"A COMPARATIVE STUDY OF THE RESULTS OF TYMPANOPLASTY WITH AND WITHOUT GEL FOAM"

By

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IN

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Under the Guidance of

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LIST OF ABBREVIATIONS

Abbreviations	Words
ENT	Ear, Nose, Throat
OPD	Outpatient Department
AOM	Acute Otitis Media
COM	Chronic Otitis Media
CSOM	Chronic Suppurative Otitis Media
TTD	Tubotympanic Disease
NCCOM	Non Cholesteatomatous Chronic Otitis Media
TM	Tympanic Membrane
ET	Eustachian Tube
EAC	External Auditory Canal
TFT	Tuning Fork Test
RN	Rinne's Test
WT	Weber's Test
ABC	Absolute Bone Conduction
PTA	Pure Tone Audiometry
AC	Air Conduction
BC	Bone Conduction
ABG	Air Bone Gap
TLWOM	Tympanoplasty Without Mastoidectomy
VAS	Visual Analogue Score

LIST OF ABBREVIATIONS

Abbreviations	Words
CHL	Conductive Hearing Loss
Hz	Hertz
i.v	Intravenous
UK	United Kingdom
USA	United States of America
dB	Decibel
HL	Hearing level
Optd	Operated
Rt	Right
Lt	Left
GA	General Anesthesia
LA	Local Anesthesia

ABSTRACT

NEED FOR STUDY

Absorbable gelatin sponge (Gelfoam) has been used for many years in middle ear surgeries. It is used routinely as a support structure in the middle ear cleft when ossicular reconstruction and tympanic membrane grafts are performed. It also helps to maintain the aeration of the middle ear and promote hemostasis. Although the gelfoam is generally well tolerated, fibrosis occasionally forms in the mesotympanum. Some of the studies indicated that absorbable gelatin sponge may be responsible for this fibrosis. However, there is currently a lack of standardization regarding the use of different types of packing agents. In fact, some have also advocated no packing.

This study was needed to compare the results of middle ear surgeries with and without gel foam so that an objective assessment of its outcome can be demonstrated with the help of pure tone audiometry results.

OBJECTIVE

This study was done to compare the outcome of tympanoplasty with and without use of gel foam.

STUDY DESIGN Prospective clinical study

MATERIALS AND METHODS

All patients undergoing tympanoplasty in the department of ENT, B.L.D.E.U'S Shri B. M. Patil Medical College Hospital & Research Centre from October 2012 to May 2014 were considered. Details of cases were recorded including history (subjective symptoms) and clinical examination with emphasis on detailed otoscopic examination preoperatively and postoperatively. All patients undergoing tympanoplasty were subjected to pure tone audiometry pre operatively, 6^{th} week, 12^{th} week and 6 months post operatively. Patients were randomly assigned to group A and group B. Group A consisted of patients who underwent tympanoplasty with gel foam and group B consisted of patients who underwent tympanoplasty without gel foam. Healing of the tympanic membrane was recorded postoperatively 6 weeks, 3 months and then 6 months later by otoscopic examination.

RESULTS

The analysis carried out revealed the following results:-

1. In the patients with using gelfoam, graft uptake rate was 89% for tympanoplasty. In patients without gelfoam, graft uptake rate was 84% at the end of six months.
2. The improvement in the subjective symptoms of ear discharge and hearing loss at 6 weeks following the surgery was 81% and 80% respectively with gel foam whereas, it was 92 % and 86 % respectively without gel foam. It improved further at the end of six months to 94% and 83% respectively in both the groups.
3. The improvement in hearing six months following tympanoplasty with gel foam as assessed by pure tone audiometry (ABG < 20dB) was 88%. Without gelfoam, it was 87 %.

CONCLUSION

In this study, the graft success rate was similar in the two groups. There is a significant improvement in the subjective symptoms of ear discharge and hearing loss following surgery almost equally in both the groups. The advantage of this technique (without gelfoam) is rapid improvement of patient's hearing after removal of the external ear canal wick which was noted six weeks after the surgery. But the results in both the groups were almost the same after six months. Hence, we conclude that the results of tympanoplasty in both the groups are the same in our study and further studies may be carried out over a longer duration to assess the long term success rate of tympanoplasty with and without the use of gelfoam.

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INTRODUCTION

Absorbable gelatin sponge (Gelfoam) has been used for many years in middle ear surgeries. Although the sponge is generally well tolerated, fibrosis occasionally forms in the mesotympanum; some studies indicated that absorbable gelatin sponge maybe responsible. A prospective study was conducted by Leining & Silberberg using three absorbable haemostatic agents in the middle ear of adult male Sprague-Dawley rats (middle and inner ear very similar to humans) to determine which promotes fibrosis to the greatest degree : absorbable gelatin sponge (gelfoam), absorbable gelatin film (gelfilm), or absorbable gelatin sheet (Instat- bovine dermal collagen). It was concluded that absorbable gelatin sponge promotes fibrosis more frequently than collagen-absorbable haemostat and absorbable gelatin film in this model.[1]

In a study by Hellstorm, gelfoam was gently inserted or firmly packed into the middle ear cavities of rats. The post-operative changes were evaluated two to three months later when, apart from some air-filled canals leading from the tympanal orifice of the eustachian tube towards the attic, the middle ear cavity had become filled with newly formed bone and an amorphous mass of adhesions and bridles. The mass consisted of loose connective tissue, with fibroblasts, vessels and inflammatory cells. The tympanic membrane was retracted and fixed to the promontory. There were no signs that any gelfoam had been removed through the eustachian tube. The authors proposed that similar tissue reactions may occur in tympanoplasties.[2]

A study was conducted by McGhee & Dornhoffer to look at the effects of implanting gelfoam independently and gelfoam & gelfilm concurrently in the bulla cavity of the Mongolian Gebril. The temporal bones were harvested and evaluated histologically

using haematoxylin and eosin staining for fibrosis. Results demonstrated a decrease in the amount of fibrosis in the animals in which gelfilm was used to protect the denuded mucosa. The results suggested that gelfoam can be used safely in the middle ear cleft to support ossicular prosthesis and tympanic membrane grafts when gelfilm is used to protect denuded mucosa.[3]

In an experimental histopathologic study conducted by Joseph RB, the effect of absorbable gelatin sponge on scar formation in the middle ear of dogs was studied. It showed the presence of gelfoam in an area denuded of mucosa produced a significant fibrosis. There was no benefit in using gelfoam soaked with hydrocortisone and antibiotics. Fibrosis was localised to denuded area on the promontory. Even though the gelfoam disappeared in two weeks, the gelfoam-induced fibrosis persisted (gelfoam as scaffold and granulation tissue formed).About three months later, mature connective tissue, dense fibrous tissue was formed.[4]

In an experimental study conducted by Hellstrom & Stenfors, absorbable gelatin sponge, commonly used in otosurgery, was mixed with high-molecular-weight and highly concentrated hyaluronic acid. The mixture was introduced into the middle ear cavities of rats. The postoperative changes were evaluated by morphologic techniques after two months and three months. The middle ear cavity contained a loose mass of connective tissue with few cells, forming sail-like bridles between air-filled spaces. The filling material was easily detached from the surroundings. The structure of the middle ear mucosa and the tympanic membrane were well preserved. Compared with the findings in a previous study, in which absorbable gelatin sponge alone was used, the

combination of gelatin sponge and hyaluronic acid caused significantly less structural alterations in the middle ear cavity.[5]

Middle ear packing agents are used in otologic surgery to provide support to the middle ear structures, maintain aeration of the middle ear, and promote haemostasis. However, there is currently a lack of standardization regarding the use of different types of packing agents. The choice of materials and how they are used remain controversial. In fact, some have recently advocated for no packing.[6]

OBJECTIVE

This study was done to compare the outcome of tympanoplasty with and without use of gel foam.

REVIEW OF LITERATURE

HISTORICAL REVIEW

1000 BC - The early Egyptian healers had a large number of perspectives available for treatment of the ear like the use of the herbs and other extracts. It is of note that ear was often attributed to brain disease and efforts directed accordingly.[7]

400 BC - One of the earliest physicians, Hippocrates, recognized that a painful, discharging ear with fever was a life threatening condition and described classic symptoms of otitis media. “Acute pain in the ear with continued, strong fever is to be dreaded, for there is danger that the man may become delirious and die.” Tools and techniques did not permit intervention or further work on chronic ear infection. Around the time Rafto described the tympanic membrane as a web like structure and as a part of the organ of hearing.

16th century - Surgery for mastoid infection was first proposed four centuries ago by Ambrose Pare on the young king Charles II of France who was dying with high fever and a discharging ear. The king’s bride, Mary, Queen of Scotland, agreed, but the king’s mother, Catherine de Medici, forbade the operation. The king died. This incident helped neither Pare’s reputation nor the fledgling specialty of otology. So another 100 years passed before the next recorded attempt at otologic intervention.

17th century - In 1640, Banzer published an account of a case of tympanic membrane repair. A pig’s bladder was stretched across an ivory tube and placed in the ear. This marks a trend in the repair of the drum, that of placing artificial membranes in the ear temporarily.

18th century - The first documented successful surgery for a mastoid infection was performed by Jean Petit of Paris. Shortly thereafter, in 1776, a Prussian surgeon named Jasser successfully performed a mastoid operation on a soldier with a draining ear. However, this new operation was discredited when Baron Berger, personal physician to the King of Denmark, persuaded a colleague to perform this procedure on Berger himself with a mistaken assumption that it would relieve his deafness and tinnitus. This operation led to sepsis and Berger's death, thus consigning the mastoid operation to obscurity for another century.

19th century - In 1853, Sir Oscar Wilde published a procedure for sepsis and suppuration of the ear. He described the post-auricular incision and removal of the mastoid cortex for purulent infections. This was the beginning of the modern era of otologic surgery. Nearly every operation that followed until today built upon this basic technique and expanded the indications and technique.

In 1873, Herman Schwartz published both indications and the procedure for removing the mastoid cortex and underlying air cells with mallet and chisel for acute mastoid infections. The art of using mallet and chisel persisted for another 75 years. In the pre-antibiotic era, simple mastoidectomy became the mainstay in the treatment of acute mastoiditis and saved many lives.

In 1877, Blake introduced the idea of placing a paper patch over the perforation, a practice that has stood the test of time. Roosa and Okneuff promoted healing of the drum by application of chemical cautery.

20th century - Surgeons were able to control disease with the techniques developed earlier. In the 1930s, antibiotics helped to achieve dry ears by treating infection. Then,

with the operating microscope, they became adept at examining the ear and developed instruments for manipulating the ear drum and the ossicles.[7]

House, Sheehy and Glasscock developed techniques for creating a satisfactory onlay graft. Shea while performing stapedectomy, during a surgical misadventure discovered that vein graft could be satisfactorily placed under the drum to repair a tear. Storrs switched to fascia and Patterson et al determined the reasons for the success of fascia as a grafting material, the popularity and techniques of tympanoplasty can be attributed to the success of many other surgeons who have refined other's techniques.

SURGICAL AND TECHNOLOGICAL DEVELOPMENTS

Management of the Infected Ear

In 1906, the first conservative surgical procedures were described by Heath and Bryant. These were modifications of radical mastoidectomy, preserving the tympanic membrane and ossicles. These were not widely accepted due to complications.

In 1910, Bondy described the classic modified radical mastoidectomy but this did not become popular until the 1940s when it was reintroduced by Day and Baron.

Antibiotics and Instrumentation

In the 1930s, medical therapy of the ear was becoming popular with the availability of sulfonamide antibiotics. Instrumentation facilitated further development. Dental drills were used for mastoid exenteration while cautery helped control haemorrhage.

Operating Microscope

Holmgren, a pioneer in fenestration Surgery for otoslerosis, was the first otologist to use the binocular operating microscope. Lempert used the optic loupe.[7]

CONCEPT OF TYMPANOPLASTY

In 1863, a landmark discovery of the workings of the middle ear was made by Hermann von Helmholtz. His description of the middle ear transformer mechanism was essentially ignored. It was not understood until 90 years later. This work formed the foundation for all reconstructive middle ear surgery.

The concept of tympanoplasty is credited to Berthold who in 1878 was thought to have performed the first true tympanoplasty. He de-epithelialised the tympanic membrane by applying a court plaster to the membrane for 3 days, then removing it with the epithelium. A skin graft was then applied. In 1914, tympanoplasty was reintroduced by Schulhof and Valdez. In 1952, the procedure was publicized and popularized by Wullstein using split thickness skin grafts.

Zollner began his work in 1952. The work of these two surgeons integrated all previous work and formed the basis for modern otologic practice. They recognized the principles introduced by Helmholtz stating “A new tympanic membrane and an adequate tympanic cavity with intact ossicles are necessary for the transformation of sound pressure upon the oval window as well as sound protection of the round window.” [7]

Concurrently, stapes surgery was being changed radically. Kessel and Miot are credited with the first series of stapes mobilization and Blake and Jack with the first stapedectomies. Rosen reintroduced stapes mobilization in 1952 and in 1956; Shea

performed the first modern stapedectomy with replacement by prosthesis. The stability of the Zeiss operating microscope spurred further advances in middle ear surgery.

The main goals of surgery include eradication of the disease, prevention of recurrence and preservation or improvement of hearing. Tympanoplasty is the surgical modality that helps achieve the above mentioned goals. In the past, most workers described success of tympanoplasty in terms of hearing improvement only when in fact elimination of infection and preservation or restoration of anatomy is also of equal importance. Therefore in the present era the results of tympanoplasty need to be reassessed keeping in mind all the above mentioned factors. The modern era of tympanoplasty was ushered in by Wullstein and Zollner. Wullstein classified the operations as types I to V, based on the concepts of sound transformation at the oval window and sound protection of the round window.[8,9] Subsequently, many otologic surgeons contributed to the development and refinement of tympanoplasty techniques.

Tympanomastoid surgery is quite successful in controlling infection and preventing recurrent disease, with reported success rate in excess of 80 – 90%.[10] However, it is well recognized that post operative hearing results are often unsatisfactory, especially in cases with advanced lesions of the ossicular chain or those with non-aeration of the middle ear. For example, when the ossicular chain has to be reconstructed, long term closure of the air bone gap to < 20 dB occurs in 40 – 70% of cases when the stapes is intact, and in only 20 – 55% when the stapes superstructure is missing.[11]Tympanoplasty is the final step in the surgical conquest of conductive hearing losses and is the culmination of over 100 years of development of surgical procedures on the middle ear to improve hearing. [12] This surgery is unique when compared to surgery

elsewhere in the body because of the constraints imposed by a combination of factors, including the pathology of COM, the vagaries of wound healing and the need for a functioning tympano-ossicular system.

Current techniques of tympanoplasty have generally evolved empirically as a result of trial and error. Otologic surgeons have a good general appreciation of various anatomical and pathological reasons for failure of tympanoplasty, such as non-aeration of the middle ear, abnormalities of the reconstructed TM and inefficient sound transmission via the reconstructed ossicular chain. However, a quantitative understanding of the acoustical consequences of structural variations of a reconstructed ear is generally lacking. Clinical observations indicate that in many instances the anatomical differences between a good and poor hearing result are seemingly minor. For example, Liston et al.[13] used intra-operative auditory evoked responses during ossiculoplasty and found that minor changes in prosthesis positioning in the order of 0.5–1.0 mm had relatively large effects on hearing (varying up to 20 dB). It is also a common clinical observation that postsurgical ears that seem almost identical in structure may demonstrate markedly differing degrees of conductive hearing loss. In other words, small changes in structure have the capacity to have large effects on function. This is also important because small changes in graft and prosthesis position can occur as part of the healing process, which is beyond the control of the otologic surgeon.

Otologists routinely place TM and ossicular grafts in a recipient middle ear milieu that is hostile as a result of active or arrested inflammatory disease. TM grafts have to be in contact with air over a relatively large portion of their surface areas and must derive nourishment and blood supply from small parts of the graft in contact with

the canal wall. Ossicular grafts and prosthesis must couple well at their ends to bone or soft tissue, but must remain suspended in air elsewhere in order to transmit sound effectively. Additionally, ossicular implants are subject to resorption from persistent or recurrent infection and extrusion from negative pressure and tubal insufficiency. In the case of homograft and synthetic prosthesis, they are also potentially subject to immune-mediated rejection.

Functional success after tympanoplasty surgery is only partly determined by the surgeon's technical skill. Other factors can also play a significant role, such as the ability of the middle ear mucosa to heal appropriately and the ability of the ear to aerate itself at normal static pressure. The latter can change over the course of months or years, which in turn can significantly affect the acoustic transmission properties of the reconstructed ear. It is interesting to note that the few studies in the literature that assess long-term hearing results show a progressive and systematic decline in initial hearing gain as a function of time. For example, Colletti et al.[11] in a study of 832 ossiculoplasty procedures found that 77% of ears had an air-bone gap of 20 dB at 6 months, but the same figure decreased to 42% at 5 years. Some of the factors pertinent to the biology and pathology of middle ear disease after tympanoplasty surgery are reviewed below. An understanding of these factors can provide insight into some of the reasons for failure of tympanoplasty and poses challenges for future research.

Biology and pathology of middle ear grafts and implants

Repair of TM perforations can be successfully achieved using a variety of grafts. Autologous tissue such as temporalis fascia, perichondrium and fat is widely used. Rates

of successful closure of perforations are uniformly high and are generally in excess of 90%. However, a small number of these grafts show undesirable pathological changes, such as proliferation of fibrous tissue and thickening, resorption and excessive thinning, and lack of epithelialization with resulting discharge. The factor or factors controlling such responses are not well understood. A wide variety of autograft, homograft and synthetic ossicular grafts and prosthesis have been employed for reconstructing the ossicular chain. Autogenous ossicle grafts probably constitute the best material available at present, since they maintain their morphological size, shape and contour for many years and they do not incite formation of new bone nor do they undergo resorption. They undergo slow replacement of non-viable bone by new bone formation through a process of "creeping substitution".[14] Autogenous cortical bone grafts and homograft ossicles behave similarly and can be utilized if autogenous ossicles are not available. Grafts made of cartilage often develop chondromalacia with loss of stiffness and a tendency to become resorbed. Hence, cartilage grafts are not optimal for ossicular reconstruction, although they are probably adequate as a buffer between the prosthesis and the TM.

A number of pathological mucosal changes can occur within the middle ear as a healing response to COM or as a sequel to surgical trauma. The changes include deposition of fibrous tissue, formation of adhesions and tympanosclerotic plaques, occurrence of cholesterol granulomas and neo-osteogenesis. These tissue responses can compromise the mechanics of the reconstructed TM and ossicles in a variety of ways: fixation of the stapes footplate, ankylosis or displacement of an ossicle strut, immobilization of the round window, immobilization of the TM, as well as more subtle interference with the mechanics of the TM or ossicles. Proliferation of fibrous tissue and

the formation of adhesions are significant problems that are more prone to occur when the middle ear mucosa is diseased, removed or traumatized. Many different materials have been placed in the middle ear in an attempt to prevent formation of adhesions and fibrous tissue. These materials include absorbable gelatin sponge (gelfoam), hyaluronic acid, silastic and teflon.

Gelfoam elicits a host inflammatory response leading to its resorption[2] in some cases, this inflammatory response results in adhesions, especially when the middle ear mucosa is deficient. Further, gelfoam is resorbed within two weeks, which is probably insufficient time for mucosal regeneration to occur. Hyaluronic acid is somewhat more difficult to handle than gelfoam[15] and is also absorbed before mucosal regeneration is likely to be completed. None of the currently available spacer materials is ideal. An ideal material will remain in place for several weeks to allow sufficient time for mucosal regeneration and will then undergo degradation and resorption so that the ear can become aerated without fibrosis.

GELFOAM AND MIDDLE EAR SURGERY

Gelfoam is a medical device intended for application to bleeding surfaces as a hemostatic. It is a water- insoluble, off- white, non- elastic, porous, pliable product prepared from purified pork skin, gelatin granules and water, for injection and is able to absorb and hold within its interstices, many times its weight of blood and other fluids. Gelfoam sterile powder is a fine, dry, heat-sterilized light powder prepared by milling absorbable gelatin sponge.

Gelfoam has hemostatic properties. While its mode of action is not fully understood, its effect appears to be more physical than the result of altering the blood clotting mechanism. When not used in excessive amounts, it is absorbed completely, with little tissue reaction. This absorption is dependent on several factors, including the amount used, degree of saturation with blood or other fluids, and the site of use. When placed in soft tissues, it is usually absorbed completely in from four to six weeks, without inducing excessive scar tissue. When applied to bleeding- nasal, rectal or vaginal mucosa, it liquefies within two to five days.

INDICATIONS : - Gelfoam sterile powder, saturated with sterile sodium chloride solution, is indicated in surgical procedures, including those involving cancellous bone bleeding, as a hemostatic device, when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is either ineffective or impractical. Although not necessary, gelfoam can be used either with or without thrombin to obtain hemostasis.

DIRECTIONS FOR USE : - Gelfoam sterile powder can be saturated with sterile, isotonic sodium chloride solution (sterile saline), before use as an adjunct to hemostasis. The envelope of gelfoam sterile powder should be opened and the contents (1 gram) poured carefully into a sterile beaker, avoiding contamination. Using sterile technique, putty like paste is prepared by adding a total of approximately 3- 4 ml of sterile saline to the gelfoam. Dispersion of the powder can be avoided by initially compressing it with the gloved fingers into the bottom of the beaker and then kneading it into the desired consistency. The resulting doughy paste may be smeared or pressed against the bleeding surface to control bleeding; when bleeding stops the excess should be removed.

Only the minimum amount of gelfoam, necessary to produce hemostasis should be used. It may be left in place at the bleeding site, when necessary; since gelfoam causes more cellular reaction than the blood clot, the wound may be closed over it. It may be left in place when applied to mucosal surfaces until it liquefies.

CONTRAINDICATIONS: - Gelfoam should not be used in closure of skin incisions because it may interfere with healing of the skin edges. This is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing. It should not be placed in intravascular compartments, because of the risk of embolization.

To prevent contamination, we should employ aseptic procedure in opening envelope and withdrawing gelfoam. If the envelope is torn or punctured, the contained gelfoam should not be used. Only the minimum amount of gelfoam necessary to achieve hemostasis should be used. Once hemostasis is attained, excess gelfoam should be carefully removed.

The use of gelfoam is not recommended in the presence of infection. It should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where gelfoam has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage. Although the safety and efficacy of the combined use of gelfoam with other agents such as topical thrombin has not been evaluated in pharmacia-controlled clinical trials, if in the physician’s judgment concurrent use of topical thrombin is medically advisable, the product literature for that agent should be consulted for complete prescribing information.

While packing a cavity for hemostasis is sometimes surgically indicated, gelfoam should not be used in this manner unless excess product not needed to maintain hemostasis is removed. Whenever possible, it should be removed after use in laminectomy procedures and from foramina in bone, once hemostasis is achieved. This is because gelfoam may swell on absorbing fluids, and produce nerve damage by pressure within confined bony spaces. The packing of gelfoam, particularly within bony cavities, should be avoided, since swelling may interfere with normal function and/or possibly result in compression necrosis of surrounding tissues.

Microfibrillar collagen has been reported to reduce the strength of methyl methacrylate adhesives used to attach prosthetic devices to bone surfaces. As a precaution, it should not be used in conjunction with such adhesives. Gelfoam is not recommended for the primary treatment of coagulation disorders. It is not recommended that gelfoam be saturated with an antibiotic solution or dusted with antibiotic powder.

ADVERSE REACTIONS: - There have been reports of fever associated with the use of gelfoam, without demonstrable infection. Gelfoam may serve as a nidus for infection and abscess formation,[16] and has been reported to potentiate bacterial growth. Giant-cell granuloma has been reported at the implantation site of absorbable gelatin product in the brain,[17] as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.[18]Foreign body reactions, “encapsulation” of fluid and hematoma have also been reported.

Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin products were used in severed tendon repair. Toxic shock syndrome has been reported in association with the use of gelfoam in nasal surgery. Fevers, failure

of absorption and hearing loss have been reported in association with the use of gelfoam during tympanoplasty.

The normal middle ear air space contains a mixture of gases whose concentration is somewhat different from that of room air.[19] Also, in the normal ear; the static pressure of the middle ear gas mixture is the same as that of the surrounding atmosphere. Common reasons for failure of tympanoplasty are total or partial non-aeration of the middle ear and development of negative static pressure. Total non-aeration of the middle ear is due to eustachian tube dysfunction and can lead to severe TM atelectasis, middle-ear effusion, and fibrocystic sclerosis of the middle ear or a combination of these changes. In some patients, the problem is selective non-aeration of the posterior mesotympanum due to deposition of fibrous tissue, while the anterior mesotympanum and protympanum remain well aerated.[20] Many postoperative ears exhibit a tendency to develop negative static pressure in the middle ear. Over the long term, this negative pressure leads to retraction and atelectasis of the reconstructed TM and functional compromise, as well as a predisposition to displacement or extrusion of ossicular prosthesis. Our present knowledge of normal eustachian tube function and dysfunction is inadequate, and elucidation of its pathophysiology is central to a clinical understanding of COM and to the success of tympanoplasty. There exists no reliable method to preoperatively predict tubal function after tympanoplasty surgery. There is also a debate as to whether eustachian tube malfunction is indeed the predominant cause for COM and for poor aeration of the middle ear after tympanoplasty. Many indigenous methods have been proposed and tried to prevent or treat non-aeration. However, these approaches have also failed to produce lasting benefit.

Another reason for failure of tympanoplasty is recurrent infection, which can lead to re-perforation of the TM and osteitis with resorption of the reconstructed ossicles. In general, this problem is infrequent, since tympanomastoid surgery for COM has a relatively good 80–90% success rate in controlling infections.[21] Recurrent infection poses a greater problem in the subgroup of patients with active COM with granulation tissue but without cholesteatoma, when compared to COM with cholesteatoma.[22] The hypothesis that has been forwarded is that this subset of cases of COM with granulation tissue may be the result of an inherent problem in the mucous membrane and hence more difficult to eradicate by surgical means.

The effectiveness of tympanoplasty also depends on patient selection and the timing of surgery (except for patients who need emergency surgery for intracranial or extracranial complications of COM). This is particularly critical when performing tympanoplasty in children with COM in whom the procedure is technically more demanding and the results less consistently good, compared with adults. Conclusive evidence is lacking, however a meta-analysis of 30 studies on pediatric tympanoplasty, for example, found that only advancing age correlated with higher rates of graft uptake. Surgical technique, prior adenoidectomy, presence of active infection, size of perforation, status of the contralateral ear and eustachian tube function may or may not predict better healing.[23,24] When the disease is less severe, even young age may not be a risk factor. In 116 children who underwent tympanoplasty for non-cholesteatomatous COM and who were followed up for 16 to 27 years, the results were the same in ears operated on at the ages of 2.5 to 7 years and 8 to 14 years. In total, 14% of ears were revised during the entire observation period.[25]

After tympanoplasty, the success of surgery is evaluated in terms of graft uptake and hearing improvement. Hearing improvements after tympanoplasty are assessed by PTA. Conventionally; the commonly used criteria for hearing improvement are closure of air bone gap or the improvement in Air Conduction threshold. The PTA test done within seven days prior to the operation is accepted. The test is performed through Air Conduction and Bone Conduction mode. The Air Conduction threshold and the Bone Conduction threshold averages were calculated by taking the averages of 500, 1000 and 2000 Hz frequencies. Regarding the conventional methods for the assessment of hearing, the AB gap closure and the AC threshold improvements are assessed. The cut off for the assessment of AB gap closure is taken as 20 dB. Patients with the postoperative AB gap closure within 20 dB are taken as having hearing improvement postoperatively.[26]

The AC threshold improvement is the other conventional method used and 30 dB is taken as the cutoff limit. The postoperative AC threshold improvement of 30 dB is taken as to give significant hearing improvement. It is found in studies that the assessment of pure tone threshold after tympanoplasty and the results do not necessarily reflect the hearing condition from the patient's perspective. Thus, it is essential to study the relationship between the subjective evaluation of post-operative hearing based on the patient's own assessment and the objective assessment by audiometry. The assessment based on PTA does not always reflect the satisfaction of patients who have been operated upon. Hence the general satisfaction after tympanoplasty is determined using Visual analogue score. It was found that the Visual analogue score (VAS) was a useful method to evaluate the degree of satisfaction of patients after surgery.[27] A bi-directional approach, one from an audiological (objective) and one from the patient's perspective

(subjective), especially using VAS, is quite useful for the post-operative assessment of hearing. [27, 28]

The role of the prognostic factors and middle ear risk index on the success of tympanoplasty has been studied.[29] Prognostic factors such as age, sex, presence of systemic diseases, location and size of perforation, duration of dry period, presence of myringosclerosis, presence of septal and conchal pathology, operation type, status of the opposite ear and middle ear risk index were investigated. The overall success rate was 74.4% and size of the perforation(<50%), healthy opposite ear, absence of myringosclerosis, more than three months dry period and low middle ear risk index were found to be significant independent prognostic factors.

Many aspects of tympanoplasty, including physiologic principles and existing philosophy regarding the treatment of chronic otitis media were studied. The various techniques of tympanoplasty that are currently used and indications for each technique have been specified in the study. Hearing results after 388 tympanoplasty procedures in which the middle ear was judged as being aerated postoperatively is presented. The best hearing results occurred after type I tympanoplasty. An intact stapes was a positive prognostic indicator when the ossicular chain had to be reconstructed.[30]

The conductive hearing loss resulting from a tympanic membrane perforation is frequency-dependent, with the largest losses occurring at the lowest sound frequencies; increases as size of the perforation increases; varies inversely with volume of the middle-ear and mastoid air space (losses are larger in ears with small volumes); and does not vary appreciably with location of the perforation. Effects of location, if any, are small.[31] Although tympanic membrane perforations are common, there have been few systematic

studies of the structural features determining the magnitude of the resulting conductive hearing loss. Recent experimental and model studies predicted that the conductive hearing loss will increase with increasing perforation size, be independent of perforation location (contarary to popular otologic belief), and increase with decreasing size of the middle ear and mastoid air space (an idea new to otology).

Tympanoplasty usually improves tonal thresholds [32, 33] and the favorable tinnitus results are very likely a consequence of this improvement, since the proper vibration of middle ear fluids re-establishes both afferent and efferent stimuli.[34] This is the classical example of the probable association between hearing improvement and tinnitus improvement that may also be seen in the clinical practice in the postoperative period of patients with middle ear effusion, ossicular chain fixation or disruption; or external acoustic meatus stenosis.[34] Patients with tinnitus and hearing loss are excellent candidates for tympanoplasty in order to control tinnitus by hearing improvement.

Theoretical risk of iatrogenic sensorineural hearing loss during surgery has induced a reluctance to perform bilateral myringoplasty/tympanoplasty type I among some otosurgeons. But bilateral myringoplasty is safe, with good results, reduces costs, and leaves the patient satisfied. The hearing impairment during postoperative ear canal packing is surprisingly modest and readily acceptable by the patients. Hearing improved significantly, and the air-bone gap was significantly reduced. The air-bone gap was closed to within 10 dB in 92% and within 20 dB in 100% of the ears.[35]

The prognostic value of pathologic and technical variables influencing the functional outcome of tympanoplasty has been studied. The status of the mucosal lining, the mastoidectomy, the availability of the malleus handle and the tympanic membrane

perforation were all significantly predictive of the hearing outcome but with differing weight according to the pathologic condition. Anatomic and technical factors diversely affect the functional outcome of tympanoplasty. A better knowledge of their predictive roles and weights may be useful in both the surgeon's judgment and in the information given to the patient.[36]

To investigate the outcome of tympanoplasty in the elderly (patients older than 60 years) compared with younger patients there have been studies conducted. Compared with results from younger patients, there was no particular disadvantage in postoperative hearing results and complications in the elderly, although preoperative bone conduction thresholds were gradually worsened with age. There is no contraindication for tympanoplasty in older patients if their physical status is the same or better than what is normal for their chronological age.[37]

The impairment of all the middle ear pressure-regulation functions was likely to cause poor outcome of tympanoplasty and it was reconfirmed that ears with mechanically obstructed ETs were a contraindication for tympanoplasty. Therefore, assessment of mastoid condition is important as well as that of the ET function before tympanoplasty.[38]

Merchant et al in their study evaluated the effects of smoking on surgical outcome and hearing results in tympanoplasty by serum cotinine analysis as an objective method. While the graft take rate in the non-smoking group was 76.8%, it was 52.4% in the smoking group and this difference was statistically significant ($p = 0.037$). While mean graft take rate in the temporalis fascia group was 25% for smokers, mean graft take rate in cartilage shield tympanoplasty group it was 88.9%, and for smokers it was 52.4%.Cotinine is a major metabolite of nicotine and is a reliable marker to differentiate

smoking patients from non-smokers. Smoking status was found as a significant prognostic factor influencing the success rate of tympanoplasty negatively and the influence of a more stable grafting technique was demonstrated on smoking patients undergoing tympanoplasty procedure.[39]

A CSOM with a very little discharge can often be treated with tympanoplasty without mastoidectomy.[40] However; there are studies that give evidence to broaden the indications to include all cases irrespective of the amount of discharge. Controversies have also continued regarding the effect of secretion on the graft success rate. Although Fisch[41] and Gibb and Chang [42] recommended that the ear be dry at the operation time, there are other authors[43, 44] who could not support this view. The effect of secretion at the time of operation on hearing results is not as clear as it is on graft success rate. Schmid et al.[45] stated that having a dry ear is a precondition to obtain an air-bone gap within 10 dB in incus transposition for non-cholesteatomatous COM. Nonetheless, Halik and Smyth,[44] who analyzed patients who had only tympanic membrane repair, found that secretion at the time of surgery had no adverse effect on hearing results. However the functional hearing results of wet and dry ears did not show a statistically significant difference.

Mastoidectomy was not necessary for successful repair of simple tympanic membrane perforations. However, mastoidectomy impacted the clinical course in patients by reducing the number of patients requiring future procedures and by decreasing disease progression. This suggests that even in the absence of active evidence of infection, mastoidectomy improved the underlying disease process. Combining mastoidectomy with tympanoplasty during repair of simple perforations in patients with no active evidence of infection remains an appropriate option and may be valuable in reducing the

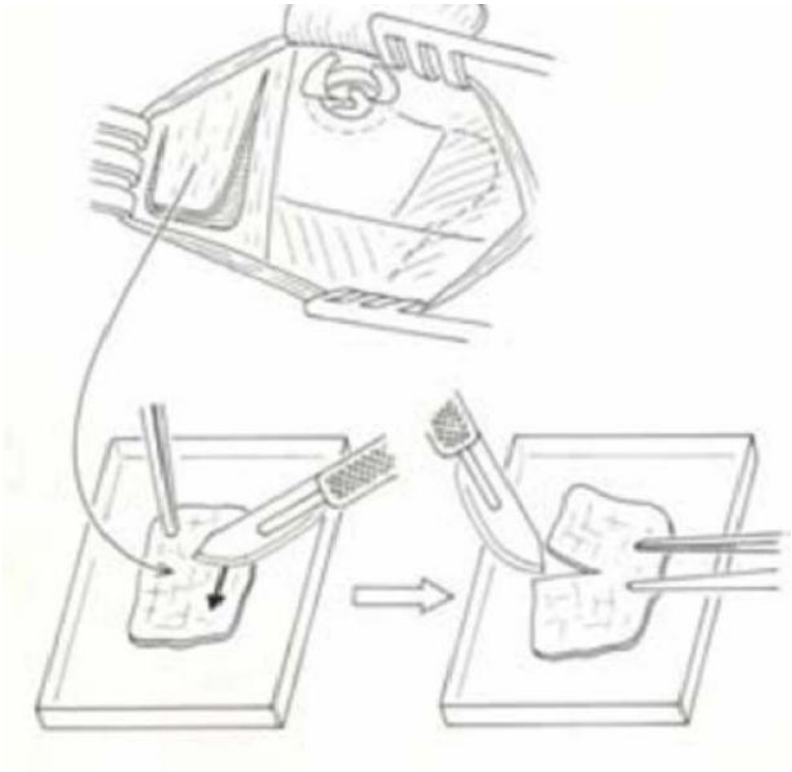
need for future surgery[46] for patients with non-cholesteatomatous COM who have failed prior tympanoplastic reconstruction, an aerating mastoidectomy may be indicated and may improve the success rate of the surgery.

There are no definitive guidelines on the indications for mastoidectomy with tympanoplasty. Fatih R. Balyan et al[47] carried out a retrospective analysis of 323 patients who underwent surgery for non-cholesteatomatous chronic otitis media in the Gruppo Otologica, Piacenza, Italy, between April 1983 and December 1993. Cases were separated into three groups according to different surgical treatment modalities and conditions of the ears at the time of operation. Group I (n = 53) consisted of cases of CSOM treated by tympanoplasty without mastoidectomy (TLWOM). Group II (n = 28) included cases of CSOM treated by tympanoplasty with mastoidectomy (TLWM). Group III (n = 242) included patients whose ears were dry at the time of surgery but who had had previous recurrent episodes of suppuration and who were treated by TLWOM. This study gives evidence that mastoidectomy performed in non-cholesteatomatous CSOM does not give a better chance for graft success rate and functional hearing results, but it adds extra effort and risk. They found that drainage from an ear affects neither perforation closure nor hearing results. Although TLWM is still the preferred line of treatment by many surgeons for non-cholesteatomatous CSOM, their results could not support this view and showed that it can be treated successfully without mastoidectomy.

PROTOCOL FOR SURGERY

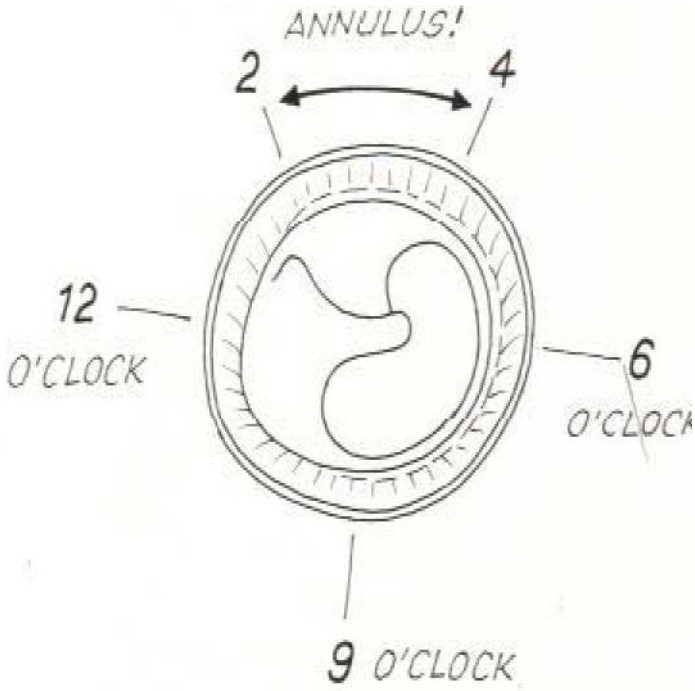
The surgery was done under local anesthesia with sedation. All patients were given premedication which included inj. fortwin 30 mg, inj. midazolam 2 mg, inj. ondensetron 4 mg and inj. glycopyrrolate 0.2 mg i.v. prior to the procedure 2% lignocaine with one in one lakh adrenaline was injected into the incision site and in the canal. Post – auricular William Wilde's incision was taken in all the patients and hemostasis ensured. The material used for the graft was the autologous temporalis fascia and this was common to all the patients. The temporalis fascia graft was harvested and kept to dry.

Figure No 1 : **Removing and preparing the temporal fascia graft**



After this meatotomy was done and mastoid retractors placed. The surgery was done using the operating microscope. The perforation was visualized and the margins of the perforation freshened. The incision was taken from 6 o' clock to 12 o' clock; tympanomeatal flap was elevated and the middle ear entered after raising the annulus. The middle ear mucosa was inspected, the ossicles seen and its mobility confirmed. The graft was then placed by underlay technique and dry gel foam was used in the middle ear to help stabilize the graft position in group A patients. In group B patients, no gelfoam was placed in the middle ear. In such patients, anterior window was created after meatotomy and wide base meatal flap is elevated. The window creation was done by taking an incision anteriorly from 2 o'clock to 4 o' clock; adjacent to the annulus; and the meatal skin along with the annulus is elevated. The temporalis fascia graft was anchored over the bone of the posterior canal wall directly and over the anterior sulcus in such cases. On confirming the position of the graft and adequate hemostasis the external auditory canal was packed with gel foam. A gauze piece with soframycin was then placed in the external auditory canal. The incision was then closed in layers after hemostasis was achieved and mastoid dressing was applied.

Figure No 2 : **Anterior window creation**



In the post-operative period the patient was monitored and facial nerve status assessed and recorded before the patient was shifted to the ward. Intravenous antibiotics were continued postoperatively on the day of surgery and patients evaluated for likely post operative complications. The patients after removal of the mastoid dressing were discharged on the day after surgery with instructions to continue the prescribed medications; antibiotics and decongestants. The suture removal was done on the 7th post operative day and external auditory canal pack removed on the 21st day after surgery. The post operative assessments of the patients were done at 3 weeks, 6 weeks and 6 months after the surgery.

The post operative assessment included the evaluation of the symptoms on the basis of self assessment scale and also the complete clinical examination.

(i) Oto- microscopic examination: Perforation - Healed or Persistent

(ii) Pure tone audiometry : Improvement in hearing

The data collected was subjected to appropriate statistical analysis.

PLAN FOR DATA ANALYSIS

Data analysis was done on the basis of objectives of the study.

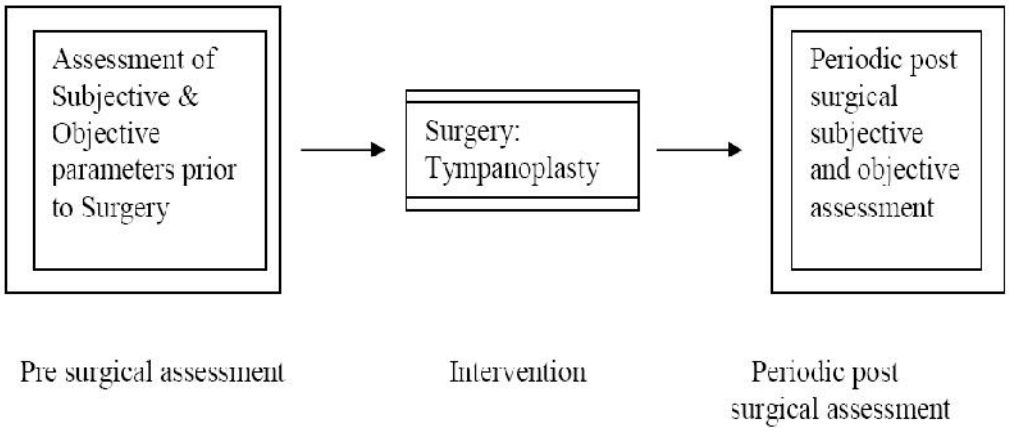
a) The subjective symptoms, pre operative and post operative at 6 weeks, 12 weeks and 6 months were analyzed for both the groups using t – test.
b) The otoscopic findings, pre operative and post operative were analyzed for both the groups using Chi square test.
c) The hearing assessment pre operative and post operative at 6 weeks, 12 weeks and 6 months were analyzed for both the groups using the t – test.

METHODOLOGY

It includes:

1. Research design
2. Setting of the study
3. Variables
4. Population
5. Sample size
6. Sampling technique
7. Criteria for selection of sample
8. Technique and tools
9. Plan for data analysis

RESEARCH DESIGN



SETTING OF THE STUDY

The study was conducted in The ENT Department of BLDE University's Shri B. M. Patil Medical College Hospital and Research Centre, Bijapur, Karnataka. This institution is a multi-specialty hospital. The study was conducted during the period October 2012 to May 2014.

VARIABLES

Dependent : (i) Clinical symptoms

(ii) Oto - microscopic findings

(iii) Pure tone audiometry

Independent : Surgery – Tympanoplasty

POPULATION

The population comprised of all the patients undergoing tympanoplasty in BLDE University's Shri B. M. Patil Medical College Hospital and Research Centre between October 2012 and May 2014.

SAMPLE SIZE

Time period of study: October 2012 to May 2014 (20 months)

Use of Gelfoam is documented in 95 % of middle ear surgeries.[48]

Formula used to calculate sample size is

$$n = [(1.96)^2 x\ p\ x\ q]/\ L^2$$

Allowable error is considered as 5 %.

Using above formula, minimum sample size is: 72.

SAMPLING TECHNIQUE

The technique used was non-probability convenience method of sampling (Random sampling).

CRITERIA FOR SELECTION OF SAMPLE

Inclusion Criteria

All patients undergoing tympanoplasty in BLDE University's Shri B. M. Patil Medical College Hospital and Research Centre between October 2012 and May 2014.

Exclusion Criteria

- Patients with unhealthy middle ear mucosa i.e. polypoidal, edematous, tympanosclerosis.
- Patients with cholesteatoma, ossicular discontinuity.
- Patients undergoing radical mastoidectomy, modified radical mastoidectomy, stapedectomy.
- Patients with anemia, diabetes mellitus, retroviral disease, renal disease, jaundice.
- Patients with history of intake of drugs like immunosuppresants.
- Patients who fail to follow up after surgery.

TECHNIQUES AND TOOL

Patients who satisfied the criteria of selection were taken as subjects of the study.

The data of the patient was collected in a case proforma as per Annexure (iv).

All the patients were subjected to: -

(A) History: A brief history of the symptoms of chronic otitis media was taken and each symptom was analyzed on the self assessment scale of 0 to 3.

Subjective parameters included:

Symptoms	SELF ASSESSMENT SCALE			
	0	1	2	3
Ear discharge	No discharge	Scanty	Intermittent	Profuse
Hearing loss	No hearing loss	Inability to hear whisper	Inability to hear conversational voices	Inability to hear loud sounds
Tinnitus	No tinnitus	Intermittent	Persistent	Persistent & Disabling

(B)	Clinical examination :	(i)	Otological examination & Oto-microscopy
		(ii)	Tuning fork tests
		(iii)	Pure tone audiometry

Patients included in the study were assessed for each of the above parameters and they were recorded prior to surgery.

Otological examination & Otoscopy

a. Size of the perforation

   1. Small (< 25% of pars tensa)
   2. Medium (25- 50% of pars tensa)
   3. Large (> 50% of pars tensa)
   4. Subtotal

b. Location of perforation

1. Anterior
2. Posterior
3. Both

c. Status of opposite ear

1. Normal
2. Old healed perforation
3. Perforation

d. Tuning fork tests:

1. Rinne's test
    - Positive
    - Negative
2. Weber test
    - Central
    - Lateralized
3. Absolute bone conduction
    - Normal as compared to that of the examiner
    - Reduced as compared to that of the examiner

e. Pure tone audiometry

1. Air conduction Threshold
2. Bone conduction Threshold
3. Air bone gap

The patients were counseled and need for surgery was explained in the language best understood by them. The patients willing for surgery were investigated and were given the date for surgery if the investigations were normal. On admission, they were subjected to pre-anesthetic check-up and posted for surgery on having acquired fitness.

(C) Surgery: Tympanoplasty

All patients for surgery were admitted one day prior to surgery. They were examined on the morning and findings confirmed. In case of an active discharge from the ear or an upper respiratory tract infection the surgery was postponed. If there was nothing untoward then patients were advised to get their hairs shaved one inch above and behind the pinna of the ear to be operated and all were given pre operative antibiotic intravenously on the morning of surgery after test dose. In the patients allergic to penicillin group of antibiotics, the appropriate alternative was given.

RESULTS

METHOD OF STATISTICAL ANALYSIS

Statistical analysis was done by using the following methods: -

a) Comparison of the subjective symptoms before and after surgery was done in both the groups using the t- test.
b) Comparison of the hearing results (Air-Bone Gap in PTA) before and after the surgery was done in both the groups using the t – test.
c) Comparison of the otoscopic findings was done in both the groups using Chi – square test.

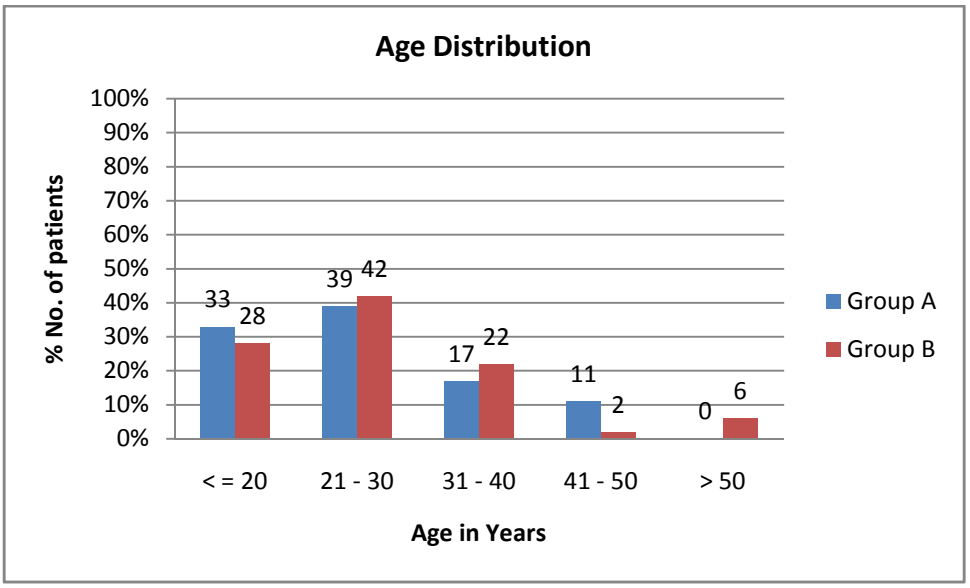
SPSS 16.0 was used to perform the statistical tests.

AGE DISTRIBUTION

Table No 1

Age	**Group A**	Group B
< = 20	12 (33 %)	10 (28 %)
21 - 30	14 (39%)	15 (42 %)
31 - 40	6 (17%)	8 (22 %)
41 - 50	4 (11 %)	1 (2 %)
> 50	0	2 (6 %)

Figure No 3



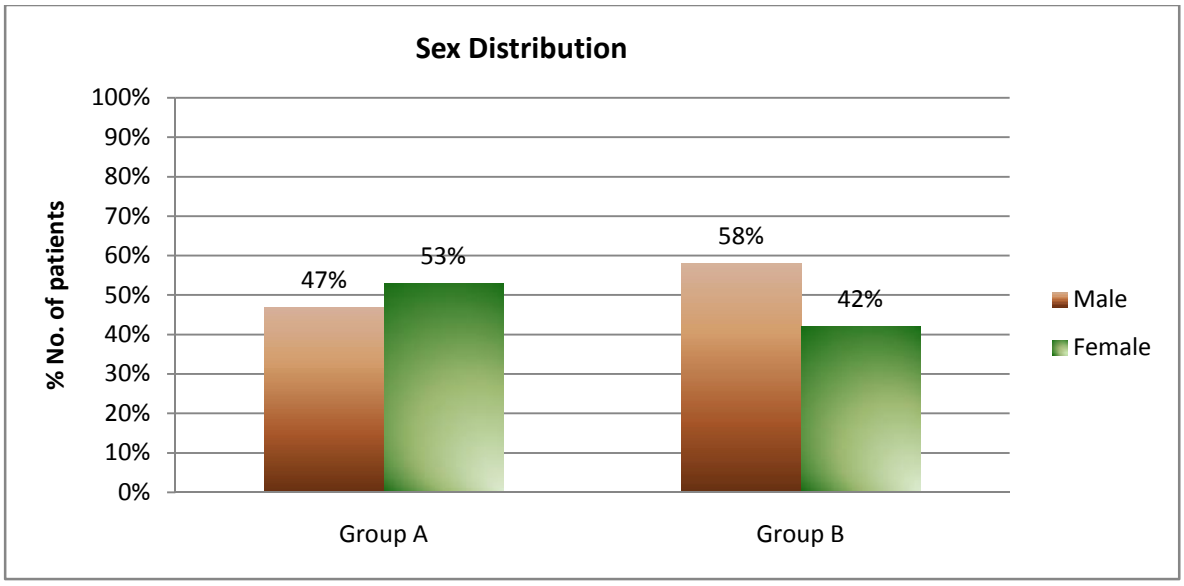
Out of 72 patients selected for this study, 36 were in Group A (With gel foam) and 36 in Group B (Without gel foam). The mean age was 26 years in group A and 28 years in group B.

SEX DISTRIBUTION

Table No. 2

Gender	Group A	Group B
Male	17 (47 %)	21 (58 %)
Female	19 (53 %)	15 (42 %)

Figure No. 4



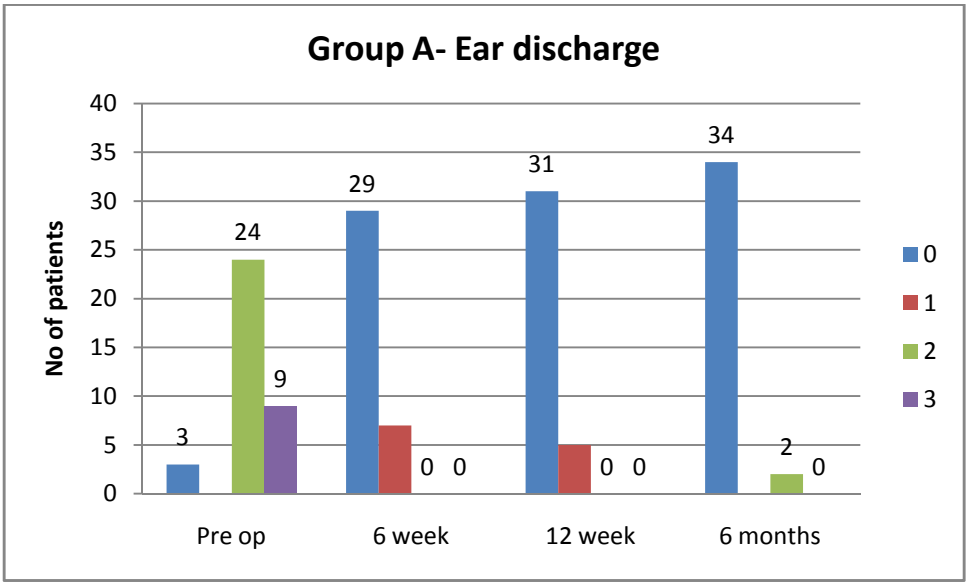
In the present study, 17 patients (47 %) were males and 19 (53 %) were females in Group A; and 21 patients (58 %) were males and 15 patients (42 %) were females in Group B.

Evaluation of Subjective symptoms: Ear Discharge (ED)

Table No. 3

Group A	Pre op	6 weeks	12 weeks	6 months
0	3	29	31	34
1	0	7	5	0
2	24	0	0	2
3	9	0	0	0

Figure No. 5

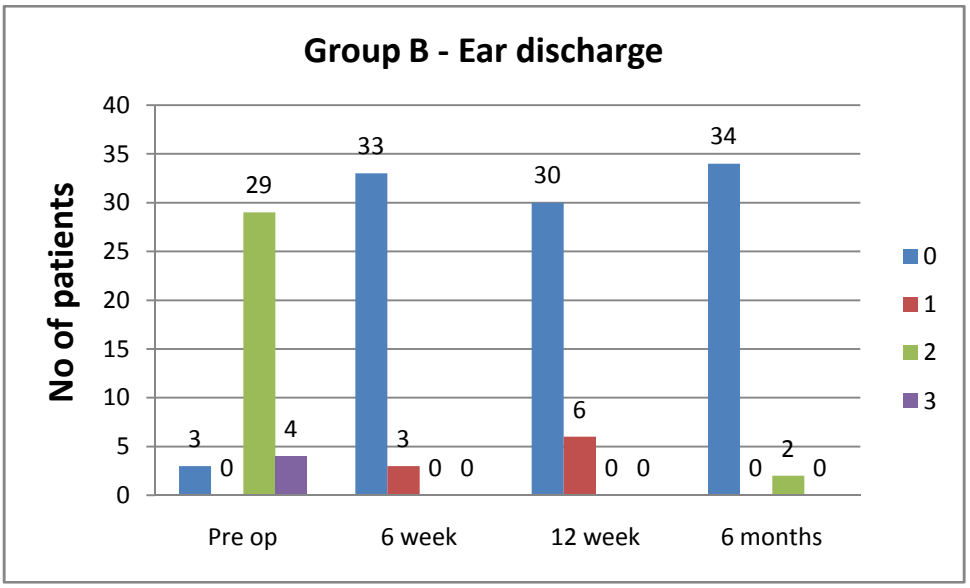


(0= No discharge, 1= Scanty, 2= Intermittent, 3= Profuse)

Table No. 4 – Ear discharge

Group B	Pre op	6 weeks	12 weeks	6 months
0	3	33	30	34
1	0	3	6	0
2	29	0	0	2
3	4	0	0	0

Figure No. 6



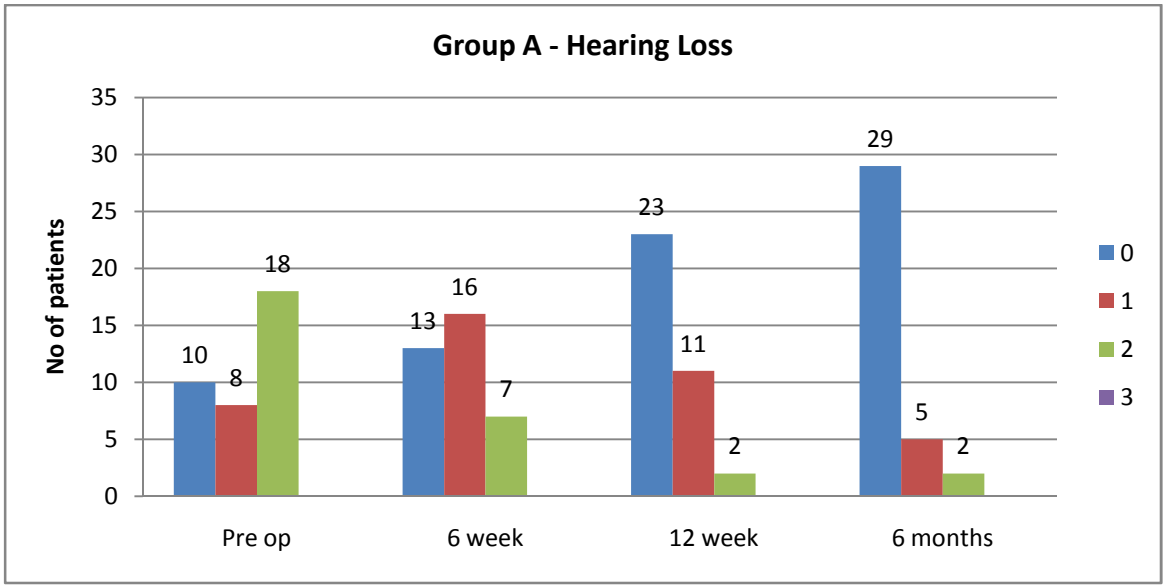
The most common symptom in the patients who presented with CSOM was ear discharge. In the present study, it was seen in 91 % of the patients in both the groups. At the time of surgery, most of the patients in both the groups had no active discharge. After the surgery, there was improvement in subjective symptoms with 81 % of the patients having no complaints of ear discharge after 6 weeks in group A (with gel foam) whereas, in group B (without gel foam) 92 % of the patients had no complaints of ear discharge. This improvement was remarkable as compared to patients with gelfoam. However, after 6 months of surgery, the improvement increased with 94 % of the patients having no complaints of ear discharge in both the groups.

Evaluation of Subjective symptoms: Hearing Loss (HL)

Table No. 5

Group A	Pre op	6 weeks	12 weeks	6 months
0	10	13	23	29
1	8	16	11	5
2	18	7	2	2
3	0	0	0	0

Figure No. 7

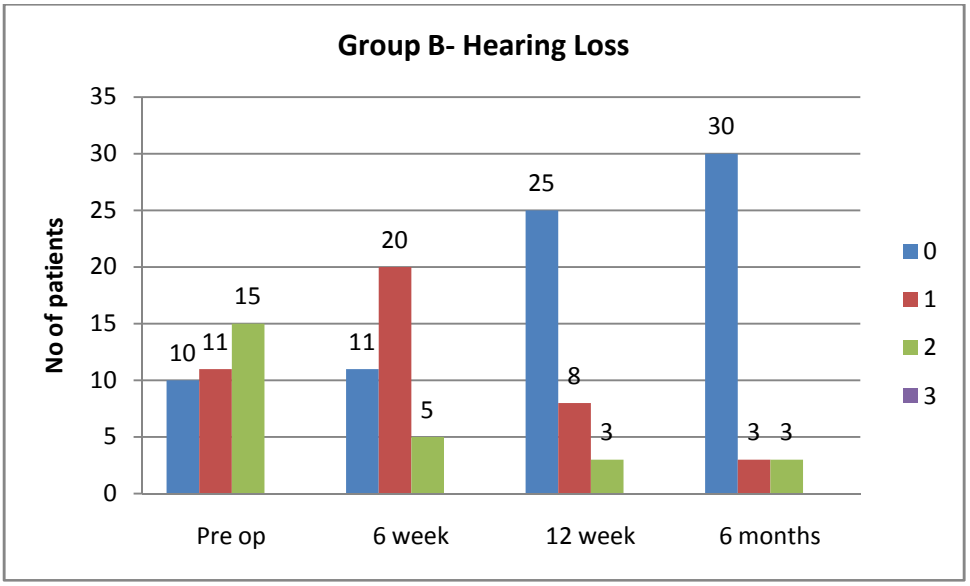


(0= No hearing loss, 1= Inability to hear whispered voices, 2= Inability to hear conversational voices, 3= Inability to hear loud sounds).

Table No. 6 – Hearing Loss

Group B	Pre op	6 weeks	12 weeks	6 months
0	10	11	25	30
1	11	20	8	3
2	15	5	3	3
3	0	0	0	0

Figure No. 8



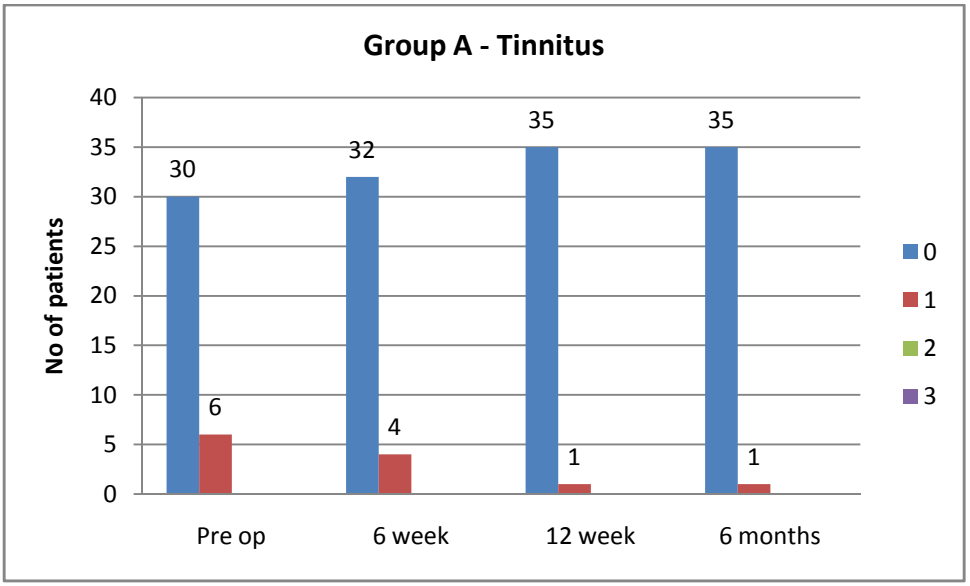
In this study, hearing loss was the symptom in 72 % of the patients in both the groups. After the surgery, improvement in hearing was seen in 80 % of the patients in group A (with gelfoam) and 86 % of the patients in group B (without gelfoam) after six weeks. This improvement was remarkable as compared to patients with gel foam. After six months of surgery, hearing improvement was noted in 80 % of the patients in group A and 83 % of the patients in group B.

Evaluation of Subjective symptoms: Tinnitus (T)

Table No. 7

Group A	Pre op	6 weeks	12 weeks	6 months
0	30	32	35	35
1	6	4	1	1
2	0	0	0	0
3	0	0	0	0

Figure No. 9

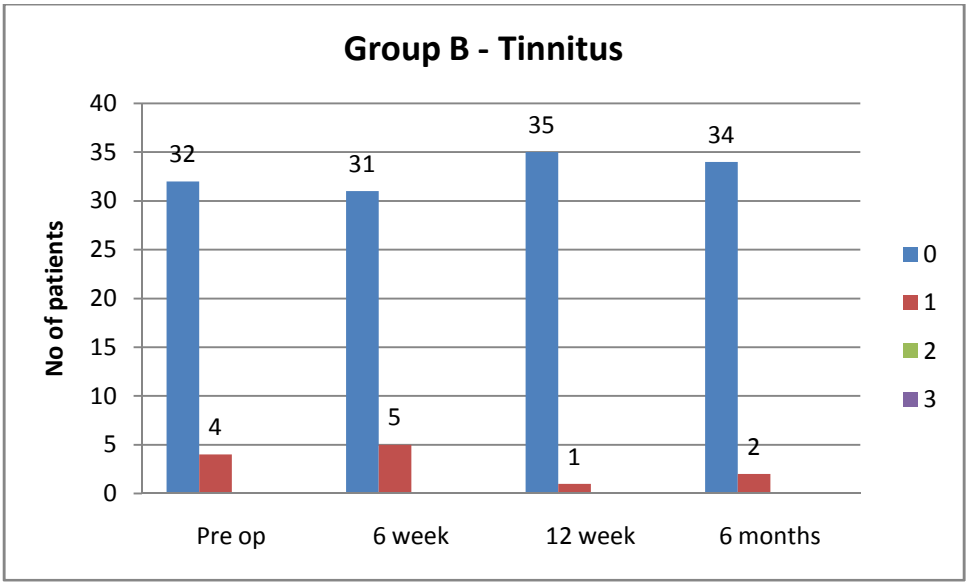


(0= No tinnitus, 1= Intermittent, 2= Persistent, 3= Persistent & Disabling)

Table No. 8 – Tinnitus

Group B	Pre op	6 weeks	12 weeks	6 months
0	32	31	35	34
1	4	5	1	2
2	0	0	0	0
3	0	0	0	0

Figure No. 10



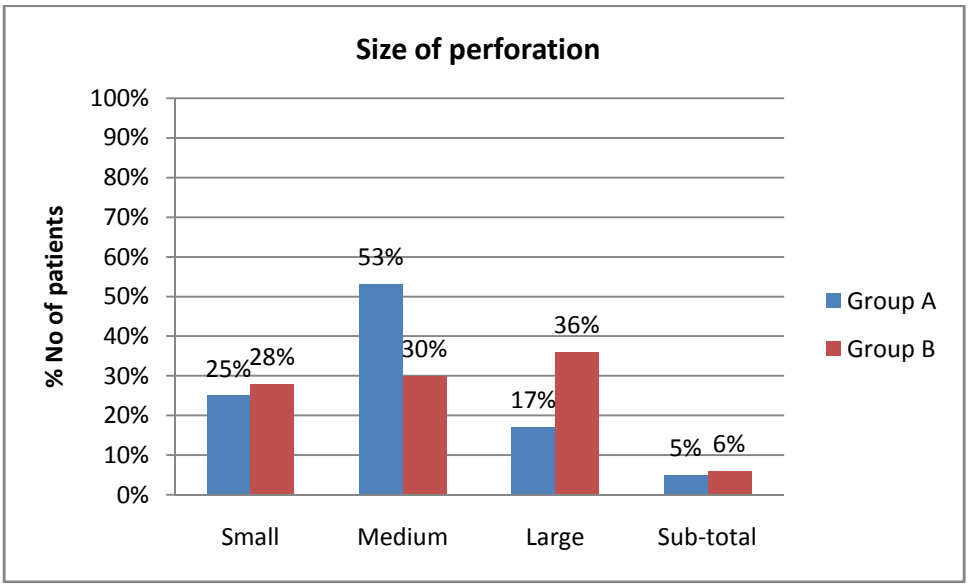
Tinnitus was the symptom in only 17 % of the patients in group A (with gelfoam) and 11 % of the patients in group B (without gelfoam).The symptom persisted in only 3 % of the patients in group A and 6 % of the patients in group B post surgery after six months and this was predominantly seen in patients who had no improvement in hearing.

OTOSCOPIC EXAMINATION: Size of perforation (Sz)

Table No. 9

Size	**Group A**	**Group B**
Small	9 (25 %)	10 (28 %)
Medium	19 (53 %)	11 (30%)
Large	6 (17 %)	13 (36 %)
Sub-total	2 (5 %)	2 (6 %)

Figure No. 11



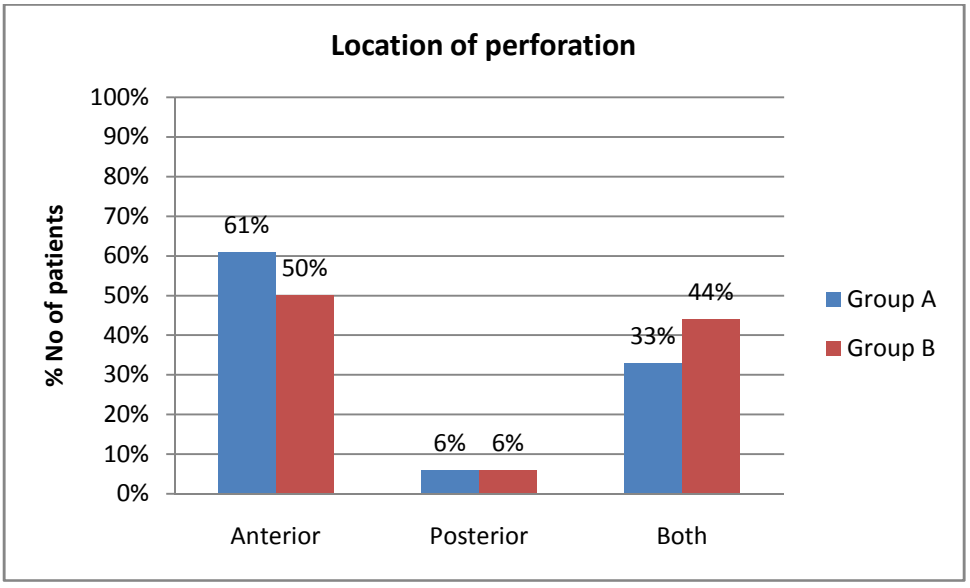
In this study, 78 % of the patients had small to medium sized perforation in group A (with gelfoam) and 58 % in group B (without gelfoam) whereas, 22 % of patients in group A and 42 % of patients in group B had a large to subtotal perforation. The size of the perforation was an otoscopic finding assessed as a factor contributing to the success of surgery.

OTOSCOPIC EXAMINATION: Location of perforation (Lp)

Table No. 10

Lp	Group A	Group B
Anterior	22 (61 %)	18 (50%)
Posterior	2 (6 %)	2 (6 %)
Both	12 (33 %)	16 (44 %)

Figure No. 12



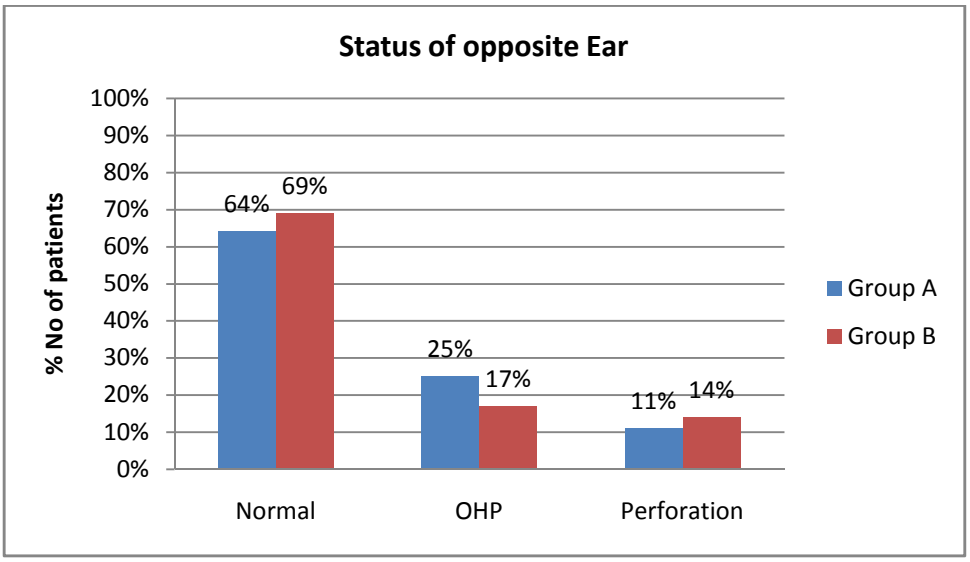
In this study, 61 % of the patients had perforation in the anterior, 6 % had perforation in the posterior quadrant and 33 % had perforation occupying both the anterior and posterior quadrants in group A (with gelfoam); Whereas, 50 % of the patients had perforation in the anterior, 6 % had perforation in the posterior quadrant and 44 % had perforation occupying both the anterior and posterior quadrants in group A (with gelfoam). The location of the perforation was assessed as a factor contributing in the success following tympanoplasty.

OTOSCOPIC EXAMINATION: Status of the Opposite Ear (SOE)

Table No. 11

SOE	**Group A**	**Group B**
Normal	23 (64 %)	25 (69 %)
OHP	9 (25 %)	6 (17 %)
Perforation	4 (11 %)	5 (14 %)

Figure No. 13



In this study, the status of the opposite ear was normal in 64 % of the patients in group A (with gelfoam) and 69 % of the patients in group B (without gelfoam) whereas, 36 % of the patients in group A and 31 % of the patients in group B had either an old healed perforation, scarred tympanic membrane or the presence of a bilateral disease. The analysis of both ears plays a key role in the prognostic assessment of each patient and hence the status of the opposite ear was evaluated as a factor influencing the success following tympanoplasty.

ASSESSMENT OF HEARING

Air -Bone Gap Analysis

Table No. 12

Group A (> 20 dB)	Pre op	6 weeks	12 weeks	6 months
Right ear	15	4	1	4
Left ear	14	7	7	5

Figure No. 14

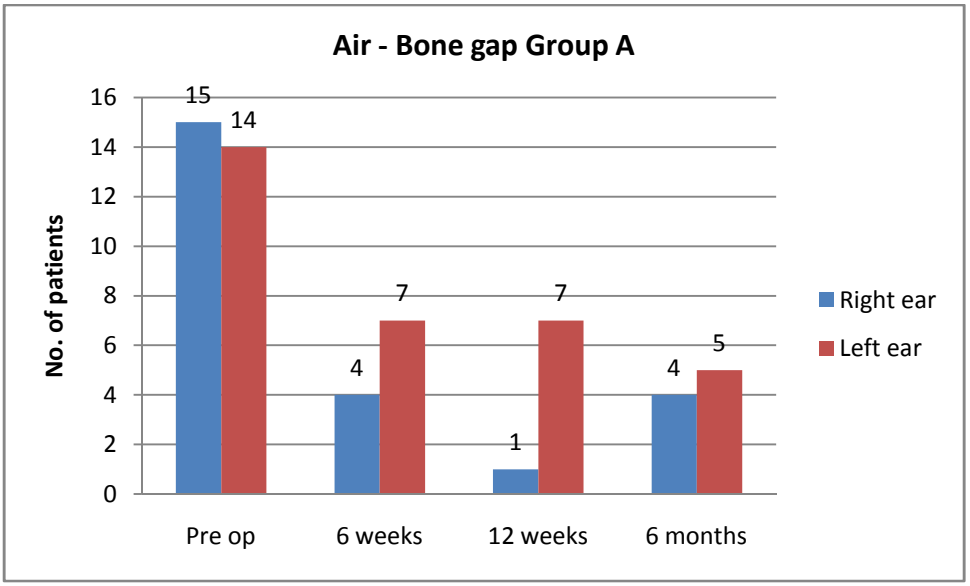
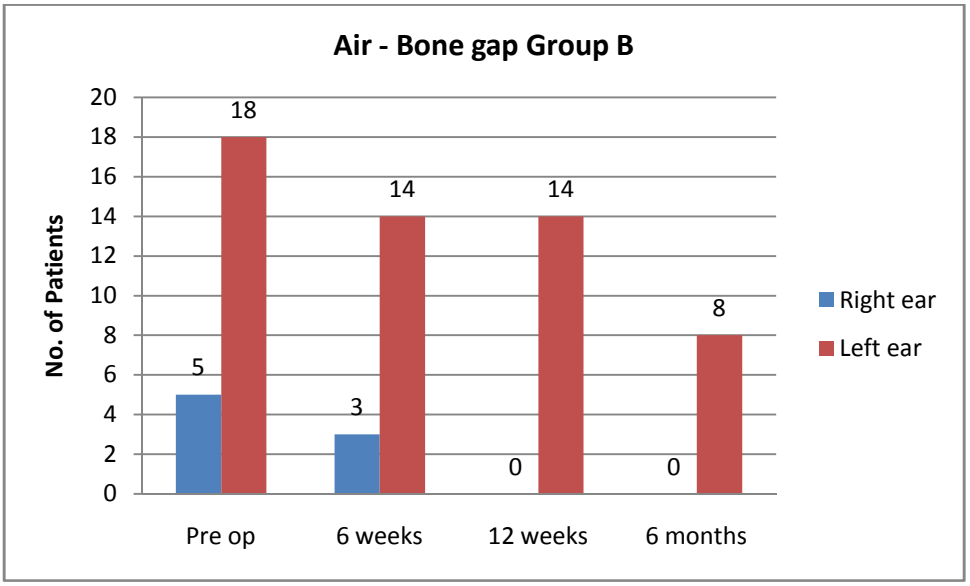


Table No. 13

Group B (> 20 dB)	Pre op	6 weeks	12 weeks	6 months
Right ear	5	3	0	0
Left ear	18	14	14	8

Figure No. 15



In this study, 81 % of the patients in group A and 64 % in group B had an ABG > 20 dB in both the groups. After tympanoplasty at six weeks, 31 % of the patients in group A (with gelfoam) and 47 % in group B (without gelfoam) had an ABG > 20 dB. The improvement in hearing was significant on assessment after six months of surgery with 86 % of the patients in group A and 81 % of the patients in group B having an ABG < 20 dB.

Comparison of the Subjective symptoms before & after surgery using t-test:-

1) **Ear Discharge**

Table No. 14

Ear Discharge (ED)									
		0		1		2		3	
	Category	Cal P	Tab P	Cal P	Tab P	Cal P	Tab P	Cal P	Tab P
Group A	Pre op vs 6 wks	2.916E-13	<.0001	0.004346	<.01	2.92E-13	<.0001	2.92E-13	<.0001
	Pre op vs 12 wks	4.266E-16	<.0001	0.0186	<.05	4.27E-16	<.0001	4.27E-16	<.0001
	Pre op vs 6 mths	1.324E-22	<.0001	-	-	1.32E-22	<.0001	1.32E-22	<.0001
Group B	Pre op vs 6 wks	5.397E-20	<.0001	0.004346	<.01	2.33E-12	<.0001	0.000912	<.001
	Pre op vs 12 wks	1.403E-14	<.0001	0.0186	<.05	2.33E-12	<.0001	0.000912	<.001
	Pre op vs 6 mths	1.324E-22	<.0001	-	-	1.27E-09	<.0001	0.000912	<.001

2) Hearing Loss

Table No. 15

Hearing Loss (HL)									
		0		1		2		3	
Group A	Category	Cal P	Tab P	Cal P	Tab P	Cal P	Tab P	Cal P	Tab P
	Pre op vs 6 wks	0.4490239	>.05	0.043317	<.05	0.005348	<.05	-	-
	Pre op vs 12 wks	0.0015275	< .01	0.423092	>.05	7.24E-06	< .001	-	-
	Pre op vs 6 mths	1.289E-06	< .001	0.358352	>.05	7.24E-06	< .001	-	-
Group B	Pre op vs 6 wks	0.796086	>.05	0.030104	<.05	0.00722	<.05	-	-
	Pre op vs 12 wks	0.0002249	< .001	0.423092	>.05	0.000719	< .001	-	-
	Pre op vs 6 mths	2.419E-07	< .001	0.015466	<.05	0.000719	< .001	-	-

3) Tinnitus

Table No. 16

Tinnitus (T)									
		0		1		2		3	
	Category	Cal P	Tab P	Cal P	Tab P	Cal P	Tab P	Cal P	Tab P
Group A	Pre op vs 6 wks	0.4963818	> 0.05	0.496382	> 0.05	-	-	-	-
	Pre op vs 12 wks	0.0445165	<0.05	0.044516	<0.05	-	-	-	-
	Pre op vs 6 mths	0.0445165	<0.05	0.044516	<0.05	-	-	-	-
Group B	Pre op vs 6 wks	0.722417	> 0.05	0.722417	> 0.05	-	-	-	-
	Pre op vs 12 wks	0.1630062	> 0.05	0.163006	> 0.05	-	-	-	-
	Pre op vs 6 mths	0.394291	> 0.05	0.394291	> 0.05	-	-	-	-

In this study, the statistical analysis of the subjective symptoms before and after surgery was carried out using the t-test in both the groups. There was a statistically significant improvement in the following symptoms post tympanoplasty in both the groups:

Ear discharge and Hearing loss ($p < 0.05$)

Ear discharge and hearing loss were the predominant complaints found in 91% and 72% of the patients respectively in both the groups whereas, tinnitus was found in only 17 % of the patients in group A and 11 % of the patients in group B.

The statistical analyses of otoscopic findings using Chi-square test are as follows : -

1) Size of the perforation

Table No. 17

Sz	**Group A**	**Group B**	**Hypothesis Testing**		
Small	9	10	DOF	3	
Medium	18	11	c2 stat	5.299177	
Large	4	10	p-Value	0.151156	> 0.05
Sub-total	1	0			

2) Location of the perforation

Table No. 18

Location	**Group A**	**Group B**	Hypothesis Testing		
Anterior	21	18	DOF	2	
Posterior	2	2	c2 stat	0.659341	
Both	9	12	p-Value	0.719161	> 0.05

3) Status of the opposite ear

Table No. 19

SOE	**Group A**	**Group B**	Hypothesis Testing		
Normal	23	25	DOF	2	
OHP	6	3	c2 stat	1.067729	
Perforation	3	3	p-Value	0.586335	> 0.05

In this study, the analysis of the otoscopic findings before and after surgery was carried out in both the groups using the Chi square analysis. The size and location of the perforation did not influence the success following tympanoplasty. The status of the opposite ear was also statistically insignificant.

Comparison of the Hearing results before and after surgery using the t-test :-

Table No. 20

AB Gap < 20 dB	p value		
Group A	4.77E-13	<.0001	Sig
Group B	8.14E-09	<.0001	Sig

In this study, the improvement in hearing was analyzed using an ABG closure of < 20 dB as significant following surgery. On PTA done pre - operatively 81 % of the patients in group A and 64 % in group B had an AB gap > 20 dB ; following tympanoplasty at 6 weeks, 31% patients had AB gap > 20 dB in group A (with gelfoam) and 47 % in group B (with gelfoam); at six months 86% patients in group A and 81 % in group B had an AB gap < 20 dB. The improvement in hearing following tympanoplasty was statistically significant at six months following surgery. ($p < 0.05$)

DISCUSSION

This study was conducted from October 2012 to May 2014. In this study, 72 patients were included and divided into 2 groups – Group A (36 pts) in which gel foam was used in tympanoplasty and Group B (36 pts) in which no gel foam was used in the middle ear. The age distribution included maximum patients in the age group 21-30 yrs with 39% and 42% in group A and group B respectively followed by 33% and 28 % in less than 20 years. The mean age was 26 years in group A and 28 years in group B. The sex distribution was males 47% (n=17) and females 53% (n=19) in group A and males 58% (n=21) and females 42% (n=15) in group B.

Bhat NA et al in their study of patients with COM reported that the factors that may influence the success rates of tympanoplasty are: age, perforation location and size, eustachian tube conditions, status of the middle ear mucosa, type of graft used and surgeon experience.[49] Age is not a factor that alters the success rates of tympanoplasty.[49] Ilana Fukuchi et al in their study found that, parameters such as perforation size and location, eustachian tube status, middle ear mucosa status, type of graft used and others hereby mentioned, such as disease development, number of infections per year, percentage of membrane involved in the perforation or monthly income did not prove to be statistically important for obtaining surgical success.[49] Aviles Jurado FJ et al in their study found that the contra lateral ear pathology and the perforation extension were associated with poor prognosis after myringoplasty.[50] In our study, age was not considered as a factor for comparison of results of tympanoplasty with and without gelfoam. The factors included in our study were perforation location and size, and status of the opposite ear.

The common symptoms in patients who presented with CSOM, tubotympanic disease as seen in this study were ear discharge (91%) and hearing loss (72%) seen in both the groups. Costa SS and colleagues' in their study found that the major symptom in non-cholesteatomatous CSOM patients is intermittent otorrhea, together with hearing loss. On doing otoscopy they found, usually a perforation in the pars tensa of the tympanic membrane of varied size and shape, the middle ear mucosa had an almost normal appearance, except for some degrees of hyperemia.[51] Macfadyean CA and colleagues in their study reported hearing impairment, apart from the disability from recurrent ear discharge, as the most frequent effect of COM. A school survey in Kenya found 63% of ears with COM had more than 30 dB hearing loss.[52]

In this study, the pre-operative assessment of patients included an oto-microscopic examination and assessment of hearing using pure tone audiometry. The findings on otoscopic examination revealed small to medium sized perforations (</= 50% of TM) in 78 % and 58% in group A and group B respectively and large to subtotal perforation (> 50% of TM) in 22% and 42% respectively. 64% of these perforations in group A and 69% in group B were in the anterior quadrant, 25% and 17% in posterior quadrant; and 11% and 14% respectively in both quadrants. The opposite ear was normal in 64% of the patients in group A and 69 % in group B, whereas 36% in group A and 31% in group B had an old healed perforation, scarred TM or presence of a bilateral disease. On pre- operative assessment of hearing using PTA in this study, 81 % of the patients in group A and 64 % in group B had an AB gap > 20 dB. The patients underwent tympanoplasty type I under local anesthesia with sedation. The approach was post aural in all the patients.

In this study, after six weeks of tympanoplasty, it was observed that there was an improvement in subjective symptoms with 81% of the patients in group A and 92 % in group B having no complaints of ear discharge and 80% of the patients in group A and 92 % in group B having a better hearing than before the surgery. The graft take up rate was 89 % in group A and 84 % in group B. The PTA had 31 % patients with AB gap > 20dB in group A and 47 % in group B.

At 3 months after the surgery, there was slight improvement in subjective symptoms with 86% of the patients in group A and 83 % in group B having no complaints of ear discharge and 64% of the patients in group A and 69 % in group B having a better hearing than before the surgery. The graft take up rate was 89 % in group A and 84 % in group B. The PTA had 22 % of the patients with AB gap > 20dB in group A and 39 % in group B.

On evaluation 6 months after the surgery, there was further improvement in subjective symptoms with 94% of the patients in both the groups having no complaints of ear discharge and 80 % of the patients in group A and 83 % in group B having a better hearing than before the surgery. The symptom of ear discharge persisted in 6% of the patients in both the groups and hearing loss was seen in around 20% of patients in both the groups. The graft take up rate was 89 % in group A and 84 % in group B. Of the less common symptoms tinnitus was observed in 17% of the patients in group A and 11% in group B which was mainly in the patients who complained of hearing impairment. On PTA 86% had AB gap < 20 dB in group A and 81 % in group B.

In this study, the success rate was found to be 89% in group A and 84 % in group B. The graft success in this study is a condition in which a healthy graft without

perforation or laterization lasts for six months after tympanoplasty. Bhat NA and colleagues in their study showed that the overall success of tympanoplasty for consultants was 81% and for trainees was 79%, with an overall success rate of 86% in children.[54] Vartiainen E and his colleagues in their results of 404 primary tympanoplasty operations; that were critically analyzed found an overall success rate of 88 % with a mean follow up period of 5.5 yrs.[49]

Postoperative hearing outcomes were considered successful, if the postoperative air-bone gap was within 20 dB.[55] In this study prior to surgery 81% of the patients in group A and 64 % in group B had an ABG > 20dB and following tympanoplasty at six months it was noted that 86% patients in group A and 84 % in group B had an ABG < 20 dB. The serviceable hearing was taken as 30 dB. In the study by Ilana Fukuchi et al the audiometric gain was found in most of the patients after the first surgery and in 100% of the patients after revision surgeries. They believed that this hearing improvement is due to the fact that there was a reduction in perforation size in most of the patients' studied.[54]

In this study, the failure to use gelfoam in the middle ear prevents immune system response against gelfoam and its complication. Moreover, in animal samples, the complete absorption of gelfoam is 45-54 days, [56] therefore, in case of using gelfoam; it remains too long in middle ear and prevents the full recovery of hearing until complete absorption of gelfoam. In the current technique, the patient's hearing is improved remarkably and immediately after removal of wick from external ear canal. In addition, the reaction of immune system is less than usual technique. In his very own technique, Fisch in tympanoplasty used spiral lateral pedicle meatal skin flap and medial meatal (instead of standard korner flaps and vascular strip flaps) with no gelfoam in the middle

ear. Rate of perforation closure at the end of the first year after surgery was 89% and after 5-15 years about 86%.[57]

Comparison of the success rate of tympanoplasty without gelfoam in the middle ear

Table No. 21

Sl no.	Name of the study	Success rate (% of graft uptake)
1.	Fisch (1994)	89 %
2.	Ghiasi S. & Tootoonchi SJ. (2008)	89 %
3.	Present study	84 %

In a study conducted by Ghiasi S. & Tootoonchi SJ, the graft success rate was 91 % for tympanoplasty in the patients with using gelfoam whereas, in the patients without gelfoam, the graft success rate was 89 % for tympanoplasty.[58] In our study, in cases without gelfoam in the middle ear, the rate of graft uptake in tympanoplasty was 89 % with gel foam at the end of six months. In cases with gelfoam usage, the rate of graft uptake was 81%, which indicates similar results. Thus, the success rate of tympanoplasty as found in our study was consistent with the results of most studies in literature. Hence, we conclude that the results of tympanoplasty in both the groups are the same in our study and further studies may be carried out over a longer duration to assess the long term success rate of tympanoplasty with and without the use of gelfoam.

CONCLUSION

1. In the patients with using gelfoam, graft uptake rate was 89% for tympanoplasty. In patients without gelfoam, graft uptake rate was 84% at the end of six months.
2. The improvement in the subjective symptoms of ear discharge and hearing loss at 6 weeks following the surgery was 81% and 80% respectively with gel foam whereas, it was 92 % and 86 % respectively without gel foam. It improved further at the end of six months to 94% and 83% respectively in both the groups.
3. The improvement in hearing six months following tympanoplasty with gel foam as assessed by pure tone audiometry (ABG < 20dB) was 86%. Without gelfoam, it was 81 %.This improvement in hearing was significant ($p < 0.05$) and maximum at six months following the surgery.
4. The advantage of this technique (without gelfoam) is rapid improvement of patient's hearing after removal of the external ear canal wick which was noted after six weeks of surgery. Also, the adverse effects of gelfoam as an external substance and its subsequent reactions are prevented. Therefore, this technique can be used widely in ear surgeries.
5. The results in both the groups were almost the same after six months. Hence, we conclude that the results of tympanoplasty in both the groups are the same in our study and further studies may be carried out over a longer duration to assess the long term success rate of tympanoplasty.

SUMMARY

- This prospective comparative clinical study was performed in 72 patients undergoing tympanoplasty in the department of ENT, B.L.D.E.U'S Shri B. M. Patil Medical College Hospital & Research Centre from October 2012 to May 2014.
- All patients were subjected to thorough history taking and clinical examination with emphasis on detailed otoscopic examination to exclude patients with unhealthy middle ear mucosa, cholesteatoma and ossicular discontinuity.
- All patients undergoing tympanoplasty were subjected to pure tone audiometry for assessment of hearing before and after surgery.
- Out of 72 patients, 36 underwent tympanoplasty with gel foam whereas, 36 patients underwent tympanoplasty without the use of gel foam.
- The uptake of graft after tympanoplasty was almost similar in the patients with using gelfoam (89%) and those without gelfoam (84%) at the end of six months.
- The improvement in the subjective symptoms of ear discharge and hearing loss at 6 weeks following the surgery was better in patients without gelfoam whereas, at the end of 6 months the improvement in these symptoms was similar in both the groups.
- The improvement in hearing six months following tympanoplasty as assessed by pure tone audiometry was the same in both the groups.

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ANNEXURE I

ETHICAL CLERANCE CERTIFICATE

ANNEXURE II

PHOTOGRAPHS

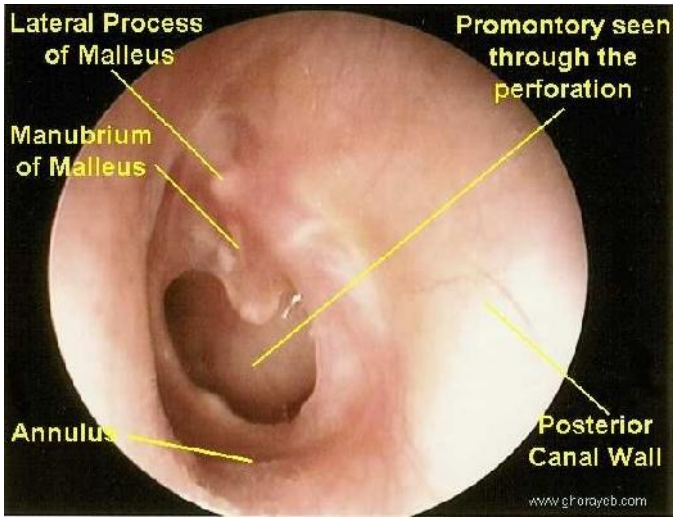
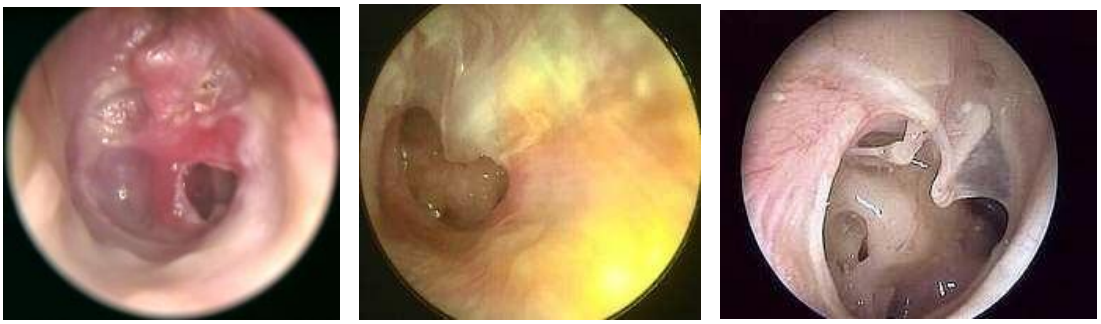


Photo 1: COM, TTD with Perforation in TM



Small size Moderate size Large size

Photo 2: Perforations of varying sizes in TM

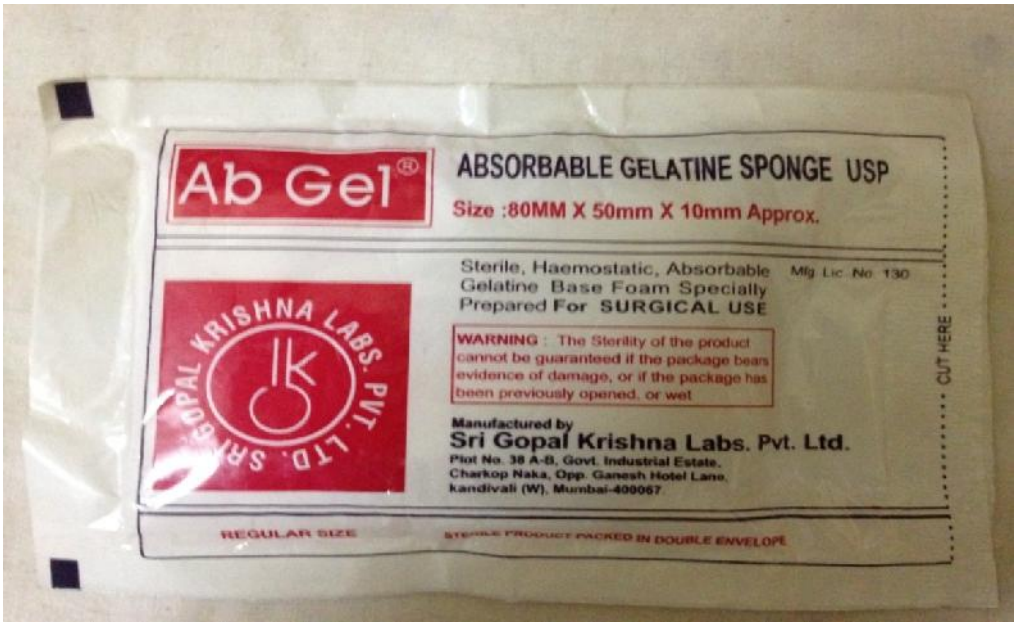


Photo 3: Absorbable gelatin sponge (Gelfoam)

Photo 4: Pure tone audiometry being performed on a patient.

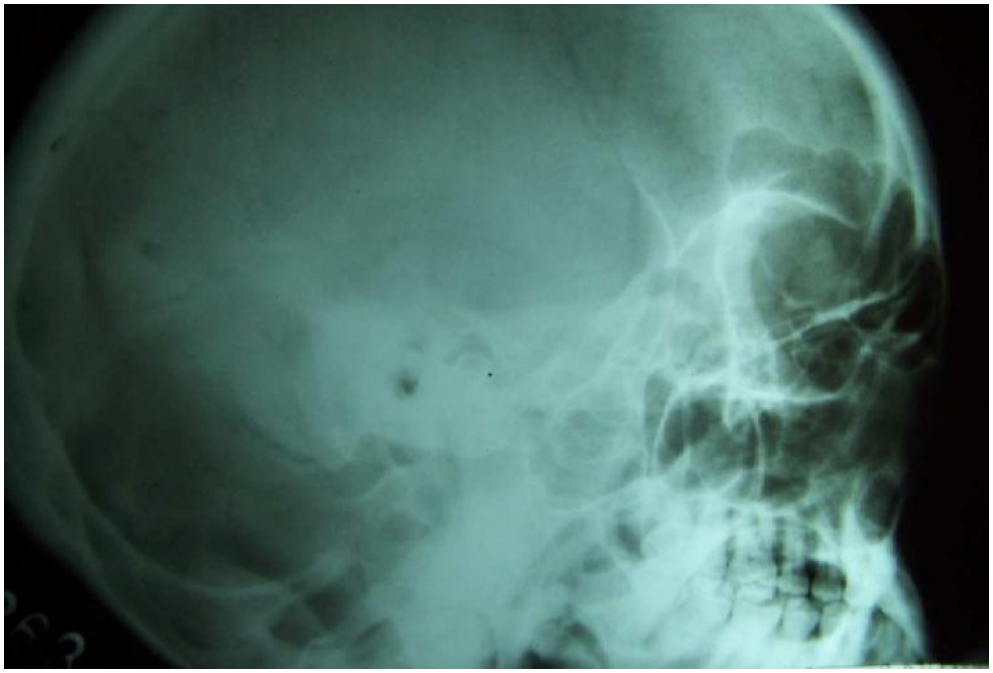


Photo No. 5: X – Ray mastoid Schuller's view (Rt) Sclerotic mastoid

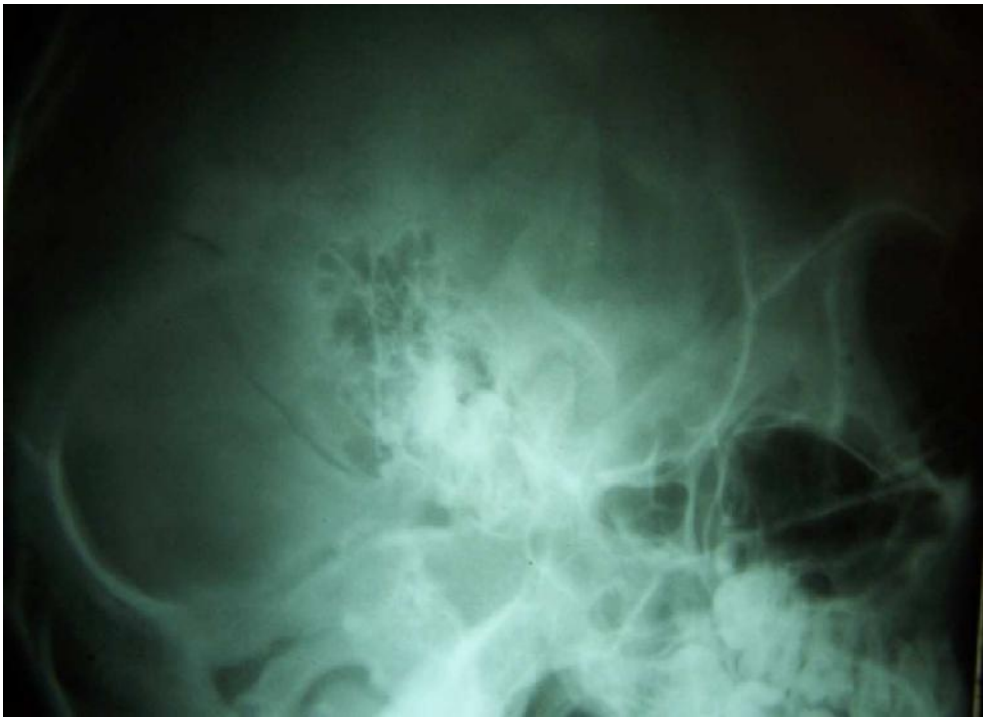


Photo No. 6: X – Ray mastoid Schuller's view (Rt) diploic mastoid

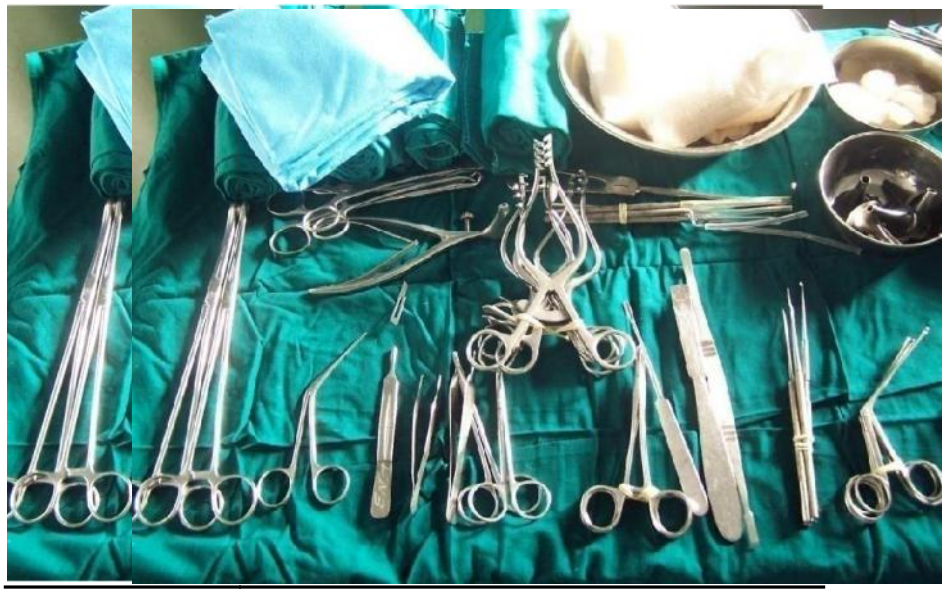


Photo No. 7: Instruments used in tympanoplasty

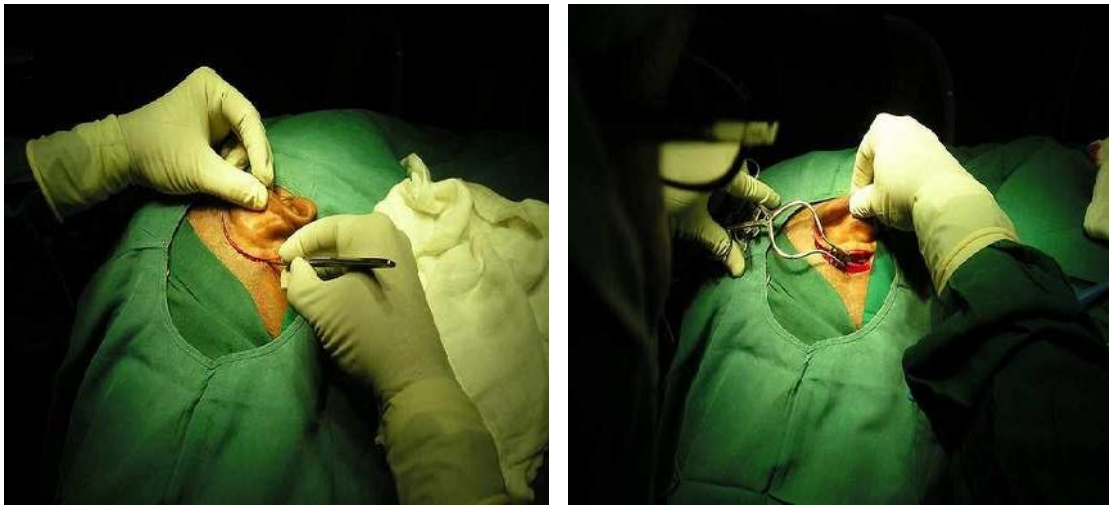
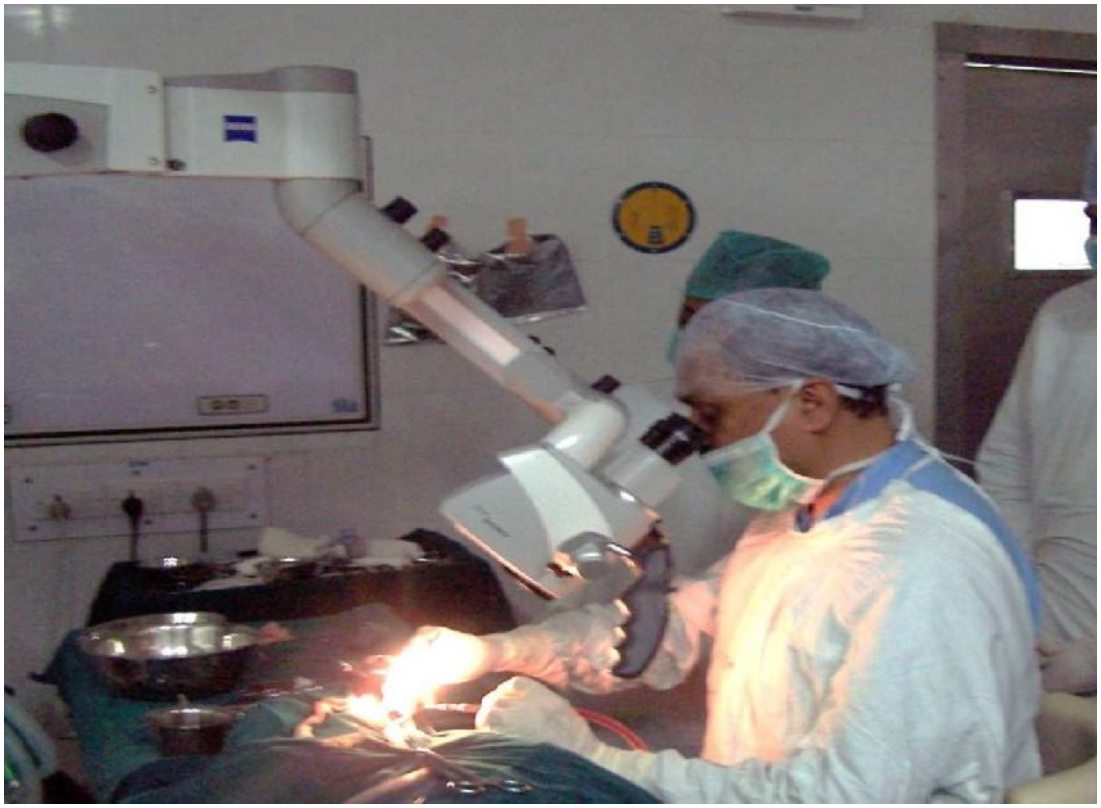


Photo No. 8: Tympanoplasty - surgical steps



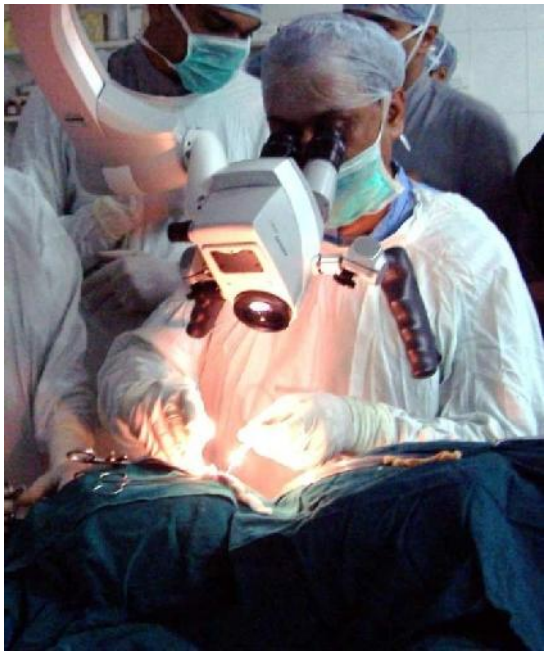


Photo No.9 Zeiss microscope inuse during tympanoplasty

ANNEXURE –III

SAMPLE INFORMED CONSENT FORM

BLDEU'S SHRI B.M.PATIL MEDICAL COLLEGE AND RESEARCH CENTRE,

BIJAPUR- 586103

TITLE OF THE PROJECT:	**A COMPARATIVE STUDY OF THE RESULTS OF TYMPANOPLASTY WITH AND WITHOUT GEL FOAM**
PG GUIDE:	**DR. R.N. KARADI** **PROFFESSOR OF E.N.T.** **B.L.D.E.U.'s Shri.B.M.Patil Medical College, Hospital & Research Centre, Bijapur, Karnataka.**
PG STUDENT:	**DR.ROHIT KUMAR JHA** **P.G. Student,** **Dept. of E.N.T.**

PURPOSE OF RESEARCH:

I have been informed that this is a study to compare the results of tympanoplasty with and without placement of gel foam.

PROCEDURE

I am aware that in addition to routine care received, I will be asked series of questions by the investigator. I have been asked to undergo the necessary investigations and treatment, which will help the investigator in this study.

RISK AND DISCOMFORTS

I understand there is no risk involved and I will experience some pain and discomfort during my procedures performed. This is mainly the result of my condition and the procedure of this study is not expected to exaggerate these feelings that are associated with the usual course of treatment.

BENEFITS

I understand that my participation in this study will help the investigator to assess the safety of use of gel foam in tympanoplasty.

CONFIDENTIALITY

I understand that the medical information produced by this study will become a part of Hospital records and will be subject to the confidentiality and privacy regulation. Information of a sensitive personal nature will not be a part of the medical records, but investigator's research file and identified only by a code number. The code-key connecting name to numbers will be kept in a separate location.

If the data are used for publication in the medical literature or for teaching purpose, no name will be used and other identifiers such as photographs and audio or videotapes will be used only with my special written permission. I understand that I may see the photographs and videotapes and hear the audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION

I understand that I may ask more questions about the study at any time; Dr. Rohit Kumar Jha is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation.

If during the study, or later, if I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL FOR WITHDRAWAL OF PARTICIPATION

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital. I also understand that Dr. Rohit Kumar Jha may terminate my participation in the study after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or physical therapist, if this is appropriate.

INJURY STATEMENT

I understand that in the unlikely event of injury to me resulting directly from my participation in this study, if such injury were reported promptly, the appropriate treatment would be available to me, but no further compensation would be provided. I understand that by my agreement to participate in this study I am not waiving any of my legal rights.

STUDY SUBJECT CONSENT STATEMENT

I confirm that Dr.Rohit Kumar Jha has explained to me the purpose of research, the study procedures that I will undergo, and the possible risks and discomforts as well as benefits that I may experience in my own language. I have read and I understand this consent form. Therefore, I agree to give consent to participate as a subject in this research project.

_____ _____

Participant / Guardian Date

_____ _____

Witness to signature Date

I have explained to _____the purpose of the research, the procedures required and the possible risks and benefits to the best of my ability in patient's own language.

_____ _____ _____

Dr. Rohit Kumar Jha Dr.R.N.Karadi Date:

(Investigator) (Guide)

ANNEXURE IV

PROFORMA FOR CHRONIC OTITIS MEDIA

PRE–OPERATIVE EVALUATION

Sl. No Name : Age: Sex : IP No.:

Address :

Occupation :

1. Clinical presentation :

	Chief complaints				
Symptom	Duration	Grading of the symptom as per self assessment scoring system			
		0	1	2	3
Ear discharge					
Hearing loss					
Tinnitus					

Any relevant history relating to nose & throat:

Any Past history

Trauma/ head injury

Surgery Medical illness

Prolonged medication

2. Clinical Examination

Wt.: (kg) Pulse: /min BP: mm of Hg.

Pallor: Present / Absent

Examination of the Ears:

Details of Otoscopic Examination & Evaluation of hearing :-

Findings	Rt	Lt
Preauricular / Postauricular region		
Pinna / EAC		
Tympanic membrane		
Findings	Right ear	Left ear
Size of perforation		
Location of perforation		
Any other findings		
Tuning fork tests : Rinne's 256 Hz		
512 Hz		
1024 Hz		
Weber's test		
ABC		

Oto - neurological examination

Nose:

Throat:

3. Investigations:

PTA

Findings	Rt	Lt
AC		
BC		
ABG		

4. Final Diagnosis

5. Plan oftreatment

PROFORMA FOR CHRONIC OTITIS MEDIA (TTD)
Details of Surgery & Post – operative evaluation

Sl.No: Name: IP No. -

Age: ___ yrs Sex: M/F

Occupation: Address:

1. Details of surgery (Tympanoplasty)

   Date of surgery:

   Anesthesia fitness:

   Surgical details:
   Ear Operated - Rt / Lt
   Operative findings -

   Post op period -

   Date of discharge -

2. Post op assessment (T1 : 6 wks; T2 : 12 wks; T3 : 6mths)

   Symptoms:

Findings (Grading as per the self assessment scoring)	T1	T2	T3
Ear discharge			
Hearing loss			
Tinnitus			

3. ClinicalExamination (Operated ear)

Ear Findings	T1	T2	T3
Preauricular / Postauricular region			
Pinna / EAC			
Tympanic membrane (Healed / Persistent perforation)			

4. Assessment of hearing :-

Findings	TFT								
	Rinne's test						Weber's test	ABC	
	256		512		1024			Rt	Lt
	Rt	Lt	Rt	Lt	Rt	Lt			
T1									
T2									
T3									

5. Investigations:

Findings	AC		BC		ABG	
	Rt	Lt	Rt	Lt	Rt	Lt
T1						
T2						
T3						

6. Additional Informationif any:

ANNEXURE V

KEY TO MASTER CHART

Abbreviations	Words
SA	Subjective assessment
ED	Ear discharge
HL	Hearing loss
T	Tinnitus
OE	Otoscopic examination
Sz	Size of the perforation
S	Small
M	Moderate
L	Large
ST	Sub total
Lp	Location of the perforation
A	Anterior
P	Posterior
B	Both

Abbreviations	Words
SOE	Status of the opposite ear
OHP	Old healed perforation
P	Persistent perforation
TFT	Tuning fork test
RN	Rinne’s test
Rt	Right
Lt	Left
WT	Weber’s test
L	Lateralized
C	Central
ABC	Absolute bone conduction
NR	Not reduced compared to the examiner
R	Reduced compared to the examiner

S NO.	Name	Age/sex	IP no	Pre -operative assessment																							
				S A			Objective assessment																					
										TFT											PTA						
				ED	HL	T	OE		SOE	RN						WT	ABC										
							Sz	LP		256Hz		512Hz		1024Hz							AC		BC		ABG		
										RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT	RT	LT
1	Bandhu Badigair	45/M	22339/12	0	0	0	M	A	OHP	+	+	+	+	+	+	L	NR	NR	20	25	10	10	10	15
2	Shridevi	12/F	22098/12	3	2	1	L	B	N	-	+	-	+	+	+	R	NR	NR	40	20	20	15	20	5
3	Iramma	43/F	23784/12	2	1	0	M	A	N	-	+	+	+	+	+	R	NR	NR	30	25	10	5	20	20
4	Kalavati	26/F	24759/12	2	2	0	M	P	N	+	-	+	+	+	+	L	NR	NR	20	35	15	15	5	20
5	Priyanka	18/F	25709/12	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20
6	Boramma	40/F	26093/12	3	2	0	L	B	P	-	-	-	-	-	-	R	NR	NR	45	35	10	5	35	20
7	Shankarawwa	32/F	29142/12	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10
8	Satish Chavan	13/F	245/13	2	2	0	M	A	N	-	+	-	+	+	+	R	NR	NR	45	20	25	10	20	10
9	Ramappa	34/M	1350/13	2	0	0	S	A	N	+	+	+	+	+	+	R	NR	NR	25	20	15	15	10	5
10	Mallikarjun	18/F	1701/13	2	2	0	L	B	OHP	+	-	+	-	+	+	L	R	R	30	55	15	25	15	30
11	Chandagouda	30/F	2572/13	3	2	0	M	A	OHP	-	-	-	+	-	+	R	NR	NR	40	35	10	15	30	20
12	Venkateshwar	30/M	2874/13	3	2	0	M	A	N	-	+	+	+	+	+	R	NR	NR	35	20	10	10	25	10
13	Shobha	20/F	3241/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20
14	Shivamma	26/F	4000/13	2	0	0	S	A	N	+	+	+	+	+	+	R	NR	NR	25	20	15	15	10	5
15	Sadashiv	42/F	4106/13	3	2	0	M	B	N	-	+	-	+	+	+	R	NR	NR	35	20	15	10	20	10
16	Saraswati	23/F	4295/13	3	0	0	S	A	P	+	+	+	+	+	+	R	NR	NR	30	25	10	10	20	15
17	Rohini	30/F	4390/13	3	0	0	S	A	P	+	+	+	+	+	+	R	NR	NR	30	25	10	10	20	15
18	Shivanand	35/M	5070/13	2	2	0	L	B	OHP	+	-	+	-	+	+	L	R	R	30	55	15	25	15	30
19	Shridevi	23/F	5698/13	0	2	0	S	A	N	+	+	+	+	+	+	L	NR	NR	20	30	15	15	5	15
20	Bouramma	25/F	6482/13	2	1	0	M	A	N	-	+	+	+	+	+	R	NR	NR	30	25	10	5	20	20
21	Shrikanth	23/F	6803/13	2	2	1	M	A	OHP	-	-	+	-	+	-	L	NR	NR	35	45	25	30	10	15
22	Vijaykumar	20/M	6832/13	2	1	0	S	A	OHP	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20
23	Sadashivappa	20/M	7508/13	0	0	0	M	A	OHP	+	+	+	+	+	+	L	NR	NR	20	25	10	10	10	15
24	Ashok Mane	30/F	7676/13	3	2	0	M	A	N	-	+	+	+	+	+	R	NR	NR	35	20	10	10	25	10
25	Mallikarjun	24/M	7966/13	2	2	1	M	B	N	-	+	+	+	+	+	R	NR	NR	30	20	10	10	20	10
26	Sagar	25/M	8861/13	2	2	0	M	B	N	+	-	+	-	+	+	L	NR	NR	25	50	10	30	15	20
27	Panchaksharayya	15/M	9289/13	2	1	0	M	A	N	-	+	+	+	+	+	R	NR	NR	30	25	10	5	20	20
28	Bhuvaneshwari	17/F	9359/13	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10
29	Jayshee	22/F	9340/13	2	0	0	M	P	N	+	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10
30	Sameer	19/F	9810/13	2	0	0	S	A	N	+	+	+	+	+	+	R	NR	NR	25	20	15	15	10	5
31	Vimala	50/F	10140/13	2	2	0	ST	B	P	-	-	+	-	+	-	L	NR	NR	25	50	10	15	15	35
32	Mahadev	17/M	10360/13	3	2	0	ST	B	N	-	+	-	+	+	+	R	R	R	40	70	20	55	20	15
33	Kasturi	32/F	11271/13	2	1	0	S	A	N	+	-	+	+	+	+	L	NR	NR	20	25	15	15	5	10
34	Devamma	25/F	13299/13	2	2	1	M	A	OHP	-	-	+	-	+	-	L	NR	NR	35	45	25	30	10	15
35	Bharatkumar	14/M	13976/13	2	1	1	S	A	OHP	+	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25
36	Anita	35/F	13891/13	2	2	1	M	B	N	-	+	+	+	+	+	R	NR	NR	30	20	10	10	20	10

`

S NO.	Name	Age/sex	IP no	Pre -operative assessment																							
				Subjective A			Objective assessment																				
										TFT									PTA							
										RN						WT	ABC		AC		BC		ABG			
				ED	HL	T	OE		SOE	256Hz		512Hz		1024Hz													
							Sz	LP		RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT	RT	LT
1	Jaibunisa	40/F	22203/12	3	2	1	L	B	N	-	+	-	+	+	+	R	NR	NR	40	20	20	15	20	5		
2	Satish	16/M	22929/13	3	2	0	L	B	P	-	-	-	-	-	-	R	NR	NR	45	35	10	5	35	20		
3	Balasingh Rajput	52/M	25400/12	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10		
4	Ramachandra	12/M	26453/12	2	1	0	M	A	N	-	+	+	+	+	+	R	NR	NR	30	25	10	5	20	20		
5	Alfiya	10/M	26987/12	2	0	0	S	A	N	+	+	+	+	+	+	R	NR	NR	25	20	15	15	10	5		
6	Chandrakant	25/M	27876/12	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
7	Santosh	14/M	28053/12	2	1	1	S	A	OHP	+	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25		
8	Kallappa	30/M	537/13	2	2	0	L	B	OHP	+	-	+	-	+	+	L	R	R	30	55	15	25	15	30		
9	Geeta	30/F	626/13	2	1	0	S	A	N	+	-	+	+	+	+	L	NR	NR	20	25	15	15	5	10		
10	Kanawwa	18/F	824/13	2	2	1	M	A	OHP	-	-	+	-	+	-	L	NR	NR	35	45	25	30	10	15		
11	Dundappa	22/M	1311/13	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10		
12	Vani	30/F	1925/13	2	0	0	M	P	N	+	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10		
13	Dundappa	25/M	2317/13	2	2	0	M	B	N	+	-	+	-	+	+	L	NR	NR	25	50	10	30	15	20		
14	Parashuram	36/M	2877/13	0	2	0	S	A	N	+	+	+	+	+	+	L	NR	NR	20	30	15	15	5	15		
15	Prerna	20/F	3587/13	2	2	0	ST	B	P	-	-	+	-	+	-	L	NR	NR	25	50	10	15	15	35		
16	Anita	27/F	3691/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
17	Gururaj	20/M	3972/13	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10		
18	Priya	18/F	4324/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
19	Bhimarao	28/M	4953/13	2	2	0	L	B	OHP	+	-	+	-	+	+	L	R	R	30	55	15	25	15	30		
20	Lata	30/F	5289/13	2	0	0	S	A	N	+	+	+	+	+	+	R	NR	NR	25	20	15	15	10	5		
21	Irappa	33/M	6108/13	0	2	0	S	A	N	+	+	+	+	+	+	L	NR	NR	20	30	15	15	5	15		
22	Shubam	23/M	6423/13	2	2	0	ST	B	P	-	-	+	-	+	-	L	NR	NR	25	50	10	15	15	35		
23	Sachin	27/M	6551/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
24	Renuka	25/F	6844/13	2	0	0	S	A	N	+	+	+	+	+	+	R	NR	NR	25	20	15	15	10	5		
25	Arif	34/M	8034/13	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10		
26	Rashmi	36/F	8173/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
27	Nayeem	28/F	9155/13	2	2	0	M	P	N	+	-	+	+	+	+	L	NR	NR	20	35	15	15	5	20		
28	Jakkamma	48/F	8400/13	2	1	0	S	A	N	+	-	+	+	+	+	L	NR	NR	20	25	15	15	5	10		
29	Mohan	52/M	9847/13	2	2	0	L	B	OHP	+	-	+	-	+	+	L	R	R	30	55	15	25	15	30		
30	Rafiq	25/M	11574/13	2	0	0	M	A	N	+	+	+	+	+	+	L	NR	NR	25	20	15	10	10	10		
31	Kashinath	35/M	11663/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
32	Ravi	12/M	12141/13	3	0	0	S	A	P	+	+	+	+	+	+	R	NR	NR	30	25	10	10	20	15		
33	Kaveri	20/F	13035/13	0	2	0	S	A	N	+	+	+	+	+	+	L	NR	NR	20	30	15	15	5	15		
34	Asha	32/F	13343/13	2	1	0	L	B	N	+	-	+	+	+	+	L	NR	NR	20	30	10	10	10	20		
35	Shivanand	34/F	13487/13	2	2	1	M	A	OHP	-	-	+	-	+	-	L	NR	NR	35	45	25	30	10	15		
36	Susheela	25/M	14470/13	3	2	0	L	B	P	-	-	-	-	-	-	R	NR	NR	45	35	10	5	35	20		

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S NO.	Post-operative assessment (6 weeks)																					
	EO	Subjective A				Objective assessment																
		ED	HL	T	OE	TFT									PTA							
						RN						WT	ABC		AC		BC		ABG			
						256Hz		512Hz		1024Hz												
						RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT		
1	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10		
2	R	0	2	1	H	-	+	+	+	+	+	R	NR	NR	35	20	20	15	15	5		
3	R	0	1	0	H	-	+	+	+	+	+	R	NR	NR	25	20	10	5	15	15		
4	L	0	2	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10		
5	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
6	R	0	1	1	H	-	-	+	-	+	-	L	NR	NR	30	35	10	5	20	30		
7	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
8	R	0	2	0	H	-	+	+	+	+	+	R	NR	NR	30	20	15	10	15	10		
9	R	0	0	0	H	+	+	+	+	+	+	R	NR	NR	20	20	15	15	5	5		
10	L	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30		
11	R	1	1	0	P	-	-	-	+	+	+	R	NR	NR	35	35	10	15	25	20		
12	R	0	2	0	H	-	+	+	+	+	+	R	NR	NR	30	20	10	10	20	10		
13	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
14	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5		
15	R	0	1	0	H	-	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10		
16	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	25	15	15	10	10		
17	R	0	0	0	H	+	+	+	+	+	+	R	NR	NR	25	25	15	15	10	10		
18	L	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30		
19	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10		
20	R	0	1	0	H	-	+	+	+	+	+	R	NR	NR	25	20	10	5	15	15		
21	L	0	1	1	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15		
22	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	10	15	10	10		
23	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10		
24	L	0	2	0	H	-	+	+	+	+	+	R	NR	NR	30	20	10	10	20	10		
25	R	0	0	0	H	+	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10		
26	L	0	1	0	H	+	-	+	+	+	+	L	NR	NR	25	30	10	15	15	15		
27	R	0	1	0	H	-	+	+	+	+	+	R	NR	NR	25	20	10	5	15	15		
28	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
29	R	0	0	0	H	+	+	+	+	+	+	R	NR	NR	20	20	10	10	10	10		
30	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5		
31	L	0	1	0	P	-	-	+	+	+	+	L	NR	NR	25	35	10	15	15	20		
32	R	0	1	0	H	-	+	+	+	+	+	R	R	R	30	70	15	55	15	15		
33	L	0	1	0	H	+	+	+	+	+	+	L	NR	NR	20	25	15	15	5	10		
34	L	0	1	1	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15		
35	L	0	0	0	H	+	+	+	+	+	+	L	NR	NR	25	30	10	15	15	15		
36	R	0	0	0	H	+	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10		

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S NO.	Post-operative assessment (12 weeks)																		
	Subjective A				Objective Assessment														
	ED	HL	T	OE	TFT									PTA					
					RN						WT	ABC		AC		BC		ABG	
					256Hz		512Hz		1024Hz										
					RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT
1	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10
2	0	1	1	H	-	+	+	+	+	+	R	NR	NR	30	20	20	15	10	5
3	1	1	0	H	-	+	+	+	+	+	R	NR	NR	35	20	10	5	15	15
4	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10
5	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
6	0	1	0	H	+	-	+	-	+	-	L	NR	NR	20	35	10	5	10	30
7	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	15
8	0	1	0	H	+	+	+	+	+	+	C	NR	NR	30	20	15	10	15	10
9	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
10	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30
11	1	1	0	P	-	-	-	+	+	+	R	NR	NR	35	35	10	15	25	20
12	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	10	10	15	10
13	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
14	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
15	0	1	0	H	-	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10
16	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10
17	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10
18	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30
19	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10
20	1	1	0	H	-	+	+	+	+	+	R	NR	NR	35	20	10	5	15	15
21	0	0	0	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15
22	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	10	15	10	10
23	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10
24	0	0	0	H	+	+	+	+	+	+	R	NR	NR	25	20	10	10	15	10
25	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10
26	0	1	0	H	+	-	+	+	+	+	L	NR	NR	25	30	10	15	15	15
27	1	1	0	H	-	+	+	+	+	+	R	NR	NR	35	20	10	5	15	15
28	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	10
29	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10
30	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
31	1	1	0	P	-	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25
32	0	0	0	H	-	+	+	+	+	+	R	R	R	30	70	15	55	15	15
33	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
34	0	0	0	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15
35	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	30	10	15	15	15
36	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10

S NO.	Post-operative assessment (6 months)																			
	Subjective A				Objective assessment															
	ED	HL	T	OE	TFT									PTA						
					RN						WT	ABC		AC		BC		ABG		
					256Hz		512Hz		1024Hz											
					RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT	
1	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
2	0	0	0	H	+	+	+	+	+	+	C	NR	NR	30	20	20	15	10	5	
3	0	1	0	H	-	+	+	+	+	+	R	NR	NR	35	25	15	10	20	15	
4	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
5	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
6	0	0	0	H	+	-	+	-	+	-	L	NR	NR	20	35	10	5	10	30	
7	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
8	0	0	0	H	+	+	+	+	+	+	C	NR	NR	30	20	15	10	15	10	
9	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
10	0	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30	
11	2	1	0	P	-	-	-	+	+	+	R	NR	NR	40	35	10	15	30	20	
12	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	10	10	15	10	
13	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
14	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
15	0	0	0	H	-	+	+	+	+	+	C	NR	NR	25	20	10	10	15	10	
16	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
17	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
18	0	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30	
19	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10	
20	0	1	0	H	-	+	+	+	+	+	R	NR	NR	35	25	15	10	20	15	
21	0	0	0	H	-	+	+	+	+	+	R	NR	NR	35	35	25	20	10	15	
22	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	10	15	10	10	
23	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
24	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	10	10	15	10	
25	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
26	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	10	10	15	10	
27	0	1	0	H	-	+	+	+	+	+	R	NR	NR	35	25	15	10	20	15	
28	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
29	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
30	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
31	2	1	1	P	-	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25	`
32	0	0	0	H	-	+	+	+	+	+	R	R	R	30	70	15	55	15	15	
33	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
34	0	0	0	H	-	+	+	+	+	+	R	NR	NR	35	35	25	20	10	15	
35	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	30	10	15	15	15	
36	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	

S NO.	Post-operative assessment (6 weeks)																					
	EO	**Subjective A**				**Objective assessment**																
		ED	HL	T	OE	TFT									PTA							
						RN						WT	ABC		AC		BC		ABG			
						256Hz		512Hz		1024Hz												
						RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT	RT	LT
1	L	0	2	1	H	-	+	+	+	+	+	R	NR	NR	40	20	20	15	20	5		
2	R	0	1	1	H	-	-	+	-	+	-	L	NR	NR	30	35	10	5	20	30		
3	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
4	L	0	1	0	H	-	+	+	+	+	+	R	NR	NR	25	20	10	5	15	15		
5	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5		
6	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
7	L	0	0	0	H	+	+	+	+	+	+	L	NR	NR	25	30	10	15	15	15		
8	L	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30		
9	L	0	1	0	H	+	+	+	+	+	+	L	NR	NR	20	25	15	15	5	10		
10	L	0	1	1	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15		
11	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
12	R	0	0	0	H	+	+	+	+	+	+	R	NR	NR	20	20	10	10	10	10		
13	L	0	1	0	H	+	-	+	+	+	+	L	NR	NR	25	30	10	15	15	15		
14	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10		
15	L	0	1	0	P	-	-	+	+	+	+	L	NR	NR	25	35	10	15	15	20		
16	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
17	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
18	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
19	L	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30		
20	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5		
21	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10		
22	L	0	1	0	P	-	-	+	+	+	+	L	NR	NR	25	35	10	15	15	20		
23	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
24	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5		
25	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
26	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
27	L	0	2	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10		
28	L	0	1	0	H	+	+	+	+	+	+	L	NR	NR	20	25	15	15	5	10		
29	L	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30		
30	L	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10		
31	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
32	R	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	25	15	15	10	10		
33	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10		
34	L	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20		
35	L	0	1	1	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15		
36	R	0	1	1	H	-	-	+	-	+	-	L	NR	NR	30	35	10	5	20	30		

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S NO.	Post-operative assessment (12 weeks)																			
	Subjective A				Objective assessment															
	ED	HL	T	OE	TFT									PTA						
					RN						WT	ABC		AC		BC		ABG		
					256Hz		512Hz		1024Hz											
					RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT	RT	LT
1	0	1	1	H	-	+	+	+	+	+	R	NR	NR	30	20	20	15	10	5
2	0	1	0	H	+	-	+	-	+	-	L	NR	NR	20	35	10	5	10	30
3	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	10
4	1	1	0	H	-	+	+	+	+	+	R	NR	NR	35	20	10	5	15	15
5	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
6	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
7	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	30	10	15	15	15
8	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30
9	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
10	0	0	0	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15
11	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	10
12	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10
13	0	1	0	H	+	-	+	+	+	+	L	NR	NR	25	30	10	15	15	15
14	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10
15	1	1	0	P	-	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25
16	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
17	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	10
18	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
19	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30
20	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
21	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10
22	1	1	0	P	-	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25
23	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
24	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
25	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	10
26	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
27	0	1	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10
28	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5
29	1	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30
30	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	15	10	10	10	10
31	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
32	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10
33	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10
34	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	30	10	10	10	20
35	0	0	0	H	-	-	+	+	+	+	L	NR	NR	35	35	25	20	10	15
36	0	1	0	H	+	-	+	-	+	-	L	NR	NR	20	35	10	5	10	30

S NO.	Post-operative assessment (6 months)																			
	Subjective A				Objective assessment															
	ED	HL	T	OE	TFT									PTA						
					RN						WT	ABC		AC		BC		ABG		
					256Hz		512Hz		1024Hz											
					RT	LT	RT	LT	RT	LT		RT	LT	RT	LT	RT	LT	RT	LT	
1	0	0	0	H	+	+	+	+	+	+	c	NR	NR	30	20	20	15	10	5	
2	0	0	0	H	+	-	+	-	+	-	L	NR	NR	20	35	10	5	10	30	
3	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
4	0	1	0	H	-	+	+	+	+	+	R	NR	NR	35	20	10	5	15	15	
5	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
6	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
7	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	30	10	15	15	15	
8	0	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30	
9	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
10	0	0	0	H	-	+	+	+	+	+	R	NR	NR	35	35	25	20	10	15	
11	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
12	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
13	0	0	0	H	+	-	+	+	+	+	C	NR	NR	25	20	10	15	15	15	
14	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10	
15	2	1	1	P	-	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25	
16	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	20	
17	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
18	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
19	0	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30	
20	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
21	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10	
22	2	1	1	P	-	-	+	-	+	+	L	NR	NR	25	40	10	15	15	25	
23	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
24	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
25	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
26	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
27	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
28	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	15	15	5	5	
29	0	2	0	P	+	-	+	-	+	+	L	R	R	30	60	15	30	15	30	
30	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
31	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	`
32	0	0	0	H	+	+	+	+	+	+	C	NR	NR	25	20	15	10	10	10	
33	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	25	15	15	5	10	
34	0	0	0	H	+	+	+	+	+	+	C	NR	NR	20	20	10	10	10	10	
35	0	0	0	H	-	+	+	+	+	+	R	NR	NR	35	35	25	20	10	15	
36	0	0	0	H	+	-	+	-	+	-	L	NR	NR	20	35	10	5	10	30	