Type V. Closed middle ear with round window protection; fenestra in the horizontal semicircular canal covered by a skin graft.

Although tympanoplasty has inherent advantages and aims to reinforce the membrane, the association with Canalplasty has been observed to facilitate visualization of the complete ring of the tympanic annulus using a singular anatomical orientation and is particularly beneficial in cases of anatomically narrow canals. [11]

Steps of Tympanoplasty

Two primary grafting techniques in tympanoplasty, namely underlay and overlay are known.

The **underlay** technique, places the graft in a medial position relative to the tympanic membrane remnant and the manubrium of the malleus.

With the **overlay** technique, the graft is placed laterally to the tympanic membrane remnant and medially to the manubrium and is known to be associated with a heightened risk of complications such as blunting of the anterior sulcus and graft lateralization, potentially leading to significant conductive hearing loss. [25]

Tympanoplasty involves a series of meticulous steps that are crucial for successful outcomes. Firstly, the postauricular incision, which typically starts from the mastoid tip and extends to just above the attachment of the helix, is strategically positioned 5 to 10 mm posterior to the postauricular crease. [6]

Subsequently, the temporalis muscle and fascia are meticulously exposed, starting from the zygomatic root. The periosteum is then incised along the linea temporalis, creating a vertical limb that forms a distinctive "T" shape before curving down towards the mastoid tip. [6]

Within the posterosuperior region of the ear canal, precisely situated between the tympanosquamous and tympanomastoid sutures, lies the vascular strip. This

specialized area of skin serves as a conduit for the deep auricular branch of the maxillary artery, facilitating the crucial blood supply needed to nourish the tympanic membrane during the healing process. [26]

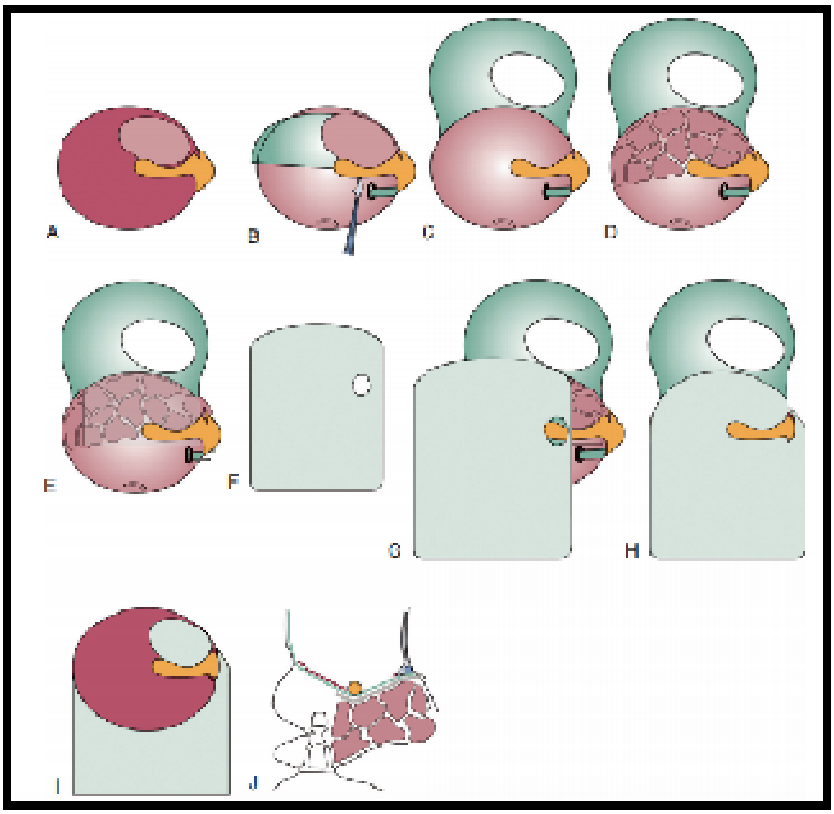
Special attention is paid to avoiding skin tears, especially at points of attachment along the tympanomastoid and tympanosquamous suture lines, ensuring the integrity of the delicate tissues within the ear canal. [6]

Innovative techniques involving strategic incisions are employed to optimize the surgical outcomes of tympanoplasty. By creating vertical incisions at the 6 and 12 o'clock positions and connecting them with a horizontal incision just lateral to the annulus, a long vascular strip is meticulously crafted. These meticulous incisions pave the way for precise placement of graft materials, a critical step in restoring the integrity of the tympanic membrane. [6]

Conversely, the medial technique is preferred for repairing posterior and inferior central perforations, total perforations, or in revision cases under the skilled hands of an experienced surgeon. This technique, when executed with precision, offers a reliable approach to addressing challenging tympanic membrane defects and ensuring favourable surgical outcomes. [6]

In lateral technique tympanoplasty, meticulous attention is paid to the placement of the graft to avoid complications such as iatrogenic cholesteatoma formation. Complete removal of the squamous epithelium from the lateral surface of the tympanic membrane remnant is crucial for maintaining the integrity of the surgical site and preventing potential postoperative issues. [6]

Fig 4: Steps of Tympanoplasty



A recent meta-analysis of type I tympanoplasty by Tan et al [27] reviewed 214 studies (26,097 patients) and found no evidence of superiority for a particular surgical approach or graft placement technique.

Furthermore, a comprehensive bony canalplasty is often necessary to facilitate anterior visualization and ensure accurate graft placement during the surgical procedure. By carefully reshaping the angle between the anterior canal wall and the tympanic membrane to approximately 90 degrees, surgeons can achieve optimal exposure of the entire annulus without the need to adjust the surgical microscope constantly [(28)]. This meticulous process may involve removing a significant portion of the anterior canal bone using specialized otologic drills with continuous irrigation, particularly focusing on the superior and inferior corners of the anterior bony canal to create a clear surgical field conducive to precise graft placement. [6]

When placing the graft during the surgical procedure, it is crucial to exercise caution to ensure that there is no overlap with any part of the wall of the anterior canal. Failure to do so may result in blunting, affecting the outcome of the surgery. It is important to note that the graft should be positioned laterally to the annulus, but medially to the malleus handle to prevent any lateralization issues .[28]

If the graft is erroneously positioned on the anterior canal wall or if the acute anterior tympanomeatal angle is compromised, it can lead to the creation of a dead space that fills with fibrous tissue, ultimately causing blunting. This blunting reduces the vibratory area of the tympanic membrane, resulting in persistent conductive hearing loss. [6]

Numerous diverse tissue grafts have been extensively discussed in the literature for the purpose of repairing the Tympanic Membrane (TM), encompassing materials such as temporalis fascia, perichondrium, cartilage, periosteum, and fat graft. Among these options, temporalis fascia emerges as the most frequently employed material in clinical practice for addressing tympanic membrane perforations.[5]

Temporalis fascia procurement can be achieved concurrently with tympanoplasty by means of a small incision located posterosuperiorly to the helix in the hair-bearing scalp, particularly when utilizing a transcanal approach .[5]

Outcomes-Graft uptake rate

A success rate of 95% has been reported post tympanoplasty when performed by highly skilled otosurgeons, which underscores and highlights the substantial impact of surgical expertise. On review of 281 myringoplasties by Plava and Ramsay [29], a closure rate of 97% was reported when performed under the skilful supervision of an experienced otosurgeon, compared with 74% among surgeons with limited experience. Similarly, Vartiainen et al [30] reported a successful closure rate of 78% for trainees in comparison to 95% for senior staff.

In contradiction to the above, assumption related to the high skills and competencies of otosurgeon, Wasson et al.'s study [31] observed that neither the skill level of the surgeon nor the specific type of graft material used had a significant impact on the closure rate or the hearing outcomes.

Many outcome assessments are based on relatively short-term follow-ups lasting 6 to 12 months, yet extended observations have indicated that some ears initially showing integrity may develop recurrent perforations later on. [32]

Other factors [33] affecting successful graft uptake include the size of the perforation. Closure rate is significantly higher for small perforations (74%) compared to larger ones (56%).

Additionally, the efficacy of graft survival in revision surgery has been examined in contrast to initial procedures. Halik and Smyth [32] reported a retention rate of only 60% for tympanic membranes after revision surgery, highlighting a significantly reduced success rate compared to what is commonly reported for primary procedures.

Hearing outcomes

In terms of auditory results, the effective closure of the tympanic membrane generally leads to only a minor enhancement in hearing capability. Achieving a full closure of the air-bone gap in myringoplasty is infrequent, as repairing a perforation in the tympanic membrane does not completely return the ear to its original condition. [4]

Failure of Surgery

A number of factors are responsible for tympanoplasty failure and well known factors are attributed to reperforation, graft lateralization, atelectasis and postop myringitis. [5]

The majority of failures tend to transpire in the early post-operative phase, primarily attributed to graft failure resulting from infections leading to graft necrosis, or the failure of the anterior portion of the graft, which is considered the most vulnerable due to the apparent hypovascularity in this specific region when compared to the remainder of the tympanic membrane. [34]

Evidence related to success rates of tympanoplasty therefore remains a topic of scientific quest.

Success rates ranging from 60% to 99% have been documented in the adult population, and from 35% to 94% in paediatric patients [35] .Further, some studies have proposed a decline in success rates over time, transitioning from an approximate 85% rate at 1 year to 78% at the 10-year mark. [36]

It is important to note that many of the studies have relatively brief follow-up durations and long-term investigations are limited in number.

Canalplasty role in Microscopic tympanoplasty

The ultimate objective of a canalplasty intervention should be the complete visualization of the entire tympanic annulus from a single perspective under the microscope, adhering to Fisch's dictum. [11]

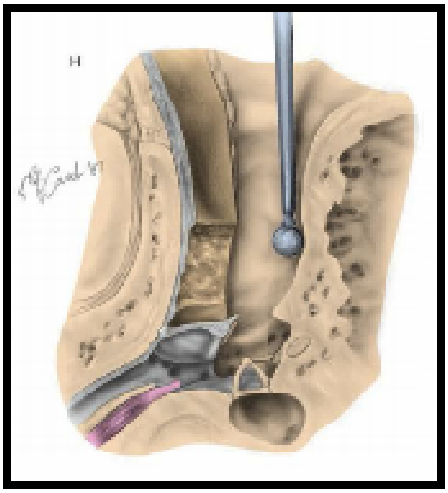


Fig 5: Canalplasty

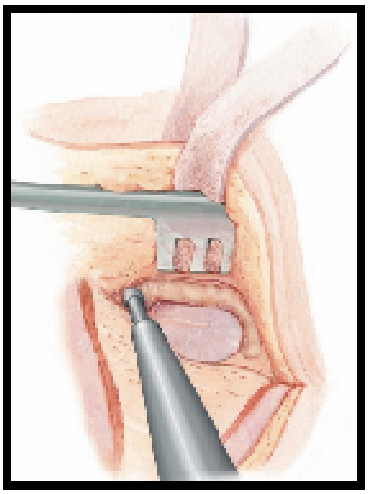


Fig 6: Canalplasty Drilling technique

Microscopic Tympanoplasty (MT) has been a prevailing surgical technique in otolaryngology since the 1950s, the postauricular incision is favoured for its superior visualization of the surgical field. With adoption of endoscopy, the transcanal approach is typically reserved for cases involving small tympanic perforations and a wide ear canal. Nevertheless, MT remains a global preference attempted via the postauricular method [37]. Microscopic Tympanoplasty (MT) exhibits a remarkable success rate, with graft acceptance rates exceeding 90%. Microscopic procedures are constrained by the narrowest segment of the ear canal, which limits visibility. [37]

Few comparative studies exist, Research indicates that closure rates of the Tympanic Membrane (TM) with ET range from 80% to 100%, similar to the success rates achieved with MT [38]. In comparison to MT, lower rates of canalplasty have been reported for ET. [39 40]

The limitations of otologic microscopy, such as restricted visibility in cases of tortuous ear canals or bony obstructions, can be overcome with canalplasty. [37]

Numerous studies have consistently pointed out that within the microscopy groups, there were instances where the tympanic annulus was not fully visualized in a range of 17% to 20% of the patients. This consequently led to the necessity of canalplasty procedures in order to address this limitation in visualization. [39]

Improved visualization is a critical element in the realm of otolaryngology, according to Vijayendra et al [40,] given its significant impact on facilitating the precise placement of graft material, particularly in the anterior anchoring of the graft within the subtotal perforation. This heightened visualization not only assists in the accurate positioning of the graft but also contributes substantially to the overall success of the procedure by ensuring an optimal placement that leads to enhanced outcomes.

According to Prakash et al [41] combining canalplasty with tympanoplasty is recommended as it enhances the visualization of the tympanic membrane, aiding in the accurate placement of the graft and preventing lateralization. Consequently, this approach leads to an improvement in overall graft uptake and hearing outcomes.

Morrison et al [42] concluded that sufficient exposure is highly important. Canalplasty is a method that can significantly enhance exposure, thereby aiding in the precise placement of grafts; traditionally, it is deemed necessary for lateral grafting but is not commonly carried out in medial graft repairs.

Following surgical procedures of the middle ear and auditory canal, enhanced visualization has also made it easier to monitor postoperative care of patients. This improved visibility leads to a more efficient postoperative care process, allowing for better monitoring and management of the patient's condition.

Success rates in Tympanoplasty

Surgical success is attributed to a well-established mucosa-lined middle ear cleft that showcases an intact tympanic membrane (TM) along with a completely preserved and mobile ossicular chain. [43]

In a recent investigation, Salviz et al [44] have illuminated the relationship between audiological results and middle ear cavity volume post-TM restoration. They have also pinpointed various other factors that may influence the success rates of tympanoplasty, such as patient age, Eustachian tube function, perforation size, smoking habits, bilateral conditions, and septal deviations. The success rate of tympanoplasty decreases significantly in cases where bilateral ear disorders and adenoid conditions are present.

Dornhoffer's research [45] emphasizes the improved success rates linked with cartilage tympanoplasty, especially in high-risk patient groups. These groups include individuals with bilateral conditions, pediatric patients, cases requiring revision surgeries, and instances of otorrhea during the operation.

Lin YC et al [46] have explicitly linked smoking as the sole factor significantly increasing the risk of failure in cartilage tympanoplasty.

According to Thiel et al [47] approximately 50 percent of individuals undergoing tympanic membrane repair procedures can anticipate the restoration of 'normal' hearing in the operated ear subsequent to the surgical intervention.

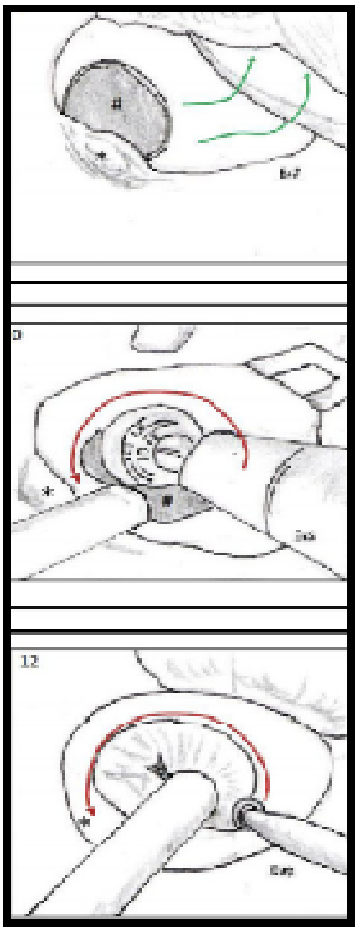


Fig 7: Canalplasty

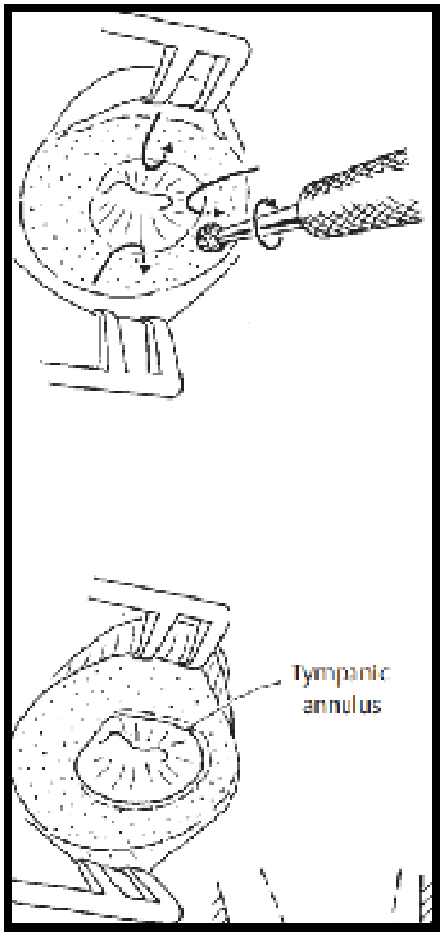


Fig 8: Canalplasty method of dissection

The role of canalplasty in association with tympanoplasty is garnering significant scientific attention. In the context of India, recently, the topic of associating canalplasty with tympanoplasty is also gaining momentum [48]. The existing body of research has primarily concentrated on achieving improved postoperative results. This includes the time dedicated to performing canalplasty, as well as the rates of underlay (medial) and overlay (lateral) graft uptake, both with and without tympanoplasty. Additionally, previous studies have explored the postoperative gain in hearing improvement and overall graft uptake. Some of these studies were retrospective in nature, which inherently introduces certain methodological limitations and biases.

Currently, there remains a scarcity of prospective studies that are specifically designed to evaluate the functional and surgical outcomes to investigate the role of canalplasty in association tympanoplasty.

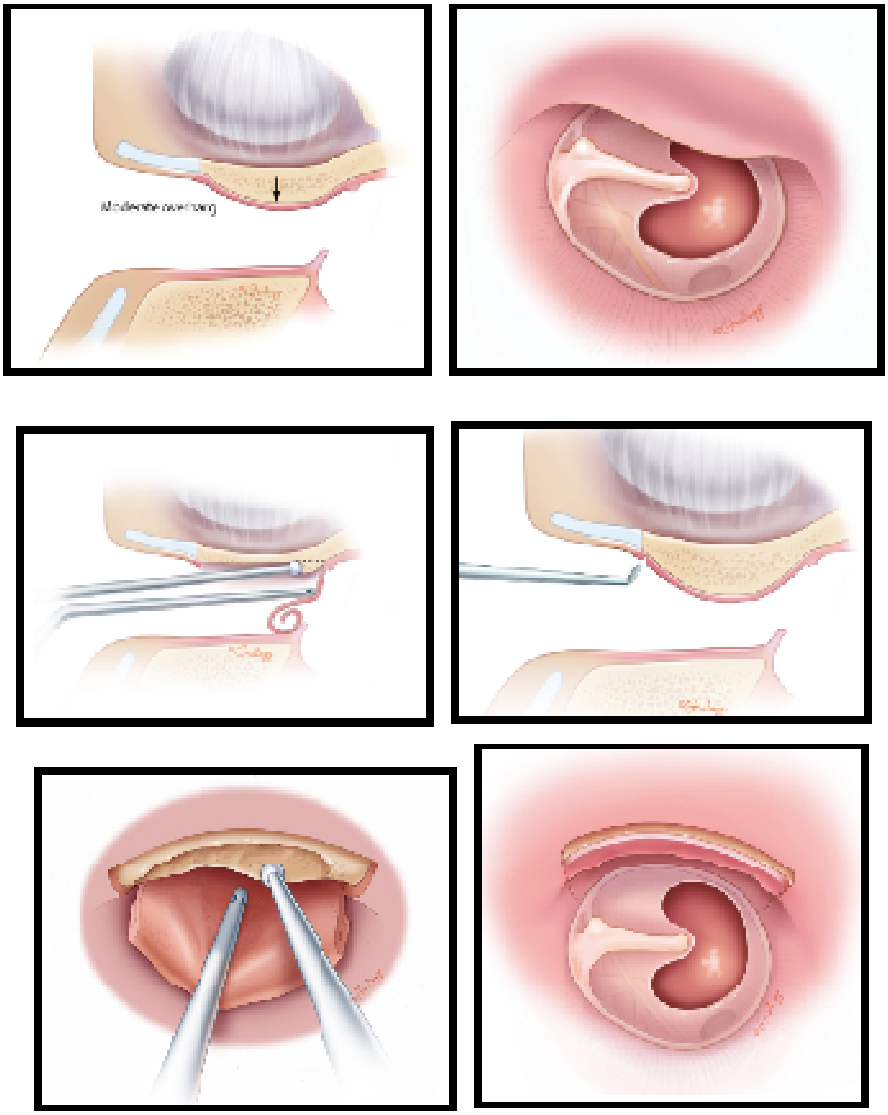


Fig 9: Steps of Canalplasty

Limitations of Tympanoplasty

Tympanoplasty is linked to a low risk of inducing sensorineural hearing loss [4]. Children below the age of 5 are generally not considered suitable candidates for tympanoplasty due to the increased risk of postoperative failure caused by otitis media

and compromised Eustachian tube function [4] .For elderly individuals and adults with significant medical conditions, a comprehensive evaluation is crucial to balance the potential advantages of surgery with the risks associated with anesthesia [4]. It is essential to evaluate the status of chronic suppurative otitis media (CSOM) in the affected ear, with active CSOM requiring medical intervention to treat infection and eliminate otorrhea, thus transitioning the condition to inactive chronic otitis media. A period of observation lasting up to 6 months is recommended, during which elective tympanoplasty may be considered if the ear remains free of discharge. [4]

Carr et al [49] have linked technical difficulties to graft failure, citing healing rates at the anterior rim of the perforation, anterior blunting, and lateralization of the graft. Additionally, subtotal perforations were found to be more prone to failure due to the lack of a remaining portion of the tympanic membrane for the graft to adhere to. Current evidence points to a lack consensus related to the topic of graft uptake and degree of hearing improvement following myringoplasty in both adult and paediatric patients.

Similarly, the research by Jurovitzki et al [50] revealed that grafts used for anterior perforations displayed lower success rates when compared to perforations located in other sites. Albera et al [51] also underscored the substantial impact that the site of perforation has on the success rate of grafts, although their findings indicated that posterior perforations tend to have a lower rate of success.

Furthermore, Yung's research [52] established a clear connection between the site of perforation and the level of improvement in hearing, uncovering that posterior perforations are linked to the most significant pre-operative hearing loss as well as post-operative gain.

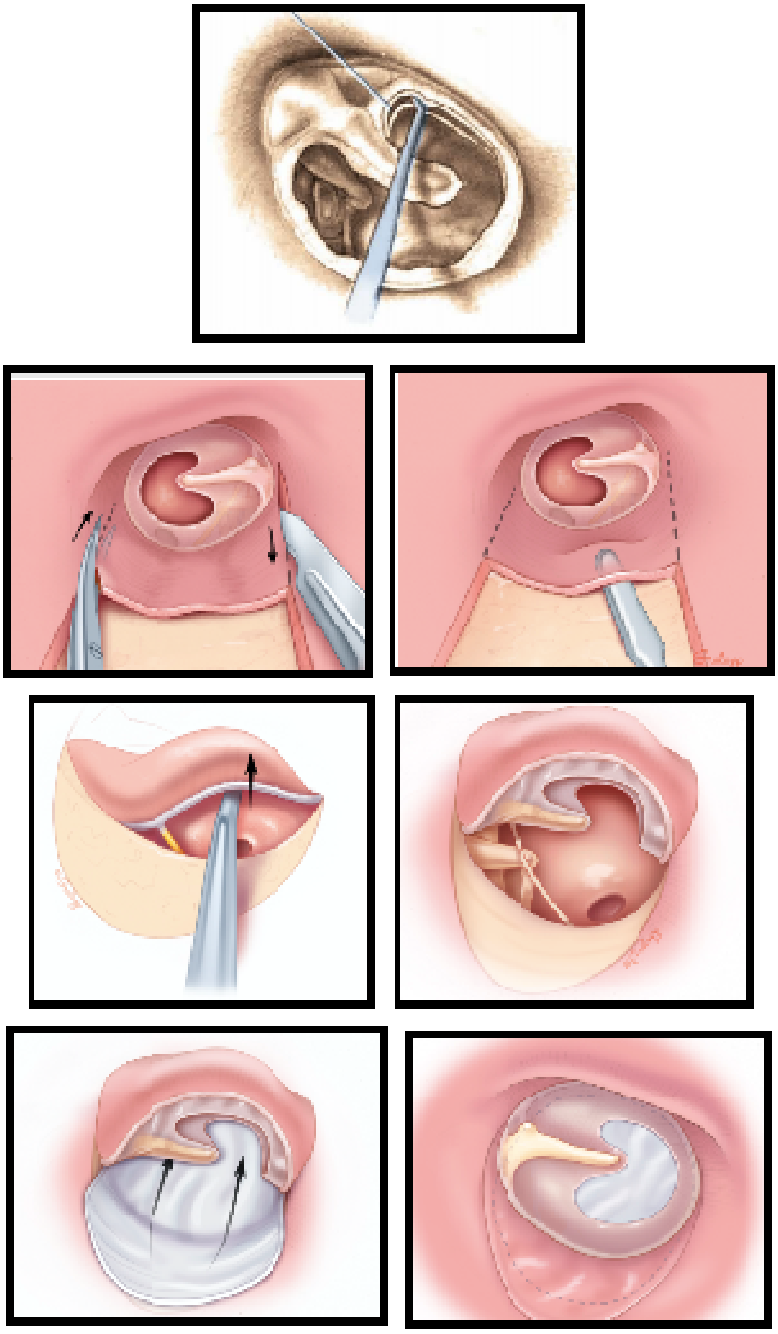


Fig 10: Steps of Tympanoplasty

MATERIALS AND METHODS

Source of Data: Patients admitted to KLE's Prabhakar Kore Hospital ENT department and with a confirmed diagnosis of Chronic Otitis Media and who were scheduled to undergo tympanoplasty

Study Design: Comparative study

Study Period: 1 year

Sample size: 50

Sample size Calculations: The sample size determination was based on a specific formula considering mean and standard deviation, with factors such as level of significance and power of the test being taken into account.

The minimum sample size formula based on mean and standard deviation is

$n = (Z\alpha+Z\beta)^2(S1+S2)^2/(X1-X2)^2$

where zα is associated with the level of significance and zβ is associated with the power of the test. At a 5% significance level, the value of zα equals 1.96, while the value of zβ is 0.84 for achieving an 80% power of the test. The resultant sample size was initially established to be 18 participants, although it was subsequently augmented to 25 individuals to ensure more definitive and robust outcomes. This augmentation necessitated the allocation of study participants into two distinct groups, namely Group A and Group B, with each group comprising 25 cases to enhance the statistical power and reliability of the analysis.

Study patients were divided into two groups

- Group A (Tympanoplasty alone n= 25)
- Group B (Canalplasty with tympanoplasty n=25)

Otoform was used to measure External Auditory Canal (EAC) and vertical and horizontal dimensions were measured in Group B patients preoperatively and postoperatively.

Sampling Technique: Study patients were divided into two groups

- Group A (Tympanoplasty alone n= 25)
- Group B (Canalplasty with tympanoplasty n=25)

Inclusion Criteria

- Patients who are prepared to provide informed consent
- Male and female individuals who are at least 18 years old.
- Patients who exhibit symptoms of inactive chronic mucosal otitis media, which is distinguished by pure conductive hearing loss.

Exclusion Criteria

The following patients were excluded from the study

- History of prior ear surgeries
- Patients unwilling to comply with study procedures and unable to follow-up
- Traumatic perforations or those with recent perforations
- Any signs suggesting ossicular discontinuity during the surgical intervention, retraction or atelectasis without a perforation , cholesteatoma

Data collection procedure: Baseline demographic information and clinical characteristics, such as gender, age at the time of surgery (with a specific differentiation between individuals aged 18 years and those above 18 years) as well as the size of the perforation, were documented.

Regarding the sampling technique, all patients underwent a thorough preoperative assessment, which included detailed history-taking and clinical examination, alongside otoscopic examination.

Tuning fork tests were conducted to ascertain the type of hearing loss, while the degree of hearing loss was quantified through pure tone audiometry.

Patients who were selected to undergo tympanoplasty were also subjected to EAC measurements by otoform.

Furthermore, other outcome measures of interest included the assessment of hearing data post-surgery.

Parameters such as postoperative air conduction Pure Tone Audiometry (PTA) between both groups were deemed clinically significant and were analyzed .

The procedure for data collection in this study involved documentation of continuous quantitative variables.

The mean and standard deviation was calculated to provide a comprehensive overview of the data.

Data Processing and Statistical Analysis

The comparison of inter-group continuous variables was conducted using appropriate statistical tools such as the unpaired student's t-test. Throughout all statistical tests conducted, a significance level of p less than 5% (0.05) was adhered to in order to identify meaningful and statistically significant outcomes. For all the tests the value of p less than 5% (0.05) was considered significant.

RESULTS

Baseline Patient demographics

Baseline characteristics for gender, age and diagnosis at the time of study recruitment are reported

Gender

In Group A, 68% of the participants were male, which was higher than the 44% male proportion in Group B. Conversely, the female proportion in Group A was 32%, lower than the 56% female proportion in Group B:

Graph 1: Gender distribution

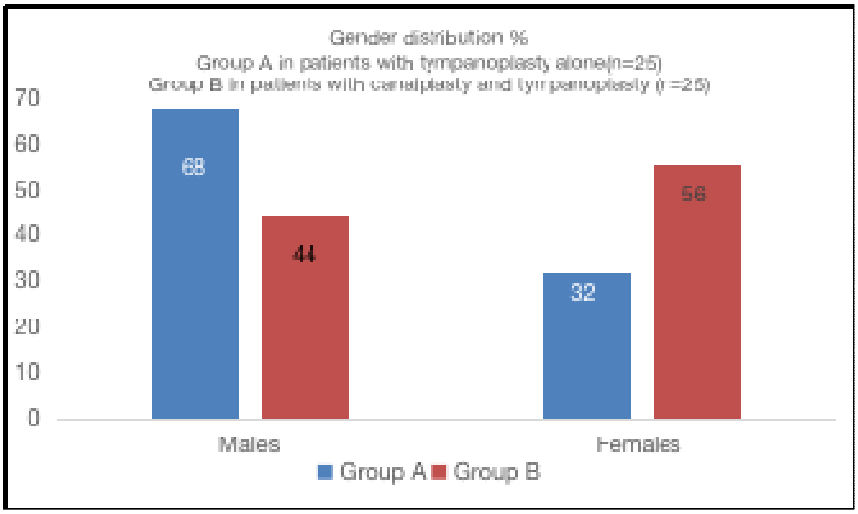


Table 1: Gender distribution

	Group A (Tympanoplasty alone)		Group B (Tympanoplasty with canalplasty)	
	(n=25)	%	(n=25)	%
Males	17	68	11	44
Females	8	32	14	56
Total	**25**	**100**	**25**	**100**

Age

Among 25 patients in each group, majority of the patients were in the range of 25-39 years of age.

Table 2 provides a summary of all age groups, recruited in both groups. The mean age groups for Group A (tympanoplasty alone) and Group B (canalplasty with tympanoplasty reported in table 2. In Group A (tympanoplasty alone) the mean age was 32.92, while, in Group B (tympanoplasty with canalplasty) the mean age was 32.88

Graph 2: Mean Age.

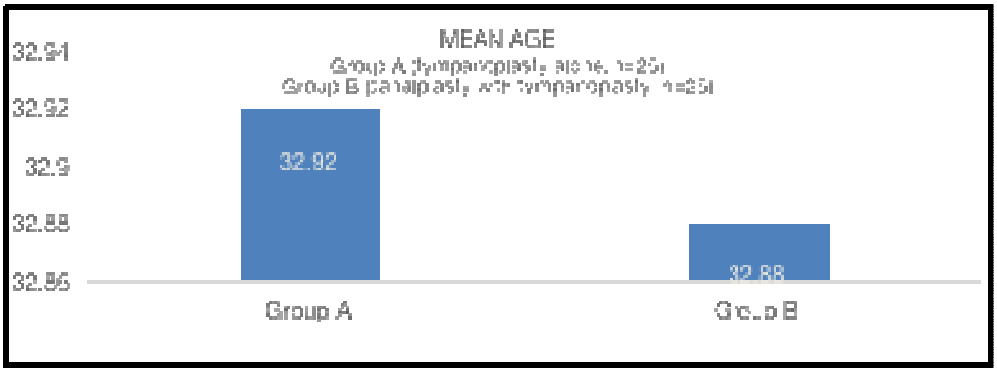


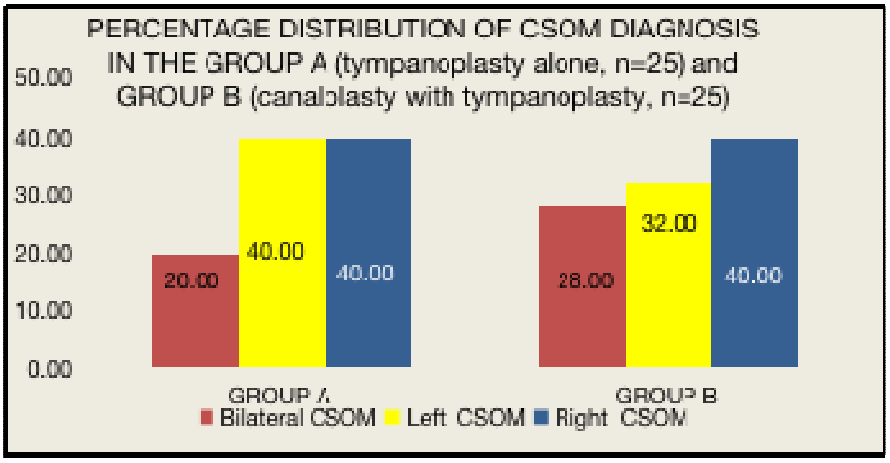
Table 2: Age distribution in Group A and Group B.

Age group (years)	**Group A** **N=25, n(%)** (mean age 32.92 yrs) (Range 19-50 years)	**Group B** **N = 25, n(%)** (mean age 32.88 yrs) (range 18-51 years)	**Total**
18–19	1 (4.00)	2 (8.00)	3
20–24	5 (20.00)	3 (12.00)	8
25–29	6 (24.00	4 (16.00)	10
30–34	1 (4.00)	3 (12.00)	4
35–39	6 (24.00)	9 (36.00)	15
40–44	2 (8.00)	2 (8.00)	4
45–49	3 (12.00)	1 (4.00)	4
50–54	1 (4.00)	1 (4.00)	2
Total	**25 (100)**	**25 (100)**	**50**

Baseline diagnosis of Chronic Suppurative Otitis Media(CSOM)

After Chronic Suppurative Otitis Media (CSOM) diagnosis was confirmed at baseline and surgical intervention planned, patients in both groups were included in the study. The proportion of patients with bilateral CSOM was 20% in Group A compared to 28% in Group B; the proportion of patients diagnosed with left CSOM was 40% in Group A and 32% in Group B; the proportion of patients with right CSOM was 40% in both the groups, Group A and Group B.

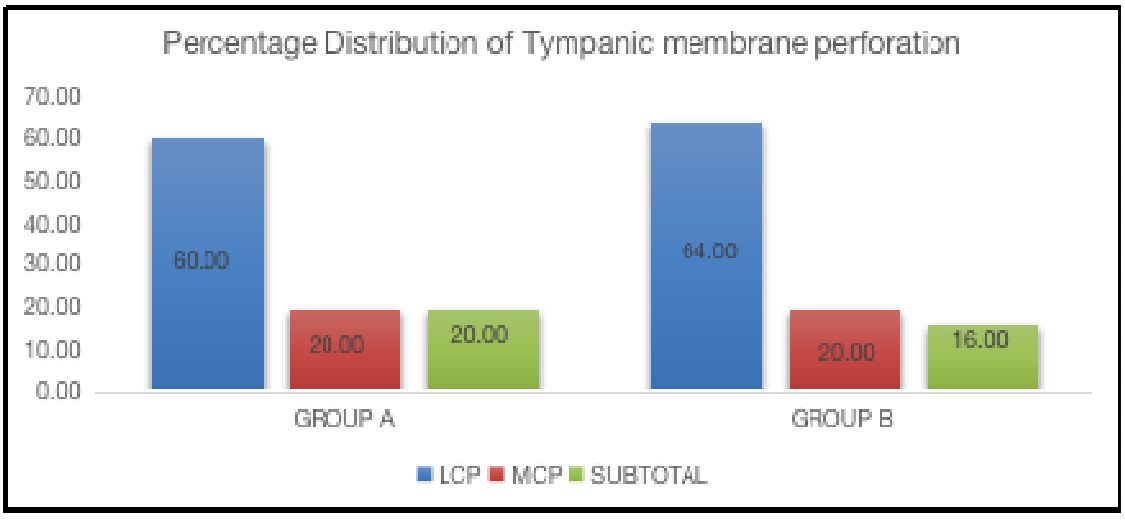
Graph 3: CSOM Diagnosis and percentage distribution in Group A and Group B.



Tympanic Membrane Perforation

Large Central Perforation (LCP), Moderate Central Perforation (MCP) and Subtotal perforation were noted in both the groups. Large Central Perforation was the dominant diagnosis in Group A (60% of patients, n=15) and Group B (64% of patients, n=16) followed by Moderate Central Perforation in Group A (20% of patients, n=5) and Group B (20% of patients, n=5), similarly, Subtotal Perforation was observed in Group A (20% of patients, n=5) and (16% of patients, n=4).

Graph 4: Tympanic Membrane Perforation in Group A and B at Baseline.



Pure Tone Audiometry

Pre and post-operative Pure Tone Audiometry (PTA) was assessed for all patients in both the groups

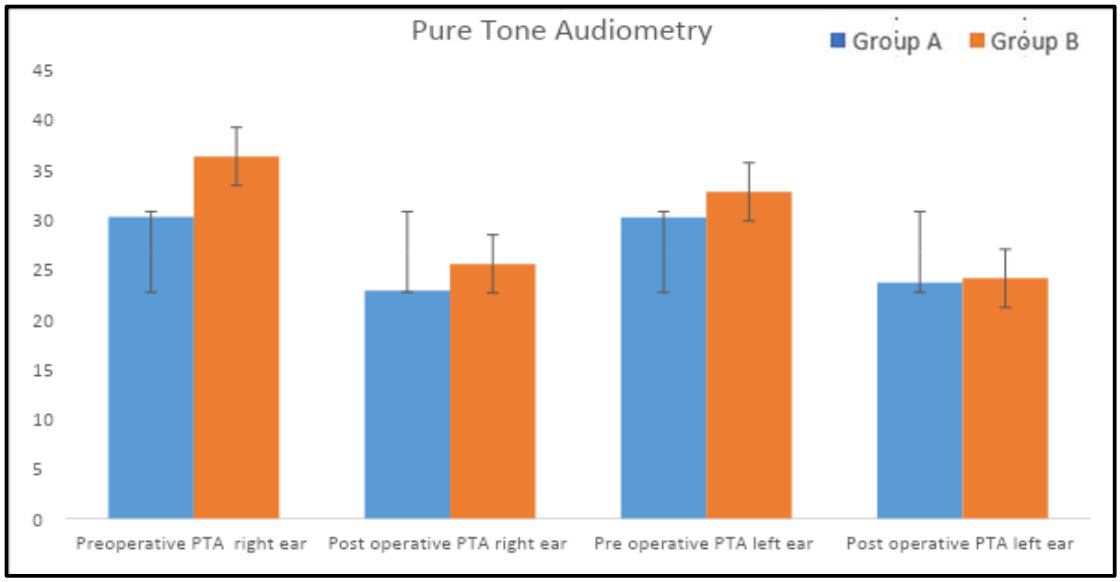
The pre-operative PTA for right ear in Group A and Group B was assessed to be similar. The mean PTA in Group A was reported to be 30.24 (S.D of 13.78); while the mean PTA for Group B was reported to be 36.32 (S.D of 15.39). No statistical significance was observed.

The post-operative PTA for right ear in Group A and Group B was also assessed to be similar. The mean PTA in Group A was reported to be 22.84 (S.D of 9.51); while the mean PTA for Group B was reported to be 25.53 (S.D of 11.31).

The pre-operative PTA for left ear in Group A and Group B was assessed to be similar. The mean PTA in Group A was reported to be 30.21 (S.D of 13.84); while the mean PTA for Group B was reported to be 33.76 (S.D of 14.41).

The post-operative PTA for left ear in Group A and Group B was also assessed to be similar. The mean PTA in Group A was reported to be 23.63 (S.D of 11.31); while the mean PTA for Group B was reported to be 24.08 (S.D 10.96).

Graph 5: Pre-operative and Post-operative right and left ear PTA in Group A and B



Graph 6: PTA: Comparison within each group.

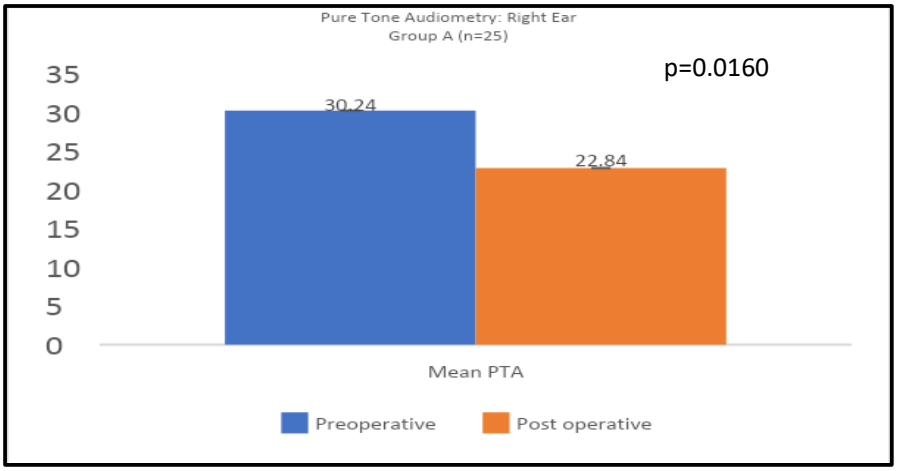
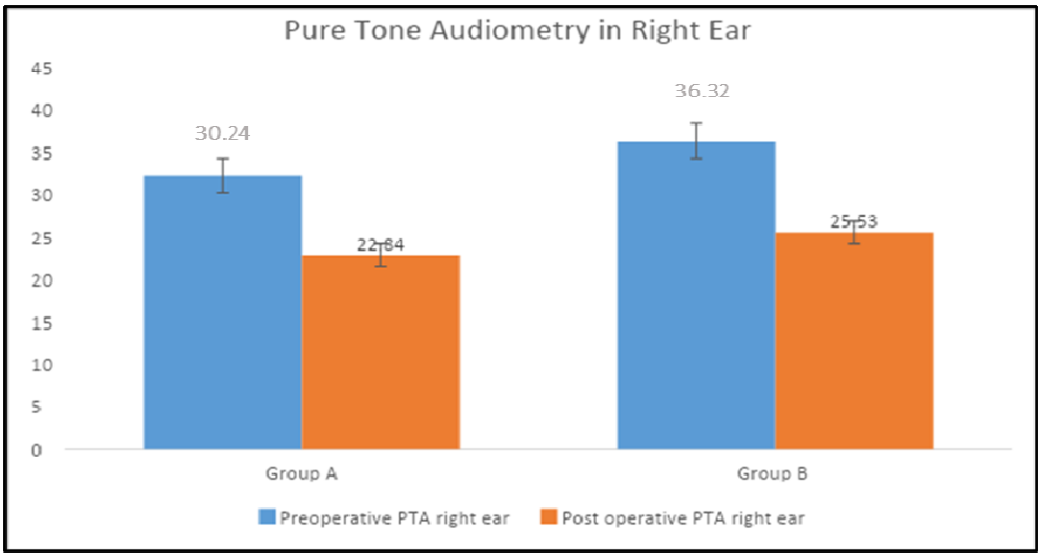


Table 3: Pre and Post-operative PTA in Group A (Right ear).

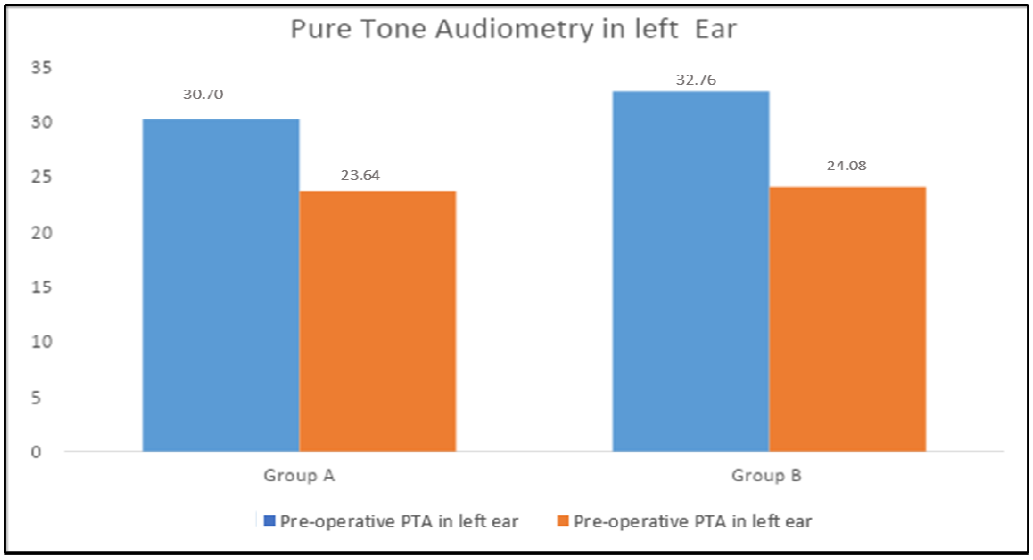
PRE-OPERATIVE PTA RIGHT EAR Group A (n=25)				POST-OPERATIVE PTA RIGHT EAR Group A (n=25)				
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE
30.24	13.78	11.66	50	22.84	9.51	10	40	0.0160

Group A: The mean difference in pre-operative and post-operative in Group A in right ear is 7.4.

Graph 7: Pure Tone Audiometry in Right Ear (Group A and B).



Graph 8: Pure Tone Audiometry in Left Ear (Group A and B).



Group A: The mean difference in pre-operative and post-operative in Group A in left ear is 7.06. There is a significant decrease in mean PTA post-operatively

Table 4: Pre and Post-operative PTA in Group A (left ear).

PRE-OPERATIVE PTA LEFT EAR Group A (n=25)				POST-OPERATIVE PTA LEFT EAR Group A (n=25)				
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE
30.70	14.37	10	50.66	23.64	11.31	10	41	0.0360

Group B: The mean difference in right ear of pre-operative and post-operative in Group B is 7.06

Table 5: Pre and Post-operative PTA in Group B (right ear).

PRE-OPERATIVE PTA RIGHT EAR Group B(n=25)				POST-OPERATIVE PTA RIGHT EAR Group B (n=25)				
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE
36.32	15.39	10	55	25.53	11.31	10	45.33	0.0034

Group B: The mean difference in left ear of pre-operative and post-operative in Group B is 10.79

Table 6: Pre and Post-operative PTA in Group B (left ear).

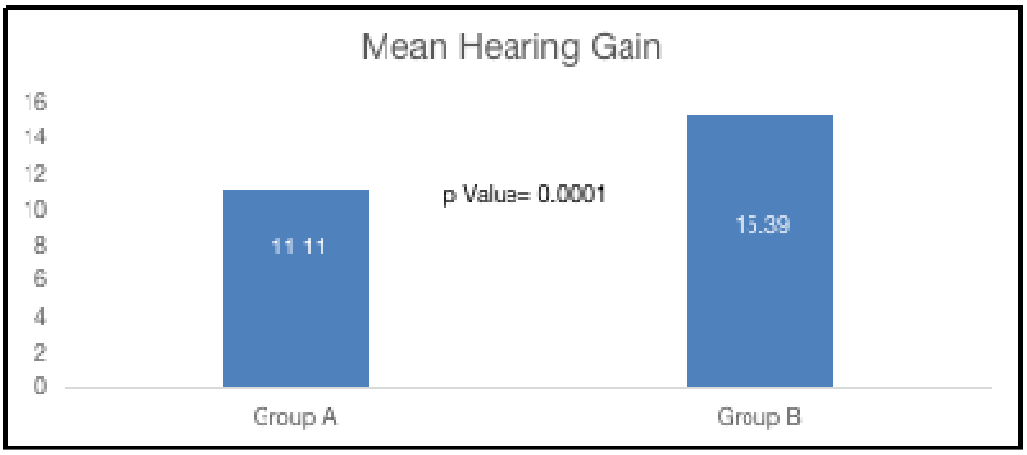
PRE-OPERATIVE PTA LEFT EAR				POST-OPERATIVE PTA LEFT EAR				
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE
32.76	14.41	10	55	24.08	10.96	10	48.66	0.0102

There is a significant decrease in mean PTA post-operatively and a significant improvement in mean hearing gains was reported in group B patients undergoing canalplasty with tympanoplasty in comparison to Group A, who underwent tympanoplasty alone

Mean Hearing Gain:

The functional outcomes were evaluated in both groups for mean hearing gains. The mean hearing gain in group A (tympanoplasty alone) was 11.11 (SD 3.23) and 15.39 (SD 3.98). The difference in mean hearing gains in Group B (canalplasty with tympanoplasty) compared to Group A was found to be highly significant (p-value 0.0001)

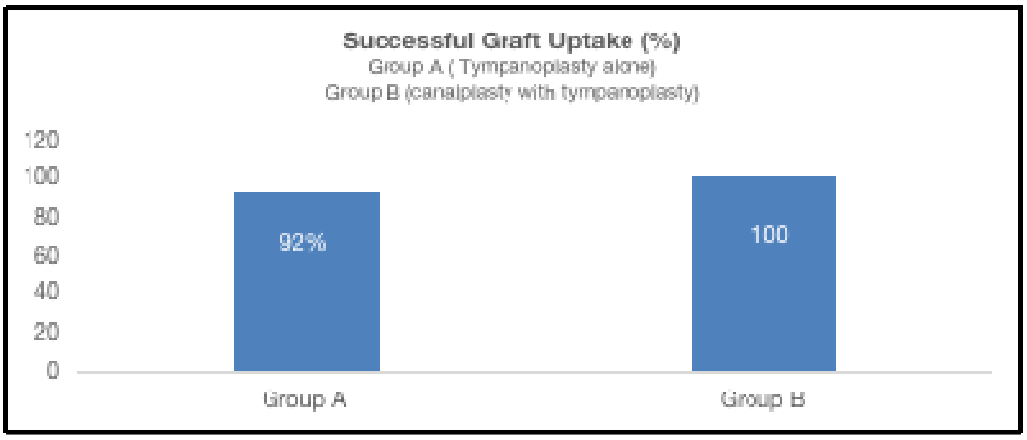
Graph 9: Post-operative mean hearing gain in Group A and B.



Graft Uptake

Surgical outcomes and results for graft uptake rate were analyzed and in both the groups and successful surgical outcomes were reported. In Group A who underwent tympanoplasty alone, the graft uptake was reported to 92%, (23/25 patients) in comparison to graft uptake of 100% in Group B whom canalplasty accompanied tympanoplasty (25/25 patients).

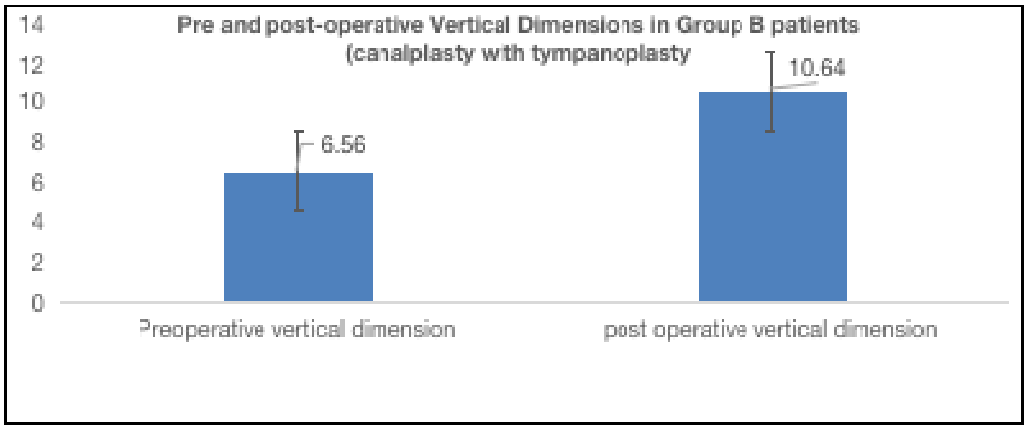
Graph 10: Post-operative graft uptake in Group A and B.



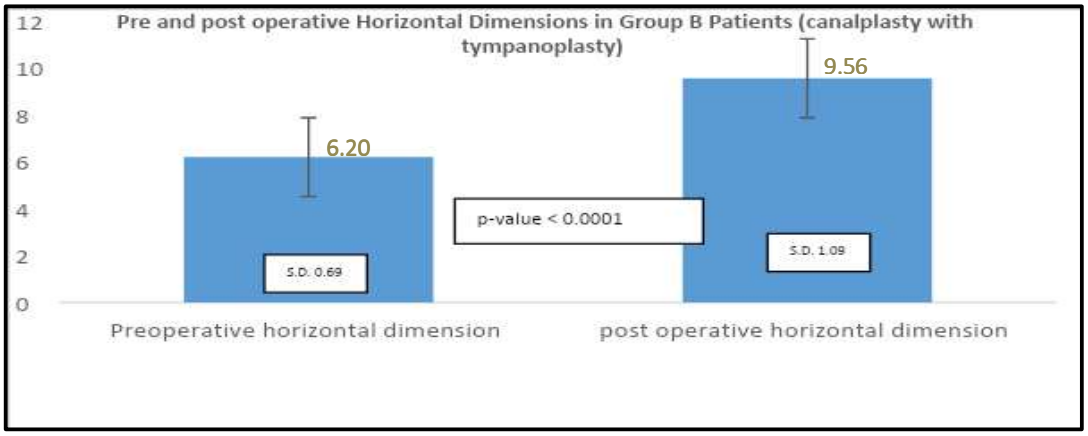
Vertical and Horizontal Dimensions in Group B

At the end of the study, in Group B patients (canalplasty with tympanoplasty) post-operative vertical dimensions were evaluated to be significantly superior to pre-operative vertical dimensions, with pre-operative mean of 6.56 (S.D. 0.78) and post-operative mean of 10.64 (S.D. 0.91)

Graph 11: Pre and post-operative Vertical dimension in Group B.



Graph 12: Pre and post-operative horizontal dimension in Group B.



Similarly, at the end of the study, in Group B patients (canalplasty with tympanoplasty) post-operative horizontal dimensions were evaluated to be significantly superior to pre-operative horizontal dimensions, with pre-operative mean of 6.20 (S.D. 0.69) and post-operative mean of 9.56 (S.D. 1.09), p-value<0.0001.

DISCUSSION

Despite significant achievements in the field of otology, a number of challenges continue to impact quality of life and other healthcare indices. [53]Currently, disorders with disabling hearing loss are estimated to impact approximately 5% of the global population (around 360 million people) with significant impact on health and well being. Furthermore, the World Health Organization (WHO) predicts that nearly 2.5 billion people worldwide (one in four) will experience some level of hearing loss by 2050. [54]

Although Tympanoplasty has been reported to yield better patient outcomes growing evidence suggests that canalplasty [55] [56] that involves the widening of the external auditory canal, is gaining acceptance as a co-interventional procedure along with tympanoplasty.

Therefore, the current study evaluated the role of canalplasty when accompanied with tympanoplasty, with primary etiology of hearing impairment in acquired conditions such as chronic otitis media.

In our study, a total of 25 patients were allocated to Group A (with tympanoplasty alone and 25 patients were allocated to Group B (when tympanoplasty was accompanied by canalplasty).

In our study, similar baseline characteristics for age, gender and primary diagnosis of Chronic Suppurative Otitis Media (CSOM) was reported for both groups, Group A and Group B.

While majority of patients with diagnosis of CSOM were in the 20-49 years age group, the mean (SD) age of patients recruited in Group A was 32.92 (9.33) years;

while the mean (SD) age of patients recruited in Group B was 32.88 (8.46) years of age.

Dimensions of External Auditory Canal (EAC)

With different methods yielding different results in the same patient, the measurement of EAC continues to remain a topic of interest with no universally accepted method to date. [58 59]

In one study of EAC, six distinct standardized anatomical measurements to determine the width of the osseous external auditory canal were reviewed by Mahboubi et al [17] based on the feasibility, our current study opted to focus only on vertical and horizontal dimension.

Preoperative Dimensions

The current study reported a mean preoperative vertical dimension of 6.5 mm with a range of 5 mm to 8 mm and a Horizontal dimension of 6.2 mm with a range of 5 mm to 7.5mm.

Post operative Dimensions

The current study reported a mean post operative vertical dimension of 10.6 mm (range 9 mm and 12 mm) and a mean Horizontal dimension of 9.5 mm (range of 7.5 mm -12 mm).

El Anwar et al [14] evaluated 100 CT scans to measure EAC. The mean vertical and horizontal dimensions of EAC at entry (mean 7.75mm±1; 6.1mm±0.8); bony part of the cartilaginous section, (7.88mm±1; 6.22 mm±0.9); isthmus (6.88mm±0.97; 5.2mm ±0.76) and medial end (7.1mm±0.9; 5.4±0.85) of EAC were reported.

In an anatomical investigation on cadavers, Ahmad et al [16] discovered that the average dimensions of the isthmus of the external auditory canal were 5.7 mm horizontally and 8.2 mm vertically.

Proper burrs, adequate vasoconstriction, and the safeguarding of the skin flap are fundamental prerequisites for the appropriate execution of a canalplasty procedure. It is permissible to excise up to 5 mm of the anterior and posterior walls, and up to 13 mm of the floor during the course of the operation. The key to a triumphant canalplasty operation lies in the preservation of the fragile canal skin. [11]

Graft uptake

Graft uptake disparities have been reviewed in a number of studies.

Kumaraswamy et al [60] documented a 100% graft acceptance rate at the conclusion of the 3rd post-operative month in the group receiving canalplasty. Verma et al [11] documented a overall success rate of 95% when canalplasty was performed with myringoplasty. In another study Singh et al [(55)] reported graft uptake rates of 93.3%.

Taneja's research findings [56] indicated a notable increase in graft uptake, reaching 91.3%, in cases where tympanoplasty was complemented with canalplasty procedures. Similar to published studies, where graft uptake was assessed after a 3-month period, 98% of the cases demonstrated successful outcomes. [57]

Prakash et al also demonstrated a success rate of 100% in patients undergoing tympanoplasty with canalplasty. [48]

In our study, we report successful graft uptake in 100% patients in group where canalplasty was performed, when compared to success rates of 92% in patients with tympanoplasty alone.

Hearing outcomes:

Substantial variability has been observed in the methods employed to describe hearing outcomes across different studies [14.] Further a number of studies [61] have explored the impact of canaloplasty on hearing outcomes in patients undergoing type 1 tympanoplasty. In the present study, efforts were made to eliminate confounding variables as much as possible to ensure a more accurate assessment of outcomes.

The results obtained in this study exhibited similar trends to previous research by Prakash M.D et al [50] 11.08dB PTA mean hearing gain in canalplasty and 9.2dB without canalplasty, Kumaraswamy et al [60] et al reported 18.86dB in canalplasty and 8.24dB without canalplasty (mean PTA hearing gain), Prasad et al [64] reported 22.6dB and 18dB with and without canalplasty respectively (mean PTA hearing gain), Singh et al [55] reported 15dB and 12 dB hearing gain with and without canalplasty (mean PTA hearing gain) indicating better Post op hearing gain in patients undergoing canaloplasty alongside tympanoplasty, as opposed to those undergoing tympanoplasty alone.

Several studies have associated surgical alterations to osseus external auditory canal (OEAC) with noticeable changes to resonance characteristics. Further, post canalplasty, the significance of epithelia lining of the EAC, and the role of keratinizing squamous epithelium in producing cerumen has been reviewed to aid the healing process. [62] [63]

In our study, which included two distinct participant groups, we observed a significant improvement in auditory capabilities for both groups. Notably, individuals who had undergone tympanoplasty along with canal widening exhibited a more pronounced degree of improvement.

LIMITATIONS OF THE STUDY

It has been well documented that that single-center trials are influenced by local practices, patient demographics, and specific resources available at the center, which can limit the generalizability of results to non-tertiary centers or other populations. While our study took place in a tertiary care academic centre, the study design centered on recruiting patients from a single centre. Additionally, the limited sample size and heterogeneity within a single centre may potentially affect the external validity of our conclusions.

Although our study was prospective and aimed to compare the impact of canalplasty on successful outcomes for patients undergoing tympanoplasty, we acknowledge that the study design omitted randomization. Furthermore, unlike some retrospective studies with a 6-month follow-up period, our study duration was limited to 3 months. This shorter follow-up period restricted a comprehensive assessment of post-operative graft uptake rates. Longer follow-up durations in other studies allow for more thorough and accurate analyses of long-term outcomes assessing the role of canalplasty in patients requiring tympanoplasty, underscoring the importance of extended follow-up periods in research design.

CONCLUSIONS

The present research provides further support to the increasing body of evidence that favors the combination of canalplasty with tympanoplasty over tympanoplasty alone.

The inclusion of canalplasty in the treatment of patients undergoing tympanoplasty has shown to consistently result in better post-surgical and functional outcomes, particularly in terms of graft acceptance and improvement in postoperative hearing.

Consequently, it is justifiable to suggest that canalplasty should be considered and integrated as an adjunct procedure in standard ear surgeries that necessitate tympanoplasty, with the aim of enhancing and optimizing overall outcomes in otology.

The integration of canalplasty into routine tympanoplasty procedures serves to elevate the overall effectiveness and success rates of otological surgeries, offering patients a more comprehensive and beneficial treatment approach for their ear conditions.

Otology is a fascinating and a complicated subject as the challenges faced by the surgeon in the post-operative follow up period range from reperforation, myringitis, graft lateralization and in some instances good graft uptake does not always imply satisfactory hearing outcome.

Thus, the adoption of canalplasty alongside tympanoplasty represents a progressive step towards achieving superior results and improved patient satisfaction in the field of otolaryngology.

This combination therapy not only enhances the surgical outcomes but also contributes to advancing the standards of care in the management of ear disorders, highlighting the significance of integrating innovative approaches to enhance patient care and treatment efficacy in otological practice.

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1. **Error! No bookmark name given.**

2. Prasad KC. A Comparative Study to Determine Hearing Outcome in Type 1 Tympanoplasty With and Without Canaloplasty in Tubotympanic Type of Chronic Suppurative Otitis Media. Indian Journal of Otolaryngology and Head & Neck Surgery. 2023 Dec;75(4):3344-8.

ANNEXURE I - CONSENT FORM FORMAT

KAHERs JNMC, BELAGAVI

Name of Student/Principal Investigator:

Name of Guide/Co Investigators:

Objective:

- To assess improvement in conductive hearing loss post-operatively in patients who have undergone canalplasty with tympanoplasty
- To analyze improvements in surgical outcomes

Introduction: Tympanoplasty refers to any operation involving reconstruction of the tympanic membrane and/or the ossicular chain. In the majority of cases the damage is likely to be a persisting perforation of the drum but there are also situations where a thin or retracted drum may need to be reinforced. The aim of middle ear surgery is aimed at reduction of the patients hearing disability.

Canalplasty is circumferential enlargement of osseous external auditory canal by removing the bony overhanging canal bulge to visualize the entire tympanic membrane. This surgical procedure can be used gain access for other procedures(improving the access)- tympanoplasty or it can be an end to itself (for a stenosed EAC).[2]

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study "**THE ROLE OF CANALPLASTY IN TYMPANOPLASTY AND TO ASSESS ITS FUNCTIONAL AND SURGICAL OUTCOMES".** My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE II - PROFORMA

"ASSESSMENT OF HEARING IN PATIENTS WITH VITILIGO - A ONE YEAR OBSERVATIONAL STUDY IN KLES Dr PRABHAKAR KORE HOSPITAL"

Date:

Name:

Age:OP/IP no:

Sex: Date of assessment:

Address: Date of discharge:

Occupation: Diagnosis:

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness

Past History

Family History:

General Physical Examination -

ENT Examination

1.EAR EXAMINATION:

Right Left

Pinna

Pre auricular area

Post auricular area

External auditory canal

Tympanic membrane

TUNING FORK TESTS:

Rinne's test 256 Hz

512 Hz

1024 Hz

Weber's test:

Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION

2.NOSE EXAMINATION

External appearance

- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test Anterior RhinoscopyPosteriorRhinoscopy

PNS EXAMINATION

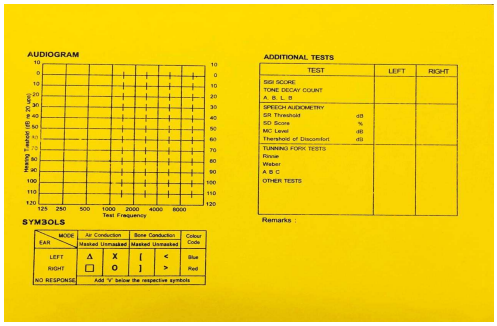
THROAT EXAMINATION:

NECK EXAMINATION

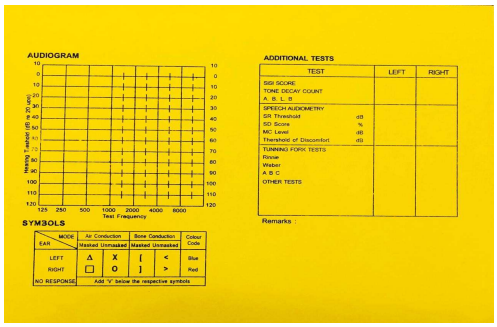
DIAGNOSIS:

PURE TONE AUDIOMETRY:

Preop RIGHT LEFT



Postop RIGHT LEFT



EAC diameter- preop and postop

ANNEXURE III - CLINICAL PHOTOGRAPHS

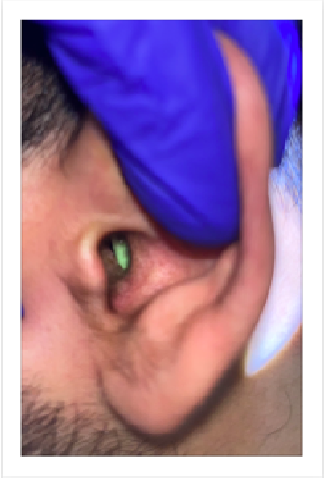
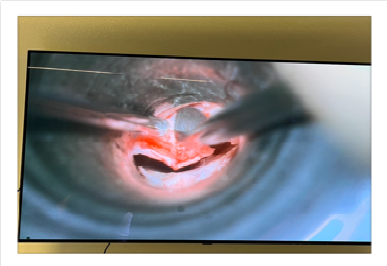


Photo 1: EAC DIMENSION MEASUREMENT **Photo 2: EAC DIMENSION MEASUREMENT**

Measurement of Vertical and Horizontal dimensions of EAC



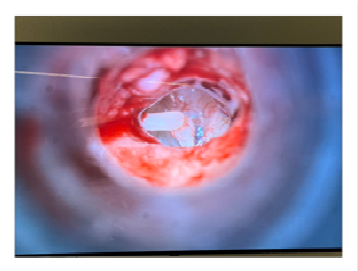


Photo 3: INTRA-OP TYMPANOPLASTY WITH CANALPLASTY

Pre and post canalplasty

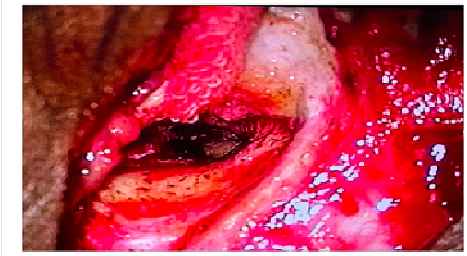
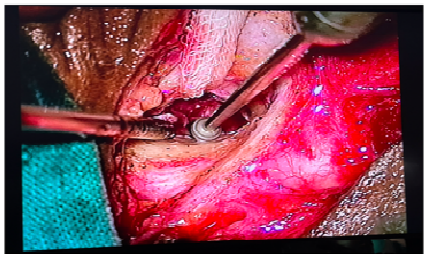
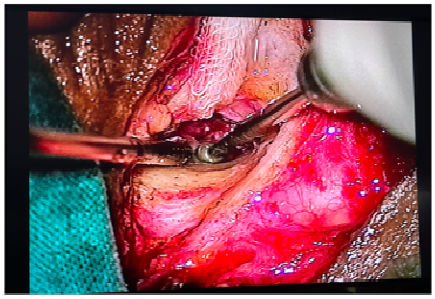
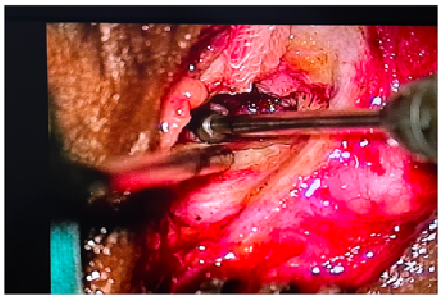





Photo 4: INTRA-OP TYMPANOPLASTY WITH CANALPLASTY

Pre and post canalplasty

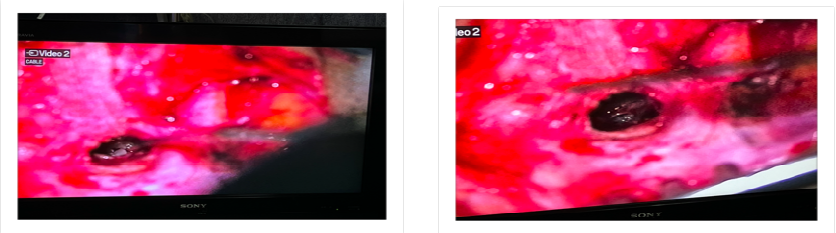


Photo 5: INTRA-OP TYMPANOPLASTY WITHOUT CANALPLASTY

Pre and post tympanoplasty without canalplasty

Photo 6: PTA MACHINE

PTA machine

Photo 7: PTA ROOM

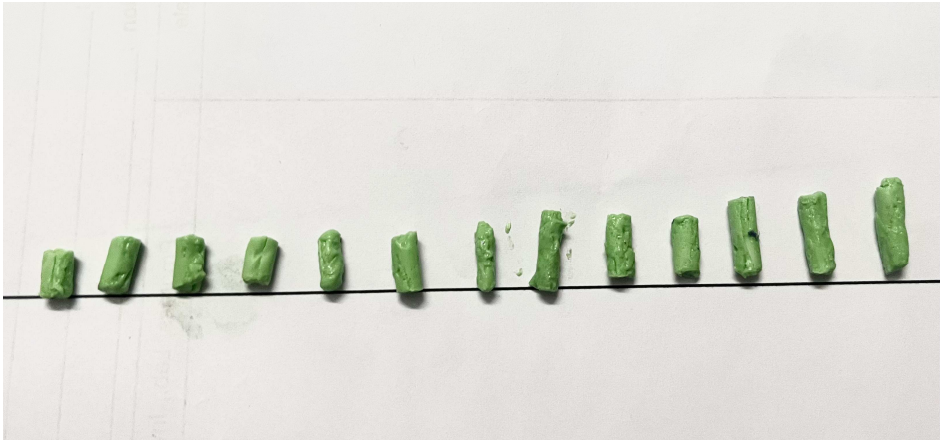


Photo 8: OTOFORM PLEDGETS

ANNEXURE IV – MASTER CHART

S.No	Name	Age	Sex	Diagnosis	Type	Surgery	Perforation	Preop PTA	Postop PTA	Hearing Gain	Graft Uptake
1	Sumitra	50	F	R CSOM	Type 1	Tympanoplasty	LCP	R-36.66 L-25	R-20.66 L-18	16	Yes
2	Dadakhalandar	39	M	B/l CSOM	Type 1	Tympanoplasty	LCP	R-50 L-35	R-35 L-30	15	Yes
3	Shivanand	29	M	R CSOM	Type 1	Tympanoplasty	MCP	R-32.33 L-15	R-18.33 L-10	14	Yes
4	Ruksana	46	F	R CSOM	Type 1	Tympanoplasty	LCP	R-38.33 L-15	R-25 L-10	13.33	Yes
5	Santosh	21	M	B/l CSOM	Type 1	Tympanoplasty	LCP	R-28.33 L-40	R-25 L-28	12	Yes
6	Amitha	24	F	L CSOM	Type 1	Tympanoplasty	MCP	R-11.66 L-30	R-11.66 L-20.66	9.33	Yes
7	Irfan	28	M	L CSOM	Type 1	Tympanoplasty	LCP	R-12 L-48.66	R-10 L-33.66	15	Yes
8	Sunil	22	M	B/l CSOM	Type 1	Tympanoplasty	SUBTOTAL	R-30 L-40.66	R-25 L-30.66	10	Yes
9	Shivappa	43	M	L CSOM	Type 1	Tympanoplasty	SUBTOTAL	R-12 L-48	R-12 L-41	7	Yes
10	Anita	20	F	R CSOM	Type 1	Tympanoplasty	LCP	R-40.66 L-12	R-32.66 L-10	8	Yes
11	Shweta	27	M	R CSOM	Type 1	Tympanoplasty	MCP	R-35 L-10	R-24 L-10	11	Yes
12	Santosh	38	M	L CSOM	Type 1	Tympanoplasty	LCP	R-15 L-40	R-10 L-32	8	yes
13	Chetan	22	M	R CSOM	Type 1	Tympanoplasty	SUBTOTAL	R-46.66 L-12	R-31.66 L-10	15	Yes
14	Shiv	19	M	R CSOM	Type 1	Tympanoplasty	LCP	R-30 L-15	R-25 L-15	5	No
15	Darshath	39	M	L CSOM	Type 1	Tympanoplasty	MCP	R-25 L-50.66	R-20 L-38.66	12	Yes
16	Laxmi	37	F	L CSOM	Type 1	Tympanoplasty	LCP	R-20 L-45	R-20 L-37	8	Yes
17	Ravindra	45	M	L CSOM	Type 1	Tympanoplasty	LCP	R-15.33 L-50.66	R-10.33 L-40.66	10	Yes

18	Savitri	32	F	L CSOM	Type 1	Tympanoplasty	Subtotal	R-15 L-45	R-15 L-40	5	No
19	Radhika	29	F	R CSOM	Type 1	Tympanoplasty	LCP	R-50 L-15.33	R-40 L-10.33	10	yes
20	Rajappa	41	M	B/l CSOM	Type 1	Tympanoplasty	MCP	R-45.33 L-30	R-36.33 L-30	9	yes
21	Shridhar	26	M	R CSOM	Type 1	Tympanoplasty	LCP	R-41.66 L-21.66	R-30.66 L-15	11	Yes
22	Rehana	36	F	B/l CSOM	Type 1	Tympanoplasty	LCP	R-50 L-30.66	R-35 L-28.66	15	Yes
23	Somanappa	47	M	L CSOM	Type 1	Tympanoplasty	MCP	R- 15 L-30	R-13 L-19.66	11	Yes
24	Arpit	35	M	L CSOM	Type 1	Tympanoplasty	LCP	R-15 L-35	R- 12 L-20	15	Yes
25	Girish	28	M	R CSOM	Type 1	Tympanoplasty	SUBTOTAL	R- 45 L- 15	R-32.66 L-12	13	Yes

S.No	Age	Sex	Diagnosis	Surgery		Perforation	Preop	Postop	Dimensions Preop		Dimensions Postop		Hearing Gain	Graft Uptake
1	20	M	L CSOM	Tympanoplasty	Canalplasty	MCP	R-10 L-46.66	R-10 L-36.66	V-7mm	H-6mm	V-10mm	H-8mm	10	Yes
2	29	F	L CSOM	Tympanoplasty	Canalplasty	MCP	R-19 L-45.33	R-14 L-32.33	v-8mm	H-7mm	V-12mm	H-9mm	13	Yes
3	30	F	R CSOM	tympanoplasty	Canalplasty	LCP	R-45 L-20	R-35 L-20	v-7.5mm	H-6mm	V-11mm	H-10mm	10	Yes
4	35	F	R CSOM	tympanoplasty	Canalplasty	LCP	R-40 L-20	R-20 L-15	V-6mm	H-7mm	V-10mm	H-11mm	20	Yes
5	39	F	b/l CSOM	Tympanoplasty	Canalplasty	MCP	R-41 L-25	R-30 L-20	V-7.5mm	H-7mm	V-12mm	H-10mm	11	Yes
6	36	F	L CSOM	Tympanoplasty	Canalplasty	MCP	R-15.66 L-35	R-15.66 L-25	V-6mm	H-5.5mm	V-10mm	H-8.5mm	10	Yes
7	28	M	L CSOM	Tympanoplasty	Canalplasty	LCP	R-35 L-38	R-35 L-25	V-7mm	H-6.5mm	V-12mm	H-9mm	13	Yes
8	18	F	b/l CSOM	Tympanoplasty	Canalplasty	subtotal	R-55 L-50.66	R-40 L-48.66	V-6mm	H-7mm	V-9mm	H-11mm	15	Yes
9	38	F	R CSOM	Tympanoplasty	Canalplasty	LCP	R-50.33 L-45	R-38.33 L-41	V-7.5mm	H-6mm	V-10.5mm	H-9mm	12	Yes
10	36	M	R CSOM	Tympanoplasty	Canalplasty	LCP	R-51.66 L-15	R-37.33 L-15	V-6.5mm	H-6.5mm	V-10mm	H-9mm	14.33	Yes
11	34	M	b/l CSOM	Tympanoplasty	Canalplasty	MCP	R-28 L-40.66	R-26 L-24.33	V-7.5mm	H-6.5mm	V-11mm	H-10mm	16.33	Yes
12	49	M	R CSOM	Tympanoplasty	Canalplasty	LCP	R-38.66 L-12	R-24.33 L-10	V-6.5mm	H-7.5	V-10mm	H-12mm	14.33	Yes
13	19	F	b/l CSOM	Tympanoplasty	Canalplasty	LCP	R-51.66 L- 30	R-33.33 L-25	V-6.5mm	H-7mm	V-10mm	H-11mm	18.33	Yes
14	27	M	R CSOM	Tympanoplasty	Canalplasty	LCP	R-50 L-20	R-31.66 L-15	V-5.5mm	H-6.5mm	V-10mm	H-9mm	19.33	Yes

15	41	F	L CSOM	Tympanoplasty	Canalplasty	LCP	R-18.33 L-41.66	R-15 L-20.66	V-7.5mm	H-6.5mm	V-12mm	H-9mm	21	Yes
16	23	F	b/l CSOM	Tympanoplasty	Canalplasty	LCP	R-48.66 L-53.66	R-45.33 L-35.33	V-6.5mm	H-6mm	V-10.5mm	H-9mm	18.33	Yes
17	35	F	R CSOM	Tympanoplasty	Canalplasty	subtotal	R-53.33 L-21.66	R-16.66 L-15	V-7mm	H-5.5	V-12mm	H-10mm	16.66	Yes
18	30	M	b/l CSOM	Tympanoplasty	Canalplasty	LCP	R-46.66 L-55	R-41.66 L-43	V-5.5mm	H-6mm	V-10mm	H-8mm	12	Yes
19	37	M	R CSOM	Tympanoplasty	Canalplasty	LCP	R-48.66 L-10	R-34.33 L-10	V-6mm	H-6.5mm	V-9.5mm	H-7.5mm	14.33	Yes
20	24	M	L CSOM	Tympanoplasty	Canalplasty	LCP	R-12 L-41.66	R-10 L-30.66	V-7mm	H-6mm	V-11mm	H-10mm	11	Yes
21	37	F	R CSOM	Tympanoplasty	Canalplasty	LCP	R-48.33 L-12	R-24.33 L-10	V-6mm	H-5.5	V-10mm	H-9mm	24	Yes
22	41	F	R CSOM	Tympanoplasty	Canalplasty	subtotal	R-45.66 L-15	R-25.33 L-10	V-6.5mm	H-6mm	V-11mm	H-10mm	20	Yes
23	51	M	L CSOM	Tympanoplasty	Canalplasty	subtotal	R-15 L-46.66	R-10 L-31.33	V-5mm	H-5mm	V-10.5mm	H-11mm	15.33	Yes
24	36	M	L CSOM	Tympanoplasty	Canalplasty	LCP	R-15 L-36.66	R-10 L-22.33	V-6.5mm	H-5mm	V-10mm	H-10mm	14.33	Yes
25	29	F	b/l CSOM	Tympanoplasty	Canalplasty	LCP	R-25.33 L-41.66	R-15 L-20.66	V-5.5mm	H-5mm	V-12mm	H-9mm	21	Yes