

A Dissertation on

**ROLE OF BIOLOGICAL FIBRIN TISSUE ADHESIVE
IN ENT & HEAD & NECK SURGERIES**

Submitted to

**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
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APRIL 2016

DECLARATION

I, **Dr. R.DEVENDIRAN**, solemnly declare that the dissertation, titled "**ROLE OF BIOLOGICAL FIBRIN TISSUE ADHESIVE IN ENT & HAED & NECK SURGERIES**" is a bonafide work done by me during the period of September 2013 to July 2015 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 Hospital, 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 2016.

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CERTIFICATE

This is to certify that the Dissertation - “**ROLE OF BIOLOGICAL FIBRIN TISSUE ADHESIVE IN ENT & HEAD & NECK SURGERIES**” presented by **DR.R.DEVENDIRAN**, is an original work done in the Department of Otorhinolaryngology, Government Stanley Medical College and Hospital, Chennai in partial fulfillment of regulations of the Tamil Nadu Dr. M.G.R. Medical University for the award of degree of M.S. (Otorhinolaryngology) Branch IV, under my supervision during the academic period 2013-2016.

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1. ABSTRACT

The tissue adhesives have been used for various surgical procedures as a part of reinforcement of surgical sutures. In our study, conducted in the department of ENT, Stanley medical college, Chennai, we have observed and evaluated the effectiveness of this biological fibrin tissue glue in our ENT & HEAD & NECK surgeries.

Objectives

To observe and evaluate the effectiveness of biological fibrin tissue adhesive in the ENT and Head & Neck surgeries as a supplementary procedure to conventional techniques.

Methods

40 patients have been chosen, after the execution of inclusion and exclusion criteria, based on review of literatures. Biological fibrin tissue glue TISSEEL has been used as supplementary to the conventional surgeries and the effects were evaluated post operatively.

Results

Out of 15 patients of total laryngectomy, 1 patient (6.6%) developed post op bleeding from the wound, 1 patient (6.6%) developed pharyngo cutaneous fistula. Out of 18 patients of tympanoplasty, 3 patients (16.6%) developed excessive granulation tissue in external auditory canal post operatively, 14 patients (77%), showed post operative hearing improvement, 1 patient (5.5%) deteriorated hearing level. 3 patients (16.6%) had residual perforation, 1 patient (5.5%) had recurrent disease. Of 5 patients of endoscopic CSF rhinorrhea repair, 1 patient (25%), developed meningitis and 1 patient had loss of smell.

Conclusion

Though we had got comparable results to the conventional techniques, we cannot definitely come to conclusion that tissue glue surgeries are effective , because of our sample size was too small. We have to further study the same in large trials.

Key words : fibrin tissue glue, tissue adhesive

2. OBJECTIVES

To study and observe the post operative effects of biological fibrin tissue adhesive , by using it as a supplement in the conventional ENT & head & neck surgeries like tympano/myringoplasty, endoscopic CSF rhinorrhea repair, pharyngeal closure of total laryngectomy, excision of laryngocoele, cleft palate repair.

INCLUSION CRITERIA

1. Age: 15-65 years.
2. For those who undergo ENT & HEAD & NECK surgeries where tissue adhesion/ fixation may be needed

EXCLUSION CRITERIA

1. <15 or >65 years of age.
2. Those who are allergic to bovine products
3. Patients with thrombo embolic disorders

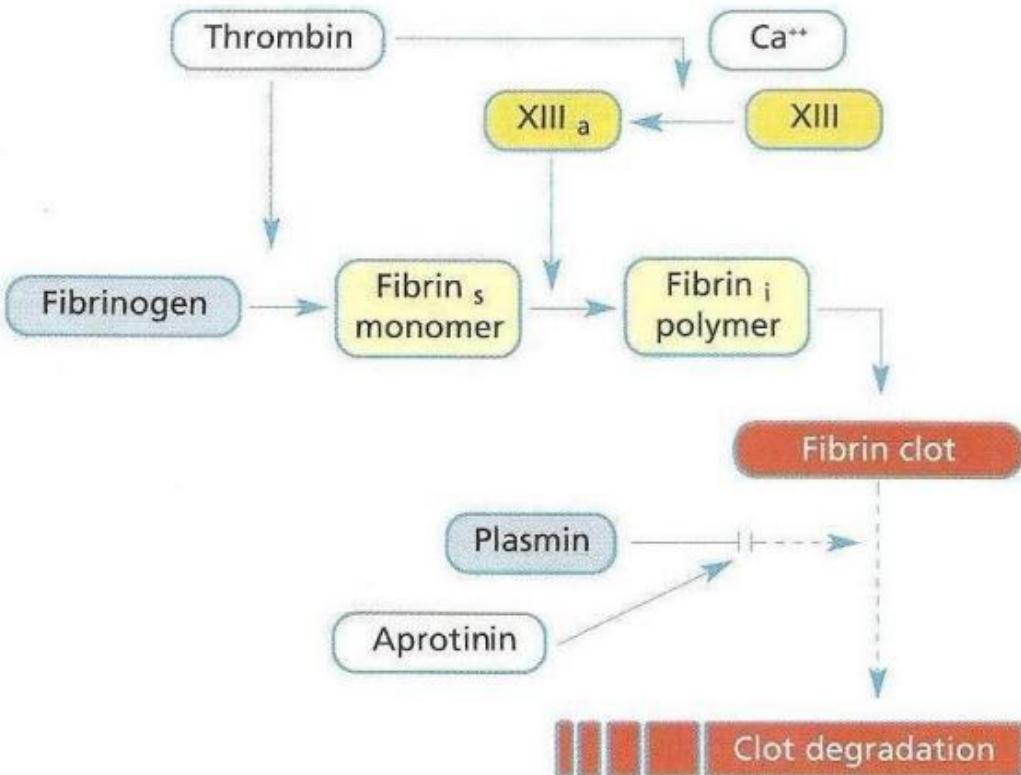
4. INTRODUCTION

Usefulness of adhesive materials for wound suturing or for fixation and stabilization of tissues, can be known long from ancient times. Initially bee wax, natural rubber , pitch had been used for covering the wound with comparable results. In the surgical methods of minimally invasive techniques, mostly in mucosal regions, secured fixation of skin grafts, implants and transplants are of great importance. In these situations , tissue glues are utilized as method of choice. From 1940, homologous fibrin glue is the most commonly used tissue adhesives.

Mechanism of fibrin tissue glue based adhesion

The fibrinogen and thrombin, in fibrin glue, cause the formation of cross-linked fibrin as that of the terminal phase of blood coagulation. The fibrinogen concentration in this glue, is 20 to 25 times more than that of circulating blood. So, fibrin is formed very fast. Another component , factor XIII, makes fibrin matrix indissoluble .

Also, most biological fibrin tissue adhesives contain anti-fibrinolytic substances such as aprotinin, tranexamic acid for strengthening the adhesion by preventing the fibrinolysis .



DEGRADATION OF FIBRIN TISSUE GLUE:

Fibrin deposits are degraded in several ways:

1. By proteolytic enzymes produced by inflammatory cells,
2. By phagocytosis by macrophages
3. By bacteriolysis (either by producing plasminogen activating factors or by production of direct acting fibrinolysin).

The time duration of biodegradation depends on the amount of fibrinogen and aprotinin used and the site of application (mostly 1-9 weeks).

Advantages:

- better adhesion in moist conditions
- nil heat is produced during fixation
- faster curing time (30sec)
- dissolution without major reactions in less than a week

Disadvantages:

- adhesive strength is not strong enough
- stress-labile adhesion
- bovine origin aprotinin has (even if low) risk of transmitting of diseases
- risk of transmission of blood-borne pathogens , as derived from blood products.

Indications:

- Adhesion of tissues,
- Haemostasis during adhesion,
- Support of wound healing

Contraindications of fibrin tissue glue:

1. arterial or heavy venous bleeding,
2. Thromboembolic disorders
3. allergic to bovine products

The time taking for resorption of adhesive will depend on the amount applied and on the site where it is applied. A fast resorption seen in areas with higher blood supply (mucosa, oral, nasal, gastrointestinal, parenchymatic organs). Cell culture studies showed positive effects of wound healing by fibroblasts.

Biological fibrin tissue glues are available in different trade names as TISSUCOL, TISSEEL, CROSSEAL, BERIPLAST. In our hospital we use TISSEEL fibrin glue commonly.

**QUALITATIVE AND QUANTITATIVE COMPOSITION OF
TISSEEL**

The ingredients are obtained by fractionating the pooled human plasma.

TISSEEL- components:



Sealer Protein solution

Active Ingredients

-Aprotinin (synthetic/ bovine) [3000KIU/ml]

-Factor XIII (10-50 U; one unit=amount contained in 1 ml of fresh normal plasma)

- Fibrinogen (high concentration 75-115 mg/ml)
- plasma fibronectin (2-9 mg/ml)
- plasminogen (40-120 g/ml)

Thrombin Solution

- Thrombin (human) [4 or 500 IU/ml]
- Calcium chloride solution (40 mmol /l)

Excipients

-Albumin (human)

-Histidine

-Nicotinamide

-Polysorbate 80

-Sodium citrate

-Water for injections

-Albumin (human)

-Sodium chloride

-Water for injections

1, 2 or 5 ml deep frozen sealer protein solution (with synthetic aprotinin) and 1, 2 or 5 ml deep frozen thrombin solution (with calcium chloride) combine to make 2, 4 or 10 ml ready-to-use fibrin sealant solution.

Reconstruction and application:***Preparing the TISSEEL Kit (Freeze-Dried)***

SHOULD NOT BE EXPOSED MORE THAN 37 DEGREE CELCIUS

SHOULD NOT MICROWAVE

SHOULD NOT FREEZE AFTER RECONSTITUTION

We have to use separate transfer devices and syringes for reconstitution of Thrombin solution and sealer protein solutions for application to avoid premature clotting.

We have to use the reconstituted solution within 4 hours of preparation. Freeze-dried Sealer Protein Concentrate is reconstituted in Fibrinolysis Inhibitor Solution and thrombin is reconstituted in Calcium Chloride Solution. The both solutions are then mixed using the DUPLOJECT Preparation and Application System, or an equivalent delivery system approved by FDA for use of TISSEEL, to form the Fibrin Sealant.

Prewarming TISSEEL Kit with FIBRINOTHERM

We have to keep all four vials from the TISSEEL Kit into the prewarmed wells of the FIBRINOTHERM, using the correct sized

adapter ring(s), and allow them to warm for up to 5 min. (room temperature product will take less time).



Preparation of Sealer Protein Solution with FIBRINOTHERM

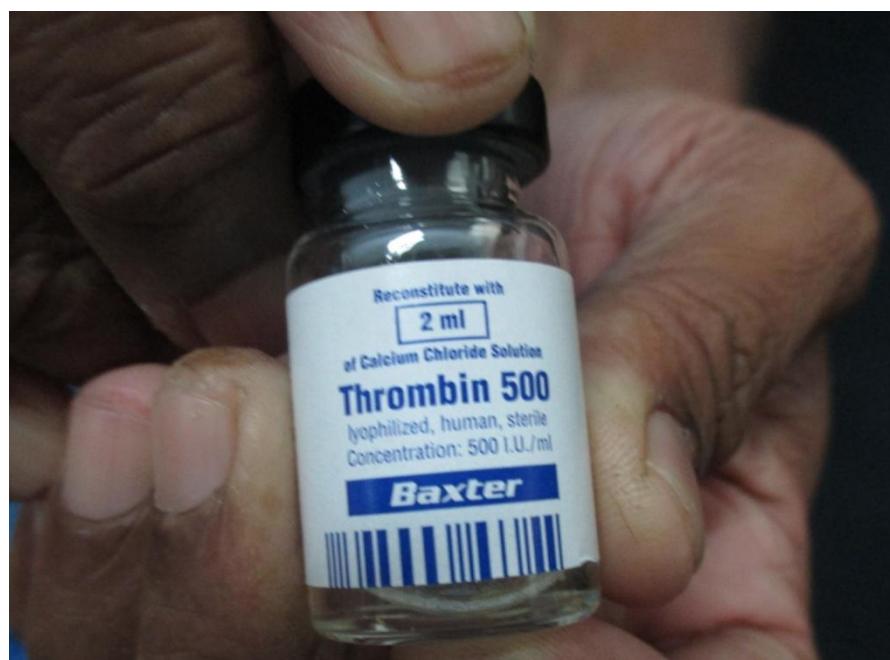
1. We have to remove the caps of the Sealer Protein Concentrate and the Fibrinolysis Inhibitor Solution vials.
2. Transfer the Fibrinolysis Inhibitor Solution into the vial of the freeze-dried Sealer Protein Concentrate using the sterile reconstitution components. We have to make sure that the product is completely soaked by swirling gently.

3. Keep the vial into the largest opening of the FIBRINOTHERM device with the matched adaptor. Switch on the stirrer and make all Sealer Protein Concentrate is dissolved completely.
 - We have to discard the vial if sealer protein concentrate is not dissolved completely within 20 minutes, and to prepare the fresh solution.
 - We have to keep the Sealer Protein Solution at 37°C without stirring. To ensure homogeneity, stir just before drawing up the solution. Reconstitution is completed only when no undissolved particles are seen.



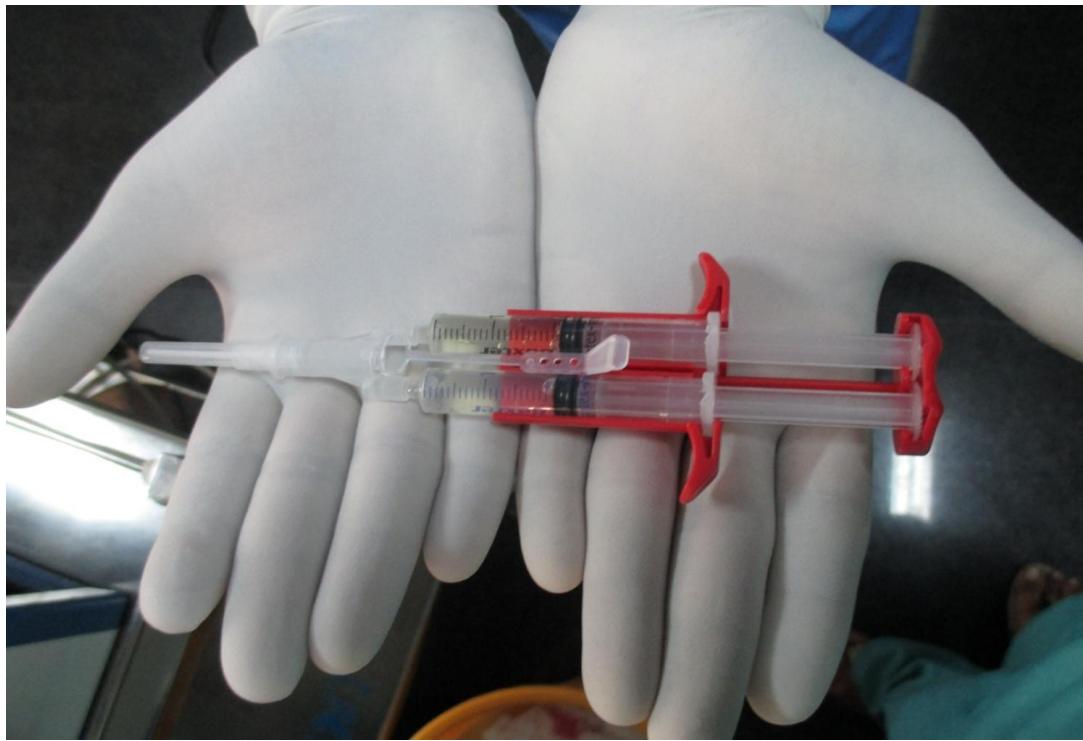
Preparation of Thrombin Solution with FIBRINOTHERM

We have to follow the same steps as Preparation of Sealer Protein with FIBRINOTHERM for reconstitution of thrombin with calcium chloride solution by using appropriate vials.



Transfer of TISSUE GLUE to the Sterile Field

The circulating nurse should clean the tops of the vials with a antiseptic solution and allow to dry. The scrub nurse should withdraw the sterile solutions while the circulating nurse holds the non-sterile vials. The solutions have to be withdrawn slowly by firm constant aspiration to reduce large air bubbles entering the syringe .



4. REVIEW OF LITERATURE:

Fibrin glues have been used mostly in cardiothoracic , gastrointestinal and neurosurgery cases. The studies on usefulness of fibrin glue in ENT surgeries are very few and in that too, most are animal based studies. Only few case studies are available at present .

Fibrin glues have been used in myringoplasty. In 2007 Sakagami et al. reported success rate of 78% in myringoplasty underlay technique with various grafts in 391 patients of central tympananic membrane perforations. The success rate of myringoplasty without fibrin tissue glue was lower. Because of insufficient stiffness, this is not recommended for reconstruction of the ossicular chain with loss of the long process of the incus.

There is major challenge to invent appropriate suitable devices in microscopic surgeries, where the amount of glue to be used is too small in quantity.

Draf et al.in 1980 and Hosemann et al. in1991 used to fix transplants in dural repair by endonasal technique with better results. The insufficient adhesive strength caused by displacement of transplanted material into the inner nose. Also they found very difficult

in application of gel in surgical fields as unavailability of suitable application systems.

In 2003, Daneshrad et al used fibrin glues for the prevention of septal hematomas and for the suturing methods of mucosa in nasal septal surgeries. He observed better healing processes in 100 patients.

Erkan et al. observed the effect of fibrin tissue glue on rabbit's nasal mucosal tissues. A characteristic inflammatory tissue reaction with , increased thickness of mucosa , reduced perichondrial and cartilage thickness as well as cartilage damage, was seen histologically. The amount of tissue glue used and the form in which it used, played major role in that study.

The publications, about the use of tissue glue for mucosal closure in the gastrointestinal tract surgeries, are very few . In 1989 Weerda et al. used the fibrin glue to seal a mucosal lesion in the transaction of the wall of Zenker's diverticulum. Fibrin tissue glue was used in small esophagus lesions of iatrogenic causes with partly better results.

1981,Naumann und Lang described the fixation of the mucosa in laryngeal widening by using fibrin tissue adhesive. Adhesions in the lower trachea and the bronchial system, mainly in emphysematous

lung, bronchopleural fistulae to prevent leakages during wedge resection of the lung showed better results . Takagi et al. tested the effect of fibrin glues on wound healing in tracheal anastomoses of rats and noticed decreased development of collagen and hydroxyproline in the those rabbits where fibrin glue used additionally to suture.

RELEVANT ANATOMY

RELEVANT ANATOMY OF EAR

External Auditory canal

It is 24 mm long canal. The outer one-third (8 mm) and inner two-thirds (16 mm) are formed by cartilaginous and bony parts respectively.

Fissures of Santorini are the defects seen in floor of cartilaginous portion of external auditory canal (EAC). EAC is S shaped. Lateral part is pointing upwards , backwards and medially. Medial part is pointing downwards, forwards and inferiorly. The narrowest constricted part of the external auditory canal is called the Isthmus ,which is 5 mm short of tympanic membrane in the bony segment. Anterior canal wall and floor of meatus are longer than the posterior wall and roof . Tympanic plate

of temporal bone forms the anterior , posterior walls and floor of the canal, while squamous temporal bone forms part of posterior canal wall & floor of EAC.

Because of the differences in the lengths of the canal wall, there is recess near the inferior wall. It is called as meatal recess. The skin of the EAC is tightly attached to the walls , and that is the reason for severe pain in otitis externa as the pressure is more. Hair, sweat and ceruminous glands are seen only in the cartilaginous part of the EAC.

EAC is related anteriorly to the condylar process of mandible , superiorly to the middle cranial fossa , posterioly to the mastoid air cell system.

Nerve supply :

Anterior wall and roof - auriculotemporal branch of mandibular nerve.

Posterior wall and floor – auricular branch of vagus (Arnold's nerve).

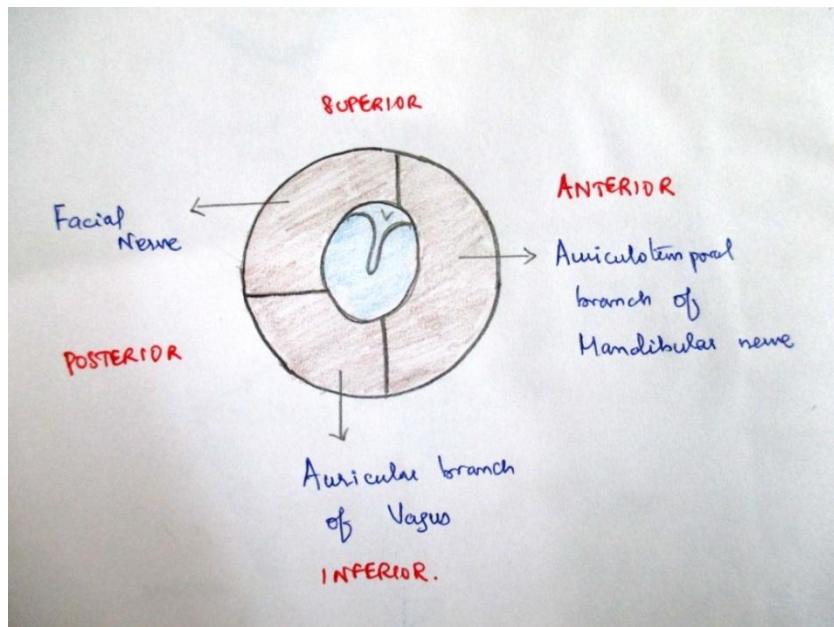


Fig. showing nerve supply of external auditory canal

Middle Ear Cavity (Tympanic cavity)

This is a space situated in the petrous part of temporal bone medial to tympanic membrane. It is irregular and biconcave in shape. The middle ear is divided anatomically into three regions. They are epitympanum, mesotympaum and hypotympaum. This is 15 mm in both vertical and anteroposterior dimensions, while horizontal diameter is 6 mm in upper part, 4 mm in lower part and 2 mm at the level of umbo.

It contains air, ossicles, mucosal folds and tendons of tensor tympani and stapedius muscles. Middle ear communicates anteriorly

with nasopharynx in its lateral wall through auditory tube and posteriorly with mastoid antrum and its air cell system by aditus.

Walls of middle ear

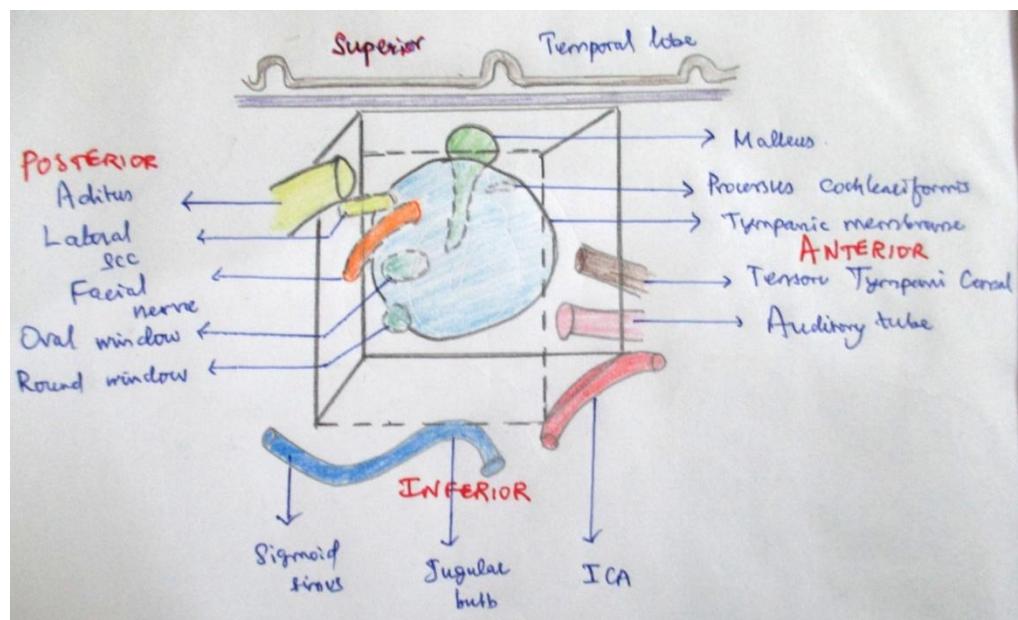


Fig. showing structures of walls of middle ear

Roof: It is called as Tegmen tympani and it is formed by parts of petrous and squamous temporal bones. There is a suture line between these bones (petrosquamous suture line). This suture line transmits the veins between the middle ear cavity and intracranial structures.

Floor: This is formed by a thin plate of bone which separates the middle ear cavity from jugular bulb of IJV at the lower end of sigmoid sinus. It contains a small opening near the medial wall for the branch of

glossopharyngeal nerve (Jacobson's nerve) which forms the tympanic plexus over the promontory of middle ear.

Lateral wall: is formed by tympanic membrane which separates middle ear from external acoustic meatus. It is semitransparent, pearly grey in color and it is 9-10 mm tall, 8-9 mm wide and 0.1mm thick.

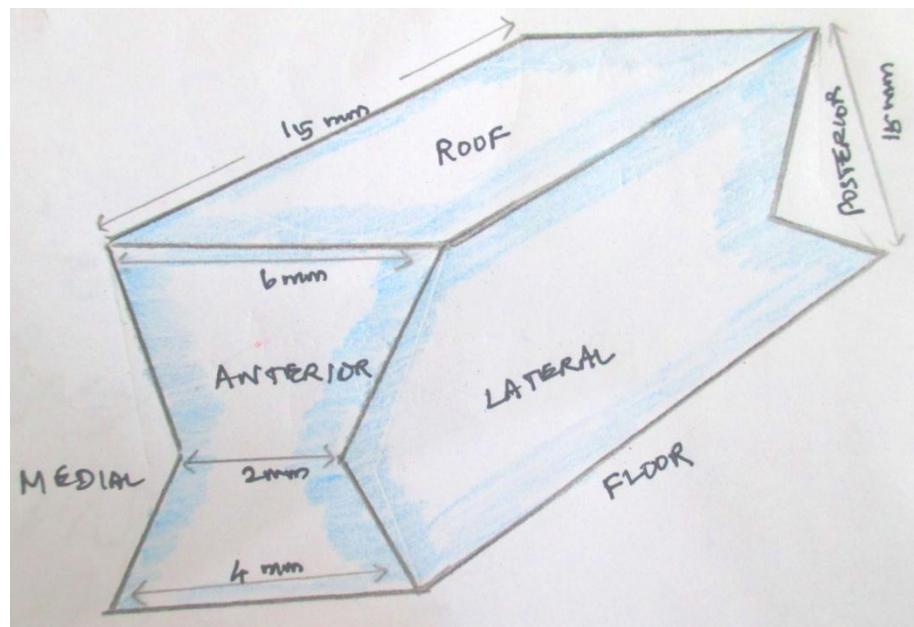


Fig. Showing dimensions of middle ear cavity

The infants have thicker tympanic membrane than an adult. Tympanic membrane is located at an angle of 55 degree with the inferior wall of EAC. Total amount of surface area of tympanic membrane is 85 sq mm, whereas vibrating surface is only 55 sq mm in size.

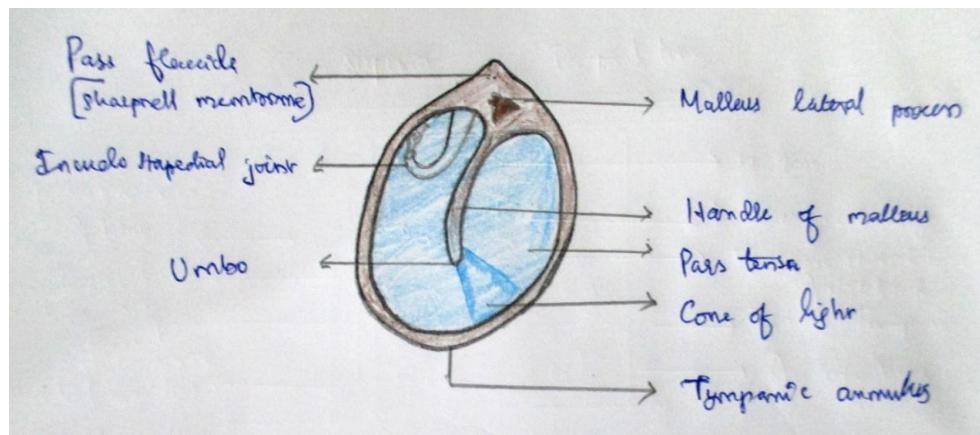


Fig : shows landmarks of normal tympanic membrane

Margins of the tympanic membrane is firm & thickened to form the fibrous annulus which sits in the tympanic bony sulcus. In the upper part of the tympanic membrane ,annulus is absent as there is deficient tympanic sulcus. The membrane is made up of two parts. The lower tense part, with all three layers of tympanic membrane, is called Pars tensa and the upper flaccid part, without middle fibrous layer ,which lies above the anterior and posterior malleolar folds, is called Pars flaccida (otherwise known as Sharpnell's membrane) which is 2 to 3 mm thick in average.

The tympanic membrane contains three layers derived from the three embryological germ layers. They are :

Outer skin lined epithelial layer derived from ectoderm.

Middle fibrous layer derived from mesoderm. This layer contains outer circular and inner middle fibers.

Inner mucosal layer derived from endoderm. It is the extension of the mucosa of the middle ear cavity.

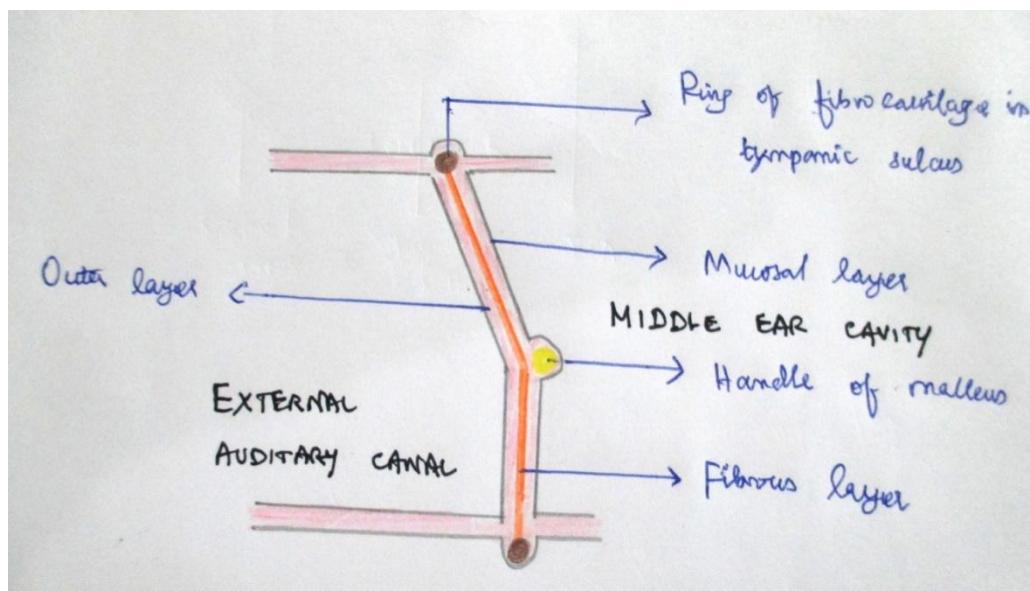


Fig. showing three layers of tympanic membrane

Nerve supply :

Anterolateral surface by - auriculotemporal branch of mandibular nerve,

Posterolateral surface - Arnold's nerve (auricular branch of vagus),

Medial surface - Jacobson's nerve (tympanic branch of glossopharyngeal nerve).

Blood supply :

Outer epithelial layer - deep auricular branch of the maxillary artery,

Middle and fibrous layers - stylomastoid branch of occipital or posterior auricular artery, tympanic branch of maxillary artery.

Veins drain to external jugular vein and transverse sinus.

Medial wall: This contains

- **Promontory:** is seen as a bulge in the medial wall. Actually this is caused by projection of cochlea at its basal turn into the middle ear cavity.
- **Fenestra vestibuli** (otherwise known as oval window) : a depression seen posterior and superior to the promontory ,which forms the lateral end of scala vestibuli. It is 3.25×1.75 mm in dimension . This oval window is covered by a foot plate of stapes which is fixed by annular ligament to the margins of oval window.
- **Fenestra cochleae** (otherwise known as round window): a depression seen posteroinferior to promontory, opens into scala tympani of cochlea, measuring 1.5×1.3 mm. It is closed by secondary tympanic membrane. The posterior semicircular canal ampulla is closely situated to the oval window.

- **Fallopian canal of facial nerve** : This is seen as a prominent ridge which lies above the oval window curving inferiorly into posterior wall. There is a hook like bony projection ,seen on the medial wall of the middle ear just anterior to the oval window .It is called as Processus Cochleariformis. It acts as a pulley to the tensor tympani muscle tendon.

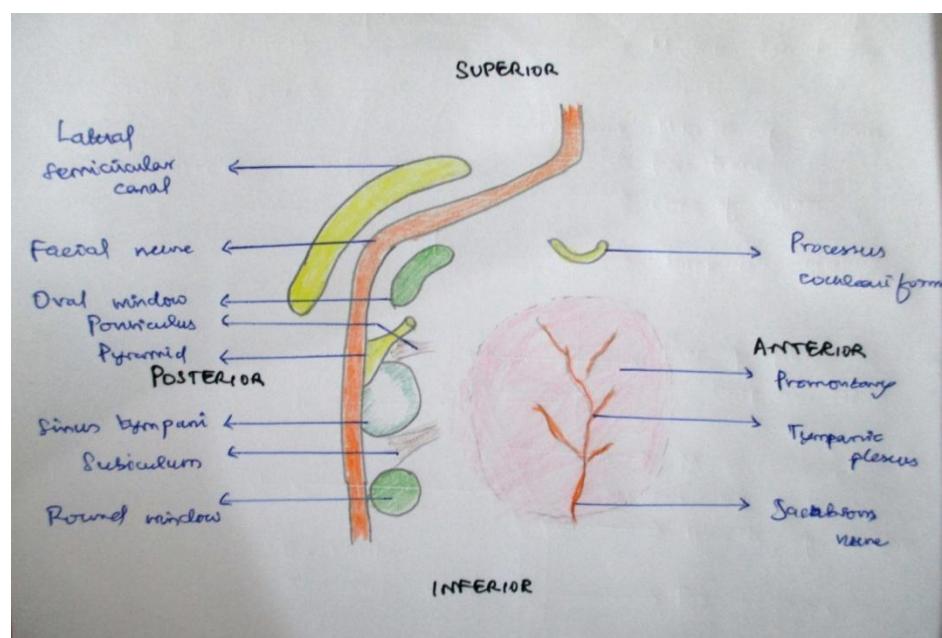


Fig: schematic diagram of the medial wall of middle ear

Posterior wall of middle ear : It contains

- **Pyramidal eminence** : a bony projection seen on the posterior wall along the facial nerve course. It contains the stapedius muscle.
- **Aditus**: The aditus to mastoid antrum (otomastoid foramen or entrance or aperture to the mastoid antrum) is a large irregular aperture that leads backward from the attic into tympanic or mastoid antrum..

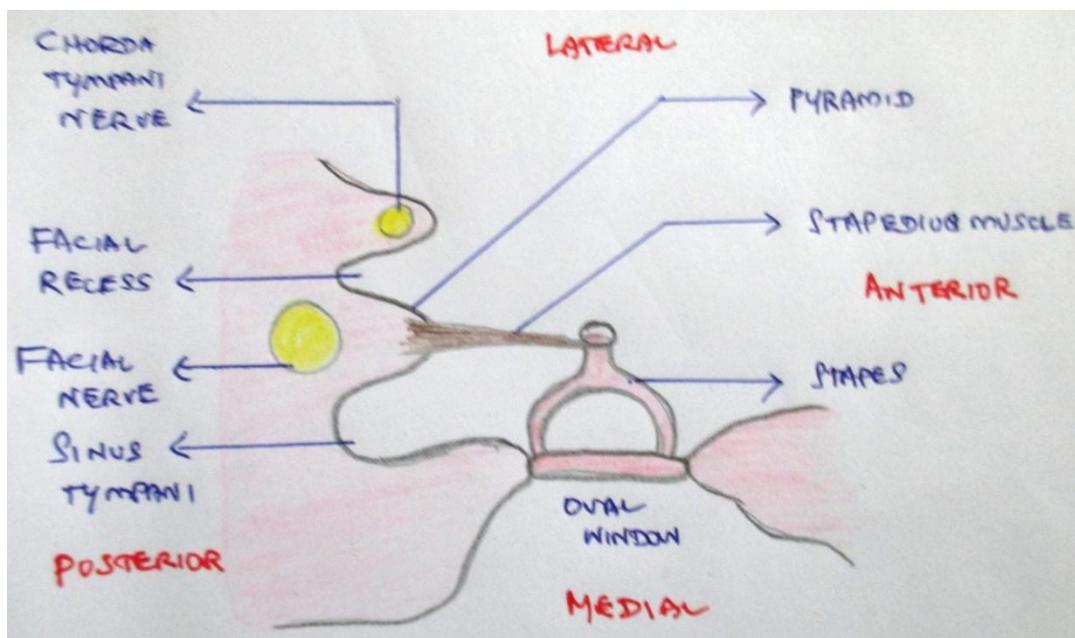


Fig. shows structures of the posterior wall of middle ear cavity

- **Fossa incudis** : a depression seen on the posterior wall in the epitympanic region, which holds the short process of the incus cartilage.
- **Facial recess:**

This is a depression on lateal part of the posterior wall & it lies lateral to the vertical mastoid segment of the 7th cranial nerve.

Boundaries of the facial recess:

Superiorly : fossa incudis with short process of incus

Medially : facial nerve with its external genu

Anterolaterally : by tympanic membrane

Laterally : chorda tympani nerve

Posterior tympanotomy without disturbing the tympanic membrane can be done through the facial recess.

Anterior wall: It has the following openings.

- Superiorly- canal for tensor tympani muscle extending to medial wall towards processus cochleariformis.
- Inferiorly - osseous opening of auditory tube .
- Glasserian fissure – known as opening for carotid canal –which contains sympathetic caroticotympanic nerves from the internal carotid artery.
- Canal of Huguier- this canal transmits chorda tympani nerve.

Auditory middle ear Ossicles

These are malleus, incus and stapes .

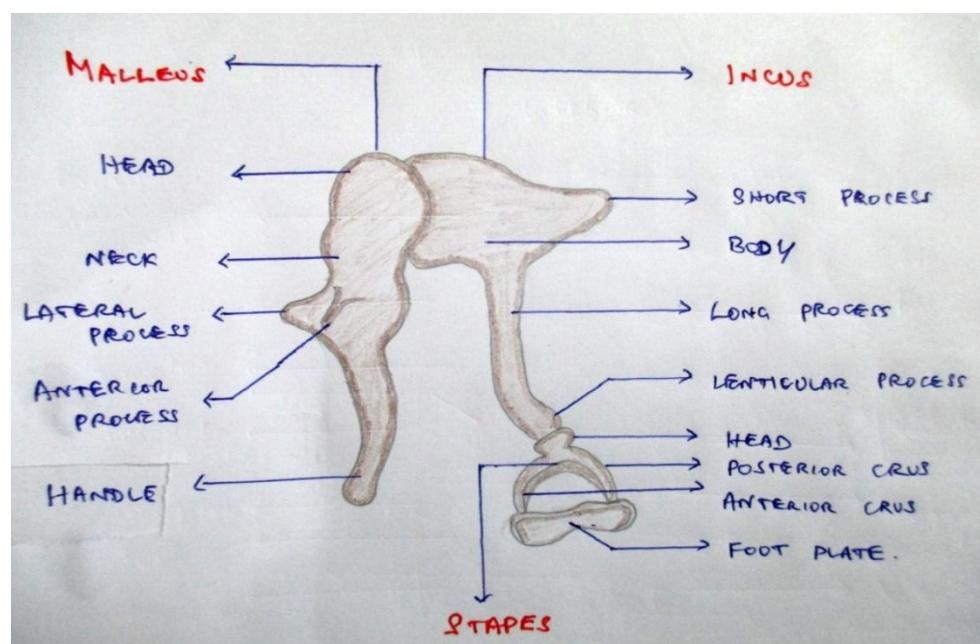


Fig. shows parts of three middle ear ossicles

Malleus: This mallet shaped ossicle, is 8 to 9 mm long, weighs 23 to 25mg and is the largest of the three ossicles. Parts of malleus are head, neck, handle, lateral and anterior processus. Head of the malleus lies in attic and articulates with the incus body.

Incus: This an anvil shaped cartilage, weighs 25 to 30 mg. Parts of the incus are the body, short process, long process and lenticular process.

Stapes: It weighs 2.5 to 3 mg. This is the smallest and shortest bone of the whole human body. Parts of the stapes are head, neck, two crurae, and foot plate. Foot plate closes the oval window.

Blood supply for ossicles are by branches of anterior, posterior and inferior tympanic arteries.

Muscles of middle ear

Stapedius muscle : This muscle originates from pyramidal eminence near its apex and is attached to the neck of stapes. It is supplied by stapedial branch of facial nerve from its vertical segment.

Actions: Both the muscles contract and dampen the sound transmission, when exposed to high intensity sounds. Thus they have a protective role . Paralysis of stapedial nerve causes hyperacusis.

Tensor tympani muscle : It originates from cartilaginous part of the auditory tube and part of greater wing of sphenoid bone. It is inserted to the handle of malleus near its root. It gets its nerve supply from mandibular division of trigeminal nerve.

Compartments and mucosal spaces of tympanic cavity

Attic communicates with mesotympanum by two openings in the medial side of epitympanic diaphragm. They are called as Isthmus tympanicus anticus and Isthmus tympanicus posticus. Upper part of mesotympanum has three compartments— anterior and posterior pouch of Von Troltsch and inferior incudal space .

These mucosal spaces play an important role in the spread of cholesteatoma form its origin.

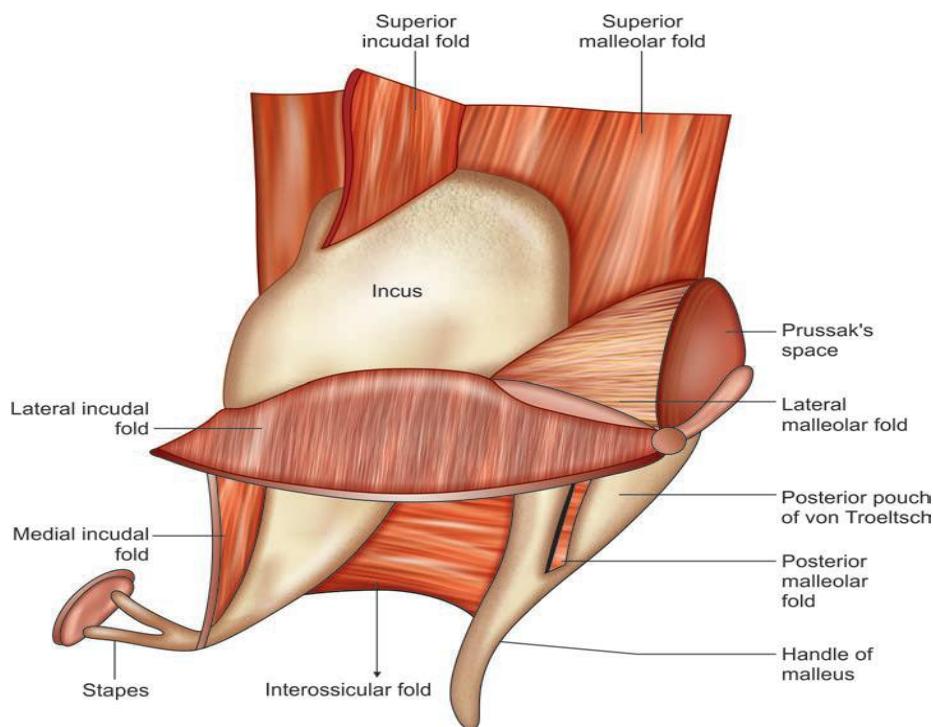


Fig: Middle ear spaces

Prussak's space: It is a small triangular shaped mucosal space in the attic region.

Boundaries of prussak space:

Medially- neck of malleus

Laterally – pars flaccida

Inferiorly- lateral process of malleus

Superiorly –lateral malleolar fold

Attic cholesteatoma commonly originates from the prussak space.

Facial recess and sinus tympani: Sinus tympani (otherwise known as infrapyramidal recess) is a triangular space which lies medial to vertical part of facial nerve between the ponticulus and subiculum. It begins at oval window and occupies a space deep to vertical mastoid part of 7th nerve and pyramid, crossing behind round window niche to hypotympanum. Facial recess, otherwise known as suprapyramidal recess, is bounded by, chorda tympani (laterally), facial nerve (medially) and fossa incudis (above) .

Mucous Membrane of Middle Ear

Tympanic cavity is lined by ciliated columnar epithelium near the opening of Eustachian tube (anterior and inferior part of tympanum). Posterior part is lined by cuboidal epithelium . Epitympanum and mastoid air cells are lined by non ciliated flat epithelium.

Blood supply of middle ear :

Anterior tympanic artery – branch of maxillary artery
 Superior tympanic artery – branch of middle meningeal artery
 Posterior tympanic artery – branch of stylomastoid artery which is a branch of posterior auricular artery
 Inferior tympanic artery – branch of ascending pharyngeal artery and deep auricular artery.

Lymphatics: drain to pre auricular and parotid and level 2 cervical lymph nodes.

Veins: drain into superior petrosal sinus and pterygoid venous plexus.

Nerve supply : from the tympanic plexus which is formed by union of tympanic branch of glossopharyngeal nerve and sympathetic branches from internal carotid artery. Mastoid antrum is supplied by meningeal branch of mandibular nerve.

RELAVANT ANATOMY OF NOSE

The nasal cavity is divided into equal sized cavities by midline septum. Anteriorly it opens into the external nares through vestibule and posteriorly into nasopharynx through the choanae. The posterior mucosa lined part is called nasal cavity proper and anterior skin lined region is known as vestibule.

Lateral Wall of Nasal Cavity

Bones forming lateral nasal wall :

- Medial pterygoid plate of sphenoid bone
- Perpendicular plate of palatine bone

- Ethmoid: Lateral mass of ethmoidal bone
- Inferior turbinate
- Lacrimal bone
- Maxillary bone : Frontal process and medial surface maxilla and medial wall of maxillary sinus
- Nasal bone

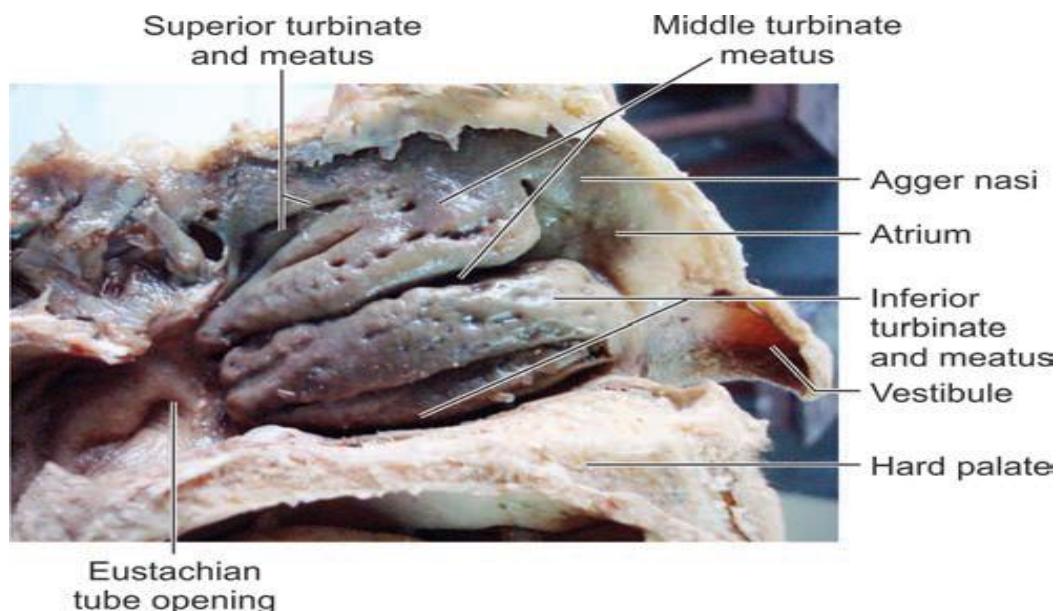


Fig: cadaveric lateral nasal wall showing turbinates and meatuses

Turbinates: Three fingers like bony projections are seen on the lateral wall of nose. They are superior, middle and inferior turbinates.

–the smallest superior turbinate is a part of ethmoid bone. It is placed posterio-superior to the middle turbinate and so not usually seen on examining through anterior rhinoscopy.

- the middle turbinate is the part of the ethmoid bone
- the inferior turbinate , the biggest and longer turbinate, is a separate bone.

In some rare cases, there is a small supreme turbinate seen near the roof of the nasal cavity.

Meatuses: The spaces lying lateral and inferior to the corresponding turbinates are called meatuses.

– *Inferior meatus*: It is situated along the entire length of the lateral nasal wall. Nasolacriaml duct opens into the inferior meatus approximately 1 cm posterior to the anterior end of inferior turbinate. Its nasal end is protected by a mucosal valve called Hasners valve.

– *Middle meatus* : It is situated below and lateral to the middle turbinate. Maxillary, frontal and anterior ethmoidal sinuses open here.

Atrium: This depression is situated in front of the middle meatus just above the vestibule.

– *Superior meatus*: It is the smallest meatus and situated only in the posterior third of lateral wall . Posterior ethmoidal sinuses drain in this space. This space lies behind the ground lamella of middle ear.

Sphenoethmoidal Recess: It is situated above the superior turbinate. The sphenoid sinus drains into this space medial to middle turbinate. Its ostium is situated 1-1.5 cm above the upper margin of choanae near the posterior end of nasal septum.

Medial Wall: is formed by the nasal septum

Roof: has 3 parts

- anterior sloping part is formed by nasal bones,
- middle horizontal part is formed by cribriform plate of ethmoid
- posterior sloping part is formed by body of sphenoid bone.

Floor: This is formed by hard palate which separates the nasal cavity from oral cavity. Palatine process of maxilla forms the anterior three fourth of hard palate and posterior one fourth of palate is formed by horizontal process of palatine bone.

Nasal Septum

It is divided into three parts. Anteriorly situated columellar and membranous parts can be moved sideways but not the posteriorly situated septum proper part.

1. ***Columellar Septum:*** The columella contains two medial crurae of both lower lateral cartilages, which are anchored together by the fibrous tissue. It is covered on both sides by skin.
2. ***Membranous Septum:*** This cartilage deficient part of membranous septum is placed between columellar septum and caudal part of quadrangular septal cartilage .This part is actually contains only double layers of skin.
3. ***Septum Proper:*** It is covered on both sides by mucous membrane and consists of osteocartilaginous framework. Anteriorly the large quadrangular cartilage is seen as a wedged structure between vomer and palatine bone. Posterior bony part is formed by perpendicular plate of ethmoid bone in its upper part and vomer bone in lower part. Other bones, which make very small contributions include anterior nasal spine of maxilla, crest of nasal bones, nasal spine of frontal bone, crests of palatine and maxilla, rostrum of sphenoid.

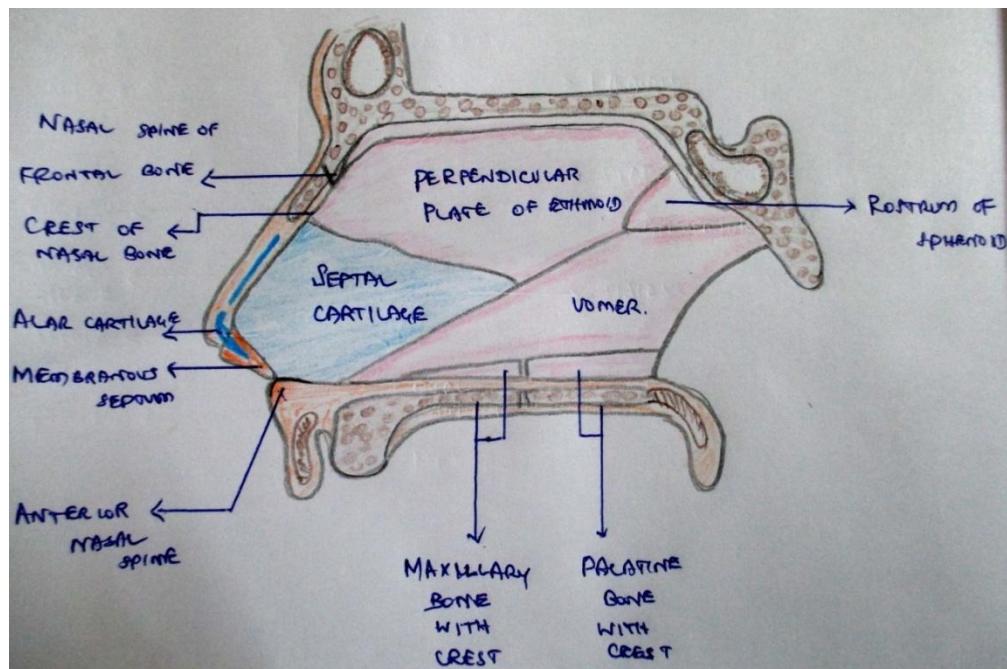


Fig. shows structures forming nasal septum

Septal Cartilage: It forms major framework of anterior part of nasal septum.

Inferior margin: This lies in the groove formed by maxillary and palatine crest .

Superior margin: It fuses with the upper lateral cartilages of external nose. Hence any deviations of the septal cartilage are associated with external deviation of nose.

Middle Meatus and Osteomeatal Complex

Middle meatus is a space which lies below and lateral to the middle turbinate. It represents the posterior half of the lateral nasal wall. The osteomeatal complex includes middle turbinate, bulla ethmoidalis, uncinate process, maxillary ostium in ethmoidal infundibulum. It has the critical drainage pathway of maxillary, frontal and anterior ethmoidal paranasal sinuses.

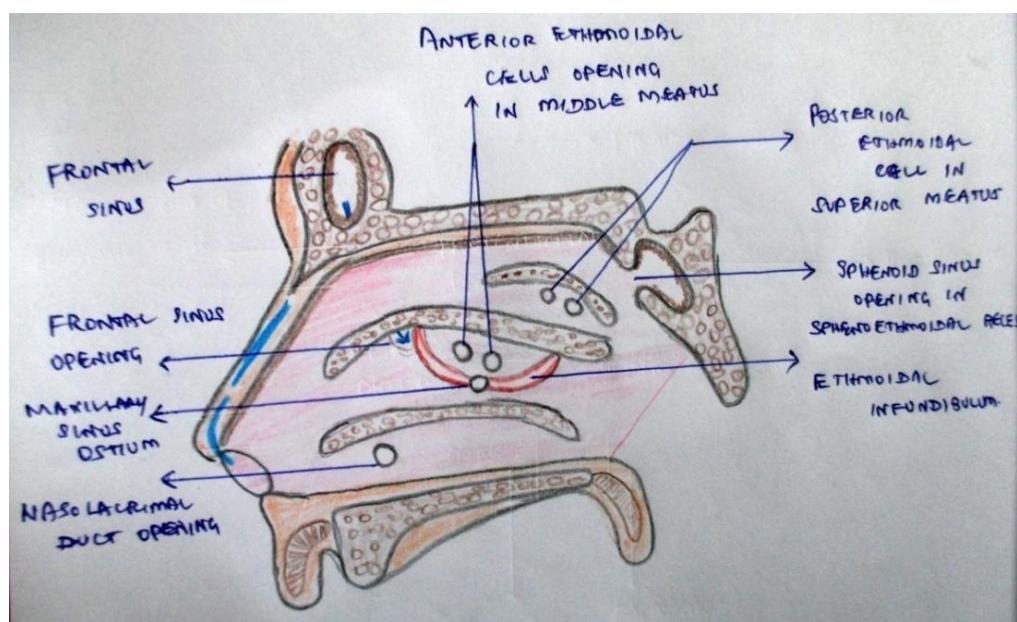


Fig. shows structures of lateral nasal wall

Middle Turbinate: This ethmoidal turbinate is attached to the lateral nasal wall through the ground basal lamella. It has three parts with different orientations in all three parts. Its posterior part is in horizontal plane and is attached to the palatine bone. This part forms the

roof of the middle meatus. Middle part is oriented in frontal plane and is attached to the lamina papyracea. Anterior part is in sagittal orientation and is attached to the lateral part of cribriform plate.

Fracture of middle turbinate during endoscopic sinus surgery can cause damage to the cribriform plate and cause CSF rhinorrhea.

Paradoxical middle turbinate : In some cases, instead of being bent laterally, the middle turbinate may have its convex side laterally. This anatomical abnormality is called as Paradoxical middle turbinate. This can interfere with the drainage pathway of paranasal sinuses and can cause sinusitis.

Concha Bullosa: Pneumatised middle turbinate is called Concha bullosa. This anatomical variation is seen in 30% normal population. Mostly it is asymptomatic. Rarely can it interfere with sinus drainage pathway.

Bulla Ethmoidalis: This is the most constant and largest ethmoidal air cell. It lies medial to the lamina papyracea and anterior to ground lamella of middle turbinate. Depending upon the pneumatisation, it can reach up to skull base superiorly, ground lamella of middle turbinate posteriorly. Sometimes bulla will be completely

nonpneumatized. In this condition there will be bony mound on the lateral wall. This will be called as Torus lateralis.

Lateral Sinus of Grunwald: When the pneumatization of bulla ethmoidalis does not reach the skull base or ground lamella , there will be a space above and behind the bulla ethmoidalis. This space is called Lateral sinus of Grunwald. It opens medially into the nasal cavity through the superior hiatus semilunaris.

Hiatus Semilunaris: This is a two dimensional space which lies between the posterior free border of uncinate process and anterior wall of bulla ethmoidalis. This will lead to a three dimension cleft laterally this cleft is known as the Ethmoidal Infundibulum.

Uncinate Process: This thin part of ethmoid bone, sickle shaped, runs from anterosuperiorly to posteroinferiorly and forms the medial wall and floor of the ethmoidal infundibulum.

It has two borders. Free posterior border forms the anterior border of Hiatus semilunaris. Anteoinferior border is attached to the lateral nasal wall.

It has two ends. Anterosuperior end is highly variable in attachment. It can be attached to the lamina papyracea, skull base or middle turbinate. Depending upon the attachment frontal sinus drainage pathway will vary. Posteroinferior end is attached to the inferior turbinate. This part divides the lower membranous portion of middle meatus into anterior and posterior fontanellae.

Agger Nasi: Anterior most ethmoidal air cell is called Agger nasi. This is seen just anterior to the anterior end of middle turbinate. It gets its aeration from frontal recess. If it is enlarged, it can obstructs the frontal recess and interferes with frontal sinus drainage pathway.

Ethmoidal Infundibulum:

Boundaries:

- *Lateral:* Lamina papyracea.
- *Medial:* Uncinate process and frontal process of maxilla and sometimes lacrimal bone.

Anterior ethmoidal and maxillary sinuses drain into the ethmoidal infundibulum. Frontal sinus opens into the anterosuperior part of infundibulum just posterior to posterior wall of agger nasi cells (curved ridge running downwards and forwards above the atrium).

Blood Supply of Nose

Nasal cavity is supplied by branches of both internal and external carotid arteries.

Posteroinferior part of the nasal cavity is supplied by the sphenopalatine and greater palatine branches of the internal maxillary artery which is a branch of external carotid artery.

Anteroinferior part is supplied by external labial branches of the facial artery which is a branch of external carotid artery.

Superior part of nasal cavity is supplied is by anterior and posterior ethmoidal arteries which are the branches of ophthalmic artery which is a branch of internal carotid artery.

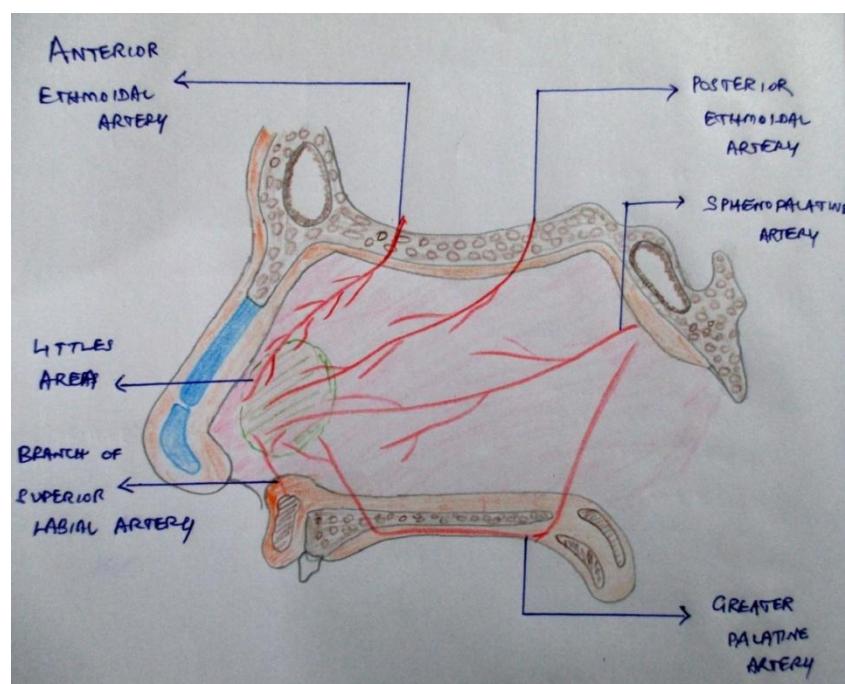


Fig: blood supply of nasal septum .

Submucosal Vascular Plexus

The nasal cavity mucosa has rich submucosal vascular plexus which consists of arterioles, capillaries, venules and venous sinusoids. This structure is comparable to the erectile tissues of external genitals. They are under autonomous nervous control. Parasympathetic stimulation will cause vasodilatation and congestion of submucosal plexus.

Nerve Supply of Nasal Cavity

Olfactory nerves carry sensation of smell from olfactory region of nose. This consists of upper one third of nasal septum and its corresponding areas of lateral nasal wall.

Nerves of common sensation are anterior ethmoidal nerve, sphenopalatine and branches of infra orbital nerve. Parasympathetic and sympathetic nerves pass through the sphenopalatine ganglion.

RELATED ANATOMY OF LARYNGOPHARYNX

Hypopharynx (Laryngopharynx)

This is the lowest part of the pharyngeal tube. This lies partly posterior and lateral in relationship to the larynx on both sides. It extends from level of the hyoid to the level of lower border of

cricoid cartilage and related to the C4,C5, C6 cervical vertebrae. It communicates with Oropharynx in upper part and continuous with the oesophagus at the level of the cricoid cartilage.

It is divided into three parts .

1.Pyriform fossa

2. Post cricoid region

3.Posterior pharyngeal wall

Pyriform sinus

It is a recess on both sides of the larynx and an inverted pyramid like structure .It extends from the pharyngo-epiglottic fold superiorly to the apex inferiorly. It communicates with post cricoid region.

It is bounded by the Aryepiglottic fold medially and the thyrohyoid membrane and thyroid cartilage laterally .

Post Cricoid region

It extends from the level of arytenoid cartilage and connecting folds to the inferior border of cricoids cartilage .It thus forms the anterior wall of hypopharynx .

Posterior Pharyngeal wall

It extends from the level of the hyoid bone to the level of cricoarytenoid joint.

Layers of the pharyngeal wall

The pharyngeal wall is made up of four layers

1. Mucous membrane

Nasopharynx is lined by pseudostratified ciliated columnar & Oropharynx and Laryngopharynx are lined by stratified squamous epithelium.

2. Pharyngeal aponeurosis

It lies between the mucosal and muscular layers and thickened In the upper part and is called pharyngobasilar fascia.

3. Two Muscular layers

Outer layer consists of superior, middle and inferior constrictors muscles. Inner layer consists of three muscles namely stylopharyngeus, palatopharyngeus and salphingopharyngeus.

Nerve supply of pharynx

The pharyngeal plexus which supplies to the upper part of the pharynx (including the surface of the tonsil and all the muscles of the Pharynx), except the stylopharyngeus muscle which is supplied by the glossopharyngeal nerve.

	Thyroid	Cricoid	Eiglottis
Shape	Shield	ring	Leaf
Parts	Two lamina joins at an angle of 90 & 120 degrees in male and female respectively	Anterior narrower arch and posterior border lamina	Mobile suprahyoid and fixed infrahyoid parts
Muscles attached	Sternothyroid, thyrohyoid, inferior constrictor, thyroarytenoid	Inferior constrictor, cricothyroid and cricoarytenoid	aryepiglotticus
Membranes / ligaments attached	Thyrohyoid and cricothyroid membrane	Cricothyroid membrane	Thyroepigotticus ligament
Functions	Protects the larynx	Laryngotracheal connections	Guards the laryngeal inlet
histology	Hyaline cartilage	Hyaline cartilage	Fibro elastic cartilage

Framework of the larynx

The cartilages of the larynx are three unpaired and three paired cartilages. The unpaired cartilages are thyroid, cricoid, epiglottis.

Paired Cartilages:

The paired cartilages are arytenoids, corniculate and cuneiform. The arytenoids cartilages form the posterior support for the laryngeal folds. It has two processes. Vocal process pointing anteriorly attached to the vocal cord and forms posterior commissure of glottis and muscular process gives attachments to the laryngeal muscles. The arytenoids articulate with the lamina of the cricoid cartilages. The corniculate and cuneiform cartilages articulate with the apex of the Arytenoids.

Ligaments of larynx

The ligaments are classified as intrinsic ligaments and extrinsic ligaments.

The extrinsic ligaments join the larynx with the hyoid and trachea

The thyrohyoid membrane connects the upper border of thyroid cartilage to the hyoid bone. This membrane is pierced by Superior laryngeal nerve and vessels.

The Cricothyroid Ligament connects the upper border of the cricoid to the lower border of thyroid cartilage.

The hyoepiglottis ligament connects hyoid to the epiglottis.

The Intrinsic membrane is a fibro elastic membrane which connects the laryngeal cartilages, strengthens the joints and creates an internal frame work.

	Upper Quadrilateral Membrane	Lower conus elasticus
Superior attachment	Aryepiglottic fold	Thyroid to vocal process
Inferior attachment	Vestibular folds	Cricoids
Ligaments	Inferior border of vestibular ligament	Superior border of vocal ligament

Muscles of Larynx:

The muscles of the larynx are divided into extrinsic and intrinsic muscles

Sl no	Name of the muscle	Attachment	Function	Nerve
1.	Posterior Cricoarytenoid	Cricoid Lamina to muscular process of arytenoids	Opens the glottis (Abduction)	Recurrent Laryngeal Nerve
2.	Lateral Cricoarytenoid	Cricoid Lamina to muscular process of arytenoids	Closes the glottis (Adduction)	Recurrent Laryngeal Nerve
3.	Interarytenoid	Arytenoid to Arytenoid	Closes the posterior commissure	Recurrent Laryngeal Nerve
4.	Thyroarytenoidis (Vocalis)	Thyroid to the Arytenoid medial fibres	Internal Tensor	Recurrent Laryngeal Nerve
5.	Cricothyroid	Cricoid to thyroid	External Tensor	External Laryngeal Nerve

Interior of the Larynx

The cavity extends from laryngeal inlet to the beginning of the lumen of the trachea at the lower border of cricoid cartilage. This is divided by the vestibular and vocal folds into three compartments.

The superior part vestibule is above the vestibular folds .The Ventricle or sinus of the larynx lies in between vestibular and vocal folds.

The laryngeal inlet is formed by aryepiglottic folds with free margin of epiglottis and mucosa in between the arytenoids and this is called as epilarynx.

Glottis is defined area of larynx that lies at level of vocal cords to level of about 10mm below the vocal cords.

Subglottis is region of larynx extending from 10mm below the vocal cords to level of lower border of cricoid cartilage.

The sinus of the larynx is situated in between vestibular and vocal folds elongated in the anterior part as saccule. The saccule contains mucous glands and hence is known as oil can of larynx.



Fig: showing the normal vocal cords, interarytenoid area and subglottic region.

Mucous Membrane:

The supraglottic & subglottic areas are lined by epithelium of pseudostratified ciliated columnar type. The squamous epithelium is seen over the vocal cords and Transitional epithelium on few places. The mucous glands are situated all over the membrane more so over the posterior surface of epiglottis and saccule. These mucosal glands are not seen over the vocal cord .The vocal cords are lubricated by the saccule.

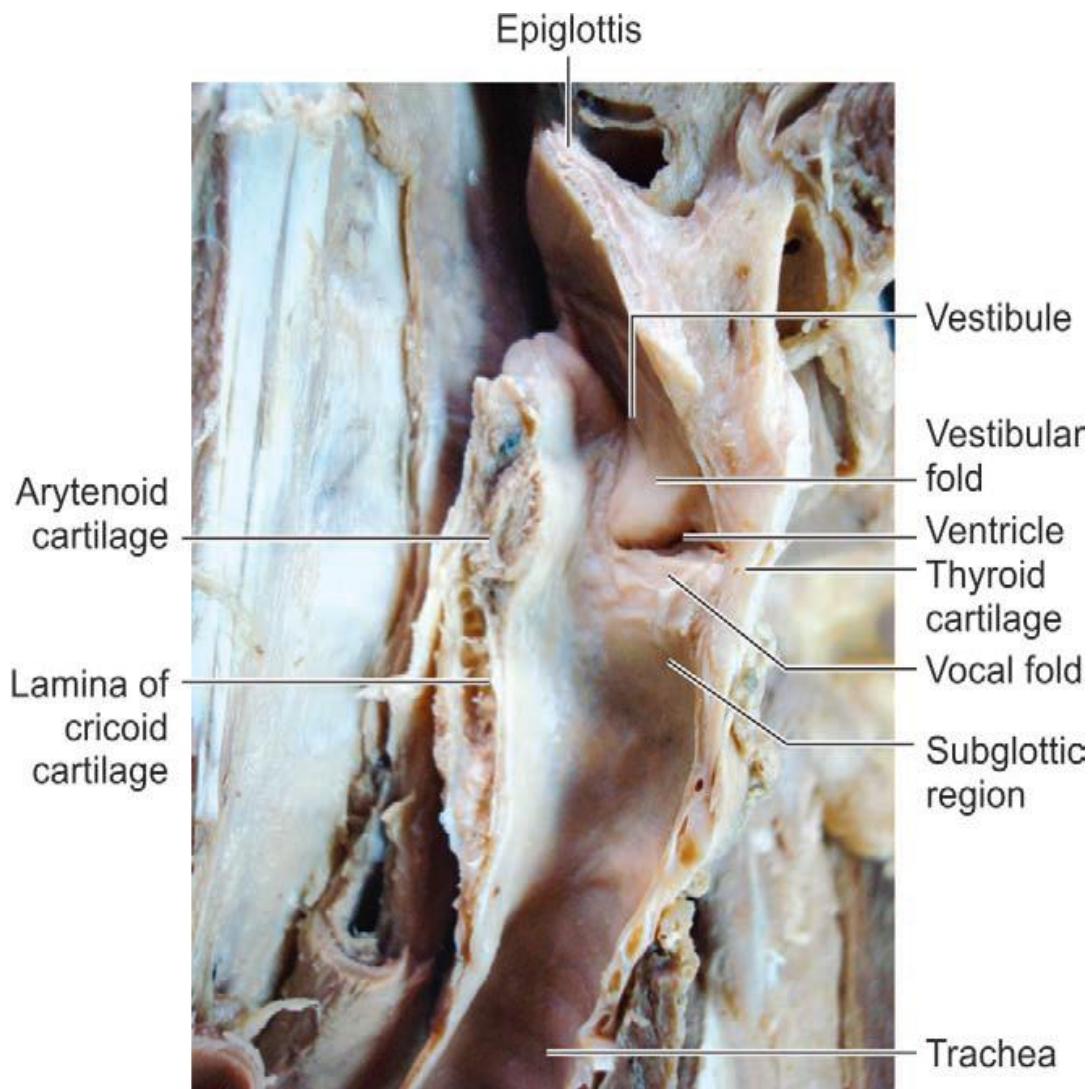


Fig: sagittal section of cadaveric larynx

Spaces in the Larynx.

Preepiglottic space

This is a potential space in front of epiglottis. It has a rich supply of lymphatics.

Boundaries

Anteriorly - Thyrohyoid membrane and Thyroid cartilage

Posteriorly- Epiglottis

Laterally – communicates with the paraglottic space

Inferiorly– Attachment of epiglottis with thyroid cartilage

Superiorly – Hyoepiglottic ligament

Paraglottic Space (Space of Tucker)

This lies on the both sides of the larynx lateral to saccule and

anterior to the pyriform fossa.

Boundaries

Anteriorly – Communicates with preepiglottic space

Posteriorly- anterior reflection of the pyriform fossa.

Laterally – Thyroid lamina

Medially- Quadrangular membrane and conus elasticus

Reinke's space

Sub epithelial space lying over the vocal ligaments

Boundaries

Anteriorly - Anterior commissure

Posteriorly- Posterior commissure

Laterally – Vocalis muscle

Medially - Free margin of vocal cord

Superiorly– superior arcuate line

Inferiorly – Inferior arcuate line

MATERIALS AND METHODS

40 Patients (Male and female in the age group of 15-45 years) who attended the ENT Out Patient Department for ENT surgeries wherein the tissue adhesion needed, during the period September 2013 to July 2015, who satisfied the inclusion criteria were enrolled for the study after getting an informed written consent.

Study design:

Observational descriptive study

Study place:

Department of ENT, Government Stanley Hospital.

Sample size: based on reviewed literatures, the sample size was calculated by using the following formula

$$n = \frac{Z^2 p(1 - p)}{d^2}$$

Expected Prevalence (p) = 0.88 (88 %)

Precision (d) = 0.1

Z-Value = 1.96

Calculated sample size = 40

15 cases of carcinoma larynx (tissue glue used in pharyngeal mucosal closure after total laryngectomy)

18 cases of chronic suppurative otitis media (tissue glue used in tympanoplasty)

5 cases of traumatic CSF leak (tissue glue used in closure of dural defect)

2 cases of laryngocele (tissue glue used in mucosal closure)

Study method and follow up:

After meeting the inclusion and exclusion criteria, Patients were randomly selected based on history, physical examination and relevant radiological investigations.

Biological fibrin tissue adhesive was used as a supplementary to conventional surgical procedures. After the surgical steps are over, tissue adhesive is used as a layer over the surgical field.

The post operative effects of fibrin tissue adhesive were evaluated in the review follow up periods of 1 week & monthly up to 6 months.

Total laryngectomy cases were observed for post operative bleeding, post operative sepsis, pharyngocutaneous fistula.

Patients with tympanoplasty were observed clinically for post operative events in the external auditory canal and middle ear. Patient were followed with pure tone audiometry for audiological assessment and also followed for 6 months for residual or recurrent perforation.

Cases of CSF rhinorrhea repair and laryngocele repair were followed for post operative wound sepsis and recurrent of disease.



Fig - fibrin tissue adhesive used in the closure of CSF rhinorrhea due to post traumatic posterior table fracture of left frontal sinus.



Fig - fibrin tissue adhesive kept over the roof of the ethmoid sinus in a case of CSF rhinorrhea of iatrogenic origin.

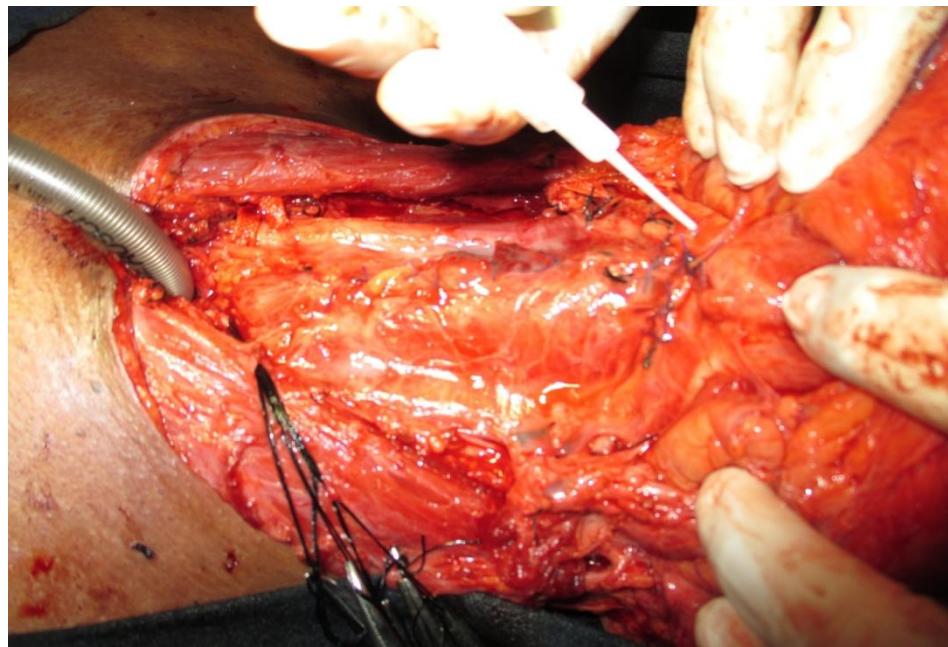


Fig. – fibrin tissue adhesive is being used after pharyngeal mucosal closure during total laryngectomy.

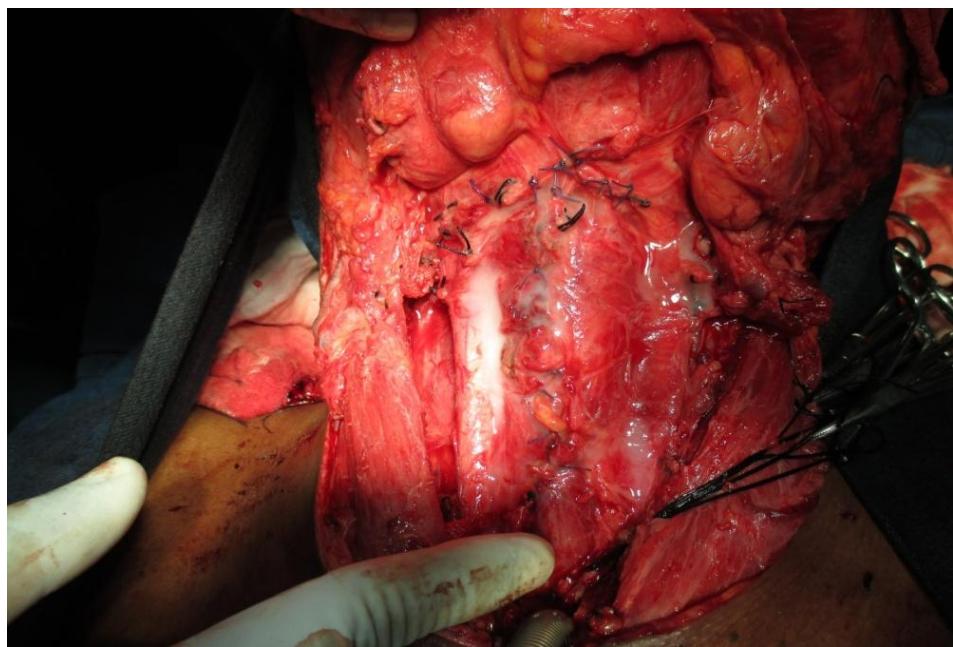


Fig. layer of fibrin tissue glue over pharyngeal closure suture line

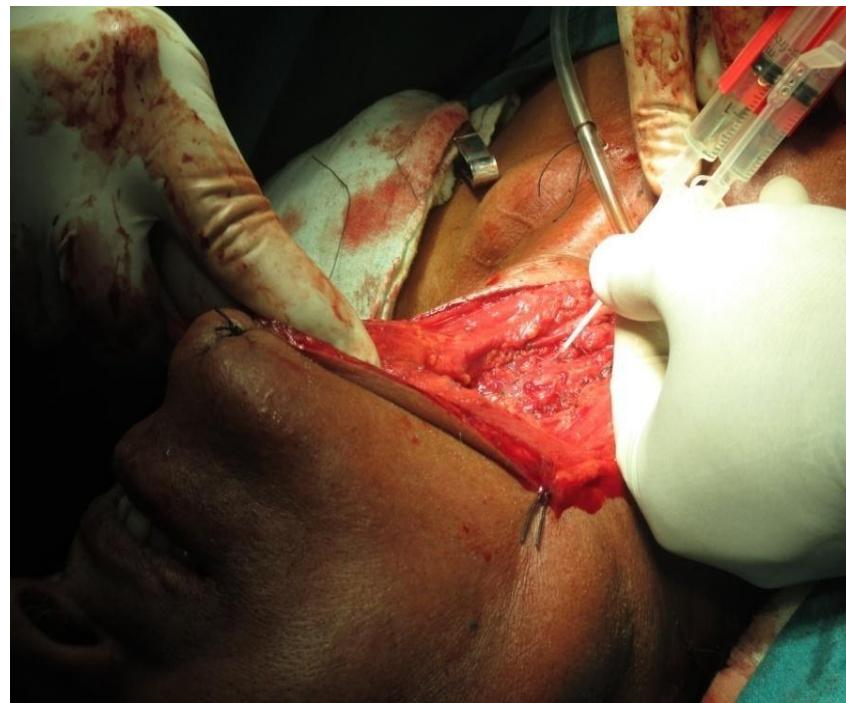


Fig. tissue glue being applied over the suture line with duplojet syringe.

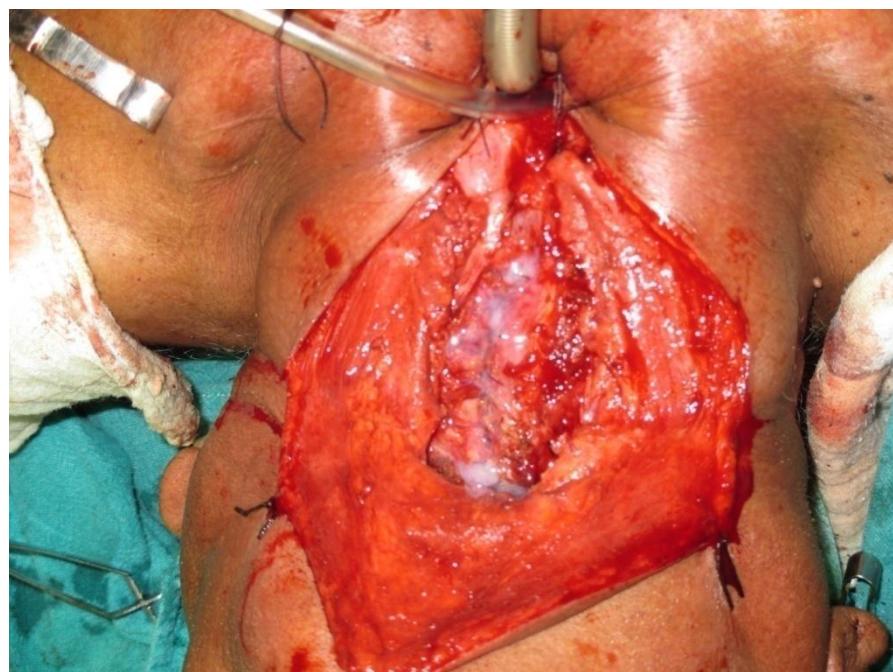


Fig. layered tissue glue over pharyngeal closure suture

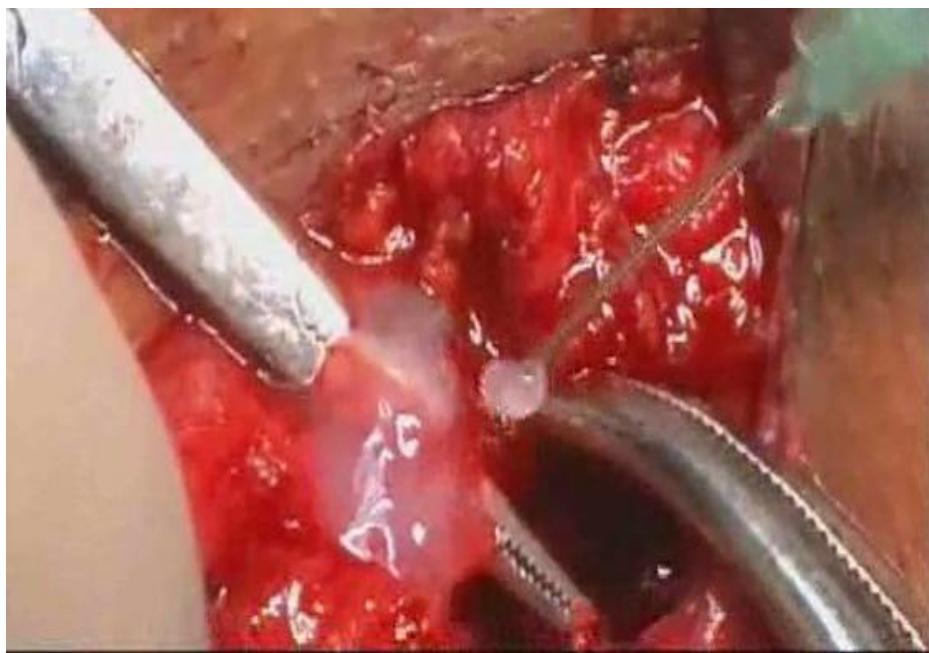


Fig. tissue glue being applied over the laryngeal mucosal suture after laryngocele excision.

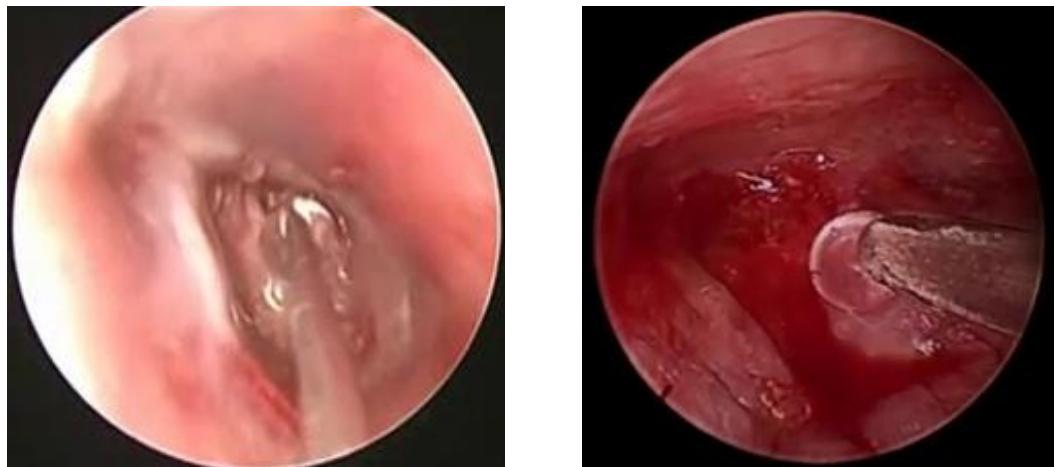


Fig. fibrin glue being applied after graft placement and tymapnomeatal flap repositioning in two separate cases.

RESULTS & DISCUSSION

INTERPRETATION AND ANALYSIS OF DATA

Groups * Gender Crosstabulation

		Gender		Total	
		Male	Female		
Groups	CSF LEAK REPAIR	Count	5	0 5	
		% within Gender	18.5%	0.0% 12.5%	
	LARYNGECTOMY	Count	14	1 15	
		% within Gender	51.9%	7.7% 37.5%	
	LARYNGOCELE EXCISION	Count	2	0 2	
		% within Gender	7.4%	0.0% 5.0%	
	TYMPANOPLASTY	Count	6	12 18	
		% within Gender	22.2%	92.3% 45.0%	
Total		Count	27	13 40	
		% within Gender	100.0%	100.0% 100.0%	

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	17.512 ^a	3	.001
Likelihood Ratio	20.184	3	.000
N of Valid Cases	40		

a. 5 cells (62.5%) have expected count less than 5. The minimum expected count is .65.

Agerange * Gender Crosstabulation

			Gender		Total	
			Male	Female		
Agerange	15-25	Count	3	2	5	
		% within Gender	11.1%	15.4%	12.5%	
	26-35	Count	9	8	17	
		% within Gender	33.3%	61.5%	42.5%	
	36-45	Count	3	2	5	
		% within Gender	11.1%	15.4%	12.5%	
	46-55	Count	9	1	10	
		% within Gender	33.3%	7.7%	25.0%	
	56-65	Count	3	0	3	
		% within Gender	11.1%	0.0%	7.5%	
Total		Count	27	13	40	
		% within Gender	100.0%	100.0%	100.0%	

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	5.651 ^a	4	.227
Likelihood Ratio	6.976	4	.137
N of Valid Cases	40		

a. 7 cells (70.0%) have expected count less than 5. The minimum expected count is .98.

Results of total laryngectomy with fibrin tissue reinforcement

Out of 15 patients of total laryngectomy with tissue glue used, 1 patient (6.6%) developed severe post operative bleeding from wound on 3 rd post op day. Wound exploration done and hemostasis obtained. 1 patient developed (6.6%) pharyngocutaneous fistula with protrusion of pharyngeal mucosa.

Groups * Gender Crosstabulation

			Gender		Total
			Yes	No	
Groups	PHARYNGOCUTANEOU S FI	Count	1	14	15
		% within Gender	11.1%	27.5%	25.0%
	POST OP BLEEDING FRO	Count	1	14	15
		% within Gender	11.1%	27.5%	25.0%
	POST OP SEPSIS	Count	3	12	15
		% within Gender	33.3%	23.5%	25.0%
	SUTURES REMOVAL DELA	Count	4	11	15
		% within Gender	44.4%	21.6%	25.0%
Total		Count	9	51	60
		% within Gender	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.529 ^a	3	.317
Likelihood Ratio	3.620	3	.306
N of Valid Cases	60		

a. 4 cells (50.0%) have expected count less than 5. The minimum expected count is 2.25.

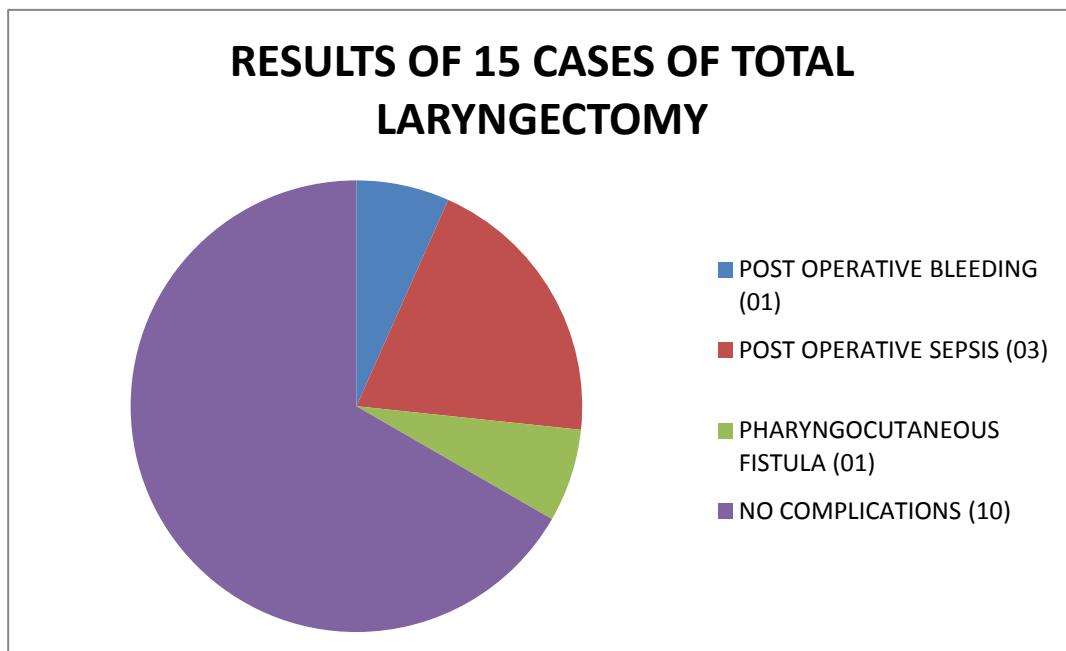




Fig. post laryngectomy patient (tissue glue used intra operatively) with pharyngocutaneous fistula with protrusion of pharyngeal mucosa.

3 patients (20%) developed post operative wound sepsis. 11 patients got their external wound sutures removed on 7 th post operative day.

Wakisaka et al. encountered a 27% rate of PCF after TL in their cohort of 63 cases with conventional total laryngectomy.

Fazal I Wahid et al got wound infection in 6 patients (23.07%) and 4 patients (15.38%) developed pharyngocutaneous fistula with conventional total laryngectomy of 26 cases.



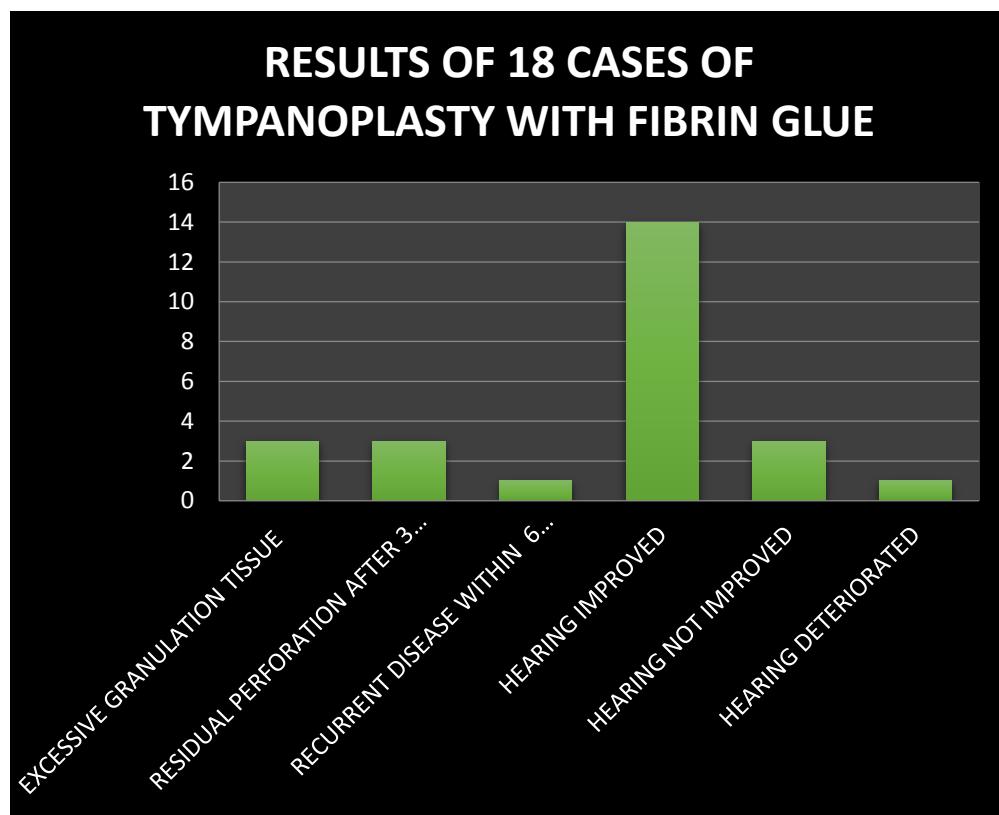
Figure shows post operative total laryngectomy status with
wound sepsis



Fig. shows post total laryngectomy tracheostoma with wound sepsis.

Results of tympanoplasty cases with fibrin tissue glue:

Out of 18 cases of tympanoplasty with fibrin glue, 3 patients (16.6%), developed excessive granulation tissue in the external auditory canal and over tympanic membrane graft. 14 patients (77%) were improved their hearing level and 1 patient (5.5%) got her hearing deteriorated. 3 patients (16.6%) had residual perforation after 3 months and 1 patient (5.5%) had recurrent perforation after 6 months.



Mostafa et al. found improvement in hearing level with fibrin glue in 23 patients out of 25 (92%).

Sakagami et al. report about a success rate of 78% in underlay myringoplasty with fascia with fibrin glue in 391 ear surgeries.

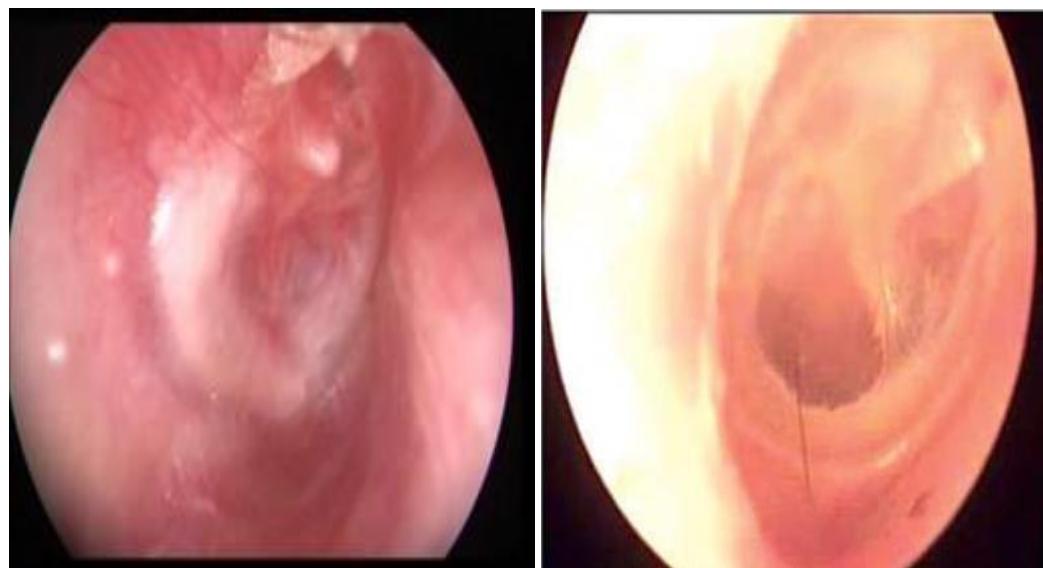


Fig. showing post myringoplasty status at 3 months of different patients



Fig. showing excessive granulation tissue over graft in a patient of post tympanoplasty with fibrin glue

		Agerange Crosstabulation					
		Agerange					Total
Groups	ABNORMALLY EXCESSIVE	Male 15 - 30	Male 31 - 45	Female 15 - 30	Female 31 - 45	Female 46 - 60	
		Count	0	1	1	1	0 3
	NORMAL	% within Agerange	0.0%	33.3%	20.0%	16.7%	0.0% 16.7%
		Count	3	2	4	5	1 15
	Total	% within Agerange	100.0%	66.7%	80.0%	83.3%	100.0% 83.3%
		Count	3	3	5	6	1 18
		% within Agerange	100.0%	100.0%	100.0%	100.0%	100.0% 100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.440 ^a	4	.837
Likelihood Ratio	1.990	4	.738
N of Valid Cases	18		

a. 9 cells (90.0%) have expected count less than 5. The minimum expected count is .17.

POST OP AUDIOGRAM AFTER 3 MONTHS

CRITERIA:

Improved: PTA average threshold improves >15 db

Not improved: PTA average threshold improves < 15 db

Deteriorated: PTA average threshold decreases >15 db

Groups * Agerange Crosstabulation

		Agerange					Total	
		Male 15 - 30	Male 31 - 45	Female 15 - 30	Female 31 - 45	Female 46 - 60		
Groups	DETERIORATE	Count	0	0	0	1	0	1
		% within Agerange	0.0%	0.0%	0.0%	16.7%	0.0%	5.6%
	IMPROVED	Count	3	1	5	4	1	14
		% within Agerange	100.0%	33.3%	100.0%	66.7%	100.0%	77.8%
	NOT IMPROVED	Count	0	2	0	1	0	3
		% within Agerange	0.0%	66.7%	0.0%	16.7%	0.0%	16.7%
Total		Count	3	3	5	6	1	18
		% within Agerange	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	9.429 ^a	8	.307
Likelihood Ratio	9.338	8	.315
N of Valid Cases	18		

a. 15 cells (100.0%) have expected count less than 5. The minimum expected count is .06.

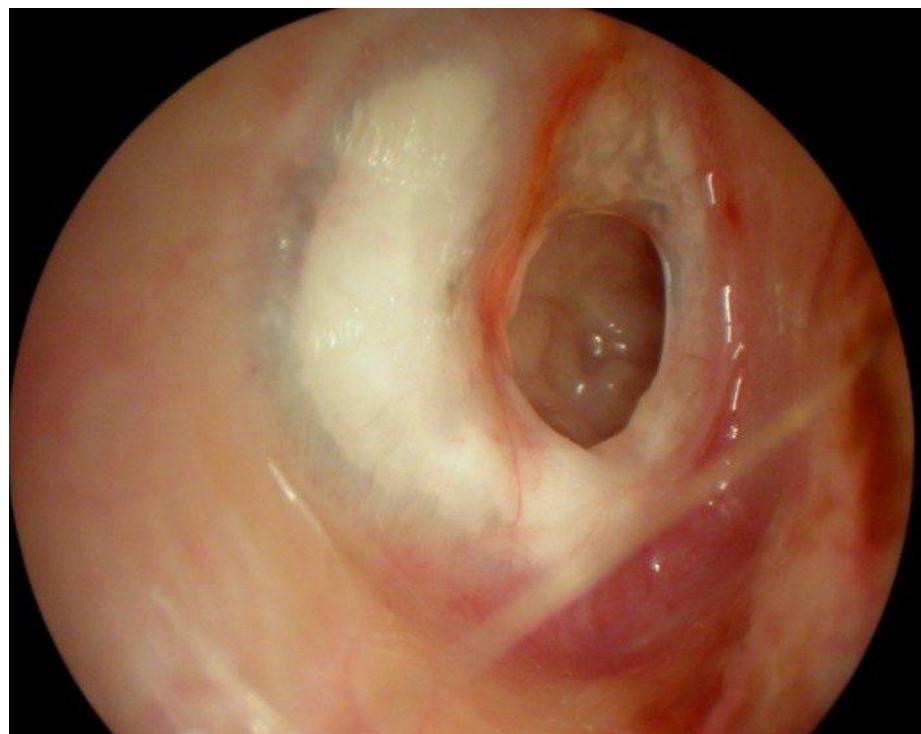
RESIDUAL PERFORATION AFTER 3 MONTHS

Fig. showing residual perforation after 3 months with tympanosclerotic changes.

Groups * Agerange Crosstabulation

		Agerange					Total
		Male 15 - 30	Male 31 - 45	Female 15 - 30	Female 31 - 45	Female 46 - 60	
Groups	NO	Count	3	2	5	4	15
		% within Agerange	100.0%	66.7%	100.0%	66.7%	100.0% 83.3%
	YES	Count	0	1	0	2	0 3
		% within Agerange	0.0%	33.3%	0.0%	33.3%	0.0% 16.7%
Total		Count	3	3	5	6	1 18
		% within Agerange	100.0%	100.0%	100.0%	100.0%	100.0% 100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.600 ^a	4	.463
Likelihood Ratio	4.763	4	.312
N of Valid Cases	18		

a. 9 cells (90.0%) have expected count less than 5. The minimum expected count is .17.

RECURRENT DISEASE AFTER 6 MONTHS



Fig. shows recurrent disease in a previous tympanoplasty case with fibrin glue

Groups * Agerange Crosstabulation

			Agerange					Total
Groups	NO	Count	Male 15 - 30	Male 31 - 45	Female 15 - 30	Female 31 - 45	Female 46 - 60	
		% within Agerange	100.0%	100.0%	100.0%	83.3%	100.0%	94.4%
YES	Count	0	0	0	1	0	1	5.6%
		% within Agerange	0.0%	0.0%	0.0%	16.7%	0.0%	
Total	Count	3	3	5	6	1	18	100.0%
		% within Agerange	100.0%	100.0%	100.0%	100.0%	100.0%	

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.118 ^a	4	.714
Likelihood Ratio	2.317	4	.678
N of Valid Cases	18		

a. 9 cells (90.0%) have expected count less than 5. The minimum expected count is .06.

Results of laryngocoele excision with fibrin glue

Out of 2 patients 1 patient had post operative wound sepsis. No patient had post operative bleeding or recurrence

Results of endoscopic repair of CSF rhinorrhea with fibrin glue

Out of 5 patients, 1 patient (25%) developed meningitis in first post operative week and 1 patient (25%) developed loss of smell after 6 months. No patient had residual or recurrent CSF leak (100% success).

Hanna Gilat et al got 80% results, with 22 patients repaired successfully out of 27 patients.

RESULTS OF CSF LEAK REPAIR WITH FIBRIN GLUE

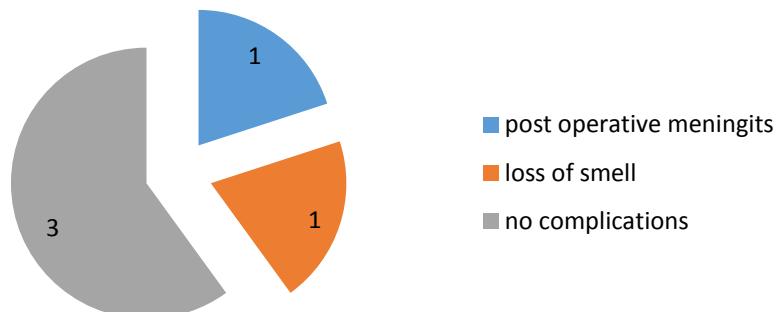


Fig. post operative endoscopic view of post endoscopic CSF rhinorrhea patient

CONCLUSION:

In our study, post operative effects of biological fibrin tissue glue in ENT & Head and Neck surgeries were observed. The study was conducted in our Department of ENT, Stanley medical college hospital from September 2013 to July 2015.

Fibrin tissue adhesive was used in 40 cases (including 15 cases of total laryngectomy, 18 cases of tympanoplasty, 5 cases of CSF rhinorrhea repair, 2 cases of laryngocele excision) as a supplementary to conventional surgeries. Post operatively patients were observed for a period of 6 months and evaluated for the effectiveness /complications of fibrin tissue adhesive. But because of too small number of samples, definitive conclusions could not be made.

ANNEXURES

A.BIBILOGRAPHY

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B. PROFORMA

Name:

Age:

Sex:

IP No:

PRESENTING COMPLAINTS:

Ear pain/ear discharge/ hard of hearing/ vertigo/abnormal sound
in the ear

Nasal block/ loss of smell/nasal pain/ facial pain/ nasal discharge/
excessive sneezing/ headache/snoring

Difficulty or painful swallowing/throat pain/voice
change/difficulty in breathing/any swelling in the neck

HISTORY OF PRESENT ILLNESS:

Specific complaint: onset, duration, progression, associated symptoms, diurnal variation, aggravating or relieving factors.

Ear pain: continuous/intermittent, type & site of pain,

Ear or nasal discharge: quantity, type of discharge, foul smelling or not, blood stained or not/ associated with injury or not.

PAST HISTORY:

Any previous illness/ surgery/ previous blood or organ transplantation/ thromboembolic or coagulation diseases/ chronic drug intake/cardiac disorders allergic disorders

PERSONAL HISTORY:

H/o Diet, Bowel, bladder habits

FAMILY HISTORY:

Order of birth, menstrual history, any similar illness in family.

OCCUPATIONAL HISTORY:

Any h/o exposure to dust or allergens in home or workplace.

TREATMENT HISTORY:

Any h/o treatment for previous illnesses/ surgeries

GENERAL EXAMINATION:

Built, Nourishment, Consciousness, orientation, febrile or not, any pallor, icterus, cyanosis, clubbing, significant lymphadenopathy, Pulse rate, Blood Pressure.

SYSTEMIC EXAMINATION:

Cardiovascular System,

Respiratory System,

Central Nervous System,

Gastrointestinal System

LOCAL EXAMINATION:**NOSE:**

External Contour, Columella, Vestibule, Septum,

Anterior Rhinoscopy

	Inferior Turbinate	Inferior Meatus	Middle Turbinate	Middle Meatus	Septum	Floor
Right						
Left						

Posterior Rhinoscopy,

	Choanae	Post end of Middle Turbinate	Post end of Inferior Turbinate	Post end of Septum	Auditory Tube Orifice	Fossa of Rosenmuller
Right						
Left						

Cotton Wool Test, Cold Spatula Test, Cottle Ring Test, PNS Tenderness

Diagnostic Nasal Endoscopy.

THROAT:

Lips, perioral area,

gums, oral mucosa, floor of mouth, tongue, teeth,

palate, pillars, tonsils, uvula, posterior pharyngeal wall.

EAR:

Pinna,

Preauricular area,

post auricular area,

external auditory canal,

tympanic membrane.

TUNING FORK TESTS:

Rinne's Test,

Weber's Test,

Absolute Bone Conduction Test.

NECK:

Any swelling or palpable Lymph nodes.

INVESTIGATIONS:

- a) CBC, RFT, Blood Grouping and typing
- b) Urine Routine
- c) RBS
- d) HIV and Hep B
- e) Bleeding time/clotting time & Coagulation profile
- f) Other relevant investigations according to surgery planned.

DIAGNOSIS:**SURGERY:** Procedure

Anaesthesia

Technique & approach

C. MASTER SHEET

TOTAL LARYNGECTOMY CASES

1	MOHAMMED HANIFA	58/M	20283	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
2	SENTHILKUMAR	45/M	11262	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
3	SUBRAMANIAN	54/M	27674	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
4	CHINNAPAIYAN	45/M	25142	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
5	SAMBATH	55/M	38965	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
6	PARASURAMAN	58/M	41882	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
7	GOPAL	50/M	1460152	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
8	MAGIMAI ANTHONY	60/M	1463449	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
9	MUNUSAMY	40/M	1519565	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA
9	ETHIRAJ	52/M	147571	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA

10	KAVITHA	28/F	38226	CARCINOMA HYPOPHARYNX	TOTAL LARYNGOPHARYNG ECTOMY / GA
11	RAJU	55/M	56434	CARCINOMA LARYNX	TOTAL LARYNGECTOMY /GA
12	JOSEPH	48/M	34564	CARCINOMA LARYNX	TOTAL LARYNGECTOMY /GA
13	SYED LATHIFF	55/M	65434	CARCINOMA LARYNX	TOTAL LARYNGECTOMY /GA
14	VADIVELU	46/M	98743	CARCINOMA LARYNX	TOTAL LARYNGECTOMY /GA
15	MARIMUTHU	54/M	34254	CARCINOMA LARYNX	TOTAL LARYNGECTOMY / GA

TYMPANOPLASTY CASES

1	NAVANEETHAM	23/F	1932707	LEFT CSOM – TTD	LEFT CORTICAL MASTOIDECKOMY WITH TYMPANOPLASY / GA
2	SUGUNA	40/F	219652	LEFT CSOM – TTD	LEFT CORTICAL MASTOIDECKOMY WITH TYMPANOPLASY / GA
3	KALAISELVI	40/F	322581	LEFT CSOM – TTD	LEFT CORTICAL MASTOIDECKOMY WITH TYMPANOPLASTY/GA
4	KARUKKAVEL RAJ	24/M	276367	LEFT CSOM- TTD	RIGHT CORTICAL MASTOIDECKOMY WITH TYMPANOPLASTY/GA

5	ABELAI @ABEL RAJ	33/M	988881	LEFT CSOM – TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASY / GA
6	SASIKALA	30/F	22551	RIGHT CSOM TTD	RIGHT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA
7	KOKILA	28/F	239511	LEFT CSOM TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA
8	DURGESA	18/M	122598	B/L CSOM TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA
9	KALVIKUMAR	35/M	19043	LEFT CSOM TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASY / GA
10	FATHIMA	34/F	172618	LEFT CSOM TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY /GA
11	KALPANA	35/F	21468	RIGHT CSOM TTD	RIGHT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA
12	CHANDRA	55/F	283789	RIGHT CSOM TTD	RIGHT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASY / GA
13	JANAKIRAMAN	27/M	210129	RIGHT CSOM TTD	RIGHT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASY / GA
14	BANU	32/M	34526	RIGHT CSOM TTD	RIGHT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA
15	PRIYA	28/F	246357	LEFT CSOM TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY GA
16	SHOBANA	32/F	23980	RIGHT CSOM TTD	RIGHT CORTCAL MASTOIDECTOMY WITH

					TYMPANOPLASTY /GA
17	SANGEETHA	25/F	56432	LEFT CSOM TTD	LEFT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA
18	SARASWATHI	35/F	45927	RIGHT CSOM TTD	RIGHT CORTICAL MASTOIDECTOMY WITH TYMPANOPLASTY / GA

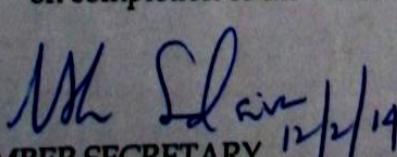
CSF RHINORHHEA CASES

1	DAVID	35/M	67293	POST TRAUMATIC CSF RHINORRHEA	ENDOSCOPIC REPAIR / GA
2	VASANTH	24/M	72654	POST TRAUMATIC CSF RHINORRHEA	ENDOSCOPIC REPAIR / GA
3	RAJESH	27/M	86345	POST TRAUMATIC CSF RHINORRHEA	ENDOSCOPIC REPAIR / GA
4	RAVI	32/M	93564	POST TRAUMATIC CSF RHINORRHEA	ENDOSCOPIC REPAIR / GA
5	SHERIFF	29/M	102974	POST TRAUMATIC CSF RHINORRHEA	ENDOSCOPIC REPAIR / GA

LARYNGOCELE CASES

1	RAMALINGAM	35/M	23653	EXTERNAL LARYNGOCELE	EXTERNAL APPROACH EXCISION / GA
2	SURESH	29/M	43567	EXTERNAL LARYNGOCELE	EXTERNAL APPROACH EXCISION / GA

D. ETHICAL COMMITTEE APPROVAL LETTER

<u>INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1</u>	
Title of the Work	: Role of biological fibrin tissue adhesive in ENT and Head Neck Surgeries
Principal Investigator	: Dr.R. Devendiran
Designation	: PG in M.S (E.N.T.)
Department	: Department of E.N.T. Government Stanley Medical College, Chennai-10
<p>The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 10.01.2014 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM</p>	
<p>The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.</p>	
<p>The Principal investigator and their team are directed to adhere to the guidelines given below:</p>	
<ol style="list-style-type: none"> 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 from 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	

E. PATIENT INFORMATION SHEET

தகவல் படிவம்

தங்களுக்கு செய்த பரிசோதனைகள் மூலம் தங்களுக்கு.

நோய் உள்ளது தெரியவந்துள்ளது. இந்த நோயை குணப்படுத்த பலவகை அறுவைசிகிச்சை முறைகள் உள்ளன. அதில் உங்களுக்கு _____ முறை பயன்படுத்தப்படவுள்ளது.

இந்த அறுவை சிகிச்சையில் உயிரியல் திசுபசை (BIOLOGICAL TISSUE GLUE) பயன்படுத்தப்படவுள்ளது. மேலும் இந்த முறையின் மூலம் ஏற்படும் விளைவுளை ஒப்பிட ஆய்வு மேற்கொள்ளப்பட உள்ளது.இது குறித்த உங்களின் நோய் மற்றும் அதன் விவரங்களை ஆய்வில் பயன்படுத்த விரும்புகிறோம். தாங்கள் விரும்பினால் மருத்துவ ஆய்விலிருந்து எப்பொழுது வேண்டுமானாலும் விலகிக் கொள்ளலாம். எந்த சட்டசிக்கலுக்கும் இடமில்லாமல் எப்பொழுது வேண்டுமானாலும் தங்கள் ஆய்விலிருந்து விலகிக் கொள்ளலாம். இந்த ஆய்வின்மூலம் கிடைக்கும் தகவல்களும் பரிசோதனை முடிவுகளும் தங்களின் ஒப்புதலின்மூலம் மட்டும் ஆய்வில் பயன்படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம்:

ஆய்வாளரின் பெயர்:

இடம்:

நாள்:

F. INFORMED CONSENT FORM

சுய ஒப்புதல் படிவம்

ஆராய்ச்சி நிலையம் : காது, மூக்கு, தொண்டை பிரிவு

ஸ்டான்லி அரசு பொது மருத்துவமனை
மற்றும் மருத்துவ கல்லூரி

பங்கு பெறுபவரின் பெயர்:

பங்கு பெறுபவரின் எண் :

மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டுள்ளது.
 எனது நோய் _____ மற்றும் அதன் நிலை
 தெரியபடுத்தப்பட்டது. எனது நோய் பற்றிய சந்தேகங்களை
 கேட்கவும் அதற்கான தகுந்த விளக்கங்களை பெறவும்
 வாய்ப்பளிக்கப்பட்டது. இந்த நோயை குணப்படுத்தும் அறுவை
 சிகிச்சை முறைகள் _____.
 விளக்கப்பட்டுள்ளது. அந்த அறுவை சிகிச்சையில் உயிரியல் திசு
 பசை (BIOLOGICAL TISSUE GLUE) பயன்படுத்தப்படுவது பற்றி
 விளக்கப்பட்டது. இதை எனது அறுவை சிகிச்சையின் போது
 பயன்படுத்த சுயநினைவுடன் சம்மதிக்கிறேன். இந்த அறுவை
 சிகிச்சையின் விளைவுகளை ஆய்வில் பயன்படுத்தவும்
 தன்னிச்சையாக சம்மதிக்கிறேன். எக்காரணத்தினாலும் எந்தக்
 கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் இவ்வாய்வில்
 இருந்து விலகிக்கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் பரிசோதனை முடிவுகளையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்க தேவைப்பட்டால் என்னையும் எனக்கு நடக்கும் அறுவை சிகிச்சையையும் புகைப்படம் எடுக்கவும் நான் முழு மனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்: கட்டை விரல் ஒப்பம்

நாள்:

இடம்:

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்:

ஆய்வாளரின் பெயர்:

இடம்:

G. PLAGIARISM

The Tamil Nadu Dr.M.G.R.Medical... TNMGRMU EXAMINATIONS - DUE 30-...

Originality GradeMark PeerMark

ROLE OF BIOLOGICAL FIBRIN TISSUE ADHESIVE IN ENT &HEAD & NECK
BY DEVENDIRAN RAJENDRAN

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A Dissertation on

ROLE OF BIOLOGICAL FIBRIN TISSUE ADHESIVE IN
ENT & HEAD & NECK SURGERIES

18 Submitted to

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

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