A Dissertation on

A STUDY ON
FAT GRAFT MYRINGOPLASTY

Submitted to the

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfilment of the requirements

For the award of the degree of

M.S.BRANCH IV

(OTORHINOLARYNGOLOGY)

GOVERNMENT STANLEY MEDICAL

COLLEGE & HOSPITAL

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY,

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APRIL 2014

DECLARATION

I, **Dr. SRIKAMAKSHI.K**, solemnly declare that the dissertation, titled **"A Study on Fat Graft Myringoplasty"** is a bonafide work done by me during the period of December 2011 to November 2013 at Government Stanley Medical College and Hospital, Chennai under the expert supervision of **PROF. DR. T. BALASUBRAMANIAN, M.S., D.L.O.,** Professor and Head, Department Of Otorhinolaryngology, Government Stanley Medical College and hospitals, Chennai.

This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of the rules and regulations for the M.S. degree examinations in Otorhinolaryngology to be held in April 2014.

Place: Chennai-1

Date: **DR.SRIKAMAKSHI.K**

CERTIFICATE

This is to certify that the dissertation - **"A STUDY ON FAT GRAFT MYRINGOPLASTY"** presented by **DR.SRIKAMAKSHI.K,** is an original work done in the Department of Otorhinolaryngology, Government Stanley Medical College and Hospital, Chennai in partial fulfillment of regulations of the Tamilnadu Dr. M.G.R. Medical University for the award of degree of M.S. (Otorhinolaryngology) Branch IV, under my supervision during the academic period 2011-2014.

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ABSTRACT

To close perforations of the tympanic membrane till date, temporalis fascia has been the most commonly used graft material. In this study, the usage of fat as graft material to close dry small central perforations of the tympanic membrane has been evaluated. Patients between 15 - 50 years of age (both male and female) with inactive mucosal Chronic Otitis Media with small central perforations , limited to 1 quadrant of the tympanic membrane, with dry ear for atleast 6 weeks,with not more than 40dB conductive hearing loss were included in the study. Adipose tissue, of approximately twice the size of the perforation, was harvested from the posterior aspect of the lobule of the affected ear, and used to close the perforation like a dumbbell. The patients were followed up at 1 week, 2 weeks, 4 weeks, 6 weeks, 3 months and 6 months post-operatively. They were assessed for successful uptake of the fat graft in terms of closure of the perforation and mobility of the tympanic membrane and improvement in hearing by Pure Tone Audiometry.

INTRODUCTION

Perforation of the tympanic membrane is one of the most common clinical presentations in patients attending an ENT – OPD. These perforations have been classified by Saliba and others into 4 grades based on the size of the perforation; of which the management of the 1st grade of perforations (<25% of the total surface area of the pars tensa) has been discussed here.[16]

Among these, the common causes for the small sized perforations are Chronic Otitis Media, trauma and residual perforations followed previously failed tympanoplasty techniques. Additional causes among the pediatric age group are ascending infections due to adenoids, tympanostomy tube extrusion. By and large, temporalis fascia is the most commonly used grafting material used for the closure of the tympanic membrane perforations irrespective of the size. This is a study on the usage of adipose tissue (fat) for the closure of the small-sized perforations of the tympanic membrane. The advantages over conventional temporalis fascia myringoplasty were in terms of an easier and quicker operative technique which seemed to render the more cumbersome conventional procedure unnecessary for this group of patients. It was expected that fat due to some of its inherent physical properties

would serve well. Also, since there would be much less handling of middle-ear structures, lesser post-operative morbidity and a better post-operative quality of life, determined by the Chronic Ear Survey was anticipated.

To put it in a nutshell, the purpose of this study is to assess the usefulness and efficacy of fat as a graft material for the closure of small-sized tympanic membrane perforations based on certain clinically significant parameters.

AIMS & OBJECTIVES

AIM OF THE STUDY:

The aim of this study was to evaluate the usage of fat as a graft material to close small tympanic membrane perforations.

OBJECTIVES OF THE STUDY:

To assess the success of the surgery in terms of:

a) The improvement in hearing (by Pure Tone Audiometry)

b) Closure and mobility of the tympanic membrane

On closure of small central perforations of the tympanic membrane with fat as the graft material (taken either from the ear lobule or abdomen).

MATERIALS AND METHODS

Patients (male and female in the age group of 15-50 years) who attended ENT Out - Patient Department with Chronic Suppurative Otitis Media – Tubo-tympanic disease (inactive mucosal chronic otitis media) with small central perforations of the tympanic membrane (limited to one quadrant - < 30% of the total surface area of the pars tensa) with conductive hearing loss with no complications were selected for this study. 40 such patients (who satisfied the inclusion criteria) were enrolled in the study after obtaining informed and written consent.

Study design	:	Interventional Study
Study place	:	Department of ENT, Government Stanley Medical College & Hospital.
Study and Follow - up period	:	December 2011 to November 2013.
Sample size	:	40 patients
Sampling technique	:	Consecutive (non - Random) Sampling.

INCLUSION CRITERIA:

a) Small central perforation limited to 1 quadrant or occupying less than 30% of the total surface area of the pars tensa of the tympanic membrane.

b) Inactive disease(dry ear) for atleast 6 weeks

c) Age:15-50 years

d) No other foci of sepsis in the nose/throat/other ear.

e) No evidence of cholesteatoma or ossicular pathology.

f) No previous otological surgery in the ear of interest.

g) Conductive Hearing loss of not more than 40dB.

EXCLUSION CRITERIA:

a) Central perforation involving more than 1 quadrant or occupying more than 30% of the total surface of the pars tensa of the tympanic membrane, subtotal or total perforations.

b) Active disease (presence of discharge) in particular ear of interest.

c) < 15 or > 50 years of age.

d) Any foci of sepsis in nose /throat /other ear.

e) Presence of cholesteatoma or findings suggestive of ossicular pathology.

f) h/o previous otological surgeries in particular ear of interest. Conductive hearing loss of more than 40dB or presence of sensorineural component of hearing loss. Patients will be assessed clinically and audiologically (Pure Tone Audiometry) both pre- and post-operatively.

FORMULA FOR CALCULATING SAMPLE SIZE:

The sample size **'n'** (number of patients to be enrolled in the study for the results to be meaningful) was calculated using the following formula (calculated from a target population of 100 patients suffering from small central perforations of the tympanic membrane):

$$n = \frac{z_{\alpha}{}^{2} pq}{l^{2}}$$

where:

p - proportion of success expected (80% - based on review of literature[13,17,23,25,35,43,44,43])

q = (1 – p)

l - limit of accuracy (absolute precision) – taken as 10 %

$\mathbf{z_{\alpha}}$ – 1.96 (a constant)

by applying this formula (obtained from and applied in *Epi Info* database and statistics software for public health professionals) **'n'** value was arrived at as '39'. We enrolled 40 patients in our study.

EQUIPMENT USED:

1. 4mm – wide angled zero degree Hopkin's endoscopes.

2. Video equipment consisting of three chip camera.

3. Routine middle ear micro-surgical instruments such as sickle knife, Rosen's knife, pick, alligator, cup forceps, micro-suction etc.

4. High definition LED monitor placed opposite the surgeon and positioned across the patient's head.

5. Advanced Digital Dual-Channel Audiometer to perform the Pure Tone Audiometry for audiological examination of the patient pre and post-operatively.

PRE-OPERATIVE PREPARATION:

1. Xylocaine test dose was given to all patients selected for the study, using 0.1ml of 2% xylocaine which was injected into the left forearm intra-dermally, with the patient in the supine position with all emergency drugs available at hand in case of an allergic reaction to the test dose.

2. The patients were advised to take a full body and head bath the night before surgery.

3. The patients were kept nil per-oral after 10pm the night before surgery.

4. Informed and written consents were obtained prior to surgery from both the patient and his/her attendant.

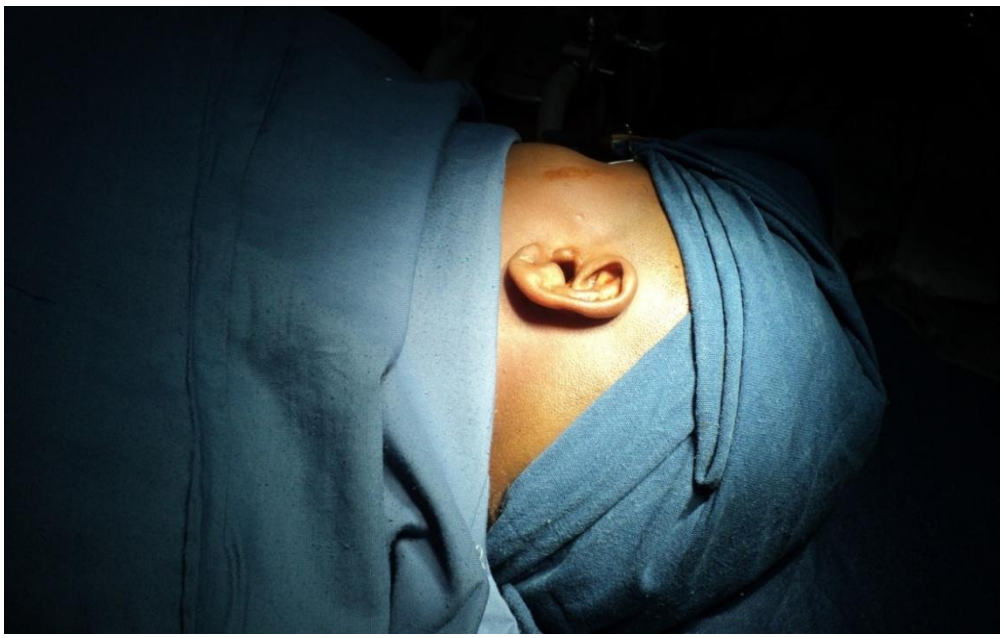
5. The patients were put on a course of antibiotics pre-operatively.

6. Patients for whom it was planned to harvest fat from the abdomen, parts were prepared appropriately.

7. The Chronic Ear Survey questionnaire was given to all patients to be filled pre-operatively and the forms preserved for comparison post-operatively.

TABLE OF INSTRUMENTS USED

AFTER PAINTING AND DRAPING



ANAESTHESIA:

General Anaesthesia with oro-tracheal intubation was preferred for patients who's co-operation under Local Anaesthesia was doubtful. However, irrespective of the technique of anaesthesia, infiltration using the formulation of 2% xylocaine with adrenaline (1 in 80,000) was utilized in the 4 quadrants of the external auditory canal and over the area of fat harvest if abdominal fat was used.

However, if ear lobule fat was used, plain 2% xylocaine solution was used for infiltration.

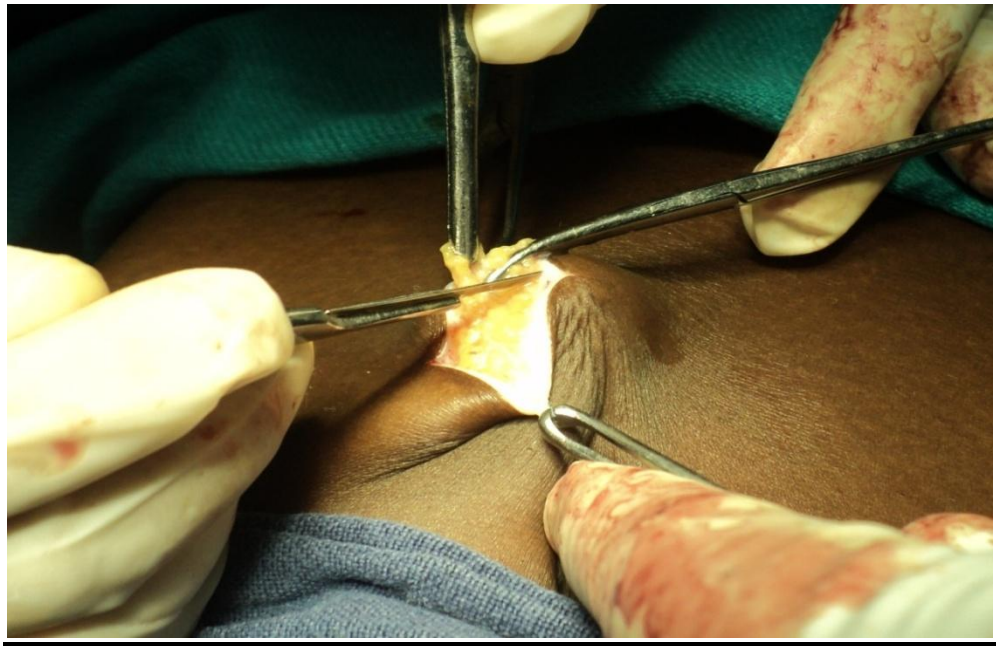
STEPS OF THE PROCEDURE:

- The patient was made to lie in supine position with head turned towards the opposite site.
- The procedure was done in most cases under local anaesthesia. In excessively anxious patients, who's co-operation under local anaesthesia was doubtful, general anaesthesia was used. Infiltration was given using premixed solution of 2% xylocaine with 1 in 80,000 adrenaline as described previously.
- Fat graft, about 2 times the size of the perforation was harvested from the posterior aspect of the lobule of the affected ear . In some patients, in whom we felt that the ear lobule fat might not be sufficient in quantity or the patient expressed cosmetic concerns, abdominal fat was used. It was generally harvested from the left iliac fossa or peri-umbilical region.

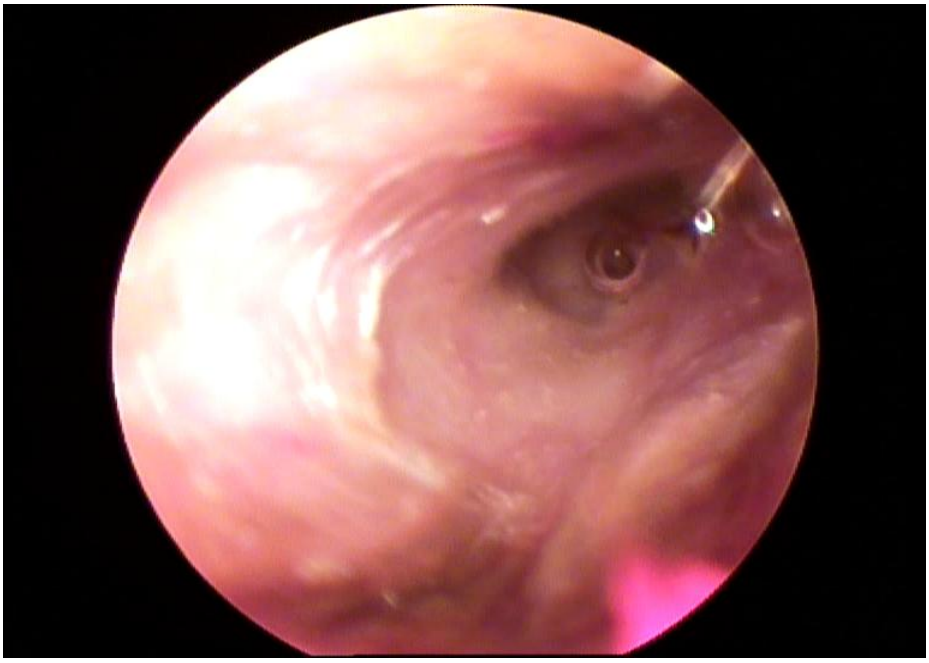
- The approach to the procedure was trans-canal (endaural/per-meatal) under endoscopic guidance. Examination On Table was done before closure of the perforation to observe the middle ear mucosa taking particular note of the eustachian tube orifice, ossicular chain status, presence of any granulation /cholesteatoma /retraction pockets.
- The margins of the perforation were freshened using a sickle knife. The fat graft was introduced into the perforation and made to fit snugly like a dumbbell after filling the middle ear with gelfoam for support. The fat graft was overlaid with gelfoam in the external auditory canal. After ensuring complete haemostasis, dressing was applied. The patient was discharged the next day if there were no other problems / complications.

EAR LOBULE FAT HARVEST

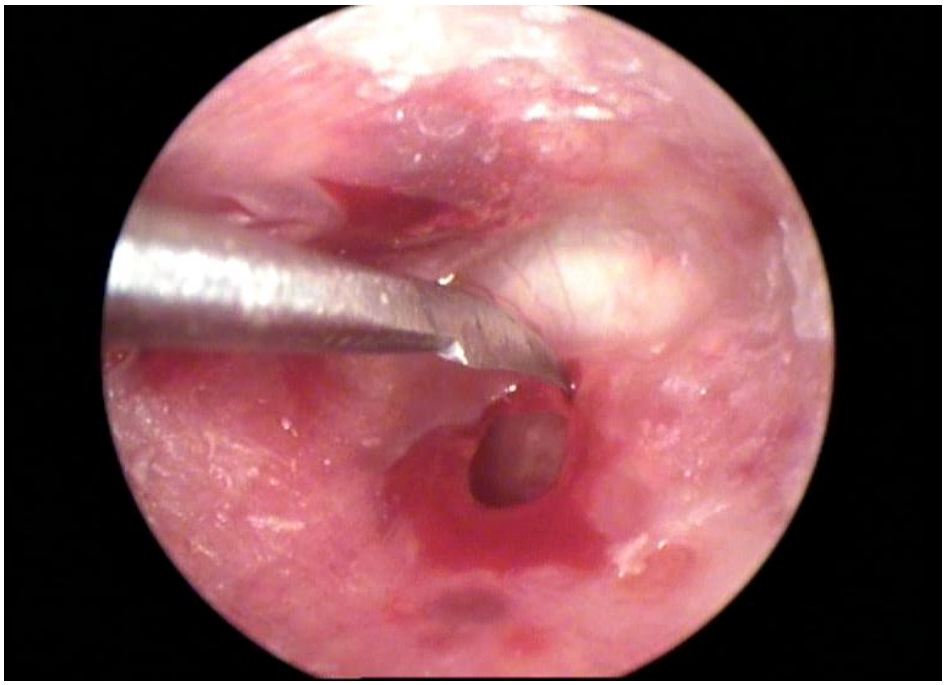
ABDOMINAL FAT HARVEST



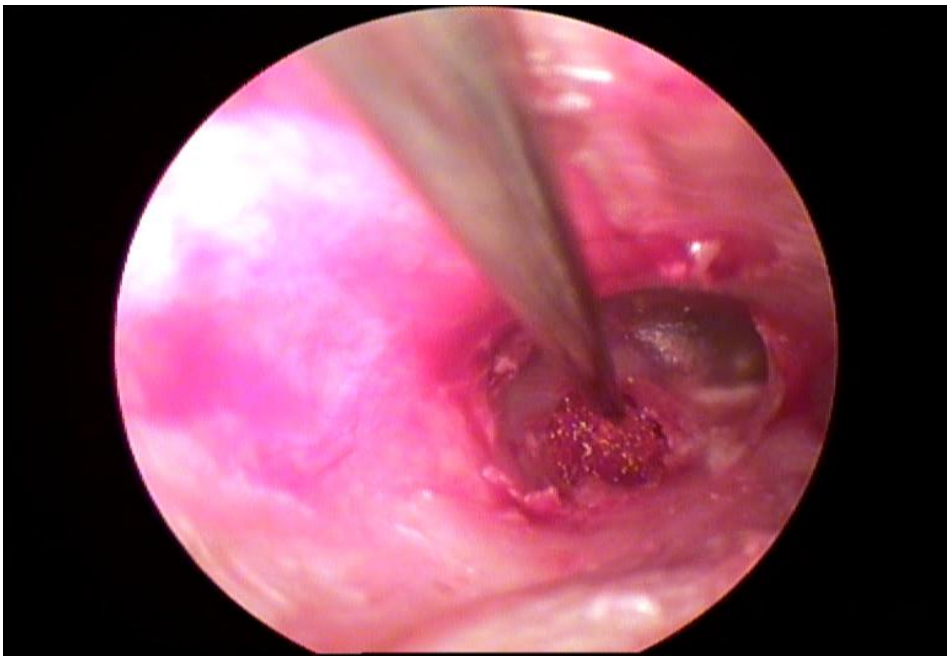
INFILTRATING THE WALLS OF EXTERNAL AUDITORY CANAL



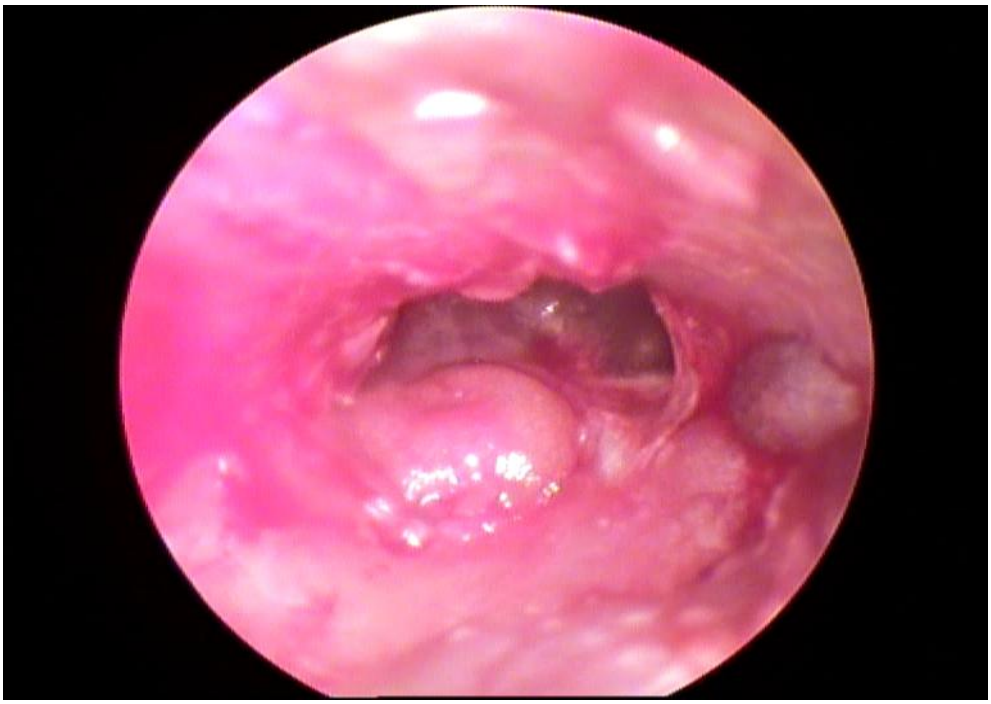
FRESHENING THE MARGINS OF THE PERFORATION



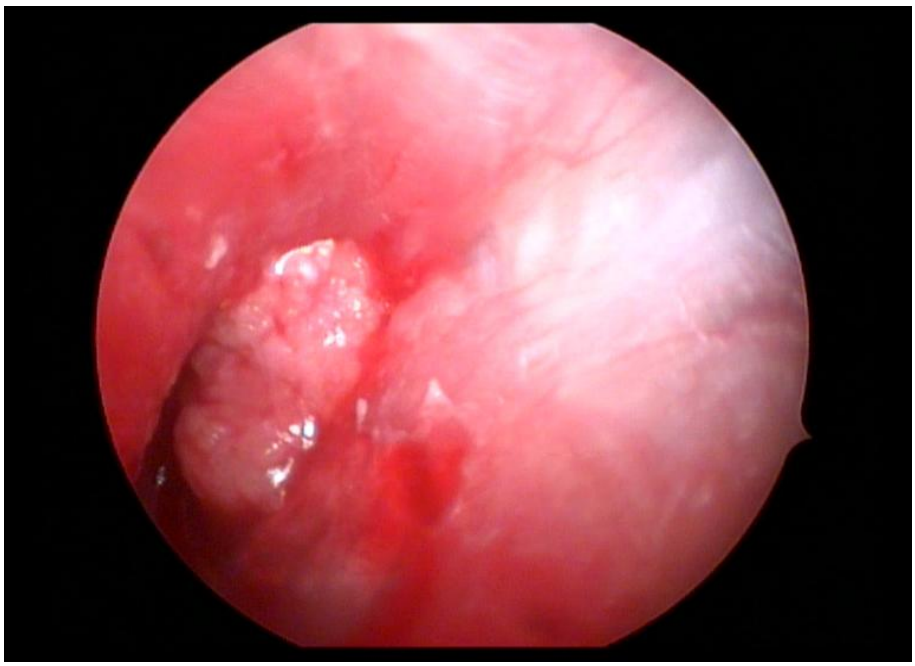
GELFOAM BEING PLACED IN THE MIDDLE EAR



EAR LOBULE FAT SNUGLY PLACED INSIDE THE PERFORATION



ABDOMINAL FAT FITTED INTO THE PERFORATION



GELFOAM SUPPORT PLACED AROUND FAT GRAFT

- The average operating time when using ear lobule fat from draping to dressing was 20 – 30 minutes. However when abdominal fat was used, the procedure seemed to take slightly more time, compared to the time taken using ear lobule fat. The difference was due to the extra time required to ensure snug fit of the abdominal fat into the perforation. Abdominal fat which is less dense than ear lobule fat needed to be piled into the perforation in greater quantity and packed tightly with simultaneous oozing out of oil from the fat which resulted in a net decrease in the fat volume. Hence the procedure seemed to be slightly more time – consuming.

POST-OPERATIVE MANAGEMENT:

The patients were put on a course of appropriate antibiotics for a week along with analgesics and antihistaminic drugs and multi-vitamins. In cases of suspected post-operative infection, antibiotics were continued for 1 more week based on culture and sensitivity reports. Only simple ear dressing was used. Gelfoam kept in the external auditory canal was not disturbed. Patients with uneventful post-operative courses (no suspicion of infection) were discharged on the 3rd post - operative day generally; and asked to come back for the 1st follow-up visit after 4 more days. Post-operatively, patients are instructed to keep the ear dry and avoid forceful nose-blowing or sneezing for atleast 4 weeks. The Chronic Ear Survey questionnaire was given to be filled by all the patients at their 6th month post-

operative visit. The responses given by the individual patient before and after surgery to each question under each sub-heading of the questionnaire was compared for an assessment of the post-operative quality of life of the patient following fat graft myrigoplasty.

FOLLOW-UP:

The patients were followed up at 1 week, 2 weeks, 4 weeks, 6 weeks, 3 months and 6 months post - operatively. He/she was assessed by oto – endoscopy on all visits for any granulation formation, graft displacement or infection and Pure Tone Audiometry at 3 months and 6 months. An advantage of this technique over conventional procedures using temporalis fascia where tympano-meatal flap needs to be elevated and the procedure is more cumbersome with a lot more meddling in the middle ear, is that many of the complaints that the patients have post-operatively following the temporalis fascia procedures such as pain, aural fullness, tinnitus are absent in fat graft myringoplasty patients post-operatively. This was evident by the lack of significant complaints and expression of subjective comfort ant ease by our study group patients at their early post-operative visits.

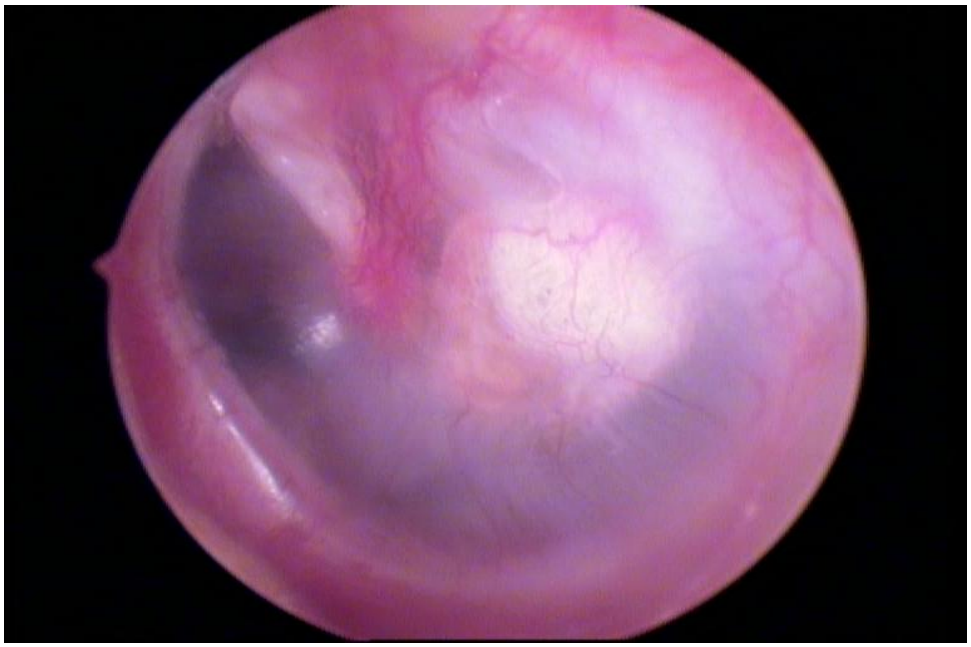
CRITERIA TO DEFINE A CASE AS HAVING A SUCCESSFUL OUTCOME:

- Closure and mobility of the reconstructed tympanic membrane as assessed by oto – endoscopy at follow up (3 months post-operatively).

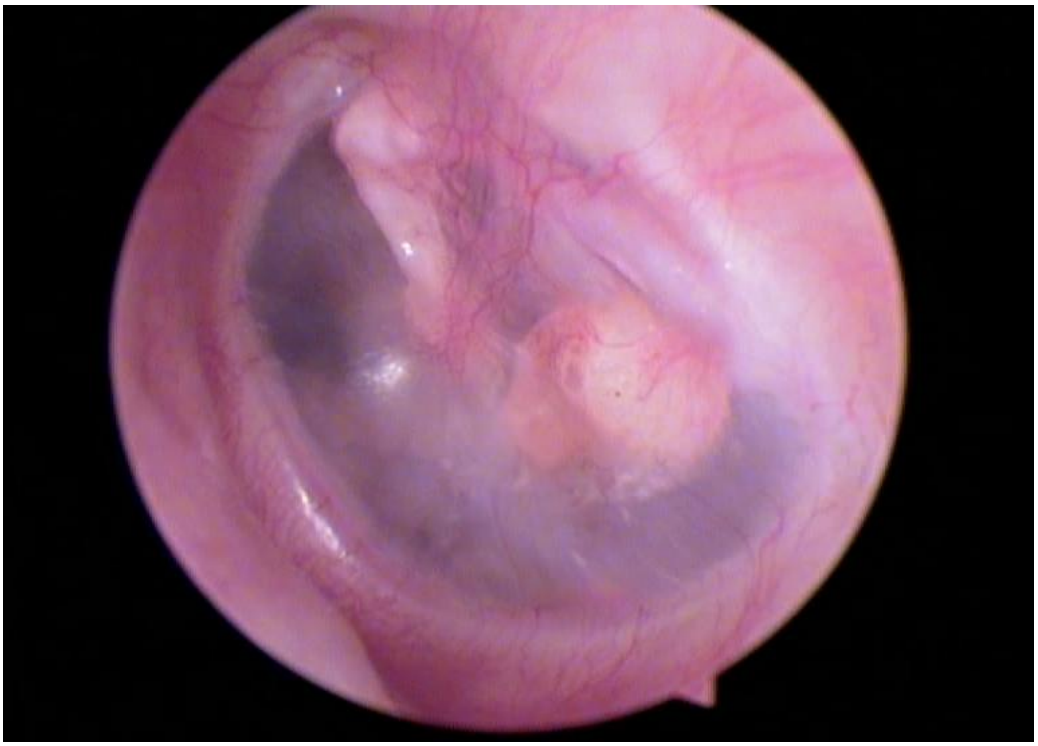
- Improvement in hearing as assessed by Pure Tone Audiometry at follow up (3 months post-operatively).

POST – OPERATIVE DAY 31

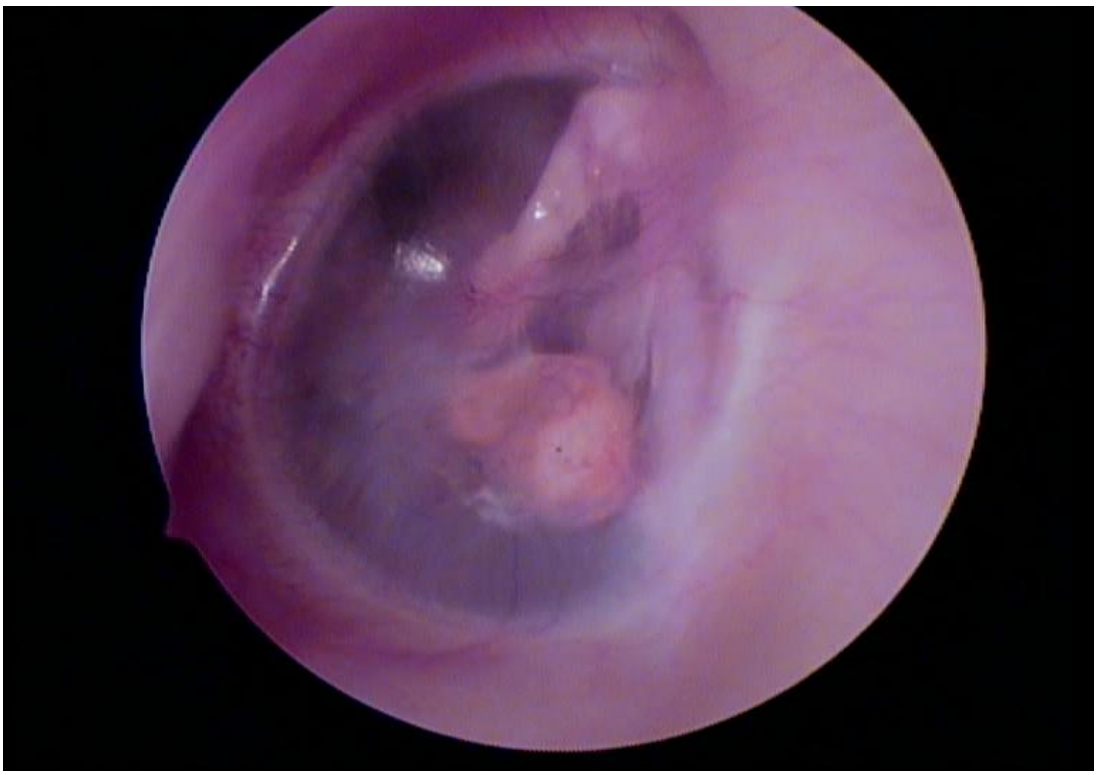
POST – OPERATIVE DAY 60



POST – OPERATIVE DAY 120

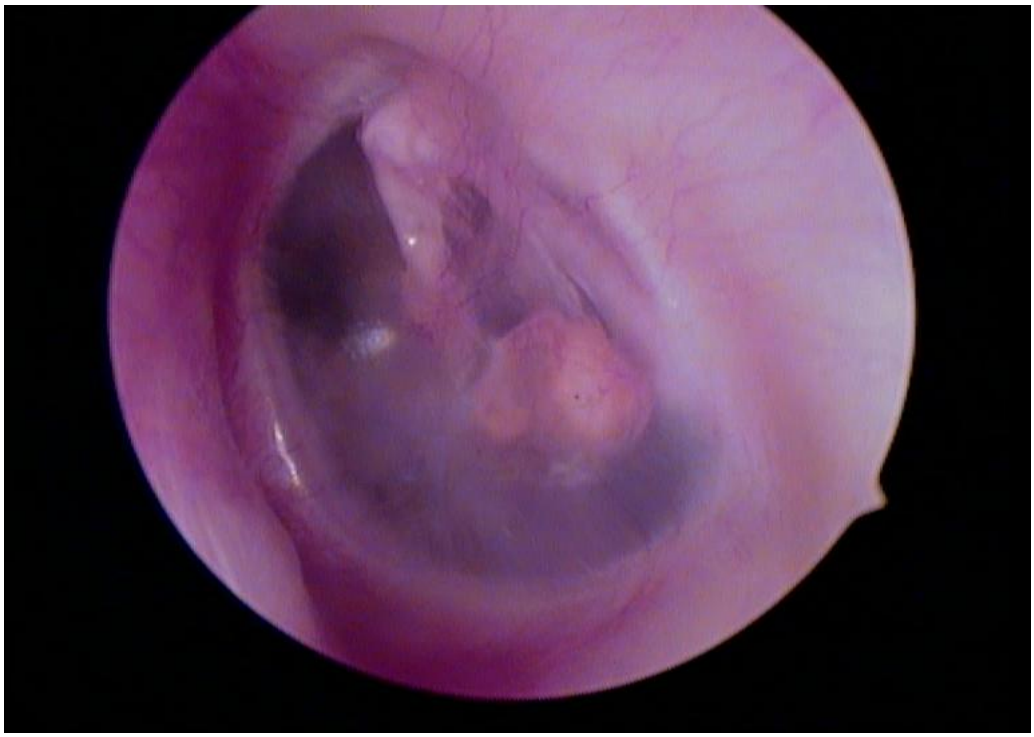


POST – OPERATIVE DAY 180

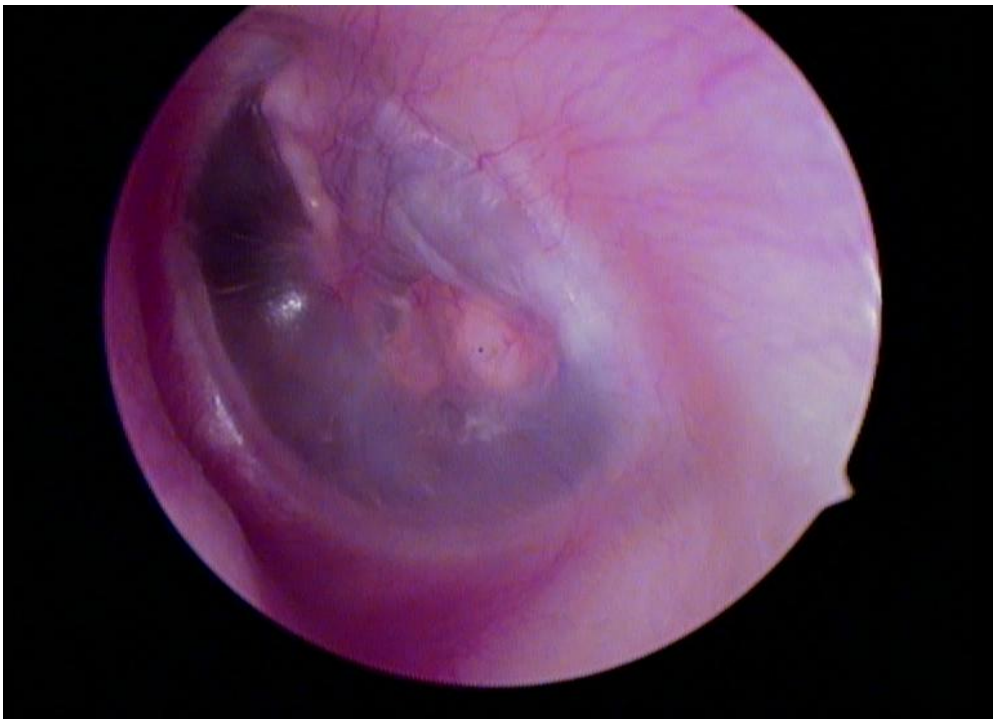


TESTING TYMPANIC MEMBRANE MOBILITY AT 3 MONTHS POST-OPERATIVELY

BEFORE VALSALVA MANUEVRE



WITH VALSALVA MANUEVRE



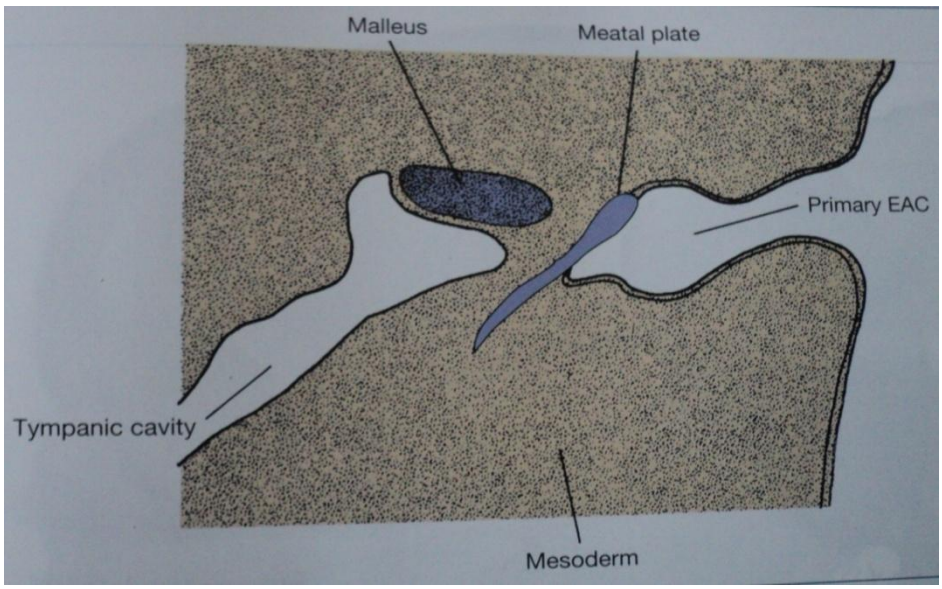
ANATOMY:

RELEVANT EMBRYOLOGY:

The development of the tympanic membrane and tympanic ring occurs in close association with the external auditory canal and the whole temporal bone. At about the 2nd month of intra-uterine life, the ectoderm of the dorsal part of the 1st branchial groove (which also gives rise to the external auditory canal) meets the endoderm of the tubo-tympanic recess (from the 1st pharyngeal pouch). There is then an ingrowth of mesoderm between these 2 structures. From the depths of the primary external auditory canal, a cord of epithelial cells grow into the mesenchyme to form the solid (meatal) plate. The fibrous layer of the tympanic membrane (the lamina propria) is formed from this mesenchyme next to the meatal plate. [1]

The tympanic ring elements fuse by about the 10th week. However, a defect remains superiorly, called the notch of Rivinus. This is associated with the concurrent growth of a solid cord of epithelial cells, which majorly gives rise to the external auditory canal. However, the cells at the medial end of the cord give rise to the superficial layer of the tympanic membrane. The inner layer of the eardrum is formed from the epithelial lining of the 1st pharyngeal pouch.

EMBRYOLOGICAL DEVELOPMENT OF TYMPANIC MEMBRANE



NORMAL RIGHT TYMPANIC MEMBRANE

ANATOMY OF THE TYMPANIC MEMBRANE

The tympanic membrane is of the shape of an irregular cone with the apex at the umbo. It is an elliptical disc shaped structure stretched obliquely at the medial end of the external auditory canal. It also forms the lateral wall of the mesotympanum and a small part of the epitympanum as well. It is broader above than below. It measures about 9 – 10 mm in diameter from postero-superior to antero-inferior and 8 – 9mm in the plane perpendicular to this. It forms an acute angle (55 degrees) with the floor of the external auditory canal in adults (in the neonate however, the angulation of the tympanic membrane is horizontal). It is fixed in the tympanic sulcus by the fibrous annulus. This tympanic sulcus is constituted by the tympanic ring. This tympanic sulcus does not extend to the roof of the canal. Apart from providing support to the tympanic membrane, this tympanic ring also functions to prevent epithelial ingrowth (which could lead to the formation of congenital cholesteatoma at the junction of the 1^{st} and 2^{nd} branchial arches). The eardrum is firmly attached to the malleus at the umbo and lateral process. It is loosely attached to the malleus by the *plica mallearis* – a thin mucosal fold in between. The tympanic membrane is divided into 2 parts – the superior pars flaccida or Shrapnell's membrane which is triangular in shape and the inferior pars tensa. The lamina propria of the pars tensa is composed of type II collagen

and is hence thin and strong. Whereas that of the pars flaccida is made of type I collagen which consists of thckers and lossely arranged collagen fibrils, and is hence more elastic in nature than the pars tensa. The boundary between these two parts is formed by *the anterior and posterior tympanic stria (malleolar folds)* which run between the lateral process of the malleus in the centre to the anterior and posterior tympanic spines respectively. The structure of the tympanic membrane is trilaminar. The outer surface is formed of squamous epithelium while the inner surface is an extension of the mucosal lining of the middle ear and mastoid air cell system (common origin from the tubo-tympanic recess). The *pars propria* made of fibrous tissue is present between these two layers. It splits at the level of the umbo to surround the distal tip of the malleus. The middle fibrous layer consists of both circular and radiating fibres of connective tissue. A condensation of the fibrous layer at the rim is called the *fibrous annulus.* From its superior limits, the fibrous annulus runs centrally towards the lateral process of the malleus as the anterior and posterior malleolar folds.

Sensory nerve supply to the lateral surface of the tympanic membrane is similar to that of the external auditory canal. The posterior and inferior parts of the tympanic membrane is supplied by the auriculo-temporal nerve, while the anterior and superior parts are supplied by the auricular branch of the vagus (Arnold's nerve) and

some fibres from the seventh cranial nerve. The medial aspect of the tympanic membrane is supplied by the tympanic branch of the glossopharyngeal nerve (Jacobson's nerve).

The blood supply to the eardrum is from vessels that supply the middle ear and the external auditory canal. The vessels lie in the connective tissue layer of the lamina propria. The deep auricular branch of the internal maxillary artery forms a peripheral ring, branches from which supply the lateral surface of the tympanic membrane. The medial surface of the tympanic membrane is also supplied by the internal maxillary artery through its anterior tympanic branch and also by the stylomastoid branch of the posterior auricular artery, posteriorly. Twigs from the middle meningeal artery also supply the tympanic membrane. Venous drainage parallels the arterial supply. The veins drain into the transverse sinus, dural sinus, external jugular vein and plexus around the Eustachain tube.

THE 3 LAYERS OF THE TYMPANIC MEMBRANE:

The outer epidermal layer: This is continuous with the skin of the external auditory canal. It is composed of 4 layers:

Stratum corneum

Stratum granulosum

Stratum spinosum

Stratum basale

The lamina propria: This layer is more prominent in the pars tensa. It is made up of an sub-epithelial connective tissue layer, a sub-mucosal connective tissue layer, an outer radiate collagenous layer and an inner circular collagenous layer. The arrangement of these fibres is random in the pars flaccida. However in the pars tensa, the outer fibres are arranged radially while the arrangement of the deeper fibres is circular/parabolic/transverse.

Inner Mucosal Layer: In the pars tensa, the cells are low cuboidal or squamous or ciliated columnar type. These ciliated cells are however not found to be present in the pars flaccida.

RELEVANT PHYSIOLOGY:

Sound signals need to be transmitted from the air of the external environment to the fluids of the inner ear. It has been estimated that there is a loss of about 30dB at this air-fluid interface. It is the function of the external and middle ears to reduce this loss and improve the sound (pressure) conducted to the inner ear. The middle ear does this function through the action of the tympanic membrane and the ossicles. This is called the *transformation of sound power.*[1]

The major transformer mechanism for this is the ratio of the tympanic membrane to the stapes footplate (the area ratio). This contributes about 26dB gain.

The other transformer mechanism is the ossicular lever. This is however responsible for only about 2dB gain.[26]

Hence by these 2 transformer mechanisms, it was postulated that the theoretical *middle ear sound pressure gain* should be about 28dB. However, measurements of actual middle-ear sound-pressure gain revealed that the gain was only about 20dB maximum, at a frequency fo 1000 Hertz, with lesser gains at other frequencies. The reasons for this difference were arrived at as:

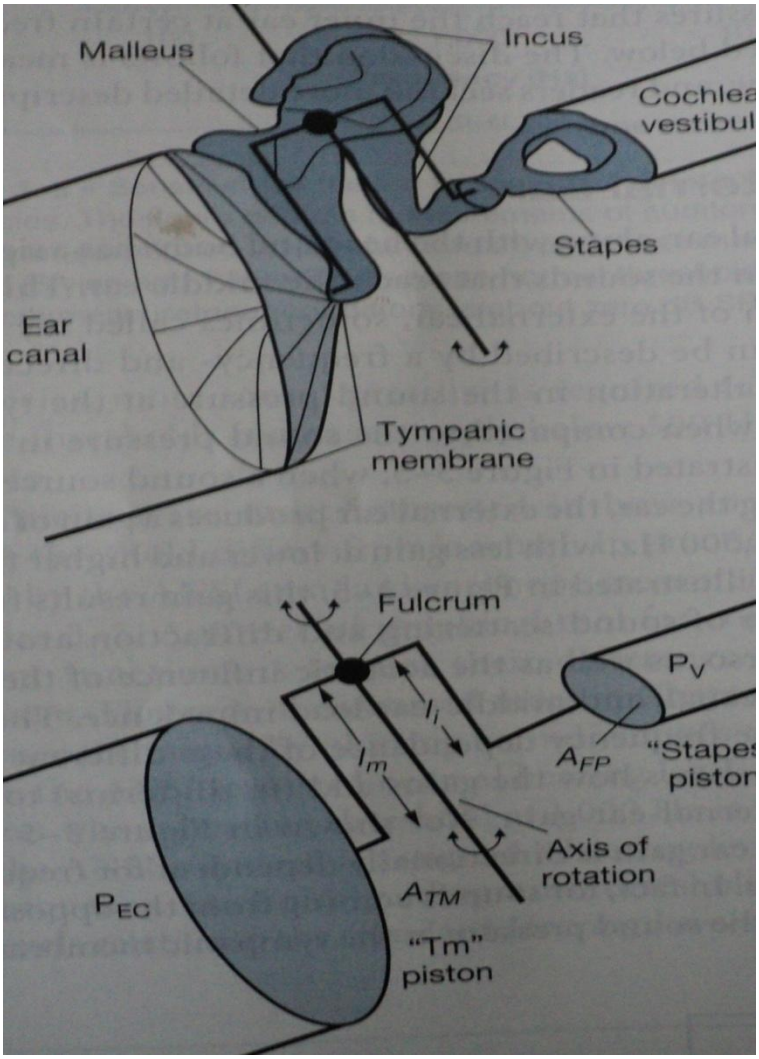
- The entire tympanic membrane does not move as a rigid body. At lower frequencies, the entire tympanic membrane moves with the same phase. But at higher frequencies, the vibrating pattern of the eardrum becomes more complicated with different parts of the tympanic membrane vibrating as separate portions with different phases. This reduces the efficacy of sound coupling of the tympanic membrane.

- There is loss of energy, to stretch the tympanic membrane and ossicular ligaments, and to accelerate the mass of the middle-ear components.

- Slippage in the movement of the ossicles.

The effective essential stimulus to the inner ear is the difference in the sound pressure between the two cochlear (oval and round) windows. This is done by preferential increase in sound pressure at the oval window by the tympano-ossicular system. Also, the intact tympanic membrane shields and protects the round window from the sound pressure in the external ear.

THE MIDDLE EAR SOUND TRANSFORMER



ROLE OF EAR DRUM IN SOUND CONDUCTION:

The ear drum conducts sound from the external ear to the middle ear. Bekesy postulated that the ear drum moved like a stiff plate up to frequencies of 2 kHz. He also suggested that the inferior edge of the drum is flaccid and moves the most. At frequencies above 6 kHz the vibrating pattern becomes more complex and chaotic. This reduces the efficiency of sound transfer mechanism.

The handle of the malleus is attached to the centre of the ear drum. This allows sound vibrations on any portion of the ear drum to be transmitted to the ossicles.

The ossicles of middle ear are suspended by ligaments in such a way that the combined malleus and incus acts a single lever, having its fulcrum approximately at the border of the ear drum.

The tympanic membrane contributes to round window protection and acoustic separation of the round window from the oval window by preferential transmission of sound impulses by the tympanic membrane through the ossicular system to the oval window.

CONTRIBUTION OF THE EARDRUM TO THE IMPEDANCE TRANSFORMER:

The surface area of ear drum is about 55 mm2; whereas the surface area of the stapes is about 3 mm2.

The surface area of the tympanic membrane hence is anatomically 20-fold greater than that of the stapes footplate. However, it is the central 2/3rd of the total surface area of the tympanic membrane that vibrates. Hence this works out to a 14-fold higher effective surface area of the tympanic membrane over the stapes footplate. The tympanic membrane gathers force over its entire surface and transmits this to the smaller area of the footplate of stapes. This causes an increase in the pressure at the level of foot plate of stapes.

The forces collected over the ear drum are concentrated on a smaller area, so that the pressure at the oval window is increased.

Buckling effect of ear drum : The ear drum curves from its rim to its attachment to the manubrium. The buckling effect causes greater displacement of the curved ear drum and less displacement for the handle of the malleus. This causes high pressure low displacement system. Transmission of low frequency sounds is affected by the elastic stiffness of various components of the middle ear

cavity. The ligamentous structure contributing maximally to this is the annular ligament. It actually fixes the foot plate of stapes circumferentially to the oval window. It has been found to contribute to the stiffness of the system to low frequency sounds (<500Hz). When the ear drum moves in response to sound waves, air inside the middle ear cavity gets compressed which in turn reduces the movement of the ear drum. This effectively dampens conduction of low – frequency sounds. Above a frequency of 200 Hz, the movement of the eardrum gets broken into separate zones. This break up becomes more significant with increase in the sound frequency. This in turn reduces the coupling of vibrations of the ear drum to the stapes. Whenever there is middle ear damage (in the form of tympanic membrane perforations in our case); sound transmission gets affected in terms of :

Improper coupling of the tympanic membrane to the ossicles.

- *Round window Baffle* : Differential sound pressure levels at the round and oval windows may get affected. This pressure differential is extremely important in order to set the cochlear fluids moving.

ETIOLOGY OF TYMPANIC MEMBRANE PERFORATIONS:[1,4,9,13,25]

INFECTIOUS CAUSES

- Episodes of acute otitis media.
- The perforation usually heals once the underlying condition is treated and resolves.

TRAUMATIC CAUSES

The type of trauma that has resulted in a perforation of the tympanic membrane may be:

- Blunt trauma
- Penetrating injuries - self-inflicted (wax removal)
- Barotrauma - caused by deep sea diving / rapid airplane descent / hyperbaric oxygen therapy
- Blast injuries
- Slap injuries - encountered in cases of assault and aquatic sports accidents. Here a column of compressed air of sufficient pressure is generated within the external auditory canal that causes implosion of the tympanic membrane.
- Thermal injuries - poor healing rates due to tissue necrosis

IATROGENIC CAUSE

The most common iatrogenic cause for a perforation of the tympanic membrane is ventilating tube insertion. This is most commonly done for children suffering from otitis media with effusion. It has been reported to occur in 4.6% of the patients following a tympanostomy. Larger the tube diameter, and longer the retention time, higher is the risk of a chronic perforation. It can also occur in adults when the same procedure is done for drug instillation (example steroid, gentamycin) into the middle/inner ear for therapeutic purposes.

RESIDUAL PERFORATIONS

The most common causes for residual perforations following tympanoplasty / myringoplasty procedures are an unidentified / neglected upper respiratory tract infection or allergy, inadequate Eustachian tube function and anatomic factors, such as a bulge of the anterior canal wall which interfered with a satisfactory view of the anterior rim of the perforation / anterior annulus sulcus.

More than 90% of traumatic tympanic membrane perforations heal spontaneously within 3 months. The epithelial migration patterns of the tympanic membrane which helps remove desquamated epithelial cells and keratin debris is responsible for this excellent healing property of the tympanic membrane. This epithelial migration has been found to start from the region of the umbo and proceed centripetally.

Whenever there is an acute injury, platelets aggregate to cause vasoconstriction and form a thrombus. An inflammatory response follows with inflow of macrophages, neutrophils and bioactive cytokines to the site of injury. The growth of squamous epithelium across the perforation is facilitated by the formation of a matrix of glycosaminoglycogens and proteoglycans. This serves as a scaffold for the growth of the mucosal and fibrous layers of the tympanic membrane (neotympanum).

PATHOPHYSIOLOGY OF TYMPANIC MEMBRANE PERFORATIONS:

Acute perforations usually start healing by 12 hours, initiated by the proliferation of squamous cells at the edges of the perforation. At the end of the healing process, a neo-tympanum is formed, which is thinner than normal tympanic membrane because of the absence of the middle fibrous layer. When this epithelial growth fails to occur across the perforation, a chronic Perforation results.[1]

PATHOLOGY:

A permanent small central perforation of the tympanic membrane is a type of Chronic Inactive Otitis Media without any concurrent infective or inflammatory process in the mastoid or middle ear. The perforation is surrounded by normal residual tympanic membrane around its entire rim.[1] Usually, the junction of

the mucosa of the medial tympanic membrane layer and the outer squamous epithelial cell layer meet at the edge of the perforation. Sometimes, the epithelial cells migrate medially across the edge of the perforation. Although the cause for such migration still remains unknown, such migration has important clinical consequences. If these medially migrated epithelial cells are not removed during surgical repair of the tympanic membrane, an iatrogenic cholesteatoma can result.

HISTOLOGY OF TYMPANIC MEMBRANE PERFORATIONS:

Squamous epithelium extends medially across the edge of the perforation. Hyaluronan, fibronectin,, epidermal growth factor and other glycosaminoglycogens which play an important role in wound healing, are present scantily in chronic tympanic membrane perforations, which is probably responsible for the arrest of healing and failure to close spontaneously. Hence, complete removal of the perforation rim befor placing the graft is extremely important to prevent epithelial entrapment within the middle ear. It has been found in experimental animal studies, that the first layer to close a tympanic membrane perforation is the epidermis. Fibrous layer healing is secondary. Also, the vascular distribution in the ear drum determines the site of response in this fibrous layer. This process usually starts by 48 hours and is done by 9 days. The epithelial lining of the neotympanum is not formed by in-situ proliferation, but

by migration from the periphery. This is accounted for by the absence of basal cells in that layer in the neotympanum. Studies have demonstrated that epidermal growth factor, heparin and hyaluronic acid improve the rate of healing and quality of the scar in chronic tympanic membrane perforations.[1]

Saliba's classification of tympanic membrane perforations reported in 2008:[32]

- grade I, small (for perforations <25% of the TM surface);
- grade II, medium (for perforations 25%-50% of the TM surface);
- grade III, large (for perforations >50%-75% of the TM surface); and
- grade IV, total (for perforations >75% of the TM surface).

ACOUSTICS AND MECHANICS OF TYMPANIC MEMBRANE PERFORATIONS:

In patients having perforations of the tympanic membrane, the fenestra cochleae starts playing a more active, but troubling role in the mechanics of sound transmission and hearing. This is because a perforation of the ear drum, removes protection for the round window from sound which results in sound reaching both fenestrae nearly simultaneously, thus cancelling the resulting movements of the perilymph.

Conductive Hearing Loss ranging from negligible to 50dB can be caused by tympanic membrane perforations. The primary mechanism by which conductive hearing loss is caused by tympanic membrane perforations is due to loss in the sound-pressure difference across the tympanic membrane. The primary drive for the movement of the tympanic membrane and ossicles is provided by this sound - pressure difference across the eardrum. Perforations can also induce some physical changes in the tympanic membrane such as:[1]

- Reduction in the area of the tympanic membrane
- Changes in coupling of tympanic membrane motion to the malleus

The hearing loss caused by a perforation depends on :

The size of the perforation
The frequency of the sound
Middle-ear air-space volume

The hearing loss induced by a perforation is highest at lower frequencies. With increase in frequency, the hearing loss generally decreases. Also, larger the perforation, greater would be the hearing loss. The middle - ear air - space (combined volume of the middle ear and mastoid air) also determines perforation induced hearing loss: lesser the volume, greater the air-bone gap. Two different ears with identical perforations can have different conductive hearing loss

values by 20-30 dB if there is significant difference in the middle - ear air - space volume. Hence a perforation with a very sclerotic mastoid will produce a greater air-bone gap than when the mastoid is well-pneumatized. Also, the air-bone gap in a dry perforation is lesser than that in a wet and draining perforation. This is because, when there is an infection, the volume of middle ear and mastoid air is lesser than in the dry state. Experimental and clinical studies have shown that there is no statistically significant difference in the air-bone gaps caused by different location of identically-sized perforations. It has been hypothesized that this clinical perception of difference in hearing loss caused by perforations of same size in different location is actually caused by differences in the volume of the middle ear and mastoid air between the 2 ears.

MANAGEMENT OF TYMPANIC MEMBRANE PERFORATIONS:[1]

EXPECTANT MANAGEMENT is a good plan as there is a high probability of spontaneous closure of the perforation.

EARLY INTERVENTION helps patients return to their jobs and usual lifestyles quickly and also helps in the faster resolution of hyperacusis.

USE OF OTOTOPICAL MEDICATION in the face of an uncomplicated/dry perforation is not encouraged. This is because the

wet environment induced by the topical drug would impair fibroblast proliferation which in turn would adversely affect the healing process. Also, there is the risk of ototoxicity to be considered.

MYRINGOPLASTY:

This term was first used by Wullstein in 1953 to describe the surgical reconstruction of the middle ear mechanisms that had been destroyed or impaired by suppurative disease. Myringoplasty has been defined by Wormald as the surgical closure of perforations of the tympanic membrane without any ossicular reconstruction.[45] Most authors consider myringoplasty as a surgical technique for the repair or reconstruction of the tympanic membrane. It is also often referred to as type 1 tympanoplasty, which is not very accurate.

HISTORY OF MYRINGOPLASTY:[2,32]

The history of myringoplasty dates back to 1640 when Banszer attempted to close tympanic membrane perforations using a small tube of elk horn surrounded by pig's bladder.

In 1878 , *Berthold* used full thickness skin graft as grafting material and also coined the term **"myringoplastik".**

Similar procedures were attempted by *Ely in 1881 and Tangemann in 1884.*

In the 1950s, techniques of tympanoplasty were introduced by *Zollner and Wullstein*for the treatment of patients affected by otitis media. Initially *skin* was the material of choice to close tympanic membrane perforations.

Later:

In 1954, *amniotic membrane* was used by Schrimpf.

In 1956 Hall used *autologous mucous membrane of the cheek* as grafting material.

In 1958, Holewinski tried using *cornea.*

In 1959, Claros - Domenech checked out *periosteum.*

In 1960, Shea used *vein graft.*

In 1964, Portmann and others attempted closing tympanic membrane perforations using *connective tissue.*

Originally *"onlay"* technique was practised. *"Underlay"* technique was introduced by Shea and Austin in 1961, modified and improved further by Hough in 1970. *Sandwich and plugging techniques* (like Fat Graft Myringoplasty) came into vogue in some centres for the closure of small – sized tympanic membrane perforations.

It was in 1962 that Ringerberg conducted a study with *adipose tissue* as grafting material.

Goodhill in 1963, used *perichondrium.*

In 1959, Ortengren and later Storrs resorted to *fascia.*

There was a simultaneous trend developing towards the usage of

ALLOGRAFTS:

In 1961, Preobrazkensky tried out *Dura.*

Tympanic membrane itself was studied independently by 3 doctors as possible grafting material, namely:

1964 – Chalat

1966 – Marquet and

In 1970 – Betow.

HISTORY OF FAT GRAFT MYRINGOPLASTY:[15]

Coming to the topic at hand, the first attempt to use fat in perforation closure of tympanic membranes is attributed to *Jordan C Ringerberg*. This method of repair of small tympanic membrane perforations was confirmed by Sterkers in 1964 with the use of compressed abdominal fat. It was again later reconfirmed by Terry et al and Gross and others.

PRINCIPLE OF MYRINGOPLASTY:

It is based on the concept that the graft material will provide a base for the migration of epithelium. The squamous epithelium that has grown around and beneath the margins of the perforation is excised. The remaining opening is then covered with the grafting material which promotes epithelialisation. The graft should provide a matrix into which angiogenesis can take place and epithelium can spread on its surface. The source of this new epithelium is usually the basal cells of the squamous layer of both the medial aspect of the external auditory canal skin and the tympanic membrane.

An ideal myringoplasty technique should :[1]

a. Restore sound protection to the round window.

b. Restore the vibratory area of the tympanic membrane which would in turn improve hearing and reduce tinnitus.

c. Restore the sound pressure transformation to the oval window by connecting the substituted graft material to the stapes footplate through an intact ossicular chain.

d. Reduce the susceptibility and incidence of middle ear mucosa to infection from the external auditory canal.

MYRINGOPLASTY TECHNIQUES

LOCAL ANAESTHETIC INFILTRATION:

This is done using a premixed solution of 2% xylocaine with 1 in 80,000 adrenaline in our centre.

The tympanic branches of the auriculo-temporal nerve which supply the anterior meatal wall and tympanic membrane are blocked by infiltration into the anterior meatal wall at the junction of the bony and cartilaginous external auditory canal. Infiltration can also be given to the region of the incisura terminalis to block the auricular branches of this never that supply the upper part of the auricle and skin above the meatus.

The branches of the greater auricular nerve to the auricle and meatus are blocked by infiltration at several points behind the auricle over the mastoid process.

The auricular branch of the vagus is blocked by injection of the periosteum of the anterior surface of the mastoid process and skin of the floor of the meatus.

SURGICAL APPROACHES FOR MYRINGOPLASTY:

1. Postaural
2. Endaural (Transcanal)
3. Endomeatal
4. Transmeatal

Among these, the post-aural and endaural approaches are commonly used.

Indications for the Endaural (Transcanal) approach are:

1. Small or medium sized perforation
2. Wide canal with good visibility of the anterior end of the canal

SUITABILITY OF FAT FOR MYRINGOPLASTY:[13,15,32,34,45]

The effectiveness of fat as graft material in myringoplasty has been described in detail by Ringenberg.[32] He studied the properties of fat in 3 locations - earlobe, abdomen and buttocks. He arrived at the conclusion that ear lobule fat is the best in type if the 3 as it is most dense, with the fat cells more compactly arranged with more quantity of connective tissue. This permits better growth of the mucosal and epithelial layers of the tympanic membrane. However, the quantitiy of ear lobule fat may not be sufficient to close larger sized perforations. Fat in the region below the mastoid tip and behind the sterno-cleido mastoid muscle can also be used. While temporalis fascia is only an inert support for perforation closure, fat represents a good source of revascularisation for the neotympanum. Adipogenesis always followed the angiogenesis. Fat also promotes revascularisation of the non-vascular areas and cicatrisation. These

properties are due to the secretory nature of the adipose cells which produces a lot of metabolites and proteins. During the process of spontaneous healing of tympanic membrane perforations, there tends to be a continuous inflow of epithelial cells from the outer squamous layer of the external auditory canal and tympanic membrane remnant. Fat provides the supportive matrix for the influx of reparative cells and nutrients. Angiogenesis to the fat graft can be divided into 3 categories depending on the source of blood supply : from the handle of malleus, tympanic rim and mixed with equal distribution from both sources. Gelfoam placed in the middle ear helps prevent any adhesion formation between the fat graft and promontory mucosa. The fat generally loses 50% of its bulging by the 2^{nd} post-operative month. 45% of the remaining is lost by the 4^{th} post-operative month; and by the 6^{th} month, all that remains is a small stain of the fat graft over the tympanic membrane thickness. It has been found that the fat cells atrophy while the connective tissue strands persist as a scaffold for the migration and growth of squamous epithelium and mucosa over it. The neotympanum including the grafted areas are freely mobile post-operatively. For this procedure, fat of appropriate size needs to be harvested (about twice the size of the perforation). If the fat is oversized, it may cause a tear in the perforation or undue stretching of the margins of the perforation which could lead on to necrosis or atrophy later. An undersized fat graft may result in a dehiscence.

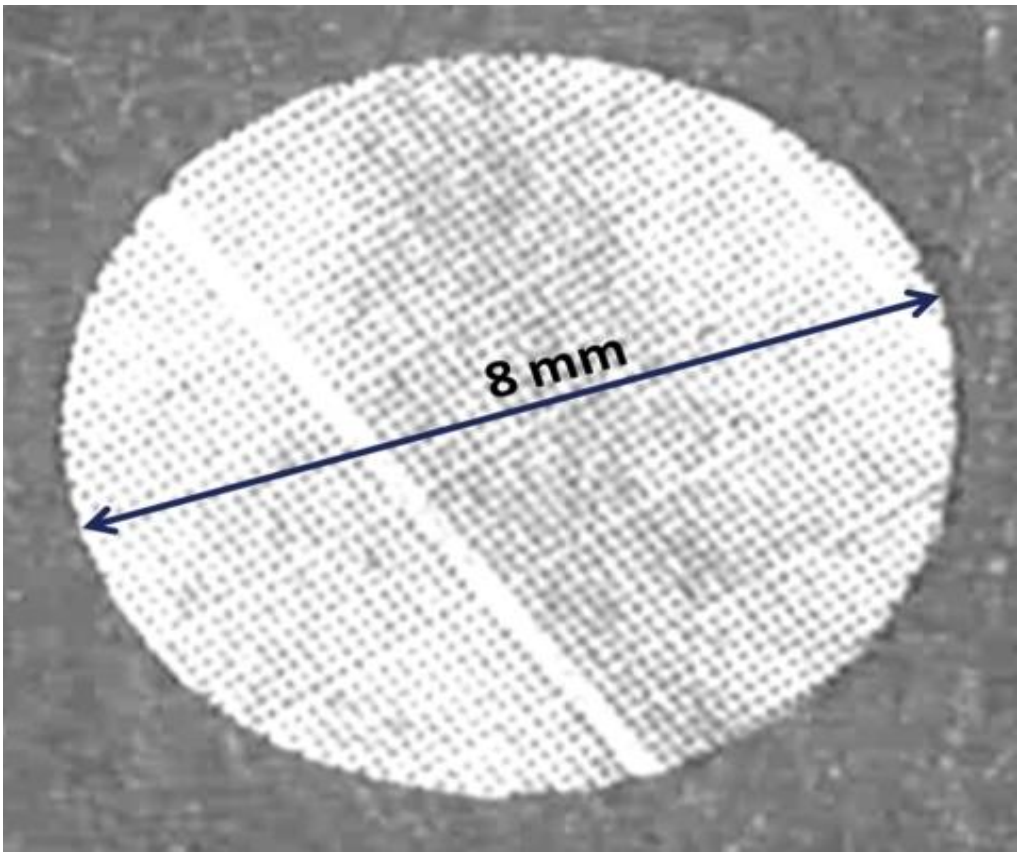
Clinical criteria published by Fiorio and Barbieri , for the selection of cases for fat graft myringoplasty: [45]

1. Period of time elapsed from previous surgery should be equal to or longer than 6 months.
2. Perforation of the pars tensa that is no larger than 5 mm.
3. Non-marginal localization, i.e. not involving the annulus or exposing the malleus handle.
4. Absence of calcific plaques or atrophic areas adjacent to the perforation.
5. Normal appearance of mucosa of the tympanic cavity.
6. Absence of any acute inflammation.
7. Absence of discharge from the middle ear in last 3 months.
8. No evidence of cholesteatoma.
9. No planned ossicular reconstruction.
10. Absence of major Eustachian tube dysfunction.

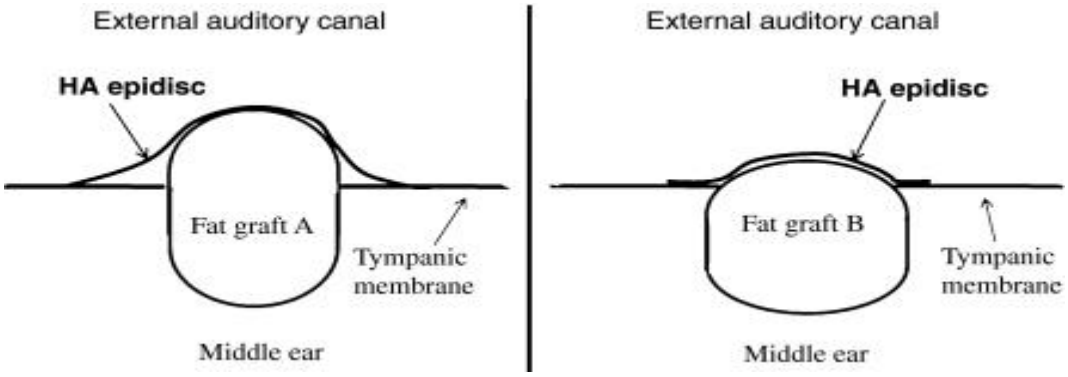
ADDITION OF HYALURONIC ACID TO THE FAT GRAFT:[15,32]

The addition of hyaluronic acid to the at graft has been shown to significantly improve the success rate of myringoplasty; such that it becomes independent of the size of the perforation; and

comparable to the overlay and underlay techniques of myringoplasty. It is a non-toxic material. Hyaluronic acid (which is available as a transparent otologic lamina) prevents dehydration of the perforation margins and promotes centripetal migration of the epithelial cell layer over the fat support. It also has a role to play in the healing regulation pattern of the fibrous layer. All this activity occurs during the angiogenesis phase (before adipogenesis). This hyaluronic acid which is safe and biodegradable, tends to dissolve completely within 2 months time. Hence its use alone as a graft material has been a failure. The perforation has been found to persist , while the hyaluronic acid graft has disappeared, within 2 months time. For the use of hyaluronic acid fat graft, it is imperative that the margins of the perforation are visible all around. If the anterior rim of the perforation is not clearly visualised, HAFGM would not be a suitable procedure. Many of the complications that are commonly encountered with the conventional underlay and overlay techniques such as medialisation / lateralisation of the graft, blunting of the anterior sulcus, formation of epithelial pearls are minimal with HAFGM. An intimate contact between the hyaluronic acid epidisc, fat graft and epithelial remnant all around the margins of the perforation is necessary. However there should not be any excessive pressure from gelfoam placed laterally, as this could impede epithelial migration.



Epidisc otologic lamina



Improper and correct placement of fat graft and Hyaluronic acid epidisc over perforation

CHEMICAL MYRINGOPLASTY : [1]

Suitable for small central perforations of the tympanic membrane. Under vision, the edges of the perforation are cauterized using trichloroacetic acid. This procedure destroys the squamous epithelium that has grown across the rim of the perforation. As a result, the fibroblasts get exposed and this promotes healing of the lamina propria. Silver nitrate can also be alternatively used.

UNDERLAY TECHNIQUE:[1]

The tympanomeatal flap is elevated including the fibrous annulus, and the graft (usually temporalis fascia) is placed medial to the tympanic membrane remnant and annulus and malleus manubrium.

ONLAY TECHNIQUE[1]

Very technically demanding procedure. The outer epithelial layer of the tympanic membrane alone is elevated along with the skin of the external auditory canal. The fibrous annulus is left in-situ. The graft is placed lateral to the tympanic annulus and medial to the malleus manubrium. This technique carries the inherent risks of anterior sulcus blunting and lateralization of the graft, both of which can cause conductive hearing loss to a significant degree. Other risks include delayed healing and the formation of epithelial pearls due to inability to remove the squamous epithelium of the tympanic membrane remnant and external auditory canal completely.

INTERLAY TECHNIQUE

Here the graft material is placed between the middle fibrous and inner layer of the tympanic membrane. It is not a routinely practised procedure as it is very difficult to perform.

OTHER GRAFTING MATERIALS:

The most commonly used grafting material in myringoplasty istemporalis fascia.

In 1970, Moon introduced the usage of the **areolar tissue superficial to the temporalis fascia** for this procedure. It has also been highly recomended by Glasscock due to its location in a relatively avascular plane which results in minimal bleeding during its harvest. It is also more comfortable to handle and even in cases of failure, the temporalis fascia still remains to be used. Tragal cartilage and its perichondrium. Aural cartilage and its perichondrium.

Myringoplasty with two layers of tissue (temporalis fascia and auto / allo – cartilaginous plate) for the neotympanum (outer and inner layers). The cartilaginous plate is believed to replace the fibro - elastic tissue layer of the tympanic membrane which would provide stability and mobility to the neotympanum. It is also

believed to permit the permeation on nutrients necessary for the uptake of the fascial graft. [53] Cartilage "shield" grafts from the cymbha concha.

Scar tissue.

Peri-umbilical superficial fascia[22]

Peri-umbilical fat (100% closure rate in paediatric population)[39,40]

Fascia lata

vein

cornea

dura mater

tympanomeatal graft

free skin graft from the external auditory canal (80% success rate in a study conducted in Sweden in 1961 and published in Acta Oto Laryngologica)[38]

bovine jugular vein

calf caecal serosa

Hyaluronic Acid (Hyaluronic Acid Fat Graft Myringoplasty)

Alloderm : acellular, chemically treated dermal homograft.[27]

Cigarette paper and carbon paper for the paper-patch method (cigarette paper was found to have good cell adhesion properties and better bio-compatibility on studying using Scanning Electron Microscopy)[29,30,54]

Tutopatch : a xenograft obtained from bovine perichondrium.

Fibroin (silk fibroin scaffold : a structural protein obtained from silkworms)[33]

Human amniotic membrane (a study has revealed better closure rates of both air-bone gap and perforation when compared to that obtained with conventional temporalis fascia)[35]

Alloplastic materials made of silicone for improving the hearing in patients with perforations of the eardrum.

THE CHRONIC EAR SURVEY:[64,65]

The Chronic Ear Survey is an instrument that can be used to assess the effect of chronic otitis media on the quality of life of the patient and the outcomes of its treatment. It was developed by Nadol and others in 2000. It provides information about the total ear-specific health of the patient, as well as information regarding the activity restriction of the patient due to the disease, his/her symptoms and the usage of medical resource due to chronic otitis media in the form of sub-scores.[64] It is the only disease-specific quality-of-life outcome survey available currently for chronic ear disease. It consists of 13-Likert scale questions which have been subdivided into 3 sub-categories. The AR subscale deals with the effect of chronic ear disease on the day-to-day life of the patient. The ST subscale assesses the presence of symptoms due to the disease while the MR subscale evaluates the degree to which the services of medical personnel and drugs had to be used due to the disease. There are a number of other subjective outcome specific quality-of-life measures such as the Hearing Satisfaction Scale, Hearing Handicap inventory for the Elderly, the Glasgow Benefit Inventory etc. However, all of these are either related to hearing of general health and are not disease-specific.[65] Please turn over for the Chronic Ear Survey questionnaire.

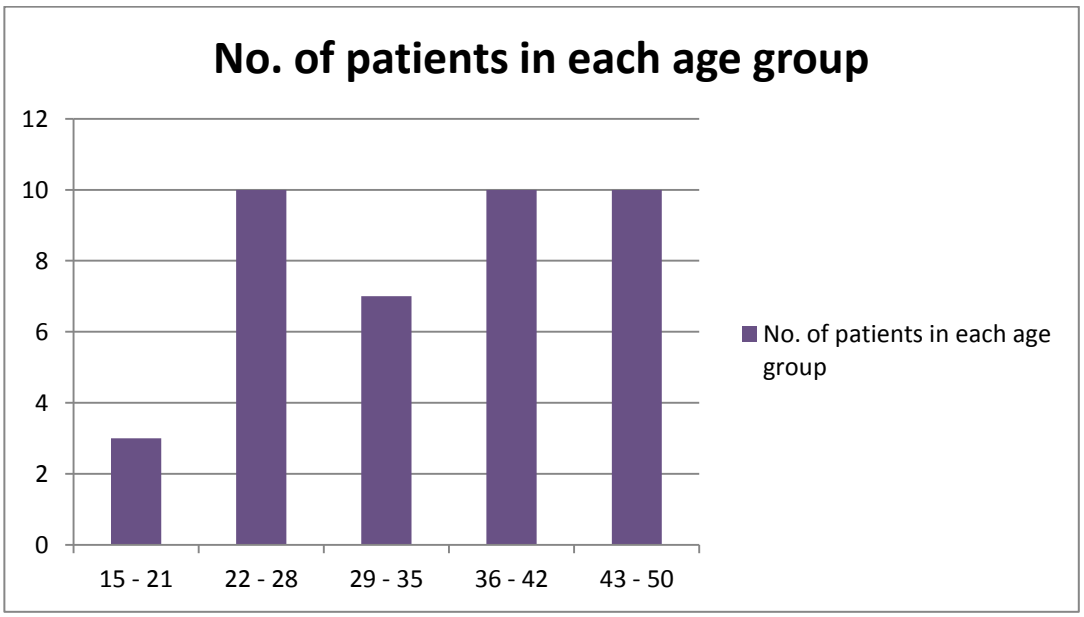
Table 1. Chronic Ear Survey

Item No.	Question and Reply Choices
	Activity Restriction–Based Subscale
1	Because of your ear problem, you don't swim or shower without protecting your ear. Definitely true/true/false/definitely false
2	At the present time, how severe a limitation is the necessity to keep water out of your ears? Very severe/severe/moderate/mild/very mild/none
3	In the past 4 weeks, has your ear problem interfered with your social activities with friends, family, or groups? All of the time/most of the time/a good bit of the time/some of the time/a little of the time/none of the time
	Symptom Subscale
1	Your hearing loss is: Very severe/severe/moderate/mild/very mild/none
2	Drainage from your ear is: Very severe/severe/moderate/mild/very mild/none
3	Pain from your ear is: Very severe/severe/moderate/mild/very mild/none
4	Odor from your ear is very bothersome to you and/or others: Definitely true/true/don't know/false/definitely false
5	The hearing loss in your affected ear bothers you: All of the time/most of the time/a good bit of the time/some of the time/a little of the time/none of the time
6	In the past 6 mo, please estimate the frequency that your affected ear has drained: Constantly/≥5 times, but not constantly/3-4 times/1-2 times/not at all
7	The odor from your affected ear bothers you and/or others: All of the time/most of the time/a good bit of the time/some of the time/a little of the time/none of the time
	Medical Resource Utilization Subscale
1	In the past 6 mo, how many separate times have you visited your physician, specifically about your ear problem? >6 Times/5-6 times/3-4 times/1-2 times/not at all
2	In the past 6 mo, how many separate times have you used oral antibiotics to treat your ear infection? >6 Times/5-6 times/3-4 times/1-2 times/not at all
3	In the past 6 mo, how many separate times have ear drops been necessary to treat your ear condition? >6 Times/5-6 times/3-4 times/1-2 times/not at all

OBSERVATIONS AND RESULTS

Age distribution

	N	Mean	Standard Deviation
Age (years)	40	35.7	10.29



A total of 40 patients were enrolled in the study with ranging from 16 to 50 years. The mean age of the study population was 35.7 years with a standard deviation of 10.29 years. There was an equal distribution of patients in the age groups between 22-28 years, 36-42 years and 43-50 years (10 patients in each of the 3 age groups contributing 25% each to the study group). The lowest number was in the age group between 15-21 years (7.5%) while in the age group of 29-35 years, there were 7 patients (17.5%).

Gender ratio

Gender	Frequency	Percent
Male	20	50.0
Female	20	50.0
Total	40	100.0

Of the 40 patients enrolled in the study, there were exactly 20 males and 20 females, thus each group contributing 50% to the total study population. There had been no deliberate attempt to enroll equal number of male and female patients in the study. Gender did not contribute any statistical significance to the study.

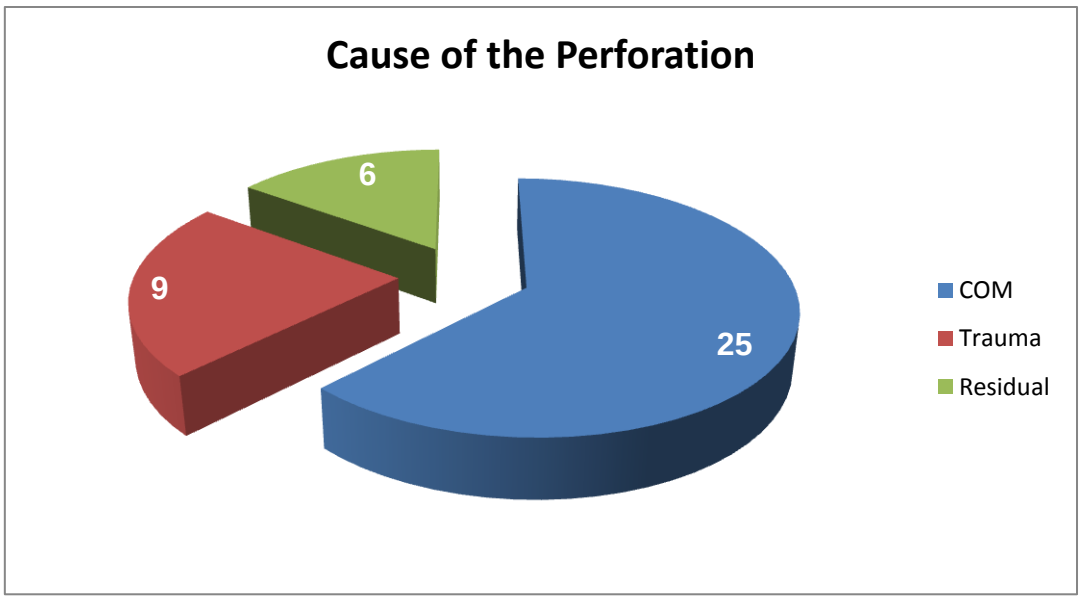
Ratio of operated ear side (left vs right)

Ear	*Frequency*	*Percent*
Left	19	47.5
Right	21	52.5
Total	40	100.0

of the 40 ears operated, 19 were left ears (47.5%) and 21 were right ears (52.5%). We did not encounter any special or specific difficulties or adopt variations in technique in terms of the side of the ear operated.

Cause of the perforation:

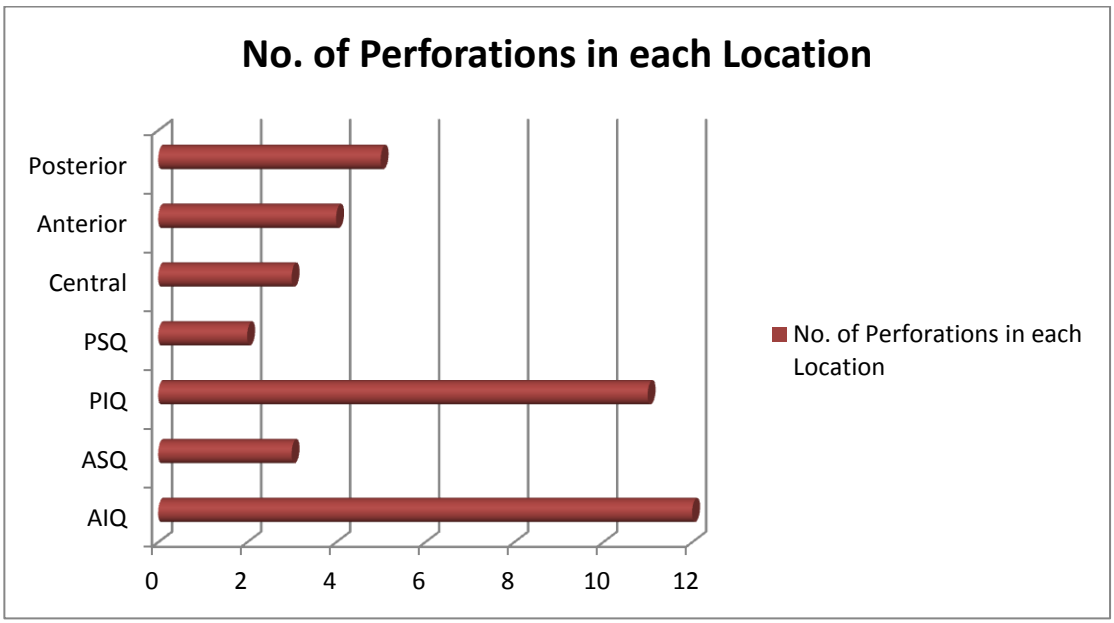
Perforation cause	Frequency	Percent
Com	25	62.5
Trauma	9	22.5
Residual	6	15.0
Total	40	100.0



62.5% of the patients in the study (25 patients) suffered from Chronic Otitis Media. Thus they contributed the major chunk of the study population which is in keeping with the general trend of patients with tympanic membrane perforations. 22.5% (9 in number) of the patients were traumatic perforations, while the remaining 15% (6 in number) were residual perforations following previously failed tympanoplasty procedures.

Location of perforation:

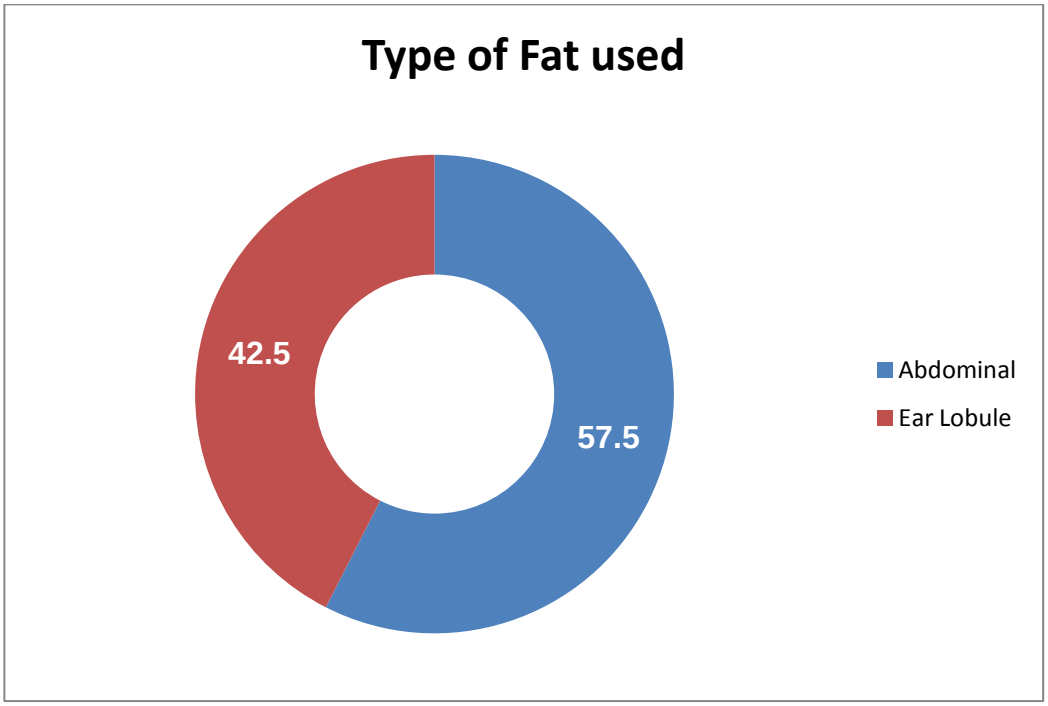
Perforation location	Frequency	Percent
AIQ	12	30.0
ASQ	3	7.5
PIQ	11	27.5
PSQ	2	5.0
Central	3	7.5
Anterior	4	10.0
Posterior	5	12.5
Total	40	100.0



The distribution of the perforation location was as elaborated above in the table and chart, with the majority of the perforations in the inferior quadrants (antero-inferior and postero-inferior) and least number of perforations in the superior quadrants (antero-superior and postero-superior).

Type of fat used (ear lobule vs abdominal)

Fat used	Frequency	Percent
Abdominal	23	57.5
Ear lobule	17	42.5
Total	40	100.0



Though at the outset of the study, the plan had been to use ear lobule fat only, we had to resort to abdominal fat harvested through a peri-umbilical incision in 57.5% (23) of the patients.

Operating time

	N	Mean	Standard Deviation
Operating time (mins)	40	28.1	3.81

Independent samples T-Test to compare mean operating time

	Fat used	N	Mean	Std. Deviation	P-Value
Operating time (mins)	Abdominal	23	28.13	3.841	0.954
	Ear lobule	17	28.06	3.881	

The average time taken to complete one fat graft myringoplasty from draping to dressing was 28.1 minutes with a standard deviation of 3.81 minutes. 23 cases were done using abdominal fat while ear lobule fat was used in the remaining 17 cases. Fat graft myringoplasty done using abdominal fat took 28.13 minutes average time with a standard deviation of 3.841 minutes while the procedure done using ear lobule fat consumed an average time of 28.06 minutes with a standard deviation of 3.881 minutes. It is obvious by eyeball testing and also statistically (p value > 0.05), that there is no significant difference in the operating time in terms of the type of fat used.

Average of AC: Air Conduction (pre and post-operative) (by applying Student's 't' test)

Variables	N	Mean	Std. Deviation	P-Value
PTA (Pre Op) (dB) AC	40	35.63	3.953	<0.001
PTA (Post Op) (dB) AC	40	27.45	3.782	

Pure Tone Audiometry was done for all 40 patients pre- and 3 months post-operatively. Air Conduction, Bone Conduction thresholds and Air-Bone-Gap was calculated each time for all patients. The average pre-operative Air Conduction threshold was 35.63 dB with a standard deviation of 3.953 dB. The Average Air conduction threshold after the procedure was 27.45 dB with a standard deviation of 3.782 dB. Thus the air conduction threshold improved by 8.18 dB after the procedure. *The Student's 't' test for paired samples* was applied to these values and p value arrived at which was found to be less than 0.05 and hence significant. This disproves the Null Hypothesis that there is no significant difference in the Air conduction thresholds of the patients pre- and post-operatively. Since this surgery addresses only the conductive component of hearing and the sensorineural component is left untouched, there was absolutely no difference in the bone conduction thresholds of the patients pre and post-operatively.

Air Bone Gap – pre and post - operative (by applying Student's 't' test)

Variables	N	Mean	Std. Deviation	P-Value
PTA (Pre Op) (dB) ABG	40	21.25	5.158	<0.001
PTA (Post Op) (dB) ABG	40	13.10	4.511	

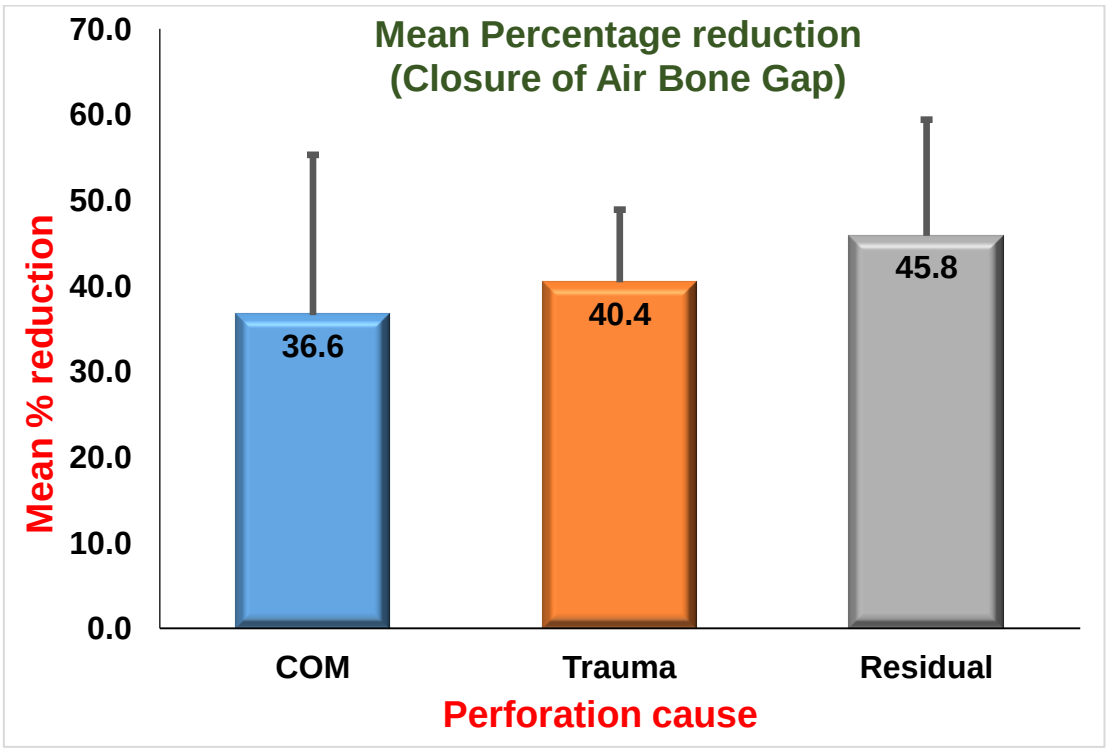
The Air Bone Gap is calculated as an average of the difference in the Air and Bone conduction thresholds at 500, 1000 and 2000 Hertz. This was calculated for all 40 patients in the study. The mean air bone gap pre-operatively was 21.25 dB with a standard deviation of 5.158 dB while the mean air bone gap post-operatively, was 13.10 dB with a standard deviation of 4.511 dB. The difference between the mean pre- and post-operative air bone gap is 8.15 dB. *The Student's 't' test for paired samples* was applied to these values and p value was calculated which was found to be less than 0.05. This is significant which disproves the Null Hypothesis that there is no significant difference in the air bone gap pre and post-operatively.

Percentage Reduction (Closure of Air Bone Gap)

	N	Mean	Standard Deviation
Percentage reduction (Closure of ABG)	40	38.83	16.29

One way ANOVA to compare the mean Percentage reduction (Closure of Air Bone Gap) among the Perforation causes

Perforation cause	N	Mean	Std. Deviation	P-Value
COM	25	36.5733	18.72400	0.445
Trauma	9	40.4074	8.48819	
Residual	6	45.8333	13.57080	
Total	**40**	**38.8250**	**16.29482**	



Another way to quantify the hearing improvement after fat graft myringoplasty is in terms of the percentage reduction of the Air Bone Gap post-operatively. By what percentage of the pre-operative value, did the air bone gap decrease after surgery, was calculated for every patient. The mean percentage reduction in air bone gap post-operatively was 38.83% with a standard deviation of 16.29%. When the same was arrived at separately for each cause of the perforation, the mean percentage reduction in air bone gap post-operatively was 36.6% for perforations due to Chronic Otitis Media, 40.4% for traumatic perforations and 45.8% for residual perforations.

Though statistically, there is no significant difference in the percentage reductions of air bone gap in terms of the different causes of the perforation (p value >0.05), by eyeball testing we can see that the percentage reduction in air bone gap after surgery for residual perforations is 9.2% more than that for perforations due to Chronic Otitis Media and about 5.4% greater than traumatic perforations, which is quite an interesting observation. The percentage reduction in air bone gap post-operatively for traumatic perforations is 3.8% more than those caused by chronic otitis media.

Tympanic Membrane mobility – pre & post - operative

		Post Op TM mobility					
		Present		**Absent**		**Total**	
		N	%	N	%	N	%
Pre Op TM mobility	Present	0	.0	0	.0	0	.0
	Absent	38	95.0	2	5.0	40	100.0
	Total	**38**	**95.0**	**2**	**5.0**	**40**	**100.0**

Of the 40 patients operated, none had tympanic membrane mobility pre-operatively in the affected ear (with the perforation). When the tympanic membrane mobility was assessed 3 months post-operatively by pneumatic otoscopy and Valsalva manoeuvre, it was found to be present in 38 of the 40 patients (in both the grafted and untouched areas of the tympanic membrane). This translates to a success percentage of 95% in terms of tympanic membrane mobility, and a 5% failure rate. We will see quite soon that this correlates with the overall success and failure rate attained in the study.

Success- failure rate

Outcome	Frequency	Percent
Success	38	95.0
Failure	2	5.0
Total	**40**	**100.0**

OUTCOME	COM		TRAUMA		RESIDUAL	
	Frequency	%	Frequency	%	Frequency	%
SUCCESS	23	92	9	100	6	100
FAILURE	2	8	0	0	0	0
TOTAL	25	100	9	100	6	100

The overall success rate in the study, as per the previously defined criteria was 95% (i.e. 38 of the 40 cases), which in turn means that the failure rate was 5% (2 of the 40 cases). If we were to look at the success and failure rates individually in terms of the cause of the perforation, it was seen that 100% success rate (0 failures) was attained in cases of perforation due to trauma and residual perforations(9 trauma and 6 residual perforations in the study). The 2 failures were in the Chronic Otitis Media group. 23 of the 25 perforations caused by Chronic Otitis Media were closed successfully (92% success rate). The failure rate was 8% in this group (2 cases).

RESULTS OF THE CHRONIC EAR SURVEY QUESTIONNAIRE :

We administered this questionnaire to all our patients at the time of their enrolment into this study and at the time of their visit at 6 months post-operatively. We found by eyeball testing that there was definite movement up this Likert scale, for all patients in whom the procedure had been successful, overall and also specifically in the Activity Restriction and Medical Resource utilisation sub-scales by at-least 2 grades. No special or specific statistical tests were applied to evaluate the results and responses of this questionnaire. Since our patients did not have many of the survey relevant symptoms pre-operatively itself such as earache or ear discharge, there was not much of a significant change in the symptoms subscale. Only the 2 patients with failed procedure did not show an improvement in the survey scores. The purpose of this questionnaire was to assess whether the quality of life of our patients had improved post-operatively as a result of the surgery, let alone the objective measurements.

REVIEW OF LITERATURE

ANIMAL STUDIES

Myringoplasty with fat or paper patch or no intervention was done for tympanic membrane perforations in **guinea pigs** and results compared at 4 weeks microscopically histologically by Gold SR & Chaffoo in 1991. The healing rate with fat myringoplasty was far better than with paper patch and the control group. [1]

In Turkey, in 1998 a study on tympanic membrane perforations in 60 **rats** using fat/paper patch as graft material or no intervention was conducted. For small perforations, fat and paper patch yielded very high closure rates (with fat being marginally better than paper-patch). As the size of the perforation increased, the success rate dropped significantly. [6]

SIMILAR STUDIES IN ADULTS:

In an elaborate study on fat graft myringoplasty done in Egypt in 2012, an overall success rate of 88.2% with a post-operative hearing improvement of 15dB has been reported. They have admitted patients into the study by applying the inclusion criteria of Fiorio and Barbeiri strictly. Either ear lobule or peri-umbilical abdominal fat has been used. After placing the fat graft like a dumbbell, it was line all around with gelfoam over which a silastic sheet was spread.

Over this sheet, the external auditory canal was filled with gelfoam and antibiotic drops. They recommend this technique as a simple, short cost-effective procedure with minimal risk, trauma and pain for the closure of small perforations of the tympanic membrane. [45]

A Study done in Turkey in 2005 assessed the usage of **fat** as graft material for myringoplasty in primary versus revision surgery. Though the results were encouraging overall, primary surgery yielded slightly higher success rates compared to revision surgery. [5] A study conducted in Korea in 2000 reports successful usage (71% success rate) of **fat graft to close residual perforations** that occur following failed tympanoplasty using temporalis fascia graft. [25]

A study in Italy in 2007 reports the **use of fat as graft material to close residual / recurrent tympanic membrane perforations (1 – 5 mm)** with 87% success rate. However no statistically significant improvement in hearing level was noted. The angiogenic properties of fat help to compensate for the poor blood supply in the vicinity of the perforation. [9]

Konstantinidis et al., in a hospital in Greece conducted a study to assess the outcome of **fat** myringoplasty in a series of patients in January 2013. They observed a mean improvement of 9.3dB in the Air-Bone gap. Myringosclerosis did not seem to affect the outcome.

Anterior location of the perforation and size > 30% of pars tensa were poor prognostic factors. [13]

A study done by Kaddour H S in 1992 recommends that fat graft myringoplasty can be done as a day - care procedure under local anaesthesia (EMLA cream). In this study, there was a 80% closure rate with 11dB hearing gain. As per this particular study, this procedure is indicated for perforations less than 30% of pars tensa.[17]

A very similar study to this was done in 1992 where adipose plug myringoplasty was done on 28 patients over a 4 – year period.[18]

A study done by a group in Switzerland in 2003, published in Laryngorhinootologie reported successful outcomes with fat myringoplasty wherein the **fat graft was covered by a silk strip soaked in Garamycin ointment.** [23]

A study published in the Acta Otorhinolaryngologica advocates the technique of fat plug myringoplasty for closing small perforations of the tympanic membrane where the fat was harvested from the ear lobe. [24]

A study on fat plug myringoplasty done by U Chalishazar published in the Indian Journal of Otolaryngology and Head and Neck Surgery advises that this procedure can be done in the Out-

Patient Department with minimum morbidity for the patient. However, they also stress that the patient selection for this procedure is extremely important to ensure good results.

They report a 90% success rate. Bilateral fat myringoplasties have also been successful in this study. [36]

A study on myringoplasty done in Korea in 2001 by Park CW and others using autogenous fat as grafting material reports that the success rate obtained was equivalent to that attained with temporalis fascia (90.7%). The only factor that seemed to influence the outcome of the procedure was the size of the perforation. [37]

A study done by Konstatidinis and others n Greece in 2009 recommends fat graft myringoplasty as a cost-effective alternative to conventional temporalis fascia graft myringoplasty for closure of small perforations of the tympanic membrane that can be performed under Local Anaesthesia in the Out - Patient setting. Perforation size greater than 1 quadrant is unfavourable. Fat was harvested from the ear lobe in all patients. They report a 81.8% closure rate. Only one patient developed a small haematoma at the site of fat harvest. The post-operative hearing gain ranged from 6 to 15 dB. [43]

A study was conducted in Korea in 2002 **on Fat Graft Myringoplasty after trimming margins of perforation using CO2**

laser. The use of CO2 laser did not seem to affect the outcome in any way. [44]

A study conducted in Korea in 2011, published in the Acta Oto Laryngologica, about the results with **fat graft myringoplasty** has reported good closure rates with fat in both small and large sized perforations. However the improvement in hearing in terms of narrowing of the Air- Bone Gap has fallen as the size of the perforation increases. The location of the perforation did not seem to affect the results. [31]

Monoj Mukherjee and Ranjan Paul have coined the term **"Minimyringoplasty"** for the same technique of Fat Graft Myringoplasty in their article published in the Indian Journal of Otorhinolaryngology Head and Neck Surgery in 2011.[50]

STUDIES IN THE PAEDIATRIC POPULATION:

A study conducted by R B Mitchell and others in 1997 approves the use of fat as graft material for the closure of tympanic membrane perforations in **children.** They say that fat myringoplasty can be done as a day-care procedure for children with good results. Age of the child did not seem to affect the outcome. They report a 92% success rate. [3]

A Prospective Study in Israel was done to assess the outcomes of fat graft myringoplasty in **adult and paediatric** populations for small and large size perforations immediately and long-term.

Overall success rate	–	81.6%
Closure rates for Small perforations	–	78.6% ;
Large perforations	–	90% ;
Adult	–	85.2% ;
Pediatric	-	72.7%

Speech reception thresholds also improved significantly post-operatively.[8]

A study was done on adipose plug myringoplasty in **children**. The most common indications were – post-inflammatory, post-extrusion of ventilating tubes, post-traumatic, residual perforation following previous myringoplasty. [16]

A Study in the Children's Hospital in Pittsburgh, between 2000 and 2005 on 604 children on myringoplasty techniques and graft materials. They found gelfoam myringoplasty to be more successful than paper patch or fat myringoplasty. Factors that seemed to affect the outcome include patient's age, H/O Down's syndrome, perforation etiology, ventilation tubes (presence and placement, number of prior tubes) and graft material used. [19]

Encouraging results after **bilateral fat graft myringoplasties in children** has been reported by Mitchell R B and others at the Children's Medical Centre in Tennessee. [52]

COMPARITIVE STUDIES WITH OTHER GRAFT MATERIALS:

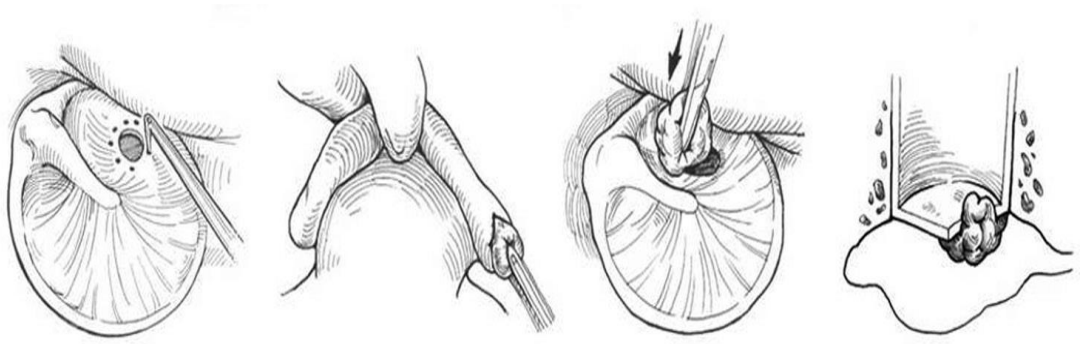
Saadat et al. in their study have reported the use of **Alloderm**, which is an acellular Human dermal matrix for the successful closure of tympanic membrane perforations. It is proclaimed that it serves as a connective tissue matrix providing soft tissue Support and becomes integrated into the surrounding soft tissue bed. Human donor skin is appropriately processed to remove all its cellular components for generation of Alloderm after screening. This has been tried as an alternative to fat myringoplasty with successful outcomes in the author's study. [2]

A study in Turkey has **compared the use of paper-patch, fat and perichondrium** for the closure of tympanic membrane perforations less than 3mm (trans-canal approach, local anaesthesia). Fat and perichondrium have produced equal and superior results (86.7%) compared to paper-patch (66.7%) in terms of closure.[4]

A paper published in the Laryngoscope as recent as 2011, **compares Gelfoam Plug Myringoplasty to Fat Graft Myringoplasy.** They claim that the closure rates are similar for the 2 techniques but

Gelfoam Plug Myringoplasty is a quicker and simpler technique to perform. [41]

Comparison between 4 autogenous graft materials – temporalis fascia, tragal perichondrium, fat, areolar tissue; was done in a study in Kolkata in 2005-2006. Fat plug myringoplasty was done in the usual way, while the underlay technique was employed with the other graft materials. They have reported that pre-operative hearing loss and post-operative tympanic membrane perforation closure is better for the younger than the older age group; and for anterior than posterior perforations. They have also said that for small sized perforations, both the pre-operative hearing loss and the post-operative gain in hearing is better than for larger sized perforations. They have observed best results with temporalis fascia. Failure cases in their study were due to upper respiratory tract infections, post-operative infections, poor adherence to advice regarding post-operative care etc. [42]



A study in Korea compared **fat and perichondrium myringoplasty** for small chronic perforations of the tympanic membrane and found the results to be similar, in terms of closure of the perforation and Air-Bone Gap. [56]

A study was done in New Orleans in 1994 by Boyce RG and others on the effectiveness and limitations of autogenous fat, non – vascularised muscle and fascia as **graft / transplantation material in ENT and Head and Neck Surgery**. Although the use of autogenous fat grafts in head and neck surgery has been associated with some unpredictability, fat remains an excellent choice for obliteration of frontal sinuses, for myringoplasty, and for limited soft – tissue augmentation. In most applications, significant resorption of the transplanted fat can be expected, and it should be compensated for accordingly by initial overcorrection.[20]

STUDIES ON HAFGM

A study in Canada reported in the Archives of Otolaryngology Head and Neck Surgery, compared the outcomes of myringoplasty **using Hyaluronic – Acid Fat Graft and plain fat graft to close pediatric tympanic membrane perforations**. They found a significantly higher success rate using HAFGM (90%) as against FGM (57%). Hence they have advocated HAFGM as a good day care procedure to be comfortably done under local anaesthesia for the pediatric population. Age of the child or site of the perforation did not seem to affect the outcome. [10]

A study published in the Laryngoscope in **2011 compared the techniques of HAFGM, Underlay and Overlay techniques of myringoplasty** and found them to be equivalent in terms of successful outcome (closure / hearing improvement). HAFGM had the advantage of much shorter operating time (less than 1/4th of the time taken for the underlay and overlay techniques).[11]

A study was published in 2011 in the Archives of Otolaryngology Head and Neck Surgery comparing the techniques of Hyaluronic Acid Fat Graft Myringoplasty (HAFGM), underlay and overlay techniques in the Pediatric Population. While the underlay and overlay techniques required general anaesthesia, HAFGM could be done under local anaesthesia as an out-patient procedure requiring no hospitalisation for the children. Closure rates were similar while the time taken for HAFGM was less than one-third of the time consumed for the other 2 techniques. Identification of the anterior perforation rim, however, is necessary for performing HAFGM. Post-operatively, air-bone gap closure was better with HAFGM and also there was no incidence of worsening of the bone conduction thresholds because of HAFGM.[12]

Perforations of the tympanic membrane represent a serious morbidity during the phase of speech and language development of a child. A study in Australia exemplifies the properties of **hyaluronic acid** which make it important for wound healing, more relevantly –

tympanic membrane repair. It is believed to improve the quality of the neo - tympanum, accelerate the healing process, improve hearing. It is also bio - degradable, safe and biocompatible to the ear. [55]

A study done by Saliba and others in Montreal University in 2008. HAFGM was done under local anaesthesia as a day - care procedure in Montreal University between January 2007 - 2008 for 21 consecutive patients.

rior *and others had* concluded that repair of tympanic membrane perforations with hyaluronic acid ester films alone is not to be recommended. In his series, five patients were operated under general anesthesia, the edges of the perforation were freshened and a sheet of Hyaluronic Acid, trimmed to a size roughly 2 mm larger in diameter than the perforation, was tucked through the perforation. The Hyaluronic Acid had dissolved but the perforations remained the same size in all five patients. The study was subsequently aborted. This is the first report of the new technique of Hyaluronic Acid epidisc associated Fat Graft Myringoplasty.

In this study, the fat graft was used as a support for epithelial cell migration Stimulated by the Hyaluronic Acid. An intimate contact between the Hyaluronic Acid epidisc and the intact epithelial edge around the perforation is mandatory. An excessive pressure on the HA epidisc by the lateral gelfoam dressing should be avoided; it could block the epithelial migration.

Hyaluronic Acid is a non-ototoxic material. Sensorineural hearing loss reported in patients who had undergone tympanoplasty procedures has not been noticed in any study on fat myringoplasty; neither in any of this series.

The global success rate of HAFGM reached 91%. The mean air - bone gap improvement for the operated ears was 17 dB. The HAFGM is ideal for perforations of all sizes in all quadrants if a complete visualization of the margin is possible. There is no need for general anesthesia and also HAFGM yields high success rates which are better than with fat alone or than Hyaluronic Acid alone.[15]

Myringoplasty is more difficult in children due to smaller anatomy, recurrent Upper Respiratory tract Infections and poor Eustachian tube function. Hence techniques where elevation of the annulus is not required would be better. Therefore techniques of fat graft myringoplasty and hyaluronic acid fat graft myringoplasty are highly suitable for children. [32]

STUDIES ON FACTORS AFFECTING OUTCOME:

A study conducted by Khan and others in 2012 to **determine the effect of the size of central perforations of the tympanic membrane on the outcome of myringoplasty** revealed that smaller the size of the perforation, better are the chances of healing after surgery. [60]

Wasson and others conducted a study in 2009 to look into **the influence of perforation size on the results of myringoplasty** and to determine the gain in hearing after successful closure of tympanic membrane perforations of different sizes. The conclusion of the study was that the size of the perforation did not influence the outcomes of surgery in a statistically significant way. It was also found that the audiometric gains in air conduction post-surgery correlated directly with the pre-operative size of the perforation. [61]

A study was conducted by Sarker MZ and others in 2011 to evaluate the **factors that seem to affect the post-operative hearing improvement and rate of graft uptake following myringoplasty.** Their results were that post-operatively, hearing gain was more for larger sized perforations while graft uptake rate was greater for small-sized perforations. [62]

A study was conducted in 2007 by Bertoli GA and others to determine the **effectiveness of fat graft myringolasty for the repair of tympanic membrane perforations; with respect to the size and site of the perforation**. The closure rates were higher for smaller than larger perforations (93.7% vs 70.7%) and posterior perforations fared better than anteriorly located perforations (90.5% vs 67.7%). The conclusion of the study was that fat graft myringoplasty can be considered as the procedure of choice for small inferior and posterior tympanic membrane perforations.[63]

SIMILAR STUDIES USING OTHER UNCONVENTIONAL GRAFT MATERIALS:

A study done in New York in 2003, published in the Laryngoscope describe the trial with acellular dermal allograft (Alloderm) in **adult chinchillas** with persistent tympanic membrane perforations. They report a 78% success rate which ranks higher than closure using rice paper (66% success rate). This acellular dermis histologically seems to get incorporated into the middle fibrous layer of the tympanic membrane. [27]

Study on **guinea pig eardrums** (with large persistent tympanic membrane perforations) using fibrin glue reinforced paper patch myringoplasty. Did not demonstrate significant difference in healing when compared to plain paper patch myringoplasty. [29]

A study published in the European Archives of Otorhinolaryngology in 2007 describes the usage of **paper patch as graft material in myringoplasty after trimming the margins of the perforation using CO2 laser**. Result rates have been encouraging in perforations less than 4 mm, but dropped drastically in perforations 6 mm or larger in size.[30]

Fibroin, a core structural protein in silk from silkworms, has been widely studied with biomedical applications in mind. Several cell types, including keratinocytes, have grown on silk biomaterials, and scaffolds manufactured from silk have successfully been used in

wound healing and for tissue engineering purposes. This review focuses on the current available grafts for myringoplasty and their limitations, and examines the biomechanical properties of silk, assessing the potential benefits of a silk fibroin scaffold as a novel device for use as a graft in myringoplasty surgery.[33]

A study conducted in Malaysia from 1999 to 2001 recommends the use of **human amniotic membrane** as a good alternative graft material to temporalis fascia. They report of outcomes similar and comparable to temporalis fascia graft conventional myringoplasty for perforations of all sizes. Human amniotic membrane is a non-antigenic graft material with low risk of inducing an immunological reaction in the host and good anti-microbial properties. [35]

A study published by Ajulo and others in London in 1997, reports the successful usage of **peri-umbilical superficial fascia as grafting material** for myringoplasty.[22]

As early as 1961, a study conducted in Sweden was published in the Acta Oto Laryngologica about the successful **usage of free skin graft from the external auditory canal** to close tympanic membrane perforations. They have reported a 80% closure rate. [38]

A study done in St. Petersburg ENT Research Institute describes a new technique of **myringoplasty with two layers of tissue (temporalis fascia and auto/allo-cartilagenous plate)** for the neotympanum (outer and inner layers). The cartilaginous plate is believed to replace the fibro-elastic tissue layer of the tympanic membrane which would provide stability and mobility to the neotympanum. It is also believed to permit the permeation on nutrients necessary for the uptake of the fascial graft. [53]

The tympanic membrane plays an important role in the tympano-ossicular system for sound transmission. Techniques of myringoplasty using **cigarette and carbon paper for the paper-patch method** has been tried out. It was found that cigarette paper had better bio-compatibility and cell-adhesion features when studied using fibroblast cells and Scanning Electron Microscopy. Published in the European Archives of Otorhinolaryngology in 2012.[54]

100% closure rate with **peri – umbilical fat** as graft material in the pediatric population has been reported in a study published in August 2012 in the International Journal of Paediatric Otorhinolaryngology; as against ear lobule fat and post - auricular fat.[39]

DISCUSSION

INTERPRETATION AND ANALYSIS OF THE RESULTS & LITERATURE:

ANALYSIS OF DEMOGRAPHIC DATA:

AGE:

The mean age of the study population was 35.7 years. Trauma as the cause of perforation was more in the younger age range from 15 to 35 years (8 out of the 9 traumatic perforations), while chronic otitis media dominated in the older age range of 35 – 50 years. Since residual perforations were after failed tympanoplasty procedures previously, and since this tympanoplasty itself was done for a type of chronic otitis media only, residual perforations also were more in the older age group (5 out of the 6 residual perforations).

Literature strongly recommends the use of the technique in the pediatric population as a day-care procedure under local anaesthesia for the closure of small-sized perforations[3,8,16,19,52]. However, this study was restricted to the adult population as this is the first study of its kind here.

GENDER:

Incidentally, equal number of male and female patients had been enrolled in this study (20 males and 20 females). There had been no conscious attempt to achieve this. From a population of 100 patients with Chronic Otitis Media who attended the ENT OPD of Stanley Medical College and Hospital during the study period and satisfied the inclusion criteria for this study, 40 were selected by Consecutive (Non – Random) Sampling. The gender of the patient did not affect the outcome of the technique in any significant way.

ANALYSIS OF THE FACTORS AFFECTING THE OUTCOME OF THE PROCEDURE :

LATERALITY OF THE AFFECTED / OPERATED EAR:

Of the 40 ears operated, 21 (52.5%) were right and 19 (47.5%) were left. There were no bilateral cases. Laterality of the ear did not per se affect the results in any significant way; it was the location of the perforation in the ear which made a difference as will be discussed subsequently. Literature approves the performance of bilateral myringoplasties using this technique also (either simultaneously or consecutively after a time lag).[36,43,45]

SIZE OF THE PERFORATION:[13,17,31,37,43,60,62,63]

There is a general consensus in literature, that smaller the size of the perforation, better suited it is for fat graft myringoplasty with higher closure rates. A small sized perforation is taken as one that is less than 30% of the total surface area of the pars tensa. Thus perforations less than 5mm diameter are chosen for this study. Studies by Sarker MZ and others in 2011, Bertoli GA and others in 2007, Khan and others in 2012, Konstantidinis and others in 2009 and 2013, Park CW and others in Korea in 2001,2011, Kaddour HS in 1992 agree with this generalisation.

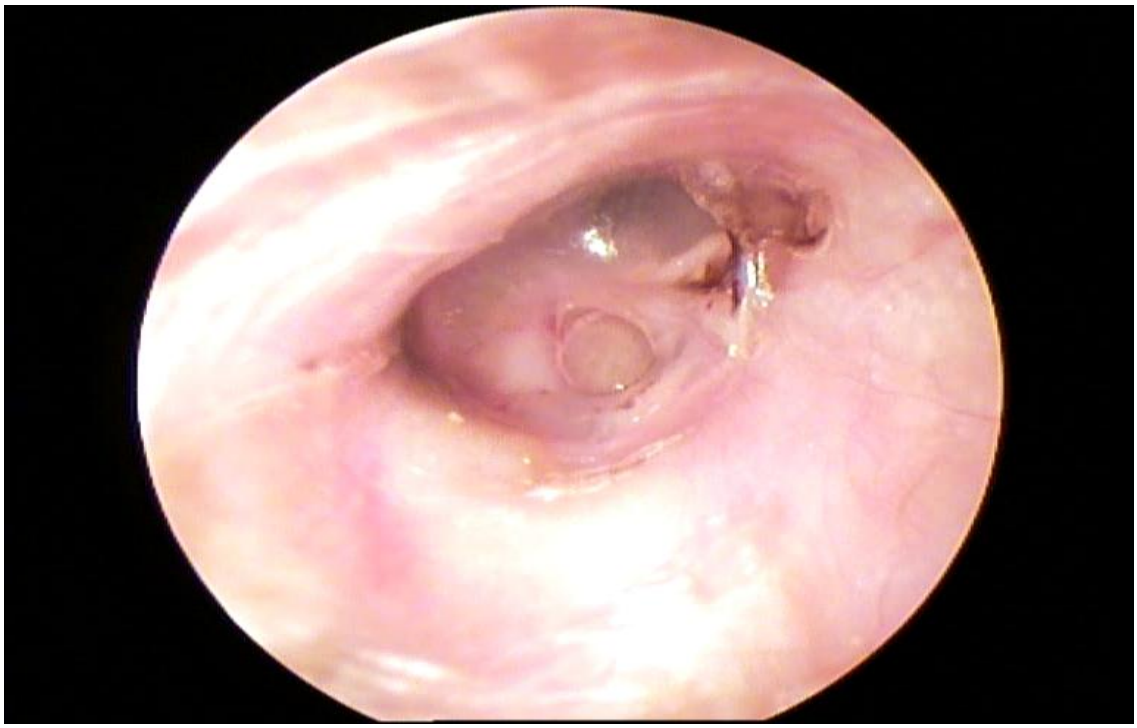
LOCATION OF THE PERFORATION:[63]

Location of the perforation as a factor affecting cannot be ruled out, as in our study itself, one of the failures was due to a very anterior location of the perforation with a very closely placed anterior wall overhang which prevented adequate reach to the anterior rim of the perforation. Posterior and inferior location of the perforation is considered to be favourable for this technique.

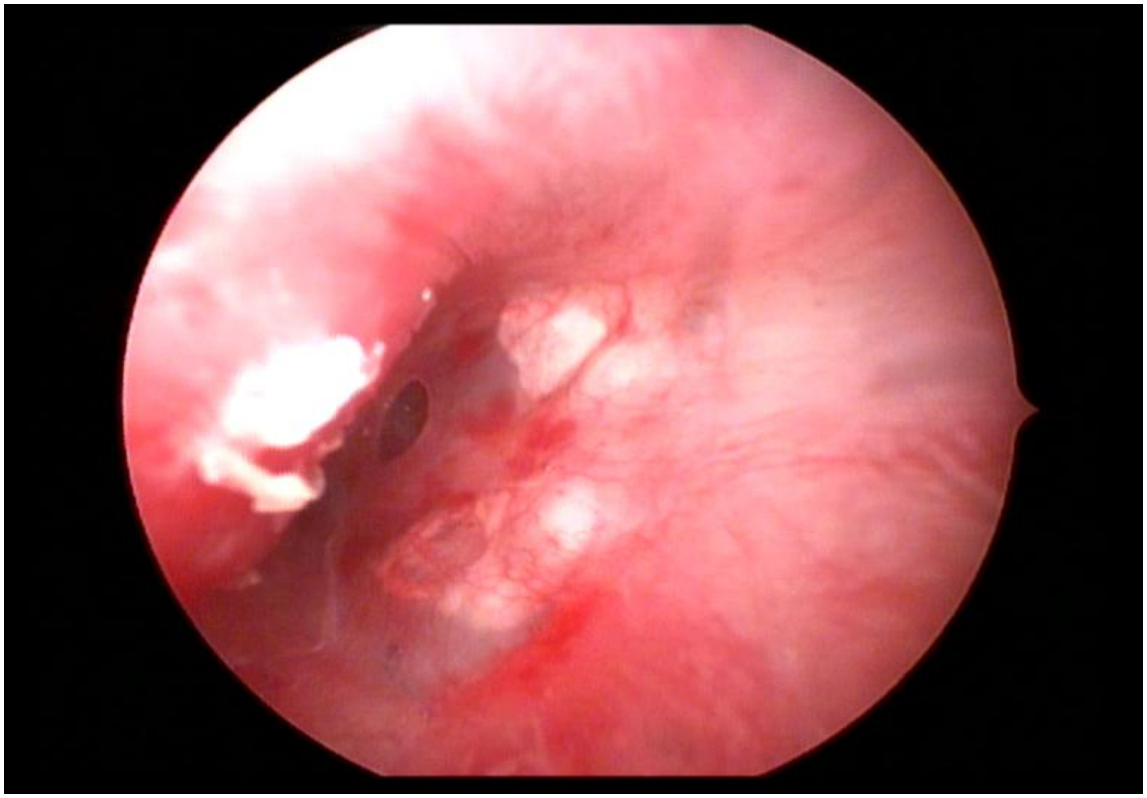
CAUSE OF THE PERFORATION:

Apart from the 3 causes of the perforations encountered by in our study, another commonly mentioned cause of perforation in literature that is being treated with fat graft myringoplasty is

POSTERIOR PERFORATION



ANTERIOR PERFORATION WITH OVERLYING BONY OVERHANG IN ANTERIOR EXTERNAL AUDITORY CANAL WALL



perforation post – tympanostomy tube extrusion. This is a very common indication in children. But since, we dealt with only adult population in our study, we did not encounter it as a cause of perforation.

It can be seen from the results section under this heading, that 100% closure was attained with traumatic and residual perforations, while the success rate with perforations due to chronic otitis media was only 92%.

This means, that among the 3 causes of the perforations, we can expect Better and more consistent results in future cases by this surgery for small perforations caused by trauma or residual perforations than for those caused by Chronic Otitis Media.

The usual nature of the traumatic and residual perforations to be small-sized makes them ideal candidates for this technique of myringoplasty.

TYPE OF FAT USED :

Though at the start of the study, we had intended to use only ear lobule fat, due to its inherent advantages over fat in other locations, we had to resort to usage of abdominal fat in the course of the study. In fact in the end, we had used abdominal fat in more number of patients than ear lobule fat (23 as against 17). This was due to cosmetic concerns expressed by female patients about

harvesting ear lobule fat and doubts about the availability of sufficient quantity of fat in the ear lobule region in poorly built adult males. However, the area of fat harvest did not affect the outcomes ultimately in any significant way, though we did have concerns about the operating time. This was because ear lobule fat is more dense and compact, and can thus be easily made to fit snugly into the perforation.

However, abdominal fat, which is less dense, with more loosely arranged fat cells and less connective tissue stroma, requires more effort to attain a snug fit into the perforation. As the abdominal fat is piled in, oil tends to ooze out of the fat, thus reducing its volume and density. As a result, more abdominal fat needs to used. But ultimately, after analysing the data and computing the results, to our surprise, there was hardly any difference in the operating time between fat graft myringolasties done using ear lobule and abdominal fat. (both approximately 28 minutes). This was because, the time gained in the transcanal procedure in ear lobule fat graft myringoplasty had already been lost during fat harvest. When ear lobule fat is harvested, the surgeon tends to devote more time in the accurate closure of the wound for cosmetic reasons, which is not the case when abdominal fat is harvested. Thus, at the end of the day, there is no net difference in the operating time in terms of the type of fat used.

ANALYSIS OF THE AUDIOLOGICAL GAIN:

The air conduction thresholds reduced by 8.18 dB post-operatively. The p value calculated by applying Student's paired t test for the pre and post operative air conduction thresholds was also significant disproving the Null hypothesis that there is no significant difference in the pre- and post-operative air conduction thresholds. Thus the surgery was effective in improving the air conduction thresholds and in turn the hearing level of the operated patients. The mean post-operative air bone gap was 8.15 dB lesser than the mean pre- operative value. The calculated p value was also significant. That means that the surgery has resulted in a reduction in the air bone gap; which is actually the measure of conductive hearing loss in an Audiogram. This proves that the surgery has helped to improve the hearing level of the patient.

S.No.	Study	Mean improvement in air bone gap (dB)
1	CURRENT STUDY	8.15
2	SALIBA & OTHERS	17 dB
3	FIORINO & BARBEIRI	Non-significant
4	HASSAN MOUSTAFA & OTHERS	15dB
5	KONSTATINIDIS & OTHERS, 2013	9.3 dB
6	KONSTATINIDIS & OTHERS, 2009	6 – 15 dB
7	KADDOUR H S, 1992	11dB

Another interesting way to quantify the reduction in air bone gap has been attempted by the calculation of the percentage reduction in the pre-operative air bone gap post-operatively. The mean post-operative percentage reduction in the air bone gap was found to be 38.83%. This kind of quantification, presentation and interpretation of the results would help to appreciate better the efficacy and capacity of the procedure in attaining one of the objectives stated at the outset of the study, and also help to analyse and understand the most appropriate and best indications for this technique. In the chart given in the results section under this heading, it can be seen that the percentage reductions in air bone gap have been calculated separately for the 3 causes of perforation. The mean reduction in air bone gap was 36.6 % for perforations due to chronic otitis media, 40.4% for traumatic perforations and 45.8% for residual perforations post-operatively. The end of the tail above each bar (that represents the percentage reduction in air bone gap for each cause of perforation) marks the maximum percentage reduction attained in an individual patient with perforation due to the three causes. Thus, the maximum percentage reduction in air bone gap for perforations due to chronic otitis media was 55%, 48% in traumatic perforations and 60% in residual perforations. We can see that residual perforations still top the list in terms of successful audiological outcomes. But the

maximum percentage reduction in air bone gap was higher for a case with chronic otitis media than traumatic perforations. Thus we can conclude, that the outcomes in traumatic perforations of small size treated with fat graft myringoplasty can be to an extent predicted and expected to lie within a range (40 – 50% in our case), whereas the same cannot be said of small-sized perforations caused by chronic otitis media treated with fat graft myringoplasty. This shows that there are other factors that could possibly determine the outcome of surgery and hearing improvement for chronic otitis media patients. After a detailed review of literature, it can be stated with considerable confidence that this is probably the first attempt of its kind to quantify the hearing improvement after fat graft myringoplasty in terms of percentage reduction of the air bone gap.

TYMPANIC MEMBRANE MOBILITY AND SUCCESS / FAILURE RATE:

There were 2 failures of the 40 patients operated. The failure was in terms of failure of perforation closure. This in turn translated to both absent tympanic membrane mobility and no improvement in hearing (air bone gap) post-operatively. In the sense, there were no failures in term of just one of the criteria. Of the 2 failures, 1 was due to post-operative wound infection while the other was caused by an anatomic factor. The perforation had been located very much

anteriorly, close to a bulge in the anterior wall of the external auditory canal. Hence adequately snug fit of the fat graft could not be attained which resulted in a displacement of the graft post-operatively.

S.NO	FAT GRAFT MYRINGOPLASTY STUDY	SUCCESS RATE (%)
1	CURRENT STUDY	95
2	EGYPT, 2012	88.2
3	KADDOUR H S, 1992	80
4	U CHALISHAZAR	90
5	KONSTATINIDIS & OTHERS, 2009	81.8
6	KOREA, 2001	90.7%

S.NO	STUDY	SUCCESS RATE IN CLOSING RESIDUAL PERFORATIONS (%)
1	CURRENT STUDY	100
2	KOREA, 2000	71
3	ITALY, 2007	87

THE CHRONIC EAR SURVEY:[64, 65]

This questionnaire was administered pre-operatively and 3 months post-operatively to the patients for an assessment of their post-operative quality of life following this technique (whether there was an improvement or not). Although complex statistical analyses were not applied to analyse the responses to this questionnaire, by jus simple eyeball testing, it was obvious that there was a definite improvement in the quality of life of these patients following this surgery, by atleast 2 grades up this Likert scale, in each of the sub-headings and also overall. Although elaborate studies have been done to assess the post-operative quality of life of the patients following temporalis fascia graft myringoplasty using the Chronic Ear Survey, this is probably the first study to assess the same using this questionnaire for fat graft myringoplasty.

CONCLUSION

Various grafting materials are used for myringoplasty with varying outcomes. The choice of graft affects not only the outcome of surgery, but also determines the complexity of the procedure and the time taken for the same. The purpose of this study was therefore to qualitatively and quantitatively assess the results of myringoplasty for small central perforations of the tympanic membrane using fat as grafting material, in terms of post-operative closure of the Air-Bone Gap and tympanic membrane mobility. The results have been quite encouraging. An added advantage of this technique that we realized during the course of this study, was the excellent post-operative quality of life of the operated patients, assessed in terms of the Chronic Ear Survey and also evident by the absence of the usual post-operative complaints following a conventional myringoplasty. Though literature does advocate and approve the use of this technique as a day-care procedure for similar indications in children, we restricted our study to the adult population, as this is our first venture in this particular arena. The most critical factor that determines the outcome of this procedure is proper patient selection. Factors that can be responsible for failure include improper technique (especially of fat placement), anatomical factors (bony overhangs obscuring the view of the rim of the perforation) and post-operative infection.

ANNEXURES

BIBLIOGRAPHY:

1. Glasscock-Shambaugh 'Surgery of the Ear' – Sixth Edition.
2. Gold, S. R. and Chaffoo, R. A. K. (1991), Fat myringoplasty in the Guinea pig. The Laryngoscope, 101: 1–5. doi: 10.1288/00005537-199101000-00001
3. Saadat, D., Ng, M., Vadapalli, S. and Sinha, U. K. (2001), Office Myringoplasty With Alloderm. The Laryngoscope, 111: 181–184. doi: 10.1097/00005537-200101000-00033
4. R. B. Mitchell, Kevin D. Pereira and Rande H. Lazar (1997). Fat graft myringoplasty in children – a safe and successful day-stay procedure. The Journal of Laryngology & Otology, 111, pp 106-108. doi:10.1017/S002221510013659X.
5. Engin Dursun MD et al. Comparison of paper-patch, fat, and perichondrium myringoplasty in repair of small tympanic membrane perforations Otolaryngol Head Neck Surg March 2008 vol. 138 no. 3 353-356
6. O B Ozgursoy and I Yorulmaz (2005). Fat graft myringoplasty: a cost-effective but underused procedure. Journal of Laryngology & Otology, 119, pp 277-279. doi:10.1258/0022215054020377.
7. Imamoglu M et al. Fat plug and paper patch myringoplasty in rats. The Journal of Otolaryngology. [1998, 27(6):318-321].

8. TERRY, R. M., BELLINI, M. J., CLAYTON, M. I. and GANDHI, A. G. (1988), FAT GRAFT MYRINGOPLASTY—A PROSPECTIVE TRIAL**.** Clinical Otolaryngology & Allied Sciences, 13: 227–229. doi: 10.1111/j.1365-2273.1988.tb01123.x

9. Landsberg R, Fishman G, DeRowe A, Berco E, Berger G. Fat graft myringoplasty: results of a long-term follow-up. J Otolaryngol. 2006 Feb;35(1):44-7.

10. Fiorino F, Barbieri F. Fat graft myringoplasty after unsuccessful tympanic membrane repair. Eur Arch Otorhinolaryngol. 2007 Oct;264(10):1125-8. Epub 2007 May 9. PubMed PMID: 17487499.

11. Saliba I, Knapik M, Froehlich P, Abela A. Advantages of hyaluronic acid fat graft myringoplasty over fat graft myringoplasty. Arch Otolaryngol Head Neck Surg. 2012 Oct;138(10):950-5.

12. Saliba I, Woods O. Hyaluronic acid fat graft myringoplasty: a minimally invasive technique. Laryngoscope. 2011 Feb;121(2): 375-80.

13. Saliba I, Froehlich P. Hyaluronic acid fat graft myringoplasty: an office-based technique adapted to children. Arch Otolaryngol Head Neck Surg. 2011 Dec;137(12):1203-9.

14. Konstantinidis I, Malliari H, Tsakiropoulou E, Constantinidis J. Fat myringoplasty outcome analysis with otoendoscopy: who is the suitable patient? Otol Neurotol. 2013 Jan;34(1):95-9.

15. Ringenberg, J. C. (1978), Closure of tympanic membrane perforations by the use of fat. The Laryngoscope, 88: 982–993.

16. Saliba, I. (2008), Hyaluronic acid fat graft myringoplasty: how we do it. Clinical Otolaryngology, 33: 610–614

17. Gross CW, Bassila M, Lazar RH, Long TE, Stagner S. Adipose plug myringoplasty: an alternative to formal myringoplasty techniques in children. Otolaryngol Head Neck Surg. 1989 Dec;101(6):617-20.

18. KADDOUR, H. S. (1992), Myringoplasty under local anaesthesia: day case surgery. Clinical Otolaryngology & Allied Sciences, 17: 567–568.

19. Chodynicki S, Rózańska-Kudelska M. [Fat tissue in the treatment of tympanic membrane perforations]. Otolaryngol Pol. 1998;52(6):661-4.

20. Sckolnick, J. S., Mantle, B., Li, J. and Chi, D. H. (2008), Pediatric Myringoplasty: Factors That Affect Success—A Retrospective Study. The Laryngoscope, 118: 723–729.

21. Boyce RG et al. The use of autogenous fat, fascia, and nonvascularized muscle grafts in the head and neck. Otolaryngologic Clinics of North America. [1994, 27(1):39-68]

22. *P Todd Nichols MD et al.* Relationship Between Tympanic Membrane Perforations and Retained Ventilation Tubes. *Arch Otolaryngol Head Neck Surg*. 1998;124(4):417-419.

23. AJULO, S.O., MYATT, H.M. and ALUSI, G. (1993), Peri-umbilical superficial fascial graft myringoplasty—a simple alternative. Clinical Otolaryngology & Allied Sciences, 18: 433–435.

24. Hagemann M, Häusler R. [Tympanoplasty with adipose tissue]. Laryngorhinootologie. 2003 Jun;82(6):393-6.

25. Hernández Madorrán JM, Urrutikoetxea Sarriegui A, Sanjosé Torices J, Pérez

26. www.drtbalu.com

27. Woo HY et al. Fat Myringoplasty in Graft Failures. Korean J Otolaryngol-Head Neck Surg. 2000 Apr;43(4):369-372.

28. Laidlaw, D. W., Costantino, P. D., Govindaraj, S., Hiltzik, D. H. and Catalano, P. J. (2001), Tympanic Membrane Repair With a Dermal Allograft. The Laryngoscope, 111: 702–707. doi: 10.1097/00005537-200104000-00025.

29. Bertoli, Gian Antonio, et al. "Fat graft myringoplasty: An office procedure for the repair of small perforations of the tympanic membrane." *Mediterranean Journal of Otology* 3 (2007): 120-5.

30. DiLeo MD et al. Fibrin-Glue-Reinforced Paper Patch Myringoplasty of Large Persistent Tympanic Membrane Perforations in the Guinea Pig. ORL 1996;58:27–31

31. Lee, S. H., Jin, S. M., Lee, K. C., & Kim, M. G. (2008). Paper-patch myringoplasty with CO2 laser for chronic TM perforation. *European Archives of Oto-Rhino-Laryngology*, *265*(10), 1161-1164.

32. Kim, Dong-Kee, et al. "Clinical efficacy of fat-graft myringoplasty for perforations of different sizes and locations." *Acta oto-laryngologica* 131.1 (2011): 22-26.

33. Saliba, I., & Froehlich, P. (2011). Hyaluronic acid fat graft myringoplasty: an office-based technique adapted to children. *Archives of Otolaryngology—Head & Neck Surgery*, *137*(12), 1203.

34. *Brett Levin†, Rangam Rajkhowa, Sharon Leanne Redmond and Marcus David Atlas.* Grafts in myringoplasty: utilizing a silk fibroin scaffold as a novel device. November 2009, Vol. 6, No. 6, Pages 653-664

35. Ringenberg, J. C. (1962), Fat graft tympanoplasty. The Laryngoscope, 72: 188–192. doi: 10.1288/00005537-196202000-00005

36. Myringoplasty, Underlay. "Amniotic Membrane to Temporalis Fascia Graft."*Med J Malaysia* 60.5 (2005): 585.

37. Chalishazar, U. (2005). Fat plug myringoplasty. *Indian Journal of Otolaryngology and Head and Neck Surgery*, *57*(1), 43-44.

38. Park, Chul Won, et al. "The outcome of myringoplasty using autogenous fat graft." *Korean Journal of Otolaryngology-Head and Neck Surgery* 44.9 (2001): 920-924.

39. Wastenson, N. (1961). Myringoplasty with a free graft from the external auditory canal. *Acta Oto-Laryngologica*, *53*(2-3), 563-570.

40. Kwong, K. M., Smith, M. M., & Coticchia, J. M. (2012). Fat graft myringoplasty using umbilical fat. *International Journal of Pediatric Otorhinolaryngology*, *76*(8), 1098-1101.

41. Koc, Sema, et al. "Fat graft myringoplasty with the newly developed surgical technique for chronic tympanic membrane

perforation." *European Archives of Oto-Rhino-Laryngology* (2013): 1-5.

42. Niklasson, A. and Tano, K. (2011), The Gelfoam® plug: An alternative treatment for small eardrum perforations. The Laryngoscope, 121: 782–784. doi: 10.1002/lary.21451

43. Singh, B. J., et al. "A comparative study of different graft materials used in myringoplasty." *Indian Journal of Otolaryngology and Head & Neck Surgery*61.2 (2009): 131-134.

44. Konstantinidis, I., et al. "Fat Myringoplasty as an Office-Based Procedure."*Skull Base* 19.S 02 (2010): A066.

45. Kim, Jin Hong, et al. "Fat myringoplasty trimmed with CO2 laser." *Korean Journal of Otolaryngology-Head and Neck Surgery* 45.2 (2002): 127-131.

46. Hegazy, Hassan Moustafa. "Fat graft myringoplasty–A prospective clinical study." *Egyptian Journal of Ear, Nose, Throat and Allied Sciences* (2013).

47. Saliba, Issam, et al. "Advantages of Hyaluronic Acid Fat Graft Myringoplasty Over Fat Graft MyringoplastyAdvantages of Hyaluronic Acid Fat Graft." *Archives of Otolaryngology–Head & Neck Surgery* 138.10 (2012): 950-955.

48. Jiu-yong, S. H. I. "98 cases of ear drum repair under improved endoscopy."*China Journal of Endoscopy* 6 (2010): 017.

49. Mukherjee, Monoj, and Ranjan Paul. "Minimyringoplasty: Repair of Small Central Perforation of Tympanic Membrane by Fat Graft:

A Prospective Study."*Indian Journal of Otolaryngology and Head & Neck Surgery* (2012): 1-3.

50. Sinha, Vikas, et al. "Fat Plug Myringoplasty: Cost effective surgery with high success rate for small central perforation." *World Articles in Ear, Nose and Throat* 2.2 (2009).

51. Li, Peng, et al. "The selection and strategy in otoendoscopic myringoplasty with autogenous adipose tissue." *Indian Journal of Otolaryngology and Head & Neck Surgery* 62.1 (2010): 25-28.

52. Gibb, Alan G., and Sing-Kiat Chang. "Myringoplasty." *The Journal of Laryngology & Otology* 96.10 (1982): 915-930.

53. Mitchell, R. B., et al. "Bilateral fat graft myringoplasty in children." *Ear, nose & throat journal* 75.10 (1996): 652-656.

54. Sitnikov, V., et al. "Modern Concepts in Myringopla**sty."** *Balkan Journal of Otology & Neuro-Otology, Vol. 4, No 2-3:93—95*

55. Altuntaş, Emine Elif, and Zeynep Sümer. "Biocompatibility evaluation of cigarette and carbon papers used in repair of traumatic tympanic membrane perforations: experimental study." *European Archives of Oto-Rhino-Laryngology*270.1 (2013): 81-86.

56. Teh, Bing Mei, et al. "A review on the use of hyaluronic acid in tympanic membrane wound healing." *Expert opinion on biological therapy* 12.1 (2012): 23-36.

57. Kim, Jeong Eun, et al. "Comparison of Myringoplasty for the Chronic Small Tympanic Membrane Perforations: Fat versus Perichondrium." *Korean Journal of Otorhinolaryngology-Head and Neck Surgery* 54.5 (2011): 329-333.

58. Ringenberg, J. C. (1962), Fat graft tympanoplasty. The Laryngoscope, 72: 188–192. doi: 10.1288/00005537-196202000-00005

59. *Kyu Hwan Jung et al. Quality-of-life survey after primary and revision ear surgery using the Chronic Ear Survey. Arch Otolaryngol Head Neck Surg.* 2010;136(4):358-365.

60. Khan MZ et al. Influence of size of tympanic membrane perforation on outcome of myringoplasty. Pakistan Journal of Otolaryngology;2012;28:38-41.

61. Wasson JD et al. Myringoplasty: impact of perforation size on closure and audiological improvement. J Laryngol Otol 2009 Sep; 123(9):973-7.

62. Sarker MZ et al. Factors affecting surgical outcome of myringoplasty. Bangladesh J Otorhinolaryngol 2011; 17(2):82-87.

63. Bertoli GA et al. Fat Graft Myringoplasty: An office procedure for the repair of small perforations of the tympanic membrane. Mediterr J Otol 2007;3:120-125.

64. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. Laryngoscope. 2000 Mar;110(3 Pt 3):32-5.

65. Kyu Hwan Jung, MD et al. Quality-of-life assessment after primary and revision ear surgery using the Chronic Ear Survey. *Arch Otolaryngol Head Neck Surg.* 2010;136(4):358-365.

PROFORMA

STUDY ON FAT GRAFT MYRINGOPLASTY

NAME :

AGE / SEX:

OCCUPATION:

OP/ IP.NO:

ADDRESS:

DOA:

DOS:

DOD:

I. CHIEF COMPLAINTS

1. C/O Ear Discharge :
2. C/o Hard of Hearing:

II. HISTORY OF PRESNT ILLNESS

1. H/o Ear Discharge:

	Duration	Colour	Smell	Amount	Nature	Agg fac	Rel fac
Right							
Left							

2. H/o Hard of hearing :

	Onset	Duration
Right		
Left		

Yes / No

3. H/o Earache:
4. H/o Vertigo :
5. H/o Tinnitus:
6. Nasal Complaints:

a. H/o Discharge:
b. H/o Obstruction:
c. H/o Disturbances of smell:
d. H/o Sneezing:
e. H/o Post Nasal Discharge:

7. Throat Complaints:

a. H/o Throat pain:
b. H/o. Dysphagia / Odynonophagia:
c. H/o Snoring:
d. H/o Mouth Breathing:

III. Past History:

1. Medical

a. H/o Allergy

b. Exposure to noise pollution

c. H/o any medical illness:

2. Surgical

a. H/o Previous surgery in ear / Nose/ Throat:

b. H/o Any other previous surgery:

3. H/o Trauma:

IV. Family H/o

a. H/o hard of hearing in any other family members

V. General Examination

a. General Condition:

b.

Anemia	Jaundice	Cyanosis	Clubbing	Pedal edema	GLINE

c. Vitals:

VI. Systemic examination:

a. CVS:

b. RS:

c. P/A:

d. CNS:

VII. ENT examination:

1. Examination of Ear:

a. External Ear:

	Right	Left
Pinna		
Preauricular region		
Postauricular region		
EAC		

b. Tympanic Membrane:

Perforation:

	Right	Left
Size		
Shape		
Margins		
Location		
Middle Ear		

c. Other findings

	Right	Left
Retraction		
Perforation		
Granulation		
Discharge		
Chol.flakes		
Ossicles		
Color of TM		
T. Sclerosis		

d. Turning fork test:

	Right	Left
Rinne's256 Hz		
512 Hz		
1024 Hz		
Weber's		
ABC		
Fistula test		
Facial nerve function		
3 Point tenderness		
Valsalva manuovre		

2. Examination of Nose:

	Right nostril	Left nostril
External framework		
Septum		
Turbinates		
Meati		
Mucosa		

3. Examination of Throat

a. Oral cavity:

b. Oropharynx:

4. IDL findings:

5. Post nasal examination:

VIII. Investigations:

1. CBC, RFT, Grouping and typing,
2. Urine routine
3. HIV, Hep - B
4. CXR, ECG.
5. PTA:
6. X –Ray mastoid:
7. CT – PNS:
8. Oto – Endoscopy:
9. DNE:
10. Aural Swab:

SURGERY

Procedure: DOS

Anaesthesia:

Approach:

Ear to be operated on:

EOT findings:

a. TM : Perforation:

Size	Shape	Margins	Location	Middle ear nuecosa

b. Ossicular status:

c. Eustachian tube orifice:

d. Cholesteatoma:

FOLLOW UP

POST – OPERATIVE VISIT	COMPLAINTS	OTO – ENDOSCOPY	PTA
VISIT 1 1WEEK			
VISIT 2 2WEEKS			
VISIT 3 4WEEKS			
VISIT 4 6WEEKS			
VISIT 5 3 MONTHS			
VISIT 6 6MONTHS			

ETHICAL COMMITTEE APPROVAL LETTER

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : A Study on Fat Graft Myringoplasty

Principal Investigator : Dr.K.Srikamakshi

Designation : PG in M.S (ENT)

Department : Department of ENT
Government Stanley Medical College,
Chennai-1

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 12.10.2011 at the Modernized Seminar Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate form the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY,
IEC, SMC, CHENNAI

30/11/11

PATIENT INFORMATION SHEET

தகவல் படிவம்

தங்களுக்கு செய்த பரிசோதனைகள் மூலம் தங்கள் காதில் நோய் (CSOM – Tubotympanic Disease) இருப்பது தெரியவந்துள்ளது. இதன் விளைவாக தங்களின் செவிச்சவ்வில் (Tympanic membrane) ஓட்டை ஏற்பட்டு உள்ளது.

இந்த நோயை குணப்படுத்த பலவகை அறுவை சிகிச்சை முறைகள் உள்ளன. அதில் ஒன்றான Fat Graft Myringoplasty அறுவை சிகிச்சை முறை பயன்படுத்தப்பட உள்ளது. இந்த அறுவை சிகிச்சை முறையில் தங்களின் (Ear lobule) காதுச்சோனையில் (வெளிக்காது) உள்ள கொழுப்பை எடுத்து தங்களின் செவிச்சவ்வின் ஓட்டை அடைக்கப்படும். மேலும் இந்த அறுவை சிகிச்சையின் விளைவுகளை ஒப்பிட்ட ஆய்வு மேற்கொள்ளப்பட உள்ளது. இது குறித்த விவரங்களை ஆய்வில் பயன்படுத்த விரும்புகிறோம்.

தாங்கள் விரும்பினால் மருத்துவ ஆய்விலிருந்து எப்பொழுது வேண்டுமானாலும் விலகிக் கொள்ளலாம். எந்த சட்ட சிக்கலுக்கும் உட்படாமல் எப்பொழுது வேண்டுமானாலும் தங்கள் ஆய்விலிருந்து விலகிக் கொள்ளலாம்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களும் பரிசோதனைமுடிவுகளும் தங்களின் ஒப்புதலின் மூலம் மட்டும் ஆய்வில் பயன்படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம்:

ஆய்வாளரின் பெயர்:
இடம் :

நாள்:

PATIENT CONSENT FORM

சுய ஒப்புதல் படிவம்

ஆராய்ச்சி நிலையம் : **காது, மூக்கு, தொண்டை பிரிவு**
ஸ்டான்லி அரசு பொது
மருத்துவமனை மருத்துவக் கல்லூரி

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் எண் :

மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. எனது செவிச்சவ்வில் (Tympanic membrane) ஓட்டை ஏற்பட்டுள்ளது என்பது தெரியப்படுத்தப்பட்டது. எனது காது நோய் பற்றிய சந்தேகங்களை கேட்கவும் அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது. இந்த நோயைகக் குணப்படுத்த பலவகை அறுவை சிகிச்சை முறைகள் உள்ளன என்பதும், எனக்கு அதில் ஒன்றான Fat Graft Myringoplasty அறுவை சிகிச்சை முறை பயன்படுத்தப்பட உள்ளது என்பதும், இந்த முறையில் எனது (Ear lobule ல்) காதுச்சோனையில் (வெளிக்காது) உள்ள கொழுப்பை எடுத்து எனது செவிச்சவ்வில் உள்ள ஓட்டை அடைக்கப்பட்டும் என்பது விளக்கப்பட்டது. இந்த அறுவை சிகிச்சையின் விளைவுகளை ஆய்வில் பயன்படுத்தவும் தன்னிச்சையாக சம்மதிக்கிறேன். எக்காரணத்தினாலும் எந்தக் கட்டத்திலும் எந்தசட்ட சிக்கலுக்கும் உட்படாமல் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் பரிசோதனை முடிவுகளையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும். ஆதை பிரசுரிக்கவும் தேவைப்பட்டால் என்னையும் எனக்கு நடக்கும் அறுவை சிகிச்சையையும் புகைப்படம் எடுக்கவும் நான்முழு மனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்: நாள் :

கட்டை விரல் ஒப்பம் இடம் :

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்:

ஆய்வாளரின் கையொப்பம்: நாள் :

ஆய்வாளரின் பெயர் : இடம்:

EAR	PERFORATION			PTA (pre-op) (dB)			pre-op TM	FAT USED	OPERATING	PTA
	SIZE(mm)	LOCATION	CAUSE	AC	BC	ABG	MOBILITY		TIME(mins)	AC B
LEFT	4	AIQ	COM	40	10	30	absent	ear lobule	30	30
RIGHT	3.5	PIQ	COM	35	10	25	absent	abdominal	33	28
LEFT	4	POSTERIOR	TRAUMA	40	15	25	absent	ear lobule	28	30
RIGHT	4	ASQ	TRAUMA	35	15	20	absent	abdominal	32	26
RIGHT	3.5	AIQ	COM	40	20	20	absent	ear lobule	35	40
RIGHT	3.5	PIQ	COM	40	15	25	absent	ear lobule	25	32
RIGHT	4	AIQ	COM	40	20	20	absent	abdominal	25	35
RIGHT	3	PIQ	TRAUMA	35	15	25	absent	abdominal	25	25
LEFT	3.5	POSTERIOR	COM	35	10	15	absent	ear lobule	28	28
LEFT	4	PIQ	COM	40	15	25	absent	abdominal	30	30
RIGHT	3	ANTERIOR	RESIDUAL	40	20	20	absent	ear lobule	27	30
LEFT	3	AIQ	COM	35	20	15	absent	abdominal	25	27
LEFT	3	PIQ	TRAUMA	35	10	25	absent	ear lobule	28	27
RIGHT	4	CENTRAL	COM	40	15	25	absent	abdominal	30	30
RIGHT	3	AIQ	COM	30	10	20	absent	ear lobule	32	22
LEFT	4	AIQ	COM	30	15	15	absent	abdominal	25	20
RIGHT	3.5	PSQ	COM	40	15	25	absent	ear lobule	27	28
LEFT	3	ANTERIOR	COM	30	10	20	absent	abdominal	35	24
RIGHT	4	PIQ	TRAUMA	40	15	25	absent	abdominal	29	30
LEFT	4	ASQ	COM	30	15	15	absent	abdominal	35	28
LEFT	3	AIQ	RESIDUAL	30	15	15	absent	ear lobule	20	20
RIGHT	3	PIQ	COM	35	10	25	absent	abdominal	25	28
RIGHT	4	CENTRAL	COM	40	15	25	absent	ear lobule	30	30
LEFT	3.5	ANTERIOR	COM	30	15	15	absent	abdominal	32	25
RIGHT	3.5	POSTERIOR	TRAUMA	40	10	30	absent	abdominal	28	30
LEFT	3	AIQ	COM	35	20	15	absent	abdominal	30	27
RIGHT	3	PIQ	COM	35	20	15	absent	abdominal	25	26
LEFT	3	PIQ	COM	35	15	20	absent	ear lobule	29	25
LEFT	3	AIQ	COM	35	15	25	absent	ear lobule	30	30
RIGHT	3	AIQ	RESIDUAL	30	10	20	absent	abdominal	23	25
RIGHT	3.5	PIQ	TRAUMA	35	10	25	absent	abdominal	25	25
LEFT	3	AIQ	RESIDUAL	30	15	15	absent	ear lobule	20	23
RIGHT	4	CENTRAL	TRAUMA	40	10	30	absent	ear lobule	30	28
LEFT	3.5	POSTERIOR	TRAUMA	40	10	30	absent	abdominal	28	30
LEFT	3	ASQ	COM	30	15	15	absent	abdominal	32	25
RIGHT	3.5	ANTERIOR	RESIDUAL	35	10	25	absent	abdominal	22	25
LEFT	3	PSQ	COM	40	15	25	absent	ear lobule	32	30
RIGHT	3	PIQ	COM	35	20	15	absent	ear lobule	26	27
RIGHT	3.5	POSTERIOR	COM	35	20	15	absent	abdominal	29	27
LEFT	3	AIQ	RESIDUAL	30	15	15	absent	abdominal	24	22

ABSTRACT:

To close perforations of the tympanic membrane till date, temporalis fascia has been the most commonly used graft material. In this study, the usage of fat as graft material to close dry small central perforations of the tympanic membrane has been evaluated. Patients between 15 - 50 years of age (both male and female) with inactive mucosal Chronic Otitis Media with small central perforations , limited to 1 quadrant of the tympanic membrane, with dry ear for atleast 6 weeks,with not more than 40dB conductive hearing loss were included in the study. Adipose tissue, of approximately twice the size of the perforation, was harvested from the posterior aspect of the lobule of the affected ear, and used to close the perforation like a dumbbell. The patients were followed up at 1 week, 2 weeks, 4 weeks, 6 weeks, 3 months and 6 months post-operatively. They were assessed for successful uptake of the fat graft in terms of closure of the