

## **PROJECT REPORT**

# **EFFECT OF CANAL WIDENING (TYPE I TYMPANOPLASTY) ON HEARING SENSITIVITY**

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## ABSTRACT

Chronic suppurative otitis media (CSOM) is a chronic inflammation of the middle ear and mastoid cavity that is characterised by discharge from the middle ear through a perforated tympanic membrane for at least 6 weeks. The pattern and degree of hearing loss greatly vary in individuals with CSOM. Conductive hearing loss is the most common pattern. This could be managed conservatively or surgically. Mastoidectomy and/or tympanoplasty are frequently used management procedure CSOM. The present study aimed to investigate the efficacy of the Type I tympanoplasty through a canal widening procedure on hearing sensitivity. The study was carried out on two groups of participants. Group I included 25 participants who underwent Type I tympanoplasty with canal widening procedure and group II included 25 participants who had already undergone Type II tympanoplasty without canal widening procedure. The audiometric results of pre-operative condition and post-operative condition at 1 months and 3 months were documented for further analysis. The results revealed that the mean difference of pre-post (1 month) air conduction threshold was 12.68 dB in group I and 5.5 dB in group II participants. The mean difference of pre-post (3 month) air conduction threshold was 18.86 dB in group I and 8.24 dB in group II participants. There was a significant difference in thresholds that was obtained between the two groups and across conditions. The study provides clear evidence that Type I tympanoplasty with canal widening procedure provides a better improvement in hearing sensitivity for individuals with CSOM, where surgical procedure is an indication.

*Keyword:* CSOM, Pre –post operation, hearing sensitivity, air conduction thresholds



## INTRODUCTION

The ability to hear is an important sensory function for communication and better quality of life. The sense of hearing is important, not only to understand the expression of people around, but also for proper development of speech and language. Disorders affecting hearing can be congenital or acquired. Yet, it is the preventable and correctable conditions in the above mentioned categories, which demand attention. The leading cause of hearing loss in acquired disorders being chronic otitis media (COM) is both preventable and correctable to certain extent as well. Chronic otitis media (COM) is the chronic inflammation of mucoperiosteal lining of the middle ear cleft characterized by ear discharge, a permanent perforation of the tympanic membrane and impairment in hearing. It is estimated that 6% of Indian population suffers from chronic middle ear disease and the majority of the cases especially seen in the rural population. The incidence of chronic otitis media is high in developing countries because of poor socioeconomically status, overcrowding, poor personal hygiene, poor nutrition and lack of health education.

Chronic otitis media of mucosal variety can be managed in two ways, conservative and surgical management. The main aim is to restore the anatomy and function of the middle ear. Small perforations usually heal spontaneously but when the edges of the perforation are covered by stratified squamous epithelium, a perforation becomes permanent and does not heal spontaneously. Procedures such as grafting the tympanic membrane alone, or in combination with Ossiculoplasty (Tympanoplasty with ossicular chain reconstruction), comprise the varying subtypes of Tympanoplasty. Tympanoplasty nowadays is one of the common ear surgeries to be performed. The aim is to strive to achieve an intact neo tympanum with normal hearing acuity.

Type- 1 Tympanoplasty is performed when there is tympanic membrane perforation without any ossicular damage. Patent external ear is prerequisite for successful ear surgery. Various anatomical variants or abnormalities may obstruct its lumen, resulting in conductive hearing loss.

The widening of external auditory canal is called Canalplasty which is an integral part of Tympanoplasty technique. The removal of overhanging canal walls provides complete exposure of the anterior edge of tympanic membrane. Drilling the posterior and inferior walls, widen the bony canal which allows complete visibility of the entire tympanic annulus. This helps in better placement of the graft material. In this study, an attempt has been made to study the efficacy of the Type I Tympanoplasty with canal widening procedure on hearing sensitivity.

### **AIM**

To investigate the efficacy of the Type I tympanoplasty through a canal widening procedure on hearing sensitivity.

### **OBJECTIVES**

1. To evaluate and compare the audiometric findings of pre and post Type I tympanoplasty through a canal widening procedure.
2. To evaluate and compare the audiometric findings of pre and post Type I tympanoplasty without canal widening procedure.
3. To compare the audiometric findings of pre and post Type I tympanoplasty with and without canal widening procedure.

## REVIEW OF LITERATURE

Otitis media (OM) refers to complex infectious and inflammatory diseases affecting the middle ear (Dickson, 2014). It can be broadly divided into acute and chronic. Acute otitis media (AOM) is typified by the rapid onset of signs of inflammation, specifically bulging and possible perforation of the tympanic membrane, fullness and erythematic, as well as symptoms associated with inflammation such as otalgia, irritability and fever (Pukander, 1983; Harkness & Topham, 1998). Despite appropriate antibiotic therapy, AOM may progress to chronic suppurative OM (CSOM) characterized by persistent drainage from the middle ear associated with a perforated ear drum (Reed, Wintermeyer & Nahata, 1994; Harkness & Topham, 1998). Hearing impairment is one of the most common sequelae of CSOM (Aarhus et al., 2015).

### **Microbiology and Pathogenesis of CSOM:**

The frequent cause of OM is bacterial infectivity of the middle ear. AOM is primarily originated by *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* (Sierra et al., 2011; Qureishi et al., 2014). However, *Pseudomonas aeruginosa* and *Staphylococcus aureus* are the most common aerobic microbial isolates for CSOM, pursued by *Proteus vulgaris* and *Klebsiella pneumonia* (Prakash et al., 2013). CSOM can also have co-infections with more than one type of bacterial and viral pathogen (Bakaletz, 2010). CSOM has also been reported to be due to Fungi (Asish et al., 2014; Juyal et al., 2014) with various culture reports which are usually treated with antibiotic ear drops, which causes suppression of bacterial flora and the subsequent emergence of fungal flora (Schrader & Isaacson, 2003). However, there has been much disparity on the rate of isolation of fungi which can be attributed to the climatic conditions, since the damp and muggy environment.

Occurrence of CSOM dependent on a number of factorial disease and its interfaces between ecological, bacterial, multitude and inherited hazards (Rye et al., 2012; Li et al., 2013). It is vital to recognize the genetic materials that contribute to CSOM vulnerability, which will provide insights into the biological intricacy of this infection and contribute to recover the means of prevention and treatment (Allen et al., 2014).

### **Tympanic membrane perforations:**

Tympanic membrane perforations commonly occur as a result of infections or trauma. Recurrent or persistent infection can lead to chronic suppurative otitis media which can be characterized by ear discharge (otorrhoea) over 2-6 weeks through a perforation of the tympanic membrane. Typical findings may also include thickened granular middle ear mucosa, mucosal polyps, and cholesteatoma within the middle ear (Acuin, 2007). This type of perforation is usually central, and the middle ear lining becomes thickened and chronically inflamed. Based on the positions of the perforation on the tympanic membrane, they may be central, marginal, and attic perforation( Ritenour, 2008). In central perforation, the perforation is within the pars tensa or with the annulus intact. However, in marginal perforation, there is destruction of the annulus and the sulcus tympanicus. The attic perforations involve the pars flaccida and usually associated with cholesteatoma Gelfand, (1997). The size and location of the perforation depend on the infectious agent, the severity and the chronicity, generally, with the middle ear empyema that is produced in otitis media. However, perforations may become persistent with recurrent infections that impair the regenerative process. Large kidney shaped perforations may occur with  $\beta$ -hemolytic *streptococci*. There is fulminant necrosis and sloughing of the drum caused by necrotizing toxins and the proteolytic enzymes, viruses, tuberculosis and an aggressive external

otitis may also involve the drum (Glasscock, & Gulya, 2003). The traumatic injury could also be a common cause for blunt and penetrating physical insults, barotraumas, acoustic and blast injury and, less commonly, thermal and chemical burns iatrogenic perforations may also result from myringotomy and ventilation tube insertion for tympanic membrane. The incidence is about 0.86%. However, tnic membrane has a powerful ability to heal itself. As reported by Rossa (1876) “the tympanic membrane has a regenerative power, to that of no other membrane in the body”. Kristensen (1992) noted that the rate of spontaneous healing of traumatic perforations is approximately 78.7%. Foreign body trauma and ventilation tube removal had better healing results (80-100%) than thermal injury (38%). Spontaneous healing decreases after 30 years of age. This was thought to be due to reduced blood supply, reduced cellularity, less complaints collagen and more rigid elastin in the fibrous layer. The size and site of the perforation also have an effect on healing, with large and central kidney shaped perforations having the least chance to heal spontaneously (Strohm, 1986). Likewise, perforations of the postero superior quadrant, due to the loss of this well vascularised region, epithelial regeneration is interfered with, malnutrition and immune suppression impair healing. The presence of highly cellular pneumatized mastoid air cell system favours spontaneous healing (Armstrong, 1972, Sham-baugh & Glasscock, 1980).

### **Concepts of healing of the tympanic membrane:**

To understanding of tympanic membrane healing is the concept of epithelial migration. Two types, of epithelial migration have been described. The tympanic membrane (TM) consists of three layers: an outer layer composed of keratinized squamous epithelium, an intermediate mesodermal fibrous layer and an inner endodermal mucosal layer. When in a solution of

continuity, TM regenerates from two mechanisms of epithelial migration known. One is the centrifugal movement from the navel of TM. The second pattern mitotic considered essential to the healing of continuity solutions, is the centripetal force, which occurs throughout pars tensa of TM, with more activity around the tympanic ring. In myringoplasty, the graft serves as a replacement of the stratum corneum current slide on which epithelial migration in order to repair the perforation (Costa, Cruz, OKluwe, & Smith, 1980; Bunzen, Campos, Sperandio, & Neto, 2006). In contrast to wound healing in other tissues, mitotic activity is not only confined to the wound edges but can be seen throughout the pars tensa, with highest activity seen around the annulus and 2mm away from the wound edges, and to do lesser degree, around the manubrium. This distant migration is further suggested by the lack of proliferative basal cells in the wound edges, which normally would be very active in other tissues. Immediately after the perforation, there is retraction of the edges of pars tensa followed by hemostatic and inflammatory changes. Epithelial hypertrophy and advancement of the wound edges begin as early as 48 hours after the trauma, the squamous epithelial layer migrates, attempting to bridge the perforation, and then followed by fibrous proliferation.

The hypertrophic wound edges close the gap followed by the other layers of the advancing epithelium. This supports the “scaffolding” theory long accepted as the mechanism by which patch material or other graft materials such as fascia, vein or perichondrium works. The material acts as a substitute for the stratum corneum, under which the lower epidermal layers can proceed to close the defect. Further proof of the primary role of the epithelium in closing defects is seen with the use of graft replacement membranes. In these cases, despite an adequate mucosal and epithelial layer, the lamina propria has only a few disorganized fibrils without fibroblasts instead of the well-structured connective tissue and fibrous network. Thus the healing

of lamina propria always lags behind that of the epithelium and mucosa. Sometimes, healing of the lamina propria may even fail leading to a dimeric membrane, with only a few disorganized fibrils in the lamina propria (Johnson., Smallman,.. & Kent, 1990).

## **Treatment**

The major treatment for CSOM is a grouping of aural toilet and topical antimicrobial drops. Although systemic oral or parenteral antibiotics are available as options, they are less commonly used due to the fact that topical antibiotics in grouping with aural toilet are able to accomplish significantly superior tissue absorptions than systemic antibiotics (in the order of 100–1000 times greater). Surgery, in the way of mastoidectomy, was conventionally the mainstay of therapy. However, retrospective studies have suggested that mastoidectomy is not superior to more conservative therapies such as aural toilet and topical and systemic antibiotics for uncomplicated CSOM. Restoration of the tympanic membrane or tympanoplasty is a further surgical technique often used for persistent perforations after the active infection of CSOM has been treated (Mittal et al, 2015).

### **Tympanoplasty:**

Tympanoplasty describes the surgical reconstruction of the middle ear mechanisms that had been impaired or destroyed by suppurative disease. Over the years definitions and classifications have been proposed by various authors. Finally, the definition of Tympanoplasty adopted by most authors is an operation in which the reconstructive procedure is limited to the repair of tympanic membrane perforation with reconstruction of middle ear mechanism (Wullstien, 1953; Zöllner, F. 1955; Sergi, Galli, De Corso, Parrilla, & Paludetti, 2011).

### **Basis and principle:**

Depends on the fact that the graft material contains collagen matrix and this performs the graft super structure function i.e., supports the migration of host epithelium. This is the basis for autologous as well as homologous graft. Also an ideal tympanoplasty restores the sound protection for the round window by constructing a closed air containing middle ear against the round window membrane and restores the sound pressure transformation for the oval window by connecting substitute membrane (graft) with the stapes foot plate through an intact ossicular chain (Glasscock, & Gulya, 2003).

### **Advantages of closure of tympanic membrane:**

According to Shambaugh et al, (1980) the various benefits of tympanoplasty includes the following:

- i. It restores the vibratory area of membrane and affords round window protection, thereby improving hearing and lessens tinnitus.
- ii. It lessens the susceptibility of the middle ear mucosa for the infection through the external auditory canal.

### **The various indications of tympanoplasty:**

1. To prevent further infection of the ear via the Eustachian tube and external auditory canal.
2. To improve hearing.
3. To prevent tympanosclerosis
4. To enable proper fitting of hearing aid
5. To enable recruitment in certain professionals
6. To prevent caloric effect



7. To protect the round window.

**Contraindications as reported by Glasscock, & Gulya, (2003) include:**

***Absolute contraindications are –***

1. Malignant neoplasms of outer and middle ear
2. Uncontrolled cholesteatoma
3. Malignant otitis media
4. Invasive life threatening infections with pseudomonas of outer and middle ear
5. Suspected threatened intracranial complications of ear disease.

***The relative contraindications are –***

1. Dead ear or ear without useful cochlear function.
2. Acute exacerbation of chronic otitis media.
3. Allergic type of chronic tubotympanitis.
4. Chronic otitis externa.
5. Nonfunctioning Eustachian tube.
6. Only or much better hearing ear.
7. Child <3 years, due to risk of recurrent otitis media.
8. Repeated surgical failures causing extensive middle ear fibrosis.
9. Uncooperative patients.
10. Septic foci in the nose, throat or paranasal sinuses, nasopharynx, where the septic foci, should be managed first.
11. Acute exacerbations of chronic otitis media should be controlled appropriately.
12. Bleeding disorders.
13. Atticoantral type of chronic suppurative otitis media.

**Pre-requisites for ideal tympanoplasty:**

1. A complete history and otolaryngologic examination should be performed on all patients.
2. Otomicroscopy to be done to rule out cholesteatoma and to inspect and assess the status of the middle ear mucosa and site of perforation. Preferably the perforations should be dry.
3. Eustachian tube function is assessed by having the patients perform valsalva or politzer inflation.
4. Pure tone audiogram to assess the type of deafness, the cochlear reserve and the intensity of deafness.
5. There should be no focus of infection in the nose, paranasal sinus, throat and nasopharynx.
6. Mobile and intact ossicular chain.
7. There should be pure conductive deafness.
8. The patient is counseled preoperatively as to the nature of the problem, the proposed treatment and alternative therapies, expected outcome, and potential complications.
9. X-ray of the mastoids to know the type of mastoid air cells system, whether the dura is low laying or the sigmoid sinus anteriorly placed.

**Procedure:**

Tympanoplasty is classified into five different types, originally described by Wullstein (1956) which was further modified into six types Fisch, May, & Linder, (1994).

There are six basic types of tympanoplasty procedures:

**Type I** tympanoplasty is called myringoplasty, and only involves the restoration of the perforated eardrum by grafting.

**Type II** tympanoplasty is used for tympanic membrane perforations with erosion of the Malleus. It involves grafting onto the Incus or the remains of the Malleus.

**Type III** tympanoplasty is indicated for destruction of two ossicles, with the Stapes still intact and mobile. It involves placing a graft onto the Stapes head and providing protection for the assembly.

**Type IV** tympanoplasty is used for ossicular destruction, which includes all or part of the Stapes arch. It involves placing a graft onto or around a mobile stapes footplate.

**Type V** tympanoplasty is used when the footplate of the stapes is fixed. It includes fenestration procedure or platinectomy.

**Type VI** tympanoplasty is also called as sono- inversion surgery. All sound waves enter through the round window keeping the oval window covered.

Depending on its type tympanoplasty can be performed under local or general anesthesia.

**Advantages of general anaesthesia:**

Patient remains still throughout the procedure making it technically easier. Infiltration agents such as lignocaine with adrenaline can still be used. Helpful for children and apprehensive patients.

**Advantages of local anaesthesia:**

- Allows hearing and facial nerve function to be tested.
- Results in slightly less bleeding.
- Postoperative nausea and vomiting is less.
- Early ambulation and reduced cost.

In all cases, local anesthesia should be accompanied by adequate sedation. Sedation should be sufficient to allay apprehension and put the patient at ease, but it should not depress the respiration or blood pressure to a marked degree.

#### **LOCAL ANAESTHETIC TECHNIQUE:**

Various local anaesthetic techniques are employed in tympanoplasty. According to Mohamed, El-Begermy, Rabie, Ezzat, & Sheesh, (2016). There are majorly three techniques, Plaster technique, Jonkee's technique and Wullestein technique. The Jonkee's technique is used for endaural incision. Wullstien and plaster techniques are used for post-aural incision. The most widely used is the plaster technique.

#### **PLASTER TECHNIQUE:**

According to this technique 2% lignocaine with 1:2 lakh concentration of adrenaline is used. 0.5 cc is injected postaurally in the midline, 0.5 cc superior and 0.5 cc inferior to it, then another 0.5 cc is given through the postural prick to the posterior canal of the external auditory canal. Then 0.3 cc each is injected into the four quadrants of the external auditory canal at 12, 3, 6 and 9 O'clock position.

#### **SURGICAL TECHNIQUE:**

##### *Position of the patient:*

The patient is placed supine on the operating table with the head slightly rotated, so that the ear to be operated upon faces upwards. The head is positioned so that a line drawn through the tragus and the antihelix and lobule is parallel to the floor.

#### **APPROACHES:**

Various types of incisions can be used for performing the surgery which depends on the size and site of the perforation (Cavaliere, Mottola, Rondinelli, & Iemma, 2009).

**TRANSCANAL** (Rosen's incision):

1. Suitable for small perforations.
2. Difficult in narrow canals.
3. Gives a very limited access.

**ENDAURAL** (Lempert's incision):

1. It is suited for posterior and central perforations.
2. Anterior access is very limited.

**POSTAURICULAR** (Wilde's incision):

It is suited for all types of perforations.

1. Gives a wide exposure of the middle ear.
2. Suitable for patients with narrow canal and anterior canal wall bulge.
3. It can be easily widened if dealing with extensive mastoid air cell system.
4. Most of the surgeries nowadays are done through this approach.
5. Temporalis fascia for grafting the tympanic membrane to be harvested through the same incision.

**TECHNIQUE OF POSTAURICULAR INCISION:**

The incision can either be in the retro-auricular fold or up to 1-2 cm posterior to it. It follows the curve of the fold beginning at the upper attachment of a pinna and continuing 0.5 cm behind the postaural fold downward to the tip of the mastoid process. The incision usually cuts across the posterior auricular artery or its larger branches, hence digital pressure by the finger

tips helps to control any excessive bleeding. The blade of the scalpel is held perpendicular to the surface so as not to bevel the incision, while skin, subcutaneous tissue and periosteum are incised, the bleeders are caught with a hemostats and electro cautery done. The periosteal incision is put either in a 'T' shaped or 'V' (Morimitsu) shape and the periosteum elevated exposing the mastoid process and the spine of Henle (Shea., & Gardner, 2010).

### **INCISION OF THE CANAL SKIN:**

There are various methods in which the incision of the canal skin can be performed in tympanoplasty (Fagan, 2014; Hol, Nguyen, Schlegel-Wagner, Pabst, & Linder, T. E. 2010).

#### **1) POSTERIOR VASCULAR STRIP (SHEEHY, 1989):**

It is started transcanal with an ear speculum two radial incisions are put along the tympanosquamous and tympanomastoid suture lines. Then a medial circumferential incision 1mm lateral to the annular connecting the two radial incisions is made. This part is retracted outwards from within. Next, a lateral circumferential incision is put from 12 O'clock position, connecting the suture lines. The skin is elevated entirely along with the drum remnant, epithelium of the malleus and Shrapnel's membrane. This is taken out and kept in physiological solution to place back in later stages. Then the postaural approach is used to enter the external auditory canal.

#### ***Advantages:***

- It gives excellent exposure of the middle ear.

#### ***Disadvantages:***

- Replacement of the flap is difficult and healing is problematic.

## **2) TYMPANOMEATAL FLAP INCISION (PLESTER, 1963):**

This incision is medially based. A lateral circumferential incision put from 12-6 O'clock position. Two radial incisions are put at 12 and 6 O'clock position connecting the lateral circumferential incision. The tympanomeatal flap is elevated upto the annulus. The middle ear is entered from the notch of Rivinus superiorly and the annulus is lifted from its bony groove. Sometimes the flap becomes thick hampering the visibility of the anterior edge of the perforation. To avoid this, Palva's swinging door technique is used, where an incision is put at 9 O'clock position along the annulus.

### ***Advantages:***

- Healing is rapid and replacement of flap is easy.

### ***Disadvantages:***

- Exposure of the anterior half of the mesotympanum and tympanic membrane is not adequate. Prominent anterior canal wall accentuates the problem. This incision is most commonly used nowadays in performing tympanoplasty.

## **3) ROSEN'S INCISION (1952):**

This can be done for exploratory tympanotomy, stapedectomy and in closure of small tympanic membrane perforations situated posteriorly.

## **TECHNIQUE OF GRAFTING:**

**Over the years two grafting techniques have been used (Zollner, 1955).**

- Overlay technique
- Underlay technique

Then there were certain problems associated with overlay grafting (Packer, Mackendrick, & Solar, 1982; Glasscock, Shambaugh, & Johnson, 1990), namely.

- Lateralization of the graft
- Blunting of the anterior sulcus
- Epithelial pearls and
- Delayed healing.

So there was a change in trend and a general shift occurred towards the underlay technique of grafting. The underlay technique avoided the complications of overlay method and was quick and easy to perform. The other methods subsequently developed were Sandwich technique, Crow-Cark Tympanoplasty, swinging door technique, fascial pegging, spot welding (laser), and microclip techniques and over under tympanoplasty (Kartush, Michaelides, Becvarovski, & LaRouere, 2002). based on the earlier two basic techniques.

The underlay technique, though commonly used, had its own disadvantages (Rizer, 1997) like, there was increased failure in large perforations due to the limited bed size for the graft and middle ear space is reduced (insignificant). The failures were due to medialisation of the graft resulting in re-perforations.

### ***Historical review***

The treatment of ear diseases dates back to 1000 B.C., where Egyptian healers used herbs and their extracts. Surgery for a mastoid infection was first proposed by Ambrose Paré in 16th century. Banzer (1640) published an account of a case of tympanic membrane repair, where pig's bladder was stretched across an ivory tube and placed in the ear. The first documented



successful surgery for a mastoid infection was performed by Petit (1774) in 18th century. It was Jasser (1776) successfully performed a mastoid surgery on a soldier with a draining ear. William Wilde (1853) published a procedure for sepsis and suppuration of the ear. Later Schwarte (1873) published both indications and the procedure for removing mastoid cortex and the underlying air cells. von Troeltsch (1873) and von Bergmann (1889) expanded the simple mastoidectomy of Schwartze to include the attic and antrum. Radical mastoidectomy was described by Zaufal and Stacke (1890) for chronically draining ear. At the same time development on hearing was also experimented. Toynbee (1853) placed a rubber disk attached silver wire over a perforation. Yearsley, (1863) improved hearing by placing a cotton ball over a perforation. Blake (1877) introduced the idea of placing paper patch over perforation. Roosa and Okaneuff (1876) promoted healing of the drum by application of chemical cautery. In 20<sup>th</sup> century, with the development of antibiotics and operating microscopes, the surgeons became adapt at examining the ear and developed instruments for manipulating the drum and ossicles. House (1960), Sheehy and Glasscock (1967) developed techniques for creating a satisfactory on lay graft. Shea (1960) discovered that vein graft could be satisfactorily placed under the drum to repair a tear. Storrs (1961) switched to fascia and Patterson et al determined the reasons for the success of fascia as a grafting material. However, according to Hough (1970) and Austin (1972) the popularity and success of the techniques of tympanoplasty can be attributed to the success of many other surgeons who have refined others' techniques.

**GRAFTING MATERIALS:** The fundamental principles of the surgical procedure were described by Wullstein (1952), using a free skin graft, and Zoellner (1955), using a pedicle graft. Since then various materials were used for tympanic membrane re-construction. The following are the commonly used grafts.

### **CANAL SKIN GRAFTS:**

Soohy (1956) was the first to use the skin of the ear canal as a graft. The canal skin pedicle flap was used onto the drum remnant for closure of marginal perforations of tympanic membrane. However, House and Sheehy (1961) advanced the technique by using the canal skin as free grafts laid over the drum remnant. As ear canal skin was devoid of glands, it was thought that problems associated with full thickness and split thickness skin graft could be avoided, however the problems of desquamation and frequent cleansing persisted. The take up rate was initially excellent in tympanoplasty cases, (97%) but the problems of desquamation persisted. After long term follow up only 77% cases were successful. The major problem was that the canal skin did not hold up well in the presence of infection.

### **VEIN GRAFTS:**

The technique of placing vein graft medial to the damaged tympanic membrane was accidentally discovered (Shea & Tabb, 1960) while doing a stapedectomy, where the drum healed completely within 3 days. Mesothelium vein was an excellent graft material. But the tympanic membrane tended to atrophy after a few months and occasionally re-perforated. This did not form durable repairs of the drum.

### **TEMPORALIS FASCIA:**

The use of temporalis fascia was first described in the repair of the tympanic membrane Ortegren (1959). Subsequently the use of antilogs temporalis fascia for tympanoplasty has become common. There are two distinct temporalis fascia layers, the superficial temporalis fascia and deep temporalis fascia each with a separate blood supply. The total area of fascia

available on one side of the head is 260 cm<sup>2</sup>. The importance of this is emphasized because temporalis fascia should always be available for tympanoplasty even in repeat operations.

There are six layers superficial to skull. The pericranium is adherent to calvarium, covered by a loose layer of connective tissue. Superficial to this, in the temporal region lies the temporalis muscle covered by deep temporal fascia, which in turn is covered by superficial temporal fascia, the outer two layers are subcutaneous fat and the scalp. The superficial fascia has many synonyms like the temporoparietal layers, epicranial aponeurosis and the galeal extension. It is thin highly vascular, loosely attached to the overlying subdermal layer above zygomatic arch. It is separated from deep temporalis fascia by an avascular plane. The deep temporal fascia has clear boundaries and closely covers the temporalis muscle and its aponeurosis. The blood supply is from middle temporal artery, arising from superficial temporal artery. Histologically and morphologically there is no significant difference between the two layers. Commonly deep temporalis fascia is used in tympanoplasties as a graft material.

Ortegren (1959) was the first to describe the use of temporalis fascia as a graft. Heerman (1960) used them successfully. The superior qualities of fascia, its ready availability, its ideal handling qualities, low basal metabolism rate, marked resistance against infection, its availability in required amount and its being a ready source of fibrous tissue. All made it the standard for drum grafting, which it remains till today.

#### **PERICHONDRIUM GRAFTS:**

Goodhill (1967) was the first to use perichondrium as a graft for tympanic membrane repair. The healing results were similar to that of other fascia, but it was not as easily harvested as temporalis fascia and was available in very limited quantities. It has therefore not been widely

used. Indorewala (2002) in the studies on animal showed that fascia lata had better dimensional stability because of the uniform mesh of elastic fibers. It was found that temporalis fascia has shown to shrink and thicken more and also more unpredictably. A well seated perforation may reopen by fifth day, before the graft integration has occurred because of the graft shrinkage during the early healing phase (especially in subtotal perforation). However, it was concluded that fascia lata had a much lesser shrinkage rate.

#### **HOMOGRAFT TYMPANIC MEMBRANE:**

Merquet (1966) first described the use of homograft (allograft) tympanic membrane. Success reported was similar to that of fascia. The current difficulty with homografts is similar to other areas of human tissue transplantations. Trial by the surgeons has been done on en bloc tympano-ossicular techniques and Tympanomeatal techniques with ossicle interposition and it has been reported to be of great success. However, shortage of adequate material and the advent of the human immunodeficiency virus and Creutzfeld – Jacob disease resulted in potential hazards. Hence, the use remains infrequent although the results are excellent.

#### **CARTILAGE- PERICHONDRIUM GRAFTS:**

Perichondrium and cartilage share with fascia the quality of being mesenchymal tissue, but they are thicker and stiffer. The greatest advantage of cartilage graft has been thought to be its very low metabolic rate. It receives its nutrition by diffusion. It is easy to work with because it is pliable, and can resist deformation from pressure variations. The perceived disadvantage of the cartilage graft is that it creates an opaque tympanic membrane repair site, which could potentially hide a residual cholesteatoma.

Heermann (1970) was the first to introduce the technique of cartilage palisade. Salen and Jansen (1963) reported the use of cartilage-perichondrial composite graft for tympanic membrane reconstruction. Cartilage has a low metabolic rate and good acceptance in the middle ear. Cartilage perichondrium graft being tougher and easily neovascularized would theoretically work well in these conditions as the incorporated cartilage will provide mechanical stability and necessary stiffness to avoid retraction and reperforation (Dornhoffer, 2006). Nevertheless there may be some concern regarding poor hearing using this grafting material rather than fascia. The perceived disadvantage of the cartilage graft is that it creates an opaque tympanic membrane, which could potentially hide a residual cholesteatoma. There are many described techniques for cartilage tympanoplasty such as cartilage butterfly inlay technique, cartilage palisade technique, perichondrium cartilage island technique, cartilage mosaic technique and cartilage reinforcement technique (Neumann et al, 2003 & Dornhoffer, 2003). Overbosch (1971) was the first to describe a microslice technique in order to improve the acoustic properties of reconstructed tympanic membrane. Later Amedee et al, Milewsk, Dornhoffe and Murbe et al used cartilage palisade tympanoplasty for difficult cases and recurrent perforations and atelectasis of tympanic membrane.

Goodhill (1967) described the technique of using composite cartilage-perichondrial grafts for tympanic membrane and he used perichondrial grafts with a circumferential cartilage batten in cases with a shallow middle ear cavity, in order to avoid sagging of perichondrium onto the promontory. Other surgeons have trimmed the cartilage part of the composite cartilage-perichondrial graft into a 'shield'(Duckert et al, 1995), 'double island' (Dornhoffer, 1997), 'Mercedes Benz' sign (Spielmann & Mills, 2006), 'wheel' (Shin et al, 2007), 'crown cork' (Hartwein et a, 1992) , lamellae (Neumann & Jahnke, 2005) or 'coin with butterfly edge,

(Eavey, 1998). Unfortunately most authors reported on the overall results of tympanoplasties; relatively few analysed only type 1 tympanoplasty.

#### **OTHERS:**

Other materials used for grafting the tympanic membrane are –

- Amniotic membrane, Schrimpt (1954).
- Unterberg suggested the use of fascia lata and used by Zollner (1956).
- Autologous mucous membrane, Hall (1956).
- Cornea, Holewinski (1958).
- Autologous periosteum, Claros Domenech (1959).
- Vein graft, Shea, (1960).
- Dura mater, Preobrazkensky (1961).
- Adipose tissue, Ringenberg (1962).
- Connective tissue Portmann et al, (1964).
- Claus Jensen used heterograft tympanic membrane of bovine origin.

## METHODS

This study was prospective interventional study conducted in Department of Otorhinolaryngology and Department of Audiology, All India Institute of Speech and Hearing, Manasagangothri, Mysuru, after taking informed written consent from participants and required approval from Ethical committee. The period of study was from January 2016 - April 2017. The sample size was determined based on the earlier studies who have used similar methods for assessing the the efficacy of the Type I tympanoplasty procedure on hearing sensitivity (Patil.,Misale., Mane., & Mohite, 2014., Mokhtarinejad, Okhovat, & Barzegar, 2012). For an effect size of 0.50, power of 0.80 and significant of 0.05, the sample size obtained in the G\*power (version 3.1.9.2) software was 21. However a total number of 50 participants were included in the study. The participants were divided into two groups. Group I are those who underwent Type I tympanoplasty with canal widening procedure. The participants were in the range of 15 - 50 years (Mean age: 27.4 years, SD: 9.9), with 8 males and 17 females. Group II are those who were taken as our participants who had already undergone Type I tympanoplasty without canal widening procedure. The participants were in the range of 15 - 50 years (Mean age: 26.6 years, SD: 8.5), with 16 males and 9 females. Below Table 1 summarises the demographic information of the complaints of the participants.

Table 1.

Demographic information of the complaints of the participants

<b>Demographic information</b>	<b>Group I No. of participants</b>	<b>Group II No. of participants</b>
No of ears with c/o tinnitus	14	16
No of ears with c/o Hearing loss	25	25
No of ears with c/o ear discharge	22	19
No of ears with c/o ear pain	12	16

**Inclusion Criteria:**

1. Patients aged 15 to 50 years.
2. Medium and large dry central perforation of pars tensa.
3. Mild (26-40 db) and moderate (41-55 db) degree of conductive hearing loss.
4. Overhanging canal wall.
5. Lack of acute upper respiratory tract infection (URTI) at the time of surgery.

**Exclusion Criteria:**

1. Ossicular pathology detected by preoperative pure tone audiometry and intra operative evaluation or mixed hearing loss.
2. Granulation tissue, cholesteatoma, or polyp in the ear prior to surgery.
3. Revision cases, cases with tympanosclerosis and bony ankylosis or graft failure following surgery.



4. Clinically significant predisposing focus of infection in the sinuses, nose or throat.
5. Complications of otitis media or multiple tympanic membrane perforations.
6. Underlying diseases such as diabetes or poor immune system.

**Preoperative assessment-** All participants were subjected to detailed pre-operative history taking and clinical examination including oto-microscopic and oto-endoscopic examination. Tuning fork tests were done to determine type of hearing loss. Degree of hearing loss was determined by the audiological evaluation.

#### **PROCEDURE:**

The study that was conducted is classified as three conditions:

**Condition 1 (Pre Surgery):** All the participants (both the groups) were assessed for their audiometric thresholds before surgery. Pure tone audiometry (PTA) was carried out using GSI 61 clinical audiometer for air conduction and bone conduction thresholds for frequencies between 250 Hz to 8 kHz and from 250 Hz to 4 kHz respectively using Modified Hughson and Westlake procedure (Carhart & Jerger, 1959). Speech audiometry which includes speech recognition thresholds (SRT), and speech identification scores (SIS) was also measured. Immittance audiometry was carried out using GSI Tymstar to test middle ear pathologies and ear canal volume was noted. The obtained thresholds and values were documented. After this initial evaluation, the participants were advised for the surgery.

#### **OPERATIVE TECHNIQUE [Type I Tympanoplasty with canal widening]:**

All participants were operated under general anaesthesia with post aural approach. With post auricular incision, temporalis fascia graft was harvested. A rim of tissue was removed to

freshen the perforation margins and under surface of the remnant tympanic membrane scraped to ensure completely de-epithelialized medial surface of the remnant tympanic membrane. The posterior Tympanomeatal flap is created by making vertical incisions at 6'0 clock and 12'0 clock positions 5mm lateral to the annulus, and medial ends of these two incisions are joined by a horizontal incision. This flap is elevated from medial to lateral up to the bony- cartilaginous junction. The Superior Tympanomeatal flap is created by extending the medial end of 12'0 clock incision anteriorly up to the 2'0 clock position. The Inferior Tympanomeatal flap is created by extending the 6'0 clock incision anteriorly up to 4'0 clock position. All these flaps are joined and elevated along with the annulus following skeletonising of handle of malleus, where in the superior Tympanomeatal and the posterior Tympanomeatal flaps are joined and secured anteriorly. The external auditory canal is widened with conical cutting and diamond burrs eliminating all bony overhangs particularly in the posterior and inferior part routinely and superiorly when there is prominent Tympanosquamous suture. Malleus handle is exteriorized. After placing the temporalis fascia graft and the Tympanomeatal flaps, the Tympanomeatal flap is reflected anteriorly and the lateral process of the malleus is palpated using a sharp micro scissors the Temporalis is reflected and cut precisely over the malleus up to the tip and the graft slided beneath the malleus and the Tympanomeatal flaps reflected back to its original position and the gel foam was kept in the external auditory canal. Post auricular wound was closed and a snugly fitting, mastoid bandage was applied.

### **Condition 2 (Post Surgery, 1 month):**

All the participants who had been treated surgically were followed up for the re-evaluation of audiological testing after a period of one month. The air conduction, bone

conduction audiometric thresholds and the speech audiometry that were obtained before the surgery were again re-evaluated and documented. The status of the tympanic membrane was also viewed and recorded through endoscopic examination. However, during the follow up after 1 month the Tympanometry was not recommended as the healing process continued. Hence ear canal volume was not documented in condition 2.

### **Condition 3 (Post Surgery, 3 months):**

After the period of three months of post surgery, the participants were again followed up for the re-evaluation of audiological testing. The air conduction, bone conduction audiometric thresholds, speech audiometry and ear canal volume were again re-evaluated and documented. The status of the tympanic membrane was again recorded. All audiometric testing was carried out in a sound treated room (ANSI, S3.1 - 1991).

Outcome of surgery was regarded as successful if the ear gets dry, the tympanic membrane heals and intact and mobile at the end of 3<sup>rd</sup> month.

### **Analysis**

The data were analysed across the two groups to compare the effect of two different surgical procedures on hearing sensitivity. Within the group comparison was done for the different conditions, and pair wise comparisons were done in instances of presence of main effect. Non parametric test of Friedman test were done for within group comparison between conditions followed by wilcoxon's test if found significant owing to non normal distribution of the data. Mann -Whitney Test was done for comparison between two groups of participants.

Appropriate statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) software version 17 (SPSS Inc. Chicago).

## RESULTS

The study aimed to investigate the efficacy of the Type I tympanoplasty through a canal widening procedure on hearing sensitivity. The obtained data were subjected to statistical analysis using the Statistical Package for Social Sciences (SPSS) software version 17. Shapiro-Wilk test of normality were administered for checking the distribution of the data. As the normality was not observed ( $p < 0.05$ ), the out layers were removed. However, normality ( $p > 0.05$ ) was still not obtained hence non-parametric test Friedman test and Wilcoxon Signed-rank test were used for further analysis of the data. Descriptive statistics (mean, median & standard deviation) were analyzed for the data that were measured: pure tone average (PTA) for the frequencies 250 Hz, 500Hz, 1 kHz, 2 kHz, 4 kHz, and 8 kHz of air conduction threshold and 250 Hz, 500Hz 1 kHz, 2 kHz, and 4 kHz for bone conduction threshold, speech recognition threshold (SRT), speech identification scores (SIS) and ear canal volume (ECV) across the conditions 1) Pre-surgical treatment (condition 1) 2) Post-surgical treatment after 1 month (condition 2) and 3) Post surgical treatment after 3 months (condition 3).

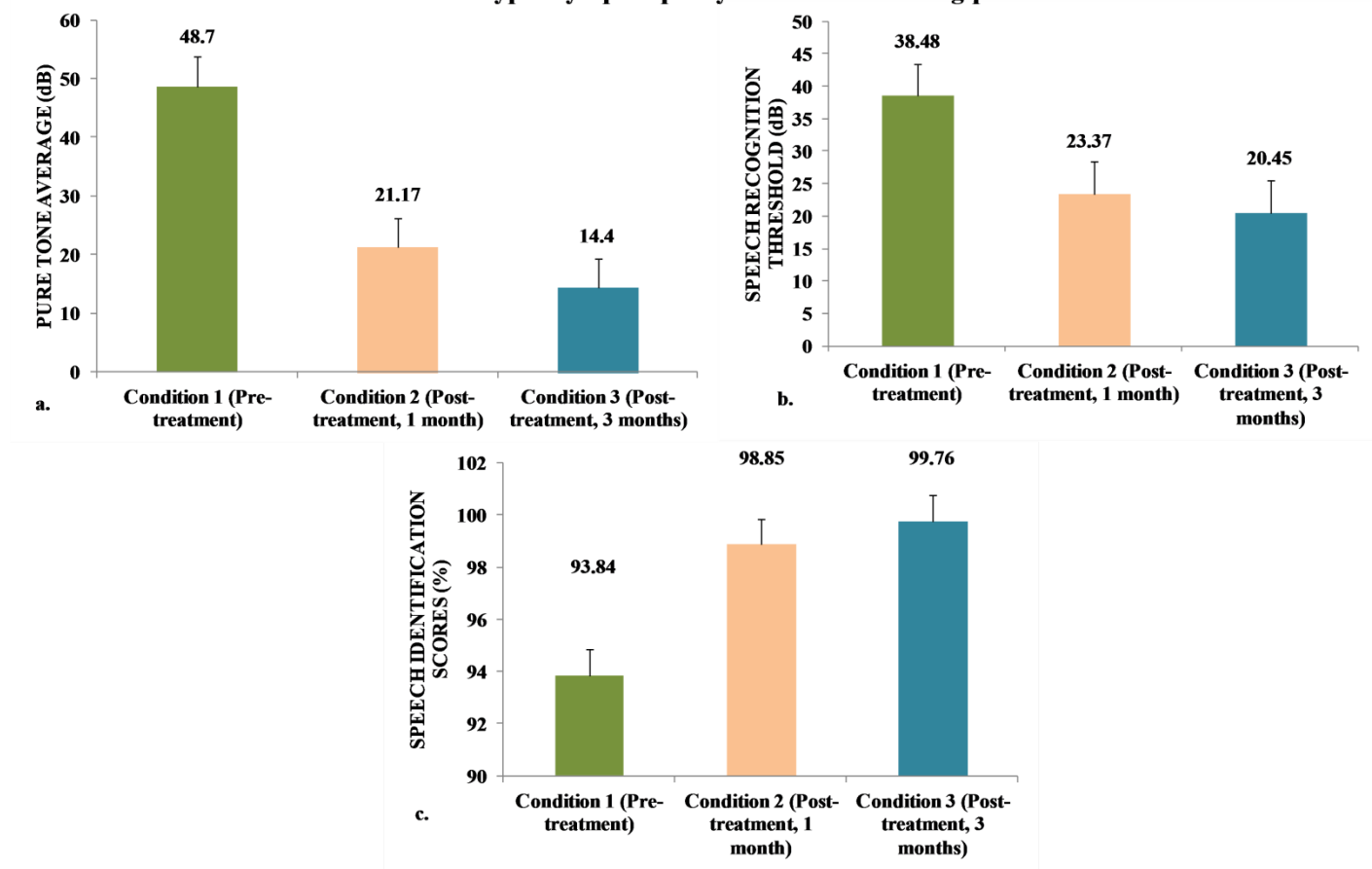
The results are describes as follows:

1. Comparison across three conditions for type I tympanoplasty with canal widening
2. Comparison across three conditions for type I tympanoplasty without canal widening
3. Comparison between the conditions for type I tympanoplasty with and without canal widening

**1. Comparison across three conditions for type I tympanoplasty with canal widening:**

The data obtained for pure tone average (PTA) for the frequencies 250 Hz, 500Hz 1 kHz, 2 kHz, 4 kHz, and 8 kHz of air conduction threshold and 250 Hz, 500Hz 1 kHz, 2 kHz, and 4 kHz for bone conduction threshold, speech recognition threshold (SRT), and speech identification scores (SIS) were analysed across the conditions 1, 2 and 3 within group I participants. Figure 1 shows the mean and standard deviation values of pure tone average, speech recognition threshold, and speech identification scores across three conditions for type I tympanoplasty with canal widening procedure of surgery.

**Type I tympanoplasty with canal widening procedure**



*Figure 1.* The mean and standard deviation of a) pure tone average, b) speech recognition threshold, c) speech identification scores across three conditions for type I tympanoplasty with canal widening.

The Figure 1 reveals that the scores of the PTA and SRT has improved from condition 1 to 2 and then to the condition 3. The SIS scores also have improved across the conditions. Figure 2 shows the mean and standard deviation values of ear canal volume (ECV) as measured from Tympanometry across two conditions in group I participants.

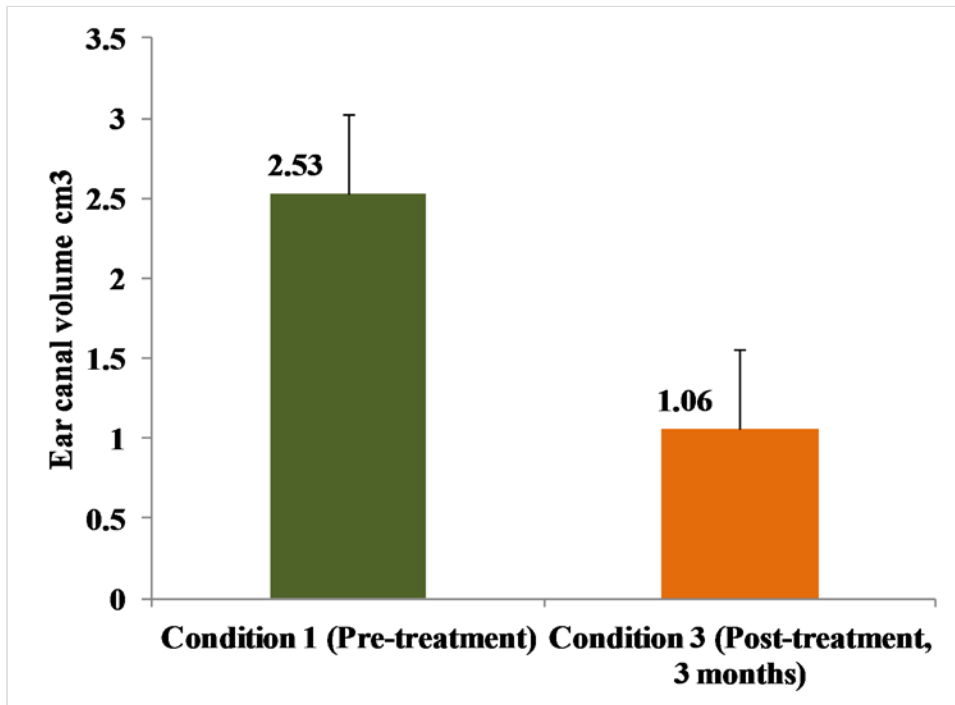


Figure 2: The mean and standard deviation values of ear canal volume across two conditions for participants underwent type I tympanoplasty with canal widening procedure.

From figure 2 it is evident that there was an improvement in the ear canal volume between condition 1 and condition 3 in participants who underwent type I tympanoplasty with canal widening procedure.

Further non parametric test of Friedman test was done for within group comparison between conditions followed by wilcoxon's test if found significant. A non – parametric Friedman test of differences among repeated measures was conducted and the chi-square value and its significant are reported in below Table 2.



Table 2.

Results of Friedman test of differences across conditions for the measures pure tone average, speech recognition threshold, and speech identification scores in group I participants

<b>Parameters</b>	<b>Chi-square values</b>	<b>Significant</b>
PTA	47.89	0.000
SRT	40.23	0.000
SIS	27.88	0.000

The Table 2 reveals that there was significant difference across the three conditions for all the parameters that were measured. Wilcoxon Signed-rank test was done for pair wise comparison. The results reveal that there was significant difference ( $p < 0.05$ ) across all the parameters and conditions ( $p < 0.05$ ) for PTA, SRT and SIS. The results of Wilcoxon Signed-rank test for the analysis of ear canal volume revealed that there was significant difference between the conditions 1 and 3 ( $Z = 4.145, p = 0.000, \eta = 0.592$ ). The statistical analysis was also done to compare across the conditions for the air conduction and bone conduction thresholds. For the air conduction thresholds the data were compared across the frequencies for 250Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz and 8 kHz. The figure 3 represents the air conduction thresholds obtained across the test frequencies and figure 4 represents the bone conduction thresholds obtained across the test frequencies for different conditions for group I participants.

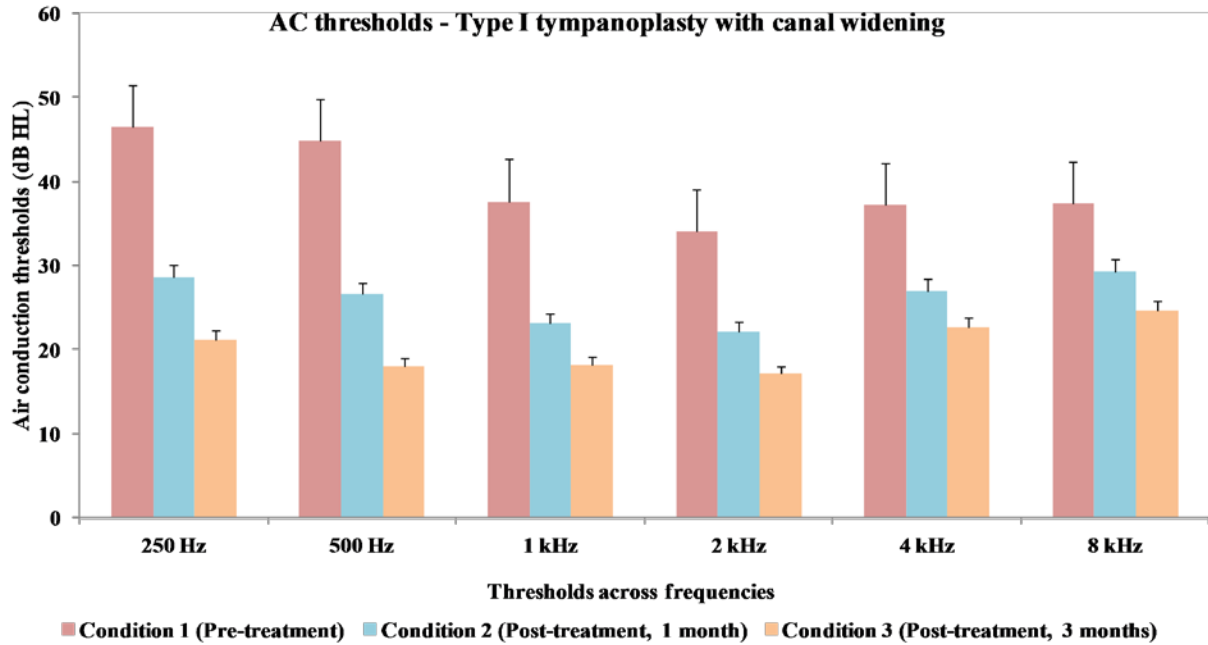


Figure 3. Air conduction thresholds across the test frequencies for different conditions for group I participants.

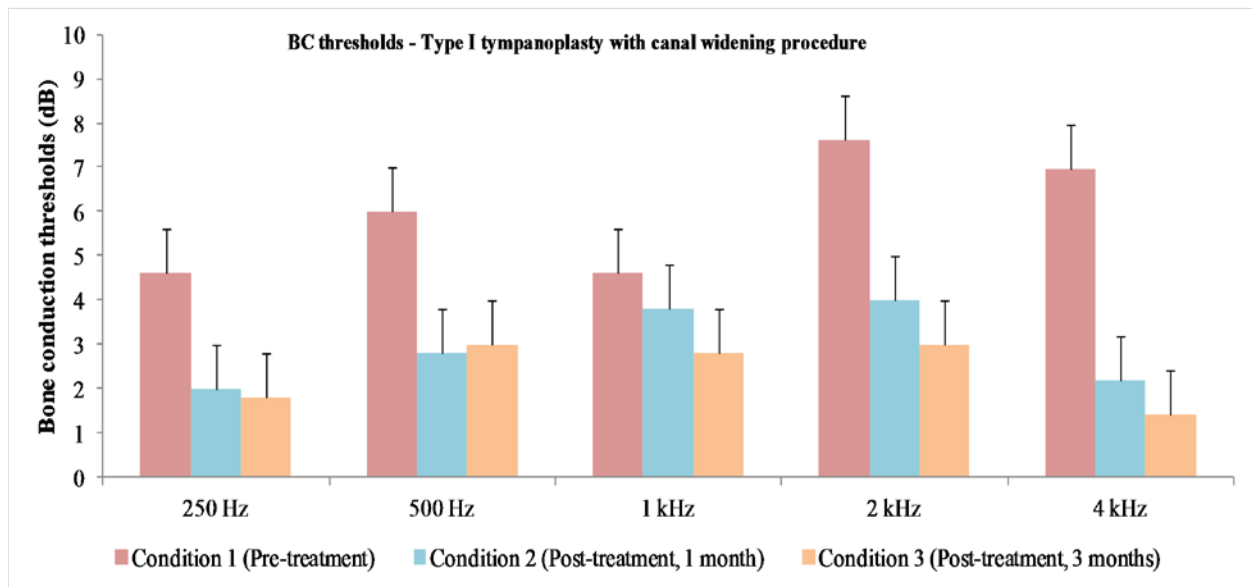


Figure 4. Bone conduction thresholds across the test frequencies for different conditions for group I participants.

Interpreting the figure 3 it reveals that the hearing loss at the lower frequencies (250 Hz and 500 Hz) are higher compared to the other frequencies in condition 1. However, comparing

with condition 2 and 3 the improvement in air conduction thresholds at lower frequencies are higher than the mid and high frequencies. And from figure 4 it can be interpreted that the threshold were within the normal range across all the three conditions for all the test frequencies of bone conduction. Further the data were statistically analysed if there are any differences between the conditions across the frequencies in specific for the air and bone conduction thresholds. Table 3 provides the results of Friedman test of differences across conditions for the measure of air conduction thresholds from 250 Hz to 8 kHz and bone conduction thresholds at different frequencies from 250 Hz to 4 kHz for group I participants.

Table 3. The results of Friedman test of differences across conditions for the measure of air conduction and bone conduction thresholds at test frequencies for group I participants.

<b>Parameters</b>	<b>Air conduction thresholds</b>		<b>Bone conduction thresholds</b>	
	<b>Chi-square values</b>	<b>Significant</b>	<b>Chi-square values</b>	<b>Significant</b>
250 Hz	45.32	0.000	5.86	0.053
500 Hz	45.91	0.000	8.77	0.012
1 kHz	37.77	0.000	1.73	0.420
2 kHz	39.69	0.000	11.79	0.003
4 kHz	27.82	0.000	23.23	0.000
8 kHz	24.69	0.000	-	-

The Table 3 reveals there was significant difference across all the conditions for all the test frequencies of air conduction threshold. Hence, Wilcoxon Signed-rank test was done for pair wise comparison. The results indicated that there was significant difference across all the pairs at

$p < 0.05$ . However for bone conduction thresholds there was significant difference only at 2 kHz and 4 kHz. Further, Wilcoxon Signed-rank test was done for pair wise comparison for bone conduction thresholds. The results for 2 kHz reveal that there was significant difference across the pairs for the conditions 1 and 2 ( $Z = -2.59, p = 0.01, \eta = 0.52$ ) and for the conditions 1 and 3 ( $Z = -3.056, p = 0.002, \eta = 0.61$ ). The results for 4 kHz also reveal that there was significant difference across the pairs for the condition 1 and 2 ( $Z = -3.169, p = 0.002, \eta = 0.63$ ) and for the pair 1 and 3 ( $Z = -3.429, p = 0.001, \eta = 0.68$ ). These results indicate that there was marked difference across all the test frequencies for the air conduction threshold across the three conditions where as there was significant difference only at 2 kHz and 4 kHz for bone conduction thresholds between the two pre and post treatment after one month of evaluation. The below figure 5 depicts the endoscopic view of tympanic membrane of a participant.



*Figure 5.* An endoscopic appearance of a participants' left ear tympanic membrane (a) Pre-operative image (b) Post-operative image at 3 months after the operation.

The above figure 5(a) depicts the central perforation of the tympanic membrane showing the tip of angle of malleus involving all the quadrants. The pre operative hearing loss is 47.5 dB (moderate conductive hearing loss). Figure 5(b) depicts the graft taken up of the tympanic membrane after 3 months. The improvement in hearing thresholds is 18.8 dB after 3 months post operatively.

## **2. Comparison across three conditions for type I tympanoplasty without canal widening**

The data obtained for pure tone average (PTA) for the air conduction frequencies at 250 Hz, 500Hz, 1 kHz, 2 kHz, 4 kHz, 6 kHz and 8 kHz and bone conduction threshold at 250 Hz, 500Hz 1 kHz, 2 kHz, and 4 kHz, speech recognition threshold (SRT), and speech identification scores (SIS) were analysed across the conditions 1, 2 and 3 within group II of participants. Figure 6 shows the mean and standard deviation values of pure tone average, speech recognition threshold, speech identification scores across three conditions for type I tympanoplasty without canal widening procedure.

### Type I tympanoplasty without canal widening procedure

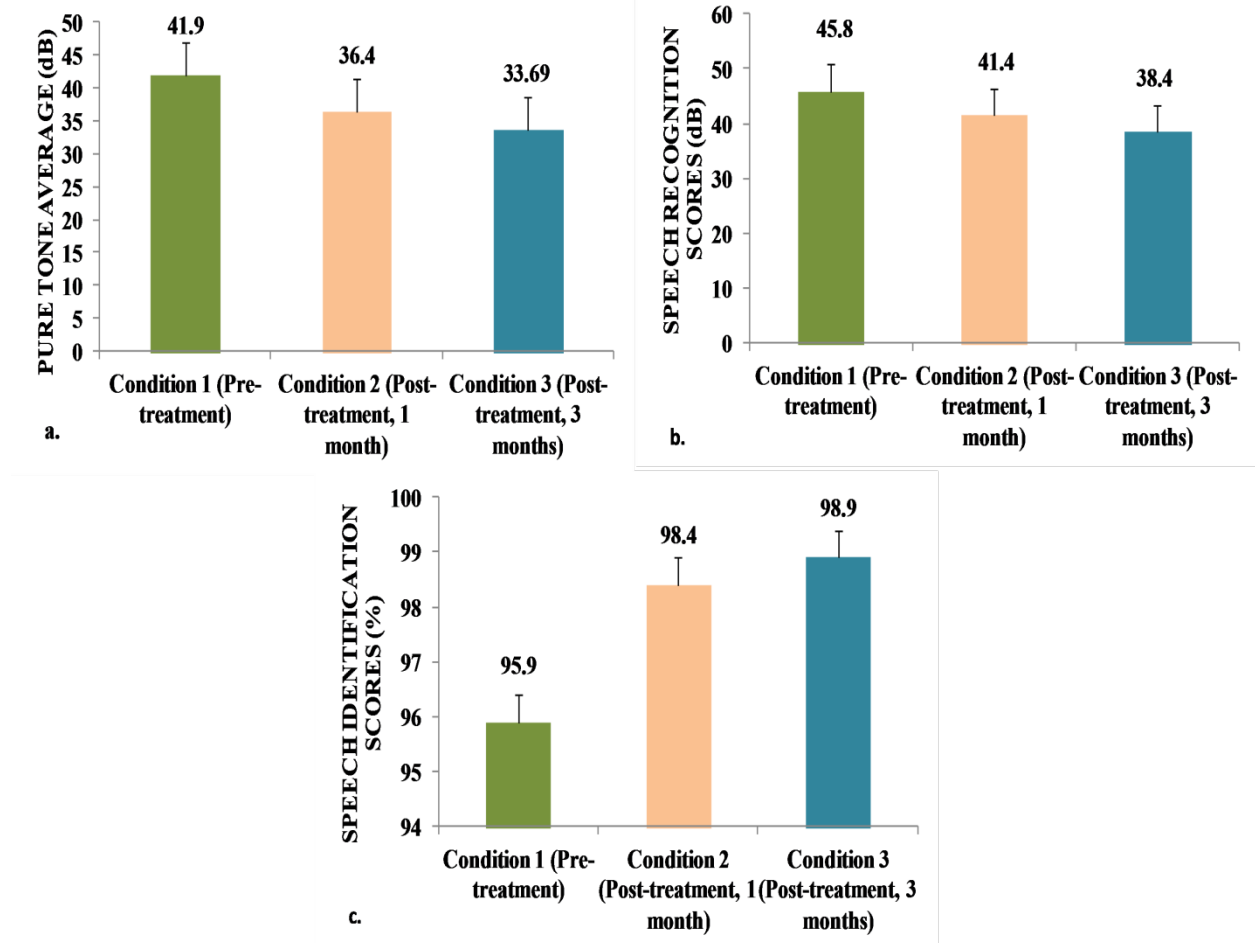


Figure 6. The mean and standard deviation of a) pure tone average, b) speech recognition threshold, and c) speech identification scores across three conditions for type I tympanoplasty without canal widening.

The figure 6 reveals that the scores of the PTA and SRT has improved from condition 1 to 2 and then to the condition 3. The SIS scores also have improved across the conditions. Figure 7 shows the mean and standard deviation values of ear canal volume (ECV) as measured from Tympanometry for group II participants.

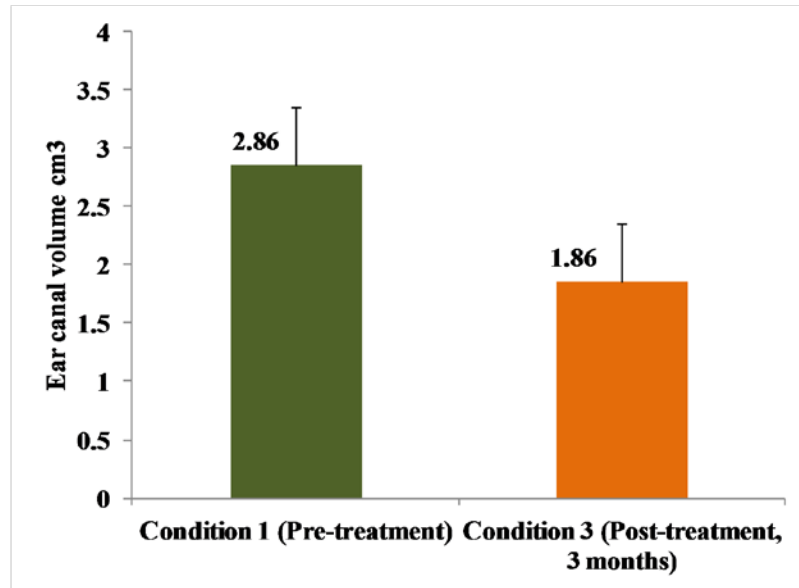


Figure 7: The mean and standard deviation values of ear canal volume across two conditions for type I tympanoplasty without canal widening.

From figure 7 it is evident that there was a significant improvement in the ear canal volume between condition 1 and condition 3. Further non parametric test of Friedman test was done for within group comparison between conditions followed by wilcoxon's test if found significant. A non – parametric Friedman test of differences among repeated measures was conducted and the chi-square value and its significant are reported in below Table 4.

Table 4. Results of Friedman test of differences across conditions for the measure of pure tone average, speech recognition threshold, and speech identification scores for group II participants.

<b>Parameters</b>	<b>Chi-square values</b>	<b>Significant</b>
PTA	28.42	0.000
SRT	19.66	0.000
SIS	13.63	0.001

From Table 4 it is evident that there was significant difference across the three conditions for all the measures, further Wilcoxon Signed-rank test was done for pair wise comparison. The results reveal that there was significant difference ( $p < 0.05$ ) across all the parameters and conditions except for the SIS of condition 2 and 3, which showed that there was no significant difference ( $Z = -1.194, p = 0.233$ ). The results of Wilcoxon Signed-rank test for the analysis of ear canal volume revealed that there was no significant difference between the conditions 1 and 3 ( $Z = -1.646, p = 0.100$ ). Comparison of results was also done for across the conditions for the air conduction and bone conduction thresholds. For the air conduction thresholds the data were compared across the frequencies for 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz and 8 kHz and for bone conduction thresholds the data were compared across the frequencies 250 Hz, 500 Hz, 1 kHz, 2 kHz, and 4 kHz. The figure 8 represents the air conduction thresholds obtained across the test frequencies and figure 9 represents the bone conduction thresholds obtained across the test frequencies for different conditions for group II participants.



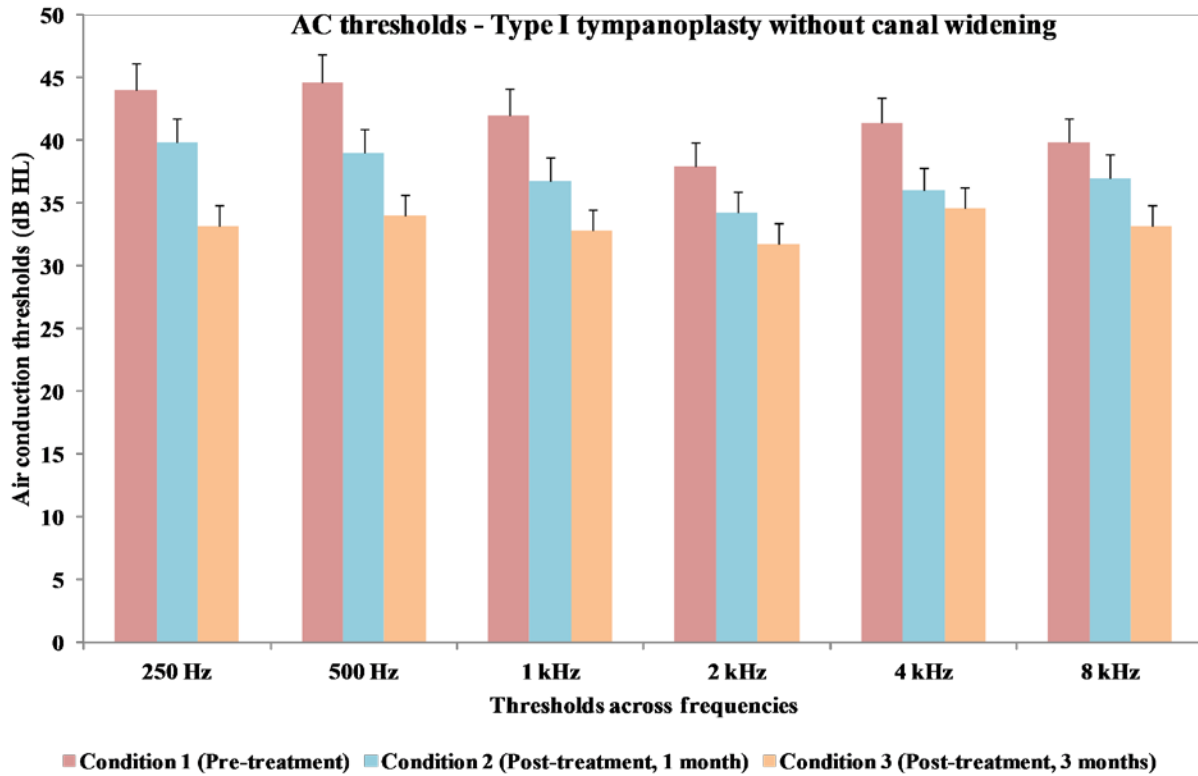


Figure 8. Air conduction thresholds obtained across the test frequencies for different conditions for group II participants.

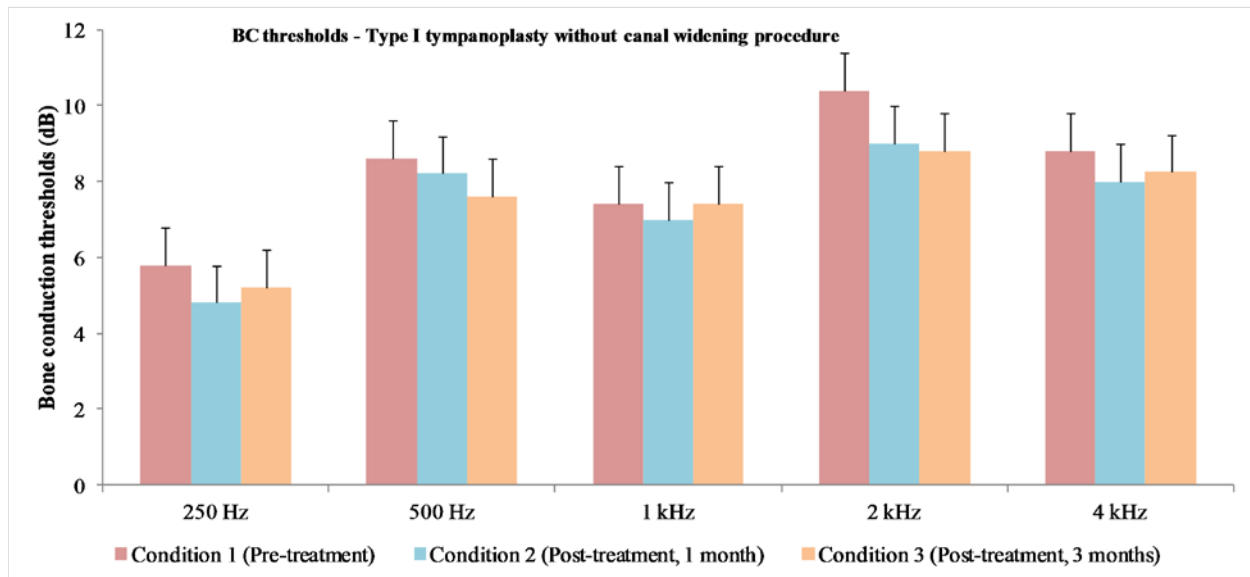


Figure 9: Bone conduction thresholds obtained across the test frequencies for different conditions for group II participants

The figure 8 reveals that there was difference across the three conditions. These differences are more at the lower frequencies than at the higher frequencies. And from figure 9 it can be interpreted that the threshold were within the normal range across all the three conditions for all the test frequencies of bone conduction. Further the data were statistically analysed if there are any differences between the conditions across the frequencies in specific for the air and bone conduction thresholds. Table 5 provides the results of Friedman test of differences across conditions for the measure of air conduction and bone conduction thresholds at test frequencies for group II participants.

Table 5.

The results of Friedman test of differences across conditions for the measure of air conduction and bone conduction thresholds at test frequencies for group II participants.

<b>Parameters</b>	<b>AC thresholds</b>		<b>BC thresholds</b>	
	<b>Chi-square Values</b>	<b>Significant</b>	<b>Chi-square values</b>	<b>Significant</b>
<b>250 Hz</b>	27.57	0.000	1.583	0.453
<b>500 Hz</b>	29.12	0.000	2.000	0.368
<b>1 kHz</b>	25.60	0.000	1.182	0.554
<b>2 kHz</b>	15.89	0.000	4.083	0.130
<b>4 kHz</b>	12.77	0.000	0.897	0.639
<b>8 kHz</b>	11.46	0.000	-	-

The results of table 5 reveal that there was significant difference ( $p < 0.05$ ) across all the frequencies except for the 4 kHz of condition 2 and 3, which showed that there was no significant effect ( $Z = -1.252, p = 0.210$ ) and at 8 kHz between condition 1 and 2 ( $Z = -1.122, p$

= 0.262) for air conduction. Whereas, the bone conduction, the threshold did not show any significant difference across any of the three conditions.

### **3. Comparison between the conditions for type I tympanoplasty with and without canal widening**

The data obtained for pure tone average (PTA) at frequencies of 250Hz, 500Hz, 1 kHz, 2 kHz, 4 kHz, and 8 kHz for air conduction thresholds and 250Hz, 500Hz, 1 kHz, 2 kHz, and 4 kHz, for bone conduction, speech recognition threshold (SRT), speech identification scores (SIS) and were analysed across the conditions 1, 2 and 3 between two different surgical procedure of type I tympanoplasty with and without canal widening. Figure 10 shows the mean and standard deviation values of a. pure tone average, b. speech recognition threshold, and c. speech identification scores across three conditions for both groups of participants.

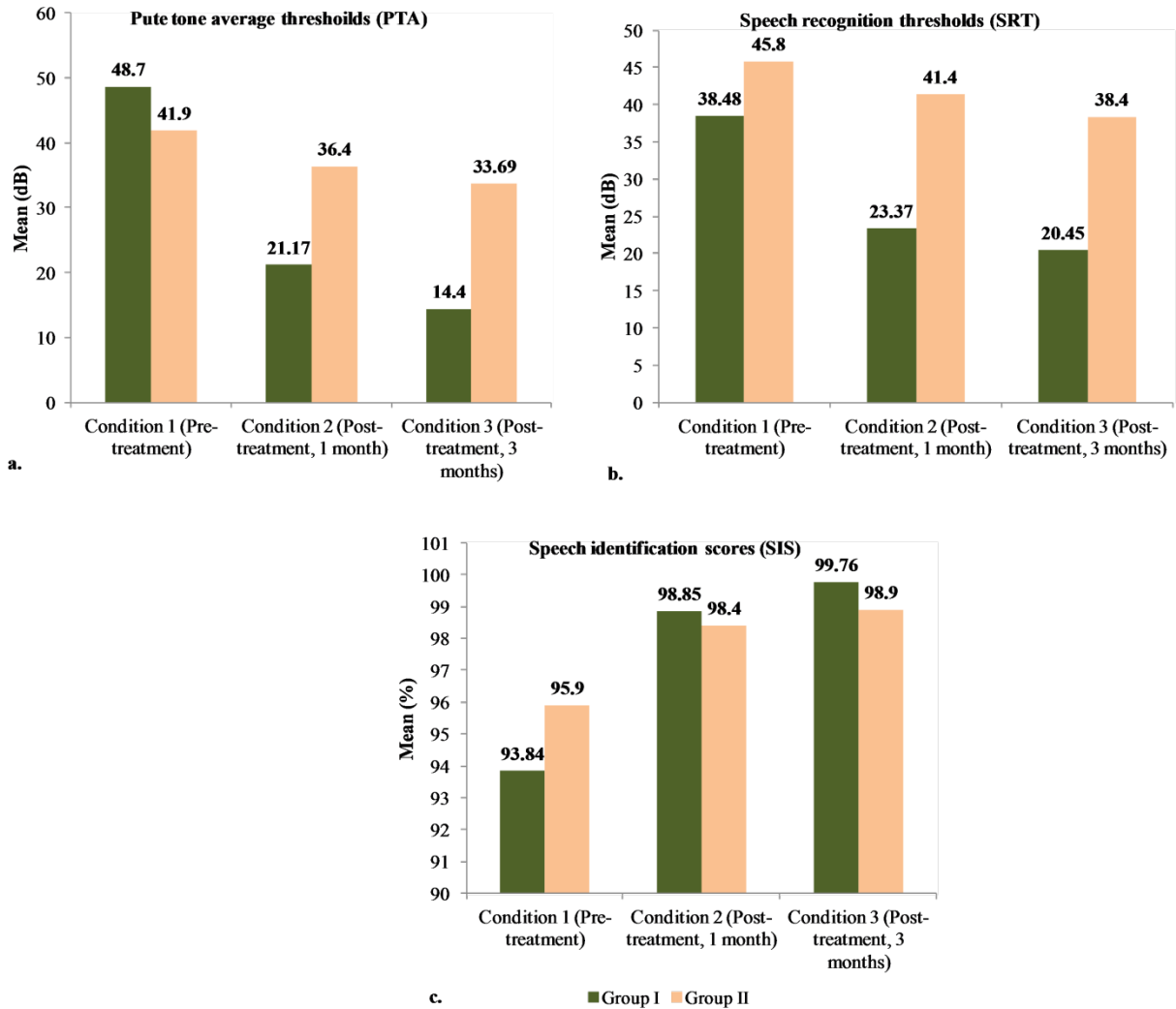


Figure 10. The mean and standard deviation of a. pure tone average threshold, b. speech recognition threshold, and c. speech identification scores across three conditions for both groups of participants

The figure 10 reveals that there was difference across the condition 2 and condition 3 across both groups of participants for pure tone thresholds and speech recognition thresholds. Mann -Whitney Test was done for comparison between two groups of participants for pure tone thresholds, speech recognition thresholds and speech identification scores across the respective condition. Table 5 indicates the results of Mann -Whitney Test.

Table 6.

Results of Mann -Whitney Test comparing across two groups for pure tone average thresholds, speech recognition thresholds and speech identification scores.

<b>Parameters</b>	<b>Conditions</b>	<b>Z</b>	<b>p value</b>	<b>η</b>
Pure tone threshold	Condition 1	-1.301	0.193	-
	Condition 2	-3.145	0.002	0.63
	Condition 3	-3.933	0.000	0.79
Speech recognition thresholds	Condition 1	-1.231	0.219	-
	Condition 2	-2.969	0.003	0.59
	Condition 3	-3.536	0.000	0.70
Speech identification scores	Condition 1	-.745	0.456	-
	Condition 2	-1.309	0.191	-
	Condition 3	-2.013	0.044	0.40

The results of Table 6 reveals that there was no significant difference between two groups of participants in condition 1 for all the parameters where as there was significant difference between groups across respective conditions of 2 and 3 for the pure tone thresholds and speech recognition scores. And speech identification scores have significant difference only in condition 3 between groups. This reveals that the two different surgical treatments had significant difference in the performance related to hearing abilities. It can be inferred that the effect Type I tympanoplasty with canal widening procedure was significantly better compared to Type I tympanoplasty without canal widening procedure. Similarly Mann – Whitney test was done across all the air conduction thresholds, bone conduction thresholds and air bone gap between two groups and across respective conditions. The results reveal that the air conduction thresholds from 250 Hz to 8 kHz had significant difference ( $p < 0.05$ ) for condition 2 and 3 between the

groups. The improvement in hearing ability with respect to difference in threshold (dB) was studied. Table 7 reveals the improvement in hearing in pure tone thresholds after 1 and 3 months of type 1 tympanoplasty with and without canal widening procedure (two groups).

Table 7.

Mean improvement in hearing thresholds (dB) after 1 and 3 months of surgery across two groups.

<b>Surgery techniques (groups)</b>	<b>Pre-operative mean PTA (dB)</b>	<b>Post-operative (1 month) mean PTA (dB)</b>	<b>Mean difference Pre-post 1 month PTA (dB)</b>	<b>Post-operative (3 months) mean PTA (dB)</b>	<b>Mean difference Pre-post 3months PTA (dB)</b>
Group I	38.14	25.46	<b>12.68</b>	19.28	<b>18.86</b>
Group II	41.93	36.43	<b>5.5</b>	33.69	<b>8.24</b>

The results of Table 7 reveals that there is a improvement of 18.86 dB in group I participants who underwent type I tympanoplasty with canal widening procedure where as the group II participants who had undergone type I tympanoplasty without canal widening had an overall hearing improvement only by 8.24 dB. The different in improvement with respect to two different surgical procedures is by 10.62.

## DISCUSSION

Chronic otitis media [COM] is a major cause of acquired hearing impairment especially in developing countries. It also gives rise to various extra and intra cranial complications which can be fatal if untreated. Restoration of the sound conducting mechanism of the middle ear can be accomplished by a surgical technique. Tympanoplasty is a surgical technique defined as reconstruction of the hearing mechanism with reconstruction of tympanic membrane. The term Tympanoplasty was first used by Wullstien (1953). Tympanoplasty is considered to be a simple, easy to complete otologic surgery, with good success rate both anatomically and functionally. Canaloplasty is the surgical procedure whereby the external auditory meatus is widened. It is usually done in conjunction with the procedures employed for correction or eradication of primary disease in middle ear. It can also be done as a primary procedure in cases of anterior bony overhang or exostosis.

In our study, comparative analysis of anatomical and functional outcomes of Type I Tympanoplasty with canal widening (canalplasty) and Type I Tympanoplasty without canal widening were done. In the present study maximum number of cases was in the age of 21-30 years with a mean age of 27.4 years for group I participants and mean age of 26.6 years for group II participants. A study conducted by Ortegren (1963), reported that maximum number of patients were in the age group > 40 years. The reason behind this could be due to presence of newer diagnostic tools to diagnose the disease at the early stage and the awareness created among the public by health care professionals related to complications associated with chronic otitis media.

Various surgeons have used different kinds of grafts to repair tympanic membrane perforations. Most popular are autogenous grafts. Zollner (1954) and Frenckner (1955) used pedicle ear canal skin graft to close perforations. Shea (1960) introduced vein graft to close tympanic membrane perforations. It goes to the credit of Heermann (1960) for introducing Temporalis fascia as a grafting material in Tympanoplasty. The graft success rate depends on various factors such as the size and site of perforation, functioning of Eustachian tube, graft placement techniques, the experience of the operating surgeon etc. The present study also used Temporalis fascia graft along with underlay technique to close the perforations and could achieve good results both in terms of drum healing and postoperative hearing improvement.

Narrow external ear canals and small middle ear structure are known factors which lower the success of Tympanoplasty. In the present study, Type I Tympanoplasty with canal widening procedure (canaloplasty) for 25 patients, by removing the bony overhangs in the external canal wall creating complete visibility of the tympanic membrane and annulus was done. The shape of the external auditory canal following canaloplasty corresponds to an inverted truncated cone. Advantages of canaloplasty over Type 1 Tympanoplasty without canal widening procedure are as follows- (a) Better visualisation- this facilitates placement of graft particularly in the anterior anchoring of graft in subtotal perforation (b) Better exposure (c) Postoperative care easier- there will be no problems with the self cleansing mechanism of external auditory canal (d) Prevent lateralisation of tympanic membrane (e) Promotes healing earlier because of rich blood supply to the graft material (f) Time gain- The time spent for performing a canal widening procedure is compensated by the time gained by improved exposure during grafting of tympanic membrane. In the present study, at the end of 3rd post-operative month the graft success rate was 100% in Type I Tympanoplasty with canal widening procedure and 96% in Type I Tympanoplasty



without canal widening procedure. In the study by Mallick, Bhalla, and Roy (2016) showed 92% graft success rate in canalplasty technique and 84% in Type I Tympanoplasty without canal widening procedure. It has been reported that canaloplasty helps in better visualization and placement of the graft. Taneja (2013) reported an increase of graft uptake to 91.3% in cases when tympanoplasty was combined with canalplasty. According to prospective interventional study Vijayendra, Ittop, and Sangeetha (2008) which support the present study that, in cases when canalplasty is done, it increases the middle ear space and also enhances the vibrating mechanism of the tympanic membrane. This helps in preventing anterior blunting and gives better hearing results. The results compiled on 100 cases who underwent canaloplasty reveal that it gives 9 dB increase gain in hearing compared to without canalplasty. It is also concluded that canalplasty gives better visualization, better graft placement and better post-operative care thus fulfilling the need of giving dry ear and improved hearing.

Yu, Chen and Cheng (2011) investigated gain for 15 ears across 500 Hz to 4 KHz at different bends of ear canal. The results revealed that the gain in the ear canal is not only by the length of the external auditory canal but also by the interior shape. Hence the study concluded that more desirable outcomes are expected during canalplasty as it is related to the shape of the ear canal. This also supports our present study there is a difference in the gain between pre and post canaloplasty compared to tympanoplasty without canalplasty. The present study had two groups of participants. The results revealed there are improvement in both the groups; however the improvement was more for the group I participants who had undergone tympanoplasty with canal widening procedure. The group II participants also had shown a marked improvement in comparison to pre and post operative thresholds. Olusesi, Opaluwah, and Hassan (2011) had pre and post operative hearing scores on 201 patients who had undergone tympanoplasty. The

thresholds of air bone gap improved by 9dB for a mean of 4 frequencies which provides evidences for efficacy of tympanoplasty. But the present study provides evidences supporting the tympanoplasty with canal widening procedure to be more superior and efficiency than just tympanoplasty.

## **CONCLUSION**

The ultimate aim of tympanic membrane grafting technique is to have new reconstructed tympanic membrane with functions as close as possible to original tympanic membrane and to prevent complications. Thus, this present study confirms the efficacy of tympanoplasty with canalplasty for better visualization of the anterior sulcus of the external auditory canal and the outcomes of the audiometric thresholds for those who underwent tympanoplasty with canalplasty are superior, effective and efficient. This study also provides a better evidence for the clinical implementation of the tympanoplasty with canalplasty as a better surgical procedure for those with conductive hearing loss due to chronic otitis media for whom surgery is indicated.

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**APPENDIX A**

**ALL INDIA INSTITUTE OF SPEECH AND HEARING, MYSORE**

**ARF PROJECT 2015-16**

**DEPARTMENT OF ENT**

**“EFFECT OF CANAL WIDENING (TYPE 1 TYMPANOPLASTY) ON HEARING SENSITIVITY”**

**PROFORMA**

AIISH Case no.:

Name: Father's/Husband's name:

Age/Sex: Contact:

DOA: DOD:

DOO:

Address:

Duration of symptoms:

Diagnosis:

Pre-op Otological examination:

Right

Left

Pre-op Audiological evaluation:

<b>Ear</b>	<b>Hearing (dB)</b>	<b>Degree of hearing loss</b>	<b>Type of hearing loss</b>
Right			
Left			

Post-op Otological examination:

Right

Left

Post-op Audiological evaluation:

<b>Ear</b>	<b>Hearing (dB)</b>	<b>Hearing gain (dB)</b>
Right		
Left		

Follow up details: